|  |
| --- |
| Clinical Evaluation Report (CER) |
| Femoral Nail Systems  (CER #500404346) |

Confidentiality Statement

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is *privileged* or *confidential* and may not be further disclosed by them. These restrictions on disclosure will apply equally to *all* future information supplied to you which is indicated as *privileged* or *confidential*.

Confidentiality Statement

The information in this document contains trade secrets and commercial information that are privileged or confidential and may not be disclosed unless such disclosure is required by applicable law or regulations. In any event, persons to whom the information is disclosed must be informed that the information is *privileged* or *confidential* and may not be further disclosed by them. These restrictions on disclosure will apply equally to *all* future information supplied to you which is indicated as *privileged* or *confidential*.

TABLE OF CONTENTS

[1. EXECUTIVE SUMMARY 8](#_Toc123219086)

[2. SECTION A CONTENT 11](#_Toc123219087)

[3. SECTION C CONTENT 16](#_Toc123219088)

[3.1. Subject Device Overview 16](#_Toc123219089)

[3.1.1. Device Description – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1) 19](#_Toc123219090)

[3.1.2. Device Description – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #2) 28](#_Toc123219091)

[3.1.3. Device Description – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3) 32](#_Toc123219092)

[3.1.4. Device Description – Expert Adolescent Lateral Femoral Nail (Device Group #4) 41](#_Toc123219093)

[3.1.5. Device Description – Hip Screw for Expert Adolescent Lateral Femoral Nail (Device Group #5) 45](#_Toc123219094)

[3.1.6. Device Description – Expert End Cap for Adolescent Lateral Femoral Nail (Device Group #6) 49](#_Toc123219095)

[3.1.7. Device Description – Expert Lateral Femoral Nail (Device Group #7) 53](#_Toc123219096)

[3.1.8. Device Description – Hip Screw for Expert Lateral Femoral Nail (Device Group #8) 57](#_Toc123219097)

[3.1.9. Device Description – Expert End Cap for Lateral Femoral Nail (Device Group #9) 61](#_Toc123219098)

[3.1.10. Device Description – Femoral Recon Nail (Device Group #10) 65](#_Toc123219099)

[3.1.11. Device Description – Recon Screw for Medullary Nail (Device Group #11) 69](#_Toc123219100)

[3.1.12. Device Description – End Cap for Femoral Recon Nail (Device Group #12) 73](#_Toc123219101)

[3.1.13. Device Description – RFN-ADVANCED Femoral Nail (Device Group #13) 76](#_Toc123219102)

[3.1.14. Device Description – Locking Attachment Washer for RFN-ADVANCED (Device Group #14) 81](#_Toc123219103)

[3.1.15. Device Description – Endcaps for RFN-ADVANCED (Device Group #15) 86](#_Toc123219104)

[3.1.16. Device Description – Expert Asian Femoral Nail (Device Group #16) 91](#_Toc123219105)

[3.1.17. Device Description – Hip Screw T25 for Asian Femoral Nail (Device Group #17) 95](#_Toc123219106)

[3.1.18. Device Description – End Cap for Expert Asian Femoral Nail (Device Group #18) 99](#_Toc123219107)

[3.2. Classification Rationale(s) 103](#_Toc123219108)

[3.3. Accessories and Compatible Devices 103](#_Toc123219109)

[3.4. Overview of Previous Generations and Similar Devices 114](#_Toc123219110)

[3.5. Clinical Evaluation Plan 114](#_Toc123219111)

[3.6. Data Appraisal Plan – Clinical and Nonclinical Performance and Safety Data 114](#_Toc123219112)

[3.6.1. Overview of Clinical Data 114](#_Toc123219113)

[3.6.2. Nonclinical Data 138](#_Toc123219114)

[3.7. Common Specifications & Applied Standards 173](#_Toc123219115)

[3.7.1. Compliance with Specific Safety and/or Performance Standards 173](#_Toc123219116)

[3.8. Clinical Evaluation Data Route (CEDR) 176](#_Toc123219117)

[3.8.1. Demonstration of Equivalence for Femoral Recon Nail 177](#_Toc123219118)

[3.8.2. Demonstration of Equivalence for RFN-ADVANCED Femoral Nail 179](#_Toc123219119)

[3.9. State of the Art (SOA) Review 182](#_Toc123219120)

[3.9.1. Objective 182](#_Toc123219121)

[3.9.2. Methodology & Results 182](#_Toc123219122)

[3.9.3. Overview of Target Clinical Condition(s) 185](#_Toc123219123)

[3.9.4. Assessment of SOA Treatment Options 186](#_Toc123219124)

[3.9.5. Key Outcome Parameters / Benefit-Risk Acceptability Criteria 190](#_Toc123219125)

[3.9.6. Conclusion 193](#_Toc123219126)

[4. SECTION D CONTENT 194](#_Toc123219127)

[4.1. Device-Specific Systematic Literature Review Methods 194](#_Toc123219128)

[4.2. Overview of Available Literature from Device-Specific Systematic Literature Review 196](#_Toc123219129)

[4.3. Device-Specific Systematic Literature Review Results by Stratification Group – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System 204](#_Toc123219130)

[4.3.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 204](#_Toc123219131)

[4.3.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 212](#_Toc123219132)

[4.3.3. Data to Support Identification of Off-Label Use/Misuse 216](#_Toc123219133)

[4.4. Device-Specific Systematic Literature Review Results by Stratification Group – Expert Adolescent Lateral Femoral Nail System 217](#_Toc123219134)

[4.4.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 217](#_Toc123219135)

[4.4.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 223](#_Toc123219136)

[4.4.3. Data to Support Identification of Off-Label Use/Misuse 225](#_Toc123219137)

[4.5. Device-Specific Systematic Literature Review Results by Stratification Group – Expert Lateral Femoral Nail System 225](#_Toc123219138)

[4.5.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 225](#_Toc123219139)

[4.5.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 231](#_Toc123219140)

[4.5.3. Data to Support Identification of Off-Label Use/Misuse 236](#_Toc123219141)

[4.6. Device-Specific Systematic Literature Review Results by Stratification Group – Femoral Recon Nailing System 236](#_Toc123219142)

[4.7. Device-Specific Systematic Literature Review Results by Stratification Group – Retrograde Femoral Nail Advanced System 237](#_Toc123219143)

[4.7.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 237](#_Toc123219144)

[4.7.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 237](#_Toc123219145)

[4.7.3. Data to Support Identification of Off-Label Use/Misuse 239](#_Toc123219146)

[4.8. Device-Specific Systematic Literature Review Results by Stratification Group – Expert Asian Femoral Nail System 239](#_Toc123219147)

[4.8.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 239](#_Toc123219148)

[4.8.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 246](#_Toc123219149)

[4.8.3. Data to Support Identification of Off-Label Use/Misuse 251](#_Toc123219150)

[4.9. Device-Specific Systematic Literature Review Results by Stratification Group – Unspecified Femoral Nails 252](#_Toc123219151)

[4.9.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 252](#_Toc123219152)

[4.9.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 252](#_Toc123219153)

[4.9.3. Data to Support Identification of Off-Label Use/Misuse 254](#_Toc123219154)

[4.10. Device-Specific Systematic Literature Review Results by Stratification Group – Multiple Femoral Nail Systems 254](#_Toc123219155)

[4.10.1. Data to Support Safety and/or Performance Conformity (Including Trending Assessment) 254](#_Toc123219156)

[4.10.2. Additional Data to Inform Identification of Safety Trends or Performance Issues 260](#_Toc123219157)

[4.10.3. Data to Support Identification of Off-Label Use/Misuse 262](#_Toc123219158)

[5. SECTION E CONTENT 263](#_Toc123219159)

[5.1. Clinical Investigations (Cis) 263](#_Toc123219160)

[6. SECTION F CONTENT 264](#_Toc123219161)

[6.1. Post-Market Surveillance (PMS) 264](#_Toc123219162)

[6.1.1. Complaint and Vigilance Data 265](#_Toc123219163)

[6.1.2. Actions 297](#_Toc123219164)

[6.2. Ongoing or Completed Post-Market Clinical Follow-Up (PMCF) 302](#_Toc123219165)

[6.2.1. PMCF Activity / RWE – Evaluation of Healthcare Outcomes Following Treatment of Distal Femur and Femoral Shaft Fracture Utilizing the DePuy Synthes Expert Retrograde/Antegrade Femoral Nail 302](#_Toc123219166)

[6.2.2. PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail 306](#_Toc123219167)

[6.2.3. PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail 309](#_Toc123219168)

[6.2.4. PMCF Activity / DUA – Summary of Retrospective Data Collection for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail 312](#_Toc123219169)

[6.2.5. PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail 316](#_Toc123219170)

[6.2.6. PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail 320](#_Toc123219171)

[6.2.7. PMCF Activity / IIS – Comparison of Short-Term Clinical Outcomes of Piriformis Fossa and Trochanteric Entry Nailing for Femoral Shaft fractures 324](#_Toc123219172)

[6.2.8. PMCF Activity / IIS – Utilizing the RFN-Advanced Retrograde Femoral Nailing System for Fixation of Distal Femur and Femoral Shaft Fractures: A Prospective Case Series 327](#_Toc123219173)

[6.2.9. PMCF Activity / IIS – Early Usage Case Series Utilizing the Retrograde Femoral Nail -Advanced for Fixation and Stabilization of the Distal Femur and Femoral Shaft 330](#_Toc123219174)

[6.2.10. PMCF Activity / IIS – Early Results of the RFN-Advanced System in the Management of Distal Femur Fractures: A Matched-Cohort Analysis 334](#_Toc123219175)

[6.2.11. PMCF Activity / Internal Registry – Lower Extremity Shaft Nail (LESN) Registry 337](#_Toc123219176)

[6.3. PMCF Plan 341](#_Toc123219177)

[7. SECTION G CONTENT 342](#_Toc123219178)

[7.1. Instructions for Use (IFU) and Other Labeling/Promotional Materials 342](#_Toc123219179)

[7.2. Summary of Safety and Clinical Performance (SSCP) 342](#_Toc123219180)

[8. SECTION H CONTENT 343](#_Toc123219181)

[8.1. Data Summary and Benefit-Risk Analysis 343](#_Toc123219182)

[8.1.1. Clinical Benefits / Performance Analysis 343](#_Toc123219183)

[8.1.2. Clinical Risks / Safety Analysis 356](#_Toc123219184)

[8.1.3. Summary of Significant Complaints / Trends / Vigilance from Previous Generations 372](#_Toc123219185)

[8.1.4. Side-Effects Acceptability 373](#_Toc123219186)

[8.1.5. Benefit-Risk Profile Acceptability 390](#_Toc123219187)

[8.2. PMCF Assessment / PMCF Plan (PMCFP) 392](#_Toc123219188)

[8.3. CER Update Frequency Assessment 404](#_Toc123219189)

[8.4. Conclusion 404](#_Toc123219190)

[8.4.1. Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) 405](#_Toc123219191)

[8.4.2. Expert Adolescent Lateral Femoral Nail System (System #2) 408](#_Toc123219192)

[8.4.3. Expert Lateral Femoral Nail System (System #3) 411](#_Toc123219193)

[8.4.4. Femoral Recon Nailing System (System #4) 414](#_Toc123219194)

[8.4.5. Retrograde Femoral Nail Advanced System (System #5) 417](#_Toc123219195)

[8.4.6. Expert Asian Femoral Nail System (System #6) 419](#_Toc123219196)

[9. APPENDICES 423](#_Toc123219197)

[9.1. Supporting References for Key Documents 423](#_Toc123219198)

[9.1.1. MDD Supporting References for Key Documents 423](#_Toc123219199)

[9.1.2. MDR Supporting References for Key Documents 428](#_Toc123219200)

[9.2. Product Codes 429](#_Toc123219201)

[9.2.1. MDD Subject Device Product Codes 429](#_Toc123219202)

[9.2.2. MDR Subject Device Product Codes 429](#_Toc123219203)

[9.3. Equivalence Table for Femoral Recon Nail 430](#_Toc123219204)

[9.4. Equivalence Table for RFN-ADVANCED Femoral Nail 435](#_Toc123219205)

[9.5. Literature Search results 445](#_Toc123219206)

[9.5.1. Systematic SOA Search 445](#_Toc123219207)

[9.5.2. Systematic SOA Review Search Appraisal Summary 446](#_Toc123219208)

[9.5.3. Device-Specific Systematic Literature Review Search 451](#_Toc123219209)

[9.5.4. Device-Specific Systematic Literature Appraisal Summary 452](#_Toc123219210)

[9.6. PMCF Activity Guide 456](#_Toc123219211)

[9.7. Bibliographies 460](#_Toc123219212)

[9.7.1. SOA Included Publications & General Publications 460](#_Toc123219213)

[9.7.2. SOA Excluded Publications 462](#_Toc123219214)

[9.7.3. Literature Included Publications 462](#_Toc123219215)

[9.7.4. Literature Excluded Publications 471](#_Toc123219216)

[9.8. Acronyms 472](#_Toc123219217)

[9.9. Applicable Guidance References 474](#_Toc123219218)

[9.10. CER Team 475](#_Toc123219219)

[9.11. CER Update Frequency Assessment 476](#_Toc123219220)

[9.12. CER Revision History 478](#_Toc123219221)

[9.13. CER Approval Signatures (E-Signatures) 479](#_Toc123219222)

CER ATTACHMENTS

The following documents are attachments to the CER (Table 1).

Table : CER Attachments

| Attachment # | Document |
| --- | --- |
| 1 | Clinical Evaluation Plan (CEP) – Rev 1 |
| 2 | Evaluator CV – Medical Affairs |
| 3 | Evaluator CV – Regulatory Affairs |
| 4 | Evaluator CV – Medical Operations |
| 5 | Evaluator DOI – Medical Affairs |
| 6 | Evaluator DOI – Regulatory Affairs |
| 7 | Evaluator DOI – Medical Operations |
| 8 | SOA Protocol (SOAP) – Internal Fixation of Femur Fractures –Distal Femur and Femoral Shaft – Rev 1 |
| 9 | SOAP – Internal Fixation of Femur Fractures – Distal Femur and Femoral Shaft – Rev 2 |
| 10 | SOA Report (SOAR) – Internal Fixation of Femur Fractures – Distal Femur and Femoral Shaft – Rev 1 |
| 11 | SOAR – Internal Fixation of Femur Fractures – Distal Femur and Femoral Shaft – Rev 2 |
| 12 | Systematic Literature Review Protocol (LRP) |
| 13 | Systematic Literature Review Report (LRR) |
| 14 | Post Market Surveillance (PMS) Sales and Complaints Ad Hoc Review |
| 15 | Femoral Nail Systems Product Codes (MDD and MDR) |
| 16 | MedOps Procedure Template Memo 27 OCT 2022 - CERs SSCPs in Progress |

# EXECUTIVE SUMMARY

The following table (Table 2) comprises an executive summary of the CER. Refer to the sections identified for supporting information.

Table : Executive Summary

|  |  |  |  |
| --- | --- | --- | --- |
| Conformity Assessment Type (Refer to Section 2): | MDD (93/42/EEC)  MDR (2017/745) | | |
| Device Group(s) Included for Subject Device(s) in Scope (Refer to Section 3.1): | Device Group # and Name:   1. Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (R/AFN and RFN) 2. Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail 3. Spiral Blade for Expert Retrograde/Antegrade Femoral Nail 4. Expert Adolescent Lateral Femoral Nail (ALFN) 5. Hip Screw for Expert Adolescent Lateral Femoral Nail 6. Expert End Cap for Adolescent Lateral Femoral Nail 7. Expert Lateral Femoral Nail (LFN) 8. Hip Screw for Expert Lateral Femoral Nail 9. Expert End Cap for Lateral Femoral Nail 10. Femoral Recon Nail (FRN) 11. Recon Screw for Medullary Nail 12. End Cap for Femoral Recon Nail 13. RFN-ADVANCED Femoral Nail (RFNA) 14. Locking Attachment Washer for RFN-ADVANCED 15. Endcaps for RFN-ADVANCED 16. Expert Asian Femoral Nail (A2FN) 17. Hip Screw T25 for Asian Femoral Nail 18. End Cap for Expert Asian Femoral Nail | | |
| Intended Purpose (IFU #): | Refer to Sections 3.1.1 – 3.1.18 | | |
| Expected Clinical Benefit: | Refer to Sections 3.1.1 and 3.1.3 | | |
| MDD Classification(s) Included in Scope (Refer to Section 2): | IIb | Implantable | |
| MDR Classification(s) Included in Scope (Refer to Section 2): | IIb | Implantable | |
| Type of CER (Refer to Section 2): | Update of the clinical evaluation without changes to scope  Update to address design, manufacturing, or labeling changes | | |
| Clinical Evaluation Data Route(s) (Refer to Section 3.8): | Clinical Route | | |
| Types of Data Included (Refer to Sections 3.6.1 and 8.4): | Data Source | | Overall Review Period of Data Source (if applicable) |
| Device-Specific Literature – Section 4 (Subject) | | 01 January 1992 – 22 August 2022 |
| Device-Specific Literature– Section 4 (Equivalent) | | Not Applicable, as equivalent devices are in-scope devices |
| PMCF – Section 6.2 (Subject) | | Not Applicable – No period associated |
| PMCF – Section 6.2 (Equivalent) | | Not Applicable, as equivalent devices are in-scope devices |
| PMS Complaints / Proactive PMS – Section 6.1 (Subject) | | 02 October 2017 to 02 October 2022 |
| PMS Complaints / Proactive PMS – Section 6.1 (Equivalent) | | Not Applicable, as equivalent devices are in-scope devices |
| Nonclinical Data (e.g., bench / analytical / simulated use / animal / cadaveric) – Section 3.6.2 | | Not Applicable – No period associated |
| Negative Change in Performance Not Previously Identified (Refer to Section 8.1.1): | No | | |
| Potential Emerging Risks Not Previously Identified in Risk Analyses (Refer to Section8.4): | No | | |
| Change in Benefit-Risk Acceptability Assessment Conclusion (Refer to Section 8.4): | No | | |
| PMCF Activities Identified in the CER (Refer to Section 8.4): | Specific PMCF\*  General PMCF | | |
| Minimum CER Update Frequency (Refer to Section 1.1): | Every year | | |
| Updates to Associated SSCPs Required (Refer to Section 8.4): | Yes | | |

\*Applicable for System #4: Femoral Recon Nailing System, and System #5: Retrograde Femoral Nail Advanced System.

# SECTION A[[1]](#footnote-2) CONTENT

The following table (Table 3) contains the administrative information associated with the CER.

Table : CER Administrative Information

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Conformity Assessment Type: | MDD (93/42/EEC)  Annex II – based on Full QMS and Technical Documentation MDR (2017/745)  Annex IX – based on QMS and Technical Documentation | | | | |
| Manufacturer(s) Name and Address: | Synthes GmbH, Eimattstrasse 3, 4436 Oberdorf, Switzerland | | | | |
| Manufacturer(s) SRN: | CH-MF-000013345 | | | | |
| Authorized Representative Name SRN (if applicable): | DePuy Ireland UC (SRN: IE-AR-000009328) | | | | |
| Authorized Representative Address (if applicable): | Loughbeg, Ringaskiddy P43 ED82 Co.Cork, Ireland | | | | |
| Device Group(s) Included for Subject Device(s) in Scope: (Refer to Section 9.2.2 for detailed list) | Device Group #: 1   * Device Group Name: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail * Basic UDI-DI (BUDI-DI) Value: 7611819a00252JD * Tradenames: Expert Retrograde/Antegrade Femoral Nail, Expert Retrograde Femoral Nail * European Medical Device Nomenclature (EMDN) Code – Description: P09120201 – INTRAMEDULLARY NAILS | | | | |
| Device Group #: 2   * Device Group Name: Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | |
| Device Group #: 3   * Device Group Name: Spiral Blade for Expert Retrograde/Antegrade Femoral Nail * Basic UDI-DI (BUDI-DI) Value: 7611819a00590K4 * Tradename: Spiral Blades for Expert Retrograde Femoral Nails * EMDN Code – Description: P09120299 – OSTEOSYNTHESIS NAILS - OTHER | | | | |
| Device Group #: 4   * Device Group Name: Expert Adolescent Lateral Femoral Nail | | | | |
| Device Group #: 5   * Device Group Name: Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | |
| Device Group #: 6   * Device Group Name: Expert End Cap for Adolescent Lateral Femoral Nail | | | | |
| Device Group #: 7   * Device Group Name: Expert Lateral Femoral Nail | | | | |
| Device Group #: 8   * Device Group Name: Hip Screw for Expert Lateral Femoral Nail | | | | |
| Device Group #: 9   * Device Group Name: Expert End Cap for Lateral Femoral Nail | | | | |
| Device Group #: 10   * Device Group Name: Femoral Recon Nail | | | | |
| Device Group #: 11   * Device Group Name: Recon Screw for Medullary Nail | | | | |
| Device Group #: 12   * Device Group Name: End Cap for Femoral Recon Nail | | | | |
| Device Group #: 13   * Device Group Name: RFN-ADVANCED Femoral Nail | | | | |
| Device Group #: 14   * Device Group Name: Locking Attachment Washers for RFN-ADVANCED | | | | |
| Device Group #: 15   * Device Group Name: Endcaps for RFN-ADVANCED | | | | |
| Device Group #: 16   * Device Group Name: Expert Asian Femoral Nail | | | | |
| Device Group #: 17   * Device Group Name: Hip Screw T25 for Asian Femoral Nail | | | | |
| Device Group #: 18   * Device Group Name: End Cap for Expert Asian Femoral Nail | | | | |
| Certificate Number and Expiration Date: | Quality Certificate:   * MDD QMS Certificate: G1 056032 0100 Expiry Date: 26 May 2024 * MDR QMS Certificate: G12 056032 0111 Expiry Date: 01 July 2026   Design Exam/Technical Document Assessment Certificate: G70 056032 0115 Expiry Date: 12 October 2027 | | | | |
| MDD Classification(s) Included in Scope (select all that apply): (Refer to Section 9.2 for detailed list) | IIb | | Implantable | | |
| MDR Classification(s) Included in Scope (select all that apply): (Refer to Section 9.2 for detailed list) | IIb | | Implantable | | |
| Applicable Codes Included in Scope per 2017/2185: | Vertical – Non-Active Implants  MDN 1102 – Osteo- and orthopaedic implants | | Horizontal – Specific Characteristics  MDS 1005 – Devices (packed/shipped) in sterile condition | | |
| Horizontal – Specific Technologies or Processes  MDT 2001 – Devices manufactured using metal processing  MDT 2008 – Devices manufactured in clean rooms and associated controlled environments | | |
| Notified Body Name (Notified Body Number): | TÜV SÜD Product Service GmbH (0123) | | | | |
| Type of CER (Refer to Section 9.12 for CER revision history): | Update of the clinical evaluation without changes to scope  Update to address design, manufacturing, or labeling changes   * Labeling updates per MDR requirements | | | | |
| Intended Purpose: | Refer to Sections 3.1.1 – 3.1.18 | | | | |
| CER Author/Evaluator Names: | Refer to Section 9.13 | | | | |
| Technical Documentation #: | Device Group # | Device Group Name | | MDD Technical File | MDR Technical File |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | TF10404 | TF10592 |
| 2 | Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | N/A |
| 3 | Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | TF10592 |
| 4 | Expert Adolescent Lateral Femoral Nail | | TF10405 | N/A |
| 5 | Hip Screw for Expert Adolescent Lateral Femoral Nail | |
| 6 | Expert End Cap for Adolescent Lateral Femoral Nail | |
| 7 | Expert Lateral Femoral Nail | |
| 8 | Hip Screw for Expert Lateral Femoral Nail | |
| 9 | Expert End Cap for Lateral Femoral Nail | |
| 10 | Femoral Recon Nail | |
| 11 | Recon Screw for Medullary Nail | |
| 12 | End Cap for Femoral Recon Nail | |
| 13 | RFN-ADVANCED Femoral Nail | | TF10404 |
| 14 | Locking Attachment Washers for RFN-ADVANCED | |
| 15 | Endcaps for RFN-ADVANCED | |
| 16 | Expert Asian Femoral Nail | | TF10405 |
| 17 | Hip Screw T25 for Asian Femoral Nail | |
| 18 | End Cap for Expert Asian Femoral Nail | |
| Key Referenced Documents: | Refer to Section 9.1 | | | | |
| Guidance Considered During Planning and Execution of CER: | Refer to Section 9.9 | | | | |

# SECTION C CONTENT

## Subject Device Overview

This clinical evaluation covers the Femoral Nail Systems, which includes the Device Groups described in Table 4 and detailed in Appendix 9.2. These devices have also been referred to as Femoral Shaft Nailing Implants and Recon Femoral Nailing Implants in the Technical Files (MDD: TF10404 and TF10405) and Technical Documentation (MDR: TF10592).

Table : Subject Devices Covered within the CER

| Device Group # | Device Group Name | Representative Image\* | Year Group First Released WW | Year Group First CE-Marked by Legal Mfr. |
| --- | --- | --- | --- | --- |
| System #1: Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail |  | 2004 | 2006 |
| 2 | Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail |  | 2004 | 2006 |
| 3 | Spiral Blade for Expert Retrograde/Antegrade Femoral Nail |  | 2004 | 2006 |
| System #2: Expert Adolescent Lateral Femoral Nail System | | | | |
| 4 | Expert Adolescent Lateral Femoral Nail |  | 2007 | 2009 |
| 5 | Hip Screw for Expert Adolescent Lateral Femoral Nail |  | 2007 | 2009 |
| 6 | Expert End Cap for Adolescent Lateral Femoral Nail |  | 2007 | 2009 |
| System #3: Expert Lateral Femoral Nail System | | | | |
| 7 | Expert Lateral Femoral Nail |  | 2004 | 2005 |
| 8 | Hip Screw for Expert Lateral Femoral Nail |  | 2004 | 2005 |
| 9 | Expert End Cap for Lateral Femoral Nail |  | 2004 | 2005 |
| System #4: Femoral Recon Nailing System | | | | |
| 10 | Femoral Recon Nail |  | 2017 | 2018 |
| 11 | Recon Screw for Medullary Nail |  | 2017 | 2021 |
| 12 | End Cap for Femoral Recon Nail |  | 2021 | 2021 |
| System #5: Retrograde Femoral Nail Advanced System | | | | |
| 13 | RFN-ADVANCED Femoral Nail |  | 2020 | 2020 |
| 14 | Locking Attachment Washer for RFN-ADVANCED |  | 2020 | 2020 |
| 15 | Endcaps for RFN-ADVANCED |  | 2020 | 2021 |
| System #6: Expert Asian Femoral Nail System | | | | |
| 16 | Expert Asian Femoral Nail |  | 2008 | 2008 |
| 17 | Hip Screw T25 for Asian Femoral Nail |  | 2008 | 2008 |
| 18 | End Cap for Expert Asian Femoral Nail |  | 2008 | 2008 |

\*The images provided are for illustration purposes only and do not represent all device specifications.

While Device Group #1 has multiple device options within the device group (refer to Section 3.1.1 for description), no variants are defined as all devices within this Device Group #1 as these groups have similar risks, functions, and indications that address the same level of disease / condition and can justifiably be expected to have comparable levels of safety and performance and all size and shape differences are minor and do not necessitate different variants.

### Device Description – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1)

Table 5 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert Retrograde / Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1) and Table 6 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1)

|  | MDD | MDR |
| --- | --- | --- |
| Associated IFU(s): | SE\_532126 | SE\_833508 |
| Associated Promotional Material(s): | Surgical Technique Guide (STG): SE\_831737 | STG: SE\_831737 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. | Bone Fixation Nails, including DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices, are intended for temporary fixation, correction and stabilization of bones. |
| Indications: | Indications for retrograde approach:  In retrograde approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the distal femur:   * 33-A1/A2/A3 * 33-C1/C2/C3.1   For the 33-C fractures, the Expert Retrograde/Antegrade Femoral Nail should be used in combination with other implants.  Additionally, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures)) in case of: * combination with fractured patella * ipsilateral femur/tibia fractures (floating knee) * combination with fractured acetabulum, pelvis, or femoral neck * combinations of the fractures mentioned above * pronounced adipositas * pregnancy * polytrauma (if numerous surgical teams are involved in treatment of patient)   Note: In case of osteoporotic bone, it is strongly recommended to utilise spiral blade locking in the distal femur.  Indications for antegrade approach:  In antegrade approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures). | Retrograde approach:   * Fractures of the distal end segment of the femur * Fractures of the middle and distal diaphyseal segment of the femur   Antegrade approach:   * Fractures of the middle and distal diaphyseal segment of the femur. |
| Contraindications: | No contraindication specific to these devices. | Retrograde approach:   * Fractures of the proximal diaphyseal segment of the femur * Multifragmentary articular fractures of the distal end segment of the femur.   Antegrade approach:   * Fractures of the proximal diaphyseal segment of the femur. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. | The DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices are recommended for use in skeletally mature patients. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. | No additional clinical claims identified in IFU, STG, website other than the intended purpose, indications, and expected clinical benefit. |
| Expected Clinical Benefits: | Not identified or required for MDD | The expected clinical benefit of internal fixation devices such as Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices when used according to instructions for use and recommended technique is:   * Achievement of bone union |
| Intended Users and User Training: | Not identified or required for MDD | These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.  Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in orthopedic surgery, are aware of general risks of orthopedic surgery, and are familiar with the product-specific surgical procedures.  This device is intended to be used by qualified health care professionals who are experienced in orthopedic surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.  All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure “Important Information” carefully before use. Ensure that you are familiar with the appropriate surgical procedure. |
| Limitations: | No identified limitations | No identified limitations beyond contraindications |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. | Potential Adverse Events, Undesirable Side Effects and Residual Risks:   * Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction * Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis. * Embolism * Damage to Vital Organs or Surrounding Structures * Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage * Dislocation * Infection * Injury to User * Malunion/Non-union * Neuro-vascular Damage * Pain or Discomfort * Phlebitis * Poor Joint Mechanics * Soft Tissue Damage (including Compartment Syndrome) * Surgical Delay |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * It is recommended that the tip of the nail is at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the A. femoralis and the branches of the N. femoralis. In cases where such long nails (>320 mm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter. * The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * The use of the drill bit for opening the medullary canal is suitable for nails Ø 9.0 to 12.0 mm. For the larger nails Ø 13.0 to 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the drill bit into the fracture site because this may displace the fracture. * The use of the awl for opening the medullary canal is suitable for nails Ø 9.0 to 13.0 mm. For the larger nails Ø 14.0 and 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the awl into the fracture site because this may displace the fracture. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final proximal position of the nail. * Do not exert force on the aiming arm, protection sleeve or drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bit. * Utilize the gray Titanium End Cap, 0 mm extension, for Femoral Nails – EX (04.003.000) to protect the nail connection threads from bone ingrowth. This facilitates nail removal and locks the most distal screw, providing a stable, fixed-angle construct. * When monitoring the position of the guide wire in AP view, the trapezoidal shape of the condyles must be taken into account. Turning the leg slightly, for a better view of the guide wire tip with respect to the medial cortex, will ensure an accurate measurement. * The use of the end cap is mandatory. Besides enabling angular stability of the spiral blade, it prevents bone ingrowth into the distal end of the nail and, therefore, facilitates the nail removal. * It is recommended that the tip of the nail is at least 5 cm below the most distal extension of the fracture zone. The possibility of dynamization must also be taken into account when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final distal position of the nail. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits in order to guarantee a good drilling precision through the proximal locking holes and to avoid breakage of the drill bits. * The use of the end cap is mandatory. Besides enabling angular stability of the distal locking screw, it prevents bone ingrowth into the proximal end of the nail and, therefore, facilitates nail removal. * When removing implants after longterm implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. | * It is recommended that the tip of the nail is at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the A. femoralis and the branches of the N. femoralis. In cases where such long nails (>320 mm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter. * The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * The use of the drill bit for opening the medullary canal is suitable for nails Ø 9.0 to 12.0 mm. For the larger nails Ø 13.0 to 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the drill bit into the fracture site because this may displace the fracture. * The use of the awl for opening the medullary canal is suitable for nails Ø 9.0 to 13.0 mm. For the larger nails Ø 14.0 and 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the awl into the fracture site because this may displace the fracture. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final proximal position of the nail. * Do not exert force on the aiming arm, protection sleeve or drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bit. * Utilize the gray Titanium End Cap, 0 mm extension, for Femoral Nails – EX (04.003.000) to protect the nail connection threads from bone ingrowth. This facilitates nail removal and locks the most distal screw, providing a stable, fixed-angle construct. * When monitoring the position of the guide wire in AP view, the trapezoidal shape of the condyles must be taken into account. Turning the leg slightly, for a better view of the guide wire tip with respect to the medial cortex, will ensure an accurate measurement. * The use of the end cap is mandatory. Besides enabling angular stability of the spiral blade, it prevents bone ingrowth into the distal end of the nail and, therefore, facilitates the nail removal. * It is recommended that the tip of the nail is at least 5 cm below the most distal extension of the fracture zone. The possibility of dynamisation must also be taken into account when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final distal position of the nail. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits in order to guarantee a good drilling precision through the proximal locking holes and to avoid breakage of the drill bits. * The use of the end cap is mandatory. Besides enabling angular stability of the distal locking screw, it prevents bone ingrowth into the proximal end of the nail and, therefore, facilitates nail removal. * When removing implants after long term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. | Implant Removal:  For Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail in retrograde position with spiral blade locking:   * Remove end cap. * Remove spiral blade. * Remove proximal locking screws. * Attach extraction screw and hammer guide. * Remove nail.   For Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde  Femoral Nail in retrograde position with standard locking:  Follow the procedure described above by removing the locking implants in the order: end cap, first distal locking screw, both proximal locking screws, second distal locking screw.  For Expert Retrograde/Antegrade Femoral Nail in antegrade position with standard locking:  Follow the procedure described above by removing the locking implants in the order: end cap, first proximal locking screw, both distal locking screws, second proximal locking screw. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-014 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). | Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F2119:  Non-clinical testing of worst-case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-) induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Group #1)

|  | MDD / MDR |
| --- | --- |
| Detailed Device Description: | The Expert Retrograde/Antegrade Femoral Nail is used for retrograde and antegrade surgical techniques and are available in various designs such as round, fluted, straight, and bent. The Expert Retrograde Femoral Nail is used for retrograde surgical technique and are available in various designs such as round, fluted, straight, and bent. The respective nailing implants (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail) is selected according to patient anatomy and fracture pattern. These nails can be used for left and right femur.  The Expert Retrograde/Antegrade Femoral Nail is available with diameters ranging from 9 to 15 mm diameters and lengths ranging from 300 mm to 480 mm. Expert Retrograde Femoral Nail is available with diameters ranging from 9 to 15 mm and lengths ranging from 160 to 280 mm. Locking configuration includes static, dynamic, standard, and spiral blade locking. The nails with a diameter of 9 to 13 mm accept Locking Screws Stardrive Ø 5.0 mm. The nails with a diameter of 14 to 15 mm accept Locking Screws Stardrive Ø 6.0 mm.  Figure : Representative Image of Expert Retrograde/Antegrade Femoral Nail |
| Materials / Formulation: (Delete all choices that do not apply) | Implantable Materials/Formulation: Titanium Alloy (TAN): Ti-6Al-7Nb (Titanium – 6% Aluminium – 7% Niobium)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin  Devices do not contain any materials incorporated into the device that contain or consist of carcinogenic, mutagenic or toxic to reproduction (CMR), or materials that could result in sensitization or allergic reaction (beyond those materials listed above) |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: (Delete all choices that do not apply) | Sterile\*  Non-Sterile  Sterilization Method:  Gamma Irradiation\*  Moist Heat (Steam)  \*Note: Only the sterile related SKUs are under MDR compliance for this device group. |
| Lifetime / Duration of Use: (Delete all choices that do not apply) | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #2)

Table 7 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #2) and Table 8 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #2)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_831737 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Indications for retrograde approach:  In retrograde approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the distal femur:   * 33-A1/A2/A3 * 33-C1/C2/C3.1   For the 33-C fractures, the Expert Retrograde/Antegrade Femoral Nail should be used in combination with other implants.  Additionally, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures)) in case of: * combination with fractured patella * ipsilateral femur/tibia fractures (floating knee) * combination with fractured acetabulum, pelvis, or femoral neck * combinations of the fractures mentioned above * pronounced adipositas * pregnancy * polytrauma (if numerous surgical teams are involved in treatment of patient)   Note: In case of osteoporotic bone, it is strongly recommended to utilize spiral blade locking in the distal femur.  Indications for antegrade approach:  In antegrade approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures). |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * It is recommended that the tip of the nail is at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the A. femoralis and the branches of the N. femoralis. In cases where such long nails (>320 mm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter. * The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * The use of the drill bit for opening the medullary canal is suitable for nails Ø 9.0 to 12.0 mm. For the larger nails Ø 13.0 to 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the drill bit into the fracture site because this may displace the fracture. * The use of the awl for opening the medullary canal is suitable for nails Ø 9.0 to 13.0 mm. For the larger nails Ø 14.0 and 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the awl into the fracture site because this may displace the fracture. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final proximal position of the nail. * Do not exert force on the aiming arm, protection sleeve or drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bit. * Utilize the gray Titanium End Cap, 0 mm extension, for Femoral Nails – EX (04.003.000) to protect the nail connection threads from bone ingrowth. This facilitates nail removal and locks the most distal screw, providing a stable, fixed-angle construct. * When monitoring the position of the guide wire in AP view, the trapezoidal shape of the condyles must be taken into account. Turning the leg slightly, for a better view of the guide wire tip with respect to the medial cortex, will ensure an accurate measurement. * The use of the end cap is mandatory. Besides enabling angular stability of the spiral blade, it prevents bone ingrowth into the distal end of the nail and, therefore, facilitates the nail removal. * It is recommended that the tip of the nail is at least 5 cm below the most distal extension of the fracture zone. The possibility of dynamization must also be taken into account when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final distal position of the nail. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits in order to guarantee a good drilling precision through the proximal locking holes and to avoid breakage of the drill bits. * The use of the end cap is mandatory. Besides enabling angular stability of the distal locking screw, it prevents bone ingrowth into the proximal end of the nail and, therefore, facilitates nail removal. * When removing implants after longterm implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-014 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Group #2)

|  | MDD |
| --- | --- |
| Detailed Device Description: | The Expert End Caps are used to block spiral blade or most distal (retrograde) or most proximal locking screw (antegrade). Expert End Cap is available without extension.  Figure : Representative Image of Expert End Cap |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium Alloy (TAN): Ti-6Al-7Nb (Titanium – 6% Aluminium – 7% Niobium)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3)

Table 9 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3) and Table 10 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3)

|  | MDD | MDR |
| --- | --- | --- |
| Associated IFU(s): | SE\_532126 | SE\_833508 |
| Associated Promotional Material(s): | STG: SE\_831737 | STG: SE\_831737 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. | Bone Fixation Nails, including DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices, are intended for temporary fixation, correction and stabilization of bones. |
| Indications: | Indications for retrograde approach:  In retrograde approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the distal femur:   * 33-A1/A2/A3 * 33-C1/C2/C3.1   For the 33-C fractures, the Expert Retrograde/Antegrade Femoral Nail should be used in combination with other implants.  Additionally, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures)) in case of: * combination with fractured patella * ipsilateral femur/tibia fractures (floating knee) * combination with fractured acetabulum, pelvis, or femoral neck * combinations of the fractures mentioned above * pronounced adipositas * pregnancy * polytrauma (if numerous surgical teams are involved in treatment of patient)   Note: In case of osteoporotic bone, it is strongly recommended to utilise spiral blade locking in the distal femur.  Indications for antegrade approach:  In antegrade approach, the Expert Retrograde/Antegrade Femoral Nail is indicated for fractures in the femoral shaft:   * 32-A/B/C (except 32-A[1-3].1 and 32-B[1-3].1 (subtrochanteric fractures). | Retrograde approach:   * Fractures of the distal end segment of the femur * Fractures of the middle and distal diaphyseal segment of the femur   Antegrade approach:   * Fractures of the middle and distal diaphyseal segment of the femur. |
| Contraindications: | No contraindication specific to these devices. | Retrograde approach:   * Fractures of the proximal diaphyseal segment of the femur * Multifragmentary articular fractures of the distal end segment of the femur.   Antegrade approach:   * Fractures of the proximal diaphyseal segment of the femur. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. | The DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices are recommended for use in skeletally mature patients. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. | No additional clinical claims identified in IFU, STG, website other than the intended purpose, indications, and expected clinical benefit. |
| Expected Clinical Benefits: | Not identified or required for MDD | The expected clinical benefit of internal fixation devices such as Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices when used according to instructions for use and recommended technique is:   * Achievement of bone union |
| Intended Users and User Training: | Not identified or required for MDD | These instructions for use alone do not provide sufficient background for direct use of the device or system. Instruction by a surgeon experienced in handling these devices is highly recommended.  Surgery is to take place according to the instructions for use following the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly. It is strongly advised that the surgery is performed only by operating surgeons who have acquired the appropriate qualifications, are experienced in orthopedic surgery, are aware of general risks of orthopedic surgery, and are familiar with the product-specific surgical procedures.  This device is intended to be used by qualified health care professionals who are experienced in orthopedic surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.  All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure “Important Information” carefully before use. Ensure that you are familiar with the appropriate surgical procedure. |
| Limitations: | No identified limitations | No identified limitations beyond contraindications |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. | Potential Adverse Events, Undesirable Side Effects and Residual Risks:   * Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction * Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis. * Embolism * Damage to Vital Organs or Surrounding Structures * Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage * Dislocation * Infection * Injury to User * Malunion/Non-union * Neuro-vascular Damage * Pain or Discomfort * Phlebitis * Poor Joint Mechanics * Soft Tissue Damage (including Compartment Syndrome) * Surgical Delay |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * It is recommended that the tip of the nail is at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the A. femoralis and the branches of the N. femoralis. In cases where such long nails (>320 mm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter. * The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * The use of the drill bit for opening the medullary canal is suitable for nails Ø 9.0 to 12.0 mm. For the larger nails Ø 13.0 to 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the drill bit into the fracture site because this may displace the fracture. * The use of the awl for opening the medullary canal is suitable for nails Ø 9.0 to 13.0 mm. For the larger nails Ø 14.0 and 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the awl into the fracture site because this may displace the fracture. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final proximal position of the nail. * Do not exert force on the aiming arm, protection sleeve or drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bit. * Utilize the gray Titanium End Cap, 0 mm extension, for Femoral Nails – EX (04.003.000) to protect the nail connection threads from bone ingrowth. This facilitates nail removal and locks the most distal screw, providing a stable, fixed-angle construct. * When monitoring the position of the guide wire in AP view, the trapezoidal shape of the condyles must be taken into account. Turning the leg slightly, for a better view of the guide wire tip with respect to the medial cortex, will ensure an accurate measurement. * The use of the end cap is mandatory. Besides enabling angular stability of the spiral blade, it prevents bone ingrowth into the distal end of the nail and, therefore, facilitates the nail removal. * It is recommended that the tip of the nail is at least 5 cm below the most distal extension of the fracture zone. The possibility of dynamization must also be taken into account when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final distal position of the nail. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits in order to guarantee a good drilling precision through the proximal locking holes and to avoid breakage of the drill bits. * The use of the end cap is mandatory. Besides enabling angular stability of the distal locking screw, it prevents bone ingrowth into the proximal end of the nail and, therefore, facilitates nail removal. * When removing implants after longterm implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. | * It is recommended that the tip of the nail is at least 5 cm above the most proximal extension of the fracture zone. Attention must be paid in the area 4 to 6 cm below the Lesser Trochanter because of the A. femoralis and the branches of the N. femoralis. In cases where such long nails (>320 mm) are used, it is recommended to place the AP locking as proximal as possible and above the Lesser Trochanter. * The possibility of dynamisation must also be considered when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * The use of the drill bit for opening the medullary canal is suitable for nails Ø 9.0 to 12.0 mm. For the larger nails Ø 13.0 to 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the drill bit into the fracture site because this may displace the fracture. * The use of the awl for opening the medullary canal is suitable for nails Ø 9.0 to 13.0 mm. For the larger nails Ø 14.0 and 15.0 mm, the use of a reaming system is recommended. * Take care to not plunge the awl into the fracture site because this may displace the fracture. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final proximal position of the nail. * Do not exert force on the aiming arm, protection sleeve or drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bit. * Utilize the gray Titanium End Cap, 0 mm extension, for Femoral Nails – EX (04.003.000) to protect the nail connection threads from bone ingrowth. This facilitates nail removal and locks the most distal screw, providing a stable, fixed-angle construct. * When monitoring the position of the guide wire in AP view, the trapezoidal shape of the condyles must be taken into account. Turning the leg slightly, for a better view of the guide wire tip with respect to the medial cortex, will ensure an accurate measurement. * The use of the end cap is mandatory. Besides enabling angular stability of the spiral blade, it prevents bone ingrowth into the distal end of the nail and, therefore, facilitates the nail removal. * It is recommended that the tip of the nail is at least 5 cm below the most distal extension of the fracture zone. The possibility of dynamisation must also be taken into account when determining the nail length and a correspondingly shorter nail should be chosen. The locking screw in the dynamic locking option can move by up to 5 mm distally. * All Expert Retrograde/Antegrade Femoral Nails can be inserted over the reaming rod. The tip of the reaming rod must be correctly positioned in the medullary canal since it determines the final distal position of the nail. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves and drill bits in order to guarantee a good drilling precision through the proximal locking holes and to avoid breakage of the drill bits. * The use of the end cap is mandatory. Besides enabling angular stability of the distal locking screw, it prevents bone ingrowth into the proximal end of the nail and, therefore, facilitates nail removal. * When removing implants after long term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. | Implant Removal:  For Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail in retrograde position with spiral blade locking:   * Remove end cap. * Remove spiral blade. * Remove proximal locking screws. * Attach extraction screw and hammer guide. * Remove nail.   For Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde  Femoral Nail in retrograde position with standard locking:  Follow the procedure described above by removing the locking implants in the order: end cap, first distal locking screw, both proximal locking screws, second distal locking screw.  For Expert Retrograde/Antegrade Femoral Nail in antegrade position with standard locking:  Follow the procedure described above by removing the locking implants in the order: end cap, first proximal locking screw, both distal locking screws, second proximal locking screw. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-014 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). | Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F2119:  Non-clinical testing of worst-case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-) induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Group #3)

|  | MDD / MDR |
| --- | --- |
| Detailed Device Description: | The Expert Retrograde/Antegrade Femoral Nail has distal combination hole facilitates locking. The surgeon can intraoperatively choose between spiral blade locking (with one spiral blade and one locking screw) and standard locking (with two locking screws).  Spiral Blades for Expert Retrograde Femoral Nails are available in lengths ranging from 45 to 100 mm.  Figure : Representative Image of Spiral Blade for Expert Retrograde/ Antegrade Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium Alloy (TAN): Ti-6Al-7Nb (Titanium – 6% Aluminium – 7% Niobium)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin  Device(s) do(es) not contain any materials incorporated into the device that contain or consist of carcinogenic, mutagenic or toxic to reproduction (CMR), or materials that could result in sensitization or allergic reaction (beyond those materials listed above) |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile\*  Non-Sterile  Sterilization Method:  Gamma Irradiation\*  Moist Heat (Steam)  \*Note: Only the sterile related SKUs are under MDR compliance for this device group. |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert Adolescent Lateral Femoral Nail (Device Group #4)

Table 11 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert Adolescent Lateral Femoral Nail (Device Group #4) and Table 12 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert Adolescent Lateral Femoral Nail (Device Group #4)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_891211 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | The Expert Adolescent Lateral Femoral Nail is indicated for use in adolescent and small-stature adult patients to stabilize:   * Fractures of the femoral shaft * Subtrochanteric fractures * Ipsilateral neck/shaft fractures * Impending pathologic fractures * Nonunions and malunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Adolescent Lateral Femoral Nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Retighten and confirm that the nail is securely connected to the insertion handle. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, or drill sleeves. Such force may prevent accurate targeting through the locking holes. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F 2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F 2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert Adolescent Lateral Femoral Nail (Group #4)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Adolescent Lateral Femoral Nail implant system is offered for standard-locking and reconstruction locking indications. The design of the nail accommodates a lateral entry site through the greater trochanter and can be used in patients where Titanium Elastic Nails are not large enough and the Expert Lateral Femoral Nail for adults is too large.  Additional Design Features:   * Anatomic nail design * Available for left or right femur * Lengths – 240 mm through 400 mm in 20 mm increments * Diameter – 8.2 mm, 9.0 mm, and 10.0 mm * Proximal locking: * Dynamization slot * Static transverse locking hole * 120° antegrade locking * Distal locking: * Two transverse locking holes   Figure : Representative Image of Expert Adolescent Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium Alloy (TAN): Titanium-6% aluminum–7% niobium alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Hip Screw for Expert Adolescent Lateral Femoral Nail (Device Group #5)

Table 13 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Hip Screw for Expert Adolescent Lateral Femoral Nail (Device Group #5) and Table 14 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Hip Screw for Expert Adolescent Lateral Femoral Nail (Device Group #5)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_891211 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | The Expert Adolescent Lateral Femoral Nail is indicated for use in adolescent and small-stature adult patients to stabilize:   * Fractures of the femoral shaft * Subtrochanteric fractures * Ipsilateral neck/shaft fractures * Impending pathologic fractures * Nonunions and malunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Adolescent Lateral Femoral Nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Retighten and confirm that the nail is securely connected to the insertion handle. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, or drill sleeves. Such force may prevent accurate targeting through the locking holes. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Hip Screw for Expert Adolescent Lateral Femoral Nail (Group #5)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Adolescent Lateral Femoral Nail implant system consists of Hip Screws.  Design Features:   * Lengths – 50 mm to 125 mm in 5 mm increments * 5.0 diameter, 3.2 mm core diameter * Partially threaded * Self-tapping, blunt tip * T25 Stardrive recess for improved torque transmission and self-retention on screwdriver   Figure : Representative Image of Expert Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium Alloy (TAN): Titanium-6% Aluminum–7% Niobium alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert End Cap for Adolescent Lateral Femoral Nail (Device Group #6)

Table 15 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert End Cap for Adolescent Lateral Femoral Nail (Device Group #6) and Table 16 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert End Cap for Adolescent Lateral Femoral Nail (Device Group #6)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_891211 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | The Expert Adolescent Lateral Femoral Nail is indicated for use in adolescent and small-stature adult patients to stabilize:   * Fractures of the femoral shaft * Subtrochanteric fractures * Ipsilateral neck/shaft fractures * Impending pathologic fractures * Nonunions and malunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Adolescent Lateral Femoral Nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Retighten and confirm that the nail is securely connected to the insertion handle. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, or drill sleeves. Such force may prevent accurate targeting through the locking holes. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F2213, ASTM F2052 and ASTM F2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert End Cap for Adolescent Lateral Femoral Nail (Group #6)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert End Cap facilitates nail extraction.  Design Features:   * Self-retaining, T40 Stardrive recess for easy pickup and insertion of the end cap * Cannulated for insertion over a guide wire * 0 mm end cap sits flush with the nail * 5 mm, 10 mm, and 15 mm end caps extend nail height if the nail is over inserted.   Figure : Representative Image of Expert End Cap for Adolescent Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium Alloy (TAN): Titanium-6% Aluminum–7% Niobium alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert Lateral Femoral Nail (Device Group #7)

Table 17 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert Lateral Femoral Nail (Device Group #7) and Table 18 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert Lateral Femoral Nail (Device Group #7)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_846534 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert Lateral Femoral Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)   Recon Locking Indications:  The Expert Lateral Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert Lateral Femoral Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Expert Lateral Femoral Nail onto the femur and check radiographically. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned. * Dispose of the guide wire. Do not reuse. * In case of small or difficult anatomy use the flexible drill bit in order to avoid damage to the far cortex. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Especially after hammering, confirm that the nail is securely connected to the insertion handle. Retighten if necessary. * Do not hammer directly on the connector or on the aiming arm. * Do not exert force on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert Lateral Femoral Nail (Group #7)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Lateral Femoral Nail implants are offered for standard-locking and reconstruction locking indications. Expert LFN nails can be implanted through the lateral entry point via the greater trochanter.  Design Features:    * Anatomical design with left and right nails * Lengths: 300–480 mm (20.0 mm increments) * Diameters: * 9.0–16.0 mm (1.0 mm increments) * 9.0–12.0 mm nails have a proximal diameter of 13.5 mm * 13.0–16.0 mm nails have a proximal diameter of 16.0 mm * Cannulation: All nails are cannulated.   Figure : Representative Image of Expert Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Hip Screw for Expert Lateral Femoral Nail (Device Group #8)

Table 19 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Hip Screw for Expert Lateral Femoral Nail (Device Group #8) and Table 20 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Hip Screw for Expert Lateral Femoral Nail (Device Group #8)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_846534 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert Lateral Femoral Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)   Recon Locking Indications:  The Expert Lateral Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert Lateral Femoral Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Expert Lateral Femoral Nail onto the femur and check radiographically. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned. * Dispose of the guide wire. Do not reuse. * In case of small or difficult anatomy use the flexible drill bit in order to avoid damage to the far cortex. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Especially after hammering, confirm that the nail is securely connected to the insertion handle. Retighten if necessary. * Do not hammer directly on the connector or on the aiming arm. * Do not exert force on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Hip Screw for Expert Lateral Femoral Nail (Group #8)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Lateral Femoral Nail implant system consist of Hip Screws.  Design Features:   * Used for recon locking (all nails) * Stardrive T25 recess (self-holding) * Self-tapping, blunt tip * Lengths: 60.0–130 mm (5.0 mm increments) * Diameter: 6.5 mm shaft diameter/4.5 mm core diameter * Thread length: 30.0 mm   Figure : Representative Image of Hip Screw for Expert Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Non-Sterile  Sterilization Method:  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Reusable  Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert End Cap for Lateral Femoral Nail (Device Group #9)

Table 21 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert End Cap for Lateral Femoral Nail (Device Group #9) and Table 22 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert End Cap for Lateral Femoral Nail (Device Group #9)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: SE\_846534 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert Lateral Femoral Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)   Recon Locking Indications:  The Expert Lateral Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert Lateral Femoral Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire, hold a sterile Expert Lateral Femoral Nail onto the femur and check radiographically. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned. * Dispose of the guide wire. Do not reuse. * In case of small or difficult anatomy use the flexible drill bit in order to avoid damage to the far cortex. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not overtighten. * Do not mount the aiming arm until the nail has been completely inserted. * If nail insertion is difficult, choose a smaller diameter nail or ream the intramedullary canal to a larger diameter. * Do not hammer directly onto the insertion handle. Especially after hammering, confirm that the nail is securely connected to the insertion handle. Retighten if necessary. * Do not hammer directly on the connector or on the aiming arm. * Do not exert force on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Adjusting for the correct anteversion before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail. * When removing implants after long-term implantation, especially in the presence of large amounts of bony ingrowth, first use a solid screwdriver to loosen the screw. The inter-lock screwdriver can then be used to remove the screw from the surgical site. If using the inter-lock screwdriver with locking screws, use a solid screwdriver for final tightening.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213, ASTM F 2052 and ASTM F2119:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert End Cap for Lateral Femoral Nail (Group #9)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert End Caps are recommended to cover the cut part of the nail as it may have a burr or sharp edges.  Design Features:   * Stardrive T40 recess (self-holding) * Lengths: * 0 mm – sits flush with end of nail * 5.0 mm, 10.0 mm, 15.0 mm and 20.0 mm * extensions – extend nail height if nail is over inserted * Diameter: * 12.0 mm for nails Ø 9.0–12.0 mm * 16.0 mm for nails Ø 13.0–16.0 mm * Cannulation: All end caps are cannulated   Figure : Representative Image of Expert End Cap for Lateral Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Non-Sterile  Sterilization Method:  Gamma Irradiation  Moist Heat (Steam) |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Femoral Recon Nail (Device Group #10)

Table 23 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Femoral Recon Nail (Device Group #10) and Table 24 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Femoral Recon Nail (Device Group #10)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1117/0978 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Femoral Recon Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1).   Recon Locking Indications:  The Femoral Recon Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally the Femoral Recon Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * Ensure that the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not attach the aiming arm to the handle yet. * Reconfirm that the correct nail (e.g. type of entry point nail, right or left sides) is assembled. * Confirm that the nail is tightly connected to the insertion handle, as hammering may loosen the connection. Retighten if necessary. * Do not strike the insertion handle directly. * Proximal locking with the antegrade locking option is not permitted when using recon screws. * If the use of recon screws is intended in combination with one transverse locking screw, the locking screw must be inserted in the static position of the locking slot (distal position of the transverse locking slot). This prevents the transverse locking screw from interfering with the recon screw. Consult the recon locking section for detailed steps. * The insertion of the transverse locking screw is not permitted if the protection sleeve interferes with the head of the inferior recon screw. * The insertion of the locking screw in the dynamic position of the locking slot (DYNAMIC/DYNA for dynamic locking in the aiming arm) is NOT permitted.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system * with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Femoral Recon Nail (Group #10)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Femoral Recon Nail implants are offered for standard-locking and reconstruction locking indications. This includes nails that are provided in a 5° proximal lateral bend design for entry through the tip of the greater trochanter, and a straight proximal length for entry through the piriformis fossa.  Following are the configurations that are available:   * Piriformis Fossa (PF) Femoral Recon Nail (FRN) with one antegrade proximal locking hole at 135° * Greater Trochanter (GT) Femoral Recon Nail (FRN) with one antegrade proximal locking hole at 140° * Left and right cannulated nails * Distal diameters: 9, 10, 11, 12, and 14 mm * Proximal diameters: 13 mm (9 – 12 mm nails), 14 mm (14 mm nail) * Lengths:   + 280 – 480 mm (20 mm increments; 9 and 10 mm nails)   + 300-480 mm (20 mm increments; 11, 12, 14 mm nails).   Figure : Representative Image of Femoral Recon Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium alloy (TAN): 6% Aluminum-7% Niobium Alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Recon Screw for Medullary Nail (Device Group #11)

Table 25 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Recon Screw for Medullary Nail (Device Group #11) and Table 26 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Recon Screw for Medullary Nail (Device Group #11)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1117/0978 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Femoral Recon Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1).   Recon Locking Indications:  The Femoral Recon Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally the Femoral Recon Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * Ensure that the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not attach the aiming arm to the handle yet. * Reconfirm that the correct nail (e.g. type of entry point nail, right or left sides) is assembled. * Confirm that the nail is tightly connected to the insertion handle, as hammering may loosen the connection. Retighten if necessary. * Do not strike the insertion handle directly. * Proximal locking with the antegrade locking option is not permitted when using recon screws. * If the use of recon screws is intended in combination with one transverse locking screw, the locking screw must be inserted in the static position of the locking slot (distal position of the transverse locking slot). This prevents the transverse locking screw from interfering with the recon screw. Consult the recon locking section for detailed steps. * The insertion of the transverse locking screw is not permitted if the protection sleeve interferes with the head of the inferior recon screw. * The insertion of the locking screw in the dynamic position of the locking slot (DYNAMIC/DYNA for dynamic locking in the aiming arm) is NOT permitted.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system * with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Recon Screw for Medullary Nail (Group #11)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Femoral Recon Nail implant system consists of recon screws.  Design Features:   * Recess: T25 Stardrive * Self-tapping tip * Lengths: 60 mm–130 mm (5 mm increments)   Figure : Representative Image of Recon Screw for Medullary Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium alloy (TAN): 6% Aluminum-7% Niobium Alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – End Cap for Femoral Recon Nail (Device Group #12)

Table 27 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with End Cap for Femoral Recon Nail (Device Group #12) and Table 28 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for End Cap for Femoral Recon Nail (Device Group #12)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1117/0978 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Femoral Recon Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1).   Recon Locking Indications:  The Femoral Recon Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally the Femoral Recon Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1. |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * Ensure that the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not attach the aiming arm to the handle yet. * Reconfirm that the correct nail (e.g. type of entry point nail, right or left sides) is assembled. * Confirm that the nail is tightly connected to the insertion handle, as hammering may loosen the connection. Retighten if necessary. * Do not strike the insertion handle directly. * Proximal locking with the antegrade locking option is not permitted when using recon screws. * If the use of recon screws is intended in combination with one transverse locking screw, the locking screw must be inserted in the static position of the locking slot (distal position of the transverse locking slot). This prevents the transverse locking screw from interfering with the recon screw. Consult the recon locking section for detailed steps. * The insertion of the transverse locking screw is not permitted if the protection sleeve interferes with the head of the inferior recon screw. * The insertion of the locking screw in the dynamic position of the locking slot (DYNAMIC/DYNA for dynamic locking in the aiming arm) is NOT permitted.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system * with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F 2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F 2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the End Cap for Femoral Recon Nail (Group #12)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Femoral Recon Nail implants system consist of end caps and are designed to protect the nail connection threads from bone ingrowth and facilitates nail removal.  Design Features:   * Recess: T40 Stardrive * Ability to extend nail height if nail is over-inserted * Diameter: 12mm * Lengths: 0 mm – 20 mm (5 mm increments)   Figure : Representative Image of End Cap for Femoral Recon Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Titanium alloy (TAN): 6% Aluminum-7% Niobium Alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – RFN-ADVANCED Femoral Nail (Device Group #13)

Table 29 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with RFN-ADVANCED Femoral Nail (Device Group #13) and Table 30 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for RFN-ADVANCED Femoral Nail (Device Group #13)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_793149 |
| Associated Promotional Material(s): | STG: SE\_820613 |
| Intended Purpose: | The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft. |
| Indications: | The Retrograde Femoral Nail Advanced implants are intended to stabilize fractures of the distal femur and the femoral shaft, including:   * Supracondylar fractures, including those with intra-articular extension * Combination of ipsilateral condylar and diaphyseal fractures * Ipsilateral femur/tibia fractures * Femoral fractures in multiple trauma patients * Periprosthetic fractures * Fractures in the morbidly obese * Fractures in osteoporotic bone * Impending pathologic fractures * Malunions and nonunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Expected clinical benefits of internal fixation devices such as Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are   * Stabilize bone segment and facilitate healing * Restore anatomical alignment and limb/extremity function |
| Intended Users and User Training: | Not required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:   * Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction * Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis * Damage to Vital Organs or Surrounding Structures Dislocation * Embolism * Infection * Injury to User * Malunion/Nonunion * Neuro-vascular Damage * Pain or Discomfort * Poor Joint Mechanics * Soft Tissue Damage (including Compartment Syndrome) * Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Warnings & Precautions: | Warnings and Precautions:  It is strongly advised that Retrograde Femoral Nail Advanced implants are implanted only by operating surgeons who are familiar with the general problems of trauma surgery and who are able to master the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.  The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.  Warnings:   * It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma. * Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials. * Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing. * Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases, should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients. * Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.   Precautions:   * For the larger, 14 mm nails, in addition to the 12.8 mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8 mm drill bit for initial opening and continue using the medullary reaming system.   Precautions (Per STG):   * To reduce the risk of malreduction during nail insertion in patients with good bone quality: * Consider achieving and maintaining fracture reduction first. * Consider directing guide wire anteriorly based on nail design and fracture pattern. * For the larger, 14mm nails, in addition to the 12.8mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8mm drill bit for initial opening and continue using the medullary reaming system. * Consult the corresponding surgical technique. * The Retrograde Femoral Nail Advanced is cannulated and can be inserted over reaming rods with a diameter up to 3.85mm at the widest point. Compatible reaming rods will pass through the hole in the center of the aiming arm. * Ensure the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not strike the insertion handle directly, to avoid damage to the handle. * Select adequate screw lengths to avoid protrusion of the screw tips and irritation of soft tissue. * The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position and tighten it as appropriate. * Do not exert force on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bits. * Avoid putting tension on the aiming arm and insertion handle, when locking the protection sleeves, as this can reduce the accuracy of the aiming arm. The sleeves need to contact the cortex, but tension can occur if the protection sleeves are pushed down too hard. * Ensure drill bits and/or screws do not interfere with other medical devices (e.g. knee prosthesis, nail, other screws) and/or critical anatomy (e.g. condylar notch/ joint space).   MRI Precautions:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Implant Removal:  In case the physician decides to remove the implants, the following steps shall be followed:   * Remove end cap. Carefully dissect the soft tissues and visualize all locking implants. Remove the end cap with Synthes Stardrive® screwdriver. Thread the extraction screw into the nail. * Remove screws connecting Locking Attachment Washer to nail, if necessary. * Remove all screws, nuts, washers. * Remove the nail. Having ensured all locking screws are removed, remove nail. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07:  Non-clinical testing of worst-case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency (RF) induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the RFN-ADVANCED Femoral Nail (Group #13)

|  | MDD |
| --- | --- |
| Detailed Device Description: | The Retrograde Femoral Nail Advanced implants consist of a cannulated femoral nail.  Design Features:   * Universal design for left or right femur * Anatomically contoured * Diameters: * Ø 9mm, Ø 10mm, Ø 11mm, Ø 12mm, Ø 14mm * Lengths: 160 mm to 480 mm * Curvature: * 1.0 m Radius of curvature * Short nails (160mm and 200mm) do not have a radius of curvature * Bend: Offered with two distal bends, standard bend (5°) and a periprosthetic bend (10°), for patients with knee prosthesis   Figure : Representative Image of RFN-ADVANCED Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-4V (TAV) Titanium Alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Locking Attachment Washer for RFN-ADVANCED (Device Group #14)

Table 31 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Locking Attachment Washer for RFN-ADVANCED (Device Group #14) and Table 32 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Locking Attachment Washer for RFN-ADVANCED (Device Group #14)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_793149 |
| Associated Promotional Material(s): | STG: SE\_820613 |
| Intended Purpose: | The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft. |
| Indications: | The Retrograde Femoral Nail Advanced implants are intended to stabilize fractures of the distal femur and the femoral shaft, including:   * Supracondylar fractures, including those with intra-articular extension * Combination of ipsilateral condylar and diaphyseal fractures * Ipsilateral femur/tibia fractures * Femoral fractures in multiple trauma patients * Periprosthetic fractures * Fractures in the morbidly obese * Fractures in osteoporotic bone * Impending pathologic fractures * Malunions and nonunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Expected clinical benefits of internal fixation devices such as Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are   * Stabilize bone segment and facilitate healing * Restore anatomical alignment and limb/extremity function |
| Intended Users and User Training: | Not required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:   * Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction * Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis * Damage to Vital Organs or Surrounding Structures Dislocation * Embolism * Infection * Injury to User * Malunion/Nonunion * Neuro-vascular Damage * Pain or Discomfort * Poor Joint Mechanics * Soft Tissue Damage (including Compartment Syndrome) * Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Warnings & Precautions: | Warnings and Precautions:  It is strongly advised that Retrograde Femoral Nail Advanced implants are implanted only by operating surgeons who are familiar with the general problems of trauma surgery and who are able to master the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.  The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.  Warnings:   * It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma. * Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials. * Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing. * Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases, should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients. * Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.   Precautions:   * For the larger, 14 mm nails, in addition to the 12.8 mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8 mm drill bit for initial opening and continue using the medullary reaming system.   Precautions (Per STG):   * To reduce the risk of malreduction during nail insertion in patients with good bone quality: * Consider achieving and maintaining fracture reduction first. * Consider directing guide wire anteriorly based on nail design and fracture pattern. * For the larger, 14mm nails, in addition to the 12.8mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8mm drill bit for initial opening and continue using the medullary reaming system. * Consult the corresponding surgical technique. * The Retrograde Femoral Nail Advanced is cannulated and can be inserted over reaming rods with a diameter up to 3.85mm at the widest point. Compatible reaming rods will pass through the hole in the center of the aiming arm. * Ensure the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not strike the insertion handle directly, to avoid damage to the handle. * Select adequate screw lengths to avoid protrusion of the screw tips and irritation of soft tissue. * The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position and tighten it as appropriate. * Do not exert force on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bits. * Avoid putting tension on the aiming arm and insertion handle, when locking the protection sleeves, as this can reduce the accuracy of the aiming arm. The sleeves need to contact the cortex, but tension can occur if the protection sleeves are pushed down too hard. * Ensure drill bits and/or screws do not interfere with other medical devices (e.g. knee prosthesis, nail, other screws) and/or critical anatomy (e.g. condylar notch/ joint space).   MRI Precautions:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Implant Removal:  In case the physician decides to remove the implants, the following steps shall be followed:   * Remove end cap. Carefully dissect the soft tissues and visualize all locking implants. Remove the end cap with Synthes Stardrive® screwdriver. Thread the extraction screw into the nail. * Remove screws connecting Locking Attachment Washer to nail, if necessary. * Remove all screws, nuts, washers. * Remove the nail. Having ensured all locking screws are removed, remove nail. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07:  Non-clinical testing of worst-case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency (RF) induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Locking Attachment Washer for RFN-ADVANCED (Group #14)

|  | MDD |
| --- | --- |
| Detailed Device Description: | The Retrograde Femoral Nail Advanced implant system also consists of a locking attachment washers (LAW). The LAW accepts 3.5 Variable Angle Screws (not in-scope of the CER) and connects to the nail via 5.0 Variable Angle OPTILINK Screws (not in-scope of the CER).  Design Features:   * Available in left and right versions * Available in two shapes designed to match the nail bend * Anatomically contoured * In situ benders to provide additional contouring   Figure : Representative Image of Locking Attachment Washer for RFN-ADVANCED |
| Materials / Formulation: | Implantable Materials/Formulation: 316L Stainless Steel  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Endcaps for RFN-ADVANCED (Device Group #15)

Table 33 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Endcaps for RFN-ADVANCED (Device Group #15) and Table 34 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Endcaps for RFN-ADVANCED (Device Group #15)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_793149 |
| Associated Promotional Material(s): | STG: SE\_820613 |
| Intended Purpose: | The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft. |
| Indications: | The Retrograde Femoral Nail Advanced implants are intended to stabilize fractures of the distal femur and the femoral shaft, including:   * Supracondylar fractures, including those with intra-articular extension * Combination of ipsilateral condylar and diaphyseal fractures * Ipsilateral femur/tibia fractures * Femoral fractures in multiple trauma patients * Periprosthetic fractures * Fractures in the morbidly obese * Fractures in osteoporotic bone * Impending pathologic fractures * Malunions and nonunions |
| Contraindications: | No contraindication specific to these devices. |
| Patient Target Group: | Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Expected clinical benefits of internal fixation devices such as Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are   * Stabilize bone segment and facilitate healing * Restore anatomical alignment and limb/extremity function |
| Intended Users and User Training: | Not required for MDD |
| Limitations: | No identified limitations |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:   * Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction * Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis * Damage to Vital Organs or Surrounding Structures Dislocation * Embolism * Infection * Injury to User * Malunion/Nonunion * Neuro-vascular Damage * Pain or Discomfort * Poor Joint Mechanics * Soft Tissue Damage (including Compartment Syndrome) * Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Warnings & Precautions: | Warnings and Precautions:  It is strongly advised that Retrograde Femoral Nail Advanced implants are implanted only by operating surgeons who are familiar with the general problems of trauma surgery and who are able to master the product-specific surgical procedures. Implantation is to take place with the instructions for the recommended surgical procedure. The surgeon is responsible for ensuring that the operation is carried out properly.  The manufacturer is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant components and/or operating techniques, the limitations of treatment methods, or inadequate asepsis.  Warnings:   * It is critical to ensure proper selection of the implant meets the needs of the patient anatomy and the presenting trauma. * Use of these devices is not recommended when there is systemic infection, infection localized to the site of the proposed implantation or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials. * Physician should consider patient bone quality to ensure it provides adequate fixation to promote healing. * Conditions that place excessive stresses on bone and implant such as severe obesity or degenerative diseases, should be considered. The decision whether to use these devices in patients with such conditions must be made by the physician taking into account the risks versus the benefits to the patients. * Compromised vascularity in the site of proposed implantation may prevent adequate healing and thus preclude the use of this or any orthopaedic implant.   Precautions:   * For the larger, 14 mm nails, in addition to the 12.8 mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8 mm drill bit for initial opening and continue using the medullary reaming system.   Precautions (Per STG):   * To reduce the risk of malreduction during nail insertion in patients with good bone quality: * Consider achieving and maintaining fracture reduction first. * Consider directing guide wire anteriorly based on nail design and fracture pattern. * For the larger, 14mm nails, in addition to the 12.8mm drill bit, the use of the medullary reaming system is needed to open the femur. In this case use the 12.8mm drill bit for initial opening and continue using the medullary reaming system. * Consult the corresponding surgical technique. * The Retrograde Femoral Nail Advanced is cannulated and can be inserted over reaming rods with a diameter up to 3.85mm at the widest point. Compatible reaming rods will pass through the hole in the center of the aiming arm. * Ensure the connection between the nail and the insertion handle is tight. Retighten if necessary. * Do not strike the insertion handle directly, to avoid damage to the handle. * Select adequate screw lengths to avoid protrusion of the screw tips and irritation of soft tissue. * The screw must not be tightened with the power tool. Disengage the power tool from the screwdriver shaft before the screw is fully seated and use the manual handle to bring the screw to its final position and tighten it as appropriate. * Do not exert force on the aiming arm, protection sleeve, drill sleeves and drill bits. These forces may prevent accurate targeting through the locking holes and damage the drill bits. * Avoid putting tension on the aiming arm and insertion handle, when locking the protection sleeves, as this can reduce the accuracy of the aiming arm. The sleeves need to contact the cortex, but tension can occur if the protection sleeves are pushed down too hard. * Ensure drill bits and/or screws do not interfere with other medical devices (e.g. knee prosthesis, nail, other screws) and/or critical anatomy (e.g. condylar notch/ joint space).   MRI Precautions:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body. |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Implant Removal:  In case the physician decides to remove the implants, the following steps shall be followed:   * Remove end cap. Carefully dissect the soft tissues and visualize all locking implants. Remove the end cap with Synthes Stardrive® screwdriver. Thread the extraction screw into the nail. * Remove screws connecting Locking Attachment Washer to nail, if necessary. * Remove all screws, nuts, washers. * Remove the nail. Having ensured all locking screws are removed, remove nail. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-06e1 and ASTM F2119-07:  Non-clinical testing of worst-case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency (RF) induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Endcaps for RFN-ADVANCED (Group #15)

|  | MDD |
| --- | --- |
| Detailed Device Description: | The Retrograde Femoral Nail Advanced implant system also consist of a cannulated end cap that protects the nail connection threads from bony ingrowth and facilitates nail removal.  Design Features:   * XL25 threaded recess facilitates secure end cap pick-up and insertion * 0mm sits flush with end of nail * 5mm and 10mm extend nail height if nail is over inserted   Figure : Representative Image of Endcaps for RFN-ADVANCED |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN) Titanium Alloy  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Expert Asian Femoral Nail (Device Group #16)

Table 35 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Expert Asian Femoral Nail (Device Group #16) and Table 36 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Expert Asian Femoral Nail (Device Group #16)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1015/0537 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert A2FN with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1).   Recon Locking Indications:  The Expert A2FN with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert A2FN is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | * Isolated femoral neck fractures * Supracondylar fractures (localisation 32) * Intertrochanteric fractures * Pertrochanteric fractures |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations beyond contraindications |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire on the AP view, hold a sterile Expert A2FN nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned or repositioned. Slide the multihole drill sleeve over the guide wire. Use the center of the multihole drill sleeve. Turn the sleeve so that the new guide wire can be inserted at the correct entry point. Possible distances from the center are 4 mm, 5 mm and 6 mm. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Refrain from hammering on the awl or applying excessive force. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not over-tighten. * Do not mount the aiming arm until the nail has been completely inserted. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Do not over tighten the compression screw; it may deform the locking screw. * Adjusting for the correct anteversion-before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, drill sleeves and drill bits. This force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Expert Asian Femoral Nail (Group #16)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Asian Femoral Nail employs a flattened lateral side to aid in insertion and extraction, potentially reducing the impingement of the lateral cortex and decreasing medialization.  Design Features:   * Multiple locking options: standard locking and recon locking * High stability through multiplanar screws * Antirotational stability * Distal dynamization option * Anatomical design with left and right nails * Diameters: 9–14 mm (1 mm increments) * Lengths: 280–460 mm (20 mm increments) * Cannulation: All nails are cannulated.   Figure : Representative Image of Expert Asian Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – Hip Screw T25 for Asian Femoral Nail (Device Group #17)

Table 37 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with Hip Screw T25 for Asian Femoral Nail (Device Group #17) and Table 38 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for Hip Screw T25 for Asian Femoral Nail (Device Group #17)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1015/0537 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert A2FN with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1).   Recon Locking Indications:  The Expert A2FN with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert A2FN is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | * Isolated femoral neck fractures * Supracondylar fractures (localisation 32) * Intertrochanteric fractures * Pertrochanteric fractures |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations beyond contraindications |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire on the AP view, hold a sterile Expert A2FN nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned or repositioned. Slide the multihole drill sleeve over the guide wire. Use the center of the multihole drill sleeve. Turn the sleeve so that the new guide wire can be inserted at the correct entry point. Possible distances from the center are 4 mm, 5 mm and 6 mm. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Refrain from hammering on the awl or applying excessive force. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not over-tighten. * Do not mount the aiming arm until the nail has been completely inserted. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Do not over tighten the compression screw; it may deform the locking screw. * Adjusting for the correct anteversion-before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, drill sleeves and drill bits. This force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.   MRI Precautions (per STG):   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the Hip Screw T25 for Asian Femoral Nail (Group #17)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Asian Femoral Nail implant system consist of hip screws.  Design Features:   * 6.5 mm shaft diameter/4.5 mm core diameter * Stardrive T25 recess (self-holding) * Thread length 30 mm * Self-tapping, blunt tip * Lengths: 60–130 mm (5 mm increments)   Figure : Representative Image of Hip Screw T25 for Asian Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

### Device Description – End Cap for Expert Asian Femoral Nail (Device Group #18)

Table 39 summarizes the key information from the IFUs/promotional material that impact the CER that are associated with End Cap for Expert Asian Femoral Nail (Device Group #18) and Table 40 summarizes other key attributes that are associated with these devices.

Table : Key Information from IFUs and Promotional Materials for End Cap for Expert Asian Femoral Nail (Device Group #18)

|  | MDD |
| --- | --- |
| Associated IFU(s): | SE\_532126 |
| Associated Promotional Material(s): | STG: DSEM/TRM/1015/0537 |
| Intended Purpose: | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus. |
| Indications: | Standard Locking Indications:  The Expert A2FN with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1).   Recon Locking Indications:  The Expert A2FN with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures).   Additionally, the Expert A2FN is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1. |
| Contraindications: | * Isolated femoral neck fractures * Supracondylar fractures (localisation 32) * Intertrochanteric fractures * Pertrochanteric fractures |
| Patient Target Group: | Not identified in the labeling. Not required for MDD. |
| Clinical Claims (source citation reference): | No additional clinical claims identified in IFU, STG, website other than the intended purpose and indications. |
| Expected Clinical Benefits: | Not identified or required for MDD |
| Intended Users and User Training: | Not identified or required for MDD |
| Limitations: | No identified limitations beyond contraindications |
| Adverse Events/Side-Effects: | Potential Adverse Events, Undesirable Side Effects and Residual Risks:  As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:  Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck’s disease, allergy/hypersensitivity reactions, compartment syndrome and side effects associated with hardware prominence, malunion, nonunion. |
| Warnings & Precautions: | Using Intramedullary Nailing Implants in patients with open epiphysis may impair bone growth. Unless included within the specific indications in the corresponding labeling, using Intramedullary Nailing Implants are therefore not recommended for use in skeletally immature patients.  Per STG:   * The correct entry point and angle are essential for a successful result. To ensure the correct position of the guide wire on the AP view, hold a sterile Expert A2FN nail onto the femur and check radiographically. * Dispose of the guide wire. Do not reuse. * The position of the guide wire will be decisive for the success of the next steps. If the position of the inserted guide wire is not optimal, it needs to be realigned or repositioned. Slide the multihole drill sleeve over the guide wire. Use the center of the multihole drill sleeve. Turn the sleeve so that the new guide wire can be inserted at the correct entry point. Possible distances from the center are 4 mm, 5 mm and 6 mm. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Refrain from hammering on the awl or applying excessive force. * After opening the proximal femur, dispose of the guide wire. Do not reuse. * Check that the connecting screw is correctly tightened. Do not over-tighten. * Do not mount the aiming arm until the nail has been completely inserted. * Do not exert forces on the aiming arm, protection sleeve, drill sleeves or drill bits. Such force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Do not over tighten the compression screw; it may deform the locking screw. * Adjusting for the correct anteversion-before making a skin incision is crucial to allow uncomplicated guide wire and screw insertion. * Do not exert force on the aiming arm, protection sleeves, drill sleeves and drill bits. This force may prevent accurate targeting through the proximal locking holes and damage the drill bits. * Drill bit location with respect to the far cortex is critical for measuring the appropriate locking screw length. * Under image intensification, verify that the hook has passed through and engaged the distant end of the nail.   MRI Precautions (per STG):  The above mentioned test relies on non-clinical testing. The actual temperature rise in the patient will depend on a variety of factors beyond the SAR and time of RF application. Thus, it is recommended to pay particular attention to the following points:   * It is recommended to thoroughly monitor patients undergoing MR scanning for perceived temperature and/or pain sensations. * Patients with impaired thermoregulation or temperature sensation should be excluded from MR scanning procedures. * Generally, it is recommended to use a MR system with low field strength in the presence of conductive implants. The employed specific absorption rate (SAR) should be reduced as far as possible. * Using the ventilation system may further contribute to reduce temperature increase in the body |
| Measures to be taken in Event of Malfunction / Change in Performance (if applicable): | Troubleshooting:  Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. |
| Magnetic Resonance Imaging (MRI) Compatibility: | Per STG:  Torque, Displacement and Image Artifacts according to ASTM F 2213-06, ASTM F 2052-14 and ASTM F2119-07:  Non-clinical testing of worst case scenario in a 3 T MRI system did not reveal any relevant torque or displacement of the construct for an experimentally measured local spatial gradient of the magnetic field of 3.69 T/m. The largest image artifact extended approximately 169 mm from the construct when scanned using the Gradient Echo (GE). Testing was conducted on a 3 T MRI system.  Radio-Frequency-(RF-)induced heating according to ASTM F2182-11a:  Non-clinical electromagnetic and thermal testing of worst case scenario lead to peak temperature rise of 9.5 °C with an average temperature rise of 6.6 °C (1.5 T) and a peak temperature rise of 5.9 °C (3 T) under MRI Conditions using RF Coils (whole body averaged specific absorption rate [SAR] of 2 W/kg for 6 minutes [1.5 T] and for 15 minutes [3 T]). |

Table : Attributes for the End Cap for Expert Asian Femoral Nail (Group #18)

|  | MDD |
| --- | --- |
| Detailed Device Description: | Expert Asian Femoral Nail implant system consist of end caps.  Design Features:   * Stardrive T40 recess (self-holding) * Lengths: 0 mm – sits flush with end of nail; 5, 10, 15 and 20 mm extensions – extend nail height if nail is over inserted * Diameters: 13 mm for nails Ø 9–14 mm * Cannulation: All end caps are cannulated   Figure : Representative Image of End Cap for Expert Asian Femoral Nail |
| Materials / Formulation: | Implantable Materials/Formulation: Ti-6Al-7Nb (TAN)  Devices do not contain any medicinal substances  Devices do not contain any tissues or cells of human or animal origin |
| Principles of Operation: | Provides structural rigidity during healing |
| Mode of Action: | Mechanical |
| State / Method of Sterilization: | Sterile  Sterilization Method:  Gamma Irradiation |
| Lifetime / Duration of Use: | Single Use   * Therapeutic Lifetime (i.e., the time for which the device is intended to perform): 6 to 9 months (time to bone healing). * Post-Therapeutic Lifetime: The remaining lifetime of the patient. |
| Rationale for Lifetime:   * Therapeutic Lifetime: Bone healing usually lasts no longer than 6-9 months. In terms of mechanical performance, the therapeutic lifetime of the femoral nailing implants is therefore seen as 6 to 9 months. * Post-Therapeutic Lifetime: Implant removal – if indicated – is performed after 1 to 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen to be the remaining lifetime of the patient (as the implant may not be removed). |
| Novel Features: | No Novel features present  Novel features present: N/A |
| Novelty of Clinical Procedure and Purpose: | Novel clinical procedure and/or purpose – Refer to Sections 3.9.4 for further discussion.  Clinical procedure and purpose consistent with current clinical practices – Refer to Section 3.9.4 for further discussion. |
| Significant Changes: | No significant changes to subject device(s) since initial CE-marking  No significant changes to subject device(s) since last CER |
| Previous Generation(s): | No previous generations  Applicable previous generation: N/A |
| Variants: | No variants  Applicable variants: N/A |

## Classification Rationale(s)

All the subject devices are MDD class IIb devices based on rule Annex IX Rule 8, where no indent applies. The subject devices, Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1) and Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3) are MDR Class IIb devices based on Annex VIII Rule 8, where no indent applies. None of the devices (i.e., Device Group #1 and #3) are considered Well-Established Technology (WET) devices as defined in MDCG 2020-6 Guidance.

## Accessories and Compatible Devices

There are no accessories associated with the Femoral Nail Systems. , , Table 43, Table 44, Table 45, Table 46, and Table 47 summarize the compatible devices associated with the subject device(s).

Table : Subject Device Associations

|  |  |
| --- | --- |
| Accessories: | None Associated  Associated (Refer to list below) |
| Compatible Devices: | None Associated  Associated (Refer to list below) |
| Systems (not packaged together): | None Associated  Associated (Refer to list below) |
| Systems / Procedure Packs (packaged together): | None Associated  Associated (Refer to list below) |

Table : Associated Devices for Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image | BUDI-DI Value | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | Locking Screws Stardrive   * Available: Ø 5.0 mm or Ø 6.0 mm |  | Not yet defined | Yes |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | * Aiming Armfor Expert R/AFN, for Standard Locking Radiolucent * Available as antegrade or retrograde |  | 7611819a00093JH | No |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | Arm for Proximal Aiming Device for Expert Retrograde Femoral Nail |  | 7611819a00093JH | No |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | Protection Sleeve 13.0 for Expert R/AFN, with Quick Coupling   * Available ad retrograde or antegrade |  | 7611819a00225JA | No |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | Multihole Drill Guide for Protection Sleeve 13.0, for Expert R/AFN   * Available ad retrograde or antegrade |  | 7611819a00225JA | No |
| 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | * Module for Proximal Aiming Device for Expert Retrograde Femoral NailAvailable for Standare Locking or Spiral Blade Locking |  | 7611819a00093JH | No |
| 3 | Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | Aiming Arm for Expert R/AFN, retrograde, for Spiral Blade Locking |  | 7611819a00093JH | No |
| 3 | Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | Measuring Device for Expert R/AFN Spiral Blade  (03.010.492) |  | Not yet defined | No |

Table : Associated Devices for Expert Adolescent Lateral Femoral Nail System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image |  | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 4 | Expert Adolescent Lateral Femoral Nail | Locking Screws Stardrive Ø 4.0 mm |  |  | Yes |
| 4 | Expert Adolescent Lateral Femoral Nail | Aiming Arm, radiolucent, for Expert Adolescent Lateral Femoral Nail  (03.010.483) |  |  | No |
| 4 | Expert Adolescent Lateral Femoral Nail | Aiming Arm for Expert Adolescent Lateral Femoral Nail  (03.010.227) |  |  | No |
| 4 | Expert Adolescent Lateral Femoral Nail | Insertion Handle, radiolucent, length 100 mm, for Expert ALFN  (03.010.488) |  |  | No |
| 4 | Expert Adolescent Lateral Femoral Nail | Insertion Handle for Expert Adolescent Lateral Femoral Nail  (03.010.226) |  |  | No |
| 4 | Expert Adolescent Lateral Femoral Nail | Protection Sleeve 13.0 for Expert Adolescent Lateral Femoral Nail, with Quick Coupling (03.010.504) |  |  | No |
| 4 | Expert Adolescent Lateral Femoral Nail | Multihole Drill Guide for Protection Sleeve 13.0, for Expert Adolescent Lateral Femoral Nail  (03.010.509) |  |  | No |

Table : Associated Devices for Expert Lateral Femoral Nail System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image |  | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 7 | Expert Lateral Femoral Nail | Locking Screw Ø 5.0 mm |  |  | Yes |
| 7 | Expert Lateral Femoral Nail | Locking Screw Ø 6.0 mm |  |  | Yes |
| 7 | Expert Lateral Femoral Nail | Aiming Arm, radiolucent, for Expert Lateral Femoral Nail  (03.010.482) |  |  | No |
| 7 | Expert Lateral Femoral Nail | Protection Sleeve 17.0 for Expert Lateral Femoral Nail, with Quick Coupling  (03.010.505) |  |  | No |
| 7 | Expert Lateral Femoral Nail | Multihole Drill Guide for Protection Sleeve 17.0, for Expert Lateral Femoral Nail |  |  | No |

Table : Associated Devices for Femoral Recon Nailing System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image |  | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 13 | Femoral Recon Nail | Locking Screw Ø 5.0 mm |  |  | Yes |
| 13 | Femoral Recon Nail | Insertion Handle, radiolucent, Femoral Recon Nail  (03.033.001) |  |  | No |
| 13 | Femoral Recon Nail | Aiming Arm, radiolucent, for Piriformis Fossa, Femoral Recon Nail  (03.033.002) |  |  | No |
| 13 | Femoral Recon Nail | Aiming Arm, radiolucent, for Greater Trochanter, Femoral Recon Nail  (03.033.003) |  |  | No |

Table : Associated Devices for Retrograde Femoral Nail Advanced System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image |  | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 16 | RFN-ADVANCED Femoral Nail | Locking Screw Ø 5.0 mm |  |  | Yes |
| 16 | RFN-ADVANCED Femoral Nail | Periprosthetic Wire Guide (03.233.000) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Drill Bit Ø 12.8mm, cannulated f/Large Quick Coupling  (03.233.001) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Drill Bit Ø 11.2mm, cannulated f/Large Quick Coupling  (03.233.002) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Connecting Screw  (03.233.003) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Nail Assembly Instrument (03.233.004) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Insertion Handle, Radiolucent (03.233.005) |  |  | No |
| 16 | RFN-ADVANCED Femoral Nail | Aiming Arm, Radiolucent (03.233.006) |  |  | No |
| 17 | Locking Attachment Washer for RFN-ADVANCED | Holding Device Locking Pin for Locking Attachment Washer  (03.233.008) |  |  | No |
| 17 | Locking Attachment Washer for RFN-ADVANCED | Holding Device Handle for Locking Attachment Washer (03.233.009) |  |  | No |

Table : Associated Devices for Expert Asian Femoral Nail System

| Device Group # | Device Name | Associated Compatible Devices | Representative Image |  | Has an impact on clinical safety or performance of Subject Device(s) |
| --- | --- | --- | --- | --- | --- |
| 10 | Expert Asian Femoral Nail | Locking Screw Ø 5.0 mm |  |  | Yes |
| 10 | Expert Asian Femoral Nail | Aiming Arm for Expert A2FN (03.010.350) |  |  | No |
| 10 | Expert Asian Femoral Nail | Insertion Handle for Expert A2FN (03.010.351) |  |  | No |
| 10 | Expert Asian Femoral Nail | Protection Sleeve 11.5/8.5, for Expert A2FN  (03.010.353) |  |  | No |
| 10 | Expert Asian Femoral Nail | Connection Screw, cannulated,  for Expert A2FN  (03.010.356) |  |  | No |
| 10 | Expert Asian Femoral Nail | Compression Screw, for Expert A2FN  (03.010.372) |  |  | No |
| 10 | Expert Asian Femoral Nail | Extraction Screw, for Expert A2FN |  |  | No |
| 11 | Hip Screw T25 for Asian Femoral Nail | Reamer Ø 4.5/6.5 mm for Hip Screws Expert A2FN  (03.010.368) |  |  | No |

## Overview of Previous Generations and Similar Devices

There are no previous generations for the subject devices (Refer to Section Sections 3.1.1 – 3.1.18).

Refer to Section 3.9.2 for identification of similar device(s).

## Clinical Evaluation Plan

See CER Attachment 1 for the associated Clinical Evaluation Plan (CEP). Table 48 identifies the cross-reference between the required CEP content and the CEP question.

Table : Cross-reference Between CEP Content Requirements and CEP Questions

| MDR CEP Requirement (Annex XIV, Part A[1a]) | CEP Question |
| --- | --- |
| * Identification of the general safety and performance requirements (GSPRs) that require support from relevant clinical data | 8 |
| * Specification of the intended purpose of the device | 5 |
| * Clear specification of intended target groups with clear indications and contra-indications | 5 |
| * Detailed description of intended clinical benefits to patients with relevant and specified clinical outcome parameters | 5 |
| * Specification of methods to be used for examination of qualitative and quantitative aspects of clinical safety with clear reference to the determination of residual risks and side-effects | 6 |
| * Indicative list and specification of parameters to be used to determine, based on the state of the art in medicine, the acceptability of the benefit-risk ratio for the various indications and for the intended purpose or purposes of the device | 9 |
| * Indication how benefit-risk issues relating to specific components such as use of pharmaceutical, non-viable animal or human tissues, are to be addressed | 10 |
| * Clinical development plan | 11 |

Identification of the Essential Requirements (ERs) that require support from relevant clinical data under the MDD are also captured in the CEP, Question 8.

## Data Appraisal Plan – Clinical and Nonclinical Performance and Safety Data

### Overview of Clinical Data

Table 49 includes a summary of the type of medical effect for all subject devices and expected clinical benefit for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1), Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3), Device Group #13: RFN-ADVANCED Femoral Nail, Device Group #14: Locking Attachment Washer for RFN-ADVANCED, and Device Group #15: Endcaps for RFN-ADVANCED

Table : Type of Clinical Performance for All Subject Devices and Clinical Benefit

| Type of Clinical Performance: (Delete choices not selected) | Direct Medical Effect |
| --- | --- |
| Expected Clinical Benefit: (Delete choices not selected) | Subject Device:  Device Group #1: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and Device Group #3: Spiral Blade for Expert Retrograde/Antegrade Femoral Nail:  The expected clinical benefit of internal fixation devices such as Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices when used according to instructions for use and recommended technique is:   * Achievement of bone union (MDR IFU: SE\_833508)   Device Group #13: RFN-ADVANCED Femoral Nail, Device Group #14: Locking Attachment Washer for RFN-ADVANCED, and Device Group #15: Endcaps for RFN-ADVANCED:  Expected clinical benefits of internal fixation devices such as Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are   * Stabilize bone segment and facilitate healing * Restore anatomical alignment and limb/extremity function (MDD IFU: SE\_793149) |

Table 50 – Table 55 includes a summary of the data included in the CER and indicates which data were of sufficient scientific validity and relevance to support the safety and/or performance conformity assessment and / or inform on the identification of safety trends or performance issues. The data with the strongest evidence pertains to the subject devices and has the lowest rank number (i.e., strongest = 1; weakest = 12). Rank definitions are derived from the hierarchy of clinical evidence described in MDCG 2020-6 for medical devices CE-marked under MDD.

Data that are identified as having sufficient scientific validity and relevance to support the safety and/or performance conformity assessment are analyzed in Sections 8.1.1 and 8.1.4 by comparing these data against the benefit-risk acceptability criteria (Section 3.9.5) established in the SOA analysis. Sufficiency of these data to support conformity is summarized in the conclusion (Section 8.4). The ERs/GSPRs that require the support of clinical data are identified in the CEP (Table 1).

Table : Type of Clinical Performance & Safety Data Included – Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature | 2 – High Quality CI with some gaps  4 – Justifiable studies with potential flaws | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature | 6 – Mixed Cohort (target & similar devices)  9 – Case reports on subject device | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| Post-market Clinical Follow-up Data – PMCF Activity / Real World Evidence (RWE)  (Adaptiv 10083084) | 3 – High Quality clinical data collections | Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #2 / Data Use Agreement (DUA)  (#0000311162) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #3 / DUA  (#0000311164) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #4 / DUA  (#0000311163) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail * Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail * Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Table : Type of Clinical Performance & Safety Data Included – Expert Adolescent Lateral Femoral Nail System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature | 2 – High Quality CI with some gaps | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature | 7 – Aggregated data (e.g., mixed cohort target / alternative or non-relevant without outcomes | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| Post-market Clinical Follow-up Data – PMCF Plan #500577392 and PMCF Activity #1 / DUA  (#0000317835) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500577392 and PMCF Activity #2 / DUA  (#0000317838) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * Expert Adolescent Lateral Femoral Nail * Hip Screw for Expert Adolescent Lateral Femoral Nail * Expert End Cap for Adolescent Lateral Femoral Nail | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Table : Type of Clinical Performance & Safety Data Included – Expert Lateral Femoral Nail System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature | 2 – High Quality CI with some gaps  4 – Justifiable studies with potential flaws | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature | 6 – Mixed Cohort (target & similar devices) | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| Post-market Clinical Follow-up Data – PMCF Plan #500577392 and PMCF Activity #1 / DUA  (#0000317835) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500577392 and PMCF Activity #2 / DUA  (#0000317838) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * Expert Lateral Femoral Nail * Hip Screw for Expert Lateral Femoral Nail * Expert End Cap for Lateral Femoral Nail | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Table : Type of Clinical Performance & Safety Data Included – Femoral Recon Nailing System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature for Subject Device | 6 – Mixed Cohort (target & similar devices) | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature for Equivalent Device (Expert Lateral Femoral Nail System) | 5 – Equivalence | Performance  Safety  Supports Conformity Assessment  Informs Identification of Safety Trends | Equivalent Device | System | No additional stratification | Section 4 |
| Device-Specific Literature for Equivalent Device (Expert Lateral Femoral Nail System) | 6 – Mixed Cohort (target & similar devices) | Safety  Informs Identification of Safety Trends | Equivalent Device | System | No additional stratification | Section 4 |
| Post-market Clinical Follow-up Data – PMCF Plan #500566412 and PMCF Activity #2 / DUA  (#0000317835) for Subject Device and PMCF Plan #500577392 and PMCF Activity #1 / DUA (#0000317835) for Equivalent Device (Expert Lateral Femoral Nail System) | 3 – High Quality clinical data collections  5 – Equivalence devices) | Performance  Safety  Supports Conformity Assessment | Subject Device  Equivalent Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500566412 and PMCF Activity #3 / DUA  (#0000317838) for Subject Device and PMCF Plan #500577392 and PMCF Activity #2 / DUA (#0000317838) for Equivalent Device (Expert Lateral Femoral Nail System) | 3 – High Quality clinical data collections  5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Subject Device  Equivalent Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500566412 and PMCF Activity #1 / Investigator Initiated Study (IIS)  (DPS-TCMF-2018-34) | 3 – High Quality clinical data collections | Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * Femoral Recon Nail * Recon Screw for Medullary Nail * End Cap for Femoral Recon Nail | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Table : Type of Clinical Performance & Safety Data Included – Retrograde Femoral Nail Advanced System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature for Subject Device | 9 – Case reports on subject device | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Equivalent Device | System | No additional stratification | Section 4 |
| Device-Specific Literature for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 6 – Mixed Cohort (target & similar devices) 9 – Case reports on subject device | Safety  Informs Identification of Safety Trends | Equivalent Device | System | No additional stratification | Section 4 |
| Post-market Clinical Follow-up Data – PMCF Plan #500441682 and PMCF Activity #2a / IIS  (DPS-TCMF-2021-033) | 3 – High Quality clinical data collections  5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500441682 and PMCF Activity #2b / IIS  (DPS-TCMF-2021-050) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500441682 and PMCF Activity #2c / IIS  (DPS-TCMF-2021-061) | 3 – High Quality clinical data collections | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500441682 and PMCF Activity #3 / Internal Registry (DST202103) | 2 – High Quality CI with some gaps | Safety  Supports Conformity Assessment | Subject Device | System  Device Group(s): N/A | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Activity / RWE  (Adaptiv 10083084) for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 5 – Equivalence | Safety  Supports Conformity Assessment | Equivalent Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #2 / DUA  (#0000311162) for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Equivalent Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #3 / DUA  (#0000311164) for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Equivalent Device | System | No additional stratification | Section 6.2 |
| Post-market Clinical Follow-up Data – PMCF Plan #500445872 and PMCF Activity #4 / DUA  (#0000311163) for Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | 5 – Equivalence | Performance  Safety  Supports Conformity Assessment | Equivalent Device | System | No additional stratification | Section 6.2 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * RFN-ADVANCED Femoral Nail * Locking Attachment Washers for RFN-ADVANCED * Endcaps for RFN-ADVANCED | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Table : Type of Clinical Performance & Safety Data Included – Expert Asian Femoral Nail System

| Included Data Sources | Rank / Hierarchy of Evidence | Addresses relevant endpoints related to Performance and/or Safety Data | Device Types Included | Devices by which Data Section is Summarized | Additional Data Stratification Groups | Cross-Reference to Data |
| --- | --- | --- | --- | --- | --- | --- |
| Device-Specific Literature | 2 – High Quality CI with some gaps  4 – Justifiable studies with potential flaws | Performance  Safety  Supports Conformity Assessment | Subject Device | System | No additional stratification | Section 4 |
| Device-Specific Literature | 6 – Mixed Cohort (target & similar devices)  9 – Case reports on subject device | Safety  Informs Identification of Safety Trends | Subject Device | System | No additional stratification | Section 4 |
| PMS (Complaints, Vigilance, Actions, Advanced Analytics) | 7 – Complaints & vigilance | Safety  Informs Identification of Safety Trends | Subject Device | Device Group(s):   * Expert Asian Femoral Nail * Hip Screw T25 for Asian Femoral Nail * End Cap for Expert Asian Femoral Nail | No additional stratification | Section 6.1 |
| Nonclinical | 12 – nonclinical/ bench/ compliance to standards | N/A – Not of sufficient scientific validity and/or relevance | Subject Device | System | No additional stratification | Section 3.6.2 |

Data Stratification Justification:

The data will be stratified by device groups in the device description (Sections 3.1.1 – 3.1.18) and PMS (Section 6.1). The systematic device-specific literature (Section 4) and the PMCF studies (Section 6.2) will not be stratified by device groups because the Systems (i.e., Expert R/AFN and Expert RFN System, Expert ALFN System, Expert LFN System, FRN System, RFNA System, and Expert A2FN System) are evaluated on their performance and safety as whole constructs in real world clinical usage and settings. Further, the key performance and safety outcomes described in Section 3.9.5 are applicable to all device groups in terms of addressing and demonstrating the success and ability of the devices to achieve its intended purpose and its safety profile.

Table 56 identifies the CER sections that reference the data summaries for all subject devices by data source.

Table : Reference to Data Summaries from All Sources

| Benefit-Risk Acceptability Criteria: | Section 3.9.5 |
| --- | --- |
| Performance: | Section 8.1.1 |
| Safety: | Section 8.1.2 |
| Summary of Significant Complaints / Trends / Vigilance from Previous Generations: | Section 8.1.3 |
| Acceptability of Residual risks / Side-Effects: | Section 8.1.4 |
| Benefit-Risk Conclusion: | Section |

### Nonclinical Data

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Provide nonclinical safety and performance evidence of from the Technical Documentation to verify / validate the Key Design Requirements identified for each Device Group/variant in Section 3.1.X and / or substantiate the benefit/risk acceptability (as referenced in Section 3.9.5).   * Consider whether separate tables are beneficial for different Device Groups. * Ensure that testing is available for all Device Groups and escalate if not. * Identify subject /representative / comparative devices tested by system/device group/variant (as appropriate). * Cross-reference reports documenting objective evidence. * Include sample sizes (if available) * Ensure that units of measure are documented and that results and acceptance criteria units match * Do not include testing on prototypes that are not representative of the finished good devices * Verify that the results described align with the content of the test description * If the conclusion says “Pass”, verify that the results meet the acceptance criteria * Include the key safety and performance nonclinical data (e.g., strength, fatigue, electrical, simulated use, MRI, animal, etc.) * Include testing to address usability. * Remove any personal information (e.g., names), as applicable * If testing was done on “worst-case” size or Device Group for a particular test, identify rationale for worst-case or cross-reference document that defines this. * State the relevance of the data to the device under evaluation. If non-subject devices were tested but are considered representative of the subject devices, a justification should be added explaining why the data are considered representative. * Evaluate and comment on the transferability and generalizability of the test methods and setting to the clinical situation, as well as adequacy of the used samples sizes. |
|  |  | **Review section for any failing tests to ensure these are not included in isolation. If a test was changed or repeated due to a previous failure, a rationale must be included to explain why a later test result is considered appropriate when a previous test failed.** |

Table 57 summarizes the nonclinical datasets verifying and validating the key design requirements associated with safety and performance of Femoral Nail Systems.

Table : Femoral Nail Systems Nonclinical Data Summary

| Reference | Device | Test Description | Acceptance Criteria | Results | Conclusion |
| --- | --- | --- | --- | --- | --- |
| System #1: Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | | |
| #0000259070  (SET\_20060218)  Static Four-Point Bend Test of a ø4.6mm Cannulated Test | Expert R/AFN and Expert RFN  Sample size(n=5) | Static Four-Point Bend Test of 9mm Cannulated Expert R/AFN (5 samples)  To determine the Bending Moment at Yield of ø4.6mm cannulated test bars with 9.0mm outer diameter and compare it with data of the reference product DePuy ART 2609-48 Nails with an outer diameter of 9mm.  A Four-Point bending test on the Expert R/AFN Prototype with an outer diameter of 9mm and a cannulation of 4.6mm, and the reference product DePuy ART 2609-48 with an outer diameter of 9mm and a slot diameter of 4mm. The Four-Point bending test was conducted per ASTM F 1268 with L = 210mm and s= c = 70mm (see figure 1), with nail sloth facing downwards. The load was applied at a rate of 10mm/min until further increase in displacement did not result in an increase in load. | The acceptance criteria in the report are not well defined. | Ø4.6mm Cannulated Test Bar – Mean bending stiffness 230.3 N/mm (σ = 2.0), Mean bending moment at yield 34.9 Nm (σ = 2.8) and Structural stiffness 32.9 Nm (σ = 0.3).  ART 2609-48 – Mean bending stiffness 119 N/mm (σ = 1.1), Mean bending at yield 18.5 Nm (σ = 0.4) and Structural stiffness 17.0 Nm (σ = 0.2).  Results obtained through the Four-Point bending test of the Ø4.6mm Cannulated Test Bar and the DePuy ART 2609-48 Nail show, that the Ø4.6mm Cannulated Test Bar, prototype of the Ø9.0mm Expert R/AFN, is stronger regarding to static mechanical performance characteristics than its reference device ART 2609-48. | Pass |
| #0000259070  (SET\_20140155)  Static Four-Point Bend Test for R/AFN EX Femoral | Expert R/AFN and Expert RFN  04.013.312-04.013.976  04.013.312S-04.013.976S  Sample size(n=3) | Static Bending Test on Intramedullary Devices (3 samples)  Determine the Bending Moment at Yield of three (3) Expert Retrograde/Antegrade Femoral Nails (Expert R/AFN) with an outer diameter of 9mm. | The acceptance criteria in the report are not well defined. This test was performed for characterization purposes only. | The Bending Moment at Yield of the medial part of Expert R/AFN (04.013.376) was evaluated. Mechanical Test SET\_20140155 performs a Four-Point bending test on the Expert R/AFN (04.013.376) with an outer diameter of 9mm and inner diameter of 4.6mm. The Four-Point bending test was conducted per ASTM F 1268 with L = 228mm and test apparatus touch points 76mm apart and 76mm from each edge, with nail curvature facing upwards. The load F was applied at a rate of 1mm/s until further increase in displacement did not result in an increase in load.  Bending moment at yield = 97.2 Nm (σ = 0.9)  The Static Bending Moment at Yield obtained through a Four- Point bending test of the Expert R/AFN (04.013.376) is 97.2Nm and can be compared with other reference data obtained with a Four-Point bending test according to ASTM standard F1264-03. | Pass |
| #0000259070  (SET\_20140154)  Dynamic Four-Point Bend Test for Expert R/AFN | Expert R/AFN and Expert RFN  04.013.376  Sample size(n=10) | Dynamic Four-Point Bend Test for Expert R/AFN Nail (10 samples)  To determine the dynamic strength of the Expert Retrograde/Antegrade Femoral Nail (Expert R/AFN) based on standard ASTM F1264. | The acceptance criteria in the report are not well defined. This test was performed for characterization purposes only. | The Fmax value was adopted from the static 4-point bending test SET\_20140155 as load basis for the dynamic test (this value corresponds to Fmax 100%). Test setup was identical to SET\_20140155, also according to ASTM F1264, where the nail seats freely in the 4-point bending device and the position of the nail was defined by a spacing of 76mm between the uppermost distal locking hole and the first lower bearing  The dynamic bending strength based on standard ASTM F1264 of an Expert Retrograde/Antegrade Femoral Nail (Expert R/AFN) with ø9.00mm (04.013.376) is approximately 50Nm (std dev not reported) after 106 cycles. | Pass |
| #0000259070  (SET\_20140156)  Static Torsion Test for Expert R/AFN | Expert R/AFN and Expert RFN  04.013.376  Sample size(n=4) | Static torsion Test for Expert R/AFN Nail (4 samples)  To determine the torsion rigidity of the Expert R/AFN Nails based on the standard ASTM F1264.  The torsion test set-up has a test length of 230 mm (the exposed part of the nail is 230mm). An Expert R/AFN nail (part #04.013.376) with a diameter of 9 mm and a length of 480 mm (Titanium–6% Aluminum–7% Niobium alloy). Is placed in the torque test set-up. | The acceptance criteria in the report are not well defined. This test was performed for characterization purposes only. | Static torsion Mean value 1.52 Nm (σ = 0.05).  The static torsion strength rigidity based on standard ASTM F1264 of an Expert Retrograde/Antegrade Femoral Nail (Expert R/AFN) with ø9.00mm (04.013.376) is 1.52Nm/° in its elastic range. | Pass |
| #0000259076  Interconnectivity and tolerance rationale for SUN, R/AFN, DFN, UNI and UFN/CFN | Expert R/AFN and Expert RFN, SUN, DFN, Universal Nail, UFN/CFN  04.013.440S-04.013.976S  04.013.340S-04.013.376S  04.013.440-04.013.976  04.013.340-04.013.376  04.013.412-04.013.936  04.013.412S-04.013.936S  04.013.312-04.013.336  04.013.312S-04.013.336S | Tech file remediation: tolerance stack and interconnectivity analysis of the femoral shaft nailing implants and associated/dedicated instrumentation in the tech file TF10404. Includes analysis of femoral nails, spiral blades, locking/holding sleeves, shaft screws, and end caps.  Safety and performance data from the post market surveillance report Post Market Surveillance Report (PMSR) for Femoral Shaft Nails (Windchill #0000250261) will be reviewed for safety signals.  The following complaint codes were analyzed:  SYNTHES: DEVICE INTERACTION: DOES NOT FIT WITH OTHER PARTS, SYNTHES: DEVICE INTERACTION: MISALIGNMENT, SYNTHES: DEVICE INTERACTION: SEIZED, SYNTHES: DEVICE INTERACTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: LOOSE, SYNTHES: DOES NOT/WILL NOT FUNCTION: WILL NOT HOLD, SYNTHES: DOES NOT/WILL NOT FUNCTION: FELL APART, SYNTHES: DOES NOT/WILL NOT FUNCTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: FUNCTIONAL ISSUE, UNSPECIFIED | The result of the rationale must confirm that the articles in scope of this document have been assessed for their safety and intended performance and no further design related actions or further investigation are required. | Occurrence rate for interconnectivity-related issues from January 2013 through December 2015 was:  All oUS components: 0.001% (n=211502)  All US components: 0.025% (n=4081)  Total all components: 0.002% (n=215583)  One of the four complaints was related to the in-scope Expert R/AFN: The Expert R/AFN nails 04.013.552, 04.013.564 and 04.013.720 used resulted in a complaint regarding slight prolongation of operation time, resolving with optional medical treatment.  Based on the occurrence rate and the absence of safety signals within the PMSR, that the implants in scope are being used in the market in a safe manner and that their interconnection with mating parts is adequate for their intended performance. | Pass |
| #0000259074  Rationale for Validation Studies R/AFN | Expert R/AFN and Expert RFN  04.013.440S-04.013.976S  04.013.340S-04.013.376S  04.013.440-04.013.976  04.013.340-04.013.376  04.013.412-04.013.936  04.013.412S-04.013.936S  04.013.312-04.013.336  04.013.312S-04.013.336S | Remediation of TF10404: Assess possible gaps in validation of the Expert R/AFN system. Evaluate the five validation studies conducted on the Expert R/AFN system.  Bioskills Lab (Windchill #0000157357) 12 April 2004: Product requirements were evaluated for the nails combined with their end caps to avoid implant loss in soft tissue.  Wet lab (Windchill #000084146 and 0000157375) 03 December 2011: Specific clinical and regulatory needs referenced in the Functional & Design Requirement matrix were validated.  Expert Nail Upgrade Lab (Windchill #000088965, 000087424, and 0000157478) 02 May 2013: Specific clinical and regulatory needs referenced in the Functional & Design Requirement matrix were validated. | The result of the rationale must confirm that the articles in scope of this document have been assessed for their safety and intended performance and do not require further action. | Bioskills Lab (Windchill #0000157357) 12 April 2004: There was no difficulty for insertion in the retrograde or antegrade approach. A reamed (over a reaming rod) or unreamed condition of the canal is possible to insert the nail. With the aid insertion and anatomical constraints, the nail geometry complies without any influence on the self-retaining feature. Therefore, it can be concluded that the devices have met the specified functional/ design requirements in conformity to the user’s needs and intended uses.  Wet lab (Windchill #000084146 and 0000157375) 03 December 2011: It can be concluded that the articles in scope are fulfilling the requirements successfully.  Expert Nail Upgrade Lab (Windchill #000088965, 000087424, and 0000157478) 02 May 2013: It can be concluded that the articles in scope are fulfilling the requirements successfully.  Based on the above-mentioned evidence the Expert R/AFN Nails are validated and do not require further action. The summarized results confirm that the articles in scope of this document have been assessed for their safety and intended performance. | Pass |
| System #2: Expert Adolescent Lateral Femoral Nail System | | | | | |
| #0000258159  (MT07-410)  Synthes ALFN Recon Locking Fatigue | Expert ALFN  04.031.925  04.031.028 | Synthes Expert ALFN Recon Locking Fatigue test (30 samples)  To develop a Wöehler curve for the Ø8.2 mm Synthes Adolescent Lateral Entry Femoral Nail with two recon screws engaged in a simulated femoral head.  Worst case rationale:  10 pcs of 04.031.925 (8.2mm Expert ALFN nail) 20 pcs of 03.031.028 (90mm Expert ALFN Recon Locking Screw) Fatigue load capacity of the nails with the proximal locking system and the corresponding screw-hole configuration in the proximal part of the Expert ALFN nail were evaluated. Cyclic loading was performed by a MTS 858 MiniBionix test machine, dry at room temperature, applying a sinusoidal Load of R=0.1 and a frequency of 2Hz for Expert ALFN Nails. Minimum, maximum and range of fatigue loads were evaluated as well as number of cycles before failure. | No acceptance criteria defined. | Fatigue load capacity of the nails with the proximal locking system and the corresponding screw-hole configuration in the proximal part of the Expert ALFN nail were evaluated. Cyclic loading was performed by a MTS 858 MiniBionix test machine, dry at room temperature, applying a sinusoidal Load of R=0.1 and a frequency of 2Hz for Expert ALFN Nails.  Minimum, maximum and range of fatigue loads were evaluated as well as number of cycles before failure.  15 separate compressive load tests were conducted. Compressive loads ranged from a minimum of 100n to a maximum of 1500n. | Pass |
| #0000258159  Expert ALFN engineering analysis | Expert ALFN  04.031.924-04.031.981  04.031.924S-04.031.981S | Expert ALFN engineering analysis  The engineering rationale compares the bending and torsion strength of the Synthes Expert ALFN to the Biomet Titanium Pediatric Femoral Nail and the Smith & Nephew Trigen Adolescent Trochanteric Antegrade Nail.  The analysis includes strength of overall construct and considers strength of the hip screw.  Calculation was done on a 8.2 mm diameter nail, therefore the worst case for cross section and area moment of inertia and 5.0 mm diameter screw which is the only available Expert ALFN screw diameter. Consequently, calculations apply to all nail and hip screw articles in scope of the Expert ALFN system.  Cross sectional analyses, area moment of inertia, and polar moment of inertia were used to compare the strength of the nails and hip screws. | The result of the test must indicate that ALFN is at least equivalent to its reference devices in the area of lowest strength and all nails and hip screws within scope have been assessed for mechanical performance further indicating that the mechanical performance of all parts in scope are sufficient. | The results of the calculations show that Expert ALFN is at least equivalent to its reference devices in the area of lowest strength. | Pass |
| #0000259039  Drawing review for risk control for sharp edges (Implants) | Expert ALFN  04.003.440-04.031.981  04.009.236S-04.009.773S | Drawing review for risk control for sharp edges (implants)  Review drawings to confirm they include the following specifications:  Edge break specifications  Edge radius defined on drawings.  Free of burrs  Includes, nails, hip screws, end caps, washers (for AFN only) | Drawings are reviewed to confirm that they include at least one of the following specifications:  1. Edge break specifications  2. Edge radius defined on drawings  3. Free of burrs | Based on drawing review, acceptance criteria of all in-scope articles have been met. | Pass |
| #0000255375  Interconnectivity and Tolerance Analysis Rationale | Expert ALFN | Tolerance analysis rationale: interconnectivity of nails, end caps, hip screws, washers (for AFN only), and locking screw/bolt with dedicated instrumentation.  Analysis of sales and complaint data from PMS Reports (Windchill #0000250261 and #0000248929) for the periods 01 January 2012 – 31 December 2014 and 01 November 2012 – 31 October 2015, respectively.  The following complaint codes were analyzed:  SYNTHES: DEVICE INTERACTION: DOES NOT FIT WITH OTHER PARTS, SYNTHES: DEVICE INTERACTION: MISALIGNMENT, SYNTHES: DEVICE INTERACTION: SEIZED, SYNTHES: DEVICE INTERACTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: LOOSE, SYNTHES: DOES NOT/WILL NOT FUNCTION: WILL NOT HOLD, SYNTHES: DOES NOT/WILL NOT FUNCTION: FELL APART, SYNTHES: DOES NOT/WILL NOT FUNCTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: FUNCTIONAL ISSUE, UNSPECIFIED | The result of the rationale must indicate that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Occurrence rate for interconnectivity-related issues was:  Expert A2FN: 0.08%  Expert ALFN: 0.01%  Expert LFN: 0.01%  The analysis of the Post Market Reports does not indicate any safety signals and shows that the articles in scope are adequate for their intended use. Therefore, based on the occurrence rate calculations and the absence of safety signals within the Post Market Reports, it can be concluded that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Pass |
| #0000258162  Rationale for Validation Studies ALFN | Expert ALFN  04.031.924-04.031.981  04.031.924S-04.031.981S  04.031.020-04.031.035  04.031.020S-04.031.035S  04.031.000-04.031.003  04.031.000S-04.031.003S | Validation rationale to address validation documentation gap – the results of a sawbones lab were not performed by a surgeon and involved the implantation of only one nail. PMS will be used to evaluate the identified gaps.  Sawbones lab summary:  Lab on 02 October 2007. A left Expert ALFN Nail (PN: 04.031.929), 125mm Hip Screws (PN: 04.031.022) and End Cap (PN:04.031.001) were implanted into a sawbones model with a set of instruments listed in the Lab. Production parts were used for the lab.  PMS summary:  PMS report (Windchill/ 0000248929)  Clinical Evaluation Report (Windchill / 0000254065) | The system must perform as specified in the technique guide. | Based on the results of the lab, the acceptance criteria that the system performs as specified in the technique guide was met.  According to the Clinical Evaluation Report, the devices of the system perform as intended and the literature evaluated demonstrates the efficacy of the Expert ALFN System, as well as its safety and performance.  According to the current PMS Reports, no safety signals are present for the assessed system. | Pass |
| System #3: Expert Lateral Femoral Nail System | | | | | |
| #0000254138  (2004028)  Dynamic Fatigue Test | Expert LFN  04.003.360  04.003.034 | Dynamic fatigue test conducted on an Expert LFN System compared to reference device AFN. Test was isolated to the proximal interface section of the Nail (2 samples).  The fatigue performance of the Expert LFN Nailing system shall be compared with the fatigue performance of Antegrade Femoral Nail (AFN) system. This Test Report 2004028 deals only comparison between the Expert LFN and the AFN subsystem with Reconstruction screws.  Parts used in test:  Nail: 04.003.360  Hip Screw: 04.003.034  Due to the nature of the applied bending load on the femoral head, the highest stress level is expected at the lateral side of the nail under recon locking. The bending load will induce compression stress at the medial side of the nail and tension stress on the lateral side of the nail.  The test set-up represented an anatomic worst-case scenario of a comminuted diaphyseal fracture without any cortical nail shaft support.  Sample size(n=2) | The Woehler curve of LFN system is parallel or higher than the AFN system indicating a higher fatigue strength. Additionally, the nail should fail before the reconstruction screws fail. | The determined limiting fatigue load of the AFN system is between 850N-900N. In comparison the Expert LFN system has its limiting fatigue load at 1600N. This shows that the Expert LFN system can in minimum bear 77.7% more load if tested on fatigue, compared to the AFN.  The determined limiting fatigue load of the AFN system was between 850-900N. The limiting fatigue load of the Expert LFN system was 1600N, demonstrating an increase compared to the AFN. Five Expert LFN specimens were tested to failure. The results indicate that every Expert LFN construct did have failure at the distal recon screw hole. Four cases of these failures included fractures of the reconstruction screws which cracked about 3-5mm from the end of the threaded zone. Therefore, the report deems this acceptance criteria was not met. It is not clear which failure mode happened first (the test report acknowledged this), and failure of the nail first would lead to a change in distribution of forces to the hip screw, hence leading to further failure modes if the test would not stop immediately. A further Finite Element Analysis (FEA) demonstrated that the failure mode of Expert LFN system is solely at the lateral side of the nail at the distal recon screw hole (MT16-386). | Pass |
| #0000254138 (2004028) – part of Dynamic Fatigue Test in LFN MTSR (MT16-386)  Finite Element Analysis | Expert LFN  04.003.360  04.003.034 | Finite Element Analysis  To test a nail with reconstruction locking as a whole construct. Finite element analyses of Expert LFN nail were performed.  The test set up was simulated similar to that of mechanical testing and material properties were used as per the nail and recon screws as well as the test set-up components.  Maximum principal stress contour plots of the proximal region of the nail were generated and analyzed for the overall nail and specifically for one of the chamfer regions of the nails. These two plots were chosen because the highest magnitude maximum principal stress, in some cases, occurs inside the screw hole region of the nail. This is not typically the region of failure of these nails, which typically occurs at the outside surface of the nails in the chamfer region. | The results of the test must indicate that the failure region of LFN nail systems will be in the distal screw hole of the proximal region of the nails and therefore the recon screw failure could be associated with load pattern changes after nail broke in the mechanical testing. | Loading conditions were similar to those performed during physical testing of these types of nail systems. The results of these analyses indicate that the failure region of Expert LFN nail systems will be in the distal screw hole of the proximal region of the nails and the therefore the recon screw failure could be associated with load pattern changes after nail broke in the mechanical testing.  Based on the analysis, the mechanical testing has shown that Expert LFN provides a better or equivalent performance to the predicate device AFN, Antegrade Femoral Nail, and meets the requirements with respect to dynamic loading strength and stiffness, fatigue strength and lifetime. | Pass |
| #0000254138  (SET\_20190351 and SET\_20200194)  Expert LFN Dynamic full construct test to evaluate nails manufactured in Mezzovico with new manufacturing process. | Expert LFN  04.003.260S | Expert LFN Dynamic full construct test to evaluate nails manufactured in Mezzovico with new manufacturing process.  To determine the median fatigue limit of the alternative manufacturing flow of the Synthes Intramedullary (IM) Nailing System Expert A2FN under specific laboratory conditions. In this test, the median fatigue limit was compared between two manufacturing alternatives. The reference device is a nail manufactured in Mezzovico (MEZ), Switzerland according to current validated processes. On the other hand, the subject device is a nail manufactured in Mezzovico (MEZ), Switzerland per new manufacturing process flow (Robodrill - Crippa). | The subject device fatigue strength mean must be non-inferior to the reference device fatigue strength mean with a margin of non-inferiority of -10% of the reference device fatigue strength mean | The calculated median fatigue limit (mFL) for the Expert LFN constructs using the new/alternative process (round 2) is 716N (Stdev = 27.5N) whereas the median fatigue limit for the Expert LFN constructs using the current process is 690N (Stdev = 27.5N). The result shows that the p-value=0 is lower than α=0.1, therefore the null hypothesis was rejected. It can be concluded that nails manufactured using the new/alternative process is non-inferior to the nails from the current process with non-inferiority margin of -10%. | Pass |
| #0000259039  Drawing review for risk control for sharp edges (implants) | Expert LFN  04.003.440 | Drawing review for risk control for sharp edges (implants)  Review drawings to confirm they include the following specifications:  Edge break specifications  Edge radius defined on drawings.  Free of burrs  Includes, nails, hip screws, end caps, washers (for AFN only) | Drawings are reviewed to confirm that they include at least one of the following specifications:  1. Edge break specifications  2. Edge radius defined on drawings  3. Free of burrs | Based on drawing review, acceptance criteria of all in-scope articles have been met. | Pass |
| #0000255375  Interconnectivity and Tolerance Analysis Rationale | Expert LFN | Tolerance analysis rationale: interconnectivity of nails, end caps, hip screws, washers (for AFN only), and locking screw/bolt with dedicated instrumentation.  Analysis of sales and complaint data from PMS Reports (Windchill #0000250261 and #0000248929) for the periods 01 January 2012 – 31 December 2014 and 01 November 2012 – 31 October 2015, respectively.  The following complaint codes were analyzed:  SYNTHES: DEVICE INTERACTION: DOES NOT FIT WITH OTHER PARTS, SYNTHES: DEVICE INTERACTION: MISALIGNMENT, SYNTHES: DEVICE INTERACTION: SEIZED, SYNTHES: DEVICE INTERACTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: LOOSE, SYNTHES: DOES NOT/WILL NOT FUNCTION: WILL NOT HOLD, SYNTHES: DOES NOT/WILL NOT FUNCTION: FELL APART, SYNTHES: DOES NOT/WILL NOT FUNCTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: FUNCTIONAL ISSUE, UNSPECIFIED | The result of the rationale must indicate that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Occurrence rate for interconnectivity-related issues was:  Expert A2FN: 0.08%  Expert ALFN: 0.01%  Expert LFN: 0.01%  The analysis of the Post Market Reports does not indicate any safety signals and shows that the articles in scope are adequate for their intended use. Therefore, based on the occurrence rate calculations and the absence of safety signals within the Post Market Reports, it can be concluded that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Pass |
| #0000255376  Rationale for Validation Studies LFN | Expert LFN  04.003.240-04.003.977  04.003.240S-04.003.977S | Validation rationale to address validation documentation gap – the results of four labs were not documented as formal validation or did not have the required traceability and were not performed by a surgeon. PMS and the clinical evaluation report will be used to evaluate the identified gaps.  Bioskills / cadaver lab summary:  Validation lab (07 May 2003): Cadaver specimen evaluation of ease of nail insertion, the ability to center the nail in the medullary canal, the ability to account for anteversion, ease of use, and location/accuracy of locking screws.  Lab minutes (04 August 2003): Product development cadaver lab evaluated three prototypes of Expert LFN with modified lateral bends to address a varus deformity. All three prototypes were successfully implanted in cadaver specimens.  Lab minutes (05 September 2003): Product development cadaver lab held to compare nail insertion between two prototypes of Expert LFN with modified lateral bends and investigate sub-trochanteric fracture reduction. Two nail prototypes were inserted in a matched pair specimen (right and left femur of the same cadaveric specimen) to understand any differences in nail insertion. Nail insertion was deemed acceptable for both prototypes, and no issues were seen inserting the nails.  Lab minutes (06 October 2004): A cadaver lab demonstrated the Expert LFN to surgeons of the Long Bone Expert Group (LBEG). A right Expert LFN Nail (PN: 04.003.560) was inserted by hand for approximately 75% of the nail length and final insertion was achieved using light hammer blows. Nail rotation was felt after approximately 60% of insertion. No issues were seen inserting the nails, and insertion was considered comparable to the standard antegrade femoral nailing technique.  PMS summary:  PMS report (Windchill / 0000250261)  Clinical Evaluation Report (Windchill / 0000254065) | The result of rationale must indicate that the devices of the system perform as intended and the literature evaluated demonstrates the efficacy of the Expert LFN System, as well as its safety and performance. | Based on the results of the labs, the nails were deemed to pass acceptance criteria.  According to the Clinical Evaluation Report, the devices of the system perform as intended and the literature evaluated demonstrates the efficacy of the Expert LFN System, as well as its safety and performance.  According to the current PMS Reports, no safety signals are present for the assessed system. | Pass |
| System #4: Femoral Recon Nailing System | | | | | |
| #0000264921  Tolerance Analysis – Verification Analysis | FRN  04.033.928S-04.033.449S  04.033.958S-04.033.479S | The objective of this tolerance analysis is to verify that the design output meets the design input specifications of the instrumentation and implants contained in the FRN system (implants and instruments) as defined in the compatibility matrix (Windchill document # 0000259817 A.49).  This verification analysis followed the guidelines provided in the work instruction Design Verification Process (W-C-S047). | All of the design input specifications for the FRN system that require a tolerance stack as a verification method in the instrument FDR and implant FDR must be successfully verified. | Source and justification for acceptance criteria were defined in each individual tolerance stack for all interactions which are not based on a reference system.  All stacks have been completed and all acceptance criteria are met. As a result, all of the design input specifications for the FRN system that require a tolerance stack as a verification method in the instrument FDR (0000259297, A.67) and implant FDR (0000077533, A.108) have been successfully verified. | Pass |
| (SET\_20170149, SET\_20170150, SET\_20170085)  Construct Fatigue Testing – Standard locking mode | FRN | The objective of this test was to determine the median fatigue limit and the failure mode for the Femoral Recon Nail System in a worst-case construct. The calculated median fatigue limit F(mFL) was determined at 1’000’000 load cycles. The calculated median fatigue limit F(mFL) of the subject Femoral Recon Nail System was compared to that of the primary predicate device Lateral Entry Femoral Nail System by applying a non-inferiority criterion.  The dynamic fatigue testing is performed per the international standard “ISO 7206-4 Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties of stemmed femoral components”. ISO 7206-4:2010(E) has been partially applied to define the overall test setup. The test constructs consist of the nail, two proximal and two distal locking screws. | The calculated median fatigue limit F(mFL) for the FRN GT construct must be non-inferior to the LFN construct | FRN GT constructs: Out of the nine (724.2) tested constructs, two (2) nails broke distally at the position of the static lateral to medial locking screw and in two (2) cases, the distal static lateral to medial locking screw broke. There was no failure in the remaining five.(Voormolen et al.) constructs.  FRN PF constructs: Out of the nine (724.2) tested constructs, one (Papadokostakis et al.) nail broke distally at the position of the static lateral to medial locking screw and in three (3) cases, the distal static lateral to medial locking screw broke. There was no failure in the remaining five ((5) constructs.  Expert LFN constructs: Out of the eight (8) tested constructs, four (724.2) constructs.  The median fatigue limits of the FRN GT (781.00N, P=0.001) and FRN PF (786.64N, P=0.006) constructs were significantly higher when compared to the Expert LFN (680.83N) construct. The Femoral Recon Nail constructs performed better than the predicate device constructs; therefore, the acceptance criteria were met.  The results of the fatigue testing of constructs with locking screws show that the subject system meets the defined acceptance criteria. The median fatigue limits of the subject devices worst-case constructs are greater than the median fatigue limit of the predicate device’s worst-case construct. The results show a comparable failure mode for the subject constructs and the predicate construct. In both, the subject system and comparator system, the failure occurs at the most proximal of the distal lateral to medial locking option. | Pass |
| (SET\_20170079, SET\_20170081, SET\_20160256)  Construct Fatigue Testing – Recon locking mode | FRN | The objective of this test was to determine the median fatigue limit and the failure mode for the Femoral Recon Nail System in a worst-case construct. The calculated median fatigue limit F(mFL) was determined at 1’000’000 load cycles. The calculated median fatigue limit F(mFL) of the subject device Femoral Recon Nail System was compared to that of the primary predicate device Lateral Entry Femoral Nail System by applying a non-inferiority criterion.  The dynamic fatigue testing is performed per the international standard “ISO 7206-4 Implants for surgery - Partial and total hip joint prostheses - Part 4: Determination of endurance properties of stemmed femoral components”. ISO 7206-4:2010(E) has been partially applied to define the overall test setup. The test constructs consist of the proximal part of the nail and two recon screws. | The calculated median fatigue limit F(mFL) for the FRN GT construct must be non-inferior to the LFN construct. The FRN GT nail shall fail at the proximal part of the nail prior to the recon screws. | FRN GT construct: Out of a total number of 14 specimens producing a failure, 14 failures of the proximal part of the nail occurred. Two failures of the recon screws were excluded from the results.  FRN PF construct: Out of a total number of 13 specimens producing a failure, 11 failures of the proximal part of the nail occurred. Five failures of the recon screws were excluded from the results.  The median fatigue limits of the FRN GT (1188.77N, P=0.000) and FRN PF (1149.62N, P=0.000) constructs were significantly higher when compared to the Expert LFN (850.84N) construct. The Femoral Recon Nail constructs performed better than the predicate device construct and the failures occurred in the proximal part of the nail prior to the recon screws; therefore, the acceptance criteria were met.  The results of the fatigue testing of constructs with recon screws show that the subject system meets the defined acceptance criteria. The median fatigue limits of the subject devices worst-case constructs are greater than the median fatigue limit of the comparator device worst-case construct. The acceptance criterion is met, since the subject device Femoral Recon Nail System performed better than the comparator device Lateral Entry Femoral Nail System.  In addition, in case of failures, the constructs failed at the proximal part of the Femoral Recon Nail, therefore the acceptance criteria regarding the failure mode is met. | Pass |
| #0000261710 Rev 3  Cross section analysis – Nail Shaft | FRN | The purpose of this cross-section analysis is to provide an engineering analysis to compare the mid shaft portion of the nail, disregarding the locking options of the worst-case nails of the Femoral Recon Nail System and predicate device Lateral Entry Femoral Nail System in terms of bending and torsional stiffness.  Three test modalities, dynamic four-point bending, static four-point bending and static torsion were considered in accordance with ASTM 1264-16 “Standard Specification and Test Methods for Intramedullary Fixation Devices” to perform the evaluation. As the subject and predicate nails are made of the same raw material and feature similar designs and dimensions, an analytical evaluation method was chosen to compare the mechanical strength of the specimens. The torsional and bending strength of both the subject and predicate devices were assessed based on their cross-sectional areas using specific formulas. | To support the decision on the cross-section design the area moment of inertia (I) and the polar moment of inertia (IP)of the shaft section of the Femoral Recon Nail (FRN GT, FRN PF) shall be within the range when compared to that of the Lateral Entry Femoral Nail (LFN).  Due to the nature of an engineering analysis, no statistical test is required to compare the values.  The following values are compared at the cross-section E-E in LMC or MMC condition:  I FRN(min) ≥ I LFN(min) LMC condition  I FRN(max) ≤ I LFN(max) MMC condition  IP FRN(min) ≥ IP LFN(min) LMC condition  IP FRN(max) ≤ IP LFN(max) MMC condition  To support the decision on the worst-case selection in terms of bending and torsional strength, the lowest value for the area moment of inertia and the polar moment of inertia of each nail type shall be determined.  Due to the nature of an engineering analysis, no statistical test is required to compare the values.  The following value is determined in cross-section E-E in LMC condition:  I FRN(min)  IP FRN(min)  I LFN(min)  IP LFN(min)  I A2FN(min)  IP A2FN(min)  I RAFN(min)  IP RAFN(min)  To determine substantial equivalence of the Femoral Recon Nail (FRN GT, FRN PF) to the Lateral Entry Femoral Nail (LFN) in worst case condition, the area moment of inertia and the polar moment of inertia of the shaft section of the Femoral Recon Nail (FRN GT, FRN PF) shall not be inferior when compared to that of the Lateral Entry Femoral Nail (LFN).  Due to the nature of an engineering analysis, no statistical test is required to compare the values.  The values compared at cross section E-E in LMC condition:  I FRN(min) ≥ I LFN(min)  IP FRN(min) ≥ IP LFN(min) | The area moment of inertia and the polar moment of inertia of the Femoral Recon Nail implants are higher when compared to that of the predicate device Entry Femoral Nail System.  An engineering analysis to compare the mid shaft portion of the nail shows that the subject devices meet the defined acceptance criteria. The area moment of inertia and the polar moment of inertia of the subject devices worst-case constructs are greater than the area moment of inertia and the polar moment of inertia of the predicate device worst-case construct. Therefore, it is concluded that the bending and torsional stiffness of the subject device is non-inferior to that of the predicate device. | Pass |
| #0000269230  Validation Report Anatomical Study | Femoral Recon Nail Implants  04.033.958S - 04.033.478S  04.033.959S - 04.033.479S | Anatomical study to compare the nail shape of the Femoral Recon Nails (FRN) to the Expert A2FN (Expert A2FN), while virtually implanted into 82 three dimensional reconstructed femora.  Seven parameters were compared to assess the nail fit. | * The median “Protrusion Area” (C5) of the FRN GT (median 478mm^2) must be less than that of the A2FN (median 1123mm^2) (p = 0.000). * The median “Protrusion Maximum Distance” (C6) of the FRN GT (median 0.850mm) must be less than that of the A2FN (median 2.280mm) (p = 0.000). * There must be no statistical difference of the median “Relative Distal End Position in the AP View” (C15-2) of the FRN GT (median 8.702%) when compared to the that of the A2FN (median 8.691%) (p = 0.738). * The mean “Relative Distal End Position in the LAT View” (C10-2) of the FRN GT (mean 13.28%) must be less than that of the A2FN (mean 24.78%) (p = 0.000). * The “Distance Proximal Nail end to outer Cortex” (C4) of the FRN GT must be less (mean -5.64mm) than that the A2FN (mean -1.873mm) (p = 0.000). * The mean “CCD Angle” (A11) of 129.793° must be less than 132.5° as the p-value of the T-Test comparing to the upper bound of 132.5° is less than 0.05. * The “Angle projected AP Plane’ and projected LM Locking option axis A\_4’ ” (C1) of the FRN GT must be less (mean 10.19°) than that the A2FN (mean 13.61°) (p = 0.000). | The FRN had a significantly smaller total surface area of nail protrusion (median 478 vs. 1123 mm2; p = 0.000) and a maximum distance of nail protrusion (median 0.850 vs. 2.280 mm; p = 0.000) when compared with the Expert A2FN. There was no significant difference in the distal tip position in the AP view (median 8.702% vs. 8.691% p = 0.738). There was a significant difference in the distal tip position in the lateral view (mean 13.28% vs. 24.78% p = 0.000). Therefore, the FRN nail is equally centered in the AP and better centered in the lateral view when compared to the Expert A2FN. The FRN had significantly less protrusion ( 5.6mm vs. 1.9mm; p = 0.000) at the proximal nail entry side when compared to the Expert A2FN. Therefore, the FRN is less prominent at the nail entry side when compared to the Expert A2FN. The anatomical CCD angle (mean 129.79°) supports the design of the FRN with a CCD angle of 130°. The FRN had a significant smaller angle between the distal lateral to medial locking option and the AP plane (mean 10.19° vs. 13.61°; p = 0.000) when compared to the Expert A2FN.  Overall, the shape bows of the FRN nail design resulted in a better fit compared with the benchmark Expert A2FN design. The defined acceptance criteria were met. | Pass |
| #0000268621  (SET\_20170248-rev1 & SET\_20170249)  Endurance testing of 14MM FRN GT and 14MM FRN PF constructs with Recon Screws | Femoral Recon Nail  04.003.034  04.033.460S  04.003.034  04.033.430S | Fatigue Testing / Endurance testing 14mm FRN GT and PF with recon screws  Sample size(n=11) | The test results must indicate that the construct fatigue strength for the 14MM FRN GT constructs with Recon Screws at 1’000’000 cycles must be greater than that of the LFN construct. | 11 samples tested at 1000N vertically to 1,000,000 cycles for both types of nails (greater trochanter and piriformis fossa). A 12th sample was included for the piriformis fossa tests as a replacement for another sample in which medial migration (upward movement) of the recon screws occurred at 167,738 cycles. All samples achieved runout (to 1 million cycles). However, PF screw construct #10b broke during disassembly after reaching 1 million load cycles. The calculated median fatigue limit of the FRN PF and GT constructs with recon screws exceeds the existing Synthes Expert LFN nail’s 95% CI upper limit of 958.91N (median fatigue limit of Expert LFN is 850.84N, 95% CI of 724.77N, 958.91N) All 11 samples survived 1 million load cycles without failure at the fatigue limit of 1000N. | Pass |
| #0000268373  MRI Mechanical Testing Report | Femoral Recon Nail  04.033.960  04.033.160  04.033.460  04.033.958  04.033.964  04.033.966  04.033.968  04.033.970  04.033.972  04.033.976  04.033.978  04.033.928  04.003.240  04.033.934  04.003.248  04.003.022 | Worst-case MRI-induced heating for FRN were tested under 1.5-T and 3.0-T conditions using MRI simulation. Worst case constructs tested included screws with nails: Construct #14 represented an FRN PF 13mm nail at 280mm length with four locking screws and two standard screws; Construct #16 represented an FRN PF 13mm nail at 340mm length with four locking screws and two standard screws. The Expert LFN comparator worst-case sample was Construct #1, a 9mm diameter Titanium nail with a 300mm length.  Sample size(n=15) | The results of the test must indicate that the FRN does not introduce a new worst case for either RF heating or Force, Torque and image artifacts and therefore, no further simulations and/or physical testing must be required. | 15 different FRN PF and FRN GT constructs were examined, along with two Expert LFN constructs. The worst-case constructs were chosen for simulation testing.  Testing of the comparator Expert LFN nail in MT15-144 yielded higher heating values for 1.5-T (96.3 W/Kg for Expert LFN; 94.2 W/Kg for FRN construct #14) and 3.0-T (35.4 W/Kg for Expert LFN; 26.4 W/Kg for FRN for construct #16). No new worst-case construct can be created using the newer FRN nails regarding RF heating. For this reason, the labeling information can be adopted from the existing top-level MRI test summary report MT15-292 | Pass |
| #0000268343  Drawing Verification Analysis for Femoral Recon Nail Implants | FRN  04.033.928S-04.033.479S | Drawing verification analysis of FRN functional design requirements and verification and validation matrix (FDR) from Windchill # 0000077533 Version A.118. Risk control actions defined in the FRN DCRM (Windchill # #0000077523 Version A.64) will also be verified. | All the Design Input Specifications listed above from the FDR (#0000077533 Version A.165) must be clearly specified on the associated product drawings in order to be verified (considered a “Pass”). Otherwise, “Fail” will be assigned to the requirement. | Based on the results of the analysis the Design Outputs meet the Design Input Specifications and the implementation of all the Risk Control Actions has been verified. Each specification exists on the product drawing(s) and thus each verification activity is marked as “Pass”. No follow-up actions have been identified. Therefore, the result of this Drawing Verification Analysis is successful and meets the acceptance criteria defined. | Pass |
| #0000270987  Design Validation Report (Nurses User Group) – Femoral Recon Nail System | FRN  04.033.063S  04.033.028S | Design Validation Report (Nurses) - Femoral Recon Nail System  Validation of some user and patient needs, risk mitigation actions and usability for the Femoral Recon Nail (FRN) Implants and Femoral Recon Nail Instruments with the nurse’s user group.  A “1 to 7” rating scale was used to assess the questions.  Sample size(n=15) | The median must be higher than 3.99 with a p-values of 0.1 or lower. | A total of 15 validation labs were conducted with different nurses.  The overall rating was 6.5 (n=15) and the defined acceptance criteria were met. No patterns of usability errors could be identified. | Pass |
| #0000269230  Validation Report Anatomical Study | FRN  04.033.958S - 04.033.478S  04.033.959S - 04.033.479S | Design Validation Report Anatomical Study  Anatomical study to compare the nail shape of the Femoral Recon Nails (FRN) to the Expert A2FN (Expert A2FN), while virtually implanted into 82 three dimensional reconstructed femora.  Seven parameters were compared to assess the nail fit. | * The median “Protrusion Area” (C5) of the FRN GT (median 478mm^2) must be less than that of the A2FN (median 1123mm^2) (p = 0.000). * The median “Protrusion Maximum Distance” (C6) of the FRN GT (median 0.850mm) must be less than that of the A2FN (median 2.280mm) (p = 0.000). * There must be no statistical difference of the median “Relative Distal End Position in the AP View” (C15-2) of the FRN GT (median 8.702%) when compared to the that of the A2FN (median 8.691%) (p = 0.738). * The mean “Relative Distal End Position in the LAT View” (C10-2) of the FRN GT (mean 13.28%) must be less than that of the A2FN (mean 24.78%) (p = 0.000). * The “Distance Proximal Nail end to outer Cortex” (C4) of the FRN GT must be less (mean -5.64mm) than that the A2FN (mean -1.873mm) (p = 0.000). * The mean “CCD Angle” (A11) of 129.793° must be less than 132.5° as the p-value of the T-Test comparing to the upper bound of 132.5° is less than 0.05. * The “Angle projected AP Plane’ and projected LM Locking option axis A\_4’ ” (C1) of the FRN GT must be less (mean 10.19°) than that the A2FN (mean 13.61°) (p = 0.000). | The FRN had a significantly smaller mean total surface area of nail protrusion (889 vs. 1306 mm2; p = 0.000) and a mean maximum distance of nail protrusion (1.4 vs. 2.6 mm; p = 0.000) when compared with the Expert A2FN. There was no significant difference in the distal tip position in the AP view (9.6% vs. 8.9% p = 0.240). There was a significant difference in the distal tip position in the lateral view (13.3% vs. 24.8% p = 0.000). Therefore, the FRN nail is equally centered in the AP and better centered in the lateral view when compared to the Expert A2FN. The FRN had significantly less protrusion ( 5.6mm vs. 1.9mm; p = 0.000) at the proximal nail entry side when compared to the Expert A2FN. Therefore, the FRN is less prominent at the nail entry side when compared to the Expert A2FN. The anatomical CCD angle (mean 129.79°) supports the design of the FRN with a CCD angle of 130°. The FRN had a significant smaller angle between the distal lateral to medial locking option and the AP plane (10.2° vs. 13.6°; p = 0.000) when compared to the Expert A2FN.  Overall, the 1.0 m bow of the FRN nail design resulted in a better fit compared with the benchmark 0.75-1.86 m bow Expert A2FN design. The defined acceptance criteria were met.  The FRN had a significantly smaller mean total surface area of nail protrusion (889 vs. 1306 mm2; p = 0.000) and a mean maximum distance of nail protrusion (1.4 vs. 2.6 mm; p = 0.000) when compared with the Expert A2FN. There was no significant difference in the distal tip position in the AP view (9.6% vs. 8.9% p = 0.240). There was a significant difference in the distal tip position in the lateral view (13.3% vs. 24.8% p = 0.000). Therefore, the FRN nail is equally centered in the AP and better centered in the lateral view when compared to the Expert A2FN. The FRN had significantly less protrusion ( 5.6mm vs. 1.9mm; p = 0.000) at the proximal nail entry side when compared to the Expert A2FN. Therefore, the FRN is less prominent at the nail entry side when compared to the Expert A2FN. The anatomical CCD angle (mean 129.79°) supports the design of the FRN with a CCD angle of 130°. The FRN had a significant smaller angle between the distal lateral to medial locking option and the AP plane (10.2° vs. 13.6°; p = 0.000) when compared to the Expert A2FN.  Overall, the 1.0 m bow of the FRN nail design resulted in a better fit compared with the benchmark 0.75-1.86 m bow Expert A2FN design. The defined acceptance criteria were met. | Pass |
| #0000270986  Design Validation Method – Femoral Recon Nail System | Femoral Recon Nail Implant; Femoral Recon Nail Instruments  04.033.032S-04.033.269S | Validation of the user and patient needs, risk mitigation actions, surgical technique, Instruction for Use (IFU) and usability for the Femoral Recon Nail (FRN) Implants and Femoral Recon Nail Instruments with the surgeon user group. A “1 to 7” rating scale was used to assess the questions. | * The lower bound mean score greater than 4.0, median greater than 3.99 with p-value 0.05 or lower. * All p-values of the sign test must be below 0.1 (with worst case confidence level of 95%). | A total of 17 validation labs were conducted with 16 different surgeons.  Based on the results of the first four labs, design changes on three FRN instruments were required. In addition, changes in the surgical technique were implemented. Therefore, the first four labs were excluded from the overall result. In lab 5 to 17, the changed instruments and changed surgical technique was assessed.  The defined acceptance criteria were met. No patterns of usability errors could be identified. | Pass |
| System #5: Retrograde Femoral Nail Advanced System | | | | | |
| #0000293480  Design verification: RFN LAW construct static test report | RFNA  02.233.105  04.233.117S | To compare the mechanical performance during static loading of the three distal fixation techniques: Retrograde Femoral Nail with screws, Retrograde Femoral Nail with screws and LAW plate, and Retrograde Femoral Nail with screws and bent LAW plate. | The mean peak load of Group 2 (RFN+LAW), and the mean peak load of Group 3 (RFN+LAW with bent tabs) must be greater than the mean peak load of the Group 1(RFN). | Retrograde Femoral Nail with screws and LAW plate (peak load = 1490 ± 90.4 N) and Retrograde Femoral Nail with screws and bent LAW plate (peak load = 1510 ± 99.9 N) have significantly higher loads using a two-sample t-test with (p<0.001) for both groups when compared to Retrograde Femoral Nail with screws (peak load = 1050 ± 81.1 N). | Pass |
| #0000293476  Design verification: RFNA Nail Static 4-Point Bend Design Verification Report | RFNA  04.013.376S  04.233.948S | The Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (Expert R/AFN) and the Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) were loaded axially in a four-point fixture to determine mechanical properties of these nails. | The offset bending moment and bending stiffness for RFN must be non-inferior to that of Expert R/AFN. | (RFNA offset bending moment = 107 ± 1.37 Nm and bending structural stiffness = 32.9 ± 0.13 Nm2) and (Expert R/AFN Bending Strength = 105 ± 2.99 Nm and a bending structural stiffness = 32.3 ± 0.22 Nm2), a two-sample t-test is significant for offset bending moment (p<0.001) with a predetermined margin of non-inferiority of 13 Nm and Bending Stiffness (p<0.001) with a predetermined margin of non-inferiority of 3.55 Nm2.  Therefore, the offset bending moment and bending stiffness for RFN are non-inferior to that of Expert R/AFN and the acceptance criteria is met. | Pass |
| #0000293478  Design verification: RFNA Nail Static Torsion Design Verification Report | RFNA  04.013.376S  04.233.948S | The Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (Expert R/AFN) and the Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) were loaded in a torsional manner to determine mechanical properties of these nails. | The torsional stiffness for RFN must be non-inferior to that of Expert R/AFN. | (RFNA torsional stiffness = 1.83 ± 0.04 Nm) and (Expert R/AFN torsional stiffness = 1.72 ± 0.02 Nm), a two-sample t-test is significant for torsional stiffness (p<0.001) with a predetermined margin of non-inferiority of 0.184 Nm; Therefore, the torsional stiffness for RFN is non-inferior to that of Expert R/AFN and the acceptance criteria is met. | Pass |
| #0000293487  Design verification: Reaming rod ball tip tensile strength | RFNA Nail (Variant 6) and Locking Attachment Washer | The objective of this testing, of the reaming rod ball tips, within the scope of the Retrograde Femoral Nail project, consisted of a tensile test. This testing was performed to ensure that the reaming rods will meet the mechanical performance required.  Two groups of six reaming rods each (annealed and cold formed) were tested per the test method in tension until failure. Each ball tip was fixtured to the crosshead of the test frame, and the non-ball end was fixtured to the base of the test frame. Each groups data was then evaluated against the benchmark (2974 N) as laid out in the test method with a 90% confidence, one sample t-test. | The resultant p-value of both t-tests must be less than or equal to 0.001 with 90% confidence and the average peak tensile load of the subject groups of reaming rods must be greater than the benchmark (2974 N). | With the resultant p-value of both t-tests <0.001, in both cases the null can be rejected in favor of the alternate hypothesis. The average peak tensile load of the subject groups of reaming rods is greater than the benchmark (2974 N). Both acceptance criteria have been met. | Pass |
| #0000293484  Design verification: LAW static torque to failure | RFNA Nail and Locking Attachment Washer  02.233.105 | The objective was to compare the peak torque attained for each individual sub-group when tightening 3.5mm and 5.0 mm VAL bone screws in their respective LAW VAL recesses. These values have been compared against their respective benchmarks, to demonstrate that the system consisting of screwdriver, VA locking screw and LAW can withstand the following insertion torques without failure: 3.0 Nm for 3.5mm VA locking screws, 7.0 Nm for 5.0mm VA locking screws. | The test results must indicate that all groups are superior to the benchmark for the size screw used. | All groups had a resultant p-value below the level of significance (0.10) indicating that all groups are superior to the benchmark for the size screw used. All acceptance criteria as laid out in the test method have been met. | Pass |
| #0000293479  Design verification: Nail poly (inlay) axial push-out | RFNA and Locking Attachment Washer  04.233.032S | This test was designed to verify the functional requirement for the Retrograde Femoral Nail systems’ ability to resist axial screw pull out in the distal portion of the nail.  Two groups of RFNA nails were tested for their resistance to axial screw pullout. One group with a poly inlay, and one group without a poly inlay. Testing involved fixturing an attachment screw to the distal end, and both rotating and tilting the nail, so the screw of interest was pulled at 5mm/min in an axial direction. The failure mode observed in all specimens was the screw pulling out of the nail/foam construct. | The mean pull-out resistance of the distal screws in each of the four locations on the RFN nail with a poly inlay must be greater than that of the corresponding locations on the RFN nail without a poly inlay with a minimum 90% confidence level. | Peak Pullout Load Data Summary - Hole 1 (Most Distal)  Group=RFN Poly  Average Peak Pullout Load (N) ± St. dev. =1240 ± 82.5  Group=RFN No Poly  Average Peak Pullout Load (N) ± St. dev.=571 ± 48.6  Peak Pullout Load Data Summary – Hole 2 (Most Proximal)  Group=RFN Poly  Average Peak Pullout Load (N) ± St. dev.=1180 ± 54.8  Group=RFN No Poly  Average Peak Pullout Load (N) ± St. dev.=518 ± 61.2  Peak Pullout Load Data Summary – Hole 3 (Lateral Oblique)  Group=RFN Poly  Average Peak Pullout Load (N) ± St. dev.=1290 ± 47.1  Group=RFN No Poly  Average Peak Pullout Load (N) ± St. dev.=585 ± 90.4  Peak Pullout Load Data Summary – Hole 4 (Medial Oblique)  Group=RFN Poly  Average Peak Pullout Load (N) ± St. dev.=1290 ± 40.3  Group=RFN No Poly  Average Peak Pullout Load (N) ± St. dev. =625 ± 94.1 | Pass |
| #0000293477  Design verification: RFNA Nail Dynamic 4-point Bend | RFNA and Locking Attachment Washer  04.013.376S  04.233.948S | The purpose of this study was to compare the mechanical performance during fatigue loading of the Expert Retrograde/Antegrade Femoral Nail 9mmx480mm to the Retrograde Femoral Nail 5° Bend 9mmx480mm.  To achieve this, the Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (Expert R/AFN) and the Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) were loaded in a 4-point bending fixture to determine mechanical fatigue properties of these nails. If the null hypothesis is rejected (p-value < 0.10) with a margin of non-inferiority of 474N, then it can be concluded that the fatigue strength of the predicate RFN is greater than the fatigue strength of the Expert R/AFN nail.  A total of six Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (Expert R/AFN) and seven Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) were tested under a compressive/compressive load sine wave form with a load ratio of 10, at 5 Hz, with one of the following loads: 4100N, 4355N, 4610N, 4865N, or 5120N. The support span was 38mm and center span 38mm. | The Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) must be non-inferior to the Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (RAFN) in fatigue strength. | The testing indicates a median fatigue limit for the Expert R/AFN nail was calculated to be 4230±270N and the median fatigue limit for the RFN nail was 4830±270N. Using a 2-sample t-test with a margin of non-inferiority of 474N, the null hypothesis is rejected and the RFN nail has a higher fatigue strength than the Expert R/AFN nail.  With these results, the acceptance criteria is met and the Retrograde Femoral Nail 5° Bend 9mmx480mm (RFN) is superior to the Expert Retrograde/Antegrade Femoral Nail 9mmx480mm (Expert R/AFN) in fatigue strength. | Pass |
| #0000293481  Poly Inlay Vibration/Transit Test | RFNA  04.233.120S | Retrograde Femoral Nail (RFN) nails which contain a polyethylene inlay were subjected to vibration and drop testing to determine whether the polyethylene inlays migrate during shipping conditions. | Distance between the distal end of the nail and the polyethylene inlay should not change more than 1mm as a result of the distribution simulation testing sequence. | All polyethylene inlays maintained their placement within the required range in the distal bore of the RFN implant (Acceptance Criterion specification of <1mm change in position). The average range of inlay migration was 0.02mm. Thus, all tested RFN inlays passed the Acceptance Criterion and fulfilled the goal of withstanding minimal migration due to vibration. | Pass |
| #0000297100  Galvanic corrosion study | RFNA and Locking Attachment Washer | The aim of the studies was to evaluate the potential for galvanic and fretting corrosion due to the different materials present in the RFNA and washer construct.  Galvanic corrosion study: The study evaluated four potential materials within the construct, Carburized 316L (C316L), 316L, Ti-6Al-4V ELI (TAV), and Ti-6Al-7Nb (TAN). This was done by creating three couples of differing materials of 316L-TAV, C316L-TAV, and TAN-TAV, as well as one control couple of TAV-TAV. These couples were tested for 72 hours, with the current density of each couple being tracked continuously.  Fretting corrosion study: The study evaluated the effect of having different material types in a cyclic loading scenario. Two constructs were evaluated consisting of 316L and carburized 316L (C316L) plates and screws mated to a long TAV nail against a TAV only construct. The constructs were loaded for 1M cycles each, while the current density was recorded continuously. | The test results must indicate no signs of accelerated corrosion rates. | Galvanic corrosion study: After 72 hours, the current densities of each of the couples was found to be not statistically different from that of the others. For all the couples, the current density had decreased and stabilized at less than 2 nA/cm2 by the end of the test duration. Mass loss calculations, pH changes, ICP-MS ion release analysis, and light microscopy all further pointed to the conclusion of low corrosion. Overall, the result showed no signs of accelerated corrosion rates.  Fretting corrosion study: No statistically significant difference was determined between any construct at 24hr or 50hr (the final time point). Additionally, the constructs were weighed after testing, and neither subject constructs showed a statistically significant different weight loss to the TAV-TAV control construct. Metal ion release was also evaluated in this study and was determined to be minimal for each of the constructs. Overall, the result showed no signs of accelerated corrosion rates. | Pass |
| #0000293897  Rational Polymer Debris | RFNA  04.233.448S-04.233.916S  04.233.017S-04.233.917S | To demonstrate that polymer debris from RFNA is comparable to polymer debris generated from MultiLoc Nail with respect to number, size and shape.  Number, size and shape of debris from MultiLoc nail was investigated in three consecutive tests addressing drilling (0000022932), assembly (0000022931), and dynamic test (0000022930). | The test results must indicate that debris from Retrograde Femoral Nail Advanced is comparable to debris from MultiLoc Humeral nail in number, size and shape and therefore above cited summary is also valid for Retrograde Femoral Nail Advanced and Tibial Nail Advanced. | It was concluded that the number, size, and shape of particles generated by the nail are comparable to MultiLoc Humeral nail. The total number of PE particles generated from a MultiLoc nail represents less than 0.001% of the number of particles generated per year from a successful hip joint replacement. These amounts of particles will not cause any local, intramedullary, or systemic negative side effects beyond what is observed with joint replacement.  Debris from Retrograde Femoral Nail Advanced is comparable to debris from MultiLoc Humeral nail in number, size and shape and therefore above cited summary is also valid for Retrograde Femoral Nail Advanced and Tibial Nail Advanced. | Pass |
| #0000293489  (Project 014173)  Retrograde Femoral Nail Design Validation Report | Retrograde Femoral Nail Implants  Class Is instruments (reaming rods), and Class IIa instruments (opening drill bits)  04.233.030-04.233.138  04.233.000-04.233.010 | Validation and saw bone assessment of the user and patient needs of the Retrograde Femoral Nail implants and Class IIa and Is instruments with a surgeon user group.  A “1 to 7” rating scale was used to assess the questions. | No patterns of usability errors must be identified. | A total of 12 validation labs were conducted with 10 different surgeons.  The defined acceptance criteria were met. No patterns of usability errors could be identified. | Pass |
| #0000295114  (Project Number: 014173)  Periprosthetic Nail Entry Point Validation Rationale | Retrograde Femoral Nails Implants  04.233.925S-04.233.249S | The objective of this rationale is to validate a user and patient need of the Retrograde Femoral Nail Implant Functional and Design Requirements Matrix. Specifically, this rationale deals with the treatment of fractures when an existing Attune knee prosthesis is present.  The entry point for a retrograde femoral nail when used in a periprosthetic application is dictated by the location of opening in the femoral component of the prosthesis. In order to ensure that entry point in periprosthetic applications is accurate, the femoral component of the attune must be in the right anatomic location. | User shall be able to treat fractures in the intended patient population in native knees and when an existing attune knee prosthesis is present. | The R&D team utilized the J&J Trumatch software which is designed to simulate and inform surgeons of the precise cuts that must be made to get an Attune femoral component in the correct anatomic location. For the design of the RFN nail, Trumatch software was used to set the location of Attune femoral components on a series of 3D scans of femurs. Setting the location of the femoral component allowed for the subsequent identification of the appropriate location for the periprosthetic nail entry point.  The validation of the Trumatch software is evidence that the correct periprosthetic entry point is represented when defining the nail bend angle and location. As a result, no further validation activities need to be carried out with regards to user need 1.100h and 1.110i as it relates to periprosthetic applications and the user needs are validated for the portion that deals with the treatment of fractures when an existing Attune knee prosthesis is present. | Pass |
| #0000295068  Predicate Device/ Reference Product Comparative Analysis | RFNA  04.233.000S-04.233.010S | The objective of this comparative analysis is to show the equivalency of the Retrograde Femoral Nail-Advanced Endcaps (RFNA Endcaps) with the Expert Retrograde/Antegrade Femoral Endcaps (R/AFN Endcaps).  The target device will be shown to have similar or identical features and/or design characteristics that indicate it will function in a similar manner to fulfill the user need, compared to the predicate device. | The user needs will be considered validated if the associated design features are shown to be similar or identical to design features of well-accepted reference products, with any gaps addressed. | All design features were shown to be similar or identical to design features of well-accepted devices in the market. Therefore, the user need associated with these design inputs is considered validated. | Pass |
| #0000295056  Predicate Device/ Reference Product Comparative Analysis | RFNA  04.233.916S-04.233.948S  04.233.016S-04.233.048S  04.233.116S-04.233.148S  04.233.216S-04.233.248S  04.233.428S-04.233.448S  04.233.917S-04.233.949S  04.233.017S-04.233.049S  04.233.117S-04.233.149S  04.233.217S-04.233.249S | The objective of this comparative analysis is to show the equivalency of the Retrograde Femoral Nail-Advanced Nail (RFNA) with the Expert Retrograde/Antegrade Femoral Nail (R/AFN).  The target device will be shown to have similar or identical features and/or design characteristics that indicate it will function in a similar manner to fulfill the user need, compared to the predicate device. | The user need will be considered validated if the associated design features are shown to be similar or identical to design features of well-accepted reference products, with any gaps addressed. | All design features were shown to be similar or identical to design features of well-accepted devices in the market. Therefore, the user need associated with these design inputs is considered validated. | Pass |
| #0000294764  RFN Nail Shape Comparison | Retrograde Femoral Nail Implant  04.233.448S-04.233.924S | The objective of this comparative analysis is designed to demonstrate that the size and location of the anatomic bow in the shaft of the Retrograde Femoral Nail (RFN) is appropriately designed for use in the femoral diaphysis.  The RFN has an anatomic bow radius of 1.0m as compared to its predicate device Retrograde/Antegrade Femoral Nail (RAFN) with a 1.5m bow radius. This change was made because of comprehensive nail fit studies that have recently been completed on other DePuy Synthes femoral nails. | The results of this analysis must indicate that the size and location of the anatomic bow in the shaft of the RFN nail is appropriately designed for use in the femoral diaphysis. | Based on the results:   * The 1.0m anatomic bow of the RFN more closely matches the shape of the femoral diaphysis as compared to the existing 1.5m anatomic bow of the predicate R/AFN. * The location of the 1.0m anatomic bow of the RFN is appropriate by comparing it to the location of the TFNA bow.   The results of this analysis indicate that the size and location of the anatomic bow in the shaft of the RFN nail is appropriately designed for use in the femoral diaphysis and therefore it can be concluded that the user and patient need for requirements have been successfully validated. | Pass |
| #0000293489  Retrograde Femoral Nail Design Validation Report | Retrograde Femoral Nail Implant  04.233.030-04.233.138  04.233.000-04.233.010 | The objective of this assessment was to validate the user and patient needs of the Retrograde Femoral Nail implants. | * Lower bound mean score to be ≥ 4.0 with a 95% confidence level, and * Median is ≥ 4 with a confidence level of 95%. | As shown in the results (Attachment 12), data that was normal had a lower bound mean score ≥ 4.0 with a 95% confidence level. For non-normal data, a 1-sample sign test showed that the median was ≥ 4 with a confidence level of 95%. Therefore, the data passed the acceptance criteria, and validation was successful for all user needs in scope of the validation except for lines 1.120d and 2.105 from the instrument FDR. | Pass |
| #0000309156  Femoral Shaft Nailing Implants | Expert R/AFN  04.013.332S-04.013.744S | The Usability Engineering File (UEF) below contains the deliverables which reside in other quality system documents and files without physically containing the documents. For example, the Known Use Hazards, Hazardous Situations and Use Errors may consist of a complaint analysis that has already been completed to support other areas of the Design History File (DHF) or Risk Management documentation (DCRM, RMR). | The results of the rationale must indicate that there are no safety signals or emerging issues further indicating that the Femoral Shaft Nailing Implants have achieved their intended performance and safety. | The absence of safety signals or emerging issues as well as the low calculated occurrence rate (≤ 0.1% based on the parts listed above in addition to the global offering of Femoral Shaft Nailing Implants) further provide evidence that the Femoral Shaft Nailing Implants have achieved their intended performance and safety including usability aspects. | Pass |
| System #6: Expert Asian Femoral Nail System | | | | | |
| #0000258158  (SET\_20080093)  Static 4-point bending test of Expert A2FN and AFN | Expert A2FN  04.009.272 | Static 4-point bending test of Expert A2FN and AFN (5 samples)  To compare the static bending strength of Expert A2FN nail with the Antegrade Femoral Nail (AFN) reference device according to ASTM F1264-03.  The 4-point bending test set-up imposes a fixed length of the nail to be tested between support and load spans. Therefore, the nail seats freely in the test set-up and only a certain section of the nail is tested, thus the test is independent of the nail length.  Sample size(n=5) | The report is not listing a clear acceptance criterion. However, based on the methods and results the following acceptance criteria is applied: the A2FN maximum static bending strength to be equal or greater than that of the reference device (AFN) | The test set up is according to ASTM F1246-03 and the nail seats freely in the 4-point bending device and the position of the nail was defined by a spacing of 50mm between the uppermost distal locking hole and the first lower bearing.  AFN – Mean force 6518 N (σ = 41)  Expert A2FN – Mean force 6855 N (σ = 198)  The results of the test meet the acceptance criteria i.e., they showed a higher maximum static bending strength of Expert A2FN with respect to the reference device | Pass |
| #0000258158  (SET\_20080095)  Dynamic 4-point bending test of Expert A2FN and AFN | Expert A2FN | Dynamic 4-point bending test of Expert A2FN and AFN (5 samples)  To compare the “Load vs Cycles” ratio of the Expert A2FN nail with the AFN reference device according to ASTM F1264-03.  The 4-point bending test set-up imposes a fixed length of the nail to be tested between support and load spans. Therefore, the nail seats freely in the test set-up and only a certain section of the nail is tested, thus the test is independent of the nail length. Consequently, this test applies to all nails in scope of the Expert A2FN system.  Sample size(n=5) | The report is not listing a clear acceptance criterion. However, based on the methods and results the following acceptance criteria is applied: the Expert A2FN “Load vs Cycles” ratio must be greater than or equal to the reference device (AFN). | For the dynamic 4-point bending test, the Fmax value was adopted from the static 4-point bending test SET\_20080093 as load basis for the dynamic test (this value corresponds to Fmax 100%). Test setup was identical to SET\_20080093, also according to ASTM F1264-03.  The results of the dynamic 4-point bending test is that the “Load vs Cycles” ratio of the Expert A2FN is superior to its reference device. | Pass |
| #0000258158  (SET\_20070748)  Dynamic Strength | Expert A2FN  04.009.248S  04.003.030  04.003.033  04.003.034  04.003.035 | Dynamic strength Expert A2FN and AFN (six nail samples, 12 hip screw samples)  To compare the dynamic load capacity of the Expert A2FN Nails to the reference AFN Nail System, in the proximal locking section of the nail with the corresponding screw-hole configuration.  Worst case rationale and scope of parts covered: The Expert A2FN nail (part # 04.009.248S) and the hip screws (parts: 04.003.030, 04.003.033, 04.003.034 04.003.035) of different lengths 100mm to 125mm) were tested. In this test, a proximal section of the nail was tested fixed with hip screws in a recon locking configuration. The bent section of the nails (distal section) has no influence on the test results. The smallest nail outer diameters of both AFN and Expert A2FN (Ø9 mm) were selected since they both have the smallest cross-sectional area, and therefore are the worst-case nails for mechanical loading. The recon screw length does not influence the test results because the test set-up allows for a fixed length engagement of the screws. Longer screws lead to a free length of the recon screw on the lateral side once they are placed into the test set up. Since all in scope hip screws are of the same diameter i.e., Ø6.5 mm this test applies to all hip screws in scope.All together 6 Expert A2FN and 7 AFN nail constructs were tested in recon locking. | The report is not listing a clear acceptance criterion. However, based on the methods and results the following acceptance criteria was applied: the A2FN dynamic load capacity to be equal or greater than the reference device (AFN). | All constructs failed with the same failure mode i.e., the nail broke at the lateral side at the inferior screw hole. AFN achieved a runout at a load of 1200N under 1.5 million load cycles without damage and the Expert A2FN Nail with a maximum load of 1800N with the same number of cycles.  The results of the test shows that the Expert A2FN has a higher dynamic load capacity compare to its reference device. | Pass |
| #0000258158  (SET\_20170224 and SET\_20170244)  A2FN Dynamic full construct test to evaluate Mezzovico nails manufactured from Suzhou blanks | Expert A2FN  04.009.260S | Expert A2FN Dynamic construct test to evaluate MEZ nails manufactured from Suzhou blank (23 samples)  To determine the median fatigue limit of the alternative manufacturing flow of the Synthes Intramedullary (IM) Nailing System Expert A2FN. In this test, the median fatigue limit was compared between two manufacturing alternatives: The reference device is a nail manufactured in Mezzovico (MEZ), Switzerland; the subject device are nail blanks manufactured in Suzhou (SUZ), China. Proximal holes milling and finishing operations are completed in Mezzovico (MEZ), Switzerland.  Sample size(n=23) | The subject device fatigue strength mean must be non-inferior to the reference device fatigue strength mean with a margin of noninferiority of -5% of the reference device fatigue strength mean. Worst case article tested in both constructs was 04.009.260S (Ø9mm, length of 400mm) | The mean fatigue limit F (mean FL) of the Expert A2FN subject device construct (660.42N, standard deviation 38.08N) is non-inferior to the Expert A2FN reference device (618.65N, standard deviation 38.21N) with a non-inferiority margin of -5%. | Pass |
| #0000258158  (SET\_20190038 and SET\_20190350)  A2FN Dynamic full construct test to evaluate nails manufactured in Mezzovico with new manufacturing process | Expert A2FN  04.009.260S | Dynamic construct test to evaluate nail manufactured at MEZ with new manufacturing process.  To determine the median fatigue limit of the alternative manufacturing flow of the Synthes Intramedullary (IM) Nailing System Expert A2FN under specific laboratory conditions. In this test, the median fatigue limit was compared between two manufacturing alternatives. The reference device is a nail manufactured in Mezzovico (MEZ), Switzerland according to current validated processes. On the other hand, the subject device is a nail manufactured in Mezzovico (MEZ), Switzerland per new manufacturing process flow (Robodrill - Crippa) | Acceptance criteria is the subject device fatigue strength mean must be non-inferior to the reference device fatigue strength mean with a margin of noninferiority of -10% of the reference device fatigue strength mean. | The mean fatigue limit F(mean FL) of the Expert A2FN subject device construct (815.343N, standard deviation 27.705N) is non-inferior to the Expert A2FN reference device (812.858N, standard deviation 27.396N) with a non-inferiority margin of -10%. | Pass |
| SE\_702711  Design verification report | Expert A2FN | Design verification report: Dynamic construct test to evaluate MEZ nails to nails manufactured from Suzhou blank. The median fatigue limit of the Synthes Intramedullary (IM) Nailing System Expert A2FN was compared between two manufacturing alternatives:  Reference device: Nail manufactured in Mezzovico (MEZ), Switzerland.  Subject device: Nail blanks manufactured in Suzhou (SUZ), China. Proximal holes milling and finishing operations are completed in Mezzovico (MEZ), Switzerland. | The mean fatigue limit F(mean FL) of the Expert A2FN subject device construct must be non-inferior to the Expert A2FN reference device. | The mean fatigue limit F(mean FL) of the Expert A2FN subject device construct (660.42N, standard deviation 38.08N) is non-inferior to the Expert A2FN reference device (618.65N, standard deviation 38.21N) with a non-inferiority margin of -5%.  The alternative manufacturing flow of the Synthes Intramedullary (IM) Nailing System Expert A2FN (Nail blanks manufactured in Suzhou (SUZ), China. Proximal holes milling and finishing operations are completed in Mezzovico (MEZ), Switzerland) can be released to production. | Pass |
| #0000259039  Drawing review for risk control for sharp edges (Implants) | Expert A2FN  04.003.440-04.031.981  04.009.236S-04.009.773S | Drawing review for risk control for sharp edges (implants)  Review drawings to confirm they include the following specifications:  Edge break specifications  Edge radius defined on drawings.  Free of burrs  Includes, nails, hip screws, end caps, washers (for AFN only) | Drawings are reviewed to confirm that they include at least one of the following specifications:   * Edge break specifications * Edge radius defined on drawings * Free of burrs | Based on drawing review, acceptance criteria of all in-scope articles have been met. | Pass |
| #0000259039  Drawing review for risk control for sharp edges (Implants) | Expert A2FN  04.003.440-04.031.981  04.009.236S-04.009.773S | Drawing review for risk control for sharp edges (implants)  Review drawings to confirm they include the following specifications:  Edge break specifications  Edge radius defined on drawings.  Free of burrs  Includes, nails, hip screws, end caps, washers (for AFN only) | Drawings are reviewed to confirm that they include at least one of the following specifications:   * Edge break specifications * Edge radius defined on drawings * Free of burrs | Based on drawing review, acceptance criteria of all in-scope articles have been met. | Pass |
| #0000255375  Interconnectivity and Tolerance Analysis Rationale | Expert A2FN | Tolerance analysis rationale: interconnectivity of nails, end caps, hip screws, washers (for AFN only), and locking screw/bolt with dedicated instrumentation.  Analysis of sales and complaint data from PMS Reports (Windchill #0000250261 and #0000248929) for the periods 01 January 2012 – 31 December 2014 and 01 November 2012 – 31 October 2015, respectively.  The following complaint codes were analyzed:  SYNTHES: DEVICE INTERACTION: DOES NOT FIT WITH OTHER PARTS, SYNTHES: DEVICE INTERACTION: MISALIGNMENT, SYNTHES: DEVICE INTERACTION: SEIZED, SYNTHES: DEVICE INTERACTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: LOOSE, SYNTHES: DOES NOT/WILL NOT FUNCTION: WILL NOT HOLD, SYNTHES: DOES NOT/WILL NOT FUNCTION: FELL APART, SYNTHES: DOES NOT/WILL NOT FUNCTION: STICKS/JAMS/STUCK, SYNTHES: DOES NOT/WILL NOT FUNCTION: FUNCTIONAL ISSUE, UNSPECIFIED | The result of the rationale must indicate that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Occurrence rate for interconnectivity-related issues was:  Expert A2FN: 0.08%  Expert ALFN: 0.01%  Expert LFN: 0.01%  The analysis of the Post Market Reports does not indicate any safety signals and shows that the articles in scope are adequate for their intended use. Therefore, based on the occurrence rate calculations and the absence of safety signals within the Post Market Reports, it can be concluded that the implants in scope are being used in the market in a safe manner, and that their interconnection with mating parts is adequate for their intended performance. | Pass |
| #0000258161  Rationale for Validation Studies Expert A2FN | Expert A2FN  04.009.236S-04.009.773S  04.009.000-04.009.004  04.009.000S-04.009.004S | Validation rationale to address validation documentation gap – the results of the two cadaver labs were not documented as formal validation and lack the required traceability. PMS will be used to evaluate the identified gaps.  Bioskills / cadaver lab summary:  Lab on 24 September 2007. These lab minutes summarize a cadaver Lab held September 8, 2007 in Hong Kong with surgeons from Shanghai, Hong Kong, Japan, and Singapore, to compare nail insertion between prototypes of Expert A2FN with different bends to investigate the relationship between locking elements and proximal nail end to be adapted to the Asian anatomy.  Lab on 01 December 2007. This cadaver lab is a follow up of the first lab done in September and involves the same surgeons. Within this lab, the surgeons compared the insertion of different Nail designs in five femur specimens.  PMS summary:  PMS report (Windchill / 0000250261)  Clinical Evaluation Report (Windchill / 0000254065) | The result of the rationale must indicate that the system perform as intended and no safety signals are present for the assessed system. | Based on the results of the two labs, the participants agree on one of the designs of the nail based on the ease of insertion as well as the good fit of the nail in the existing x-rays/MRI. The hip screws were also deemed acceptable.  According to the Clinical Evaluation Report, the devices of the system perform as intended and the literature evaluated demonstrates the efficacy of the Expert A2FN System, as well as its safety and performance.  According to the current PMS Reports, no safety signals are present for the assessed system. | Pass |

## Common Specifications & Applied Standards

Refer to the Technical Documentation identified in Section 2 for list of associated applied standards / Common Specifications.

### Compliance with Specific Safety and/or Performance Standards

Sections 3.7.1.1 – 3.7.1.2 summarize the assessment of standards that have been identified as being clinically relevant to the CER.

#### Biocompatibility

A biocompatibility assessment of the Femoral Nail Systems was completed (Table 58) in accordance with EN ISO 10993-1. According to the standard, the subject devices are categorized as permanent exposure (>30 days) and come into contact with bone and soft tissue. These types of devices typically necessitate the following tests or justifications: chemical characterization, cytotoxicity, (skin) sensitization, irritation or intracutaneous reactivity, material mediated pyrogenicity, acute systemic toxicity, sub-acute and sub-chronic toxicity, implantation effects, genotoxicity, and carcinogenicity, as described in EN ISO 10993-1. The biocompatibility assessment was based on the following criteria.

* Use of biocompatible device raw materials
* Device manufacturing process is controlled and documented including materials, sterilization and packaging (e.g., documented in Manufacturing Process)
* Device raw materials are characterized in order to confirm their properties have not been altered in the manufacturing process and surface cleanliness is verified on the final packaged product in order to establish biocompatibility of the final product fulfill the specified requirements as well as the applicable regulatory requirements.

Table : Femoral Nail Systems – Biocompatibility Tests

| Document Title | Document ID |
| --- | --- |
| System #1: Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | |
| Femoral Shaft Nailing Implants, Biological Safety Evaluation (BSE) | Windchill #500646101 |
| Spiral Blades for Expert Retrograde Femoral Nails, Biocompatibility Evaluation Report (BER) | Windchill #501139530 |
| F-S738: LRBSE CTP01051 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Non Sterile,  Biological Safety Evaluation | Windchill #500002123 |
| F-S738: LRBSE CTP01479 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Sterile | Windchill #500002143 |
| F-S738: LRBSE – CTP01277 – Elmira Neutral Salt Anodize (TAN) – Non-sterile | Windchill #500002446 |
| F-S738: LRBSE – CTP01489 – Elmira Neutral Salt Anodize (TAN) – Sterile, QMV-LRBSE | Windchill #500002447 |
| BSE01006 Mark Two Inc. Transfer to Mark Two Inc. Anodized End Cap, QMV-BSE | Windchill #500002521 |
| System #2: Expert Adolescent Lateral Femoral Nail System  System #3: Expert Lateral Femoral Nail System  System #4: Femoral Recon Nailing System  System #6: Expert Asian Femoral Nail System | |
| F-S738: LRBSE CTP01482 20% Nitric Passivation Monument-Sterile | Windchill #500002087 |
| F-S738: LRBSE CTP01051 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Non Sterile,  Biological Safety Evaluation | Windchill #500002123 |
| F-S738: LRBSE CTP01479 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Sterile | Windchill #500002143 |
| F-S738 Washer Raron Titanium non sterile, Biological Safety Evaluation | Windchill #500004346 |
| F-S738 Washer Raron Titanium non sterile, Biological Safety Evaluation | Windchill #500004348 |
| F-S738 – BSE for Thermal Rinse Process at Monument | Windchill #500007485 |
| F-S738 – Final Cleaning Titan – Synthes Raron | Windchill #500015616 |
| F-S738 – A2FN/LFN nails – Mezzovico | Windchill #500020788 |
| F-S738 Femoral Recon Nails – Implants | Windchill #500021703 |
| F-S738 – TF10405 – Recon Femoral Nailing Implants, Biological Safety Evaluation | Windchill #500352712 |
| F-S738 – LESN SRS – Screws, Nuts, Washers, Ends Caps – GRE, MON, RAR, BET.,  Biological Safety Evaluation | Windchill #500455440 |
| BER – TF10620 Recon Femoral Nailing Implants, Biocompatibility Evaluation Report | Windchill #501083479 |
| BSE01006 Mark Two Inc. Transfer to Mark Two Inc. Anodized End Cap, QMV-BSE | Windchill #500002521 |
| F-S738: BSE01008. Sterile, Mark Two Inc. & Monument, Material: TAN | BSE01008 |
| QMV-LRBSE, Balsthal | SE\_555521 |
| QMV-LRBSE, Balsthal | SE\_590581 |
| QMV-LRBSE, Balsthal | SE\_590842 |
| QMV-LRBSE, Balsthal | SE\_623321 |
| QMV-LRBSE, Balsthal | SE\_623962 |
| QMV-LRBSE, Balsthal | SE\_627958 |
| System #5: Retrograde Femoral Nail Advanced System | |
| F-S738 – LESN SRS – Screws, Nuts, Washers, Ends Caps – GRE, MON, RAR, BET., Biological Safety Evaluation | Windchill #500455440 |
| F-S738 – LESN RFN, UHMWPE, LA Washer – MON, BRA, RAR, Biological Safety Evaluation | Windchill #500458847 |

In addition, for all MDR subject devices (Appendix 9.2.2) all raw materials have been screened for the presence of Restricted Substances (RS) per the ‘Restricted Substances Screening’ procedure (103446169) as described in Windchill #0000308743. No Carcinogenic, Mutagenic, or Toxic to Reproduction (CMRs) chemicals or Endocrine Disrupting Chemicals (EDCs) were found to be present.

As a result of this biocompatibility assessment, all subject devices are considered biocompatible per EN ISO 10993-1 when used as intended.

#### Sterilization

A sterilization validation of the Femoral Nail Systems was completed (Table 59) in accordance with EN 556-1, EN ISO 11137-2, EN ISO 17664-1, EN ISO 15883-1, EN ISO 15883-2, and EN ISO 17665-1.

Table : Femoral Nail Systems – Sterility Tests

| Document Title | Document ID |
| --- | --- |
| System #1: Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | |
| Decision Finding Protocol – Sterile, Spiral Blade f/Expert™ Retrograde Femoral Nail-TAN – ELM / Früh | SE\_428388 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 9.0 mm-TAN – MON / Früh | SE\_428393 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 11.0 mm-TAN – MON / Früh | SE\_428398 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 13.0 mm-TAN – MON / Früh | SE\_428402 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 15.0 mm-TAN – MON / Früh | SE\_428408 |
| Decision Finding Protocol – Sterile, Expert™ End Cap f/Spiral Blade Locking-TAN – Mark Two / Früh | SE\_428412 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 10.0 mm-TAN – MON / Früh | SE\_428535 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 12.0 mm-TAN – MON / Früh | SE\_430391 |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 14.0 mm-TAN – MON / Früh | SE\_430397 |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 |
| Endotoxin Risk Assessment, Invasive Implantable Medical Devices | SE\_744335 |
| System #2: Expert Adolescent Lateral Femoral Nail System  System #3: Expert Lateral Femoral Nail System  System #4: Femoral Recon Nailing System  System #6: Expert Asian Femoral Nail System | |
| Sterilization Dose Equivalence Determination Form, LESN End Caps | Windchill #500402171 |
| Sterilization Dose Equivalence Determination Form, Sterile Tube Packaging – Non-cannulated Screws TAN Mez/Früh | SE\_800399 |
| Sterilization Dose Equivalence Determination Form, SRS – Recon Screw 04.046.660-730TS – GRE/FRU | SE\_805588 |
| Sterilization Dose Equivalence Determination Form, Self Retaining Locking Recon Screw for Medullary Nail | SE\_836103 |
| Risk based approach for X-ray sterilization, project scope specific SKU list | SE\_839375 |
| Dose Mapping Equivalence Determination Form, LESN End Caps | Windchill #500402158 |
| Dose Mapping Equivalence Determination Form, Sterile Tube Packaging – L Tubes | SE\_800281 |
| Dose Mapping Equivalence Determination Form, Sterile Tube Packaging – L+ Tubes | SE\_800282 |
| Dose Mapping Equivalence Determination Form, SRS – recon screw 04.046.660-730TS FRU31 | SE\_805593 |
| Dose Mapping Equivalence Determination Form, Self Retaining Locking Recon Screw for Medullary Nail | SE\_836108 |
| Decision Finding Protocol – Sterile, Hip Screws ø6.5 f/AFN TAN – BAL/ KKS / Früh | SE\_252744 |
| Decision Finding Protocol – Sterile, Washer ø3.5/2.7 TAN – RAR / Collini / Früh | SE\_252752 |
| Decision Finding Protocol – Sterile, Expert End Caps TAN f/ Femoral Nails – MEZ / Früh | SE\_387840 |
| Decision Finding Protocol – Sterile, Hip Screws T25 Ø 6.5mm self-tapping TAN – MEZ / Früh | SE\_427592 |
| Decision Finding Protocol – Sterile, End Caps f/Expert™ A2FN TAN – MEZ / Früh | SE\_427675 |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø9.0mm and 10mm cannulated TAN – MEZ / SUZ/ Früh | SE\_427678 |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø11.0mm and 12 mm cannulated TAN – MEZ / SUZ/ Paka Hänni / Früh | SE\_427701 |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø13.0mm and 14mm cannulated TAN – MEZ / SUZ/ Paka Hänni / Früh | SE\_427709 |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø9 TAN – MEZ / Paka Hänni / Früh | SE\_430361 |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø12 TAN – MEZ / Paka Hänni / Früh | SE\_430367 |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø14 TAN – MEZ / Paka Hänni / Früh | SE\_430369 |
| Decision Finding Protocol – Sterile, Expert End Caps f/ Adolescent Lateral Femoral Nails TAN – Mark II / Früh | SE\_438287 |
| Decision Finding Protocol – Sterile, Hip Screws Stardrive TAN – Bell Pro / MON / Früh | SE\_438348 |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø8.2 TAN – MON / Früh | SE\_438355 |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø9.0 TAN – MON / Früh | SE\_438360 |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø10.0 TAN – MON / Früh | SE\_438361 |
| Decision Finding Protocol – Sterile, Femoral Recon Nails – BET/ Früh | SE\_698046 |
| Clinical Processing Decision Finding Protocol For Non-Sterile Devices, LESN End Caps | Windchill #500401570 |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 |
| Decision Finding Protocol – Non-Sterile, Trauma Implants | SE\_634298 |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 |
| Decision Finding Protocol – Non-Sterile, Intramedullary Nails and Endcaps | SE\_657316 |
| Decision Finding Protocol – Non Sterile, Femoral Recon Nails | SE\_697176 |
| Decision Finding Protocol – Non-Sterile, Self Retaining Screw System – Recon Screw for Medullary Nail | SE\_825646 |
| System #5: Retrograde Femoral Nail Advanced System | |
| F-S380 Sterilization Dose Equivalence Determination, Retrograde Femoral Nail (RFN) | Windchill #500399828 |
| Sterilization Dose Equivalence Determination Form, Locking Attachment Washer for RFN | Windchill #500399833 |
| Sterilization Dose Equivalence Determination Form, LESN End Caps | Windchill #500402171 |
| Dose Mapping Equivalence Determination Form, Locking Attachment Washer for RFN | Windchill #500399242 |
| Dose Mapping Equivalence Determination Form, Retrograde Femoral Nail (RFN) | Windchill #500399752 |
| Dose Mapping Equivalence Determination Form, LESN End Caps | Windchill #500402158 |
| Clinical Processing Decision Finding Protocol For Non-Sterile Devices, LESN End Caps | Windchill #500401570 |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 |

## Clinical Evaluation Data Route (CEDR)

The clinical evaluation data route (CEDR) used to support demonstration of conformity with the relevant Essential Requirements (Annex I) of the European Council Directive 93/42/EEC (MDD) and the General Safety and Performance Requirements (Annex I) of the Medical Device Regulation (MDR) relating to the safety and performance was initially determined during the planning stage (Stage 0) in the Clinical Evaluation Plan (CEP; refer to Table 1 for Attachment number) and continuously evaluated through the execution stages (Stage 1-3). The CEDR for Femoral Nail Systems is based on the strategy outlined in Table 60. Refer to Section 3.6.1 for a detailed breakdown of available data.

Table : CEDR for All Subject Devices

| Applicable Strategy | Routes |
| --- | --- |
|  | Clinical Route (Supporting Direct or Indirect Clinical Benefit) – Including one or more of the following:   * Scientific literature directly or indirectly relating to the subject and / or equivalent device(s) (as applicable) * Clinical investigations for the subject and / or equivalent device(s) (as applicable) * Clinically relevant information coming from PMS, in particular PMCF |

While the subject devices include implantable devices, no premarket CI was conducted. Refer to Section 5.1 for a justification.

### Demonstration of Equivalence

Table 16 documents the equivalent devices used to support the conformity assessment for the identified MDD device group(s). No equivalent devices were utilized to support the conformity assessment for any of other device groups.

Table 16: Equivalent Device Summary

|  |  |
| --- | --- |
| Equivalent Device[s]: | Device Group # 1 - Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail:   * Not Applicable – Medical Device Directive (MDD) conformity was not assessed on the basis of equivalence. * Not Applicable – Medical Device Regulation (MDR) conformity of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nails were not assessed on the basis of equivalence. |
| Device Group # 3- Spiral Blade for Expert Retrograde/Antegrade Femoral Nail:   * Not Applicable – Medical Device Directive (MDD) conformity was not assessed on the basis of equivalence. * Not Applicable – Medical Device Regulation (MDR) conformity of the Spiral Blade for Expert Retrograde/Antegrade Femoral Nail was not assessed on the basis of equivalence. |
| Device Group # 10 –Femoral Recon Nail:   * Equivalent Device Name (Manufacturer): Expert Lateral Femoral Nail (Synthes GmbH) |
| Device Group # 13 – RFN-ADVANCED Femoral Nail:   * Equivalent Device Name (Manufacturer): Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Synthes GmbH) |

The rationale for this equivalence is summarized below (Sections 3.8.1.1 - 3.8.2.5).

#### Equivalence Rationale for Femoral Recon Nail

Expert Lateral Femoral Nail (Synthes GmbH) was selected as the Equivalent Device for Femoral Recon Nail (Device Group # 10) and has been in clinical use for 18 years.

The equivalent device was selected as it is a type of device that shares the same or similar clinical, technical, and biological parameters as the subject device (as required to establish equivalence) and had representative clinical data. Since minor differences in some characteristics exist between the devices, an evaluation was done (refer to Section 9.3) to assess whether there was any clinically significant difference in performance and safety based on these differences. As discussed in Section 9.3 and summarized below, it was demonstrated that the differences between the subject and equivalent device did not trigger any significant difference in safety or performance.

Table : Expert Lateral Femoral Nail Overview

|  | Subject Device: Femoral Recon Nail | Equivalent Device: Expert Lateral Femoral Nail (Synthes GmbH) |
| --- | --- | --- |
| Regulatory Status: | 15 JANUARY 2018 | 15 APRIL 2005 |
| Technical Documentation: | TF10405 | TF10405 |
| Device Descriptions and Images (Not to scale): | Femoral Recon Nail implants are intended for temporary fixation and stabilization of femoral shaft fractures, subtrochanteric fractures, and combined femoral shaft and neck fractures. Femoral Recon Nails can be implanted through the greater trochanter or piriformis fossa entry point. | Expert Lateral Femoral Nail implants is intended for temporary fixation and stabilization of femoral shaft fractures, subtrochanteric fractures, and combined femoral shaft and neck fractures. Expert LFN nails can be implanted through the lateral entry point (i.e., via Greater Trochanter). |

#### Clinical Impact of Clinical Differences for Femoral Recon Nail

The Femoral Recon Nail and Expert Lateral Femoral Nail comply with the definition of clinical equivalence as having the same clinical condition, the same intended purpose, the same site in the body, in similar populations and not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the duration of use, etc.).

#### Clinical Impact of Technical Differences for Femoral Recon Nail

Femoral Recon Nail and Expert Lateral Femoral Nail meet the definition of technical equivalence as they have similar designs, used under same conditions of use, achieve the critical performance by the same application and mode of action, and use similar methods for preparation and deployment.

As discussed in the equivalence table (Table 193), the range of dimensions of proposed devices is in a similar range as offered from the equivalent design to accommodate patient anatomy and surgical need. Femoral Recon Nail is compatible with the same existing Synthes end caps, recon screws, locking screws and angular stable locking screws as the Expert Lateral Femoral Nail. Consequently, the design features of the Expert Lateral Femoral Nail System are considered equivalent to and representative of the Femoral Recon Nail system. The devices were compared through mechanical performance. The results of the fatigue testing of constructs with Recon Femoral Nails (Femoral Recon Nail Greater Trochanter and Femoral Recon Nail Piriformis Fossa) show that the subject devices meet the defined acceptance criteria. The median fatigue limits of the subject devices worst-case constructs are greater than the median fatigue limit of the equivalent comparator worst-case construct. The acceptance criterion is met, since the subject device Femoral Recon Nails performed better than the comparator device, the Expert Lateral Femoral Nail System.

The STGs for the devices show that both systems follow the same standard series of steps for antegrade entry to the greater trochanter and both allow an entry point (5° [Femoral Recon Nail Greater Trochanter] or 10° [Expert Lateral Femoral Nail] of the femoral shaft) in line with the axis of the intramedullary canal (in the lateral view). The Femoral Recon Nail Piriformis Fossa offers an additional entry point through the piriformis fossa, which enables surgeons to determine the best approach for each patient and case. The equivalent comparator does not offer such entry point. Additionally, Synthes’ long history of using this entry point provides evidence of its safety and performance. A piriformis fossa Synthes nail product line has been in clinical use since 2004 (Expert R/AFN system, FDA approval February 2004).

Thus, there is no clinically significant difference in performance and safety of the technical differences.

#### Clinical Impact of Biological Differences for Femoral Recon Nail

Femoral Recon Nail and Expert Lateral Femoral Nail meet the requirements for biological equivalence as they both uses the same materials and are in contact with the same human tissues or body fluids / tissues and are expected to elicit the same biological response. Thus, there are no differences in biological parameters.

#### Equivalence Conclusion for Femoral Recon Nail

Clinical, technical, and biological parameters were respectively evaluated for the subject and equivalent devices. No clinically significant difference in the performance and safety of the devices was triggered by the minor differences between the devices. Therefore, Femoral Recon Nail was deemed equivalent to Expert Lateral Femoral Nail.

#### Equivalence Rationale for RFN-ADVANCED Femoral Nail

Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Synthes GmbH) was selected as the Equivalent Device for RFN-ADVANCED Femoral Nail (Device Group # 13) and has been in clinical use for 18 years.

The equivalent device was selected as it is a type of device that shares the same or similar clinical, technical, and biological parameters as the subject device (as required to establish equivalence) and had representative clinical data. Since minor differences in some characteristics exist between the devices, an evaluation was done (refer to Section 9.4) to assess whether there was any clinically significant difference in performance and safety based on these differences. As discussed in Section 9.4 and summarized below, it was demonstrated that the differences between the subject and equivalent device did not trigger any significant difference in safety or performance.

Table : Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail Overview

|  | Subject Device: RFN-ADVANCED Femoral Nail | Equivalent Device: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Synthes GmbH) |
| --- | --- | --- |
| Regulatory Status: | 21 December 2022 | 16 January 2006 |
| Technical Documentation: | TF10404 | TF10404 |
| Device Descriptions and Images (Not to scale): | The Retrograde Femoral Nail Advanced implants consist of a cannulated femoral nail. | The Femoral Shaft Nailing Implant family consists of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail. |

#### Clinical Impact of Clinical Differences for RFN-ADVANCED Femoral Nail

RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail meet the definition of clinical equivalence as they have the same intended use and contraindications, used in the same sites in the body, in the same population, performed by the same application, and have the same duration of use. There are no substantial differences in indications. The subset of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail indications evaluated for comparison are clinically equivalent to the indications of the RFN-ADVANCED Femoral Nail. Therefore, there is no impact on performance or safety of the subject devices relative to their indications.

The indications for RFN-ADVANCED Femoral Nail include both the distal femur and femoral shaft fractures that can be classified as 33 A, 33 C and 32-A/B/C. Although supracondylar fractures are not described in the indications for the equivalent device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail), these fractures may also refer to distal end segment fractures of the femur as stated in RFN-ADVANCED Femoral Nail. For ipsilateral condylar and diaphyseal fractures, such fractures are not fundamentally different than the fracture types identified under the indications for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail that includes fractures of the distal end segment of the femur and the femur, and fractures of the middle and distal diaphyseal segment of the femur. In the case of ipsilateral femur/tibia fractures and fractures from multiple trauma patients, these are unrelated to the indications being treated by Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail. However, it could be treated by either of the device via a retrograde approach. For indications relating to periprosthetic fracture, the use of retrograde nails for treatment of periprosthetic fracture is well documented both within the patient body of literature, and specifically for the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail ([Butler et al., 2019](#_ENREF_2); [Horneff et al., 2013](#_ENREF_11)). Periprosthetic fractures are not fundamentally different than the other fracture types identified under the indications for retrograde femoral nailing. Based on its principal mode of action, the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is comparable to other retrograde intramedullary nails for which there is substantial literature to support use in periprosthetic fracture. In patients with an open-box prosthetic knee, the design of the RFN-ADVANCED Femoral Nail will be better able to meet the challenges presented by distal femoral fractures in the presence of a prosthetic. Lastly, although not described in the indication language of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail, it is not contraindicated for use in osteoporotic bone, impending pathologic fractures, malunions, and non-unions and therefore are comparable to RFN-ADVANCED Femoral Nail.

RFN-ADVANCED Femoral Nail is indicated for supracondylar fractures with only intra-articular extension and excludes multifragmentary articular fractures.

Thus, there is no clinically significant difference in performance and safety of the clinical differences.

#### Clinical Impact of Technical Differences for RFN-ADVANCED Femoral Nail

RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail meet the definition of technical equivalence as they have similar designs and properties, are used under the same conditions of use, achieve the critical performance by the same application and mode of action, and use similar methods for preparation and deployment.

As discussed in the equivalence table (Table 194), the range of dimensions of proposed devices is in a similar range as offered from the equivalent comparator to accommodate patient anatomy and surgical need. Both systems are modular systems comprised of an intramedullary nail, screws, and an endcap. The Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail includes an additional blade option for fixation in the distal femur while the RFN-ADVANCED Femoral Nail includes locking attachment washers. The inlay and flat edges, of RFN-ADVANCED Femoral Nail, are generational design improvements. However, once implanted, both systems act as internal splints that provide stress sharing, help to limit damage to soft tissue in the vicinity of bone during surgery, and preserve periosteal blood supply to allow fracture healing. Consequently, the design features of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail system are considered equivalent to and representative of the RFN-ADVANCED Femoral Nail system.

The devices were compared through mechanical testing. The result of the comparative Static Bending testing of the constructs showed that the offset bending moment and bending stiffness for RFN-ADVANCED Femoral Nail was non-inferior to that of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and that the acceptance criteria was met. The result of the comparative Static Torsion testing of the construct showed that the torsional stiffness for RFN-ADVANCED Femoral Nail was non-inferior to that of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and that the acceptance criteria was met.

Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail can be implanted through both the antegrade and retrograde methods. However, RFN-ADVANCED Femoral Nail utilizes only a retrograde approach, which is a sub-set of the deployment methods for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail. The STGs for the devices show that both systems follow the same standard series of steps for retrograde entry. The entry point for both the nails is in line with the medullary canal. The entry point is at the top of the intercondylar notch, just anterior and lateral to the femoral attachment of the posterior cruciate ligament.

The non-clinical testing suggests that the bending strength, bending stiffness (Windchill #0000293476) and torsional stiffness (Windchill #00000293478) of RFN-ADVANCED Femoral Nail are similar to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and therefore do not impact the safety and performance of RFN-ADVANCED Femoral Nail.

Thus, there is no clinically significant difference in performance and safety of the technical differences.

#### Clinical Impact of Biological Differences for RFN-ADVANCED Femoral Nail

Both the nails and endcaps of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail are manufactured using TAN, following the standard (ISO 5832-11). RFNA nails are manufactured using TAV, following the standard (ISO 5832-3), while the RFN-ADVANCED Femoral Nail end caps are manufactured using TAN, following the standard (ISO 5832-11). Both TAN and TAV are biocompatible materials and have been employed successfully for over 30 years in human implants in contact with bone and soft tissue. The main nail and end cap implant material is equivalent between the two nails. Both the nails are machined and anodized as per ES0063 and sterilized via gamma sterilization. Hence, the construction process is equivalent between the two nails.

It is important to note that the RFN-ADVANCED Femoral Nail has an inlay made of UHMWPE (ISO 5834-2) which is a biocompatible material and has been employed successfully for over 20 years. Thus, there are no differences in biological characteristics. Moreover, addition of an inlay to the implant design will not significantly impact the safety and performance as it represents a minor subcomponent and would not change the overall biocompatibility of the system. This difference is a minor generational improvement and is a small subcomponent of the overall nail system. Assuming the distal locking screws are used as intended and the end cap is used, the contact between the patient and the inlay should be minimal to non-existent. Rationale assessing polymer debris from RFN-ADVANCED Femoral Nail with inlay (Windchill #0000293897) concluded that number, size, and shape of particles generated by the nail are comparable to MultiLoc Humeral nail. The total number of PE particles generated from a MultiLoc nail represents less than 0.001% of the number of particles generated per year from a successful hip joint replacement. These amounts of particles will not cause any local, intramedullary or systemic negative side effects beyond what is observed with joint replacement. Considering this inlay provides additional stability in the locking between the screw and the nail, it is on the inside of the nail, and it does not generate clinically significant debris during insertion, this additional inlay should not negatively impact safety or performance.

RFN-ADVANCED Femoral Nail is offered with a locking attachment washer. The washer is manufactured using stainless steel (ISO-5832-1) which is a biocompatible material and has been employed successfully for over 30 years in human implants and applications in contact with bone and soft tissue. The washer is an optional additional component to the system and doesn’t come in contact with the nail except via the screws. The combination of materials of nail and washer have been assessed for corrosion (Windchill #0000297100). The difference in material was not found to accelerate the rate of corrosion or fretting. Based on the rationale discussed above, there is no clinically significant difference in performance and safety of the subject device and equivalent device relative to the difference in materials offerings and the biological response towards the device as compared to each other.

#### Equivalence Conclusion for RFN-ADVANCED Femoral Nail

Clinical, technical, and biological parameters were respectively evaluated for the subject and equivalent devices. No clinically significant difference in the performance and safety of the devices was triggered by the minor differences between the devices. Therefore, RFN-ADVANCED Femoral Nail was deemed equivalent to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail.

## State of the Art (SOA) Review

### Objective

The objective of the SOA review was to systematically evaluate the State of the Art (SOA) surrounding the internal fixation of femur fractures – distal and femoral shaft. This is the intended effect addressed by treatment options associated with Synthes GmbH devices (i.e., subject devices). Hereafter, these will be referred to as the target treatment options. In addition to the subject devices, the target treatment option includes similar devices (described in Section 3.9.2). The review included a comprehensive search of the available scientific literature and external registries or other applicable data sources to achieve the following.

* Confirmation of the treatment options that comprise the state of the art
* Evaluation of the key clinical safety and performance outcomes for the benchmarks to the target treatment option
* Identification of the acceptability criteria for establishing the benefit-risk assessment

### Methodology & Results

Table 65 describes the search methodology and results for the SOA review.

Table : Summary of SOA Methodology and Results for All Subject Devices

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full SOA Report (SOAR) #: | Refer to report for full assessment (Table 1) | | | |
| Intended Device Effect for Subject Device(s): | Temporary fixation, correction, and stabilization of the femur | | | |
| Target Clinical Conditions Covered for the Subject Devices: | * Subtrochanteric fractures * Femoral shaft fractures * Ipsilateral femoral neck/shaft fractures * Fractures in distal femur | | | |
| Target Patient Group(s) Covered: | Adolescents, small-statured patients, and skeletally mature patients or patients where growth plates have fused. | | | |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: Ipsilateral femoral neck/shaft fractures to be merged as femoral shaft fractures. The fractures are stratified as femoral shaft and distal femur fractures  Medical Rationale: All the indicated fractures fall under the category of femoral fractures.  Patient target groups to be Merged: The patient target groups will not be merged. The target groups are segregated as skeletally mature and children/adolescent patients.  Medical Rationale: The subject device treats the symptoms of skeletally mature patients and has a specialized device for the adolescent / small statured patients with different skeletal growth requirements.  Anatomical locations to be Merged: Femoral neck or subtrochanteric fractures to be merged with Middle / shaft segment of the femur and the other category will be distal segment of the femur  Medical Rationale: The subject devices are indicated for treatment of distal femur fractures in combination with subtrochanteric fractures or femoral neck fractures | | | |
| Treatment Options within the State of the Art that address the Clinical Conditions / Target Patient Groups of Subject Device: | **Treatment Options:**   * Target Treatment Option: * Intramedullary Nail Fixation * Alternative Treatment Options: * External Fixation * Plate Fixation * Elastic stable intramedullary nailing (ESIN) | | | |
| Similar Device(s) / Device Group for Subject Device(s): | * All devices within Target Treatment Option. Refer to Section 3.9.4 for overview of devices within target treatment option | | | |
| Benchmark Device(s)/ Treatment(s) to be used to Establish the Acceptability Criteria: | * **Target Treatment Option (as a whole)** | | | |
| Rationale for Identified Treatment Options: | Based on the state of the art review and clinical input by the Medical Affairs (MA) Approver, the treatment options identified represent the relevant treatments that could offer comparable safety and performance for the same clinical conditions as the subject device for similar patients at a similar severity and stage of conditions and fall within what is generally acknowledged as typical standard of care within the European Union. | | | |
| Review Periods: | Previous Review(s) | Current Review | | Overall Review |
| Not Applicable | 01 July 2017 to 31 August 2022 | | 01 July 2017 to 31 August 2022 |
| Review Period Rationale: | As data on the identified treatment options are actively being reported, a standard 5-year review period was selected to identify recent publications containing specific data to assess the state of the art. | | | |
| Databases searched: | MEDLINE via OVID  EMBASE via OVID | | | |
| Literature Interfaces: | Google Scholar  Other: Springer Books, NICE Guidelines, and AO Foundation | | | |
| Assumptions: | Assumptions related to the clinical condition:   * If clinical data are presented on the applicable clinical condition, i.e. shaft and distal femoral fracture, and another clinical condition, e.g., distal femoral fracture/combined fractures, all attempts will be made to include data on the applicable clinical condition only. If the data are recorded in aggregate and not extractable as described (mixed indication cohorts), the study will be excluded from this review. * If clinical data was on the subject device or another intervention, all attempts will be made to exclude data on the subject device to avoid a bias of the treatment option group-data. If data is recorded in aggregation (mixed cohorts) and not extractable, the study will not be included in the review.   Assumptions related to the treatment options:   * For publications on the target treatment option: The brand name will be considered sufficient to identify the femoral shaft nailing system used in the given study, regardless of whether the manufacturer will be specified. If no device or brand name and no manufacturer is mentioned, the publication will be included, and data will be collected in the corresponding treatment option group.   Assumptions related to the benchmarks / acceptability criteria:   * For performance outcomes, the data at the latest timepoint will be recorded regardless of interim timepoints. * For complications, the adverse event will be collected regardless of the timepoint when it occurred in the postoperative follow-up. * Performance and safety outcome data on the subject device(s) will not be collected to avoid a bias of the treatment option data. If no device or brand name and no manufacturer is mentioned, the publication will be assumed to have used a Non-J&J in-scope device and will be included, and data will be collected in the corresponding treatment option group. | | | |
| Search Criteria: | PICOS Tool | Selection/Inclusion Criteria | | Rejection/Exclusion Criteria |
| Patient Populations | * Publication provides relevant information on the clinical condition * Publication describes risks or benefits of a treatment option | | * Publication does not include data for the intended device effect * Publication does not include data for the clinical condition * Publication does not include data for the target patient group |
| Intervention(s) |
| Comparator(s)/Context | * Full text publication | | * Abstract Only / Publications that cannot be obtained * Publications in a non-English language without an English abstract |
| Outcome(s) | * Publications quantitatively describes one or more key outcome on the benchmark(s) | | * Publication does not include data for a treatment option or provide relevant information on the clinical condition |
| Study Type(s) | * Meta-Analysis, Systematic Review, Registries * Consensus Statements, Clinical Guidelines, Position Papers/Statements * Randomized-controlled clinical trials * Other comparative studies * Cohort studies, Case Series * Other (nonsystematic) reviews * Textbooks | | * Duplicate article * Case report |
| Number Included / Excluded References: |  | Previous Review | Current Review | Overall Review |
| Included References: | Not Applicable | 31\* | 31\* |
| Excluded References: | Not Applicable | 376 | 376 |

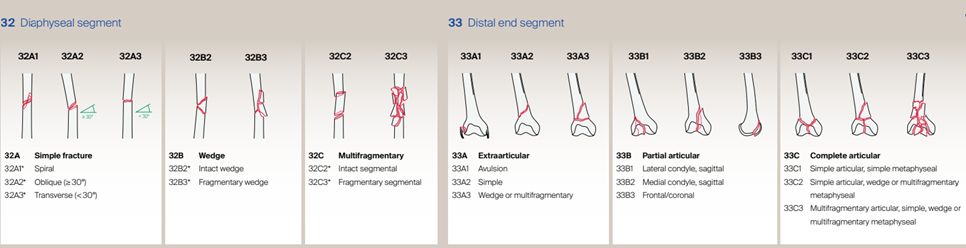
\*Note: Of the 31 included publications, 5 were ad hoc publications.

### Overview of Target Clinical Condition(s)

The femur is the strongest long tubular bone in the human body, as well as the main weight-bearing bone of the lower extremities. It is prone to fracture when struck by strong external forces, such as in car accidents, and especially in falling injuries. Femoral shaft fractures are commonly caused by strong external forces, especially falling injuries ([Jin et al., 2020](#_ENREF_14)). The annual incidence of femoral shaft fracture from motor vehicle accidents alone has been estimated to range from 1.0 to 2.9 million worldwide ([Saleeb et al., 2019](#_ENREF_30)). Fractures of the femoral neck and femoral shaft are relatively common but are rare in combination. The reported incidence of a femoral neck fracture in the setting of a femoral shaft fracture is 1–9%, with the largest retrospective review to date reporting a 3% incidence ([Mohan et al., 2019](#_ENREF_28)). The incidence of ipsilateral fractures of the femoral neck and shaft is increasing due to the rising number of high-energy motor vehicle accidents, improved survivorship after high-energy accidents, and enhanced recognition of this injury pattern ([Bishop et al., 2018](#_ENREF_1)). Fractures of the femoral shaft are uncommon, accounting for 1.4%–1.7% of all fractures in children ([Chen et al., 2020b](#_ENREF_5)). For adolescent and skeletally mature teenagers (> 12 years old), rigid antegrade entry intramedullary fixation is indicated ([Liau et al., 2021](#_ENREF_20)). Rigid intramedullary nails act as load‐sharing devices, providing adequate fixation for larger and heavier children and adolescents. Fixation methods and fracture outcomes have evolved greatly: from the early traction wards to one or more rods without bony fixation, to a plate, and ultimately, to one large intramedullary rod with proximal and distal fixation ([Koso et al., 2018](#_ENREF_18)).

According to the AO Foundation classification system, femoral fractures fall into three areas proximal, diaphyseal and distal end segments. The scope of this CER is limited to diaphyseal/femoral shaft and distal femur. Fractures occurring in the femoral shaft – alone or in conjunction with type 31-B femoral neck fractures – and distal femur fractures (AO classifications specific to 32-A, B, C and 33-A, B, C).

Figure : Types of Femoral Fractures (AO Foundation, 2018)[[2]](#footnote-3)



In an epidemiological study by ([Khan et al., 2017](#_ENREF_16)), it was reported that fractures among male patients were caused by high energy mechanisms (70.5%) whilst female patient distal femoral fractures were sustained through low energy mechanisms (82.7%). Majority of the fractures were 33-A (52.0%) followed by 33-B (30.4%) and 33-C (17.6%). Ninety-two (73.6%) of the patients underwent operative management ([Khan et al., 2017](#_ENREF_16)).

In a meta-analysis on healing, nonunion, and reoperation after internal fixation of distal femoral fractures ([Koso et al., 2018](#_ENREF_18)), distal fractures had a lower healing rate (86.6% vs. 93.7%) and a higher reoperation rate (13.4% vs 6.1%) than femoral shaft fractures (p < 0.00001), primarily due to higher rates of mechanical failure. Nonunion was the most frequent complication, occurring in 4.7% of distal fractures and 2.8% of shaft fractures. There was no difference between plate and nail fixation of distal fractures in healing, nonunion, or other causes of reoperation. Shaft fractures developed nonunion in 6.6% of unreamed nails and 2.1% of reamed nails (p = 0.002). Nonunion occurred in 2.3% of antegrade nailed fractures and 1.5% of retrograde nailed fractures (p = 0.66). Approximately one out of every eight distal fractures and one of every 16 shaft fractures required re-operation. The most common cause of fixation failure was nonunion ([Koso et al., 2018](#_ENREF_18)). For femoral fractures in children, external fixation and elastic intramedullary nailing (IMN) are the two most common treatments applied. Currently, meta-analyses point to the superiority of IMN as it has a reliable curative effect and results in a shorter hospital stay, faster fracture healing, and fewer complications ([Chen et al., 2020a](#_ENREF_4); [Imam et al., 2018](#_ENREF_13)).

### Assessment of SOA Treatment Options

The target clinical condition(s) are typically addressed utilizing several treatment options, including the target treatment option (associated with the devices in scope [Section 3.1]) and alternative treatment options, as described in Table 66 and Table 67, respectively.

Table : Overview of Target Treatment Option for All Clinical Conditions

| Target Treatment Option | Brief Description | Device Options | Representative Image | Benefits | Risks |
| --- | --- | --- | --- | --- | --- |
| Intramedullary Nail Fixation | * Following reduction, a nail is inserted in the medullary canal of the femur using a small incision. An antegrade approach may be used or a retrograde approach proximal to the knee ([Whiting et al., 2018](#_ENREF_33)). * Intramedullary nails are designed to be compatible with the body and are made from stainless steel, titanium, or alloys of these metals with a known history of biocompatibility. | * Antegrade nails * Retrograde nails |  | * Ability to reduce and contain comminuted fractures, which can be treated without loss of length ([Whiting et al., 2018](#_ENREF_33)). * Reamed and unreamed fractures had high rates of uncomplicated healing ([Koso et al., 2018](#_ENREF_18)) ([Huang et al., 2022](#_ENREF_12)).Reaming improves mechanical stability ([Medlock et al., 2018](#_ENREF_26)). * IMN is the treatment of choice for open femoral diaphyseal fractures with very good union rates ([Saleeb et al., 2019](#_ENREF_30)). * Lower reoperation rate for intramedullary nails than sliding hip screws for unstable trochanteric and subtrochanteric fractures. ([Grønhaug et al., 2022](#_ENREF_10)). * Quicker time to full weight bearing when compared to plating.([Shah et al., 2020](#_ENREF_32)). * The reconstruction nail has definitive advantages in healing time, union rates, and complications over screw+plates ([Lu et al., 2020](#_ENREF_23)). * Rigid IM nail safe and efficacious for management of diaphyseal femur fractures in the skeletally immature ([Del Balso et al., 2021](#_ENREF_6)) ([Chen et al., 2020a](#_ENREF_4); [Imam et al., 2018](#_ENREF_13)) ([Madhuri et al., 2014](#_ENREF_24)), ([Khoriati et al., 2016](#_ENREF_17)). | * Possibility of developing avascular necrosis (AVN) of the femoral head. The true incidence of AVN with adult nails remains unknown and is largely dependent on the technique used ([Khoriati et al., 2016](#_ENREF_17)). * Nonunion was the most frequent complication, occurring in 4.7% of distal fractures and 2.8% of shaft fractures ([Koso et al., 2018](#_ENREF_18)). |

Table : Overview of Alternative Treatment Options for All Clinical Conditions

| Alternative Treatment Options | Brief Description | Device Options | Representative Image | Benefits | Risks |
| --- | --- | --- | --- | --- | --- |
| External Fixation | * External fixation is a method of immobilizing the fracture while preserving soft tissue integrity using pins that pass through the skin and bone. The pin pierces the limb entirely or from one side, and a rigid scaffolding connects these pins outside the limb. | * External fixators, rods, pins, wires |  | * External fixation is recommended for fractures with serious injury of the soft tissue, multiple trauma, and high energy injury in the lower limbs to avoid intramedullary infection ([Chen et al., 2020a](#_ENREF_4)). | * Postoperative pin site infections * Open injury requiring a longer hospitalization and recovery time, longer recovery time ([Chen et al., 2020a](#_ENREF_4)). * Increased risk of infection following EF when compared to flexible intramedullary nailing for femoral diaphyseal fractures in children aged from 4 to 12 years ([Edwards et al., 2021](#_ENREF_8)). |
| Plate Fixation | * Plates are like internal splints keeping together the pieces of broken bone utilizing metal plates connected with screws to the bone. After healing is complete, plates can be left in place or they can be removed (in select cases). * The most used plates for fixation technique are metallic in origin (stainless steel or titanium) ([Saleh et al., 2021](#_ENREF_31)). | * Plates and screws |  | * Intraoperatively shorter operation time and less blood loss and postoperatively (i.e., higher union rate, shorter union time, and lower complication rate) ([Jin et al., 2020](#_ENREF_14)). * No significant differences in time to radiographic union between plate and exchange nailing time to radiographic union ([Medlock et al., 2018](#_ENREF_26)). * For periprosthetic distal femur fractures, locking plates and IMN had comparable outcomes ([Koso et al., 2018](#_ENREF_18); [Liu et al., 2019](#_ENREF_22); [Shah et al., 2020](#_ENREF_32)) | * Superficial infections and plate prominence requiring removal after union, restricted weight bearing to reduce the risk of plate failure ([Medlock et al., 2018](#_ENREF_26)). * The use of implants like condylar blade plate in distal femoral fractures have resulted in high complications. ([Neradi et al., 2022](#_ENREF_29)). * Large surgical trauma, importantly bleeding, and high probability of non-union with femoral neck fracture ([Lu et al., 2020](#_ENREF_23)). |
| Elastic stable intramedullary nailing (ESIN) | * ESIN comprises of inserting 2 elastic nails into the medullary canal via the metaphysis, advancing them through the fracture site and thrusting them into the opposite metaphysis. * Before being applied, these elastic nails are created in a concave shaped form (achieved by bending beyond the elastic limit), which allows for their precise orientation and the development of an elastic framework that resists deformation ([Mohamed and Rajeev, 2017](#_ENREF_27)). | * Elastic nails |  | * Shorter operative time and with less estimated blood loss in Elastic Stable Intramedullary Nailing in school age children ([Saleh et al., 2021](#_ENREF_31)). | * Biomechanically less stable than plates ([Saleh et al., 2021](#_ENREF_31)). * Inapplicability in adolescents with a body weight of 50 kg or greater ([Lindisfarne and Ayodele, 2020](#_ENREF_21)); ([Makarewich et al., 2020](#_ENREF_25)) |

Comparison of Treatment Options:

In a meta-analysis on healing, nonunion, and reoperation after internal fixation of distal femoral fractures ([Koso et al., 2018](#_ENREF_18)), distal fractures had a lower healing rate and a higher reoperation rate than femoral shaft fractures, primarily due to higher rates of mechanical failure. There was no difference between plate and nail fixation of distal fractures in healing, nonunion, or other causes of reoperation. For femoral fractures in children, external fixation and elastic intramedullary nailing (IMN) are the two most common treatments applied. Currently, meta-analyses point to the superiority of IMN as it has a reliable curative effect and results in a shorter hospital stay, faster fracture healing, and fewer complications (Chen et al., 2020a; Imam et al., 2018). All treatment options carry unique benefits and risks, and each may be chosen based on the surgical teams’ preference, the patients’ clinical presentation, and fracture type. Considering the risks and benefits presented, all are considered state of the art treatment options for the identified clinical conditions.

### Key Outcome Parameters / Benefit-Risk Acceptability Criteria

The outcome parameters that are most relevant to establishing the performance and safety of the subject device were based on the state of the art review of the identified benchmarks (Section3.9.2), and clinical input by the MA Evaluator and Clinical Research. These parameters were also identified in the Clinical Evaluation Plan (CEP; refer to Table 1 for Attachment number). For treatment of target clinical conditions, the key outcomes include those shown in Table 68, Table 69 and Table 70.

#### Adult Femoral Shaft

Table : Key Outcome Parameters and Benefit-Risk-Acceptability Criteria for Adult Femoral Shaft Fracture

| Parameter | Assessment | Desired Trend | Defined Acceptability Criteria |
| --- | --- | --- | --- |
| Performance | | | |
| Bone Union (% of patients) | Radiologic assessment of bony union as opposed to partial fusion or pseudarthrosis (union failure).  Rate = (union events/# of study subjects) x 100 | ↑ | 94.5% - 100%  ([Koso et al., 2018](#_ENREF_18)); ([Saleeb et al., 2019](#_ENREF_30)); ([Ekwunife et al., 2022](#_ENREF_9)) |
| Safety | | | |
| Infection (% of patients) | Infections related to index surgical procedure includes wound-related and implant-related infections.  Rate = (infection events/# of study subjects) x 100 | ↓ | 0.5% - 11.5%  ([Koso et al., 2018](#_ENREF_18)); ([Saleeb et al., 2019](#_ENREF_30)); ([Ekwunife et al., 2022](#_ENREF_9))[[3]](#footnote-4) |
| Non-union (% of patients) | Radiologic assessment of non-union during the follow-up duration of the study.  Rate = (non-union events/# of study subjects) x 100 | ↓ | 0% - 14%  ([Dingemans et al., 2018](#_ENREF_7); [Koso et al., 2018](#_ENREF_18); [Mohan et al., 2019](#_ENREF_28)) |
| Revision (% of patients) | Revision procedures refer to surgery following the index surgery that involves the adjustment, modification, removal, or replacement of the subject device or other associated devices.  Rate = (revision surgery events/# of study subjects) x 100 | ↓ | 3.8% - 7.1%  ([Yoon et al., 2017](#_ENREF_34)); ([Koso et al., 2018](#_ENREF_18)) |

#### Adult Distal Femoral Fracture

Table : Key Outcome Parameters and Benefit-Risk-Acceptability Criteria for Adult Distal Femoral Fracture

| Parameter | Assessment | Desired Trend | Defined Acceptability Criteria |
| --- | --- | --- | --- |
| Performance | | | |
| Bone Union (% of patients) | Radiologic assessment of bony union as opposed to partial fusion or pseudarthrosis (union failure).  Rate = (union events/# of study subjects) x 100 | ↑ | 71.4 – 100%  ([Shah et al., 2020](#_ENREF_32)); ([Koso et al., 2018](#_ENREF_18)) |
| Safety | | | |
| Infection (% of patients) | Infections related to index surgical procedure includes wound-related and implant-related infections.  Rate = (infection events/# of study subjects) x 100 | ↓ | 0.0% - 7.14%  ([Koso et al., 2018](#_ENREF_18)); ([Neradi et al., 2022](#_ENREF_29)) |
| Non-union (% of patients) | Radiologic assessment of non-union during the follow-up duration of the study.  Rate = (non-union events/# of study subjects) x 100 | ↓ | 4% - 7.8%  ([Byung-Ho et al., 2021](#_ENREF_3)); ([Koso et al., 2018](#_ENREF_18)); ([Neradi et al., 2022](#_ENREF_29)) |
| Revision (% of patients) | Revision procedures refer to surgery following the index surgery that involves the adjustment, modification, removal, or replacement of the subject device or other associated devices.  Rate = (revision surgery events/# of study subjects) x 100 | ↓ | 10.9% - 14.6%  ([Koso et al., 2018](#_ENREF_18)); ([Shah et al., 2020](#_ENREF_32)) |

#### Adolescent Femoral Fractures

Table : Key Outcome Parameters and Benefit-Risk-Acceptability Criteria for Adolescent Femoral Fractures

| Parameter | Assessment | Desired Trend | Defined Acceptability Criteria |
| --- | --- | --- | --- |
| Performance | | | |
| Bone Union (% of patients) | Radiologic assessment of bony union as opposed to partial fusion or pseudarthrosis (union failure).  Rate = (union events/# of study subjects) x 100 | ↑ | 100%  ([Kruppa et al., 2017](#_ENREF_19)); ([Del Balso et al., 2021](#_ENREF_6)); ([John et al., 2017](#_ENREF_15)) |
| Safety | | | |
| Infection (% of patients) | Infections related to index surgical procedure includes wound-related and implant-related infections.  Rate = (infection events/# of study subjects) x 100 | ↓ | 0.0% - 22.2%  ([Del Balso et al., 2021](#_ENREF_6)); ([Kruppa et al., 2017](#_ENREF_19)) |
| Non-union (% of patients) | Radiologic assessment of non-union during the follow-up duration of the study.  Rate = (non-union events/# of study subjects) x 100 | ↓ | 0.0% - 11.1%  ([Del Balso et al., 2021](#_ENREF_6)); ([Kruppa et al., 2017](#_ENREF_19)) |
| Revision (% of patients) | Revision procedures refer to surgery following the index surgery that involves the adjustment, modification, removal, or replacement of the subject device or other associated devices.  Rate = (revision surgery events/# of study subjects) x 100 | ↓ | 9.5% - 36.9%  ([Del Balso et al., 2021](#_ENREF_6); [Madhuri et al., 2014](#_ENREF_24))[[4]](#footnote-5) |

These parameters were selected as they represent the most significant outcomes directly related to the success or failure of the target treatment options in relation to the clinical condition. These are considered appropriate because they assess post-operative function, safety, and quality of life throughout and after the therapeutic lifetime. Other parameters, including malunion and union time were identified in the SOA review, however, they were not identified as key parameters to assess the benefit-risk acceptability of the target treatment option and hence, the subject devices. This is considered appropriate because these parameters are patient- or procedure-centric parameters, are known outcomes that do not result in any/significant intervention, did not have sufficient data for a valid comparison.

The safety and performance acceptability criteria have been identified based on an evaluation of aggregate data for the benchmark device(s). Objective data supporting the selection of the acceptance criteria can be found in the full SOA Report (refer Section 3.9.2).

Multiple factors including, but not limited to, device limitations, patient demographics, the level of potential benefit or risk, and availability of alternative treatment options can influence whether the benefits outweigh the risks. Therefore, this assessment is not as straightforward as meeting all individual acceptance criteria and must be viewed in totality. Section 8.1 discusses the assessment of benefit-risk for the subject devices considering the associated key factors.

### Conclusion

The risks and benefits of all treatment options associated with the target clinical conditions were evaluated to confirm the state of the art treatments for these clinical conditions. All treatment options carry unique benefits and risks, and each may be chosen based on the surgical teams’ preference, the patients’ clinical presentation, and fracture type. Considering the risks and benefits presented, all are considered state of the art treatment options for the identified clinical conditions.

In addition, clinical data found on the key outcome parameters for the benchmarks to the target treatment option were evaluated to establish the acceptability criteria for the benefit-risk assessment. Refer to Section 8.1 for this assessment.

# SECTION D CONTENT

## Device-Specific Systematic Literature Review Methods

The review was conducted in accordance with the prospective Systematic Literature Review Protocol. The protocol documents the explicit plan for the systematic review and details the priori methodological and analytical approaches including the search strategy, selection and eligibility criteria, data collection methods, appraisal criteria and analysis plan. Table 71 summarizes the methodology.

Table : Summary of Systematic Literature Review Methodology

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Systematic Literature Review Protocol #: | Refer to protocol for full methodology.   * Attachment to Literature Report | | | |
| Systematic Literature Review Report # and Included Devices: | Refer to report for full assessment.   * Report #: Femoral Nailing Systems (refer Table 1)   Subject Devices: Femoral Nail Systems  Equivalent Devices: N/A – as equivalent devices are in-scope devices. | | | |
| Stratification Group Name(s): | 1. Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System 2. Expert Adolescent Lateral Femoral Nail System 3. Expert Lateral Femoral Nail System 4. Femoral Recon Nailing System 5. Retrograde Femoral Nail Advanced System 6. Expert Asian Femoral Nail System 7. Unspecified Femoral Nails 8. Multiple Femoral Nail Systems | | | |
| Summary of Systematic Literature Review Methodology: | Identified publications were reviewed against pre-defined eligibility criteria utilizing the PICOS (patient populations, intervention, comparators, outcome(s), study types) tool and research questions. In addition, the publications were reviewed against relevance and scientific validity / quality criteria. | | | |
| Search Criteria: | PICOS Tool | Selection / Inclusion Criteria | Rejection / Exclusion Criteria |
| Patient Populations | * Primary clinical data on patients treated with the subject device for any clinical condition * Mixed Cohort articles (the authors reported on a cohort of patients treated with the subject device OR another device or technique and the outcomes of all patients were combined) | * The subject device was not used in the article. |
| Intervention(s) |
| Comparator(s)/Context | * Articles published in any language. Non-English language articles will be translated to English. * Full text articles will be ordered if they are not available through company subscriptions. | * If the full text cannot be obtained despite repeated attempts, the reference will be excluded. |
| Outcome(s) | * Any and all performance or safety outcomes for the assessment of the subject device. | * No safety or performance outcomes. |
| Study Type(s) | * Any study type with primary clinical data including randomized controlled trial (RCT), comparative, case series, case reports; prospective or retrospective. * Publication types including full journal articles and conference proceedings will be included. | * Study types with secondary clinical data only (reviews, meta-analysis, editorials). * Technical articles including animal studies, cadaver studies, benchtop studies, or cost analyses. * Duplicate articles or population (same article captured twice in the search or same patients described by the same authors in different publications) |
| Date Range: | * Previous Review Period: 01 January 1992 – 28 January 2021 * Current Review Period: 01 January 2021 – 22 August 2022 * Overall Review Period: 01 January 1992 – 22 August 2022 | | | |
| Databases searched: | MEDLINE  EMBASE  PubMed | | | |
| Deviations from Protocol (if any, with justification): | N/A – No deviations | | | |
| Number Included / Excluded References (Refer to Appendix 9.7 for bibliographies): | **Included References:**   1. Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System  * References of sufficient quality/relevance to support performance / safety: 6 articles * References of sufficient quality/relevance to inform performance / safety assessment for trending: 12 articles  1. Expert Adolescent Lateral Femoral Nail System  * References of sufficient quality/relevance to support performance / safety: 1 article * References of sufficient quality/relevance to inform performance / safety assessment for trending: 1 article  1. Expert Lateral Femoral Nail System  * References of sufficient quality/relevance to support performance / safety: 4 articles * References of sufficient quality/relevance to inform performance / safety assessment for trending: 12 articles  1. Femoral Recon Nailing System  * References of sufficient quality/relevance to support performance / safety: Not reported * References of sufficient quality/relevance to inform performance / safety assessment for trending: 1 article  1. Retrograde Femoral Nail Advanced System  * References of sufficient quality/relevance to support performance / safety: Not Reported * References of sufficient quality/relevance to inform performance / safety assessment for trending: 3 articles  1. Expert Asian Femoral Nail System  * References of sufficient quality/relevance to support performance / safety: 5 articles * References of sufficient quality/relevance to inform performance / safety assessment for trending: 13 articles  1. Unspecified Femoral Nails  * References of sufficient quality/relevance to support performance / safety: Not Reported * References of sufficient quality/relevance to inform performance / safety assessment for trending: 1 article  1. Multiple Femoral Nail Systems  * References of sufficient quality/relevance to support performance / safety: 1 article * References of sufficient quality/relevance to inform performance / safety assessment for trending: 2 articles   **Excluded References:** 4,801 articles | | | |

## Overview of Available Literature from Device-Specific Systematic Literature Review

Table 72 – Table 79 identifies the number of publications and patients per stratification group from the Systematic Literature Search that are of sufficient quality and relevance to potentially support safety and/or performance conformity, to inform on performance and/or safety trending, or inform on misuse / off-label trending.

Table : Appraisal Summary of Systematic Literature Review Results for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)\*** | **All data types** | 15 | 317 | 7 | 478 | 22 | 795 | 100.00 |
| Data to Support Safety and/or Performance Conformity Assessment | | | | | | | | |
| 2 | Results of high-quality relevant clinical investigations with some gaps | 1 | 87 | 1 | 154 | 2 | 241 | 100.00 |
| 4 | Outcomes from relevant studies with potential methodological flaws but where data can still be quantified and acceptability justified | 2 | 82 | 2\*\* | 50 | 4\*\* | 132 | 100.00 |
| Total Data to Support Safety and/or Performance Conformity Assessment | | 3 | 169 | 3\*\* | 204 | 6\*\* | 373 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | 2 | 100 | 2\*\* | 50 | 4\*\* | 150 | 100.00 |
| 9 | Individual case reports or conference proceedings or technical notes with aggregated clinical data on the subject device | 7 | 7 | 1 | 1 | 8 | 8 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | 9 | 107 | 3\*\* | 51 | 12\*\* | 158 | 100.00 |
| Data to Support Identification of Off-label Use/Misuse | | | | | | | | |
| `13 | Outcomes from publications reporting on major deviations relative to the indications or patient population (off-label use) or publications with major deviations relative to the intended purpose (misuse). This also includes outcomes from publications where on-label usage is aggregated with off-label/misuse and cannot be quantified and acceptability justified. | 3 | 41 | 1 | 204 | 4 | 245 | 100.00 |
| Total Data to Support Identification of Off-label Use/Misuse | | 3 | 41 | 1 | 204 | 4 | 245 | 100.00 |

\*The totals reflected in this row represent the number of unique publications. \*\*Oh et al. (2021) presented two study arms, one appraised with Rank 4 (n=23) and the other with Rank 6 (n=25).

Table : Appraisal Summary of Systematic Literature Review Results for Expert Adolescent Lateral Femoral Nail System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | 5 | 76 | 1 | 15 | 6 | 91 | 100.00 |
| Data to Support Safety and/or Performance Conformity Assessment | | | | | | | | |
| 2 | Results of high-quality relevant clinical investigations with some gaps | Not Reported | | 1 | 15 | 1 | 15 | 100.00 |
| Total Data to Support Safety and/or Performance Conformity Assessment | | Not Reported | | 1 | 15 | 1 | 15 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 7 | * Outcomes from relevant mixed cohort publications, where the subject device is aggregated with non-similar devices * Outcomes from publications which report on device use but do not report on the key performance and safety outcomes | 1 | 53 | Not Reported | | 1 | 53 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | 1 | 53 | Not Reported | | 1 | 53 | 100.00 |
| Data to Support Identification of Off-label Use/Misuse | | | | | | | | |
| 13 | Outcomes from publications reporting on major deviations relative to the indications or patient population (off-label use) or publications with major deviations relative to the intended purpose (misuse). This also includes outcomes from publications where on-label usage is aggregated with off-label/misuse and cannot be quantified and acceptability justified. | 4 | 23 | Not Reported | | 4 | 23 | 100.00 |
| Total Data to Support Identification of Off-label Use/Misuse | | 4 | 23 | Not Reported | | 4 | 23 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Expert Lateral Femoral Nail System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | 14 | 398 | 4 | 221 | 18 | 619 | 100.00 |
| Data to Support Safety and/or Performance Conformity Assessment | | | | | | | | |
| 2 | Results of high-quality relevant clinical investigations with some gaps | 3 | 51 | Not Reported | | 3 | 51 | 100.00 |
| 4 | Outcomes from relevant studies with potential methodological flaws but where data can still be quantified and acceptability justified | 1 | 154 | Not Reported | | 1 | 154 | 100.00 |
| Total Data to Support Safety and/or Performance Conformity Assessment | | 4 | 205 | Not Reported | | 4 | 205 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | 3 | 141 | 1 | 217 | 4 | 358 | 100.00 |
| 9 | Individual case reports or conference proceedings or technical notes with aggregated clinical data on the subject device | 5 | 42 | 3 | 4 | 8 | 46 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | 8 | 183 | 4 | 221 | 12 | 404 | 100.00 |
| Data to Support Identification of Off-label Use/Misuse | | | | | | | | |
| 13 | Outcomes from publications reporting on major deviations relative to the indications or patient population (off-label use) or publications with major deviations relative to the intended purpose (misuse). This also includes outcomes from publications where on-label usage is aggregated with off-label/misuse and cannot be quantified and acceptability justified. | 2 | 10 | Not Reported | | 2 | 10 | 100.00 |
| Total Data to Support Identification of Off-label Use/Misuse | | 2 | 10 | Not Reported | | 2 | 10 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Femoral Recon Nailing System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | Not Reported | | 1 | 22 | 1 | 22 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | Not Reported | | 1 | 22 | 1 | 22 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | Not Reported | | 1 | 22 | 1 | 22 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Retrograde Femoral Nail Advanced System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | Not Reported | | 3 | 3 | 3 | 3 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 9 | Individual case reports or conference proceedings or technical notes with aggregated clinical data on the subject device | Not Reported | | 3 | 3 | 3 | 3 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | Not Reported | | 3 | 3 | 3 | 3 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Expert Asian Femoral Nail System

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | 19 | 939 | 7 | 435 | 26 | 1,374 | 100.00 |
| Data to Support Safety and/or Performance Conformity Assessment | | | | | | | | |
| 2 | Results of high-quality relevant clinical investigations with some gaps | 2 | 72 | Not Reported | | 2 | 72 | 100.00 |
| 4 | Outcomes from relevant studies with potential methodological flaws but where data can still be quantified and acceptability justified | 1 | 10 | 2 | 38 | 3 | 48 | 100.00 |
| Total Data to Support Safety and/or Performance Conformity Assessment | | 3 | 82 | 2 | 38 | 5 | 120 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | 5 | 138 | 4 | 396 | 9 | 534 | 100.00 |
| 9 | Individual case reports or conference proceedings or technical notes with aggregated clinical data on the subject device | 3 | 3 | 1 | 1 | 4 | 4 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | 8 | 141 | 5 | 397 | 13 | 538 | 100.00 |
| Data to Support Identification of Off-label Use/Misuse | | | | | | | | |
| 13 | Outcomes from publications reporting on major deviations relative to the indications or patient population (off-label use) or publications with major deviations relative to the intended purpose (misuse). This also includes outcomes from publications where on-label usage is aggregated with off-label/misuse and cannot be quantified and acceptability justified. | 8 | 716 | Not Reported | | 8 | 716 | 100.00 |
| Total Data to Support Identification of Off-label Use/Misuse | | 8 | 716 | Not Reported | | 8 | 716 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Unspecified Femoral Nails

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | 1 | 114 | 1 | 29 | 2 | 143 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | 1 | 114 | Not Reported | | 1 | 114 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | 1 | 114 | Not Reported | | 1 | 114 | 100.00 |
| Data to Support Identification of Off-label Use/Misuse | | | | | | | | |
| 13 | Outcomes from publications reporting on major deviations relative to the indications or patient population (off-label use) or publications with major deviations relative to the intended purpose (misuse). This also includes outcomes from publications where on-label usage is aggregated with off-label/misuse and cannot be quantified and acceptability justified. | Not Reported | | 1 | 29 | 1 | 29 | 100.00 |
| Total Data to Support Identification of Off-label Use/Misuse | | Not Reported | | 1 | 29 | 1 | 29 | 100.00 |

Table : Appraisal Summary of Systematic Literature Review Results for Multiple Femoral Nail Systems

| APPRAISAL RANK | TYPE OF CLINICAL EVIDENCE | Previous | | Current | | Overall | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| # of Articles | # of Patients | # of Articles | # of Patients | # of Articles | # of Patients | % of PATIENTS by rank |
| **Overall Total (All Ranks)** | **All data types** | Not Reported | | 3 | 160 | 3 | 160 | 100.00 |
| Data to Support Safety and/or Performance Conformity Assessment | | | | | | | | |
| 4 | Outcomes from relevant studies with potential methodological flaws but where data can still be quantified and acceptability justified | Not Reported | | 1 | 8 | 1 | 8 | 100.00 |
| Total Data to Support Safety and/or Performance Conformity Assessment | | Not Reported | | 1 | 8 | 1 | 8 | 100.00 |
| Additional Data to Inform Identification of Safety Trends or Performance Issues | | | | | | | | |
| 6 | Outcomes from relevant mixed cohort publications where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | Not Reported | | 2 | 152 | 2 | 152 | 100.00 |
| Total Additional Data to Inform Identification of Safety Trends or Performance Issues | | Not Reported | | 2 | 152 | 2 | 152 | 100.00 |

Refer to Appendix for a detailed breakdown of this information by appraisal rank.

## Device-Specific Systematic Literature Review Results by Stratification Group – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

The aim of this section is to summarize and identify trends in the performance and safety data from published articles reporting on EXPERT R/AFN and EXPERT RFN when used as intended and in the intended patient population. There were 6 articles (373 patients) that were appraised with Rank 2 or Rank 4. Three publications (169 patients) were from the previous review while 3 publications (204 patients) were from the current review.

The distribution of the available clinical literature data across the clinical condition(s), patient target group(s), and device lifetime for the device(s) is presented in Table 80. The mean follow-up period across 4 publications (280 patients) for which it was reported ranged from 7.50 to 49.20 months where 3 publications (126 patients) had sufficient follow-up time to assess the safety and performance of the subject device. The two remaining publications (93 patients) reported a sufficient minimum follow-up.

One included publication (Oh et al., 2021) was a comparative study assessing the outcomes of standard nailing with the subject device and other devices (n=25) versus reconstruction nailing with the subject device only (n=23). The study arm with patients undergoing reconstruction nailing was appraised with Rank 4; the standard nailing group study arm was appraised with Rank 6 and will be discussed in the next section.

Table : Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System Available Literature Data

| CLINICAL DATA\* | # OF ARTICLES\* | # OF PATIENTS |
| --- | --- | --- |
| Total | 6 | 373 |
| Clinical Condition(s)/Indications MDD | | |
| Femoral shaft fracture 32-A/B/C (except subtrochanteric fractures 32-A(1-3).1 and 32-C(1-3).1) | 2 | 243 |
| Distal diaphyseal femoral shaft fractures | 1 | 87 |
| Distal femur fractures 33-A1/A2/A3 or 33-C1/C2/C3.1 | 2 | 35 |
| Distal femur fractures 33-A1/A2/A3 or 33-C1/C2/C3.1 | 1 | 8 |
| Clinical Condition(s)/Indications MDR | | |
| Fractures of the middle and distal diaphyseal segment | 4 | 330 |
| Fractures of the distal end segment of the femur | 2 | 43 |
| Surgical Approach | | |
| Antegrade nailing | 2 | 89 |
| Retrograde nailing | 2 | 43 |
| Antegrade nailing; Retrograde nailing | 2 | 241 |
| AO Classification | | |
| 32A,32B,32C | 2 | 220 |
| 33A,33C | 1 | 27 |
| Not Reported | 3 | 126 |
| Patient Population | | |
| Skeletally Mature | 6 | 373 |
| Follow-up Period Appropriate to Evaluate Safety / Performance of the Device\*\* | | |
| Yes | 5 | 219 |
| No | 1 | 154 |
| Key Performance Outcomes | | |
| Bone Union Rate ≥ 6 months | 5 | 219 |
| Key Safety Outcomes | | |
| Nonunion | 5 | 219 |
| Infection | 2 | 95 |
| Revision | 3 | 197 |

\*There were 10 study cohorts across 7 publications. The study arms may be split across categories in this column.

\*\*A minimum follow-up of 9 months was considered appropriate. Flanagan et al. (2021) with 77 patients reported insufficient follow-up while Davidson et al. (2022) did not report on mean follow-up time.

#### Data to Support Performance – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

A summary of the data described in Table 72 that pertain to key performance outcomes are documented below in Table 81.

The key performance outcome was bone union rate (%).

The outcomes are measures used to evaluate the performance of the subject device(s) based on the intended purpose and expected clinical benefit where data on each key performance outcome are presented separately. Clinical data are provided for the previous, current and overall review periods in Table 81. When only one study presented clinical outcome data, and a mean was reported for that outcome measure, only the mean (not median) was reported.

Table : Performance Outcomes – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| PERFORMANCE OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | MEAN/RATE\* | | | OUTCOME | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A)\*\*\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MEDIAN | 1ST QRT | 3RD QRT | RANGE | RANGE |
| Key Performance Outcomes | | | | | | | | | |
| Bone Union Rate (%): | Previous | 3 | 169 | N/A | | | 76.20 – 100.00 | 16.70\*\* - 49.20\*\* | N/A |
| Current | 2 | 50 | N/A | | | 100.00 – 100.00 | 30.00\*\* | N/A |
| Overall | 5 | 219 | 100.00 | 93.95 | 100.00 | 76.20 – 100.00 | 16.70\*\* - 49.20\*\* | N/A |
| Additional Performance Outcomes | | | | | | | | | |
| Time to Bone Union (Weeks): | Previous | 2 | 103 | N/A | | | 15.43 – 43.02 | 16.70 – 49.20 | N/A |
| Current | 1 | 23 | N/A | | | 19.30 | 30.00 | N/A |
| Overall | 3 | 126 | N/A | | | 15.43 – 43.02 | 16.70 – 49.20 | N/A |

\*Five or more articles are required to obtain statistically meaningful data.

\*\* Two publications did not report on mean follow-up: Ciftdemir et al. (2015) with 66 patients from the previous review and Garala et al. (2022) with 27 patients from the current review.

\*\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

These data were found to be representative of the intended patient target groups and had sufficient follow-up time to evaluate the safety and performance at least through the therapeutic lifetime of the subject device (as described in Section 3.1.1).

Key Performance Outcomes

Bone Union Rate

Five publications (219 patients) reported on bone union over a mean follow-up that ranged from 16.70 to 49.20 months across three publications for which it was reported. The median bone union rate was 100.00% (IQR: 93.95-100.00; range: 76.20-100.00).

*Previous*

Three publications (169 patients) from the previous review reported on bone union rate, which ranged from 76.20% to 100.00%.

Ru et al. (2015) conducted a study comparing the outcomes of exchanged ream nailing (ERN; n=87) and augmented compression plating (ACP; n=93) in the treatment of femoral shaft nonunion following failed fixation with intramedullary nail. Within the ERN group, there were 42 cases of nonisthmal nonunion and 45 cases of isthmal nonunion; bone union rates were 76.20% to 95.10%, respectively across these sub populations. The authors recommended the use of ACP especially in the treatment of isthmal nonunion as they saw significantly less nonunion across this group following treatment (p = 0.18). They explained one theory regarding the lack of contact area in the case of nonisthmal nonunion fixation with ERN that could complicate the anti-rotation stability during fusion.

*Current*

Two publications (50 patients) from the current review reported 100% bone union rate across all included patients, which is comparable to the range identified during the previous review.

Further details related to the results described above can be found in the full Literature Review Report (refer Table 1).

#### Data to Support Safety – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

A summary of the data described in Table 72 that pertain to key safety outcomes are documented below in Table 82.

The key safety outcomes for Expert R/AFN and EXPERT RFN were nonunion, infection and revision/device removal. The tables include safety outcome categories for which events were explicitly reported; this includes event occurrences reported with the value zero. All publications reported on adverse events. Two publications (74 patients) reported no safety events. Table 82 indicates the number of studies reporting on the respective safety outcome, along with the total sample size and the calculated median occurrence rate, inter quartiles and range, across those studies. It should also be noted that certain events may be counted in multiple categories (i.e., infection leading to a revision).

Table : Safety Event Occurrence Rates – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| EVENT DETAILS | | | | | | | | | RATE\* | | | | | | | | FINAL FOLLOW-UP (MONTHS) | | | POTENTIAL CHANGE  (Y, N, or N/A\*\*\*) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | | # OF PUBLICATIONS | | # OF PATIENTS | | # OF EVENTS | | MEDIAN | | 1st QRT | | 3rd QRT | | RANGE | | RANGE | | |
| KEY SAFETY OUTCOMES | | | | | | | | | | | | | | | | | | | | |
| Revision/Device Removal: | Previous | | 1 | | 16 | | 1 | | N/A | | | | | | 0.00 - 0.13 | | 16.70 - 21.60 | | | N/A |
| Current | | 2 | | 181 | | 6 | | N/A | | | | | | 0.03 - 0.04 | | 7.50\*\* - 7.59\*\* | | | N/A |
| Overall | | 3 | | 197 | | 7 | | N/A | | | | | | 0.00 - 0.13 | | 7.50\*\* - 21.60\*\* | | | N/A |
| Nonunion: | Previous | | 3 | | 169 | | 13 | | N/A | | | | | | 0.00 - 0.24 | | 16.70\*\* - 49.20\*\* | | | N/A |
| Current | | 2 | | 50 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 30.00\*\* | | | N/A |
| Overall | | 5 | | 219 | | 13 | | 0.00 | | 0.00 | | 0.09 | | 0.00 - 0.24 | | 16.70\*\* - 49.20\*\* | | | N/A |
| Infection: | Previous | | 2 | | 95 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 16.70 - 49.20 | | | N/A |
| Current | | NR | | | | | | | | | | | | | | | | | |
| Overall | | 2 | | 95 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 16.70 - 49.20 | | | N/A |
| ADDITIONAL SAFETY OUTCOMES | | | | | | | | | | | | | | | | | | | | |
| Reoperation: | Previous | | 2 | | 103 | | 21 | | N/A | | | | | | 0.00 - 0.24 | | 16.70 - 49.20 | | | N/A |
| Current | | NR | | | | | | | | | | | | | | | | | |
| Overall | | 2 | | 103 | | 21 | | N/A | | | | | | 0.00 - 0.24 | | 16.70 - 49.20 | | | N/A |
| Delayed Union: | Previous | | NR | | | | | | | | | | | | | | | | | |
| Current | | 1 | | 23 | | 2 | | N/A | | | | | | 0.09 | | 30.00 | | | N/A |
| Overall | | 1 | | 23 | | 2 | | N/A | | | | | | 0.09 | | 30.00 | | | N/A |
| Death: | Previous | | NR | | | | | | | | | | | | | | | | | |
| Current | | 1 | | 27 | | 1 | | N/A | | | | | | 0.04 | | NR | | | N/A |
| Overall | | 1 | | 27 | | 1 | | N/A | | | | | | 0.04 | | NR | | | N/A |
| Screw/Blade Loosening/Back-Out: | Previous | | NR | | | | | | | | | | | | | | | | | |
| Current | | 1 | | 27 | | 1 | | N/A | | | | | | 0.04 | | NR | | | N/A |
| Overall | | 1 | | 27 | | 1 | | N/A | | | | | | 0.04 | | NR | | | N/A |
| Loss of Reduction (Loss of Angulation/ Alignment): | Previous | | 1 | | 16 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 16.70 - 21.60 | | | N/A |
| Current | | NR | | | | | | | | | | | | | | | | | |
| Overall | | 1 | | 16 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 16.70 - 21.60 | | | N/A |
| Malunion: | Previous | | 1 | | 87 | | 0 | | N/A | | | | | | 0.00 | | 49.20 | | | N/A |
| Current | | NR | | | | | | | | | | | | | | | | | |
| Overall | | 1 | | 87 | | 0 | | N/A | | | | | | 0.00 | | 49.20 | | | N/A |
| Neurovascular Damage: | Previous | | 1 | | 87 | | 0 | | N/A | | | | | | 0.00 | | 49.20 | | | N/A |
| Current | | NR | | | | | | | | | | | | | | | | | |
| Overall | | 1 | | 87 | | 0 | | N/A | | | | | | 0.00 | | 49.20 | | | N/A |
| Unspecified Implant/Hardware Failure: | Previous | | 1 | | 87 | | 0 | | N/A | | | | | | 0.00 | | 49.20 | | | N/A |
| Current | | 1 | | 27 | | 0 | | N/A | | | | | | 0.00 | | NR | | | N/A |
| Overall | | 2 | | 114 | | 0 | | N/A | | | | | | 0.00 - 0.00 | | 49.20\*\* | | | N/A |
| \*Five or more articles are required to obtain statistically meaningful data  \*\*Not all publications reported on mean follow-up.  \*\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.  NR = not reported; QRT = quartile | | | | | | | | | | | | | | | | | | | |  |
|  | | | | | | | | | |  | | | | | | | |  |  | |
|  | |  | |  | |  | |  | |  | |  | |  | |  | |  |
|  | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | |  | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | | | | | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | | | | | | | | | | | | | | | | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |
|  | |  | |  | |  | |  | | | | | |  | |  |  | |

Key Safety Outcomes

Revision/Device Removal

Three publications (197 patients) from the overall review reported 7 events of revision (event rate range: 0.00-0.13).

*Previous*

Spitler, et al. (2018) with 16 patients reported one case of revision across two included study arms (event rate range: 0.00-0.13). The study compared patients treated with the subject device following nonunion (n=8) versus acute fracture (n=8). The revision occurred in the acute fracture group following postoperative diaphyseal fracture and was successfully treated with reamed exchange rod.

*Current*

Two publications (181 patients) reported 6 cases of revision (event rate range: 0.03-0.04), which fell within the event rate range seen in the previous review.

Nonunion

Five publications (219 patients) from the overall review reported 13 events of nonunion. The median event rate was 0.00 (IQR: 0.00-0.09; range: 0.00-0.24).

*Previous*

Three publications (169 patients) reported 13 events of nonunion (event rate range: 0.00-0.24).

Ru et al. (2015) presented on patients receiving the subject device for the treatment of isthmal femur fracture (n=45) and nonisthmal femur fracture (n=42); the event rate range of nonunion was 0.04 to 0.24, respectively. The true nonunion rate across all patients included in the study was 0.14. These patients eventually healed following cast immobilization (n=2) or secondary autologous bone grafting (n=10).

*Current*

Two publications (50 patients) reported 0 events of nonunion, which fell within the event rate range identified in the previous review.

Infection

Two publications (95 patients) from the previous review reported that no cases of infection occurred.

#### Data Summary – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

A summary data from the literature review supporting the conformity assessment for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System is detailed in Table 83.

Table : Systematic Literature Review Summary from Data Supporting Conformity Assessment for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

|  |  |
| --- | --- |
| Device Stratification Group: | * Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group 1) |
| Overall Literature Search Date Range: | * 01 January 1992 – 22 August 2022 |
| Total Included Publications (Patients) Supporting Performance Conformity: | * 6 publications (373 patients) (Refer to Section 9.7.3 for bibliography) |
| Total Included Publications (Patients) Supporting Safety Conformity: | * 6 publications (373 patients) (Refer to Section 9.7.3 bibliography) |
| Overall follow-up time of Publications Supporting Performance Conformity: | Mean: 7.50 – 49.20 months  Follow-up sufficient to assess performance and safety over the therapeutic lifetime for included data |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Median Range (%) | | Bone Union | 76.20 – 100 | |  |  | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Mean Rate (%) | | Infection | 0.0 – 0.0% | | Nonunion | 0.00 – 24.0% | | Revision | 0.0 – 13.0% | |  | | |
| Potential Emerging Risk: | No potential significant rate change was identified for any safety outcome or key performance outcomes (i.e., no overlap of IQR between current and previous reviews) |

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 72 that inform the identification of safety trends are documented below (Table 84 and Table 85). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Twelve publications (158 patients) were ranked 6 and 9. Four articles (150 patients) with a rank of 6 reported on safety outcomes (Table 84). Two publications (100 patients) were from the previous review while 2 publications (50 patients) were from the current review. Seven articles (7 patients) from previous review and one article (one patient) from the current review reported on safety outcomes (Table 85). All publications included for Rank 9 were case reports.

Table : Safety Outcomes: Rank 6 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| --- | --- | --- | --- | --- | --- |
| Revision/Device Removal: | Previous | 2 | 100 | 21 | 0.11 – 0.40 |
| Current | 2 | 50 | 7 | 0.12 – 0.16 |
| Overall | 4 | 150 | 28 | 0.11 – 0.40 |
| Nonunion: | Previous | 2 | 100 | 13 | 0.05 – 0.29 |
| Current | 2 | 50 | 6 | 0.08 – 0.16 |
| Overall | 4 | 150 | 19 | 0.05 – 0.29 |
| Infection: | Previous | 1 | 35 | 1 | 0.03 |
| Current | NR | | | |
| Overall | 1 | 35 | 1 | 0.03 |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 1 | 65 | 11 | 0.17 |
| Current | 1 | 25 | 11 | 0.44 |
| Overall | 2 | 90 | 22 | 0.17 – 0.44 |
| Postoperative Bone Fracture: | Previous | 1 | 35 | 2 | 0.06 |
| Current | 3 | 50 | 8 | 0.08 – 0.24 |
| Overall | 4 | 85 | 10 | 0.06 – 0.24 |
| Pain: | Previous | NR | | | |
| Current | 1 | 25 | 4 | 0.16 |
| Overall | 1 | 25 | 4 | 0.16 |
| Unspecified Implant/Hardware Failure: | Previous | 2 | 100 | 7 | 0.06 – 0.09 |
| Current | NR | | | |
| Overall | 2 | 100 | 7 | 0.06 – 0.09 |
| Delayed Union: | Previous | NR | | | |
| Current | 1 | 25 | 2 | 0.08 |
| Overall | 1 | 25 | 2 | 0.08 |
| Nail Breakage: | Previous | NR | | | |
| Current | 1 | 25 | 1 | 0.04 |
| Overall | 1 | 25 | 1 | 0.04 |
| Screw/Blade Loosening/Back-Out: | Previous | NR | | | |
| Current | 1 | 25 | 1 | 0.04 |
| Overall | 1 | 25 | 1 | 0.04 |
| Screw/Blade Malposition/Misplacement: | Previous | NR | | | |
| Current | 1 | 25 | 1 | 0.04 |
| Overall | 1 | 25 | 1 | 0.04 |
| Other Adverse Events:   * Peri-implant fracture (n=2) | Previous | NR | | | |
| Current | 1 | 25 | 2 | 0.08 |
| Overall | 1 | 25 | 2 | 0.08 |

NR = Not Reported

Table : Safety Outcomes: Rank 9 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS |
| --- | --- | --- | --- | --- |
| Revision/Device Removal:\* | Previous | 1 | 1 | 1 |
| Current | NR | | |
| Overall | 1 | 1 | 1 |
| Nonunion: | Previous | 4 | 4 | 0 |
| Current | 1 | 1 | 0 |
| Overall | 5 | 5 | 0 |
| Pain: | Previous | 1 | 1 | 0 |
| Current | 1 | 1 | 1 |
| Overall | 2 | 2 | 1 |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 1 | 1 | 1 |
| Current | NR | | |
| Overall | 1 | 1 | 1 |
| Neurovascular Damage: | Previous | 2 | 2 | 1 |
| Current | NR | | |
| Overall | 2 | 2 | 1 |
| Joint Pain: | Previous | 4 | 4 | 0 |
| Current | NR | | |
| Overall | 4 | 4 | 0 |
| Limb/Leg Length Discrepancy (LLD): | Previous | 1 | 1 | 0 |
| Current | NR | | |
| Overall | 1 | 1 | 0 |
| Stiffness/Limited Range of Motion (ROM): | Previous | 1 | 1 | 0 |
| Current | NR | | |
| Overall | 1 | 1 | 0 |
| Unspecified Implant/Hardware Failure: | Previous | 1 | 1 | 0 |
| Current | NR | | |
| Overall | 1 | 1 | 0 |

\*Patient opted for revision surgery due to malrotation

NR = Not Reported

Twelve publications (158 patients) were ranked 6 or 9. Nine previous review and 3 current review articles were assessed for identification of safety trends and no events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

A summary of the data described in Table 72 that pertain to off-label use and misuse are documented below.

Two publications (39 patients) from the previous review period reported on off-label use. Details of the publications that reported off-label use are presented in Table 86.

Table : Included Data to Inform Identification of Off-Label Use – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per to Indications | Use Details |
| --- | --- | --- | --- | --- | --- |
| Bobak, et al. (2010) | Previous | 5 | The authors conducted a salvage procedure on patients with significant comorbidities alongside supracondylar knee fractures. The nails were augmented with cement and the authors concluded that this is important when dealing with severely damaged bone where fixation is difficult. | No patients treated as indicated | In all patients, the subject device was fixated with cement instead of locking screws, which is outside of the IFU. |
| Hatem, et al. (2021) | Previous | 34 | The authors conducted a case series where the subject device was used in proximal femoral de-rotation osteotomy to address femoral torsion in subtrochanteric fractures. They concluded that their technique improves hip and spine function in this patient population | No patients treated as indicated  Some patients treated according to intended patient population | The subject device is not indicated for use in subtrochanteric fractures. Further, the youngest patient was 15 years old, and it was not mentioned how many patients were under the age of 18. |

Two publications (206 patients) period reported on misuse and off-label use. One publication was from the previous review while the other publication was from the current review. Details of the publications that reported misuse and off-label use are presented in Table 87.

Table : Included Data to Inform Identification of Misuse and Off-Label Use – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System

| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per Intended Purpose | Use Details |
| --- | --- | --- | --- | --- | --- |
| Woods, et al. (2012) | Previous | 2 | The authors describe two cases of tibiotalocalcaneal arthrodesis with IM nailing used to treat patients presenting with lower leg deformity and discomfort. They concluded that this complex procedure requires careful technical considerations including use of a longer nail and placement of the interlocking screws. | Some patients treated according to intended purpose  Some patients treated as indicated | The subject device was used in tibiotalocalcaneal arthrodesis using the subject device in retrograde formation, which is not a location it is intended or indicated for. |
| Fernandez-Arroyabe, et al. (2021) | Current | 204 | The authors compared outcomes of patients who were treated with proton pump inhibitors (PPI) with patients who did not alongside nail dynamization following tibial or femoral shaft fracture. They found that use of PPI was associated with a higher risk of fracture nonunion. | Some patients treated according to intended purpose  Some patients treated as indicated | Patients included in the study had either femoral or tibial shaft fractures. The subject device is not intended or indicated for tibial shaft fractures. |

Two publications (39 patients) from the previous review period reported on off-label use. Two publications (39 patients) from the previous review reported on misuse and off-label use. One publication (2 patients) from the previous review and one publication (204 patients) from the current review reported on a combination of misuse and off-label use. All publications were appraised with Rank 13.

## Device-Specific Systematic Literature Review Results by Stratification Group – Expert Adolescent Lateral Femoral Nail System

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

The aim of this section is to summarize and identify trends in the performance and safety data from published articles reporting on Expert ALFN when used as intended and in the intended patient population. There was one article (15 patients) from the current review period that was assessed as Rank 2.

The distribution of the available clinical literature data across the clinical condition(s), patient target group(s), and device lifetime for the device(s) is presented in Table 88. One case series (15 patients) from the current review period reported a mean follow-up of 33.6 months which is sufficient to assess the clinical performance and safety of the subject device beyond its therapeutic lifetime of at least 9 months. The included publication did not report on the following indications: internal fixation of subtrochanteric fractures or ipsilateral femoral neck/shaft fractures.

Table : Expert ALFN Available Literature Data

| CLINICAL DATA\* | # OF ARTICLES | # OF PATIENTS |
| --- | --- | --- |
| Total | 1 | 15 |
| Clinical Condition(s)/Indications | | |
| Femoral shaft fractures | 1 | 15 |
| Patient Population | | |
| Adolescent Population (>12 years old) | 1 | 15 |
| Follow-up Period Appropriate to Evaluate Safety / Performance of the Device\*\* | | |
| Yes | 1 | 15 |
| Key Performance Outcomes | | |
| Bone Union Rate ≥ 6 months | 1 | 15 |
| Key Safety Outcomes\*\*\* | | |
| Nonunion | 1 | 15 |

\*AO Classification was not reported in the included publication. Therefore, it is not relfected in this table.

\*\*A minimum follow-up of 9 months was considered appropriate

\*\*\*The publication included in this section did report on the key safety outcomes of infection or revision.

NR = not reported

#### Data to Support Performance – Expert Adolescent Lateral Femoral Nail System

A summary of the data described in Table 73 that pertain to key performance outcomes are documented below in Table 89.

The key performance outcome was bone union rate (%).

The outcomes are measures used to evaluate the performance of the subject device(s) based on the intended purpose and expected clinical benefit where data on each key performance outcome are presented separately. Clinical data are provided for the previous, current and overall review periods. When only one study presented clinical outcome data, and a mean was reported for that outcome measure, only the mean (not median) was reported.

The included publication (15 patients) reported on the key performance outcome as presented in Table 89. As no publications were identified during the previous review period, only the current/overall review period is represented in Table 89.

Table : Performance Outcomes – Expert Adolescent Lateral Femoral Nail

| PERFORMANCE OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | MEAN/RATE\* | | | OUTCOME | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A)\*\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MEDIAN | 1ST QRT | 3RD QRT | RANGE | RANGE |
| Key Performance Outcomes | | | | | | | | | |
| Bone Union Rate (% patients) | Overall | 1 | 15 | N/A | | | 100.00 | 33.60 | N/A |

\*Five or more articles are required to obtain statistically meaningful data

\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR = Not Reported

These data were found to be representative of the intended patient target groups and had sufficient follow-up time to evaluate the safety and performance at least through the therapeutic lifetime of the subject device (as described in Section 3.1.4).

Key Performance Outcomes:

Bone Union Rate:

Liebs et al. (2022) with 15 patients reported a bone union rate of 100%.

#### Data to Support Safety – Expert Adolescent Lateral Femoral Nail System

A summary of the data described in Table 73 that pertain to key safety outcomes are documented below in Table 90.

The key safety outcomes for Expert ALFN were nonunion, infection and revision/device removal. The tables include safety outcome categories for which events were explicitly reported; this includes event occurrences reported with the value zero. Table 90 indicates the number of studies reporting on the respective safety outcome in the included publication, along with the total sample size and the calculated median occurrence rate, inter quartiles and range, across those studies. It should also be noted that certain events may be counted in multiple categories (i.e., infection leading to a revision). As no publications were identified during the previous review period, only the current/overall review period is presented in Table 90.

Table : Safety Event Occurrence Rates – Expert Adolescent Lateral Femoral Nail

| EVENT DETAILS | | | | | RATE\* | | | | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A\*\*) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | # OF EVENTS | MEDIAN | 1st QRT | 3rd QRT | RANGE | RANGE |
| Key Safety Outcomes | | | | | | | | | | |
| Nonunion: | Overall | 1 | 15 | 0 | N/A | | | 0.00 | 33.60 | N/A |
| **Additional Safety Outcomes** | | | | | | | | | | |
| Screw/Blade Breakage: | Overall | 1 | 15 | 0 | N/A | | | 0.00 | 33.60 | N/A |
| Avascular Necrosis (Osteonecrosis/Bone Infarction): | Overall | 1 | 15 | 0 | N/A | | | 0.00 | 33.60 | N/A |

\*Five or more articles are required to obtain statistically meaningful data .

\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR = Not Reported.

Key Safety Outcomes:

Nonunion

Liebs et al. (2022) with 15 patients reported zero events of nonunion.

#### Data Summary – Expert Adolescent Lateral Femoral Nail System

A summary data from the literature review supporting the conformity assessment for Expert Adolescent Lateral Femoral Nail is detailed in Table 91.

Table : Systematic Literature Review Summary from Data Supporting Conformity Assessment for Expert Adolescent Lateral Femoral Nail System

|  |  |
| --- | --- |
| Device Stratification Group: | * Expert Adolescent Lateral Femoral Nail System |
| Overall Literature Search Date Range: | * 01 January 1992 – 22 August 2022 |
| Total Included Publications (Patients) Supporting Performance Conformity: | * 1 publication (15 patients) (Refer to Section 9.7.3 for bibliography) |
| Total Included Publications (Patients) Supporting Safety Conformity: | * 1 publication (15 patients) (Refer to Section 9.7.3 bibliography) |
| Overall follow-up time of Publications Supporting Performance Conformity: | Mean: 33.6 months  Follow-up sufficient to assess performance and safety over the therapeutic lifetime for included data |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of a portion of the patient population:   * The included publication did not report on the following indications: internal fixation of subtrochanteric fractures or ipsilateral femoral neck/shaft fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions. |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 100% | |  |  | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Mean Rate (%) | | Infection | Not Reported | | Nonunion | 0.0% | | Revision | Not Reported | |
| Potential Emerging Risk: | No potential significant rate change was identified for any safety outcome or key performance outcomes (i.e., no overlap of IQR between current and previous reviews) |

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 73 that inform the identification of safety trends are documented below (Table 92). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Rapp et al. (2017) with 53 patients from the previous review period was appraised with rank 7. The authors presented a mixed cohort publication where the subject device was aggregated with non-similar devices in the treatment of femoral shaft fractures. Out of 53 patients, two patients had EXPERT ALFN as the primary osteosynthesis method and up to 3 patients were revised to the subject device from other methods. The remainder of patients underwent primary osteosynthesis with Elastically Stable Intramedullary Nailing (ESIN), external fixators, or plates. This publication was identified during the previous review period; therefore, only the previous/overall review period is presented in the table.

Table : Safety Outcomes: Rank 7 – Expert Adolescent Lateral Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| --- | --- | --- | --- | --- | --- |
| Revision/Device Removal: | Overall | 1 | 53 | 20 | 0.38 |
| Infection: | Overall | 1 | 53 | 6 | 0.11 |
| Nonunion: | Overall | 1 | 53 | 2 | 0.04 |
| Reoperation: | Overall | 1 | 53 | 4 | 0.08 |
| Stiffness/Limited Range of Motion (ROM): | Overall | 1 | 53 | 3 | 0.06 |
| Nail Migration: | Overall | 1 | 53 | 1 | 0.02 |
| Limb/Leg Length Discrepancy (LLD): | Overall | 1 | 53 | 1 | 0.02 |
| Nail Malposition/Misplacement: | Overall | 1 | 53 | 1 | 0.02 |
| Avascular Necrosis (Osteonecrosis/Bone Infarction): | Overall | 1 | 53 | 1 | 0.02 |
| Postoperative Bone Fracture: | Overall | 1 | 53 | 1 | 0.02 |

One publication (53 patients) from the previous review period was appraised as rank 7 and was assessed for identification of safety trends. No events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

A summary of the data described in Table 73 that pertain to off-label use are documented below (Table 93).

Table : Included Data to Inform Identification of Off-Label Use – Expert Adolescent Lateral Femoral Nail System

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per to Indications | Use Details |
| Baumbach et al. (2011) | Previous | 1 | The authors treated a 10-year-old girl with nonunion and osteomyelitis of her internally rotated leg as well as leg length discrepancy of 5 cm. The authors used intramedullary nail and external fixator. The patient could walk at the final follow-up. | No patients treated according to intended patient population. | The subject device was used in a 10-years-old patient. |
| Pailhe et al. (2014) | Previous | 6 | The authors performed rotational femoral osteotomy in patients with excessive femoral antetorsion and in-toeing gait. The authors noted that their technique could be used in such clinical settings. | Some patients treated according to intended patient population. | The subject device was used both in adolescents and children: mean age, 13.6 years (range, 11-16 years). |
| Reynolds et al. (2012) | Previous | 15 | The authors treated pediatric femoral shaft fractures with either EXPERT ALFN or Elastic stable intramedullary nails. They noted that the patients that received EXPERT ALFN showed a shorter recovery time but the outcomes were satisfactory in both devices. | Some patients treated according to intended patient population. | The subject device was used both in adolescents and children: mean age, 13.3 years (range, 10-16 years). |
| Hashem et al. (2015) | Previous | 1 | The authors treated a 36-year-old pregnant female with pycnodysostosis for femoral shaft fracture. The authors specifically chose an adolescent-sized intramedullary nail due to the patient’s short stature and narrowed intramedullary canal. They found satisfactory results clinically and radiologically. | No patients treated according to intended patient population. | The subject device was used in a patient beyond adolescence (age: 36 years). |

Four publications (23 patients) from the previous review period reported on off-label use of the Expert ALFN. No studies reported on misuse of the Expert ALFN.

## Device-Specific Systematic Literature Review Results by Stratification Group – Expert Lateral Femoral Nail System

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

The aim of this section is to summarize and identify trends in the performance and safety data from published articles reporting on Expert LFN when used as intended and in the intended patient population. There were 4 articles (205 patients) included in the previous review period that were assessed as Rank 2 or Rank 4.

The distribution of the available clinical literature data across the clinical condition(s), patient target group(s), and device lifetime for the device(s) is presented in Table 94. One study (16 patients) reported a mean follow-up of 21 months which is sufficient to assess the clinical performance and safety of the subject device beyond its therapeutic lifetime of at least 9 months. Three studies (189 patients) did not report on follow-up. However, one of these studies (Volgas et al., 2010) stated they followed their 20 patients until complete fracture healing, indicating the follow-up time was sufficient to assess the entire therapeutic lifetime for the given patients. No included publications reported on the following indications: internal fixation of subtrochanteric fractures or ipsilateral femoral neck/shaft fractures.

Table : Expert LFN Available Literature Data

| CLINICAL DATA\* | # OF ARTICLES | # OF PATIENTS | |
| --- | --- | --- | --- |
| Total | 4 | 205 | |
| Clinical Condition(s)/Indications | | | |
| Femoral shaft fractures | 4 | 205 | |
| Patient Population | | | |
| Patients where growth plates have fused | 4 | 205 | |
| Follow-up Period Appropriate to Evaluate Safety / Performance of the Device\*\* | | | |
| Yes | 1 | 16 | |
| No | 3 | 189 | |
| Key Performance Outcomes | | | |
| Bone Union Rate ≥ 6 months | 1 | | 20 |
| Key Safety Outcomes | | | |
| Nonunion | 1 | 20 | |
| Infections | NR | | |
| Revision | 1 | 20 | |

\*AO Classification was not reported in the included publications. Therefore, it is not relfected in this table.

\*\*A minimmum follow-up of 9 months was considered approprate

NR = not reported

#### Data to Support Performance – Expert Lateral Femoral Nail System

A summary of the data described in Table 74 that pertain to key performance outcomes are documented below in Table 95.

One publication (20 patients) reported on key performance outcomes (bone union rate) as summarized in Table 19. Another publication (16 patients) reported on data related to the additional performance outcome of 36-Item SF-36 Scores, which could not be represented in the table. This is described narratively below. All publications included in this section were from the previous review. Therefore, only the previous/overall review is presented in the table.

Table : Performance Outcomes – Expert Lateral Femoral Nail System

| PERFORMANCE OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | MEAN/RATE\* | | | OUTCOME | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A)\*\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MEDIAN | 1ST QRT | 3RD QRT | RANGE | RANGE |
| Key Performance Outcomes | | | | | | | | | |
| Bone Union Rate (% patients): | Overall | 1 | 20 | N/A | | | 100.00 | NR | N/A |

\*Five or more articles are required to obtain statistically meaningful data. \*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

These data were found to be representative of the intended patient target group(s) and had sufficient follow-up time to evaluate the safety and performance at least through the therapeutic lifetime of the subject device (as described in Section 3.1.7).

Key Performance Outcomes**:**

****Bone Union Rate****

**Volgas et al. (2010) compared two reaming systems (conventional versus reamer-irrigator-aspirator) to assess the risk of fat embolism during reaming and nail placement using EXPERT LFN in 20 patients. The authors reported a bone union rate of 100% with all patients achieving fracture healing.**

Additional Performance Outcomes**:**

36-Item Short Form Health Survey (SF-36)**:**

**In the comparative cohort study by Ergisi et al. (2020), 16 patients (study group) given the EXPERT LFN during isolated femoral shaft fracture surgery were compared to 8 healthy male patients (control group). When the study group was compared to the control group, the study group had a significantly lower (p = 0.039) median SF-36 physical component score (46.95 [IQR: 40.95-53.45] versus 54.4 [IQR: 52.9-58.7], respectively).**

Further details related to the results described above can be found in the full Literature Report (refer Table 1).

#### Data to Support Safety – Expert Lateral Femoral Nail System

A summary of the data described in Table 74 that pertain to key safety outcomes are documented below in Table 96.

The key safety outcomes for EXPERT LFN were nonunion, infection and revision/device removal. The tables include safety outcome categories for which events were explicitly reported; this includes event occurrences reported with the value zero. Three articles reported safety events while one article (Liodakis, et al., 2011) did not report any safety events. Table 96 indicates the number of studies reporting on the respective safety outcome, along with the total sample size and the calculated median occurrence rate, inter quartiles and range, across those studies. It should also be noted that certain events may be counted in multiple categories (i.e., infection leading to a revision). All publications were from the previous review. Therefore, only the previous/overall review is presented in the table.

Table : Safety Event Occurrence Rates – Expert Lateral Femoral Nail System

| EVENT DETAILS | | | | | RATE\* | | | | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A\*\*) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | # OF EVENTS | MEDIAN | 1st QRT | 3rd QRT | RANGE | RANGE |
| Key Safety Outcomes | | | | | | | | | | |
| Nonunion: | Overall | 1 | 20 | 1 | N/A | | | 0.05 | NR | N/A |
| Revision/Device Removal: | Overall | 1 | 20 | 1 | N/A | | | 0.05 | NR | N/A |
| **Additional Safety Outcomes** | | | | | | | | | | |
| Joint Pain: | Overall | 1 | 16 | 10 | N/A | | | 0.63 | 21.00 | N/A |
| Loss of Reduction (Loss of Angulation/Alignment): | Overall | 1 | 154 | 41 | N/A | | | 0.27 | NR | N/A |
| Intraoperative Bone Fracture | Overall | 1 | 154 | 16 | N/A | | | 0.10 | NR | N/A |
| Cardiovascular/Myocardial Infarction/Cardiac Arrest: | Overall | 1 | 20 | 1 | N/A | | | 0.05 | NR | N/A |
| Death: | Overall | 1 | 20 | 1 | N/A | | | 0.05 | NR | N/A |
| Embolism/Pulmonary Embolism: | Overall | 1 | 20 | 1 | N/A | | | 0.05 | NR | N/A |
| Stiffness/Limited Range of Motion (ROM): | Overall | 2 | 170 | 4 | N/A | | | 0.00 – 0.03 | 21.00/NR | N/A |
| Neurovascular Damage: | Overall | 1 | 16 | 0 | N/A | | | 0.00 | 21.00 | N/A |

\*Five or more articles are required to obtain statistically meaningful data

\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR = not reported; QRT = quartile

Key Safety Outcomes:

Nonunion and Revision/Device Removal:

Volgas et al. (2010), with 20 patients, reported 1 event of nonunion (event rate: 5.0%) and 1 event of revision/device removal (event rate: 5.0%) in the same patient. This patient showed signs of nonunion that required nail exchange. No further details were provided on this patient, but the authors stated that all fractures healed by the conclusion of the study.

#### Data Summary – Expert Lateral Femoral Nail System

A summary data from the literature review supporting the conformity assessment for Expert Lateral Femoral Nail System is detailed in Table 97.

Table : Systematic Literature Review Summary from Data Supporting Conformity Assessment for Expert Lateral Femoral Nail System

|  |  |
| --- | --- |
| Device Stratification Group: | * Expert Lateral Femoral Nail System |
| Overall Literature Search Date Range: | * 01 January 1992 – 22 August 2022 |
| Total Included Publications (Patients) Supporting Performance Conformity: | * 2 publications (36 patients) (Refer to Section 9.7.3 for bibliography) |
| Total Included Publications (Patients) Supporting Safety Conformity: | * 3 publications (190 patients) (Refer to Section 9.7.3 bibliography) |
| Overall follow-up time of Publications Supporting Performance Conformity: | Mean: 21.0 months  Follow-up sufficient to assess performance and safety over the therapeutic lifetime for included data |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of a portion of the patient population:   * The included publication did not report on the following indications: internal fixation of subtrochanteric fractures or ipsilateral femoral neck/shaft fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions. |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 100% | |  |  | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Mean Rate (%) | | Infection | Not Reported | | Nonunion | 5% | | Revision | 5% | |  |  | |
| Potential Emerging Risk: | No potential significant rate change was identified for any safety outcome or key performance outcomes (i.e., no overlap of IQR between current and previous reviews) |

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 74 that inform the identification of safety trends are documented below (Table 98 and Table 99). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Twelve publications (404 patients) were ranked 6 or 9. Three previous review articles (141 patients) and one current review article (217 patients) with a rank of 6 reported on safety outcomes (Table 98). Eight articles (5 from previous and 3 from current review period), with 46 patients, reported on safety outcomes (Table 99). Seven publications (8 patients) were case reports while one publication (38 patients) was a conference proceeding describing a case series.

Table : Safety Outcomes: Rank 6 – Expert Lateral Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| --- | --- | --- | --- | --- | --- |
| Infection: | Previous | 2 | 125 | 1 | 0.00 – 0.14 |
| Current | NR | | | |
| Overall | 2 | 125 | 1 | 0.00 – 0.14 |
| Nonunion: | Previous | 3 | 141 | 11 | 0.00 – 0.09 |
| Current | 1 | 8 | 3 | 0.38 |
| Overall | 4 | 149 | 14 | 0.00 – 0.38 |
| Revision/Device Removal: | Previous | 3 | 141 | 35 | 0.06 – 0.28 |
| Current | NR | | | |
| Overall | 3 | 141 | 35 | 0.06 – 0.28 |
| Limb/Leg Length Discrepancy (LLD): | Previous | 2 | 23 | 17 | 0.14 – 1.00 |
| Current | NR | | | |
| Overall | 2 | 23 | 17 | 0.14 – 1.00 |
| Delayed Union: | Previous | NR | | | |
| Current | 1 | 217 | 91 | 0.88 |
| Overall | 1 | 217 | 91 | 0.88 |
| Stiffness/Limited Range of Motion (ROM): | Previous | 2 | 125 | 77 | 0.43 – 0.63 |
| Current | NR | | | |
| Overall | 2 | 125 | 77 | 0.43 – 0.63 |
| Reoperation: | Previous | 3 | 141 | 7 | 0.02 – 0.57 |
| Current | NR | | | |
| Overall | 3 | 141 | 7 | 0.02 – 0.57 |
| Joint Pain: | Previous | 2 | 125 | 19 | 0.00 – 0.16 |
| Current | NR | | | |
| Overall | 2 | 125 | 19 | 0.00 – 0.16 |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 2 | 125 | 14 | 0.11 – 0.14 |
| Current | NR | | | |
| Overall | 2 | 125 | 14 | 0.11 – 0.14 |
| Nail Loosening/Back-Out: | Previous | 1 | 7 | 1 | 0.14 |
| Current | NR | | | |
| Overall | 1 | 7 | 1 | 0.14 |
| Neurovascular Damage: | Previous | 2 | 23 | 1 | 0.00 – 0.14 |
| Current | NR | | | |
| Overall | 2 | 23 | 1 | 0.00 – 0.14 |
| Nail Malposition/Misplacement: | Previous | 1 | 118 | 13 | 0.11 |
| Current | NR | | | |
| Overall | 1 | 118 | 13 | 0.11 |
| Postoperative Bone Fracture: | Previous | 2 | 23 | 1 | 0.00 – 0.06 |
| Current | 1 | 217 | 0 | 0.00 |
| Overall | 3 | 240 | 1 | 0.00 – 0.06 |
| Hematoma: | Previous | 1 | 118 | 2 | 0.02 |
| Current | NR | | | |
| Overall | 1 | 118 | 2 | 0.02 |
| Screw/Blade Cut-out: | Previous | 1 | 16 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 16 | 0 | 0.00 |
| Screw/Blade Malposition/Misplacement: | Previous | 1 | 16 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 16 | 0 | 0.00 |
| Unspecified Implant/Hardware Failure: | Previous | 1 | 118 | 2 | 0.02 |
| Current | NR | | | |
| Overall | 1 | 118 | 2 | 0.02 |
| Screw/Blade Penetration into joint (Medial Protrusion): | Previous | 1 | 16 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 16 | 0 | 0.00 |
| Screw/Blade Prominence: | Previous | 1 | 16 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 16 | 0 | 0.00 |

NR – Not Reported

Table : Safety Outcomes: Rank 9 – Expert Lateral Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS |
| --- | --- | --- | --- | --- |
| Revision/Device Removal: | Previous | NR | | |
| Current | 1 | 2 | 5 |
| Overall | 1 | 2 | 5 |
| Nonunion: | Previous | 3 | 3 | 1 |
| Current | 2 | 3 | 2 |
| Overall | 5 | 6 | 3 |
| Infection: | Previous | NR | | |
| Current | 1 | 2 | 1 |
| Overall | 1 | 2 | 1 |
| Joint Pain: | Previous | 2 | 2 | 1 |
| Current | NR | | |
| Overall | 2 | 2 | 1 |
| Limb/Leg Length Discrepancy (LLD): | Previous | 2 | 2 | 1 |
| Current | 1 | 1 | 1 |
| Overall | 3 | 3 | 2 |
| Pain: | Previous | NR | | |
| Current | 2 | 2 | 1 |
| Overall | 2 | 2 | 1 |
| Reoperation: | Previous | 1 | 1 | 1 |
| Current | NR | | |
| Overall | 1 | 1 | 1 |
| Screw/Blade Breakage: | Previous | NR | | |
| Current | 1 | 2 | 2 |
| Overall | 1 | 2 | 2 |
| Nail Breakage: | Previous | NR | | |
| Current | 1 | 2 | 1 |
| Overall | 1 | 2 | 1 |
| Postoperative Bone Fracture: | Previous | NR | | |
| Current | 2 | 3 | 1 |
| Overall | 2 | 3 | 1 |
| Screw/Blade Cut-out: | Previous | NR | | |
| Current | 1 | 2 | 1 |
| Overall | 1 | 2 | 1 |
| Screw/Blade Loosening/Back-Out: | Previous | NR | | |
| Current | 1 | 2 | 1 |
| Overall | 1 | 2 | 1 |
| Unspecified Implant/Hardware Failure: | Previous | 1 | 38 | 1 |
| Current | 1 | 2 | 1 |
| Overall | 2 | 40 | 2 |
| Delayed Union: | Previous | 1 | 38 | 2 |
| Current | NR | | |
| Overall | 1 | 38 | 2 |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 1 | 1 | 0 |
| Current | NR | | |
| Overall | 1 | 1 | 0 |
| Nail Loosening/Back-Out: | Previous | NR | | |
| Current | 1 | 1 | 0 |
| Overall | 1 | 1 | 0 |
| Stiffness/Limited Range of Motion (ROM): | Previous | 1 | 1 | 0 |
| Current | NR | | |
| Overall | 1 | 1 | 0 |
| Other Adverse Events: | Previous | NR | | |
| Current | 1 | 2 | 1 |
| Overall | 1 | 2 | 1 |

Thirteen publications (412 patients) were ranked 6 or 9. Eight previous review and 5 current review articles were assessed for identification of safety trends and no events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

A summary of the data described in Table 74 that pertain to off-label use and misuse are documented below.

There was 1 study (1 patient) from the previous review period that reported on off-label use. Details of the publications that reported off-label use are presented in Table 100.

Table : Included Data to Inform Identification of Off-Label Use – Expert Lateral Femoral Nail System

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per to Indications | Use Details |
| Villatte et al. (2012) | Previous | 1 | The authors reported on a case of complicated intramedullary nailing with osteomyelitis. The patient was revised to EXPERT LFN and recovered successfully. | No patients treated according to intended patient population. | The subject device was potentially used in a skeletally immature patient. |

There was 1 study (9 patients) from the previous review period that reported on misuse and off-label use. Details of the publications that reported misuse and off-label use are presented in Table 101.

Table : Included Data to Inform Identification of Misuse and Off-Label Use – Expert Lateral Femoral Nail System

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per Intended Purpose | Use Details |
| Biz et al. (2014) | Previous | 9 | The authors treated patients with failed treatment of femur and tibia fractures: complicated cases of bone resection and bone transport. The authors concluded that intramedullary nailing could be a treatment option is such clinical settings. | Some patients treated according to intended purpose.  Some patients treated as indicated. | The subject device was used on femur and tibia: off-label use in case of tibia fractures. |

There were 2 studies (10 patients) from the previous review period that reported on off-label use (one publication; 1 patient) and misuse and off-label use (one publication; 9 patients).

## Device-Specific Systematic Literature Review Results by Stratification Group – Femoral Recon Nailing System

No article was included in this section. One mixed cohort publication used the FRN System with other systems and is included in Section 4.10, which discusses when multiple subject devices were used in aggregate.

## Device-Specific Systematic Literature Review Results by Stratification Group – Retrograde Femoral Nail Advanced System

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

No article was included in this section.

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 76 that inform the identification of safety trends are documented below (Table 102). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Three current review articles (3 patients) were included and were appraised with a rank of 9. The safety outcomes are presented in Table 102.

Table : Safety Outcomes: Rank 9 – Retrograde Femoral Nail Advanced System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS |
| --- | --- | --- | --- | --- |
| Nonunion: | Overall | 2 | 2 | 0 |
| Loss of Reduction (Loss of Angulation/Alignment): | Overall | 3 | 3 | 0 |
| Nail Migration: | Overall | 1 | 1 | 0 |
| Nail Malposition/Misplacement: | Overall | 1 | 1 | 0 |
| Pain: | Overall | 1 | 1 | 0 |
| Stiffness/Limited Range of Motion: | Overall | 1 | 1 | 0 |
| Unspecified Implant Failure: | Overall | 1 | 1 | 0 |

Three current review articles (3 patients) were appraised with a rank of 9 and reported on safety outcomes. The articles were assessed for identification of safety trends and no events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

No article was included in this section.

## Device-Specific Systematic Literature Review Results by Stratification Group – Expert Asian Femoral Nail System

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

The aim of this section is to summarize and identify trends in the performance and safety data from published articles reporting on Expert A2FN when used as intended and in the intended patient population. There were five articles (120 patients) that were appraised with Rank 2 or Rank 4. Three publications (82 patients) were from the previous review while two publications (38 patients) were from the current review.

The distribution of the available clinical literature data across the clinical condition(s), patient target group(s), and device lifetime for the device(s) is presented in Table 103. The mean follow-up across 3 publications (56 patients) for which it was reported ranged from 20.50 to 28.40 months, which is sufficient to assess the clinical performance and safety of the subject device beyond its therapeutic lifetime of at least 9 months. Two publications (64 patients) did not report on mean follow-up but were determined to have sufficient follow-up periods. Shin et al. (2020) with 56 patients and Gavaskar et al. (2021) reported a minimum follow-up of greater than 9 months across all included patients.

Table : Expert A2FN Available Literature Data

| CLINICAL DATA | # OF ARTICLES | # OF PATIENTS |
| --- | --- | --- |
| Total | 5 | 120 |
| Clinical Condition(s)/Indications MDD | | |
| Femoral shaft fracture 32-A/B/C (except subtrochanteric fractures 32-A(1-3).1 and 32-C(1-3).1) | 2 | 72 |
| Femoral shaft/Femoral neck fractures 32-A/B/C combined with 31-B | 1 | 10 |
| Femoral shaft fracture 32-A/B/C (except subtrochanteric fractures 32-A(1-3).1 and 32-C(1-3).1),Subtrochanteric fractures 32-A(1-3).1, 32-B(1-3).1 and 32-C(1-3).1 | 1 | 8 |
| Subtrochanteric fractures 32-A(1-3).1, 32-B(1-3).1 and 32-C(1-3).1 | 1 | 30 |
| AO Classification | | |
| 32C,32C2,32C3 | 1 | 16 |
| 31B2.2,31B2.3,32A,32B,32C | 1 | 10 |
| 32A1,32A2,32B | 1 | 56 |
| 32A2,32A3,32B3 | 1 | 8 |
| 32A,32B,32C | 1 | 30 |
| Follow-up Period Appropriate to Evaluate Safety / Performance of the Device\* | | |
| Yes | 5 | 120 |
| Key Performance Outcomes | | |
| Bone Union Rate ≥ 6 months | 5 | 120 |
| Key Safety Outcomes | | |
| Nonunion | 5 | 120 |
| Infection | 3 | 48 |
| Revision | 2 | 18 |

\*A minimum follow-up of 9 months was considered appropriate.

#### Data to Support Performance – Expert Asian Femoral Nail System

A summary of the data described in Table 77 that pertain to key performance outcomes are documented below in Table 104.

The key performance outcome was bone union rate (%).

The outcomes are measures used to evaluate the performance of the subject device(s) based on the intended purpose and expected clinical benefit where data on each key performance outcome are presented separately. Clinical data are provided for the previous, current and overall review periods in Table 104. When only one study presented clinical outcome data, and a mean was reported for that outcome measure, only the mean (not median) was reported.

Table : Performance Outcomes – Expert Asian Femoral Nail System

| PERFORMANCE OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | MEAN/RATE\* | | | OUTCOME | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A)\*\*\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MEDIAN | 1ST QRT | 3RD QRT | RANGE | RANGE |
| Key Performance Outcomes | | | | | | | | | |
| Bone Union Rate (% of Patients): | Previous | 3 | 82 | N/A | | | 90.00 – 100.00 | 20.50 – 28.40 | N/A |
| Current | 2 | 38 | N/A | | | 75.00 – 10.00 | 21.30\*\* | N/A |
| Overall | 5 | 120 | 90.00 | 90.00 | 98.20 | 75.00 – 100.00 | 20.50\*\* – 28.40\*\* | N/A |
| Additional Performance Outcomes | | | | | | | | | |
| Time to Bone Union (Weeks): | Previous | 3 | 82 | N/A | | | 16.10 – 25.30 | 20.50 – 28.40 | N/A |
| Current | 2 | 38 | N/A | | | 19.00 – 21.56 | 21.30\*\* | N/A |
| Overall | 5 | 120 | 21.56 | 19.00 | 23.46 | 16.10 – 25.30 | 20.50\*\* – 28.40\*\* | N/A |
| Mean Postoperative HHS: | Previous | 1 | 16 | N/A | | | 87.95 | 28.40 | N/A |
| Current | NR | | | | | | | |
| Overall | 1 | 16 | N/A | | | 87.95 | 28.40 | N/A |

\*Five or more articles are required to obtain statistically meaningful data

\*\*Two publications which reported on Bone Union Rate and Time to Bone Union did report report mean follow-up periods: Shin et al. (2020) with 56 patients from the previous review period and Gavaskar et al. (2021) with 8 patients from the current review period.

\*\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR = not reported; QRT = quartile; HHS= Harris Hip Score

These data were found to be representative of the intended patient target group(s) and had sufficient follow-up time to evaluate the safety and performance at least through the therapeutic lifetime of the subject device (as described in Section 3.1.16).

Key Performance Outcomes

Bone Union Rate

The median bone union rate across five publications (120 patients) from the overall review was 90.00% (IQR: 90.00-98.20). Only 3 publications (56 patients) reported on mean follow-up which ranged from 20.50 to 28.40 months. However, all publications were determined to have sufficient follow-up time to assess bone union.

*Previous*

Three publications (82 patients) from the previous review reported on bone union rate, which ranged from 90.00% to 100.00% over a mean follow-up that ranged from 20.50 to 28.40 months. Shin et al. (2020) with 56 patients did not report on mean follow-up time.

*Current*

Two publications (38 patients) from the previous review reported on bone union rate, which ranged from 75.00% to 90.00%. Yoon et al. (2022) with 30 patients reported a mean follow-up of 21.30 months while Gavaskar et al. (2021) with 8 patients did not report on mean follow-up time.

Gavaskar et al. (2021) presented a case series on 8 patients undergoing revision procedures with the subject device. All patients were undergoing revision procedures via an alternative technique involving retrograde trans-fracture entry due to complications from atypical fractures, morbid obesity, or previously failed fixation. The authors reported bone union in 6 out of 8 patients (75%) and 7 out of 9 fractures (77.78%). One of these patients was lost to follow-up after two failed revision procedures. The authors concluded that this technique was successful in maintaining nail trajectory leading to union.

Further details related to the results described above can be found in the full Literature Report (Table 1).

#### Data to Support Safety – Expert Asian Femoral Nail System

A summary of the data described in Table 77 that pertain to key safety outcomes are documented below in Table 105.

The key safety outcomes for Expert A2FN were nonunion, infection and revision/device removal. The tables include safety outcome categories for which events were explicitly reported; this includes event occurrences reported with the value zero. All five publications reported on adverse events. Li et al. (2016) from the previous review reported zero safety events. Table 105 indicates the number of studies reporting on the respective safety outcome, along with the total sample size and the calculated median occurrence rate, inter quartiles and range, across those studies. It should also be noted that certain events may be counted in multiple categories (i.e., infection leading to a revision).

Table : Safety Event Occurrence Rates – Expert Asian Femoral Nail System

| EVENT DETAILS | | | | | RATE\* | | | | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A\*\*\*) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | # OF EVENTS | MEDIAN | 1st QRT | 3rd QRT | RANGE | RANGE |
| Key Safety Outcomes | | | | | | | | | | |
| Nonunion: | Previous | 3 | 82 | 2 | N/A | | | 0.00 – 0.10 | 20.50\*\* - 28.40\*\* | N/A |
| Current | 2 | 38 | 5 | N/A | | | 0.10 – 0.25 | 21.30\*\* | N/A |
| Overall | 5 | 120 | 7 | 0.10 | 0.02 | 0.10 | 0.00 – 0.25 | 20.50\*\* - 28.40\*\* | N/A |
| Infection: | Previous | 1 | 10 | 1 | N/A | | | 0.10 | 20.50 | N/A |
| Current | 2 | 38 | 1 | N/A | | | 0.00 – 0.13 | 21.30\*\* | N/A |
| Overall | 3 | 48 | 2 | N/A | | | 0.00 – 0.13 | 20.50\*\* - 21.30\*\* | N/A |
| Revision/Device Removal: | Previous | 1 | 10 | 1 | N/A | | | 0.10 | 20.50 | N/A |
| Current | 1 | 8 | 1 | N/A | | | 0.13 | NR | N/A |
| Overall | 2 | 18 | 2 | N/A | | | 0.10 – 0.13 | 20.50\*\* | N/A |
| **Additional Safety Outcomes** | | | | | | | | | | |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 2 | 26 | 0 | N/A | | | 0.00 – 0.00 | 20.50\*\* - 28.40\*\* | N/A |
| Current | 2 | 38 | 10 | N/A | | | 0.00 – 0.33 | 21.30\*\* | N/A |
| Overall | 4 | 64 | 10 | N/A | | | 0.00 – 0.33 | 20.50\*\* - 28.40\*\* | N/A |
| Stiffness/Limited Range of Motion (ROM): | Previous | 2 | 26 | 2 | N/A | | | 0.00 – 0.20 | 20.50 – 28.40 | N/A |
| Current | NR | | | | | | | | |
| Overall | 2 | 26 | 2 | N/A | | | 0.00 – 0.20 | 20.50 – 28.40 | N/A |
| Nail Breakage: | Previous | NR | | | | | | | | |
| Current | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Overall | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Limb/Leg Length Discrepancy (LLD): | Previous | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Current | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Overall | 2 | 46 | 1 | N/A | | | 0.00 – 0.03 | 21.30 – 28.40 | N/A |
| Reoperation: | Previous | NR | | | | | | | | |
| Current | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Overall | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Avascular Necrosis (Osteonecrosis/Bone Infarction): | Previous | 1 | 10 | 0 | N/A | | | 0.00 | 20.50 | N/A |
| Current | NR | | | | | | | | |
| Overall | 1 | 10 | 0 | N/A | | | 0.00 | 20.50 | N/A |
| Heterotopic Ossification: | Previous | NR | | | | | | | | |
| Current | 1 | 30 | 0 | N/A | | | 0.00 | 21.30 | N/A |
| Overall | 1 | 30 | 0 | N/A | | | 0.00 | 21.30 | N/A |
| Intraoperative Bone Fracture | Previous | NR | | | | | | | | |
| Current | 1 | 8 | 0 | N/A | | | 0.00 | NR | N/A |
| Overall | 1 | 8 | 0 | N/A | | | 0.00 | NR | N/A |
| Malunion: | Previous | 1 | 10 | 0 | N/A | | | 0.00 | 20.50 | N/A |
| Current | NR | | | | | | | | |
| Overall | 1 | 10 | 0 | N/A | | | 0.00 | 20.50 | N/A |
| Joint Pain: | Previous | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Current | NR | | | | | | | | |
| Overall | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Postoperative Bone Fracture: | Previous | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Current | NR | | | | | | | | |
| Overall | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Unspecified Implant/Hardware Failure: | Previous | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Current | NR | | | | | | | | |
| Overall | 1 | 16 | 0 | N/A | | | 0.00 | 28.40 | N/A |
| Other Adverse Events:   * Sacral sore of 1 (n=1) | Previous | NR | | | | | | | | |
| Current | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |
| Overall | 1 | 30 | 1 | N/A | | | 0.03 | 21.30 | N/A |

\*Five or more articles are required to obtain statistically meaningful data. \*\*Two publications did not report on mean follow-up: Shin et al. (2020) with 56 patients from the previous review period and Gavaskar et al. (2021) with 8 patients from the current review period.

\*\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR = not reported; QRT = quartile

Key Safety Outcomes

Nonunion

Five publications (120 patients) reported 7 events of nonunion; the median event rate was 0.10 (IQR: 0.02-0.10; range: 0.00-0.25).

*Previous*

Three publications (82 patients) reported 2 events of nonunion (event rate range: 0.00-0.13). Li et al. (2016), with 16 patients, reported zero cases of nonunion.

*Current*

Two publications (38 patients) reported 5 events of nonunion (event rate range: 0.10-0.25).

As discussed in the section on performance outcomes, Gavaskar et al. (2021) presented on 8 patients with atypical fracture patterns, failed fracture fixation, or fractures comorbid with morbid obesity. Two patients (event rate: 0.25) experienced nonunion, one of which was ultimately lost to follow-up. The true nonunion rate was 0.22 (two out of 9 fractures across 8 patients).

Infection

Three publications (48 patients) reported 2 events of infection (event rate range: 0.00-0.13).

*Previous*

One publication (Oh et al., 2020) with 10 patients from the current review reported one case of infection (event rate: 0.10).

*Current*

Two publications (38 patients) reported one case of infection (event rate range: 0.00-0.13). This event rate range was comparable to the event rate range reported in the previous review period.

Revision/Device Removal

Two publications (18 patients) reported 2 events of Revision/Device Removal (event rate range: 0.10-0.13).

*Previous*

Oh et al. (2020) with 10 patients reported that one patient experienced an atrophic nonunion 7 months postoperatively, which required an autogenous iliac bone graft and augmentative plating (event rate: 0.10).

*Current*

One publication (Gavaskar et al., 2021) with 8 patients from the current review reported one case of revision (event rate: 0.13). One patient who underwent revision nailing after a failed blade plate fixation presented with nonunion 6 months postoperatively. The patient required revision to a nail plate construct with bone grafting, which also failed. The patient elected to not undergo further procedures and was lost to follow-up. This event rate was comparable with the rate from the previous review period.

#### Data Summary – Expert Asian Femoral Nail System

A summary data from the literature review supporting the conformity assessment for Expert Asian Femoral Nail System is detailed in Table 106.

Table : Systematic Literature Review Summary from Data Supporting Conformity Assessment for Expert Asian Femoral Nail System

|  |  |
| --- | --- |
| Device Stratification Group: | * Expert Asian Femoral Nail System |
| Overall Literature Search Date Range: | * 01 January 1992 – 22 August 2022 |
| Total Included Publications (Patients) Supporting Performance Conformity: | * 5 publications (120 patients) (Refer to Section 9.7.3 for bibliography) |
| Total Included Publications (Patients) Supporting Safety Conformity: | * 5 publications (120 patients) (Refer to Section 9.7.3 bibliography) |
| Overall follow-up time of Publications Supporting Performance Conformity: | Mean: 20.50 to 28.40 months  Follow-up sufficient to assess performance and safety over the therapeutic lifetime for included data |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Median (Range) (%) | | Bone Union | 90.00% (90.00-98.20) | |  |  | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Median/Mean Rate (%) (Range) | | Infection | 0.0 – 13.0% | | Nonunion | 10% (2.0 – 10.0) | | Revision | 10.0 – 13.0% | |  |  | |
| Potential Emerging Risk: | No potential significant rate change was identified for any safety outcome or key performance outcomes (i.e., no overlap of IQR between current and previous reviews) |

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 77 that inform the identification of safety trends are documented below (Table 107 and Table 108). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Fifteen publications (1,131 patients) were ranked 6 or 9. In case of Rank 6 studies, seven publications (731 patients) were from the previous review while 4 publications (396 patients were from the current review (Table 107). For Rank 9 studies, three articles (3 patients) from previous review and one article (one patient) from the current review reported on safety outcomes (Table 108) and all publications included were case reports.

Table : Safety Outcomes: Rank 6 – Expert Asian Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| --- | --- | --- | --- | --- | --- |
| Nonunion: | Previous | 7 | 731 | 27 | 0.00 – 0.13 |
| Current | 4 | 396 | 55 | 0.01 – 0.33 |
| Overall | 11 | 1,127 | 82 | 0.00 – 0.33 |
| Revision/Device Removal: | Previous | 1 | 15 | 1 | 0.07 |
| Current | 2 | 266 | 20 | 0.01 – 0.12 |
| Overall | 3 | 281 | 21 | 0.01 – 0.12 |
| Infection: | Previous | 4 | 628 | 1 | 0.00 – 0.00 |
| Current\* | 1 | 178 | 7 | 0.03 – 0.04 |
| Overall | 5 | 806 | 8 | 0.00 – 0.04 |
| Unspecified Implant/Hardware Failure: | Previous | 2 | 35 | 0 | 0.00 – 0.00 |
| Current\* | 1 | 37 | 21 | 0.47 – 0.67 |
| Overall | 3 | 72 | 21 | 0.00 – 0.67 |
| Limb/Leg Length Discrepancy (LLD): | Previous | 3 | 133 | 30 | 0.06 – 0.50 |
| Current | NR | | | |
| Overall | 3 | 133 | 30 | 0.06 – 0.50 |
| Delayed Union: | Previous | 2 | 612 | 18 | 0.00 – 0.23 |
| Current | 1 | 88 | 2 | 0.02 |
| Overall | 3 | 700 | 20 | 0.00 – 0.23 |
| Joint Pain: | Previous | 1 | 12 | 2 | 0.17 |
| Current | NR | | | |
| Overall | 1 | 12 | 2 | 0.17 |
| Loss of Reduction (Loss of Angulation/Alignment): | Previous | 3 | 133 | 3 | 0.00 – 0.08 |
| Current\* | 1 | 178 | 9 | 0.02 – 0.10 |
| Overall | 4 | 311 | 12 | 0.00 – 0.10 |
| Deep Vein Thrombosis (DVT): | Previous | NR | | | |
| Current\* | 1 | 178 | 13 | 0.03 – 0.08 |
| Overall\* | 1 | 178 | 13 | 0.03 – 0.08 |
| Chest Infection/Pneumonia: | Previous | NR | | | |
| Current\* | 1 | 178 | 10 | 0.05 – 0.07 |
| Overall\* | 1 | 178 | 10 | 0.05 – 0.07 |
| Nail Breakage: | Previous | 2 | 85 | 2 | 0.01 – 0.07 |
| Current | NR | | | |
| Overall | 2 | 85 | 2 | 0.01 – 0.07 |
| Neurovascular Damage: | Previous | NR | | | |
| Current\* | 1 | 178 | 6 | 0.02 – 0.07 |
| Overall\* | 1 | 178 | 6 | 0.02 – 0.07 |
| Intraoperative Bone Fracture: | Previous | 2 | 612 | 2 | 0.00 – 0.03 |
| Current | NR | | | |
| Overall | 2 | 612 | 2 | 0.00 – 0.03 |
| Embolism/Pulmonary Embolism: | Previous | NR | | | |
| Current\* | 1 | 178 | 2 | 0.00 – 0.02 |
| Overall\* | 1 | 178 | 2 | 0.00 – 0.02 |
| Screw/Blade Breakage: | Previous | 1 | 70 | 1 | 0.01 |
| Current | NR | | | |
| Overall | 1 | 70 | 1 | 0.01 |
| Avascular Necrosis (Osteonecrosis/Bone Infarction): | Previous | 1 | 542 | 1 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 542 | 1 | 0.00 |
| Postoperative Bone Fracture: | Previous | 1 | 542 | 1 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 542 | 1 | 0.00 |
| Screw/Blade Cut-out: | Previous | 1 | 51 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 51 | 0 | 0.00 |
| Screw/Blade Penetration into joint (Medial Protrusion): | Previous | 1 | 51 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 51 | 0 | 0.00 |
| Stiffness/Limited Range of Motion (ROM): | Previous | 1 | 12 | 0 | 0.00 |
| Current | NR | | | |
| Overall | 1 | 12 | 0 | 0.00 |
| Other Adverse Events:   * Acute respiratory distress syndrome (n=8) * Pressure sore (n=4) | Previous | NR | | | |
| Current | 1 | 178 | 12 | 0.03 – 0.09 |
| Overall | 1 | 178 | 12 | 0.03 – 0.09 |

\*Youn et al. (2021) with 178 patients reported on three study arms comparing outcomes of patients treated for isolated femur fracture (n=29), multiple fractures (n=54), or fractures in severely injured patients (n=95). Therefore, though there is only one publication, there will be an event rate range presented in the table.

NR = Not Reported

Table : Safety Outcomes: Rank 9 – Expert Asian Femoral Nail System

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS |
| --- | --- | --- | --- | --- |
| Nonunion: | Previous | 2 | 2 | 0 |
| Current | 1 | 1 | 0 |
| Overall | 3 | 3 | 0 |
| Nail Malposition/Misplacement: | Previous | 1 | 1 | 1 |
| Current | NR | | |
| Overall | 1 | 1 | 1 |
| Loss of Reduction: | Previous | 2 | 2 | 1 |
| Current | NR | | |
| Overall | 2 | 2 | 1 |
| Pain: | Previous | NR | | |
| Current | 1 | 1 | 0 |
| Overall | 1 | 1 | 0 |

NR = Not Reported

Fifteen publications (1,127 patients) were ranked 6 or 9. Ten previous review and five current review articles were assessed for identification of safety trends and no events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

A summary of the data described in Table 77 that pertain to off-label use and misuse are documented below.

Four publications (121 patients) from the previous review period reported on off-label use. Details of the publications that reported off-label use are presented in Table 109.

Table : Included Data to Inform Identification of Off-Label Use – Expert Asian Femoral Nail System

| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per to Indications | Use Details |
| --- | --- | --- | --- | --- | --- |
| Shon et al. (2020) | Previous | 20 | The authors presented a case series on patients of patients receiving the subject device in a bent form on atypical femoral fractures. They found this technique to yield good clinical outcomes and concluded it to be a valid treatment option for extremely bowed femoral fractures. | No patients treated as indicated | EXPERT A2FN is not indicated for the treatment of atypical/bowed femur fractures in osteoporotic bone. Further, the device was bent, which is not within the IFU. |
| Yoon et al. (2017) | Previous | 1 | The authors presented a patient with insufficiency fracture at the distal interlocking screw level after union of an intertrochanteric hip fracture. They concluded that this case demonstrates that physicians should be aware of the possibility for this type of stress fracture following treatment with femoral nailing. | No patients treated as indicated | The EXPERT A2FN is not indicated for intertrochanteric fractures. |
| Gao et al. (2018) | Previous | 99 | The authors conducted a study on patients presenting with proximal or lateral femoral fracture to determine which is more susceptible to implant failure. They found that free bone fragments at the junction of the greater trochanter and lateral femoral wall and a transverse fracture line across the lateral femoral wall are predictors of implant failure. | No patients treated as indicated | EXPERT A2FN is not indicated for 31-A type fractures, which were seen across all included patients. |
| Kharbanda et al. (2018) | Previous | 1 | The authors conducted a case report on a patient with adenocarcinoma breast with pertrochanteric metastasis and extensive bone loss treated with the subject device with radiotherapy and hormonal therapy. They concluded that radiotherapy may offer benefits in fracture fixation and healing to patients of this condition in the future. | No patients treated as indicated | EXPERT A2FN is not intended or indicated for the treatment of pathological fracture in the area of pertrochanteric lesion (metastasis). |

Two publications (2 patients) from the previous review period reported on misuse and off-label use. Details of the publications that reported misuse and off-label use are presented in Table 110.

Table : Included Data to Inform Identification of Misuse and Off-Label Use – Expert Asian Femoral Nail System

| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per Intended Purpose | Use Details |
| --- | --- | --- | --- | --- | --- |
| Kim et al. (2016) | Previous | 1 | The authors aimed to showcase their targeted alignment technique which involved preoperative planning in a laboratory setting by simulating forces of the intramedullary nail. They concluded that their case study shows complications arise due to excessive soft tissue tension placed on the drill/guide sleeve and therefore, placement of the nail is crucial in minimizing adverse events. | No patients treated according to intended purpose  No patients treated as indicated | The subject device is not intended or indicated for this fracture location (31-A3.3). |
| Chen et al. (2015) | Previous | 1 | The authors reported a case of osteotomy and reconstruction in a patient presenting with severe varus deformity in both proximal and diaphysis of left femur. They concluded that their technique should be considered for early intervention for this presentation. | No patients treated according to intended purpose  No patients treated as indicated | The subject device is not intended or indicated for subtrochanteric fracture. |

Six publications (123 patients) were identified in this section in the previous review and were appraised with Rank 13. Four publications (121 patients) reported on off-label use while 2 publications (2 patients) reported on a combination of misuse and off-label use.

## Device-Specific Systematic Literature Review Results by Stratification Group – Unspecified Femoral Nails

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

No article was included in this section.

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 78 that inform the identification of safety trends are documented below (Table 111). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

One publication (114 patients) was included in the previous review period and was appraised with a rank of 6. The safety outcomes are presented in Table 111.

Table : Safety Outcomes: Rank 6 – Unspecified Femoral Nail Systems

| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| --- | --- | --- | --- | --- | --- |
| Revision/Device Removal: | Overall | 1 | 114 | 35\* | 0.31 |
| Nonunion: | Overall | 1 | 114 | 10 | 0.09 |
| Joint Pain: | Overall | 1 | 114 | 47\*\* | 0.41 |
| Reoperation: | Overall | 1 | 114 | 9 | 0.08 |
| \*Most of revision events (30 out of 35) were screw removal or dynamization; \*\*Postoperatively, “moderate” pain was noted in 39 patients, and “severe pain” in 8 patients | | | | | |

One publication (114 patients) was included in the previous review period and was appraised with a rank of 6. The publication was assessed for identification of safety trends and no events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

A summary of the data described in Table 78 that pertain to off-label use and misuse are documented below (Table 112)

Table : Included Data to Inform Identification of Misuse and Off-Label Use – Unspecified Femoral Nail Systems

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Publication Reference (Author, Year) | Review Period (Previous / Current) | # Patients | Publication Summary | Characterization of Use Per Intended Purpose | Use Details |
| Popkov et al. (2021) | Current | 29 | The authors used a combined technique of intramedullary nailing and external fixation for bone lengthening in acquired leg discrepancy. The authors noted that the combined technique allowed them to avoid the major complications and showed good and excellent results. | No patients treated according to intended purpose  No patients treated as indicated  Some patients treated according to intended patient population | The subject device was used for femoral lengthening on 15 patients and tibial lengthening for 14 patients.  Additionally, the device was potentially used in skeletally immature patients (age range, 6-32 years). |

There was 1 study (29 patients) from the previous review period that reported on misuse and off-label use.

## Device-Specific Systematic Literature Review Results by Stratification Group – Multiple Femoral Nail Systems

### Data to Support Safety and/or Performance Conformity (Including Trending Assessment)

The aim of this section is to summarize and identify trends in the performance and safety data from published articles reporting on Multiple Femoral Nail Systems when used as intended and in the intended patient population. There was one article (8 patients) from the current review period that was assessed as Rank 4.

The distribution of the available clinical literature data across the clinical condition(s), patient target group(s), and device lifetime for the device(s) is presented in Table 113. One case series (8 patients) from the current review period reported a mean follow-up of 52.24 months which is sufficient to assess the clinical performance and safety of the subject device beyond its therapeutic lifetime of at least 9 months. The Femoral Nail Systems used were the Expert LFN and Expert R/AFN nails. The included publication did not report on the following MDR indication: fractures of the distal end segment of the femur.

Table : Multiple Femoral Nail Systems Available Literature Data

| CLINICAL DATA\* | # OF ARTICLES | # OF PATIENTS |
| --- | --- | --- |
| Total | 1 | 8 |
| Clinical Condition(s)/Indications MDR | | |
| Femoral shaft fractures; Fractures of the middle and distal diaphyseal segment of the femur | 1 | 8\*\* |
| Clinical Condition(s)/Indications MDD | | |
| Distal diaphyseal femoral shaft fractures | 1 | 8\*\* |
| Femoral Nail Systems | | |
| EXPERT Lateral Femoral Nail (EXPERT LFN), EXPERT Retrograde/Antegrade Femoral Nail (EXPERT R/AFN) | 1 | 8\*\* |
| Patient Population | | |
| Adolescent Population (>12 years old) | 1 | 8 |
| Follow-up Period Appropriate to Evaluate Safety / Performance of the Device\*\*\* | | |
| Yes | 1 | 8 |
| Key Performance Outcomes | | |
| Bone Union Rate ≥ 6 months | 1 | 8 |
| Key Safety Outcomes | | |
| Nonunion | 1 | 8 |
| Infection | 1 | 8 |
| Revision | 1 | 8 |

\*AO Classification was not reported in the included publication. Therefore, it is not relfected in this table.

\*\*It could not be determined how many patients received each device.

\*\*\*A minimum follow-up of 9 months was considered appropriate

#### Data to Support Performance – Multiple Femoral Nail Systems

A summary of the data described in Table 79 that pertain to key performance outcomes are documented below in Table 114.

The key performance outcome was bone union rate (%).

The outcomes are measures used to evaluate the performance of the subject device(s) based on the intended purpose and expected clinical benefit where data on each key performance outcome are presented separately. Clinical data are provided for the previous, current and overall review periods. When only one study presented clinical outcome data, and a mean was reported for that outcome measure, only the mean (not median) was reported.

The included publication (8 patients) reported on the key performance outcome. As no publications were identified during the previous review period, only the overall review period is represented in Table 114.

Table : Performance Outcomes – Multiple Femoral Nail Systems

| PERFORMANCE OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | MEAN/RATE\* | | | OUTCOME | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A)\*\* |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MEDIAN | 1ST QRT | 3RD QRT | RANGE | RANGE |
| Key Performance Outcomes | | | | | | | | | |
| Bone Union Rate (% patients): | Overall | 1 | 8 | N/A | | | 75.00 | 52.24 | N/A |
| Additional Performance Outcomes | | | | | | | | | |
| Mean Postoperative VAS Pain Score: | Overall | 1 | 8 | N/A | | | 67.50 | 52.24 | N/A |
| Mean Time to Union (Weeks): | Overall | 1 | 8 | N/A | | | 68.83 | 52.24 | N/A |
| Mean Time to Weight Bearing (Weeks): | Overall | 1 | 8 | N/A | | | 56.25 | 52.24 | N/A |

\*Five or more articles are required to obtain statistically meaningful data

\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

These data were found to be representative of the intended patient target group(s) and had sufficient follow-up time to evaluate the safety and performance at least through the therapeutic lifetime of the subject device (as described in Sections 3.1.1 and 3.1.7).

Key Performance Outcomes

Bone Union Rate

One publication (Lu et al., 2022) from the current review reported a bone union rate of 75% across 8 patients. The authors followed 8 patients that required management of limb-length discrepancy secondary to traumatic femoral bone loss and were treated with a monorail fixator-assisted intramedullary nailing. They concluded that their method was “effective” in treatment acknowledging that treatment of limb-length discrepancies by all methods of fixation often result in high complication rates.

Further details related to the results described above can be found in the full Literature Report (refer Table 1).

#### Data to Support Safety – Multiple Femoral Nail Systems

A summary of the data described in Table 79 that pertain to key safety outcomes are documented below in Table 115.

The key safety outcomes for the Multiple Femoral Nail Systems were nonunion, infection, and revision/device removal. The tables include safety outcome categories for which events were explicitly reported; this includes event occurrences reported with the value zero. Table 115 indicates the number of studies reporting on the respective safety outcome in the included publication, along with the total sample size and the calculated median occurrence rate, inter quartiles and range, across those studies. It should also be noted that certain events may be counted in multiple categories (i.e., infection leading to a revision). As no publications were identified during the previous review period, only the overall review period is presented in Table 115.

Table : Safety Event Occurrence Rates – Multiple Femoral Nail Systems

| EVENT DETAILS | | | | | RATE\* | | | | FINAL FOLLOW UP [MONTHS] | POTENTIAL CHANGE  (Y, N, or N/A\*\*) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | # OF PUBLICATIONS | # OF PATIENTS | # OF EVENTS | MEDIAN | 1st QRT | 3rd QRT | RANGE | RANGE |
| Key Safety Outcomes | | | | | | | | | | |
| Nonunion: | Overall | 1 | 8 | 3 | N/A | | | 0.38 | 52.24 | N/A |
| Revision: | Overall | 1 | 8 | 3 | N/A | | | 0.38 | 52.24 | N/A |
| Infection: | Overall | 1 | 8 | 2 | N/A | | | 0.25 | 52.24 | N/A |
| **Additional Safety Outcomes** | | | | | | | | | | |
| Heterotopic Ossification: | Overall | 1 | 8 | 1 | N/A | | | 0.13 | 52.24 | N/A |
| Pain: | Overall | 1 | 8 | 1 | N/A | | | 0.13 | 52.24 | N/A |
| Other adverse events:   * Stage 3 Osteoarthritis (n=1) * Pin site infection of external fixation (n=5) * Pin migration of external fixator (n=1) | Overall | 1 | 8 | 7 | N/A | | | 0.88 | 52.24 | N/A |

\*Five or more articles are required to obtain statistically meaningful data.

\*\*A potential change in the rate is identified through comparing the interquartile range between the previous review period and the current review period. If the interquartile ranges do no overlap then a potential change is identified and this may be indicative of a potential emerging risk. N/A = Not Applicable due to no publications identified in the previous or current review period.

NR – Not reported; QRT – Quartile

Key Safety Outcomes

Infection

One publication (Lu et al., 2022) from the current review reported 2 cases of infection across 8 patients (event rate: 0.25) related to the subject device.

Two patients had osteomyelitis caused by Staphylococcus epidermidis and Staphylococcus capitis treated by intravenous antibiotics in one patient and implant removal with antibiotic treatment in the other.

Nonunion

Lu et al. (2022) reported 3 cases of docking site nonunion (event rate: 0.38). Two cases required an exchange of nail and compression at the docking site. No further details were provided on the last patient.

Revision

Lu et al. (2022) reported 3 cases of revision (event rate: 0.38) across 8 patients. Indications for revision were docking site nonunion (n=2) and deep infection requiring implant removal (n=1).

#### Data Summary – Multiple Femoral Nail Systems

A summary data from the literature review supporting the conformity assessment for Multiple Femoral Nail Systems is detailed in Table 116.

Table : Systematic Literature Review Summary from Data Supporting Conformity Assessment for Multiple Femoral Nail Systems

|  |  |
| --- | --- |
| Device Stratification Group: | * Multiple Femoral Nail Systems |
| Overall Literature Search Date Range: | * 01 January 1992 – 22 August 2022 |
| Total Included Publications (Patients) Supporting Performance Conformity: | * 1 publications (8 patients) (Refer to Section 9.7.3 for bibliography) |
| Total Included Publications (Patients) Supporting Safety Conformity: | ☐ N/A – There were no publications that were of sufficient scientific validity and relevance that are supportive of the safety.   * 1 publications (8 patients) (Refer to Section 9.7.3 bibliography) |
| Overall follow-up time of Publications Supporting Performance Conformity: | Mean: 52.24 months  Follow-up sufficient to assess performance and safety over the therapeutic lifetime for included data |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 75.0% | |  |  | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Mean Rate (%) | | Infection | 25.0% | | Nonunion | 38.0% | | Revision | 38.0% | |
| Potential Emerging Risk: (Delete checkbox or table if not applicable) | No potential significant rate change was identified for any safety outcome or key performance outcomes (i.e., no overlap of IQR between current and previous reviews) |

### Additional Data to Inform Identification of Safety Trends or Performance Issues

A summary of the data described in Table 79 that inform the identification of safety trends are documented below (Table 117). Refer to Section 8.1.2 for safety analysis from all clinical data sources.

Two publications (152 patients) appraised with Rank 6 were identified from the current review period. Safety events are summarized in Table 117.

Kim and Song (2022) reported on 22 patients receiving the FRN, EXPERT A2FN, or Gamma3 Long Nail (Stryker, Schӧnkirchen, Germany) in the treatment of atypical femoral fractures.

Hwang et al. (2021) reported on 130 patients receiving the EXPERT LFN (n=6; 4.62%), EXPERT R/AFN (n=46; 35.38%) or other intramedullary nailing systems: T2 (Stryker, Kalamazoo, MI), Versa (Zimmer Biomet, Warsaw IN), Phoenix (Zimmer Biomet, Warsaw, IN), Affixus (Zimmer Biomet, Warsaw, IN), or TRIGEN TAN (Smith and Nephew, London, UK) in the treatment of isolated femoral shaft fractures.

Table : Safety Outcomes: Rank 6 – Multiple Femoral Nail Systems

| EVENT DETAILS | | | | |  |
| --- | --- | --- | --- | --- | --- |
| SAFETY OUTCOMES | REVIEW PERIOD | # OF ARTICLES | # OF PATIENTS | # OF EVENTS | RANGE |
| Revision/Device Removal:\* | Overall | 2 | 152 | 3 | 0.02 – 0.05 |
| Nonunion: | Overall | 1 | 130 | 5 | 0.04 |
| Limb/Leg Length Discrepancy (LLD): | Overall | 1 | 22 | 1 | 0.05 |
| Loss of Reduction (Loss of Angulation/Alignment): | Overall | 1 | 22 | 1 | 0.05 |
| Screw/Blade Cut-out: | Overall | 1 | 22 | 1 | 0.05 |
| Delayed Union: | Overall | 1 | 130 | 2 | 0.02 |
| Unspecified Implant/Hardware Failure: | Overall | 1 | 130 | 2 | 0.02 |
| Postoperative Bone Fracture: | Overall | 1 | 130 | 0 | 0.00 |

\*Indications for revision were hypertrphic nonunion with failed distal interlocking screw requring exchange nailing (n=2), removal of distal interlocking screw to improve stability and strength (n=1)

NR = Not Reported

Two current review publications (152 patients) were appraised with a rank of 6 and were assessed for identification of safety trends. No events were deemed to require additional evaluation.

### Data to Support Identification of Off-Label Use/Misuse

No article was included in this section.

# SECTION E CONTENT

## Clinical Investigations (CIs)

Table : Clinical Investigations (CI) Overview

|  |  |
| --- | --- |
| Were clinical investigations (CI) pertaining to the subject devices conducted? | Yes  No premarket clinical investigation was conducted for the Femoral Nail Systems. (See rationale below)  No post market clinical investigation was conducted for the Femoral Nail Systems. |
| Rationale: | The subject devices were originally lawfully placed on the market after CE-marking in accordance with MDD utilizing clinical data from scientific literature on an equivalent device as documented in the initial CER. As there were sufficient data, no premarket clinical investigation was required per MDD Annex X, sec. 1.1a. |

# SECTION F CONTENT

## Post-Market Surveillance (PMS)

The Quality/Reactive Data for the Femoral Nail Systems includes the data sources defined in the PMS Plan(s). Data have been provided from 02 October 2017 through 02 October 2022 as extracted from the supplemental data reviews (Attachment Referenced in Table 1).

Table : Femoral Nail Systems PMS Plan and Report Overview

| PMS Plan and Associated Report | Report Review Period and Conclusions | Supplemental PMS Data Review Period |
| --- | --- | --- |
| Shaft and Distal Femur IM Nailing (TN-005)  Plan #0000244976 G.3  PMSR #0000250261 A.44 | 01 February 2016 to 31 January 2021  Report Conclusion: No opportunities, emerging issues, or safety signals were identified. No further review or actions needed. All criteria have been reviewed and no emerging issues or signals that could affect safety and/or quality performance of the device(s) have been identified.  To continue current Post Market Surveillance. | 02 October 2017 to 02 October 2022 |
| Locking Screws and Bolts for IM Nailing (TN-008)  Plan #0000244979 G.5  PMSR #0000250208 A.34 | 01 May 2016 to 30 April 2021  Report Conclusion: No opportunities, emerging issues, or safety signals were identified. No further review or actions needed. All criteria have been reviewed and no emerging issues or signals that could affect safety and/or quality performance of the device(s) have been identified.  To continue current Post Market Surveillance |
| Femoral Recon Nail (TN-009)  Plan #500040369 E.2  PMSR #0000275810 A.17 | 01 March 2016 to 28 February 2021  Report Conclusion: No opportunities, emerging issues, or safety signals were identified. No further review or actions needed. All criteria have been reviewed and no emerging issues or signals that could affect safety and/or quality performance of the device(s) have been identified.  To continue current Post Market Surveillance. |
| Retrograde Femoral Nail Advanced (TN-010)  Plan #500444123 D.2  PMSR #500444124 A.2 | 01 April 2016 to 31 March 2021  Report Conclusion: No opportunities, emerging issues, or safety signals were identified. No further review or actions needed. All criteria have been reviewed and no emerging issues or signals that could affect safety and/or quality performance of the device(s) have been identified.  To continue current Post Market Surveillance. |
| Self-Retaining Locking Screw System (TS-002)  Plan #500443966 D.5  PMSR #500443971 B.2 | 01 April 2016 to 31 March 2021  Report Conclusion: No opportunities, emerging issues, or safety signals were identified. No further review or actions needed. All criteria have been reviewed and no emerging issues or signals that could affect safety and/or quality performance of the device(s) have been identified.  To continue current Post Market Surveillance. |

Sections 6.1.1 and 6.1.2 summarize the Worldwide (WW) Complaint and Vigilance Data and Actions/Alerts associated with the Subject Devices. Refer to Ad Hoc Report (Attachment Referenced in Table 1) for a more detailed breakdown of the data by region and description of how opportunities were calculated.

### Complaint and Vigilance Data

#### Overall Complaints Data

Table 120 summarizes the complaint data for the Subject Devices for the review periods noted.

Table : Femoral Nail Systems WW Complaint Summary

| Complaint Summary | | Previous Period | Current Period | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 23 | 12 | 62 | |
| Impacted Products (Sum of Involved Quantity) | | 26 | 13 | 68 |
| Opportunities | | 20,069 | 16,451 | 95,099 | |
| Impacted Product Event Rate | % | 0.1296 | 0.0790 | 0.0715 | |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 1 | 1 | 7 | |
| Impacted Products (Sum of Involved Quantity) | | 1 | 1 | 7 |
| Opportunities | | 4,149 | 3,208 | 19,217 | |
| Impacted Product Event Rate | % | 0.0241 | 0.0312 | 0.0364 | |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 9 | 2 | 19 | |
| Impacted Products (Sum of Involved Quantity) | | 9 | 2 | 19 |
| Opportunities | | 6,533 | 5,227 | 31,437 | |
| Impacted Product Event Rate | % | 0.1378 | 0.0383 | 0.0604 | |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 4 | 2 | 11 | |
| Impacted Products (Sum of Involved Quantity) | | 4 | 2 | 11 | |
| Opportunities | | 1,535 | 1,478 | 7,803 | |
| Impacted Product Event Rate | % | 0.2606 | 0.1353 | 0.1410 | |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 0 | 0 | 2 | |
| Impacted Products (Sum of Involved Quantity) | | 0 | 0 | 3 | |
| Opportunities | | 973 | 903 | 5,041 | |
| Impacted Product Event Rate | % | 0.0000 | 0.0000 | 0.0595 | |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 0 | 0 | 1 | |
| Impacted Products (Sum of Involved Quantity) | | 0 | 0 | 1 | |
| Opportunities | | 595 | 445 | 2,722 | |
| Impacted Product Event Rate | % | 0.0000 | 0.0000 | 0.0367 | |
| 7 – Expert Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 12 | 4 | 38 | |
| Impacted Products (Sum of Involved Quantity) | | 14 | 4 | 40 | |
| Opportunities | | 8,302 | 7,351 | 49,806 | |
| Impacted Product Event Rate | % | 0.1686 | 0.0544 | 0.0803 | |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 3 | 1 | 9 | |
| Impacted Products (Sum of Involved Quantity) | | 5 | 2 | 15 | |
| Opportunities | | 7,813 | 7,081 | 40,817 | |
| Impacted Product Event Rate | % | 0.0640 | 0.0282 | 0.0367 | |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 2 | 1 | 12 | |
| Impacted Products (Sum of Involved Quantity) | | 2 | 2 | 16 | |
| Opportunities | | 9,261 | 9,606 | 46,097 | |
| Impacted Product Event Rate | % | 0.0216 | 0.0208 | 0.0347 | |
| 10 – Femoral Recon Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 12 | 16 | 64 | |
| Impacted Products (Sum of Involved Quantity) | | 12 | 16 | 65 | |
| Opportunities | | 7,627 | 6,909 | 28,791 | |
| Impacted Product Event Rate | % | 0.1573 | 0.2316 | 0.2258 | |
| 11 – Recon Screw for Medullary Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 0 | 1 | 1 | |
| Impacted Products (Sum of Involved Quantity) | | 0 | 1 | 1 | |
| Opportunities | | 0 | 282 | 282 | |
| Impacted Product Event Rate | % | Not Applicable | 0.3546 | 0.3546 | |
| 12 – End Cap for Femoral Recon Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 0 | 0 | 0 | |
| Impacted Products (Sum of Involved Quantity) | | 0 | 0 | 0 | |
| Opportunities | | 0 | 66 | 66 | |
| Impacted Product Event Rate | % | Not Applicable | 0 | 0 | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 6 | 18 | 24 | |
| Impacted Products (Sum of Involved Quantity) | | 6 | 18 | 24 | |
| Opportunities | | 2,257 | 9,131 | 11,388 | |
| Impacted Product Event Rate | % | 0.2658 | 0.1971 | 0.2107 | |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 1 | 1 | 2 | |
| Impacted Products (Sum of Involved Quantity) | | 1 | 1 | 2 | |
| Opportunities | | 458 | 1,630 | 2,088 | |
| Impacted Product Event Rate | % | 0.2183 | 0.0613 | 0.0958 | |
| 15 – Endcaps for RFN-ADVANCED | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 0 | 0 | 0 | |
| Impacted Products (Sum of Involved Quantity) | | 0 | 0 | 0 | |
| Opportunities | | 184 | 1,008 | 1,192 | |
| Impacted Product Event Rate | % | 0 | 0 | 0 | |
| 16 – Expert Asian Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 6 | 4 | 35 | |
| Impacted Products (Sum of Involved Quantity) | | 6 | 4 | 36 | |
| Opportunities | | 6,600 | 3,701 | 39,527 | |
| Impacted Product Event Rate | % | 0.0909 | 0.1081 | 0.0911 | |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 2 | 4 | 15 | |
| Impacted Products (Sum of Involved Quantity) | | 3 | 7 | 25 | |
| Opportunities | | 11,228 | 11,328 | 49,965 | |
| Impacted Product Event Rate | % | 0.0267 | 0.0618 | 0.0500 | |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | |
| Product Complaints (Unique Complaint by Product Quantity) | | 4 | 7 | 20 | |
| Impacted Products (Sum of Involved Quantity) | | 4 | 9 | 24 | |
| Opportunities | | 2,693 | 1,489 | 16,734 | |
| Impacted Product Event Rate | % | 0.1485 | 0.6044 | 0.1434 | |

#### Complaints by Product Experience / Problem Code

Table 121 lists the complaints by Product Experience Code (PEC) and Problem Code (corresponding terminology by the International Medical Device Regulators Forum [IMDRF]). Note: Multiple codes can be chosen per complaint. The sample size (n) captures the total device quantity involved for the reported code.

Table : Femoral Nail Systems Summary of WW Complaints by Product Experience Code / Problem Code

| Product Experience Code Breakdown | | Previous Period | | Current Period | | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Complaints by Product Experience Code | Problem Code (IMDRF Code) | n | Rate (%) | n | Rate (%) | n | Rate (%) |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 5 | 0.0249 | 0 | 0.0000 | 6 | 0.0063 |
| PACKAGING : DAMAGED | Tear, Rip Or Hole In Device Packaging (A020504) | 0 | 0.0000 | 1 | 0.0061 | 6 | 0.0063 |
| STOCKING : DEVICE NOT AVAILABLE/MISSING | Appropriate Term/Code Not Available (A27) | 1 | 0.0050 | 3 | 0.0182 | 6 | 0.0063 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 3 | 0.0149 | 0 | 0.0000 | 3 | 0.0032 |
| BROKEN (2+ PIECES) : INTRAOPERATIVELY | Break (A0401) | 1 | 0.0050 | 1 | 0.0061 | 2 | 0.0021 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0021 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 2 | 0.0100 | 0 | 0.0000 | 2 | 0.0021 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0061 | 1 | 0.0011 |
| LABELING : EXPIRED | Expiration Date Error (A210101) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0011 |
| PACKAGING : FOREIGN MATTER – INSIDE STERILE PACKAGING | Device Contaminated During Manufacture Or Shipping (A1802) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0011 |
| UPON RECEIPT : DIMENSIONAL | Defective Device (A0203) | 0 | 0.0000 | 1 | 0.0061 | 1 | 0.0011 |
| VISUAL : SCRATCHED/NICKED | Scratched Material (A0415) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0011 |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : INTRAOPERATIVELY | Break (A0401) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| FUNCTIONAL : EMBEDDED DEVICE | Entrapment Of Device (A150208) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| FUNCTIONAL : LOOSE | Device Slipped (A051204) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | | | |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 3 | 0.0459 | 0 | 0.0000 | 4 | 0.0127 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| STOCKING : DEVICE NOT AVAILABLE/MISSING | Appropriate Term/Code Not Available (A27) | 0 | 0.0000 | 1 | 0.0191 | 1 | 0.0032 |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0677 | 2 | 0.0256 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0128 |
| PACKAGING : COMPROMISED STERILITY | Device Contaminated During Manufacture Or Shipping (A1802) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| PACKAGING : DAMAGED | Tear, Rip Or Hole In Device Packaging (A020504) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| UPON RECEIPT : DIMENSIONAL | Defective Device (A0203) | 0 | 0.0000 | 1 | 0.0677 | 1 | 0.0128 |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0397 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0367 |
| 7 – Expert Lateral Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 2 | 0.0241 | 1 | 0.0136 | 6 | 0.0120 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 5 | 0.0602 | 0 | 0.0000 | 6 | 0.0120 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 0 | 0.0000 | 1 | 0.0136 | 2 | 0.0040 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 1 | 0.0120 | 0 | 0.0000 | 2 | 0.0040 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 2 | 0.0241 | 0 | 0.0000 | 2 | 0.0040 |
| PACKAGING : DAMAGED | Tear, Rip Or Hole In Device Packaging (A020504) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| PACKAGING : INCORRECT PRODUCT | Manufacturing, Packaging Or Shipping Problem (A02) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| UPON RECEIPT : DEVICE DAMAGED | Device Damaged Prior To Use (A0204) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| UPON RECEIPT : DIMENSIONAL | Defective Device (A0203) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| UPON RECEIPT : MISSING FEATURES | Nonstandard Device (A020102) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| VISUAL : MISSING COMPONENTS | Use Of Device Problem (A23) | 0 | 0.0000 | 1 | 0.0136 | 1 | 0.0020 |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0049 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0049 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 2 | 0.0282 | 2 | 0.0049 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 2 | 0.0256 | 0 | 0.0000 | 2 | 0.0049 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 1 | 0.0128 | 0 | 0.0000 | 1 | 0.0024 |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0108 | 2 | 0.0208 | 8 | 0.0174 |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0065 |
| PACKAGING : DAMAGED | Tear, Rip Or Hole In Device Packaging (A020504) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| UPON RECEIPT : BURR | Defective Device (A0203) | 0 | 0.0000 | 1 | 0.0104 | 1 | 0.0022 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| VISUAL : SCRATCHED/NICKED | Scratched Material (A0415) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| 10 – Femoral Recon Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 2 | 0.0262 | 3 | 0.0434 | 18 | 0.0625 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 4 | 0.0524 | 2 | 0.0289 | 9 | 0.0313 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 1 | 0.0145 | 7 | 0.0243 |
| PACKAGING : DAMAGED | Tear, Rip Or Hole In Device Packaging (A020504) | 1 | 0.0131 | 0 | 0.0000 | 4 | 0.0139 |
| UPON RECEIPT : DIMENSIONAL | Defective Device (A0203) | 1 | 0.0131 | 1 | 0.0145 | 3 | 0.0104 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 1 | 0.0131 | 0 | 0.0000 | 3 | 0.0104 |
| BROKEN (2+ PIECES) : BROKEN (2+ PIECES) | Break (A0401) | 0 | 0.0000 | 2 | 0.0289 | 2 | 0.0069 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 2 | 0.0262 | 0 | 0.0000 | 2 | 0.0069 |
| BROKEN (2+ PIECES) : INTRAOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| CUSTOMER FEEDBACK : DISSATISFACTION | Appropriate Term/Code Not Available (A27) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0131 | 0 | 0.0000 | 1 | 0.0035 |
| FUNCTIONAL : DOES NOT FUNCTION | Mechanical Problem (A05) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| PACKAGING : COMPROMISED STERILITY | Device Contaminated During Manufacture Or Shipping (A1802) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| PACKAGING : INCORRECT PRODUCT | Manufacturing, Packaging Or Shipping Problem (A02) | 1 | 0.0131 | 0 | 0.0000 | 1 | 0.0035 |
| STOCKING : DEVICE NOT AVAILABLE/MISSING | Appropriate Term/Code Not Available (A27) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| 11 – Recon Screw for Medullary Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| 12 – End Cap for Femoral Recon Nail | | | | | | | |
| No complaints detected. | | | | | | | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 6 | 0.0657 | 6 | 0.0527 |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 2 | 0.0886 | 4 | 0.0438 | 6 | 0.0527 |
| CUSTOMER FEEDBACK : DISSATISFACTION | Appropriate Term/Code Not Available (A27) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE  TO DISASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0443 | 0 | 0.0000 | 1 | 0.0088 |
| FUNCTIONAL : FELL APART – UNATTACHED | Detachment Of Device Or Device Component (A0501) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 1 | 0.0443 | 0 | 0.0000 | 1 | 0.0088 |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0613 | 1 | 0.0479 |
| VISUAL : DAMAGED – UNSPECIFIED | Material Integrity Problem (A04) | 1 | 0.2183 | 0 | 0.0000 | 1 | 0.0479 |
| 15 – Endcaps for RFN-ADVANCED | | | | | | | |
| No complaints detected. | | | | | | | |
| 16 – Expert Asian Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 2 | 0.0303 | 0 | 0.0000 | 9 | 0.0228 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 2 | 0.0303 | 0 | 0.0000 | 7 | 0.0177 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 1 | 0.0152 | 0 | 0.0000 | 4 | 0.0101 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 0 | 0.0000 | 0 | 0.0000 | 4 | 0.0101 |
| BROKEN (2+ PIECES) : INTRAOPERATIVELY | Break (A0401) | 0 | 0.0000 | 1 | 0.0270 | 3 | 0.0076 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0270 | 3 | 0.0076 |
| VISUAL : CRACKED | Crack (A0404) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| DEVICE INTERACTION (2+ DEVICES) : WILL NOT LOCK/UNLOCK | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : EMBEDDED DEVICE | Entrapment Of Device (A150208) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 2 | 0.0178 | 0 | 0.0000 | 7 | 0.014 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 2 | 0.0177 | 2 | 0.0040 |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0040 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0040 |
| BROKEN (2+ PIECES) : PREOPERATIVELY | Break (A0401) | 0 | 0.0000 | 1 | 0.0088 | 1 | 0.0020 |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 2 | 0.0743 | 3 | 0.2015 | 13 | 0.0777 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 2 | 0.1343 | 4 | 0.0239 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE/DISASSEMBLE (2+ DEVICES) | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |
| FUNCTIONAL : LOOSE | Device Slipped (A051204) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |
| VISUAL : DAMAGED – UNSPECIFIED | Material Integrity Problem (A04) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0060 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |

#### Complaints by Harm

Table 122 lists the complaints by Harm and Investigation Finding Code (corresponding terminology by the International Medical Device Regulators Forum [IMDRF]). Note: Multiple codes can be chosen per complaint. The sample size (n) captures the total device quantity involved for the reported code.

Table : Femoral Nail Systems Summary of the WW Complaints by Harm

| Harm Breakdown | | Previous Period | | Current Period | | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Complaints by Harm | Investigation Finding (IMDRF Code) | N | Rate (%) | N | Rate (%) | N | Rate (%) |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 8 | 0.0399 | 3 | 0.0182 | 21 | 0.0221 |
| Infection | Infections (E19) Post Operative Wound Infection (E2115) | 1 | 0.0050 | 1 | 0.0061 | 7 | 0.0074 |
| Surgical Delay | Prolonged Surgery (F1908) | 4 | 0.0199 | 1 | 0.0061 | 7 | 0.0074 |
| Bone Fracture Post-op | Bone Fracture(S) (E1603) | 2 | 0.0100 | 2 | 0.0122 | 6 | 0.0063 |
| Bone Damage | Injury (E20) Unspecified Tissue Injury (E2015) | 0 | 0.0000 | 1 | 0.0061 | 2 | 0.0021 |
| Poor Joint Mechanics | Physical Asymmetry (E2332) Procedural Complications (E21) | 2 | 0.0100 | 0 | 0.0000 | 2 | 0.0021 |
| Pain | Pain (E2330) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| Soft Tissue Damage | Impaired Healing (E1707) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0011 |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 1 | 0.0312 | 3 | 0.0156 |
| Surgical Delay | Prolonged Surgery (F1908) | 1 | 0.0241 | 0 | 0.0000 | 2 | 0.0104 |
| Adverse Tissue Reaction | Foreign Body In Patient (E2008) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| Infection | Infections (E19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | | | |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 3 | 0.0459 | 1 | 0.0191 | 8 | 0.0254 |
| Infection | Infections (E19) Post Operative Wound Infection (E2115) Unspecified Infection (E1906) | 2 | 0.0306 | 0 | 0.0000 | 4 | 0.0127 |
| Soft Tissue Damage | Inflammation (E2326) Necrosis (E2327) | 1 | 0.0153 | 0 | 0.0000 | 3 | 0.0095 |
| Device Breakage – Post-Operatively | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| Poor Joint Mechanics | Procedural Complications (E21) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | | | |
| Malunion / Non-Union | Malunion Of Bone (E1617) Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0384 |
| Pain | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0256 |
| Poor Joint Mechanics | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0256 |
| Infection | Infections (E19) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| Surgical Delay | Prolonged Surgery (F1908) | 0 | 0.0000 | 1 | 0.0677 | 1 | 0.0128 |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | | | |
| Poor Joint Mechanics | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| Surgical Delay | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0367 |
| 7 – Expert Lateral Femoral Nail | | | | | | | |
| Malunion / Non-Union | Malunion Of Bone (E1617) Nonunion Bone Fracture (E1625) | 2 | 0.0241 | 0 | 0.0000 | 12 | 0.0241 |
| Pain | Pain (E2330) | 1 | 0.0120 | 1 | 0.0136 | 6 | 0.0120 |
| Infection | Infections (E19) | 1 | 0.0120 | 0 | 0.0000 | 3 | 0.0060 |
| Surgical Delay | Prolonged Surgery (F1908) | 2 | 0.0241 | 0 | 0.0000 | 3 | 0.0060 |
| Bone Fracture Post-op | Bone Fracture(S) (E1603) | 0 | 0.0000 | 1 | 0.0136 | 1 | 0.0020 |
| Device Breakage – Post-Operatively | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| Poor Joint Mechanics | Procedural Complications (E21) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 1 | 0.0128 | 1 | 0.0141 | 4 | 0.0098 |
| Bone Damage | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| Infection | Infections (E19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 1 | 0.0128 | 0 | 0.0000 | 1 | 0.0024 |
| Pain | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| Poor Joint Mechanics | Modified Surgical Procedure (F1906) Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0043 |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| Poor Joint Mechanics | Modified Surgical Procedure (F1906) Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| 10 – Femoral Recon Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 3 | 0.0393 | 5 | 0.0724 | 18 | 0.0625 |
| Malunion / Non-Union | Malunion Of Bone (E1617) Nonunion Bone Fracture (E1625) | 1 | 0.0131 | 4 | 0.0579 | 8 | 0.0278 |
| Poor Joint Mechanics | Ambulation Difficulties (E2302) Joint Laxity (E1615) Modified Surgical Procedure (F1906) Physical Asymmetry (E2332) Procedural Complications (E21) | 0 | 0.0000 | 1 | 0.0145 | 5 | 0.0174 |
| Bone Fracture Post-op | Bone Fracture(S) (E1603) | 1 | 0.0131 | 1 | 0.0145 | 4 | 0.0139 |
| Infection | Infections (E19) | 0 | 0.0000 | 1 | 0.0145 | 3 | 0.0104 |
| Bone Damage | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| Device Breakage – Post-Operatively | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| Pain | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| Discomfort | Discomfort (E2311) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| Neuro-vascular Damage | Fatigue (E2312) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| 11 – Recon Screw for Medullary Nail | | | | | | | |
| Poor Joint Mechanics | Procedural Complications (E21) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| 12 – End Cap for Femoral Recon Nail | | | | | | | |
| No harms reported. | | | | | | | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | | | |
| Malunion / Non-Union | Malunion Of Bone (E1617) Nonunion Bone Fracture (E1625) | 2 | 0.0886 | 6 | 0.0657 | 8 | 0.0702 |
| Infection | Infections (E19) Post Operative Wound Infection (E2115) | 0 | 0.0000 | 5 | 0.0548 | 5 | 0.0439 |
| Device Breakage – Post-Operatively | Failure Of Implant (E2107) | 0 | 0.0000 | 2 | 0.0219 | 2 | 0.0176 |
| Poor Joint Mechanics | Physical Asymmetry (E2332) | 2 | 0.0886 | 0 | 0.0000 | 2 | 0.0176 |
| Soft Tissue Damage | Appropriate Term / Code Not Available (E2402) Hematoma (E0505) Inflammation (E2326) Wound Dehiscence (E2340) | 0 | 0.0000 | 2 | 0.0219 | 2 | 0.0176 |
| Surgical Delay | Prolonged Surgery (F1908) | 2 | 0.0886 | 0 | 0.0000 | 2 | 0.0176 |
| Embolism | Pulmonary Embolism (E050303) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| Pain | Pain (E2330) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 1 | 0.2183 | 0 | 0.0000 | 1 | 0.0479 |
| 15 – Endcaps for RFN-ADVANCED | | | | | | | |
| No harms reported. | | | | | | | |
| 16 – Expert Asian Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 2 | 0.0303 | 1 | 0.0270 | 20 | 0.0506 |
| Malunion / Non-Union | Malunion Of Bone (E1617) Nonunion Bone Fracture (E1625) | 3 | 0.0455 | 1 | 0.0270 | 7 | 0.0177 |
| Poor Joint Mechanics | Procedural Complications (E21) Surgical Intervention (F19) | 0 | 0.0000 | 0 | 0.0000 | 4 | 0.0101 |
| Pain | Pain (E2330) | 0 | 0.0000 | 1 | 0.0270 | 2 | 0.0051 |
| Adverse Tissue Reaction | Foreign Body In Patient (E2008) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| Soft Tissue Damage | Unspecified Tissue Injury (E2015) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 4 | 0.0080 |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 1 | 0.0088 | 2 | 0.0040 |
| Pain | Pain (E2330) | 1 | 0.0089 | 0 | 0.0000 | 2 | 0.0040 |
| Poor Joint Mechanics | Joint Laxity (E1615) Procedural Complications (E21) | 0 | 0.0000 | 1 | 0.0088 | 2 | 0.0040 |
| Bone Damage | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| Bone Fracture Post-op | Bone Fracture(S) (E1603) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| Discomfort | Discomfort (E2311) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| Infection | Infections (E19) | 0 | 0.0000 | 1 | 0.0088 | 1 | 0.0020 |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | | | |
| Surgical Delay | Prolonged Surgery (F1908) | 1 | 0.0371 | 2 | 0.1343 | 11 | 0.0657 |
| Malunion / Non-Union | Nonunion Bone Fracture (E1625) | 1 | 0.0371 | 1 | 0.0672 | 2 | 0.0120 |
| Pain | Pain (E2330) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |
| Poor Joint Mechanics | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0060 |

#### Serious Incidents by Product Experience / Problem Code

Table 123 lists the worldwide serious incidents by Product Experience Code (PEC) and Problem Code (corresponding terminology by the International Medical Device Regulators Forum [IMDRF]). Note: Multiple codes can be chosen per complaint. The sample size (n) captures the total device quantity involved for the reported code.

Table : Femoral Nail Systems Summary of the WW Serious Incidents by Product Experience / Problem Code

| Worldwide Serious Incidents | | Previous Period | | Current Period | | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Complaints by Product Experience Code | Problem Code (IMDRF Code) | n | Rate (%) | n | Rate (%) | n | Rate (%) |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0021 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 2 | 0.0100 | 0 | 0.0000 | 2 | 0.0021 |
| DEVICE INTERACTION (2+ DEVICES) :  MISALIGNMENT | Device-device Incompatibility (A1702) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE  TO ASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : INTRAOPERATIVELY | Break (A0401) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE  TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| FUNCTIONAL : EMBEDDED DEVICE | Entrapment Of Device (A150208) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| FUNCTIONAL : LOOSE | Device Slipped (A051204) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | | | |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 3 | 0.0459 | 0 | 0.0000 | 4 | 0.0127 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0128 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0128 |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 7 – Expert Lateral Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 2 | 0.0241 | 1 | 0.0136 | 6 | 0.0120 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 1 | 0.0120 | 0 | 0.0000 | 2 | 0.0040 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0141 | 1 | 0.0024 |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | | | |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0065 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0104 | 2 | 0.0043 |
| UPON RECEIPT : BURR | Defective Device (A0203) | 0 | 0.0000 | 1 | 0.0104 | 1 | 0.0022 |
| 10 – Femoral Recon Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 2 | 0.0262 | 3 | 0.0434 | 18 | 0.0625 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 0 | 0.0000 | 4 | 0.0139 |
| BROKEN (2+ PIECES) : BROKEN (2+ PIECES) | Break (A0401) | 0 | 0.0000 | 2 | 0.0289 | 2 | 0.0069 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| 11 – Recon Screw for Medullary Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| 12 – End Cap for Femoral Recon Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 6 | 0.0657 | 6 | 0.0527 |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 2 | 0.0886 | 4 | 0.0438 | 6 | 0.0527 |
| FUNCTIONAL : FELL APART – UNATTACHED | Detachment Of Device Or Device Component (A0501) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| USAGE : IMPROPER IMPLANT SELECTION | Use Of Device Problem (A23) | 1 | 0.0443 | 0 | 0.0000 | 1 | 0.0088 |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 15 – Endcaps for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 16 – Expert Asian Femoral Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 1 | 0.0152 | 0 | 0.0000 | 4 | 0.0101 |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0076 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0076 |
| VISUAL : DEFORMED/BENT | Material Deformation (A0406) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : EMBEDDED DEVICE | Entrapment Of Device (A150208) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| USAGE : USE ERROR/MISUSE | Improper Or Incorrect Procedure Or Method (A2303) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS THREADED | Material Twisted / Bent (A040609) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : MISALIGNMENT | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0040 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Difficult To Advance (A150205) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0040 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Break (A0401) | 0 | 0.0000 | 1 | 0.0088 | 1 | 0.0020 |
| FUNCTIONAL : MIGRATION/BACKOUT/PULL-OUT | Migration (A010402) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | | | |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO DISASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 1 | 0.0672 | 2 | 0.0120 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE TO ASSEMBLE | Device-device Incompatibility (A1702) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0060 |
| FUNCTIONAL : LOOSE | Device Slipped (A051204) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |

#### Serious Incidents by Patient Code / Health Effect

Table 124 lists the worldwide serious incidents by Patient Code and Health Effect (corresponding terminology by the International Medical Device Regulators Forum [IMDRF]). Note: Multiple codes can be chosen per complaint. The sample size (n) captures the total device quantity involved for the reported code.

Table : Femoral Nail Systems Summary of the WW Serious Incidents by Patient Code / Health Effect

| Worldwide Serious Incidents | | Previous Period | | Current Period | | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Complaints by Patient Code | Health Effect (IMDRF Code) | n | Rate (%) | n | Rate (%) | n | Rate (%) |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 15 | 0.0747 | 6 | 0.0365 | 36 | 0.0379 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 15 | 0.0747 | 5 | 0.0304 | 35 | 0.0368 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 8 | 0.0399 | 3 | 0.0182 | 20 | 0.0210 |
| FRACTURE | Bone Fracture(S) (E1603) | 2 | 0.0100 | 2 | 0.0122 | 6 | 0.0063 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 1 | 0.0061 | 6 | 0.0063 |
| INJURY | Injury (E20) | 3 | 0.0149 | 0 | 0.0000 | 4 | 0.0042 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0021 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 2 | 0.0100 | 0 | 0.0000 | 2 | 0.0021 |
| DEVICE FAILURE | Procedural Complications (E21) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| INTERNAL INJURY | Injury (E20) | 0 | 0.0000 | 1 | 0.0061 | 1 | 0.0011 |
| LOSS OF ANATOMICAL ALIGNMENT  AFTER FRACTURE REDUCTION | Physical Asymmetry (E2332) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| PAIN | Pain (E2330) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| SERIOUS INJURY | Serious Injury/ Illness/ Impairment (F12) | 0 | 0.0000 | 1 | 0.0061 | 1 | 0.0011 |
| WOUND HEALING DELAYED | Impaired Healing (E1707) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0011 |
| WOUND INFECTION | Post Operative Wound Infection (E2115) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 1 | 0.0241 | 1 | 0.0312 | 6 | 0.0312 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 0 | 0.0000 | 1 | 0.0312 | 5 | 0.0260 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 1 | 0.0312 | 3 | 0.0156 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 1 | 0.0241 | 0 | 0.0000 | 2 | 0.0104 |
| FOREIGN BODY | Foreign Body In Patient (E2008) | 1 | 0.0241 | 0 | 0.0000 | 1 | 0.0052 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | | | |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 7 | 0.1071 | 1 | 0.0191 | 15 | 0.0477 |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 7 | 0.1071 | 1 | 0.0191 | 15 | 0.0477 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 3 | 0.0459 | 1 | 0.0191 | 8 | 0.0254 |
| INFECTION | Infections (E19) | 1 | 0.0153 | 0 | 0.0000 | 3 | 0.0095 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0064 |
| NECROSIS | Necrosis (E2327) | 1 | 0.0153 | 0 | 0.0000 | 2 | 0.0064 |
| DEVICE FAILURE | Procedural Complications (E21) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| IMPLANT FAILURE | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| INFLAMMATION | Inflammation (E2326) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| INJURY | Injury (E20) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| OSTEOMYELITIS | Unspecified Infection (E1906) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0032 |
| WOUND INFECTION | Post Operative Wound Infection (E2115) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 2 | 0.1303 | 0 | 0.0000 | 7 | 0.0897 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 2 | 0.1303 | 0 | 0.0000 | 6 | 0.0769 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0256 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0256 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0256 |
| FRACTURE MALUNION | Malunion Of Bone (E1617) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0128 |
| INFECTION | Infections (E19) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| INJURY | Injury (E20) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | | | |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 7 – Expert Lateral Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 7 | 0.0843 | 2 | 0.0272 | 26 | 0.0522 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 6 | 0.0723 | 2 | 0.0272 | 24 | 0.0482 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 2 | 0.0241 | 0 | 0.0000 | 10 | 0.0201 |
| PAIN | Pain (E2330) | 1 | 0.0120 | 1 | 0.0136 | 6 | 0.0120 |
| INFECTION | Infections (E19) | 1 | 0.0120 | 0 | 0.0000 | 3 | 0.0060 |
| INJURY | Injury (E20) | 3 | 0.0361 | 0 | 0.0000 | 3 | 0.0060 |
| DEVICE FAILURE | Procedural Complications (E21) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| FRACTURE MALUNION | Malunion Of Bone (E1617) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| FRACTURE | Bone Fracture(S) (E1603) | 0 | 0.0000 | 1 | 0.0136 | 1 | 0.0020 |
| IMPLANT FAILURE | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 1 | 0.0128 | 0 | 0.0000 | 4 | 0.0098 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 1 | 0.0128 | 0 | 0.0000 | 3 | 0.0073 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 1 | 0.0141 | 2 | 0.0049 |
| BONE INJURY | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 1 | 0.0128 | 0 | 0.0000 | 1 | 0.0024 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| MODIFIED SURGICAL PROCEDURE | Modified Surgical Procedure (F1906) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 1 | 0.0108 | 0 | 0.0000 | 5 | 0.0108 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 1 | 0.0108 | 0 | 0.0000 | 3 | 0.0065 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| INJURY | Injury (E20) | 1 | 0.0108 | 0 | 0.0000 | 1 | 0.0022 |
| MODIFIED SURGICAL PROCEDURE | Modified Surgical Procedure (F1906) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| 10 – Femoral Recon Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 3 | 0.0393 | 10 | 0.1447 | 39 | 0.1355 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 3 | 0.0393 | 9 | 0.1303 | 28 | 0.0973 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 1 | 0.0145 | 8 | 0.0278 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 1 | 0.0131 | 4 | 0.0579 | 7 | 0.0243 |
| INJURY | Injury (E20) | 2 | 0.0262 | 3 | 0.0434 | 5 | 0.0174 |
| FRACTURE | Bone Fracture(S) (E1603) | 1 | 0.0131 | 1 | 0.0145 | 4 | 0.0139 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0104 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 1 | 0.0145 | 3 | 0.0104 |
| BONE INJURY | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| IMPLANT FAILURE | Failure Of Implant (E2107) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| DISCOMFORT | Discomfort (E2311) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| FRACTURE MALUNION | Malunion Of Bone (E1617) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| JOINT INSTABILITY | Joint Laxity (E1615) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| LOSS OF ANATOMICAL ALIGNMENT  AFTER FRACTURE REDUCTION | Physical Asymmetry (E2332) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| MODIFIED SURGICAL PROCEDURE | Modified Surgical Procedure (F1906) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| SERIOUS INJURY | Serious Injury/ Illness/ Impairment (F12) | 1 | 0.0131 | 0 | 0.0000 | 1 | 0.0035 |
| WALKING DIFFICULTY | Ambulation Difficulties (E2302) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| WEAKNESS | Fatigue (E2312) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| 11 – Recon Screw for Medullary Nail | | | | | | | |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| 12 – End Cap for Femoral Recon Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 4 | 0.1772 | 15 | 0.1643 | 19 | 0.1668 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 3 | 0.1329 | 14 | 0.1533 | 17 | 0.1493 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 1 | 0.0443 | 5 | 0.0548 | 6 | 0.0527 |
| INJURY | Injury (E20) | 1 | 0.0443 | 4 | 0.0438 | 5 | 0.0439 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 4 | 0.0438 | 4 | 0.0351 |
| FRACTURE MALUNION | Malunion Of Bone (E1617) | 1 | 0.0443 | 1 | 0.0110 | 2 | 0.0176 |
| IMPLANT FAILURE | Failure Of Implant (E2107) | 0 | 0.0000 | 2 | 0.0219 | 2 | 0.0176 |
| LOSS OF ANATOMICAL ALIGNMENT  AFTER FRACTURE REDUCTION | Physical Asymmetry (E2332) | 2 | 0.0886 | 0 | 0.0000 | 2 | 0.0176 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 2 | 0.0886 | 0 | 0.0000 | 2 | 0.0176 |
| COMPARTMENT SYNDROME | Appropriate Term / Code Not Available (E2402) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| FRACTURE DELAYED UNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| HEMATOMA | Hematoma (E0505) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| INFLAMMATION | Inflammation (E2326) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| PULMONARY EMBOLISM | Pulmonary Embolism (E050303) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| WOUND DEHISCENCE | Wound Dehiscence (E2340) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| WOUND INFECTION | Post Operative Wound Infection (E2115) | 0 | 0.0000 | 1 | 0.0110 | 1 | 0.0088 |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 15 – Endcaps for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 16 – Expert Asian Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 3 | 0.0455 | 3 | 0.0811 | 15 | 0.0379 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 3 | 0.0455 | 3 | 0.0811 | 9 | 0.0228 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 7 | 0.0177 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 3 | 0.0455 | 1 | 0.0270 | 5 | 0.0126 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0076 |
| FRACTURE MALUNION | Malunion Of Bone (E1617) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 1 | 0.0270 | 2 | 0.0051 |
| FOREIGN BODY | Foreign Body In Patient (E2008) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| INJURY | Injury (E20) | 0 | 0.0000 | 1 | 0.0270 | 1 | 0.0025 |
| SERIOUS INJURY | Serious Injury/ Illness/ Impairment (F12) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| SOFT TISSUE INJURY | Unspecified Tissue Injury (E2015) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| SURGICAL PROCEDURE | Surgical Intervention (F19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 1 | 0.0089 | 3 | 0.0265 | 12 | 0.0240 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 1 | 0.0089 | 3 | 0.0265 | 8 | 0.0160 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0060 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 0 | 0.0000 | 1 | 0.0088 | 2 | 0.0040 |
| PAIN | Pain (E2330) | 1 | 0.0089 | 0 | 0.0000 | 2 | 0.0040 |
| BONE INJURY | Injury (E20) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| DISCOMFORT | Discomfort (E2311) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| FRACTURE | Bone Fracture(S) (E1603) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| INFECTION | Infections (E19) | 0 | 0.0000 | 1 | 0.0088 | 1 | 0.0020 |
| JOINT INSTABILITY | Joint Laxity (E1615) | 0 | 0.0000 | 1 | 0.0088 | 1 | 0.0020 |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | | | |
| SURGICAL INTERVENTION | Surgical Intervention (F19) | 2 | 0.0743 | 3 | 0.2015 | 6 | 0.0359 |
| MEDICAL DEVICE REMOVAL | Device Explantation (F1903) | 2 | 0.0743 | 3 | 0.2015 | 5 | 0.0299 |
| FRACTURE NONUNION | Nonunion Bone Fracture (E1625) | 1 | 0.0371 | 1 | 0.0672 | 2 | 0.0120 |
| INJURY | Injury (E20) | 1 | 0.0371 | 1 | 0.0672 | 2 | 0.0120 |
| SURGERY PROLONGED | Prolonged Surgery (F1908) | 0 | 0.0000 | 1 | 0.0672 | 2 | 0.0120 |
| DEVICE FAILURE | Procedural Complications (E21) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0060 |
| PAIN | Pain (E2330) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |
| SERIOUS INJURY | Serious Injury/ Illness/ Impairment (F12) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0060 |

#### Serious Incidents by Analysis Codes

Table 125 lists the worldwide serious incidents by Analysis Code and Health Effect (corresponding terminology by the International Medical Device Regulators Forum [IMDRF]). Note: Multiple codes can be chosen per complaint. The sample size (n) captures the total device quantity involved for the reported code.

Table : Femoral Nail Systems Summary of the WW Serious Incidents by Analysis Code

| Worldwide Serious Incidents | | Previous Period | | Current Period | | Most Recent 5 Year Period | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Complaints by Analysis Code | Investigation Finding (IMDRF Code) | n | Rate (%) | n | Rate (%) | n | Rate (%) |
| 1 – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 16 | 0.0797 | 5 | 0.0304 | 36 | 0.0379 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 3 | 0.0149 | 1 | 0.0061 | 4 | 0.0042 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 1 | 0.0050 | 0 | 0.0000 | 3 | 0.0032 |
| REPORTED CONDITION NOT CONFIRMED | No Device Problem Found (C19) | 1 | 0.0050 | 2 | 0.0122 | 3 | 0.0032 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 1 | 0.0050 | 0 | 0.0000 | 1 | 0.0011 |
| 2 – Expert End Cap for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 1 | 0.0241 | 1 | 0.0312 | 5 | 0.0260 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 0 | 0.0000 | 1 | 0.0312 | 2 | 0.0104 |
| DEVICE INTERACTION (2+ DEVICES) :  UNABLE TO ASSEMBLE | Device Not Compatible With Another Device (C0403) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0052 |
| 3 – Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 8 | 0.1225 | 1 | 0.0191 | 16 | 0.0509 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 1 | 0.0153 | 1 | 0.0191 | 3 | 0.0095 |
| FUNCTIONAL : MIGRATION/BACKOUT/  PULL-OUT | Device Migration (C0701) | 1 | 0.0153 | 0 | 0.0000 | 1 | 0.0032 |
| 4 – Expert Adolescent Lateral Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 2 | 0.1303 | 0 | 0.0000 | 7 | 0.0897 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 1 | 0.0651 | 0 | 0.0000 | 1 | 0.0128 |
| 5 – Hip Screw for Expert Adolescent Lateral Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0198 |
| 6 – Expert End Cap for Adolescent Lateral Femoral Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 7 – Expert Lateral Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 5 | 0.0602 | 2 | 0.0272 | 22 | 0.0442 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 2 | 0.0241 | 0 | 0.0000 | 3 | 0.0060 |
| VISUAL : DEFORMED/BENT | Stress Problem Identified (C0706) | 1 | 0.0120 | 0 | 0.0000 | 2 | 0.0040 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| USAGE : IMPROPER IMPLANT SELECTION | Operational Problem Identified (C13) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| VISUAL : DISCOLORED/FADING | Material And/Or Chemical Problem Identified (C06) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 1 | 0.0120 | 0 | 0.0000 | 1 | 0.0020 |
| 8 – Hip Screw for Expert Lateral Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 1 | 0.0128 | 1 | 0.0141 | 5 | 0.0122 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| DEVICE INTERACTION (2+ DEVICES) :  MISALIGNMENT | Device Not Compatible With Another Device (C0403) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0024 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 0 | 0.0000 | 1 | 0.0141 | 1 | 0.0024 |
| 9 – Expert End Cap for Lateral Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 1 | 0.0108 | 1 | 0.0104 | 7 | 0.0152 |
| REPORTED CONDITION NOT CONFIRMED | No Device Problem Found (C19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0022 |
| 10 – Femoral Recon Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 4 | 0.0524 | 9 | 0.1303 | 29 | 0.1007 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 0 | 0.0000 | 1 | 0.0145 | 11 | 0.0382 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 0 | 0.0000 | 3 | 0.0104 |
| REPORTED CONDITION NOT CONFIRMED | No Device Problem Found (C19) | 0 | 0.0000 | 1 | 0.0145 | 2 | 0.0069 |
| VISUAL : DEFORMED/BENT | Stress Problem Identified (C0706) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0069 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 0 | 0.0000 | 1 | 0.0145 | 1 | 0.0035 |
| VISUAL : DISCOLORED/FADING | Material And/Or Chemical Problem Identified (C06) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| VISUAL : FOREIGN SUBSTANCE/  DEBRIS/CLEANING/STERILIZATION | Operational Problem Identified (C13) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0035 |
| 11 – Recon Screw for Medullary Nail | | | | | | | |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 0 | N/A | 1 | 0.3546 | 1 | 0.3546 |
| 12 – End Cap for Femoral Recon Nail | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 13 – RFN-ADVANCED Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 5 | 0.2215 | 15 | 0.1643 | 20 | 0.1756 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 0 | 0.0000 | 4 | 0.0438 | 4 | 0.0351 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 1 | 0.0443 | 3 | 0.0329 | 4 | 0.0351 |
| FUNCTIONAL : FELL APART – UNATTACHED | Operational Problem Identified (C13) | 0 | 0.0000 | 2 | 0.0219 | 2 | 0.0176 |
| 14 – Locking Attachment Washer for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 15 – Endcaps for RFN-ADVANCED | | | | | | | |
| No serious incidents reported. | | | | | | | |
| 16 – Expert Asian Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 1 | 0.0152 | 3 | 0.0811 | 10 | 0.0253 |
| BROKEN (2+ PIECES) : POSTOPERATIVELY | Degradation Problem Identified (C0601) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| DEVICE INTERACTION (2+ DEVICES) :  MISALIGNMENT | Device Not Compatible With Another Device (C0403) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| NO DEFECT FOUND | No Device Problem Found (C19) | 1 | 0.0152 | 0 | 0.0000 | 2 | 0.0051 |
| VISUAL : CRACKED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 0 | 0.0000 | 2 | 0.0051 |
| VISUAL : DISCOLORED/FADING | Material And/Or Chemical Problem Identified (C06) | 2 | 0.0303 | 0 | 0.0000 | 2 | 0.0051 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE  TO ASSEMBLE | Device Not Compatible With Another Device (C0403) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : LOOSE | Device Migration (C0701) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| FUNCTIONAL : WILL NOT SEAT/ADVANCE | Mechanical Problem Identified (C07) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| REPORTED CONDITION NOT CONFIRMED | No Device Problem Found (C19) | 1 | 0.0152 | 0 | 0.0000 | 1 | 0.0025 |
| VISUAL : DEFORMED/BENT | Stress Problem Identified (C0706) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0025 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 1 | 0.0152 | 0 | 0.0000 | 1 | 0.0025 |
| 17 – Hip Screw T25 for Asian Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 1 | 0.0089 | 3 | 0.0265 | 9 | 0.0180 |
| DEVICE INTERACTION (2+ DEVICES) :  MISALIGNMENT | Device Not Compatible With Another Device (C0403) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| REPORTED CONDITION NOT CONFIRMED | No Device Problem Found (C19) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| USAGE : USE ERROR/MISUSE | Operational Problem Identified (C13) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS  THREADED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 0 | 0.0000 | 1 | 0.0020 |
| 18 – End Cap for Expert Asian Femoral Nail | | | | | | | |
| PRODUCT NOT RETURNED | No Findings Available (C20) | 0 | 0.0000 | 3 | 0.2015 | 4 | 0.0239 |
| VISUAL : STRIPPED/WORN/TWISTED/CROSS  THREADED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 1 | 0.0672 | 2 | 0.0120 |
| DEVICE INTERACTION (2+ DEVICES) : UNABLE  TO DISASSEMBLE | Device Not Compatible With Another Device (C0403) | 1 | 0.0371 | 0 | 0.0000 | 1 | 0.0060 |
| FUNCTIONAL : LOOSE | Device Migration (C0701) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |
| VISUAL : DISCOLORED/FADING | Material And/Or Chemical Problem Identified (C06) | 1 | 0.0371 | 0 | 0.0000 | 1 | 0.0060 |
| VISUAL : SCRATCHED/NICKED | Mechanical Problem Identified (C07) | 0 | 0.0000 | 1 | 0.0672 | 1 | 0.0060 |

#### Death-Related Events

There were no death-related events for any of the subject devices during the review period.

#### External Vigilance Data

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Section is only applicable if **external similar (Section 3.4) or equivalent (Section 3.8) devices** are referenced in the CER. |
|  |  | Define the external vigilance databases (e.g., MAUDE, MHRA) that were searched and any limitations of those databases. |
|  |  | Indicate the devices or terms searched, the start and end dates of the search, and a justification for review period. |
|  |  | Summarize the results in tabular format and/or narrative summaries.   * Provide detail of any death events in tabular format as well as narrative summaries. * Identify adverse events that have occurred with equivalent device and discuss whether or not these events could occur with the subject device(s). |

External vigilance data is a valuable tool providing evidence of safety signals for external (non-company-owned) devices. Since internal data are available for all company-owned devices, these databases are only utilized when an external device is used as an equivalent comparator. As there are no external devices in scope for this CER, no external vigilance data were utilized.

#### Summary of any Significant Complaints, Trends, or Vigilance for Earlier Device Iteration (If Applicable)

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Briefly summarize any significant complaints, trends, or vigilance issues associated with earlier device iterations (which may be equivalent or similar devices) and whether these have any impact on the clinical evaluation assessment. |

Not Applicable – There are no earlier device iterations (refer to Sections 3.1.1 – 3.1.18) for any Device Groups.

### Actions

#### Corrective and Preventive Actions (CAPAs)

Based on available information via post market surveillance during the overall review period (October 2017 – October 2022), there have been six EU relevant CAPAs initiated that were associated with Femoral Nail Systems, as detailed in Table 126. For further details pertaining to the CAPAs, refer to applicable CAPA file.

Table : Femoral Nail Systems CAPA Summary

| CAPA Number | CAPA Create Date | Type of Action | CAPA Title | CAPA Description | CAPA Status / Closed Date |
| --- | --- | --- | --- | --- | --- |
| CAPA-007687 | 04 January 2018 | Correction; Corrective; Preventive | Kink in Proximal-most Distal Hole after Bending per NR-0084179 | Per NC NR-0084179, the operator performing bend noticed that the bender (M0429) was kinking the proximal-most distal hole during bending, and the holes no longer passed the 5.1 / 5.3 go gage. The operator was able to remove the kinks enough by manually re-bending the parts to allow for the go gage to pass in the distal hole, but the kink mark on the sides of the holes remained. The NC was reviewed by CRB on December 19, 2017 and a CAPA has been determined to be warranted as the detection method for this defect is not robust. The required condition is that the proximal-most distal hole to be within spec of 5.1/5.3 and free from kinks. | 04 September 2018 |
| CAPA-007818 | 27 February 2018 | Correction; Corrective | NR-0091716: Chip on outer surface of Femoral Recon Nail | On 22.Feb.2018, during a form fit and function (FFF) review per W-C-S015 Form, Fit and Function Process, Markus B ttler, Staff Engineer (WWID: 410489), discovered a chip on the outer surface of the shaft area of the device (PART 04.033.040S, LOT L756523, Fem Recon Nail PF 10 r L400 TAN). Where: R&D Nails Actual Condition: Chip on outer surface of nail. Required Condition: No chips are accepted (SE\_371275 Visual Acceptance Standards Finishing / Final Inspection). | 14 May 2019 |
| CAPA-007913 | 23 March 2018 | Correction; Corrective | Complaint#PC-0000132512: Expert A2FN nail, PN#04.009.453S with distal holes in wrong position | On February 27, 2018 it was notified to Mezzovico plant the customer complaint#PC-0000132512: during surgery for femoral diaphyseal fracture performed using one piece of Expert A2FN Nail 11 le cann L360 TAN li, PN#04.009.453S, lot#L397633, lot q.ty #3, the calibration Pins could not be inserted to the distal holes of the Nail 11mm-360mm. Three distal screw holes are located approx.10 degrees and translates of 2.2mm backward from the original position. Required condition: distal screw holes positioned according drawing SE\_154690 rev.B; Actual condition: Three distal screw holes are located approx.10 degrees backward from the original position. On March 7, 2018 the NC#NR-0093184 was opened to manage the immediate actions. | 28 March 2019 |
| CAPA-008556 | 30 August 2018 | Corrective; Correction | Printed Labels missing digit on the GTIN # | This CAPA stems from NR-0101781 On 2-July-2018, a Labeling Project Lead noticed while performing label review that the 14th digit of the GTIN "human readable" number on some printed labels was missing due to a decreased barcode scale relative to the font size. The label was compared to its associated Label Master Document (LMD) and did not match. Require Condition: Per 103420434 Printing Labels in Prysm360, printed label information must match the LMD proof. See example in attachment "NR-0101781 GTIN Missing Digit.pdf". Actual Condition: Discrepancy of GTIN # on printed label and the approved master label document. Barcode on printed label contains all 14 digits of GTIN and scans correctly. The issue was escalated to the field action team for investigation as documented in Product Issue Assessment (PIA) # 1250778. The field action team determined that the non-conformance did not affect the design, form, fit or function of the devices, that the safety and efficacy of the product are not compromised and therefore determined that the affected product was "use as is." | 03 December 2019 |
| CAPA-009137 | 09 May 2019 | Corrective; Correction | Total Organic Carbon of final cleaning water above specification | At 28.03.2019 it was found by Johnson and Johnson laboratory Cilag AG that acceptance criteria for Total Organic Carbon (TOC) were not fulfilled at sample points Use Point (UP) 3 and Process Point (PP) 4 of DePuy Synthes Tuttlingen site: Required condition: W-G-S236 Rev. 7 requires TOC values of final cleaning water to be below 500 ppb. Actual condition: TOC values from 27.03.2019 were found to be 951 ppb for UP3 and 1170 ppb for PP4 (see QI-1468205). NR-0121256 was started for this initial deviation. 2 further TOC measurements (see QI-1473540, QI-1495316) after confirmation of initial deviation were tested and found outside the tolerance. Based on that a trend has been identified and it has been decided to start this CAPA to investigate the root-cause(s) and define corrective and/or preventive actions. | 11 May 2020 |
| CAPA-009155 | 21 May 2019 | Corrective | LFN Label Release Issue | On 04/26/19 the effectiveness action EM-016422 for CAPA-007367 performed by DePuy Synthes Manager of Label Design was deemed not effective - there were 19 Windchill change notifications with a delay between the release of the label record in Windchill PLM system and the Synthes US Label Print System (Prisym360). This CAPA-009155 is being opened to re-investigate the issue and create additional actions. CRB conducted on 7/2/2019 - see attached "W-J-S012 Attachment 5\_Rev 11\_CAPA-009155 Phase 1 CRB Meeting Minutes.pdf" For reference CAPA-007367 Description: On 08/18/17 at Monument Distribution Center site, during the label generate operation a Senior Packager in the Nails Packaging Department found one order of LFN nails that the LPPF and labels did not match. The Labels contained the statement "If plastic overwrap not present do not use". This statement is not on the LPPF label. Stop Shipment: 2017054 was initiated as a result of confirming that all label records on ADAPTIV Change Order 103339667 were not released in the Synthes US Label Print System Prisymedica to production status by the West Chester Label Designer at the time the CO was Released and LPPF document released. CO 103309363 was released on 8/18/17 as a process improvement to update label change process with creation of LPPF CA/CO Process work instruction 103316642 to utilize a task in ADAPTIV to formalize release of the label record in the US Synthes Label Print System Prisymedica. | 08 July 2020 |

#### Field Actions (Field Safety Notices [FSNs] or Field Safety Corrective Actions [FSCAs])

One field action (FSN) relevant to the EU were identified pertaining to Expert Asian Femoral Nail (Device Group #16) during the review period, as detailed in Table 127.

Table : Expert Asian Femoral Nail System (System #6) Field Actions and Recall Summary

| Field Action Type | Field Action Number | Date of Field Action | Impacted Countries | Field Action Details | Summary of Actions Taken | Related CAPA | Status / Disposition |
| --- | --- | --- | --- | --- | --- | --- | --- |
| FSN | 1129891 | 27 February 2018 | Malaysia, Taiwan | DePuy Synthes is initiating a medical device recall for the affected part numbers of the Expert A2FN Nails. An internal inspection identified an out of specification thread depth in the Expert A2FN Nails that may result in an incomplete connection to the aiming arm during nail insertion. | Product Recalled | CAPA-007805 | Closed |

## Ongoing or Completed Post-Market Clinical Follow-Up (PMCF)

Five PMCF activities related to the subject devices are ongoing and six PMCF activities pertaining to the subject devices have been completed, as summarized in Section 6.2.1 – 6.2.11. For further details pertaining to the PMCF activities, refer to referenced supporting documents.

### PMCF Activity / RWE – Evaluation of Healthcare Outcomes Following Treatment of Distal Femur and Femoral Shaft Fracture Utilizing the DePuy Synthes Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

Table : Summary of PMCF Activity / RWE – Evaluation of Healthcare Outcomes Following Treatment of Distal Femur and Femoral Shaft Fracture Utilizing the DePuy Synthes Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Document Number: | Adaptiv 10083084 | | | | | | |
| Corresponding Activity Number in PMCF Plan: | * N/A – Predated in the first PMCF Plan | | | | | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | | | | | |
| Type of PMCF Activity: | Real World Evidence | | | | | | |
| Devices Included: | Subject Devices: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | | | |
| Patient Population Demographics: | Variables | Overall | | Synthes | | Unspecified\* | |
| N | % | N | % | N | % |
| All | 2,617 | 100% | 1,451 | 100% | 1,166 | 100% |
| **Sex** | | | | | | |
| Female | 1,165 | 44.5% | 614 | 42.3% | 551 | 47.3% |
| Male | 1,452 | 55.5% | 837 | 57.7% | 615 | 52.7% |
| Age | | | | | | |
| 0-18 years | 188 | 7.2% | 116 | 8.0% | 72 | 6.2% |
| 19-64 years | 1,708 | 65.3% | 959 | 66.1% | 749 | 64.2% |
| 65+ years | 721 | 27.6% | 376 | 25.9% | 345 | 29.6% |
|  | | | | | | |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| Fracture Type | | | | | | |
| Distal Femur | 757 | 28.9% | 427 | 29.4% | 330 | 28.3% |
| Femoral Shaft | 1,980 | 75.7% | 1,104 | 76.1% | 876 | 75.1% |
| Clinical Characteristics | | | | | | |
| Periprosthetic Fracture (PPFx) | 42 | 1.6% | 17 | 1.2% | 25 | 2.1% |
| Ipsilateral Shaft/Distal Femur Fx | 105 | 4.0% | 69 | 4.8% | 36 | 3.1% |
| Ipsilateral Femur/Tibia Fx | 277 | 10.6% | 164 | 11.3% | 113 | 9.7% |
| Polytrauma | 1,846 | 70.5% | 1,085 | 74.8% | 761 | 65.3% |
| Osteoporosis | 174 | 6.6% | 98 | 6.8% | 76 | 6.5% |
| Obesity | 199 | 7.6% | 104 | 7.2% | 95 | 8.1% |
| Malunion at index | 2 | 0.1% | 2 | 0.1% | 0 | 0.0% |
| Nonunion at index | 26 | 1.0% | 10 | 0.7% | 16 | 1.4% |
| \*Note: Patients implanted with a Expert R/AFN that could not be attributed to Synthes (Unspecified manufacturer) were included as a comparator group. | | | | | | |
| Patient Numbers: | 2,617 | | | | | | |
| Intent of PMCF Activity: | General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | | | | | |
| Objectives and Endpoints: | Objectives:   * Among patients who are implanted with the Expert R/AFN System for treatment of a distal femur or femoral shaft fracture: * Estimate the 90-day and 12-month cumulative incidence of subsequent surgery, nonunion, and malunion stratified by Synthes and Unspecified retrograde/antegrade femoral nails * Describe the patient demographic characteristics * Describe the patient clinical characteristics * Among patients who were implanted with the Expert R/AFN System for treatment of a distal femur or femoral shaft fracture, for whom there is also evidence of prior TKR on the same side as the fracture (to assess periprosthetic usage): * Estimate the 90-day and 12-month cumulative incidence of subsequent surgery, nonunion, and malunion stratified by Synthes and Unspecified retrograde/antegrade femoral nails. * Describe the patient demographic characteristics * Describe the patient clinical characteristics   Endpoints:   * Subsequent surgery at 90 days and 12 months. * Post-operative nonunion from the index procedure to 12 months post-operative. * Post-operative malunion from the index procedure to 12 months post-operative. | | | | | | |
| Inclusion Criteria: | * Treatment between January 1, 2004 and September 30, 2019 * Billing charge for a Synthes Expert R/AFN System or Unspecified retrograde/antegrade nail manufacturer * Procedure for surgical repair of a distal femur or femoral shaft fracture during index surgical episode. * Diagnosis with a distal femur or femoral shaft fracture during index surgical episode. * Hospital had continuous participation in the Healthcare Database for 12-months post index surgery. | | | | | | |
| Exclusion Criteria: | * The surgical facility did not contribute to the Healthcare Database continuously for 12 months following the index surgery date * Patients with surgery dates after Q3 2018 * Unknown patient age or sex | | | | | | |
| Length of Follow-up and Intervals: | 12 months | | | | | | |
| PMCF Activity location(s) & Transferability to EU: | * United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | | | | | |
| PMCF Activity Status: | Completed | | | | | | |
| Key Performance Outcomes with Included Data: | Not Reported | | | | | | |
| Summary of Other Performance Outcomes: | Not Reported | | | | | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Rate (%)\* | | Nonunion at 12 months | Overall: 3.3% (48/1,451) – 3.6% (42/1,166)  PPFx Subpopulation: 5.9% (1/17) – 4.0% (1/25) | | Subsequent surgery\*\* (including Revision at 12 months) | Overall: 2.6% (38/1,451) – 4.5% (53/1,166)  PPFx Subpopulation: 5.9% (1/17) – 8.0% (2/25) | | \*Note: The overall ranges provided in the above table include any device identified as “Expert R/AFN” regardless of whether the manufacturer will be specified or not.  \*\*Note: Subsequent surgery, defined as the patient returning after their index surgery for an additional femur fracture repair surgery or hardware removal procedure, on the same side as the index surgery. | | | | | | | | |
| Summary of Other Safety Outcomes: | * Malunion at 12 months * Overall: 0.3% (4/1,451) – 0.3% (4/1,166) * PPFx Subpopulation: 0.0% (0/17) – 0.0% (0/25) | | | | | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | | | | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | | | | | |
| Death Events and Corresponding Details: | No deaths reported | | | | | | |
| Activity Limitations: | Other:   * This was a retrospective observational cohort study without randomization. The study collected limited patient demographics and patient comorbidities; thus, all potential confounders could not be controlled in the analyses. * Patients who had a diagnosis code for nonunion or malunion at the time of their index procedure could be mis-specified as having nonunion or malunion later if that diagnosis code was carried forward. This could lead to overestimation of nonunion or malunion outcomes. * In this study, a US population was used to estimate on-label uses of DePuy Synthes Expert R/AFNs for an EU population. This study is generalizable to the EU population because the surgical and clinical practices of patients receiving this procedure are consistent across the US and EU populations. * ICD 9 codes do not include left or right designations; co-occurring femur/tibia fractures and co-occurring shaft/distal fractures based on ICD-9 diagnosis codes were assumed to be ipsilateral. The same assumption was utilized for ICD 10 codes where the side was designated as “unspecified”. The application of these assumptions may have resulted in an overestimation of these characteristics. * The Healthcare Database represents data from 970 hospitals around the US but are not a random selection of US hospitals and hospital outpatient procedures are underrepresented in the database. Although the database represents all regions and most payers, this characteristic of the database may affect the generalizability of the study results. * The search strategy designed in this study may have underestimated the prevalence of products in the database if the search strategy missed any incorrectly coded entries for target devices such as misspellings. * The Healthcare Database is not a longitudinal patient database; rather, it is a longitudinal hospital database for the duration of continuous participation for each institution. Patients who receive care at another hospital, even within the Healthcare Database, will be represented as a new patient. * Misclassifications due to the secondary use of billing data may have led to under or overestimation of cohort size and the variables summarized in this study. | | | | | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | None | | | | | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | No elevated risk of subsequent surgery, nonunion or malunion was identified among patients implanted with Expert R/AFN Systemin this RWD study. | | | | | | |

### PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

Table : Summary of PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Windchill #0000311162 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500445872 * General PMCF Activity #: 2 | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | |
| Patient Population Demographics: | Variable | Group (N = 179) | |
| Age (At time of surgery, yrs) | Mean (SD) | 36 (16) |
| Median | 31 |
| Min, Max | 16, 85 |
| Gender, n (%) | Female | 69 (39) |
| Male | 110 (61) |
| Approach\* n (%) | Retrograde | 127 (70) |
| Antegrade | 55 (30) |
| Fracture classification\* n (%) | Extraarticular fractures that involve the femoral metaphysis and/or the femoral diaphysis | 163 (90) |
| Intraarticular fractures that involve the femoral metaphysis and/or the femoral diaphysis | 2 (1) |
| Subtrochanteric | 2 (1) |
| Segmental Fractures | |
| Combination Femoral shaft and femoral neck, or intertrochanteric femur | 9 (5) |
| Segmental femoral shaft | 2 (1) |
| Combination, segmental femoral shaft with basicervical neck fracture | 1 (0.5) |
| Combination segmental femoral shaft with pertrochanteric femoral fracture | 1 (0.5) |
| Combination segmental femoral shaft with proximal and distal components | 1 (0.5) |
| Supracondylar femur with impending femoral neck fracture | 1 (0.5) |
| \*total of 182 includes 3 bilateral cases | | |
| Patient Numbers: | 179 patients (182 fractures) | | |
| Intent of PMCF Activity: | General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  A data provision agreement was pursued in order to generate data to be considered as part of the overall clinical evaluation and post-marketing safety and surveillance of the Expert R/AFN System. The data collected is intended to supplement the available literature and on-going clinical activities.  Endpoints:   * Preoperative * Patient demographics (age at time of surgery and gender) * Indication * Fracture Classification * Operative * Surgical Technique- Approach * Implants utilized, including supplemental fixation, if any * Intra-Operative complications, related to the device or procedure * Postoperative * Duration of follow-up * Radiographic union status * Time to union * Post-Operative complications, related to the device or procedure * Reoperations/Removal | | |
| Inclusion Criteria: | * Treatment with the Expert R/AFN System between November 2017 and December 2019 * Patients with either 6 months of follow up or evidence of healing | | |
| Exclusion Criteria: | * Treatment using other than the Expert R/AFN System. * Patients without the required follow up or who had not healed. | | |
| Length of Follow-up and Intervals: | Mean, SD, (Range): 7 ± 6 months (1 – 36) | | |
| PMCF Activity location(s) & Transferability to EU: | * Mississippi, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 93% (170/182) | |  | | | | |
| Summary of Other Performance Outcomes: | * Time to Union (average): 3 ± 2 months (range, 1-15) | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 0% (0/182) | | Nonunion | 0% (0/182) | | Revision | 0% (0/182) | | \*Note: The reported key safety outcomes in the above table are complications related to the device (nail, end cap, and spiral blade) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: * Fat Embolism Syndrome: 0.5% (1/182) * Displacement of segmental fracture fragment: 0.5% (1/182) * Postoperative Complications (non-device related): * Nonunion: 4% (8/182) * Infection: 2% (4/182) * Heterotopic Ossification: 1.6% (3/182) * Knee stiffness: 1.6% (3/182) * Peri-implant fracture: 0.5% (1/182) * Other: 6% (12/182); 4 pulmonary embolisms, 2 urinary tract infections, and one each of the following: postoperative rotational deformity, deep vein thrombosis, failed femoral neck fracture, limited hip motion, knee contracture, and missed femoral neck fracture * Postoperative Complications (device related): * Hardware prominence: 1% (2/182) requiring removal of screws (not in scope of this CER) * Reoperation: 19 patients underwent 20 reoperations * Reoperation not due to postoperative complication: 2 reoperations * Reoperation due to postoperative complication: 18 reoperations | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No death reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | Overall Device-Related Complications: 2 (hardware prominence of distal interlocking screws (not in scope of this CER) and required reoperations to remove the screws). | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | One hundred eighty-two fractures were treated with an Expert R/AFN System in 179 patients, primarily via the retrograde approach 127/182 (70%) and most often for the treatment of polytrauma, followed by isolated femoral shaft and supracondylar fractures with intraarticular extension. Two device related complications were reported, both of which were hardware prominence of distal interlocking screws and required reoperations to remove the screws. The most frequent post-operative complication was non-union 4%, following by infection 2%, heterotopic ossification 1.6% which were non-device related. Ninety-three percent of fractures healed, and the average time to union was 3 months.  The data set provided for patients treated with the Expert R/AFN System provides information to show that the product performs as intended and that there are no safety signals. | | |

### PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

Table : Summary of PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Windchill #0000311164 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500445872 * General PMCF Activity #: 3 | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | |
| Patient Population Demographics: | Variable | Group (N = 65) | |
| Age (At time of surgery, years) | Mean (SD) | 36 (16) |
| Median | 32 |
| Min, Max | 18, 87 |
| Gender, n (%) | Female | 16 (25) |
| Male | 49 (75) |
| Fracture Type (n)\* | Distal Femur | 14 |
| Femoral Shaft | 53 |
| \*total of 67 includes 3 bilateral cases | | |
| Patient Numbers: | 65 patients (68 bones) | | |
| Intent of PMCF Activity: | General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  A data provision agreement was pursued in order to generate data to be considered as part of the overall clinical evaluation and post-marketing safety and surveillance of the Expert R/AFN System. The data collected is intended to supplement the available literature and on-going clinical activities.  Endpoints:   * Preoperative * Patient demographics (age at time of surgery and gender) * Indication * Fracture Classification * Operative * Surgical Technique- Approach * Implants utilized, including supplemental fixation, if any * Intra-Operative complications, related to the device or procedure * Postoperative * Duration of follow-up * Radiographic union * Time to Union * Post-Operative complications, related to the device or procedure * Reoperations/Removal of fixation device | | |
| Inclusion Criteria: | * Treatment with the Expert R/AFN System, via the retrograde approach between 01 January 2015 to 31 December 2019 * Patients who had either 6 months of follow up or evidence of healing | | |
| Exclusion Criteria: | * Treatment using other than the Expert R/AFN System via the retrograde approach. * Patients without the required follow up or who had not healed. | | |
| Length of Follow-up and Intervals: | Mean (Range): 263 days (19 – 1072) | | |
| PMCF Activity location(s) & Transferability to EU: | * Pennsylvania, , United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 93% (63/68) | |  | | | | |
| Summary of Other Performance Outcomes: | * Time to union (average): 135 days with a range of 50-366 days | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome | Rate (%) | | Infection | 0% (0/68) | | Nonunion | 0% (0/68) | | Revision | 0% (0/68) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, end cap, and spiral blade) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: * Reintubation: 1.5% (1/68) * Bronchospasm: 1.5% (1/68) * Postoperative Complications (non-device related): * Deep Vein Thrombosis: 5.6% (4/68) * Pulmonary Embolism: 2.9% (2/68) * Infection: 2.9% (2/68) * Malunion: 1.5% (1/68) * Nonunion: 2.9% (2/68) * Other: 5.7% (4/68); one case each of fat emboli syndrome, callous overgrowth over the posterolateral mid-thigh, knee stiffness, and quadricepsplasty with heterotopic ossification of the femur * Postoperative Complications (device related): 0 events * Reoperations: 9% (6/65) patients | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | None | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Sixty eight bones were implanted with an Expert R/AFN System in 65 patients via the retrograde approach. No patients experienced a device related complication. Ninety-three percent of bones had a fracture union, and the average time to union was 135 days. The most frequent post-operative complication (non-device related) was deep vein thrombosis, which occurred in 4% of bones treated, followed by pulmonary embolism, infection and non-union, which each occurred in approximately 3% of bones treated. Only two patients underwent reoperations that were considered by the investigator to be post-operative complications: one went on to union and one did not.  The data set provided for patients treated with the Expert R/AFN System provides information to show that the product performs as intended and that there are no safety signals. | | |

### PMCF Activity / DUA – Summary of Retrospective Data Collection for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

Table : Summary of PMCF Activity / DUA – Summary of Retrospective Data Collection for Patients Treated with the Expert Retrograde/Antegrade Femoral Nail (Device Group 1)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Windchill #0000311163 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500445872 * General PMCF Activity #: 4 | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | |
| Patient Population Demographics: | Variable | Group (N=59) | |
| Age (At time of surgery, years) | Mean (SD) | 35 (16) |
| Median | 30 |
| Min, Max | 18, 77 |
| Gender, n (%) | Female | 26 (44%) |
| Male | 33 (56%) |
| Approach\* n (%) | Retrograde | 59 (97%) |
| Antegrade | 2 (3%) |
| Type of fracture\* n (%) | Open | 48 (79%) |
| Closed | 13 (21%) |
| Fracture classification\* n (%) | Extraarticular fractures that involve the femoral metaphysis and/or the femoral diaphysis | 52 (85.2%) |
| Intraarticular fractures that involve the femoral metaphysis and/or the femoral diaphysis | 5 (8.2%) |
| Subtrochanteric proximal femur fracture | 2 (3.3%) |
| Proximal femur, medial femoral condyle | 1 (1.6%) |
| Segmental femur fracture | 1 (1.6%) |
| \*total of 61 includes 2 bilateral cases | | |
| Patient Numbers: | 59 patients (61 fractures) | | |
| Intent of PMCF Activity: | General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  A data provision agreement was pursued in order to generate data to be considered as part of the overall clinical evaluation and post-marketing safety and surveillance of the Expert R/AFN System. The data collected is intended to supplement the available literature and on-going clinical activities.  Endpoints:   * Preoperative * Patient demographics (age at time of surgery and gender) * Indication * Fracture Classification * Operative * Surgical Technique – Approach (i.e., Retrograde or Antegrade for Nails) * Implants utilized, including supplemental fixation, if any * Intra-Operative complications, related to the device or procedure * Postoperative * Duration of follow-up * Healing status/radiographic outcomes at final follow-up (ex. Union rate) * Post-Operative complications, related to the device * Reoperations/Removal of fixation device | | |
| Inclusion Criteria: | * Treatment with the Expert R/AFN System between July 2016 and June 2018 * Patients who had either 6 months of follow up or evidence of healing | | |
| Exclusion Criteria: | * Treatment using other than the Expert R/AFN System. * Patients without the required follow up or who had not healed. | | |
| Length of Follow-up and Intervals: | Mean, SD (Range): 14 ± 9 months (2 – 44) | | |
| PMCF Activity location(s) & Transferability to EU: | * Virginia, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 95% (58/61) | |  | | | | |
| Summary of Other Performance Outcomes: | * Time to union (average): 6 ± 3 months (range, 2-19) | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 0.0% (0/61) | | Nonunion | 4.9% (3/61) | | Revision | 0.0% (0/61) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, end cap, and spiral blade) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: 0 events * Postoperative Complications (non-device related): 3 cases of arthrofibrosis, 1 case of delayed union, and 4 cases of other (one case each of Iliotibial (IT) band syndrome, irrigation, and debridement of an infected Morel-Lavallee injury with hematoma, peroneal nerve paresthesia, and a post-traumatic osteoarthritis) * Postoperative Complications (device related): * Requiring reoperations: 3 were related to prominent screws, 1 was related to arthrofibrosis and 2 were related to knee pain. * Not requiring reoperations: 2 reports of knee pain, one of which included cicatrix formation at the end of the nail and 2 reports of screw loosening\*. * Reoperations: 11 events * Related to postoperative complication: 51% (9/61) * Unrelated to postoperative complications: 3.3% (2/61)   \*Note: The reports of screw loosening were the patients who were not included in the rest of the PMCF study report because they did not meet inclusion criteria, as both were lost to follow up at 3 months, and healing was unknown. | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | Overall Device Related Complications: 13 complications   * Requiring reoperations: * 3 complications were related to prominent screws, of which, screw (not in scope of this CER) was removed for one event * 1 was related to arthrofibrosis * 2 were related to knee pain, of which distal locking screws (not in scope of this CER) were removed in both events * Not requiring reoperations: 3 nonunions, 2 reports of knee pain, one of which included cicatrix formation at the end of the nail and 2 reports of screw loosening. | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Sixty one fractures were treated with an Expert R/AFN System in 59 patients, primarily via the retrograde approach 59/61 (97%) and most often for the treatment of extraarticular fractures that involved the femoral metaphysis and/or the femoral diaphysis; 34/61 (56%). Thirteen device related complications were reported, 6 of which required reoperations. Of the 6 device related events requiring reoperation, 3 were related to prominent screws, 1 was related to arthrofibrosis and 2 were related to knee pain. Three non-unions were reported. Of the 3 nonunions 2 patients were lost to follow-up and in the last case, the patient was a paraplegic, did not walk and had no pain. The patient was asymptomatic and following discussion no further intervention was undertaken. Ninety-five percent of fractures healed, and the average time to union was 6 months.  The data set provided for patients treated with the Expert R/AFN System provides information to show that the product performs as intended and that there are no safety signals. | | |

### PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail (Device Groups 4, 7, and 10)

Table : Summary of PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail (Device Groups 4, 7, and 10)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Document Number: | Windchill #0000317835 | | | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500577392 * General PMCF Activity #: 1 | | | | |
| * PMCF Plan #: 500566412 * General PMCF Activity #: 2 | | | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | | | |
| Type of PMCF Activity: | Retrospective Chart Review | | | | |
| Devices Included: | Subject Devices:   * Expert Adolescent Lateral Femoral Nail (Expert ALFN) System * Expert Lateral Femoral Nail (Expert LFN) System   Femoral Recon Nailing (FRN) System | | | | |
| Patient Population Demographics: | Variable | | Expert LFN System  (N = 219) | Expert ALFN System  (N= 56) | FRN System (N=25) |
| Age (At time of surgery, years) | Mean (SD) | 37.5 (15.6) | 17.7 (11.6) | 34.8 (13.7) |
| Median | 33 | 15 | 31 |
| Min, Max | 14, 81 | 10, 83\*\*\* | 18, 76 |
| Gender, n (%) | Female | 53 (24.2%) | 25 (44.6%) | 4 (16.0%) |
| Male | 166 (75.8%) | 31 (55.4%) | 21 (84.0%) |
| Smoking status, n (%) | Current Smoker | 68 (31.0%) | 7 (12.5%) | 5 (20.0%) |
| Former Smoker | 33 (15.1%) | 1 (1.8%) | 9 (36.0%) |
| Never Smoked | 118 (53.9%) | 48 (85.7%) | 11 (44.0%) |
| Comorbidities\* | Diabetes | 21 | 3 | 0 |
| Osteoporosis | 19 | 2 | 2 |
| Polytrauma | 25 | 13 | 8 |
| Alcohol Use | 4 | 1 | 1 |
| THC/Drug Use | 8 | 2 | 1 |
| Obesity | 7 | 2 | 0 |
| Hypertension | 16 | 0 | 0 |
| Chronic Obstructive Pulmonary Disease | 1 | 0 | 1 |
| Hypersensitivity Lung Disease | 9 | 0 | 0 |
| Coronary Artery Disease | 3 | 0 | 0 |
| Cancer | 5 | 0 | 1 |
| Other | 23 | 2 | 4 |
| Fracture classification | Shaft fracture | 212\*\* | 52 | 25 |
| Neck fracture | 0 | 1 | 0 |
| Neck/Shaft combination fracture | 4 | 0 | 0 |
| N/A | 4 | 3 | 0 |
| Locking mechanism | Standard locking | 20 | 35 | 0 |
| Recon locking | 200\*\* | 21 | 25 |
| \*Patients may have presented with more than one comorbidity.  \*\*Includes 1 bilateral case  \*\*\* 83 year-old patient implanted with ALFN was described as a small stature adult | | | | |
| Patient Numbers: | * ALFN: 56 patients (56 fractures) * LFN: 219 patients (220 fractures) * FRN: 25 patients (25 fractures) | | | | |
| Intent of PMCF Activity: | General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | | | |
| Objectives and Endpoints: | Objectives:  A data provision agreement was pursued in order to generate data to be considered as part of the overall clinical evaluation and post-marketing safety and surveillance of these femoral nailing systems. The data collected is intended to supplement the available literature and on-going clinical activities.  Endpoints:  The data included both safety and performance information and patients were followed for at least 9 months, or until healing, in order to cover the therapeutic lifetime of the subject devices. | | | | |
| Inclusion Criteria: | * Treated with Expert LFN System, Expert ALFN System, or FRN System between January 2014 and October 2021 * Patients who had either 9 months of follow up or evidence of healing | | | | |
| Exclusion Criteria: | * Treatment using other than Expert ALFN System, Expert LFN System or FRN System for treatment of femoral shaft fractures. * Patients without the required follow up or who had not healed | | | | |
| Length of Follow-up and Intervals: | Mean (Range):   * Expert ALFN System: 5.5 months (1.5 – 36) * Expert LFN System: 5.5 months (1 – 18) * FRN System: 4.5 months (3 – 9) | | | | |
| PMCF Activity location(s) & Transferability to EU: | * Michigan, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | | | |
| PMCF Activity Status: | Completed | | | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome for Expert ALFN System | Mean (%) | | Bone Union | 100% (56/56) | |  | | | | | | |
| |  |  | | --- | --- | | Key Performance Outcome for Expert LFN System | Mean (%) | | Bone Union | 98.6% (217/220) | |  | | | | | | |
| |  |  | | --- | --- | | Key Performance Outcome for FRN System | Mean (%) | | Bone Union | 100% (25/25) | |  | | | | | | |
| Summary of Other Performance Outcomes: | * Time to Union (Average): * For Expert ALFN System: 3.2 ± 1.1 months (range, 1.5-7) * For Expert LFN System: 3.9 ± 1.5 months (range, 1.5-10) * For FRN System: 3.7 ± 1.4 months (range, 1.5-8) * Return to work/activities (Average): * For Expert ALFN System: 3.2 ± 1.4 months (range, 1.5-9) * For Expert LFN System: 4.7 ± 2.9 months (range, 1.5-18) * For FRN System: 3.5 ± 1.5 months (range, 0.5-8) | | | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome for Expert ALFN System\* | Rate (%) | | Infection | 0% (0/56) | | Nonunion | 0% (0/56) | | Revision | 3.6% (2/56)\*\*† | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, hip screws, and end caps) in scope. An analysis of overall complications is listed in the below row.  \*\*Note: There was one case of fracture instability/shortening complication which required a revision to the fracture fixation by removing the broken screw. The study did not clearly state whether the broken screw is a locking screw or a hip screw. Hence, this event is considered under key safety outcome, revision. There was another case of planned hardware removal since the patient experienced discomfort and could feel the screw. The study did not clearly state whether the screw removed is a locking screw or a hip screw. Hence, this event is considered under key safety outcome, revision.  †Note: There was one case of broken distal interlock leading to screw removal, another case of pain at distal interlock leading to screw removal, and another case of harware prominence leading to removal of distal screw. However, these three device-related events were not considered under the key safety outcome, revision, because the revision/removal has occurred to the distal locking screws, which is not in scope of this CER. | | | | | | |
| |  |  | | --- | --- | | Key Safety Outcome for Expert LFN System\* | Rate (%) | | Infection | 0% (0/219) | | Nonunion | 0.5% (1/219) | | Revision | 0.5% (1/219) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, hip screws, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | | | |
| |  |  | | --- | --- | | Key Safety Outcome for FRN System\* | Rate (%) | | Infection | 0% (0/25) | | Nonunion | 0% (0/25) | | Revision | 0% (0/25) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, recon screws, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: 15 complications in 13 patients * In Expert ALFN group: 1 patient (1 case of difficult reduction) * In Expert LFN group: 9 patients (11 complications; 6 cases of difficult reduction, 2 cases of difficult airway, 1 case of small fat emboli, 1 case of high estimated blood loss, and 1 case of extensive washout of open wound) * In FRN group: 3 patients (2 cases of difficult reduction and 1 case of gunshot wound causing femoral artery injury and grafting) * Postoperative Complications (non-device related): * In Expert ALFN group: 2 complications (one case of weakness and one case of knee stiffness) * In Expert LFN group: 25 complications (four cases of weakness, two cases of pain, one case of nonunion, three cases of infection, two cases of heterotopic ossification, two cases of knee stiffness, four cases of delayed healing, two cases of leg length discrepancy, and five cases of other: two pulmonary embolisms, one significant swelling, one fall with fracture distal to IM nail, and one below knee amputation secondary to trauma) * In FRN group: 6 complications (two cases of weakness, one case of pain, one case of infection, one case of delayed healing, and one case of other: antalgic gait) * Postoperative Complications (device related): * In Expert ALFN group: 3 complications; one case of broken distal interlock screw, another case of pain at distal interlock screw, and another case of hardware prominence. All three cases required to remove distal interlock screws (not in scope of this CER). * In Expert LFN group: 1 complication: one case of hardware prominence. The prominent screw lead to hardware removal of distal interlock (not in scope of this CER) * In FRN group: 1 device-related complication: hardware prominence and no revisions required. * Rehospitalizations: Fifteen patients underwent 15 rehospitalizations * In Expert ALFN group: 9.0% (5 rehospitalizations) * In Expert LFN group: 4.6% (10 rehospitalizations) * In FRN group: 0% (0 rehospitalizations) | | | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | | | |
| Death Events and Corresponding Details: | No deaths reported | | | | |
| Activity Limitations: | None | | | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | Overall Device-Related Complications:   * In Expert ALFN group: 5 complications * 3 complications; one case of broken distal interlock screw, another case of pain at distal interlock screw, and another case of hardware prominence. All three cases required to remove distal interlock screws (not in scope of this CER). * 2 complications; one case of fracture instability/shortening complication which required a revision to the fracture fixation by removing the broken screw and another case of planned hardware removal since the patient experienced discomfort and could feel the screw. * In Expert LFN group: 2 complications * In the first case, prominent screw led to hardware removal of distal interlock (not in scope of this CER). * In the second case, nonunion was observed which required removal of LFN nail and replacement with non-DPS nail. * In FRN group: 1 device-related complication: hardware prominence. This was described as mild and did not require a reoperation. | | | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Three hundred and one fractures were treated with either Expert LFN System, Expert ALFN System, or FRN System in 300 patients. These femoral shaft nails were most often used for femoral shaft fractures, followed by subtrochanteric fractures. Seven device related complications were reported, four cases of hardware prominence, two cases of pain, and one case of fracture instability/shortening. The most frequent post-operative complication was weakness (2.3%), followed by pain (1.7%), delayed healing (1.7%), hardware prominence (1.3%), and infection (1.3%). Ninety-nine percent of fractures healed, and the average time to union was 3.7 months.  The data set provided for patients treated with Expert LFN System, Expert ALFN System, and FRN System provides evidence to demonstrate that the products performed as intended and that there were no safety signals. | | | | |

### PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail (Device Groups 4, 7, and 10)

Table : Summary of PMCF Activity / DUA – Summary of Retrospective Data for Patients Treated with the Lateral Femoral Nail, Adolescent Lateral Femoral Nail, and the Femoral Recon Nail (Device Groups 4, 7, and 10)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Document Number: | Windchill #0000317838 | | | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500577392 * General PMCF Activity #: 2 | | | | |
| * PMCF Plan #: 500566412 * Specific and General PMCF Activity #: 3 | | | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | | | |
| Type of PMCF Activity: | Retrospective Chart Review | | | | |
| Devices Included: | Subject Devices:   * Expert Adolescent Lateral Femoral Nail (Expert ALFN) System * Expert Lateral Femoral Nail (Expert LFN) System   Femoral Recon Nailing (FRN) System | | | | |
| Patient Population Demographics: | Variable | | Expert LFN System  (N = 2) | Expert ALFN System  (N = 10) | FRN System (N = 42) |
| Age (At time of surgery, years) | Mean (SD) | 40.5 (23.3) | 24.0 (18.7) | 40.3 (17.1) |
| Median | 40.5 | 14 | 37 |
| Min, Max | 24, 57 | 10, 61 | 16, 73 |
| Gender, n (%) | Female | 1 (50.0%) | 4 (40.0%) | 15 (35.7%) |
| Male | 1 (50.0%) | 6 (60.0%) | 27 (64.3%) |
| Smoking status, n (%) | Current Smoker | 0 (0.0%) | 0 (0.0%) | 22 (52.4%) |
| Former Smoker | 1 (50.0%) | 0 (0.0%) | 5 (11.9%) |
| Never Smoked | 1 (50.0%) | 10 (100.0%) | 15 (35.7%) |
| Comorbidities\* | Diabetes | 1 | 1 | 4 |
| Osteoporosis | 0 | 2 | 5 |
| Hypertension | 0 | 1 | 17 |
| Osteomyelitis | 0 | 1 | 0 |
| Sickle Cell | 0 | 1 | 0 |
| Asthma | 0 | 1 | 3 |
| Stroke | 0 | 1 | 0 |
| Rheumatoid arthritis | 0 | 1 | 1 |
| Anemia | 0 | 0 | 3 |
| Cancer | 0 | 0 | 2 |
| Fibromyalgia | 0 | 0 | 1 |
| Chronic obstructive pulmonary disease | 0 | 0 | 2 |
| Obesity | 0 | 0 | 2 |
| Chronic steroid use | 0 | 0 | 2 |
| Gout | 0 | 0 | 1 |
| Congestive heart failure | 0 | 0 | 1 |
| Fracture classification | Shaft fracture | 2 | 9 | 37 |
| Neck fracture | 0 | 0 | 0 |
| Neck/Shaft combination fracture | 0 | 0 | 3 |
| N/A | 0 | 1 | 2 |
| Locking mechanism | Standard locking | 0 | 6 | 5 |
| Recon locking | 2 | 4 | 37 |
| \*Patients may have presented with more than one comorbidity | | | | |
| Patient Numbers: | * Expert ALFN System: 10 patients (10 fractures) * Expert LFN System: 2 patients (2 fractures) * FRN System: 42 patients (42 fractures) | | | | |
| Intent of PMCF Activity: | Specific PMCF\* – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment  \*Note: For Femoral Recon Nail group only. | | | | |
| Objectives and Endpoints: | Objectives:  A data provision agreement was pursued in order to generate data to be considered as part of the overall clinical evaluation and post-marketing safety and surveillance of these femoral nailing systems. The data collected is intended to supplement the available literature and on-going clinical activities.  Endpoints:  The data included both safety and performance information and data included intra/post-operative complications and union rates, for the therapeutic lifetime of the subject device (i.e. 6 months or until union can be determined). | | | | |
| Inclusion Criteria: | * Treated with Expert LFN System, Expert ALFN System, or FRN System between 01 January 2017 and 31 December 2019 * Patients who were in the specified age population, had either 6 months of follow up or evidence of healing. | | | | |
| Exclusion Criteria: | * Treatment using other than Expert ALFN System, Expert LFN System, or FRN System for femoral shaft fractures. * Patients without the required follow up or who had not healed. | | | | |
| Length of Follow-up and Intervals: | Mean (Range):   * Expert ALFN System: 94.6 ± 53.6 weeks (43 – 231) * Expert LFN System: 121.5 ± 122.3 weeks (35 – 208) * FRN System: 61.8 ± 40.0 weeks (24 – 195) | | | | |
| PMCF Activity location(s) & Transferability to EU: | * Mississippi, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | | | |
| PMCF Activity Status: | Completed | | | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome for Expert ALFN System | Mean (%) | | Bone Union | 100% (10/10) | |  | | | | | | |
| |  |  | | --- | --- | | Key Performance Outcome for Expert LFN System | Mean (%) | | Bone Union | 50% (1/2) | |  | | | | | | |
| |  |  | | --- | --- | | Key Performance Outcome for FRN System | Mean (%) | | Bone Union | 93% (39/42) | |  | | | | | | |
| Summary of Other Performance Outcomes: | * Time to Union (Average): * For Expert ALFN System: 46.3 ± 36.2 weeks (range, 20-144) * For Expert LFN System: 35 weeks * For FRN System: 34.1 ± 23.3 weeks (range, 13-124) * Return to work/activities (Average): * For Expert ALFN System: 27.3 ± 8.7 weeks (range, 20-37) * For Expert LFN System: 35 weeks * For FRN System: 22.3 ± 11.0 weeks (range, 3-58) | | | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome for Expert ALFN System\* | Rate (%) | | Infection | 0% (0/10) | | Nonunion | 0% (0/10) | | Revision | 0% (0/10) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, hip screws, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | | | |
| |  |  | | --- | --- | | Key Safety Outcome for Expert LFN System\* | Rate (%) | | Infection | 0% (0/2) | | Nonunion | 0% (0/2) | | Revision | 0% (0/2) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, hip screws, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | | | |
| |  |  | | --- | --- | | Key Safety Outcome for FRN System\* | Rate (%) | | Infection | 0% (0/42) | | Nonunion | 4.7% (2/42)\*\* | | Revision | 7.1% (3/42)\*\* | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nail, recon screws, and end caps) in scope. An analysis of overall complications is listed in the below row.  \*\*Note: In the FRN group, there was one case of hardware failure due to nonunion and required revision. In the second case, the patient was hospitalized twice for screw back out, both times leading to a revision; once at 3 weeks and once at 9 weeks and later the patient was diagnosed with nonunion, which was not until 31 weeks. The study did not clearly state whether the type of screw (locking or hip screw) which required revision. Hence, this event is considered under key safety outcome, revision. | | | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: 0 complications * Postoperative Complications (non-device related): * In Expert ALFN group: 2 complications (one case of osteomyelitis and once case of right hip surgical wound dehiscence) * In Expert LFN group: 4 complications (one case of nonunion, two cases of wound infection, and one case of septic arthritic hip with loss of articular cartilage space) * In FRN group: 7 complications (one case of nonunion, two cases of delayed union, one case of surgical site infection, and three cases of pulmonary embolism) * Postoperative Complications (device related): * In Expert ALFN group: 0 events * In Expert LFN group: 0 events * In FRN group: 0 events * Rehospitalizations: 16 rehospitalizations (13 patients) * In Expert ALFN group: 8 rehospitalizations (7 patients) * In Expert LFN group: 3 rehospitalizations (2 patients) * In FRN group: 5 rehospitalizations (4 patients) | | | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | | | |
| Death Events and Corresponding Details: | No deaths reported | | | | |
| Activity Limitations: | None | | | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | Device-Related Complications in the FRN Group: 2 patients   * One patient experienced hardware failure due to nonunion and required a revision. * Second patient underwent two revisions due to screw back out, once at 3 weeks and once at 9 weeks and was later diagnosed with nonunion, which was not until 31 weeks. | | | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Fifty-four fractures were treated with either Expert LFN System, Expert ALFN System, or FRN System in 54 patients. These femoral shaft nails were most often used for femoral shaft fractures and subtrochanteric fractures. Ninety-three percent of fractures healed (bone union was reported to be a hundred percent in ALFN, fifty percent in LFN, and ninety-three percent in FRN group). One in two patients experienced nonunion in LFN and 3/42 patients in FRN. There were no cases of device related infection reported. No cases of hardware removal were reported for ALFN and LFN, while two patients reported events of hardware removal for FRN.  The data set provided for patients treated with Expert LFN System, Expert ALFN System, and FRN System provides evidence to demonstrate that the products performed as intended and that there were no safety signals. | | | | |

### PMCF Activity / IIS – Comparison of Short-Term Clinical Outcomes of Piriformis Fossa and Trochanteric Entry Nailing for Femoral Shaft fractures

Table : Summary of PMCF Activity / IIS – Comparison of Short-Term Clinical Outcomes of Piriformis Fossa and Trochanteric Entry Nailing for Femoral Shaft fractures (Device Group 10)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Study Identification Number: DPS-TCMF-2018-34  PMCF Evaluation Report: Windchill #500770504 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500445872 * General PMCF Activity #: 1 | | |
| * PMCF Plan #: 500566412 * General PMCF Activity #: 1 | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Investigator Initiated Study | | |
| Devices Included: | Subject Devices:   * Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System\* * Femoral Recon Nailing (FRN) System   \*Note: The data for this system is pending (study in-progress), the system-related information will be updated in the next revision of the clinical evaluation upon receiving the updated information or data for this device group from the PMCF study report. | | |
| Patient Population Demographics: | Variable | FRN Group (N = 37) | |
| Gender, n (%) | Male | 30 (81.1) |
| Female | 7 (18.9) |
| Age, years | Mean (SD) | 36 (17.7) |
| Median | 31 |
| Min, Max | 18, 88 |
| Side of fracture, n (%) | Right | 23 (62.2) |
| Left | 14 (37.8) |
| Fracture Type, n (%) | Femoral shaft | 21 (56.8) |
| Subtrochanteric | 16 (43.2) |
| AO Classification, n (%) | 32A1 | 4 (10.8) |
| 32A2 | 5 (13.5) |
| 32A3 | 5 (13.5) |
| 32B2 | 1 (2.7) |
| 32B3 | 10 (27.0) |
| 32C1 | 3 (8.1) |
| 32C2 | 2 (5.4) |
| 32C3 | 7 (18.9) |
| Mechanism of injury, n (%) | High Impact | 32 (86.5) |
| Low Impact | 5 (13.5) |
| Entry point, n (%) | Greater Trochanter | 25 (67.6) |
| Piriformis Fossa | 12 (32.4) |
| Patient Numbers: | 37 patients | | |
| Intent of PMCF Activity: | Specific PMCF – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  The objective of the study is to compare the clinical outcomes, operative complications, and rates of reoperation for adult femoral shaft fractures treated with either a nail with a piriformis fossa entry (Expert R/AFN) or a nail with both a piriformis fossa entry and a trochanteric entry point (FRN).  Endpoints:  Operative complications such as nonunion, malunion, loss of reduction, malalignment (angular, rotational, and length), reoperation, broken implants, and deep infection will be reported at 3 months, 6 months, and 12 months. | | |
| Inclusion Criteria: | * Charts from 01 January 2010 to 01 April 2022 * Age 18-89 * All patients treated with antegrade IM nailing for a femoral shaft or subtrochanteric femur fracture with either the DePuy Synthes Femoral Recon nail System or the DePuy Synthes Expert R/AFN System and FRN System neck and shaft fractures | | |
| Exclusion Criteria: | * Age less than 18 or greater than 89 * Patients with a prior femur fracture or other deformity of the femur * Patients with less than 3-months of documented follow-up care. * Fractures treated with retrograde nailing technique * Intertrochanteric fractures * Pregnant women * Prisoners | | |
| Length of Follow-up and Intervals: | Patients were followed for 3 months, 6 months, and 12 months, or until healing | | |
| PMCF Activity location(s) & Transferability to EU: | * Pennsylvania, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Pending / In-Progress, Expected Availability / Completion: Q2 2023  Interim Activities Completed | | |
| Key Performance Outcomes with Included Data: | Not Reported | | |
| Summary of Other Performance Outcomes: | Not Reported | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 13.5% (5/37) | | Nonunion | 10.8% (4/37) | | Revision | 2.7% (1/37) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nails, recon screws, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Intraoperative Complications: 11 complications * Postoperative Complications: * Delayed union: 7 events * Malalignment/malrotation: 2 events * Deep vein thrombosis: 2 events * Pulmonary embolism: 4 events * Other: 9 events in 8 patients (three cases of heterotopic ossification, two cases of foot drop, two cases of osteomyelitis, one case of avascular necrosis and migration of the femoral head, and one case of short segment high-grade stenosis of the femoral artery) * Reoperations: 5 patients * Hardware removal: 2 patients * IM nail removal: 1 patient * Revision of distal locking screws: 1 patient | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | One patient underwent removal of IM nail and debridement of osteomyelitis; the nail was replaced with antibiotic spacer. | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | The data set provided for patients treated with FRN System provides evidence to demonstrate that the products performed as intended and that there were no safety signals.  Final report is expected in Q2 2023. | | |

### PMCF Activity / IIS – Utilizing the RFN-Advanced Retrograde Femoral Nailing System for Fixation of Distal Femur and Femoral Shaft Fractures: A Prospective Case Series

Table : Summary of PMCF Activity / IIS – Utilizing the RFN-Advanced Retrograde Femoral Nailing System for Fixation of Distal Femur and Femoral Shaft Fractures: A Prospective Case Series (Device Group 13)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Study Identification Number: DPS-TCMF-2021-033 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500441682 * Specific and General PMCF Activity #: 2a | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Investigator Initiated Study  Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Retrograde Femoral Nail Advanced (RFNA) System | | |
| Patient Population Demographics: | Variables | RFN-ADVANCED Femoral Nail (N = 30) | |
| Age (mean ± SD) | 49.2 ± 21.7 (range 15-91) | |
| Gender | Male: 15 (50%) | |
| Female: 15 (50%) | |
| BMI (mean ± SD) | 29 ± 7.4 | |
| ASA (mean ± SD) | 2.53 ± 0.8 | |
| Current smokers, n (%) | 5 (16.7%) | |
| Diabetes, n (%) | 6 (20%) | |
| Type of Fracture/Injury | Distal Femur Fracture | 12 (40%) |
| Femoral Shaft Fracture | 12 (40%) |
| Segmental Femur Fracture | 2 (6.7%) |
| Femur Nonunion | 4 (13.3%) |
| Intra-articular Fractures | 5 (16.7%) |
| Periprosthetic Fractures | 5 (16.7%) |
| Open Fractures | 2 (6.7%) |
| \*The single patient under 18 years old (age 15) was determined to be skeletally mature by the attending orthopaedic surgeon performing the surgery. | | |
| Patient Numbers: | 30 patients to date | | |
| Intent of PMCF Activity: | Specific PMCF – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  The primary objective is to evaluate healing and complication rates of patients that receive RFNA for fixation of femoral shaft or distal femur fractures. Secondary objectives include functional outcomes and pain levels.  Endpoints:  Data collection at follow up will include radiographs (healing), physical exam, functional status, pain scores, and complications. | | |
| Inclusion Criteria: | * Distal femur or femoral shaft fracture requiring surgery * Evaluation and treatment at study site * Skeletally mature and/or 18 years or older * Ability to understand the content of the patient information/Informed Consent Form (prospective only) * Signed and dated Ethics Committee (EC)/Institutional Review Board (IRB) approved written informed consent | | |
| Exclusion Criteria: | * Any not medically managed severe systemic disease * Their doctor has decided that it is in the patient’s best interest to receive a different method of fixation * Their doctor has determined that the patient has a condition that would make them unsuitable for participation in the study. * Pregnancy or women planning to conceive within the subject participation period (1 year) * Pregnancy will be self-reported and no test will be performed to test for it. * Prisoner * Participation in any other pharmacologic or medicinal product study within the previous month that could influence the results of this study. | | |
| Length of Follow-up and Intervals: | Average Follow-up: 18 ± 10.7 weeks (range 2 – 48 weeks) | | |
| PMCF Activity location(s) & Transferability to EU: | * California, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Pending / In-Progress, Expected Availability / Completion: Q4 2024  Interim Activities Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 93.3% (28/30) | |  | | | | |
| Summary of Other Performance Outcomes: | * Pain Scores measured using the Visual Analog Scale (VAS) at most recent follow up: 2.14 ± 2.41 * Ambulatory With/Without Assistive Device (i.e., Cane/Walker) at most recent follow up: 96.7% (29/30) | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 0% (0/30) | | Nonunion/Malunion | 6.7% (2/30) | | Revision | 0% (0/30) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nails and locking attachment washer) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Complications: * Hardware Removal: 0% (0/30) * 90-day Re-admission to the ED patients: 6.7% (2/30) * Mortality: 0% (0/30) | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | None | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Based on the results of this study, 93.3% of fractures healed which is indicative that the device is performing as intended and there were no safety signals.  Final report is expected in Q4 2024. | | |

### PMCF Activity / IIS – Early Usage Case Series Utilizing the Retrograde Femoral Nail -Advanced for Fixation and Stabilization of the Distal Femur and Femoral Shaft

Table : Summary of PMCF Activity / IIS – Early Usage Case Series Utilizing the Retrograde Femoral Nail -Advanced for Fixation and Stabilization of the Distal Femur and Femoral Shaft (Device Group 13)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Study Identification Number: DPS-TCMF-2021-050 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500441682 * General PMCF Activity #: 2b | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Investigator Initiated Study  Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Retrograde Femoral Nail Advanced (RFNA) System | | |
| Patient Population Demographics: | Variables | RFN-ADVANCED Femoral Nail (N = 54) | |
| Frequency | Percent |
| Sex | | |
| Female | 20 | 37 |
| Male | 34 | 63 |
| Race | | |
| African American | 24 | 44 |
| Caucasian | 28 | 52 |
| Hispanic | 2 | 4 |
| Tobacco Use | | |
| Current | 27 | 50 |
| Former | 3 | 6 |
| Never | 24 | 44 |
| Gustilo Anderson Classification | | |
| I | 2 | 10 |
| II | 2 | 10 |
| IIIA | 14 | 70 |
| IIIB | 0 | 0 |
| IIIC | 2 | 10 |
| Mechanism of injury | | |
| Fall from standing | 7 | 13 |
| Motor vehicle crash | 27 | 50 |
| Motorcycle crash | 1 | 2 |
| Gunshot | 13 | 24 |
| Crush injury | 2 | 4 |
| ATV | 1 | 2 |
| Other | 3 | 6 |
| AO Classification | | |
| 32-A1 | 3 | 6 |
| 32-A2 | 10 | 19 |
| 32-A3 | 10 | 19 |
| 32-B1 | 4 | 7 |
| 32-B2 | 0 | 0 |
| 32-B3 | 2 | 4 |
| 32-C1 | 5 | 9 |
| 32-C2 | 3 | 6 |
| 32-C3 | 5 | 9 |
| 33-A1 | 0 | 0 |
| 33-A2 | 1 | 2 |
| 33-A3 | 3 | 6 |
| 33-B1 | 0 | 0 |
| 33-B2 | 0 | 0 |
| 33-B3 | 0 | 0 |
| 33-C1 | 0 | 0 |
| 33-C2 | 4 | 7 |
| 33-C3 | 4 | 7 |
| Patient Numbers: | 53 patients (54 fractures). However, outcome data was available on 20 retrospective patients at the time of interim report generation. | | |
| Intent of PMCF Activity: | Specific PMCF – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  The primary objective of this study is to describe the outcomes of patients with distal femur and femoral shaft fracture after treatment with the DePuy Synthes RFN-ADVANCED Femoral Nail. Specifically, to describe union rates of these fractures at 6 months after treatment with DePuy Synthes RFN-ADVANCED Femoral Nail.  Secondary objective: Rates of infection, implant breakage, malunion, and symptomatic implant removal after treatment with DePuy Synthes RFN-ADVANCED Femoral Nail. Other information on device-related adverse events will be analyzed. An evaluation of the subjects’ clinical and radiographic follow up records will be evaluated for any adverse events related to the device.  Endpoints:  Study Data collection will include:   * Demographics and medical history * Operative details * Radiographic assessment of healing and alignment * Complications including fracture related infection, reoperation and revision. * Time to full weight bearing | | |
| Inclusion Criteria: | * Distal femur and femoral shaft fractures treated with the DePuy Synthes Retrograde Femoral Nail Advanced System over a 12-month period (February 2021 -February 2022). * Subjects 18 years or older at the time of index procedure * Subjects who have at least 6 months of follow-up | | |
| Exclusion Criteria: | * Less than 6 months of follow up, pathologic fractures, and patients <18 years of age will be excluded from the study. | | |
| Length of Follow-up and Intervals: | 6 months | | |
| PMCF Activity location(s) & Transferability to EU: | * Alabama, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Pending / In-Progress, Expected Availability / Completion: Q4 2023  Interim Activities Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 77% (10/13\*) | | \*Note: Nineteen patients with 20 fractures had adequate follow-up (at least 6 months after treatment with RFNA), of which, 10 demonstrated radiographic and/or clinical consolidated and 3 were diagnosed with nonunion; therefore 10/13 (77%) who could be assessed for healing demonstrated union. Healing was ongoing for the remaining 7. | | | | |
| Summary of Other Performance Outcomes: | Not reported | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 10% (2/20) | | Nonunions | 5% (1/20) | | Revisions | 5% (1/20) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nails and locking attachment washer) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Complications (non-device related): * Mild knee or thigh pain: 4 events * Aseptic Nonunion: 2 events * Patellofemoral arthritis: 1 event * Pulmonary embolism of unknown etiology: 1 event * Foot drop secondary to neurovascular injury: 1 event * Lower extremity weakness secondary to concomitant spinal injury: 1event * Hardware Removal and Reoperation: 3 events * Aseptic nonunion (non-device related): 2 events * Non-septic nonunion (device or procedure related): 1 event | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | Other:   * This study was not powered to detect statistical significance. * Limitations to this study include having a small sample size, relatively short follow up and not being powered to detect infrequent complications. | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | One case of non-septic nonunion likely due to excessive motion at the fracture site and it might be due to device or procedure related or could be combination of both. | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Data was obtained from 20 cases with adequate follow up (19 patients with 20 fractures). Of the fractures that could be assessed for healing, 10 resulted in radiographic and/or clinical consolidation and 3 were diagnosed with nonunion; therefore resulting in a 77% (10/13) union rate for the Retrograde Femoral Nailing Advanced System (RFNA). The remaining seven patients showed interval healing and will continue to be monitored. Knee pain was the most common complication after surgery, however, that is a common and expected complication of retrograde femur nailing. Three patients went on to nonunion, two of which were secondary to hardware infection.  The data set provided for patients treated with RFNA System provides evidence to demonstrate that the products performed as intended and that there were no safety signals. | | |

### PMCF Activity / IIS – Early Results of the RFN-Advanced System in the Management of Distal Femur Fractures: A Matched-Cohort Analysis

Table : Summary of PMCF Activity / IIS – Early Results of the RFN-Advanced System in the Management of Distal Femur Fractures: A Matched-Cohort Analysis (Device Group 13)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Study Identification Number: DPS-TCMF-2021-061 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500441682 * Specific and General PMCF Activity #: 2c | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment | | |
| Type of PMCF Activity: | Investigator Initiated Study  Retrospective Chart Review | | |
| Devices Included: | Subject Devices: Retrograde Femoral Nail Advanced (RFNA) System | | |
| Patient Population Demographics: | Variable | RFN-ADVANCED Femoral Nail (N = 84) | |
| Age | Mean, ±SD | 57.6, ±21.39 |
| Gender (%) | Female | 45 (53.6) |
| Male | 39 (46.4%) |
| Race (%) | Caucasian | 68 (8) |
| African American | 16 (19) |
| BMI | Mean, ±SD | 31.8, ±9.25 |
| Smoking (%) | Yes | 35 (41.7) |
| No | 49 (58.3) |
| ASA Score (%) | I | 2 (2.4) |
| II | 24 (28.6) |
| III | 53 (63.1) |
| IV | 5 (6) |
| Comorbidities (%) | Myocardial infarct | 5 (6) |
| Congestive heart failure | 4 (4.7) |
| Peripheral vascular disease | 14 (16.6) |
| Cerebrovascular disease | 4 (4.7) |
| Dementia | 5 (6) |
| Chronic pulmonary disease | 7 (8.3) |
| Connective tissue disease | 2 (2.4) |
| Mild liver disease | 1 (1.2) |
| Diabetes without complications | 20 (23.8) |
| Diabetes with end-organ damage | 1 (1.2) |
| Hemiplegia | 3 (3.5) |
| Moderate or severe renal disease | 3 (3.5) |
| A solid tumor (non-metastatic) | 3 (3.5) |
| Moderate or severe liver disease | 1 (1.2) |
| AO/OTA Classification (%) | 33A2 | 22 (26.1) |
| 33A3 | 33 (39.3) |
| 33C1 | 6 (7.1) |
| 33C2 | 15 (17.9) |
| 33C3 | 8 (9.5) |
| Type of fracture (%) | Closed | 65 (77.4) |
| Open | 19 (22.6) |
| Gustilo Classification (%) | I | 5 (26.3) |
| II | 3 (15.8) |
| IIIA | 10 (52.6) |
| IIIC | 1 (5.3) |
| Periprosthetic Fracture | Yes | 20 (23.8) |
| No | 64 (76.2) |
| Patient Numbers: | 84 patients to date | | |
| Intent of PMCF Activity: | Specific PMCF – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | Objectives:  The goal of our investigation is to describe the outcomes associated with the use of the Synthes RFN-Advanced (RFNA) Retrograde Femoral Nail system, in the management of fractures of the distal femur (AO/OTA types 33A2-3, 33C1-3).  Endpoints:  Rate of reoperation for catastrophic failure, infection, bone graft, additional fixation, delayed union and/or nonunion with RFNA vs. locked lateral plating, radiographic union, minor complications, alignment and patient reported outcomes. | | |
| Inclusion Criteria: | Inclusion criteria   * Adult patients (age 18 years or older) * Fracture involving the distal femoral metaphysis with or without articular extension (AO33A2, AO33A3, AO33C1, AO33C2, AO33C3); both in the presence and in the absence of a total knee prosthesis or other implant * Underwent operative fixation with the RFNA System * Minimum 6 months of follow-up   Inclusion criteria for matched cohort   * Adult patients (age 18 or older) * Fracture involving the distal femoral metaphysis with or without articular extension (AO33A2, AO33A3, AO33C1, AO33C2, AO33C3); both in the presence and in the absence of a total knee prosthesis or other implant * Underwent operative fixation with lateral locking plate * Minimum 6 months of follow-up | | |
| Exclusion Criteria: | * Patients undergoing operative fixation of a femur fracture with an RFNA-System implant that is not AO/OTA type 33A or 33C * Patients treated with an RFNA implant for non-acute pathology such as nonunion or revision operative fixation | | |
| Length of Follow-up and Intervals: | Patients will be followed until union or 1 year post-operative. | | |
| PMCF Activity location(s) & Transferability to EU: | * Location: Tennessee, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations. | | |
| PMCF Activity Status: | Pending / In-Progress, Expected Availability / Completion: Q4 2022  Interim Activities Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union | 81.08\* (30/37) | | \*Note: In the short term follow-up, 34.5% (29/84) of fractures were healed by surgeon determination. When isolating patients with at least 6 months of follow-up (n=37), 30 patients had an mRUST score of 10 or higher, indicative of healing (81.08%) and the remnant population are currently being actively followed for union. | | | | |
| Summary of Other Performance Outcomes: | * Pain (VAS Score) at last follow-up (Mean ± SD): 2.36 ± 3.13 * Weightbearing (WB) status (%) at last follow-up: * Full WB: 51 (53.6%) * WB As tolerated: 22 (26.2%) * Touchdown WB: 3 (3.6%) * Non-WB: 8 (9.5%) | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 2.4% (2/84) | | Nonunion | 3.5% (3/84) | | Revision | 1.2% (1/84) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nails and locking attachment washer) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * Catastrophic failure: 1.2% (1/84) * Superficial Infection: 1.2% (1/84) * Screw backout requiring removal: 11.9% (10/84) * Death: 2.4% (2/84) | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | Two deaths (2.4%) reported in the study which were unrelated to the injury or the procedure. | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | None | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | Based on patients with at least 6 months of follow-up (n=37), 30 (81.08%) had scores indicative of healing as per surgeon determination, which demonstrates good performance. The remaining population are currently being followed for union. Two cases of deep infection were reported and there was one case of nail related revision surgery at 11 months post-op.  The data set provided for patients treated with RFNA System provides evidence to demonstrate that the products performed as intended and that there were no safety signals. | | |

### PMCF Activity / Internal Registry – Lower Extremity Shaft Nail (LESN) Registry

Table : Summary of PMCF Activity / Internal Registry – Lower Extremity Shaft Nail (LESN) Registry (Device Group 13)

|  |  |  |  |
| --- | --- | --- | --- |
| Document Number: | Protocol Number: DST202103 | | |
| Corresponding Activity Number in PMCF Plan: | * PMCF Plan #: 500441682 * Specific and General PMCF Activity #: 3 | | |
| Sufficiency of Scientific Validity and Relevance to Support Conformity Assessment: | Data support conformity assessment  Data only inform identification of safety trends or performance issues  Data do not support conformity assessment or inform on identification of safety trends or performance issues (i.e., meet the criteria for off-label or misuse) | | |
| Type of PMCF Activity: | Internal Registry Review | | |
| Devices Included: | Subject Devices: Retrograde Femoral Nail Advanced (RFNA) System | | |
| Patient Population Demographics: | Characteristic | Parameter or Category | RFNA (N = 24)1 |
| Age at Time of Index Surgery (years), N | N missing | 0 |
| Mean | 52.04 |
| SD | 16.32 |
| Median | 57.00 |
| Min, Max | 22.00, 78.00 |
| Age by Range, N (%) | 12 – 21 years | 0 (0.0) |
| 22 – 29 years | 4 (16.7) |
| 30 – 39 years | 1 (4.2) |
| 40 – 49 years | 5 (20.8) |
| 50 – 59 years | 3 (12.5) |
| 60 – 69 years | 9 (37.5) |
| 70 – 79 years | 2 (8.3) |
| Sex, N (%) | Male | 13 (54.2) |
| Female | 11 (45.8) |
| Ethnicity, N (%) | Hispanic or Latino | 2 (8.3) |
| Not Reported | 1 (4.2) |
| Not Hispanic or Latino | 21 (87.5) |
| Race, N (%) | Asian | 1 (4.2) |
| Black | 7 (29.2) |
| White | 14 (58.3) |
| Other | 1 (4.2) |
| Not Reported | 1 (4.2) |
| Body Mass Index kg/m2 | N, N missing | 24, 0 |
| Mean | 32.85 |
| SD | 10.16 |
| Median | 29.54 |
| Min, Max | 19.52, 57.49 |
| Targeted Medical History, N (%) | Yes | 10 (41.7) |
| No | 14 (58.3) |
| Medical History Conditions\*, N (%) | Blood supply impairment (chronic) | 0 (0.0) |
| Diabetes | 2 (11.1) |
| Chronic Kidney Disease | 1 (5.6) |
| Morbid Obesity | 2 (11.1) |
| Osteoarthritis | 0 (0.0) |
| Osteoporosis | 3 (16.7) |
| Smoking History | 6 (33.3) |
| Other | 4 (22.2) |
| Fracture Types\*, N (%) | Bilateral | 0 (0.0) |
| Contralateral | 1 (4.2) |
| Ipsilateral | 2 (8.3) |
| Unilateral | 21 (87.5) |
| Femoral Shaft AO/OTA Fracture Classification, N (%) | 32A (simple) | 6 (25.0) |
| 32B (wedge) | 5 (20.8) |
| 32C (multifragmentary) | 4 (16.7) |
| N/A – no femoral shaft fracture | 9 (37.5) |
| Distal Femur Fracture AO/OTA Fracture Classification, N (%) | 33A (extraarticular) | 8 (33.3) |
| 33C (complete articular) | 3 (12.5) |
| N/A – no distal femur fracture | 13 (54.2) |
| Gustilo classification, N (%) | Type II | 1 (12.5) |
| Type IIIA | 6 (75.0) |
| Type IIIB | 1 (12.5) |
| Tscherne classification, N (%) | Grade 0 | 5 (31.3) |
| Grade I | 11 (68.8) |
| \*More than one response per subject is possible for this category.  1N is the number of subjects. Bi-lateral subjects are counted once.  \*\*Data extracted on 02SEP2022 | | |
| Patient Numbers: | 24 patients to date | | |
| Intent of PMCF Activity: | Specific PMCF – intended to proactively gather and evaluate clinical data to answer a specific objective  General PMCF – intended to proactively monitor use of the device to address unknown areas of emerging risks posed by changes in the clinical environment | | |
| Objectives and Endpoints: | * To understand clinical outcomes, including union rates and time to union, of subjects undergoing fracture fixation and stabilization, or who require a revision due to a malunion or nonunion, of the femur with the DePuy Synthes intramedullary RFNA. Subjects with impending pathologic fracture will be included. * Evaluation of union, i.e., healing will be a combination of radiographic and clinical assessment. Union will be considered achieved based on radiographic images, and no pain at the fracture site indicative of nonunion | | |
| Inclusion Criteria: | * Skeletally mature adults age ≥ 22 years of age * Subject receives an RFNA based on a diagnosis of open or closed, unilateral or bilateral femoral shaft or distal femur fracture; revision of malunion or nonunion of previous fracture, or impending pathologic fracture that will be treated operatively as part of standard of care. In addition, the following will be included: * Femoral shaft or distal femur fracture can be periprosthetic (PPFx) fracture after total or unicondylar knee arthroplasty, or total or hemi hip arthroplasty requiring nail osteosynthesis. * Subject (legally authorized representative if subject is a minor) voluntarily signs the IRB/EC approved consent form(s), as applicable * Subject must be able to read and understand questions and responses in an available translated language for patient reported outcomes (PROs)   \*Note: The registry includes information on another device (Tibial Nail Advanced). The registry also evaluates outcomes in patients who receive more than one (either TNA, RFNA or both) device. | | |
| Exclusion Criteria: | * Participation in any other medical device or medicinal product study within the previous month. Participation in observational studies is allowed. * In the opinion of the Principal Investigator, subject is unable to comply with the requirements of the registry. * Subject has known allergies to implant components. | | |
| Length of Follow-up and Intervals: | * Follow up clinic visits will be performed until the subject is deemed healed (3 months minimum, up to 12 months after surgery) * Device or procedure related adverse events will be captured through 12 months post-operative | | |
| PMCF Activity location(s) & Transferability to EU: | * Locations\*: * Texas, United States * Indiana, United States * Tennessee, United States * Transferability to EU: This study has generalizability to the EU population because the clinical presentation of patients receiving the subject device should not differ across the US and EU populations. Furthermore, use of the subject device is expected to be similar across surgeons, hospitals and regions among US and EU populations.   \*At the time of the Registry data cutoff on 02 September 2022, three sites were enrolling into the Registry, but as of the date of the report (31 October 2022), six sites were open to enrollment and five sites had enrolled at least one subject. The registry plans to enroll at up to 10 US sites. | | |
| PMCF Activity Status: | Pending / In-Progress, Expected Availability / Completion: Q3 2024  Interim Activities Completed | | |
| Key Performance Outcomes with Included Data: | |  |  | | --- | --- | | Key Performance Outcome | Mean (%) | | Bone Union   * At 6 weeks (N = 16) * At 3 months (N = 7) | * 0% (0/16) * 28.6% (2/7) | |  | | | | |
| Summary of Other Performance Outcomes: | * Mean VAS Score\* (N = 24): * At 6 weeks score: 38.5 * At 3 months score: 13.14 * ED-5D-5L Mean Health Index Score\*\*: * At 6 weeks: 0.48 * At 3 months: 0.63 * EQ-5D-5L Mean Visual Analogue Scale\*\*\*: * At 6 weeks: 64.31 * At 3 months: 85.29   \*VAS score is between 0-100 with 0 being no pain and 100 being worst pain  \*\*EQ-5D-5L health index values values range from –0.109 to 1, with ‘0’ meaning dead and ‘1’ meaning perfect health, less than 0 meaning worse than dead  \*\*\*EQ-5D-5L VAS scale reports values between 0—100 with ‘0’ indicating worst imaginable health and ‘100’ indicating best imaginable health | | |
| Key Safety Outcomes with Included Data: | |  |  | | --- | --- | | Key Safety Outcome\* | Rate (%) | | Infection | 4.2% (1/24) | | Nonunion | 0.0% (0/24) | | Revision | 0% (0/24) | | \*Note: The reported key safety outcomes in the above table are complications related to the devices (nails, locking attachment washer, and end caps) in scope. An analysis of overall complications is listed in the below row. | | | | |
| Summary of Other Safety Outcomes: | * In the RFNA group, there were 6 events in 5 subjects with 5 of them being serious. The 6 events were acute blood loss (anemia), pseudomonas infection, compartment syndrome, knee pain (due to screw back out), and 2 device failures, which were both screw back outs. All of these events were assessed as serious except the acute blood loss. * The pseudomonas and compartment syndrome resulted in reoperations for an irrigation with debridement and fasciotomy with skin graft, respectively. * The pain due to screw back out and 2 device failures all resulted in revisions, where the screws were removed. In one screw back out case, the subject was asymptomatic, but a decision was made to remove the screw. * Hardware Removal: 3 events; requiring removal of screws | | |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events | | |
| Deviations from PMCF Plan/Protocol & Rationale: | No deviations | | |
| Death Events and Corresponding Details: | No deaths reported | | |
| Activity Limitations: | None | | |
| Summary of Safety and/or Performance Events Attributed to the Device: | None | | |
| Overall Conclusions & Impact on the Clinical Evaluation Assessment: | The data collection for this registry is still ongoing and available data will be included in the next scheduled PMCF evaluation report. Most subjects had not yet reached the 3 month follow up at the time of the data cut-off. No subjects were assessed as healed at the 6 week follow up and 2/7 (28.6%) subjects were assessed as healed at the 3 month follow up. Patient reported outcomes are indicating a positive trend towards restoring the limb function. From a safety point of view, the RFNA revision rate were all resulting from screw removals, no nail related safety events were reported. There are no new risks or harms reported that would significantly impact the clinical evaluation assessment as of this update. | | |

## PMCF Plan

Refer to Section 8.2 for PMCF Assessment and overview of PMCF plan.

# SECTION G CONTENT

## Instructions for Use (IFU) and Other Labeling/Promotional Materials

Refer to Section 3.1.1 – 3.1.18 for a summary of key information from the associated IFUs and other promotional materials.

Refer to Section 8.1.2 for assessment that the IFU is adequately supported by clinical evidence and is in line with the risk analysis and clinical evaluation. To relay residual risks to patients and healthcare professionals.

## Summary of Safety and Clinical Performance (SSCP)

SSCP(s) for the subject device(s) have been created as shown in Table 139.

Table : SSCP Stratification

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| System Name | Device Group # | Device Group Name | SSCP # | SSCP Part B Required (Yes/No[[5]](#footnote-6)) | CER Triggered Update to Existing SSCP (Yes, No, N/A – Initial SSCP) |
| Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | 1 | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail | 500603865 | Yes | Yes |
| 3 | Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | 500603865 | Yes | Yes |

# SECTION H CONTENT

## Data Summary and Benefit-Risk Analysis

### Clinical Benefits / Performance Analysis

The Femoral Nail Systems consist of six in-scope systems within Synthes femoral shaft and recon femoral nail implant families namely: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System, Expert Adolescent Lateral Femoral Nail System, Expert Lateral Femoral Nail System, Femoral Recon Nailing System, Retrograde Femoral Nail Advanced System, and Expert Asian Femoral Nail System. The Femoral Nail Systems have been in clinical use for 18 years (received initial US FDA clearance in 05 February 2004 for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System and received initial CE mark on 15 April 2005 for Expert Lateral Femoral Nail System). These implants are designed for the alignment, rectification, and union of the fractures femoral bone. There were no additional clinical claims identified in IFU, STG, website other than the intended purpose and indications (refer Sections 3.1.1 – 3.1.18).

Table : Intended Purpose and Expected Clinical Benefits

|  | MDD | MDR |
| --- | --- | --- |
| Intended Purpose: | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | |
| Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.  (IFU: SE\_532126) | Bone Fixation Nails, including DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices, are intended for temporary fixation, correction and stabilization of bones.  (IFU: SE\_833508) |
| Expert Adolescent Lateral Femoral Nail System, Expert Lateral Femoral Nail System, Femoral Recon Nailing System, Retrograde Femoral Nail Advanced System, and Expert Asian Femoral Nail System | |
| Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.  (IFU: SE\_532126) | N/A – These devices are under MDD conformity. |
| Retrograde Femoral Nail Advanced System | |
| The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft.  (IFU: SE\_793149) | N/A – These devices are under MDD conformity. |
| Expected Clinical Benefits: | Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | |
| Not identified or required for MDD | The expected clinical benefit of internal fixation devices such as Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices when used according to instructions for use and recommended technique is:   * Achievement of bone union   (IFU: SE\_833508) |
| Retrograde Femoral Nail Advanced System | |
| Expected clinical benefits of internal fixation devices such as Retrograde Femoral Nail Advanced implants when used according to instructions for use and recommended technique are   * Stabilize bone segment and facilitate healing * Restore anatomical alignment and limb/extremity function.   (IFU: SE\_793149) | N/A – These devices are under MDD conformity. |

Nonclinical data (Section 3.6.2) ensures that devices are able to perform as intended which is demonstrated through a series of verification tests (static bend test, dynamic bend test, static fatigue strength test, dynamic fatigue strength test, dynamic loading, fatigue construct testing, tensile strength, and static torsion, static torque) and all these tests met established requirements. The design validation activities ensured that finished device design and manufacturing conform to defined customer requirements (user and patient needs). Therefore, the nonclinical testing evidence supports that the device performs as intended as well as establish the subject device as state-of-the-art.

Clinical performance of the Femoral Nail Systems were further demonstrated with the support of the clinical literature (Section 4) and PMCF (Section 6.2). The clinical data on the subject devices demonstrate improvement in patient reported outcomes as noted in Table 148 – Table 154 which shows the key performance data in comparison to the target treatment option acceptability criteria established in the state of the art review. Further, these data suggests that all the subject devices perform acceptably for patients treated with fractures of femoral shaft and distal femur when used as intended within the target patient population.

As the devices are used as a construct in real world practice, data described in clinical literature and PMCF studies are represented by the usage of these devices as a system, which is reflective of the performance of the singular device groups. A summary of the datasets that were identified in Section 3.6.1 as having sufficient scientific validity and relevance to support the performance conformity assessment relative to the acceptance criteria are documented below (Table 141 – Table 147).

Table : Clinical Data Supporting Performance Conformity Assessment for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.3.1) | * Femoral shaft fractures * Distal femur fractures | 373 | Not Reported | 31.5 – 74.4 years | Not Reported | 7.50 – 49.20 months |
| PMCF Activity / DUA  (Section 6.2.2) | * Femoral shaft fractures * Distal femur fractures | 179 | 31 years | 16 – 85 years | 7 months | 1 – 36 months |
| PMCF Activity / DUA  (Section 6.2.3) | * Femoral shaft fractures * Distal femur fractures | 65 | 32 years | 18 – 87 years | 263 days | 19 – 1072 days |
| PMCF Activity / DUA  (Section 6.2.4) | * Femoral shaft fractures * Distal femur fractures | 59 | 30 years | 18 – 77 years | 14 months | 2 – 44 months |

Table : Clinical Data Supporting Performance Conformity Assessment for Expert Adolescent Lateral Femoral Nail System (System #2)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.4.1) | * Femoral shaft fractures | 15 | Not Reported | 14 years | 33.60 months | 33.60 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 56 | 15 years | 10 – 83 years | 5.5 months | 1.5 – 36 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 10 | 14 years | 10 – 61 years | 94.6 weeks | 43 – 231 weeks |

\*Note: Expert Adolescent Lateral Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and ipsilateral femoral neck/shaft fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Performance Conformity Assessment for Expert Lateral Femoral Nail System (System #3)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.5.1) | * Femoral shaft fractures | 36 | Not Reported | 30.6 – 34.8 years | 21 months | 21 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 219 | 33 years | 14 – 81 years | 5.5 months | 1 – 18 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 2 | 40.5 years | 24 – 57 years | 121.5 weeks | 35 – 208 weeks |

\*Note: Expert Lateral Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Performance Conformity Assessment for Femoral Recon Nailing System (System #4)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Subject Device Data Sources Details | | | | | | |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 25 | 31 years | 18 – 76 years | 4.5 months | 3 – 9 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 42 | 37 years | 16 – 73 years | 61.8 weeks | 24 – 195 weeks |
| Equivalent Device Data Source Details (Expert Lateral Femoral Nail System) | | | | | | |
| Device-Specific Literature (Section 4.5.1) | * Femoral shaft fractures | 36 | Not Reported | 30.6 – 34.8 years | 21 months | 21 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 219 | 33 years | 14 – 81 years | 5.5 months | 1 – 18 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 2 | 40.5 years | 24 – 57 years | 121.5 weeks | 35 – 208 weeks |

\*Note: Femoral Recon Nailing System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Performance Conformity Assessment for Retrograde Femoral Nail Advanced System (System #5)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median/Mean | Overall Range | Mean | Overall Range |
| Subject Device Data Sources Details | | | | | | |
| PMCF Activity / IIS  (Section 6.2.8) | * Femoral shaft fractures * Distal femur fractures | 30 | 49.2 years | 15 – 91 years | 18 weeks | 2 – 48 weeks |
| PMCF Activity / IIS  (Section 6.2.9) | * Femoral shaft fractures * Distal femur fractures | 20 | Not Reported | 18 – 86 years | Not Reported | 6 months |
| PMCF Activity / IIS  (Section 6.2.10) | * Distal femur fractures | 84 | 57.6 years | Not Reported | Not Reported | Until union or 1 year post-operative |
| Equivalent Device Data Source Details (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | | | | | | |
| Device-Specific Literature  (Section 4.3.1) | * Femoral shaft fractures * Distal femur fractures | 373 | Not Reported | 31.5 – 74.4 years | Not Reported | 7.50 – 49.20 months |
| PMCF Activity / DUA  (Section 6.2.2) | * Femoral shaft fractures * Distal femur fractures | 179 | 31 years | 16 – 85 years | 7 months | 1 – 36 months |
| PMCF Activity / DUA  (Section 6.2.3) | * Femoral shaft fractures * Distal femur fractures | 65 | 32 years | 18 – 87 years | 263 days | 19 – 1072 days |
| PMCF Activity / DUA  (Section 6.2.4) | * Femoral shaft fractures * Distal femur fractures | 59 | 30 years | 18 – 77 years | 14 months | 2 – 44 months |

Table : Clinical Data Supporting Performance Conformity Assessment for Expert Asian Femoral Nail System (System #6)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.8.1) | * Femoral shaft fractures | 120 | Not Reported | 34.5 – 73.1 years | Not Reported | 20.50 – 28.40 months |

\*Note: Expert Asian Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Performance Conformity Assessment for Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.10.1) | * Femoral shaft fractures | 8 | Not Reported | 37.75 years | 52.24 months | 52.24 months |

#### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for Femoral Shaft Fractures and Distal Femur Fractures

Clinical evidence of the key performance outcomes for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for femoral shaft fractures and distal femur fractures are summarized below (Table 148).

Table : Performance Outcome Summary – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for Femoral Shaft Fractures and Distal Femur Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | Femoral Shaft Fractures: 94.5 – 100%  Distal Femur Fractures: 71.4 – 100%  Overall: 71.4 – 100% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 76.20 – 100.0% | Device-Specific Literature for Femoral Shaft Fractures and Distal Femur Fractures (Section 4.3.1) (219 patients, f/u: 16.70 – 49.20 months) | 76.20 – 100.00% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 93% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 93% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 95% |

The range of outcome scores for the use of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for femoral shaft fractures and distal femur fractures for the key outcome parameter (bone union), is within the range identified in the acceptance criteria. Therefore, the device key performance outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Adolescent Lateral Femoral Nail System (System #2) for Adolescent Femoral Fractures

Clinical evidence of the key performance outcomes for Expert Adolescent Lateral Femoral Nail System (System #2) for adolescent femoral fractures are summarized below (Table 149).

Table : Performance Outcome Summary – Expert Adolescent Lateral Femoral Nail System (System #2) for Adolescent Femoral Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | 100% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 100% | Device-Specific Literature  (Section 4.4.1) (15 patients, f/u: 33.60 months) | 100% |
| PMCF Activity / DUA  (Section 6.2.5) (56 patients (56 fractures), f/u: 1.50 – 36 months) | 100% |
| PMCF Activity / DUA  (Section 6.2.6) (10 patients (10 fractures), f/u: 43 – 231 weeks) | 100% |

The range of outcome scores for the use of the Expert Adolescent Lateral Femoral Nail System (System #2) for adolescent femoral fractures for the key outcome parameter (bone union), is within the range identified in the acceptance criteria. Therefore, the device key performance outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Lateral Femoral Nail System (System #3) for Femoral Shaft Fractures

Clinical evidence of the key performance outcomes for Expert Lateral Femoral Nail System (System #3) for femoral shaft fractures are summarized below (Table 150).

Table : Performance Outcome Summary – Expert Lateral Femoral Nail System (System #3) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | 94.5 – 100% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes, with justification below for minor deviation. |
| 50 – 100% | Device-Specific Literature  (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 100% |
| PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1.00 – 18 months) | 98.6% |
| PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 50% |

\*Note: Volgas et al., 2010 stated they followed their 20 patients until complete fracture healing, indicating the follow-up time was sufficient to assess the entire therapeutic lifetime for the given patients.

The range of outcome scores for the use of the Expert Lateral Femoral Nail System (System #3) for femoral shaft fractures exceed the range identified in the acceptance criteria for bone union, these scores are still considered to be consistent with the state of the art benchmarks. Because the patient with low bone union rate (50%) had recalcitrant nonunion of proximal femur (non-device related), for which, nail exchange and autografting surgery was performed. Additionally, the study has smaller sample size (2 patients), which is likely the reason for lower bone union rates. Excluding this PMCF study, the bone union range would be 98.6 – 100% which is within the range identified in the acceptance criteria.

#### Femoral Recon Nailing System (System #4) for Femoral Shaft Fractures

Clinical evidence of the key performance outcomes for Femoral Recon Nailing System (System #4) for femoral shaft fractures are summarized below (Table 151).

Table : Performance Outcome Summary – Femoral Recon Nailing System (System #4) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device and Equivalent Device (Expert Lateral Femoral Nail System) | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | 94.5 – 100% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes, with justification below for minor deviation. |
| 50 – 100% | Subject Device:  PMCF Activity / DUA  (Section 6.2.5) (25 patients (25 fractures), f/u: 3 – 9 months) | 100% |
| Subject Device:  PMCF Activity / DUA  (Section 6.2.6) (42 patients (42 fractures), f/u: 24 – 195 weeks) | 93% |
| Equivalent Device:  Device-Specific Literature  (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 100% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 98.6% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 50% |

\*Note: Volgas et al., 2010 stated they followed their 20 patients until complete fracture healing, indicating the follow-up time was sufficient to assess the entire therapeutic lifetime for the given patients.

The range of outcome scores for the use of the Femoral Recon Nailing System (System #4) for femoral shaft fractures exceed the range identified in the acceptance criteria for bone union, these scores are still considered to be consistent with the state of the art benchmarks. Because the patient with low bone union rate (50%) had recalcitrant nonunion of proximal femur (non-device related), for which, nail exchange and autografting surgery was performed. Additionally, the study has smaller sample size (2 patients), which is likely the reason for lower bone union rates. Excluding this equivalent device’s PMCF activity, the bone union range would be 93 – 100% which is within the range identified in the acceptance criteria.

#### Retrograde Femoral Nail Advanced System (System #5) for Femoral Shaft Fractures and Distal Femur Fractures

Clinical evidence of the key performance outcomes for Retrograde Femoral Nail Advanced System (System #5) for femoral shaft fractures and distal femur fractures are summarized below (Table 152).

Table : Performance Outcome Summary – Retrograde Femoral Nail Advanced System (System #5) for Femoral Shaft Fractures and Distal Femur Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device\* and Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | Femoral Shaft Fractures: 94.5 – 100%  Distal Femur Fractures: 71.4 – 100%  **Overall**:  71.4 – 100**%** | Overall Value Range | Data Source\* / Cohort | Value (Range) | Yes |
| 76.20 – 100.0% | Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.8) (30 patients, f/u: 2 – 48 weeks) | 93.3% |
| Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.9) (13 patients\*\*, f/u: 6 months) | 77%\*\* |
| Subject Device:  PMCF Activity / IIS for Distal Femur Fractures  (Section 6.2.10)  (37 patients\*\*\*, f/u: until union or 1 year post-operative) | 81.08\*\*\* |
| Equivalent Device:  Device-Specific Literature for Femoral Shaft Fractures and Distal Femur Fractures (Section 4.3.1) (219 patients, f/u: 16.70 – 49.20 months) | 76.20 – 100.00% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 93% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 93% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 95% |

\*Note: The PMCF Activity / Registry is not considered in the above table for analysis because the bone union rates reported in ths activity were at 6 weeks and 3 months. This activity status is in still in progress.

\*\*Note: Nineteen patients with 20 fractures had adequate follow-up (at least 6 months after treatment with RFNA), of which, 10 demonstrated radiographic and/or clinical consolidated and 3 were diagnosed with nonunion; therefore 10/13 (77%) who could be assessed for healing demonstrated union. Healing was ongoing for the remaining 7.

\*\*\*Note: In the short term follow-up, 34.5% (29/84) of fractures were healed by surgeon determination. When isolating patients with at least 6 months of follow-up (n=37), 30 patients had an mRUST score of 10 or higher, indicative of healing (81.08%) and the remnant population are currently being actively followed for union.

The range of outcome scores for the use of the Retrograde Femoral Nail Advanced System (System #5) for femoral shaft fractures and distal femur fractures for the key outcome parameter (bone union), is within the range identified in the acceptance criteria. Therefore, the device key performance outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Asian Femoral Nail System (System #6) for Femoral Shaft Fractures

Clinical evidence of the key performance outcomes for Expert Asian Femoral Nail System (System #6) for femoral shaft fractures are summarized below (Table 153).

Table : Performance Outcome Summary –Expert Asian Femoral Nail System (System #6) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | 94.5 – 100% | Overall Central Value Range | Data Source / Cohort | Central Value (Range) | Yes |
| **90.00 (90.00 – 98.20)** | Device-Specific Literature  (Section 4.8.1) (120 patients, f/u: 20.50 – 28.40 months) | 90.00 (90.00 – 98.20) |

The range of outcome scores for the use of the Expert Asian Femoral Nail System (System #6) for femoral shaft fractures for the key outcome parameter (bone union), is within the range identified in the acceptance criteria. Therefore, the device key performance outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail[[6]](#footnote-7) ) for Femoral Shaft Fractures

Clinical evidence of the key performance outcomes for Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail ) for femoral shaft fractures are summarized below (Table 154).

Table : Performance Outcome Summary – Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail ) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Bone Union at ≥ 6 months | ↑ | 71.4 – 100% | Overall Value Rate | Data Source / Cohort | Value (Rate) | Yes |
| 75.0% | Device-Specific Literature  (Section 4.10.1) (8 patients, f/u: 52.24 months) | 75.0% |

The range of outcome scores for the use of the Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail ) for the key outcome parameter (bone union), is within the range identified in the acceptance criteria. Therefore, the device key performance outcomes are considered to be consistent with those for the state of the art benchmarks.

### Clinical Risks / Safety Analysis

The identified risks with the use of the Femoral Nail Systems include patient harms outlined within the Risk Management Report (RMR) and Design and Clinical Risk Management (DCRM) files specific to the in-scope devices. Synthes GmbH takes all necessary steps to ensure that risks are reduced as far as possible by applying the available state-of-the-art techniques in designing and manufacturing the subject devices to reduce risks. All risks including acceptable risks were assessed individually in these documents. Femoral Nail Systems risk documentation covering all in-scope parts, as outlined within the risk documents, are listed below (Table 155).

Table : Risk Management Documents

| Risk Management Document | Reference Number |
| --- | --- |
| System #1: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | |
| Femoral Shaft Nailing Implants RMR | Windchill #0000259337 |
| Femoral Shaft Nailing Implants DCRM | Windchill #0000257474 |
| Femoral Shaft Nailing Implants DCRM for Generic Risks | Windchill #0000259158 |
| System #2: Expert Adolescent Lateral Femoral Nail System, System #3: Expert Lateral Femoral Nail System, and System #6: Expert Asian Femoral Nail System | |
| Recon Femoral Nailing Implants RMR | Windchill #0000258778 |
| Recon Femoral Nailing Implants DCRM | Windchill #0000257162 |
| Recon Femoral Nailing Implants DCRM for Generic Risks | Windchill #0000258658 |
| System #4: Femoral Recon Nailing System | |
| Femoral Recon Nail RMR | Windchill #0000077525 |
| Femoral Recon Nail DCRM | Windchill #0000077523 |
| System #5: Retrograde Femoral Nail Advanced System | |
| Retrograde Femoral Nail and Locking Attachment Washer RMR | Windchill #0000273585 |
| Retrograde Femoral Nail and Locking Attachment Washer DCRM | Windchill #0000216378 |

The applicable risk documents were reviewed to compile residual harms for the subject devices assessed during the risk management process which necessitated further action. The residual risks are identified as risks either with “High” or “As far as possible” (AFAP) risk levels. The risk compilation specific to the subject devices identified nine (9) harm with High risk levels and eighteen (18) harm with AFAP risk levels within DCRMs (see Table 156). The potential harms associated to the High and AFAP risk levels are listed below in Table 156 with the residual severity of harm score and residual probability of occurrence score (post risk control). All risks remaining after implementation of reduction/mitigation actions are judged as tolerable in relation to the medical benefits of the subject devices. There are a number of hazards associated with each harm identified in the table, the overall risk evaluation and list of all residual risks that have a potential to result in each harm and can be found in the DCRMs (Table 156).

Table : Femoral Nail Systems High and AFAP Harms

| DCRM Document (Windchill #) | Possible Harms | Highest Risk Level | Residual Severity | Residual Probability of Occurrence (PoC) |
| --- | --- | --- | --- | --- |
| System #1: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System\* | | | | |
| 0000257474 | Embolism | HIGH | 5 | 1 |
| Embolism | 5 | 2 |
| Bone Damage – Major | AFAP | 4 | 1 |
| Injury to User – Major | 4 | 1 |
| System #2: Expert Adolescent Lateral Femoral Nail System, System #3: Expert Lateral Femoral Nail System, and System #6: Expert Asian Femoral Nail System | | | | |
| 0000257162 | Bone Damage – Major | HIGH | 4 | 2 |
| Damage to vital organs | 5 | 1 |
| Embolism | 5 | 1 |
| Bone Damage – Moderate | AFAP | 3 | 3 |
| Device Breakage – Post-operatively – Moderate | 3 | 3 |
| Infection – Major | 4 | 1 |
| Injury to User – Major | 4 | 1 |
| Malunion / Non-union – Moderate | 3 | 3 |
| Surgical Delay – Moderate | 3 | 3 |
| 0000258658 | Injury to user – Major | AFAP | 4 | 1 |
| System #4: Femoral Recon Nailing System | | | | |
| 0000077523 | Bone Damage – Major | HIGH | 4 | 2 |
| Damage to vital organ | 5 | 1 |
| Embolism | 5 | 1 |
| Bone Damage – Moderate | AFAP | 3 | 3 |
| Damage to Surrounding Structures – Moderate | 3 | 3 |
| Infection – Major | 4 | 1 |
| Injury to User – Major | 4 | 1 |
| Poor Joint Mechanics | 3 | 3 |
| Surgical Delay – Moderate | 3 | 3 |
| System #5: Retrograde Femoral Nail Advanced System | | | | |
| 0000216378 | Embolism | HIGH | 5 | 1 |
| Adverse Tissue Reaction – Major | AFAP | 4 | 1 |
| Infection – Major | 4 | 1 |
| Injury to User – Major | 4 | 4 |

\*Note: Femoral Shaft Nailing Implants DCRM for Generic Risks (Windchill #0000259158) does not contain any HIGH or AFAP harms.

The below tables (Table 157 – Table 162) compares all harms identified in clinical data (literature, PMCF and PMS complaints) to the anticipated harms captured in the risk documentation and, where appropriate, conveyed to the user via the Instructions for Use (IFU) for the Femoral Nail Systems. All harms were appropriately covered and there were no new or emerging risks.

Table : Harms Identified by Clinical Data Source for Expert Retrograde Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1)

| Harm category | Harm Identified within Literature (Sections 4.3.1, 4.3.2, 4.10.1 and 4.10.2) | Harm Identified within PMS  (Section 6.1) | Harm Identified within PMCF (Section 6.2) | Harm Identified in Risk Analysis  (#0000257474 and #0000259158)  (Section ) | Residual Risk Identified in IFU | |
| --- | --- | --- | --- | --- | --- | --- |
| (MDD: SE\_532126)  (Section 3.1.1 to 3.1.3) | (MDR: SE\_833508)  (Section 3.1.1 & 3.1.3 |
| Adverse Tissue Reaction | No | Yes | No | Accept: Adverse Tissue Reaction – Moderate (Windchill #0000257474 and #0000259158) | Yes – allergy/hypersensitivity reactions | Yes – Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction |
| Bone Damage | No | Yes | Yes | AFAP: Bone Damage – Major (Windchill #0000257474) | Yes – functional impairment of the musculoskeletal system | Yes – Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis |
| Bone Fracture Intra-op/Post-op | Yes | Yes | Yes | Accept: Bone Fracture Intra-op – Moderate (Windchill #0000257474 and #0000259158)  Accept: Bone Fracture Post-op – Moderate (Windchill #0000257474 and #0000259158) | Yes – functional impairment of the musculoskeletal system | Yes – Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis |
| Device Breakage | Yes | No | No | Accept: Device Breakage – Post-operatively – Moderate (Windchill #0000257474) | No – Not mentioned  Device breakage is a failure, not a harm. It would manifest as some other harm (nonunion, pain, fracture, etc.). | Yes – Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Device Loosening | Yes | No | Yes | Accept: Device Loosening – Moderate (Windchill #0000257474) | Yes – side effects associated with hardware prominence | Yes – Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Deep Vein Thrombosis | No | No | Yes | Accept: Damage to Surrounding Structures – moderate (Windchill #0000257474 and #0000259158) | Yes – thrombosis | Yes – Damage to Vital Organs or Surrounding Structures |
| Embolism | Yes | No | Yes | HIGH: Embolism (Windchill #0000257474) | Yes – embolism | Yes – Damage to Vital Organs or Surrounding Structures |
| Infection | Yes | Yes | Yes | Accept: Infection – Moderate (Windchill #0000257474 and #0000259158) | Yes – infection | Yes – Infection |
| Injury to User | No | No | No | AFAP: Injury to User – Major (Windchill #0000257474)  Accept: Injury to user – moderate (Windchill #0000259158 | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device. | Yes – Injury to User |
| Malunion/ Nonunion | Yes | Yes | Yes | Accept: Malunion / Non-union – Moderate (Windchill #0000257474 and #0000259158) | Yes – malunion, nonunion | Yes – Malunion/Non-union |
| Pain | Yes | No | Yes | Accept: Pain – Moderate (Windchill #0000257474) | Yes – Sudeck’s disease and side effects associated with hardware prominence | Yes – Pain or Discomfort |
| Peroneal Nerve Paresthesia | No | No | Yes | Neuro-vascular Damage – Moderate (Windchill #0000257474) | No – Not mentioned.  Acceptable risk – The occurrence rate of the risk associated with this harm is reduced to the lowest level possible. | Yes - Neuro-vascular Damage |
| Poor Joint Mechanics | Yes | Yes | Yes | Accept: Poor Joint Mechanics (Windchill #0000257474) | Yes – functional impairment of the musculoskeletal system | Yes – Poor Joint Mechanics |
| Soft Tissue Damage | Yes | Yes | No | Accept: Soft Tissue Damage – Marginal (Soft Tissue Irritation) (Windchill #0000257474)  Accept: Soft Tissue Damage – Moderate (Windchill #0000257474) | Yes – damage to soft tissues incl. swelling | Yes – Soft Tissue Damage (including Compartment Syndrome) |
| Surgical Delay | No | Yes | No | Accept: Surgical Delay – Moderate (Windchill #0000257474 and #0000259158)  Accept: Surgical Delay – Marginal (Windchill #0000257474) | No – Not mentioned.  Acceptable risk – The occurrence rate of the risk associated with this harm is reduced to the lowest level possible. | Yes – Surgical Delay |

Table : Harms Identified by Clinical Data Source for Expert Adolescent Lateral Femoral Nail System (System #2)

| Harm category | Harm Identified within Literature (Section 4.4.1 and 4.4.2) | Harm Identified within PMS (Section 6.1) | Harm Identified within PMCF (Section 6.2) | Harm Identified in Risk Analysis  (#0000257162 and #0000258658)  (Section ) | Residual Risk Identified in IFU  (MDD IFU: SE\_532126)  (Section 3.1.4 to 3.1.6) |
| --- | --- | --- | --- | --- | --- |
| Bone Damage | Yes | No | No | HIGH: Bone Damage – Major (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Bone Fracture Post-op | Yes | No | No | Accept: Bone Fracture Post-op – Moderate (Windchill #0000258658) | Yes – functional impairment of the musculoskeletal system |
| Damage to vital organs | No | No | No | HIGH: Damage to vital organs (Windchill #0000257162) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device. |
| Device Breakage – Post-operatively | No | No | No | AFAP: Device Breakage – Post-operatively – Moderate (Windchill #0000257162) | No – Not mentioned  Device breakage is a failure, not a harm. It would manifest as some other harm (nonunion, pain, fracture, etc.). |
| Device Loosening | Yes | No | No | Accept: Device Loosening – Moderate (Windchill #0000257162) | Yes – side effects associated with hardware prominence |
| Embolism | No | No | No | HIGH: Embolism (Windchill #0000257162) | Yes – embolism |
| Infection | Yes | Yes | Yes | AFAP: Infection – Major (Windchill #0000257162)  Accept: Infection – Moderate (Windchill #0000258658) | Yes – infection |
| Injury to User | No | No | No | AFAP: Injury to User – Major (Windchill #0000257162 and #0000258658) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device |
| Malunion/Nonunion | Yes | Yes | No | AFAP: Malunion / Non-union – Moderate (Windchill #0000257162)  Accept: Malunion / Non-union – Moderate (Windchill #0000258658) | Yes – malunion, nonunion |
| Pain | No | Yes | Yes | Accept: Pain – Moderate (Windchill #0000257162) | Yes – Sudeck’s disease and side effects associated with hardware prominence |
| Poor Joint Mechanics | Yes | Yes | No | Accept: Poor Joint Mechanics (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Surgical Delay | No | Yes | No | AFAP: Surgical Delay – Moderate (Windchill #0000257162)  Accept: Surgical Delay – Moderate (Windchill #0000258658) | No – Not mentioned.  The occurrence rate of the risk associated with this harm is reduced to as far as possible. |

Table : Harms Identified by Clinical Data Source for Expert Lateral Femoral Nail System (System #3)

| Harm category | Harm Identified within Literature (Section 4.5.1, 4.5.2, 4.10.1 and 4.10.2) | Harm Identified within PMS (Section 6.1) | Harm Identified within PMCF (Section 6.2) | Harm Identified in Risk Analysis  (#0000257162 and 0000258658)  (Section ) | Residual Risk Identified in IFU  (MDD IFU: SE\_532126)  (Section 3.1.7 to 3.1.9) |
| --- | --- | --- | --- | --- | --- |
| Bone Damage | Yes | Yes | No | HIGH: Bone Damage – Major (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Bone Fracture Post-op | Yes | Yes | No | Accept: Bone Fracture Post-op – Moderate (Windchill #0000258658) | Yes – functional impairment of the musculoskeletal system |
| Damage to vital organs | No | No | No | HIGH: Damage to vital organs (Windchill #0000257162) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device. |
| Device Breakage | Yes | Yes | No | AFAP: Device Breakage – Post-operatively – Moderate (Windchill #0000257162) | No – Not mentioned  Device breakage is a failure, not a harm. It would manifest as some other harm (nonunion, pain, fracture, etc.). |
| Device Loosening | Yes | No | No | Accept: Device Loosening – Moderate (Windchill #0000257162) | Yes – side effects associated with hardware prominence |
| Embolism | No | No | No | HIGH: Embolism (Windchill #0000257162) | Yes – embolism |
| Infection | Yes | Yes | Yes | AFAP: Infection – Major (Windchill #0000257162)  Accept: Infection – Moderate (Windchill #0000258658) | Yes – infection |
| Injury to User | No | No | No | AFAP: Injury to User – Major (Windchill #0000257162 and #0000258658) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device |
| Malunion/Nonunion | Yes | Yes | Yes | AFAP: Malunion / Non-union – Moderate (Windchill #0000257162)  Accept: Malunion / Non-union – Moderate (Windchill #0000258658) | Yes – malunion, nonunion |
| Pain | Yes | Yes | No | Accept: Pain – Moderate (Windchill #0000257162) | Yes – Sudeck’s disease and side effects associated with hardware prominence |
| Poor Joint Mechanics | Yes | Yes | No | Accept: Poor Joint Mechanics (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Soft Tissue Damage | Yes | No | No | Accept – Soft Tissue Damage – Marginal (Soft Tissue Irritation) (Windchill #0000257162)  Accept – Soft Tissue Damage – Moderate (Windchill #0000257162) | Yes – damage to soft tissues incl. swelling |
| Surgical Delay | No | Yes | No | AFAP: Surgical Delay – Moderate (Windchill #0000257162)  Accept: Surgical Delay – Moderate (Windchill #0000258658) | No – Not mentioned.  The occurrence rate of the risk associated with this harm is reduced to as far as possible. |

Table : Harms Identified by Clinical Data Source for Femoral Recon Nailing System (System #4)

| Harm category | Harm Identified within Literature (Section 4.10.2) | Harm Identified within PMS (Section 6.1) | Harm Identified within PMCF (Section 6.2) | Harm Identified in Risk Analysis (#0000077523)  (Section ) | Residual Risk Identified in IFU  (MDD IFU: SE\_532126)  (Section 3.1.10 to 3.1.12) |
| --- | --- | --- | --- | --- | --- |
| Bone Damage | Yes | Yes | No | HIGH: Bone Damage – Major | Yes – functional impairment of the musculoskeletal system |
| Bone Fracture Post-op | No | Yes | No | Accept: Bone Fracture Post-op – Moderate | Yes – functional impairment of the musculoskeletal system |
| Damage to vital organs | No | No | No | HIGH: Damage to vital organ | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device. |
| Deep Vein Thrombosis | No | No | Yes | AFAP: Damage to Surrounding Structures – Moderate | Yes – thrombosis |
| Device Breakage | No | Yes | No | Accept: Device Breakage – Post-operatively – Moderate | No – Not mentioned  Device breakage is a failure, not a harm. It would manifest as some other harm (nonunion, pain, fracture, etc.). |
| Device Loosening | Yes | No | No | Accept: Device loosening – Moderate | Yes – side effects associated with hardware prominence |
| Embolism | No | No | Yes | HIGH: Embolism | Yes – embolism |
| Infection | No | Yes | Yes | HIGH: Infection – Major | Yes – infection |
| Injury to User | No | No | No | AFAP: Injury to User – Major | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device |
| Malunion/Nonunion | Yes | Yes | Yes | Accept: Malunion / Non-union – Moderate | Yes – malunion, nonunion |
| Neuro-vascular Damage |  | Yes |  | Accept: Neurovascular Damage – Moderate | Yes – iatrogenic neural and vascular injury |
| Pain | No | Yes | Yes | Accept: Pain – Moderate | Yes – Sudeck’s disease and side effects associated with hardware prominence |
| Poor Joint Mechanics | No | Yes | No | AFAP: Poor Joint Mechanics | Yes – functional impairment of the musculoskeletal system |
| Surgical Delay | No | Yes | No | AFAP: Surgical Delay – Moderate | No – Not mentioned.  The occurrence rate of the risk associated with this harm is reduced to as far as possible. |

Table : Harms Identified by Clinical Data Source for Retrograde Femoral Nail Advanced System (System #5)

| Harm category | Harm Identified within Literature (Section 4.7.2) | Harm Identified within PMS (Section 6.1) | Harm Identified within PMCF (Section 6.2) | Harm Identified in Risk Analysis (#0000216378)  (Section ) | Residual Risk Identified in IFU  (MDD IFU: SE\_793149)  (Section 3.1.13 to 3.1.15) |
| --- | --- | --- | --- | --- | --- |
| Adverse Tissue Reaction | No | No | No | AFAP: Adverse Tissue Reaction – Major | Yes – Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction |
| Bone Damage | No | No | No | Accept: Bone Damage – Marginal  Accept: Bone Damage – Moderate | Yes – Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis |
| Device Breakage | No | Yes | No | Not Reported  The occurrence of this harm is very low and has occurred in 0.018% (i.e., 2 complaints) of the devices sold (11,388) during the five year PMS review period. | Yes – Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Device Loosening | No | No | Yes | Accept: Device Loosening – Moderate | Yes – Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage |
| Embolism | No | No | Yes | HIGH: Embolism | Yes – Embolism |
| Infection | No | Yes | Yes | AFAP: Infection – Major | Yes – Infection |
| Injury to User | No | No | No | AFAP: Injury to User – Major | Yes – Injury to User |
| Malunion/Nonunion | No | Yes | Yes | Accept: Malunion/Non-union – Moderate | Yes – Malunion/Nonunion |
| Neuro-vascular Damage | No | No | Yes | Accept: Neurovascular Damage – Moderate | Yes – Neuro-vascular Damage |
| Pain | No | Yes | Yes | Accept: Pain – Moderate | Yes – Pain or Discomfort |
| Poor Joint Mechanics | No | Yes | No | Accept: Poor Joint Mechanics | Yes – Poor Joint Mechanics |
| Soft Tissue Damage | No | Yes | Yes | Accept: Soft Tissue Damage – Moderate | Yes – Soft Tissue Damage (including Compartment Syndrome) |
| Surgical Delay | No | Yes | No | Accept: Surgical Delay – Marginal  Accept: Surgical Delay – Moderate | No – Not mentioned.  The occurrence rate of the risk associated with this harm is acceptable. |

Table : Harms Identified by Clinical Data Source for Expert Asian Femoral Nail System (System #6)

| Harm category | Harm Identified within Literature (Sections 4.8.1, 4.8.2, and 4.10.2) | Harm Identified within PMS (Section 6.1) | Harm Identified in Risk Analysis  (#0000257162 and #0000258658)  (Section ) | Residual Risk Identified in IFU  (MDD IFU: SE\_532126)  (Section 3.1.16 to 3.1.18) |
| --- | --- | --- | --- | --- |
| Adverse Tissue Reaction | No | Yes | Accept: Adverse Tissue Reaction – Moderate (Windchill #0000257162 and #0000258658) | Yes – allergy/hypersensitivity reactions |
| Bone Damage | Yes | Yes | HIGH: Bone Damage – Major (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Bone Fracture Post-op | Yes | Yes | Accept: Bone Fracture Post-op – Moderate (Windchill #0000258658) | Yes – functional impairment of the musculoskeletal system |
| Damage to vital organs | No | No | HIGH: Damage to vital organs (Windchill #0000257162) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device. |
| Device Breakage – Post-operatively | Yes | No | AFAP: Device Breakage – Post-operatively – Moderate (Windchill #0000257162) | No – Not mentioned  Device breakage is a failure, not a harm. It would manifest as some other harm (nonunion, pain, fracture, etc.). |
| Device Loosening | Yes | No | Accept: Device Loosening – Moderate (Windchill #0000257162) | Yes – side effects associated with hardware prominence |
| Embolism | Yes | No | HIGH: Embolism (Windchill #0000257162) | Yes – embolism |
| Infection | Yes | Yes | AFAP: Infection – Major (Windchill #0000257162)  Accept: Infection – Moderate (Windchill #0000258658) | Yes – infection |
| Injury to User | No | No | AFAP: Injury to User – Major (Windchill #0000257162 and #0000258658) | No – Not Mentioned  This harm has not been reported in any of the clinical data sources with the use of subject device |
| Malunion/Nonunion | Yes | Yes | AFAP: Malunion / Non-union – Moderate (Windchill #0000257162)  Accept: Malunion / Non-union – Moderate (Windchill #0000258658) | Yes – malunion, nonunion |
| Neurovascular Damage | Yes | No | Accept: Neuro-vascular Damage – Moderate (Windchill #0000257162) | Yes – iatrogenic neural and vascular injury |
| Pain | Yes | Yes | Accept: Pain – Moderate (Windchill #0000257162) | Yes – Sudeck’s disease and side effects associated with hardware prominence |
| Phlebitis | Yes | No | Accept: Phlebitis (Windchill #0000257162) | Yes – iatrogenic neural and vascular injury |
| Poor Joint Mechanics | Yes | Yes | Accept: Poor Joint Mechanics (Windchill #0000257162) | Yes – functional impairment of the musculoskeletal system |
| Soft Tissue Damage | Yes | Yes | Accept – Soft Tissue Damage – Marginal (Soft Tissue Irritation) (Windchill #0000257162)  Accept – Soft Tissue Damage – Moderate (Windchill #0000257162) | Yes – damage to soft tissues incl. swelling |
| Surgical Delay | No | Yes | AFAP: Surgical Delay – Moderate (Windchill #0000257162)  Accept: Surgical Delay – Moderate (Windchill #0000258658) | No – Not mentioned.  The occurrence rate of the risk associated with this harm is reduced to as far as possible. |

Potential adverse events, undesirable side effects and residual risks, as detailed in the IFU, are listed below and are quantified for the subject device as follows (Table 163). The analysis includes all the associated data that are of sufficient scientific validity and relevance to the intended use to be suitable to assess the safety and performance. The median rate (multiple datasets) or rate (single dataset) of reported harms is shown along with the corresponding follow-up time, when reported, for the same population. All the identified risks were found to be acceptable when weighed against the benefits of the subject device.

Table 163: IFU Residual Risks/Harms Identified from Identified Clinical Data Sources Used to Assess Safety and Performance of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and Spiral Blade for Expert Retrograde/Antegrade Femoral Nail

| IFU Residual Risk / Harm Category | Rate of Reported Residual Risks / Harms for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail and Spiral Blade for Expert Retrograde/Antegrade Femoral Nail | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Scientific Literature | | PMCF – Real World Evidence | | PMCF – Data Use Agreement | |
| Median/Mean Rate (Range) (%) | Mean Follow-Up (Range) (months) | Rate (%) | Follow-Up (months) | Rate (%) | Follow-Up (months) |
| Adverse Tissue Reaction, Allergy/Hypersensitivity Reaction | NR | NR | NR | NR | NR | NR |
| Bone Damage including Intra-and Post-Operative Bone Fracture, Osteolysis, or Bone Necrosis | NR | NR | NR | NR | NR | NR |
| Embolism | NR | NR | NR | NR | 0.0 | 1 – 36 |
| Damage to Vital Organs or Surrounding Structures | NR | NR | NR | NR | 0.0 | 1 – 36 |
| Symptoms resulting from Implant Migration, Loosening, Bending, or Breakage | 0.0 – 4.00 | 49.20 | NR | NR | NR | NR |
| Dislocation | NR | NR | NR | NR | NR | NR |
| Infection | 0.00 – 0.00 | 16.70 – 49.20 | NR | NR | 0.0 | 1 – 44 |
| Injury to User | NR | NR | NR | NR | NR | NR |
| Malunion/Non-union | | | | |  |  |
| Nonunion | 0.00 – 24.00 | 16.70 – 49.20 | 3.3 – 3.6 | 12 | 0.0 – 4.90 | 1 – 44 |
| Malunion | 0.00 | 49.20 | 0.3 – 0.3 | 12 | 0.0 | 1 – 35 |
| Neuro-vascular Damage | 0.00 | 49.20 | NR | NR | 0.0 | 2 – 44 |
| Pain or Discomfort | NR | NR | NR | NR | 6.56 | 2 – 44 |
| Phlebitis | NR | NR | NR | NR | NR | NR |
| Poor Joint Mechanics | 0.00 | 16.70 – 21.60 | NR | NR | 0.0 – 1.6 | 1 – 44 |
| Soft Tissue Damage (including Compartment Syndrome) | NR | NR | NR | NR | NR | NR |
| Surgical Delay | NR | NR | NR | NR | NR | NR |

NR – Not Reported

Risk Quantification Limitations:

The rates in Table 163 are specific to the publications/reports identified and are not necessarily reflective of device-related complication rates associated with the entire patient population. Individual data sources may report complication rates that differ from those listed in Table 163. This can be due to a number of factors which include the following.

* Some publications / reports may be excluded from this calculation if they do not have sufficient scientific validity and relevance to quantify the safety outcomes. Examples of publications / reports that may be excluded include the following:
  + data with gaps that cannot be justified (e.g., missing information, publication bias, time lag bias, insufficient follow-up, low sample size, insufficient statistical analysis, off-label use, misuse)
  + data that are not appropriately stratified for device intended purpose (e.g., by device type, indication, patient population, stage of disease/condition, anatomical area, standard of care not representative of European Union practices)
  + data with endpoints that are not appropriate to assess the identified safety outcomes
* Reported risks/harms may be procedure- or patient-related rather than device-related as the reason for the risk/harm is not always discernable from the publication.
* Individual studies only evaluate a subset of the full patient population and these publications / reports may or may not quantitatively report on complication rates.
* Publications/reports may contain selective, smaller, or different patient populations, diagnoses, or severity of disease/condition with narrow diversity, based upon the research question being asked that may improperly skew quantitative comparisons.
* Publication/report variability in the post-operative follow-up time period for which the complication rates are reported creating heterogeneous data.
* Publication/report variability in the definition of complications / adverse events or the parameters used for measurement.

### Summary of Significant Complaints / Trends / Vigilance from Previous Generations

Not Applicable – As referenced in Section 3.4, there are no previous generations of the subject devices.

### Side-Effects Acceptability

Acceptability of the side-effects related to the Femoral Nail Systems needs to be interpreted considering the acceptability of side-effects from the target treatment options (intramedullary nail fixation) and the acceptability can be demonstrated using key safety outcomes, which is representative of the subject devices. The key safety outcomes include infection, nonunion, and revision.

All risks have been assessed in the DCRM (Table 156). The overall risk versus benefit analysis weighs all risks compared to the patient benefit. The DCRM was reviewed and approved by a cross functional team ensuring that there are no conflicting risk controls and/or requirements. No emerging issues or risks were identified through an assessment of all available clinical data (Table 157 – Table 162). The severity and probability of occurrence of risks was properly identified and based on data derived from the Design and Clinical Management analysis.

PMS data (Section 6.1) was reviewed for the Femoral Nail Systems for the 5 year review period (02 October 2017 to 02 October 2022), for which, there was low complaints (0.08%) rate reported for 448,133 units sold globally. Additionally, all harm reported in the PMS were less than (0.03%) and the most commonly reported harms were surgical delay (0.02%), malunion/nonunion (0.1%), and infection (0.1%). Further, embolism was one of the most common possible harm reported in the DCRMs (Table 156) with the use of intramedullary nails. However, there was only one case of embolism (0.0002%) reported during the five year PMS review period. There were no deaths reported in the PMS data with the use of Femoral Nail Systems.

Adverse events were identified from 2,162 patients across 61 on-label publications from the clinical literature (Section 4) and from 3,502 patients across 11 PMCF studies (completed and on-going) (Section 6.2). The clinical data (literature and PMCF) reviewed for the Femoral Nail Systems show that no new or emerging risks have been identified through this clinical evaluation. The reviewed clinical data do not suggest any further risk mitigation or required amendments to the product information, IFU, or warnings.

To assess whether the subject devices provide a state-of-the-art treatment option to address the target clinical conditions and to assess whether the side-effects related to the Femoral Nail Systems are acceptable, the key safety outcomes for the subject devices were assessed against the target treatment option (intramedullary nail fixation) described in the SOA. As demonstrated in Table 171 – Table 176, the subject devices meet the target treatment option acceptability criteria established in the state of the art review (Section 3.9.5).

As the devices are used as a construct in real world practice, data described in clinical literature and PMCF studies are represented by the usage of these devices as a system, which is reflective of the safety of the singular device groups. A summary of the datasets that were identified in Section 3.6.1 as having sufficient scientific validity and relevance to support the safety conformity assessment relative to the acceptance criteria are documented below (Table 164 – Table 170)

Table : Clinical Data Supporting Safety Conformity Assessment for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.3.1) | * Femoral shaft fractures * Distal femur fractures | 373 | Not Reported | 31.5 – 74.4 years | Not Reported | 7.50 – 49.20 |
| PMCF Activity / RWE  (Section 6.2.1) | * Femoral shaft fractures * Distal femur fractures | 2617 | Not Reported\* | 10 – 89 years | Not Reported | 3 – 12 months |
| PMCF Activity / DUA  (Section 6.2.2) | * Femoral shaft fractures * Distal femur fractures | 179 | 31 years | 16 – 85 years | 7 months | 1 – 36 months |
| PMCF Activity / DUA  (Section 6.2.3) | * Femoral shaft fractures * Distal femur fractures | 65 | 32 years | 18 – 87 years | 263 days | 19 – 1072 days |
| PMCF Activity / DUA  (Section 6.2.4) | * Femoral shaft fractures * Distal femur fractures | 59 | 30 years | 18 – 77 years | 14 months | 2 – 44 months |

\*Note: There was no overall median provided in this PMCF study report, however, individual median values were provided for each device group. i.e., Synthes patients had a median (range) age of 42 (12-89) years and Unspecified patients had a median (range) age of 48 (10-89) years.

Table : Clinical Data Supporting Safety Conformity Assessment for Expert Adolescent Lateral Femoral Nail System (System #2)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.4.1) | * Femoral shaft fractures | 15 | Not Reported | 14 years | 33.60 months | 33.60 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 56 | 15 years | 10 – 83 years | 5.5 months | 1.5 – 36 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 10 | 14 years | 10 – 61 years | 94.6 weeks | 43 – 231 weeks |

\*Note: Expert Adolescent Lateral Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and ipsilateral femoral neck/shaft fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Safety Conformity Assessment for Expert Lateral Femoral Nail System (System #3)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.5.1) | * Femoral shaft fractures | 190 | Not Reported | 30.6 – 34.8 years | 21.0 months | 21.0 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 219 | 33 years | 14 – 81 years | 5.5 months | 1 – 18 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 2 | 40.5 years | 24 – 57 years | 121.5 weeks | 35 – 208 weeks |

\*Note: Expert Lateral Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Safety Conformity Assessment for Femoral Recon Nailing System (System #4)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Subject Device Data Sources Details | | | | | | |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 25 | 31 years | 18 – 76 years | 4.5 months | 3 – 9 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 42 | 37 years | 16 – 73 years | 61.8 weeks | 24 – 195 weeks |
| PMCF Activity / IIS  (Section 6.2.7) | * Femoral shaft fractures | 37 | 31 years | 18 – 88 years | Not Reported | 3 – 12 months |
| Equivalent Device Data Source Details (Expert Lateral Femoral Nail System) | | | | | | |
| Device-Specific Literature (Section 4.5.1) | * Femoral shaft fractures | 190 | Not Reported | 30.6 – 34.8 years | 21.0 months | 21.0 months |
| PMCF Activity / DUA  (Section 6.2.5) | * Femoral shaft fractures | 219 | 33 years | 14 – 81 years | 5.5 months | 1 – 18 months |
| PMCF Activity / DUA  (Section 6.2.6) | * Femoral shaft fractures | 2 | 40.5 years | 24 – 57 years | 121.5 weeks | 35 – 208 weeks |

\*Note: Femoral Recon Nailing System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Safety Conformity Assessment for Retrograde Femoral Nail Advanced System (System #5)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median/Mean | Overall Range | Mean | Overall Range |
| Subject Device Data Sources Details | | | | | | |
| PMCF Activity / IIS  (Section 6.2.8) | * Femoral shaft fractures * Distal femur fractures | 30 | 49.2 years | 15 – 91 years | 18 weeks | 2 – 48 weeks |
| PMCF Activity / IIS  (Section 6.2.9) | * Femoral shaft fractures * Distal femur fractures | 20 | Not Reported | 18 – 86 years | Not Reported | 6 months |
| PMCF Activity / IIS  (Section 6.2.10) | * Distal femur fractures | 84 | 57.6 years | Not Reported | Not Reported | Until union or 1 year post-operative |
| PMCF Activity / Internal Registry  (Section 6.2.11) | * Femoral shaft fractures * Distal femur fractures | 24 | 57.0 years | 22 – 78 years | Not Reported | 3 – 12 months |
| Equivalent Device Data Source Details ( Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | | | | | | |
| Device-Specific Literature (Section 4.3.1) | * Femoral shaft fractures * Distal femur fractures | 373 | Not Reported | 31.5 – 74.4 years | Not Reported | 7.50 – 49.20 |
| PMCF Activity / RWE  (Section 6.2.1) | * Femoral shaft fractures * Distal femur fractures | 2617 | Not Reported\* | 10 – 89 years | Not Reported | 3 – 12 months |
| PMCF Activity / DUA  (Section 6.2.2) | * Femoral shaft fractures * Distal femur fractures | 179 | 31 years | 16 – 85 years | 7 months | 1 – 36 months |
| PMCF Activity / DUA  (Section 6.2.3) | * Femoral shaft fractures * Distal femur fractures | 65 | 32 years | 18 – 87 years | 263 days | 19 – 1072 days |
| PMCF Activity / DUA  (Section 6.2.4) | * Femoral shaft fractures * Distal femur fractures | 59 | 30 years | 18 – 77 years | 14 months | 2 – 44 months |

\*Note: There was no overall median provided in the PMCF activity #1 or study report, however, individual median values were provided for each device group. i.e., Synthes patients had a median (range) age of 42 (12-89) years and Unspecified patients had a median (range) age of 48 (10-89) years.

Table : Clinical Data Supporting Safety Conformity Assessment for Expert Asian Femoral Nail System (System #6)

| Data Source (Cross Ref.) | Indications Covered\* | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.8.1) | * Femoral shaft fractures | 120 | Not Reported | 34.5 – 73.1 years | Not Reported | 20.50 – 28.40 |

\*Note: Expert Asian Femoral Nail System is indicated for fixation of femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures. All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions.

Table : Clinical Data Supporting Safety Conformity Assessment for Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail)

| Data Source (Cross Ref.) | Indications Covered | Total # Patients | Patient Age | | Follow-Up | |
| --- | --- | --- | --- | --- | --- | --- |
| Median | Overall Range | Mean | Overall Range |
| Device-Specific Literature (Section 4.10.1) | * Femoral shaft fractures | 8 | Not Reported | 37.75 years | 52.24 months | 52.24 months |

#### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for Femoral Shaft Fractures and Distal Femur Fractures

Clinical evidence of the key safety outcomes for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for femoral shaft fractures and distal femur fractures are summarized below (Table 171).

Table : Safety Outcome Summary – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1) for Femoral Shaft Fractures and Distal Femur Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | Femoral Shaft Fractures: 0.5 – 11.5%  Distal Femur Fractures: 0.0 – 7.14%  Overall: 0.0 – 11.5% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 0.0% | Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (87 patients, f/u: 49.20 months) | 0.0 – 0.0% |
| Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (8 patients, f/u: 16.70 months) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 0.0% |
| Nonunion (% of patients) | ↓ | **Femoral Shaft Fractures**: 0 – 14%  **Distal Femur Fractures**:  4 – 7%  **Overal**l: 0.00 – 14% | Overall Value Range | Data Source / Cohort | Value (Range) | No |
| 0.00 – 24.0% | Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (176 patients, f/u: 30.0 – 49.20 months) | 0.0 – 24.0% |
| Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (43 patients, f/u: 16.70 – 21.60 months) | 0.0 – 12.5% |
| PMCF Activity / RWE for Femoral Shaft Fractures and Distal femur Fractures (Section 6.2.1) (2,617 patients, f/u: 3 – 12 months) | 3.3 – 3.6% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 4.9% |
| Revision (% of patients) | ↓ | **Femoral Shaft Fractures**: 3.8 – 7.1%  **Distal Femur Fractures**: 10.9 – 14.6%  **Overall**: 3.8 – 14.6% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 13.0% | Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (154 patients, f/u: 7.50 – 7.59 months) | 3.9 – 2.6% |
| Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (43 patients, f/u: 16.70 – 21.60 months) | 0.0 – 13.0% |
| PMCF Activity / RWE for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.1) (2,617 patients, f/u: 3 – 12 months) | 2.6% – 4.5%\* |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 0.0% |

\*Note: Subsequent surgery, defined as the patient returning after their index surgery for an additional femur fracture repair surgery or hardware removal procedure, on the same side as the index surgery.

The range of outcome scores for the use of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System for femoral shaft fractures and distal femur fractures for all the key outcome parameters are within the range identified in the acceptance criteria. Therefore, the device key safety outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Adolescent Lateral Femoral Nail System (System #2) for Adolescent Femoral Shaft Fractures

Clinical evidence of the key safety outcomes for Expert Adolescent Lateral Femoral Nail System (System #2) for adolescent femoral shaft fractures are summarized below (Table 172).

Table : Safety Outcome Summary – Expert Adolescent Lateral Femoral Nail System (System #2) for Adolescent Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | 0.0 – 22.2% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 0.0% | PMCF Activity / DUA  (Section 6.2.5) (56 patients (56 fractures), f/u: 1.5 – 36 months) | 0.0% |
| PMCF Activity / DUA  (Section 6.2.6) (10 patients (10 fractures), f/u: 43 – 231 weeks) | 0.0% |
| Nonunion (% of patients) | ↓ | 0.0 – 11.1% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 0.0% | Device-Specific Literature (Section 4.4.1) (15 patients, f/u: 33.60 months) | 0.0% |
| PMCF Activity / DUA  (Section 6.2.5) (56 patients (56 fractures), f/u: 1.5 – 36 months) | 0.0% |
| PMCF Activity / DUA  (Section 6.2.6) (10 patients (10 fractures), f/u: 43 – 231 weeks) | 0.0% |
| Revision (% of patients) | ↓ | 9.5% - 36.9% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 3.6% | PMCF Activity / DUA  (Section 6.2.5) (56 patients (56 fractures), f/u: 1.5 – 36 months) | 3.6% |
| PMCF Activity / DUA  (Section 6.2.6) (10 patients (10 fractures), f/u: 43 – 231 weeks) | 0.0% |

The range of outcome scores for the use of the Expert Adolescent Lateral Femoral Nail System for adolescent femoral fractures for all the key outcome parameters are within the range identified in the acceptance criteria. Therefore, the device key safety outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Lateral Femoral Nail System (System #3) for Femoral Shaft Fractures

Clinical evidence of the key safety outcomes for Expert Lateral Femoral Nail System (System #3) for femoral shaft fractures are summarized below (Table 173).

Table : Safety Outcome Summary – Expert Lateral Femoral Nail System (System #3) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | 0.5 – 11.5% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 0.0% | PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.0% |
| PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |
| Nonunion (% of patients) | ↓ | 0 – 14% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes  Yes, with justification below for minor deviation.  ☐ No |
| 0.0 – 5.0% | Device-Specific Literature (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 5.0% |
| PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.5% |
| PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |
| Revision (% of patients) | ↓ | 3.8 – 7.1% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes  Yes, with justification below for minor deviation.  ☐ No |
| 0.0 – 5.0% | Device-Specific Literature (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 5.0% |
| PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.5% |
| PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |

\*Note: Volgas et al., 2010 stated they followed their 20 patients until complete fracture healing, indicating the follow-up time was sufficient to assess the entire therapeutic lifetime for the given patients.

The range of outcome scores for the use of the Expert Lateral Femoral Nail System for femoral shaft fractures for all the key outcome parameters, are within the range identified in the acceptance criteria. Therefore, the device key safety outcome are considered to be consistent with those for the state of the art benchmarks.

#### Femoral Recon Nailing System (System #4) for Femoral Shaft Fractures

Clinical evidence of the key safety outcomes for Femoral Recon Nailing System (System #4) for femoral shaft fractures are summarized below (Table 174).

Table : Safety Outcome Summary – Femoral Recon Nailing System (System #4) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device and Equivalent Device (Expert Lateral Femoral Nail System) | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | 0.5 – 11.5% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 13.5% | Subject Device:  PMCF Activity / DUA  (Section 6.2.5) (25 patients (25 fractures), f/u: 3 – 9 months) | 0.0% |
| Subject Device:  PMCF Activity / DUA  (Section 6.2.6) (42 patients (42 fractures), f/u: 24 – 195 weeks) | 0.0% |
| Subject Device:  PMCF Activity / IIS  (Section 6.2.7)  (37 patients, f/u: 3 – 12 months or until healing) | 13.5% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |
| Nonunion (% of patients) | ↓ | 0 – 14% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 10.8% | Subject Device:  PMCF Activity / DUA  (Section 6.2.5) (25 patients (25 fractures), f/u: 3 – 9 months) | 0.0% |
| Subject Device:  PMCF Activity / DUA  (Section 6.2.6) (42 patients (42 fractures), f/u: 24 – 195 weeks) | 4.7% |
| Subject Device:  PMCF Activity / IIS  (Section 6.2.7)  (37 patients, f/u: 3 – 12 months or until healing) | 10.8% |
| Equivalent Device:  Device-Specific Literature (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 5.0% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.5% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |
| Revision (% of patients) | ↓ | 3.8 – 7.1% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 7.1% | Subject Device:  PMCF Activity / DUA  (Section 6.2.5) (25 patients (25 fractures), f/u: 3 – 9 months) | 0.0% |
| Subject Device:  PMCF Activity / DUA  (Section 6.2.6) (42 patients (42 fractures), f/u: 24 – 195 weeks) | 7.1% |
| Subject Device:  PMCF Activity / IIS  (Section 6.2.7)  (37 patients, f/u: 3 – 12 months or until healing) | 2.7% |
| Equivalent Device:  Device-Specific Literature (Section 4.5.1) (20 patients, f/u: Not Reported\*) | 5.0% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.5) (219 patients (220 fractures), f/u: 1 – 18 months) | 0.5% |
| Equivalent Device:  PMCF Activity / DUA  (Section 6.2.6) (2 patients (2 fractures), f/u: 35 – 208 weeks) | 0.0% |

\*Note: Volgas et al., 2010 stated they followed their 20 patients until complete fracture healing, indicating the follow-up time was sufficient to assess the entire therapeutic lifetime for the given patients.

The range of outcome scores for the use of the Femoral Recon Nailing System for femoral shaft fractures for all the key outcome parameters, are within the range identified in the acceptance criteria. Therefore, the device key safety outcome are considered to be consistent with those for the state of the art benchmarks.

#### Retrograde Femoral Nail Advanced System (System #5) for Femoral Shaft Fractures and Distal Femur Fractures

Clinical evidence of the key safety outcomes for Retrograde Femoral Nail Advanced System (System #5) for femoral shaft fractures and distal femur fractures are summarized below (Table 175).

Table : Safety Outcome Summary – Retrograde Femoral Nail Advanced System (System #5) for Femoral Shaft Fractures and Distal Femur Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device and Equivalent Device (Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System) | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | Femoral Shaft Fractures: 0.5 – 11.5%  Distal Femur Fractures: 0.0 – 7.14%  Overall: 0.0 – 11.5% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 10.0% | Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.8) (30 patients, f/u: 2 – 48 weeks) | 0.0% |
| Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.9) (20 patients, f/u: 6 months) | 10% |
| Subject Device:  PMCF Activity / IIS for Distal Femur Fractures  (Section 6.2.10)  (84 patients, f/u: until union or 1 year post-operative) | 2.4% |
| Subject Device:  PMCF Activity / Internal Registry for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.11)  (24 patients, f/u: 3 – 12 months) | 4.2% |
| Equivalent Device:  Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (87 patients, f/u: 49.20 months) | 0.0 – 0.0% |
| Equivalent Device:  Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (8 patients, f/u: 16.70 months) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 0.0% |
| Nonunion (% of patients) | ↓ | **Femoral Shaft Fractures**: 0 – 14%  **Distal Femur Fractures**: 4 – 7%  **Overall**: 0.0 – 14% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes  Yes, with justification below for minor deviation.  ☐ No |
| 0.0 – 24.0% | Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.8) (30 patients, f/u: 2 – 48 weeks) | 6.7% |
| Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.9) (20 patients, f/u: 6 months) | 5% |
| Subject Device:  PMCF Activity / IIS for Distal Femur Fractures  (Section 6.2.10)  (84 patients, f/u: until union or 1 year post-operative) | 3.5% |
| Subject Device:  PMCF Activity / Internal Registry for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.11)  (24 patients, f/u: 3 – 12 months) | 0.0% |
| Equivalent Device:  Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (176 patients, f/u: 30.0 – 49.20 months) | 0.0 – 24.0% |
| Equivalent Device:  Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (43 patients, f/u: 16.70 – 21.60 months) | 0.0 – 12.5% |
| Equivalent Device:  PMCF Activity / RWE for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.1) (2,617 patients, f/u: 3 – 12 months) | 3.3 – 3.6% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 4.9% |
| Revision (% of patients) | ↓ | **Femoral Shaft Fractures**: 3.8 – 7.1%  **Distal Femur Fractures**: 10.9 – 14.6%  **Overall**: 3.8 – 14.6% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.0 – 13.0% | Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.8) (30 patients, f/u: 2 – 48 weeks) | 0.0% |
| Subject Device:  PMCF Activity / IIS for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.9) (20 patients, f/u: 6 months) | 5% |
| Subject Device:  PMCF Activity / IIS for Distal Femur Fractures  (Section 6.2.10)  (84 patients, f/u: until union or 1 year post-operative) | 1.2% |
| Subject Device:  PMCF Activity / Internal Registry for Femoral Shaft Fractures and Distal Femur Fractures  (Section 6.2.11)  (24 patients, f/u: 3 – 12 months) | 0.0% |
| Equivalent Device:  Device-Specific Literature for Femoral Shaft Fractures (Section 4.3.1) (154 patients, f/u: 7.50 –7.59 months) | 3.9 – 2.6% |
| Equivalent Device:  Device-Specific Literature for Distal Femur Fractures (Section 4.3.1) (43 patients, f/u: 16.70 – 21.60 months) | 0.0 – 13.0% |
| Equivalent Device:  PMCF Activity / RWE for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.1) (2,617 patients, f/u: 3 – 12 months) | 2.6 – 4.5%\* |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.2) (179 patients (182 fractures), f/u: 1 – 36 months) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.3) (65 patients (68 bones), f/u: 19 – 1072 days) | 0.0% |
| Equivalent Device:  PMCF Activity / DUA for Femoral Shaft Fractures and Distal Femur Fractures (Section 6.2.4) (59 patients (61 fractures), f/u: 2 – 44 months) | 0.0% |

\*Note: Subsequent surgery, defined as the patient returning after their index surgery for an additional femur fracture repair surgery or hardware removal procedure, on the same side as the index surgery.

The range of outcome scores for the use of the Retrograde Femoral Nail Advanced System for femoral shaft fractures and distal femur fractures for all the key outcome parameter, are within the range identified in the acceptance criteria. Therefore, the device key safety outcomes are considered to be consistent with those for the state of the art benchmarks.

#### Expert Asian Femoral Nail System (System #6) for Femoral Shaft Fractures

Clinical evidence of the key safety outcomes for Expert Asian Femoral Nail System (System #6) for femoral shaft fractures are summarized below (Table 176).

Table : Safety Outcome Summary – Expert Asian Femoral Nail System (System #6) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? (Delete choice not selected) |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | 0.5 – 11.5% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes |
| 0.00 – 13.0% | Device-Specific Literature  (Section 4.8.1) (48 patients, f/u: 20.50 – 21.30 months) | 0.00 – 13.0% |
| Nonunion (% of patients) | ↓ | 0 – 14% | Overall Central Value Range | Data Source / Cohort | Central Value (Range) | Yes |
| 10.0% (2.0 – 10.0) | Device-Specific Literature  (Section 4.8.1) (120 patients, f/u: 20.50 – 28.40 months) | 10.0% (2.0 – 10.0) |
| Revision (% of patients) | ↓ | 3.8% - 7.1% | Overall Value Range | Data Source / Cohort | Value (Range) | Yes, with justification below for minor deviation. |
| 10.0 – 13.0% | Device-Specific Literature  (Section 4.8.1) (18 patients, f/u: 20.50 months) | 10.0 – 13.0% |

The range of outcome scores for the use of the Expert Asian Femoral Nail System for femoral shaft fractures for the key outcome parameters, infection and nonunion are within the range identified in the acceptance criteria. Therefore, the device key safety outcomes are considered to be consistent with those for the state of the art benchmarks.

While the range of outcome scores for the use of the Expert Asian Femoral Nail System for femoral shaft fractures exceed the range identified in the acceptance criteria for outcome parameter, revision, these scores are still considered to be consistent with the state of the art benchmarks. Because one patient in the study (Gavaskar et al., 2021) underwent revision nailing (13.0%) after a failed blade plate fixation presented with nonunion 6 months postoperatively. The patient required revision to a nail plate construct with bone grafting, which also failed. The patient elected to not undergo further procedures and was lost to follow-up.

#### Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail[[7]](#footnote-8)) for Femoral Shaft Fractures

Clinical evidence of the key safety outcomes for Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail) for femoral shaft fractures are summarized below (Table 177).

Table : Safety Outcome Summary – Multiple Femoral Nail Systems (Expert Lateral Femoral Nail and Expert Retrograde/Antegrade Femoral Nail) for Femoral Shaft Fractures

| Key Outcome Parameter | Desired Outcome | Acceptance Criteria  (Section 3.9.5) | Subject Device | | | Consistent with Acceptability Criteria? |
| --- | --- | --- | --- | --- | --- | --- |
| Infection (% of patients) | ↓ | 0.5 – 11.5% | Overall Value Rate | Data Source / Cohort | Value (Rate) | No |
| 25.0% | Device-Specific Literature  (Section 4.10.1) (8 patients (1 study), f/u: 52.24 months) | 25.0% |
| Nonunion (% of patients) | ↓ | 0.0 – 14% | Overall Value Rate | Data Source / Cohort | Value (Rate) | No |
| 38.0% | Device-Specific Literature  (Section 4.10.1) (8 patients (1 study), f/u: 52.24 months) | 38.0% |
| Revision (% of patients) | ↓ | 3.8 – 7.1% | Overall Value Rate | Data Source / Cohort | Value (Rate) | No |
| 38.0% | Device-Specific Literature  (Section 4.10.1) (8 patients (1 study), f/u: 52.24 months) | 38.0% |

The range of outcome scores for the use of the Multiple Femoral Nail Systems (Expert Lateral Femoral and Expert Retrograde/Antegrade Femoral Nail) for femoral shaft fractures exceeded the range identified in the acceptance criteria for all outcome parameters, these scores are considered to be consistent with the state of the art benchmarks with the justification provided below.

The study assessed outcomes in eight patient patients with post-traumatic femoral defects, who were managed by monorail external fixation over an intramedullary nail. Of the included eight patients, six of them were injured due to road traffic accidents and two of them due to gunshot wounds. In addition to the fact that all the patients had post-traumatic bone defects, these patients had severe fractures with acute bone loss and were temporarily stabilized with open reduction internal fixation prior to management by monorail external fixation. Further, the study reported two cases (25.0%) of osteomyelitis caused by Staphylococcus epidermidis and Staphylococcus capitis. One of the patient with an osteomyelitis had cellulitis as well and the second patient with osteomyelitis had pin site infection also, these cases were treated by intravenous antibiotics in one patient and removal of infected metalwork with antibiotic treatment in the other patient. There were three cases (38.0%) of nonunion at docking site, of which two cases required an exchange of nail and compression at the docking site. Additionally, the author has stated the small sample size and retrospective design as limitation to this study. The author has concluded the study stating that monorail external fixation over an intramedullary nail is an effective option for managing post-traumatic femoral defects and returning the patients quality of life to a comparable level with the normal population.

### Benefit-Risk Profile Acceptability

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete summary of the available clinical data that can support safety and performance presented in aggregate.   * **Performance Example:** Reported <performance outcome 1> rates from all clinical data sources identified that the use of <subject device> led to a <high/low outcome rates/scores> at final follow up and improvements in function (as measured using <performance outcome 2>) and pain (as measured using <performance outcome 3>) were shown for patients, with <good to excellent> post-operative scores for most patients. These improvements were seen across device types and clinical indications. |
|  |  | Analyze if the benefits of the subject device (Section 8.1.1) outweigh the risks (Section 8.1.2) relative to SOA benchmark treatments to allow the continued use of the device as intended. Utilize the criteria established in Section 3.9.5 to assess the benefit-risk ratio.   * Note: The decision for whether the benefits outweigh the risk should not simply be made on whether all the individual acceptance criteria are met. This decision is multi-factorial and may be impacted by the following. * all the acceptance criteria (in totality) * the extent of probable benefits (type, magnitude, and duration of benefits and probability of patient experiencing one or more benefits) * extent of probable risks/harms (type, severity, number, rate, and duration of risks/harms and probability of patient experiencing one or more risks/harms) * uncertainty of benefit risk data over the entire patient target group * Whether the effectiveness/tolerance of the treatments vary by subpopulation * Whether there are uncertainties or limitations of clinical data, undesirable side-effects, potential for misuse * availability of alternate treatment options * severity of disease/condition * Whether the disease or condition is so severe that patients will tolerate a higher amount of risk for a smaller benefit * disease chronicity, and * If the disease is chronic, whether the illness can be managed with less invasive or difficult treatments * the course of the disease/condition if left untreated * Whether the patients can live with an acceptable quality of life without treatment If any individual acceptance criterion is not met, a justification must be included to substantiate why the overall benefit risk ratio is still favorable. |
|  |  | If the subject devices are MDR Annex XVI devices, discuss the level of risk for the devices when used as intended relative to the SOA benchmark devices.   * Note: These devices must not present a risk at all or the risk presented must not be more than the maximum acceptable risk related to the product’s use which is consistent with a high level of protection for the safety and health of persons (per GSPR 9). |
|  |  | Describe how the device lifetime has been verified and evaluation of function or safety/performance of device. |

To sum up, the performance of the subject devices has been demonstrated through the review of nonclinical and clinical data (clinical literature and PMCF). Nonclinical testing (Section 3.6.2) of the subject devices meet design requirements and user needs to substantiate intended performance. The follow-up time is sufficient to assess the performance and safety of the treatment option and the subject devices. Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to a high outcome rates at final follow up and were seen across device types and clinical indications (see Section 8.1.1).

The expected clinical benefit of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System when used according to instructions for use and recommended technique is the achievement of bone union. This benefit is supported by evidence from the clinical literature and PMCF which shows that bone union rates are comparable to those reported for target treatment option in the state of the art.

Performance was evaluated through a series of mechanical tests and design validation activities to demonstrate the Femoral Nail Systems design outputs meet the design requirements (design inputs), ensure that finished device design and manufacturing conform to defined customer requirements (user and patient needs), and substantiate the system as state-of-the-art for the intended clinical indication. When data were analyzed against the acceptance criteria that Synthes defined in the testing protocols, all tests passed (Section 3.6.2). Biocompatibility testing concluded that the devices in scope are biologically safe for their intended use (Section 3.7.1.1).

In terms of safety outcomes, the rates for infection, nonunion, and revision were acceptable and consistent with those found in the state of the art when used as intended (see Section 8.1.4). Considering the duration of the benefits and risks of the therapy and subject devices, the duration of the benefit is long-term to permanent, whereas the adverse events are usually temporary and can be treated.

Further, the safety of the Femoral Nail Systems has been demonstrated through the review of the PMS data. The PMS analysis for the subject devices reported low complaints rate for the 5-year review period (from 02 October 2017 to 02 October 2022) (see Section 6.1).

To assess the acceptability of the clinical safety and performance data used to confirm conformity with the MDR, the key outcomes for subject device name(s) were compared to like outcomes[[8]](#footnote-9) for the state-of-the-art benchmark treatment options and were found to be comparable. Only data sources of sufficient scientific validity and relevance were used to establish the acceptability criteria for assessing benefit-risk. Furthermore, the type, magnitude, and duration of possible benefits were considered relative to the type, severity, number, rate, and duration of risks/harms to determine whether the benefits outweigh the residual risks over the lifetime of the device.

In addition to device design features, the clinical outcomes can be impacted by multiple factors including, but not limited to, additional surgical procedures, surgical technique, peri-operative management, and many other patient related factors.

The review of clinical data did not identify any new or previously unrecognized risks. The residual risks associated with the Femoral Nail Systems are considered acceptable.

Benefit-Risk Profile Acceptability Summary

Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Femoral Nail Systems are utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art (Section 3.9).

## PMCF Assessment / PMCF Plan (PMCFP)[[9]](#footnote-10)

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Assess whether additional specific and/or general PMCF are warranted.   * This is required for all devices. * To help guide the justification for either conducting or forgoing specific PMCF activities, address the questions from MEDDEV 2.12/2 and MDCG 2020-7 PMCFP Guidance shown in Appendix 9.6 to help identify if there are any open questions from the Clinical Evaluation. * For MDR, if the route of conformity is based on equivalence, PMCF activities are required to demonstrate safety and performance of the device. |
|  |  | If there are “**no circumstances that drive the need for specific PMCF**”, provide a justification with adequate rationale why specific PMCF activities are deemed unnecessary. |
|  |  | If “**any circumstances are identified for which specific PMCF should be considered**”, explicitly discuss each identified circumstance (i.e., open questions stemming from the Clinical Evaluation) and state whether this prompts the need for specific PMCF. Provide sufficient information, via summary or cross-reference, in the rationale to duly justify not conducting specific PMCF. Note: There may be applicable circumstance that don’t warrant specific PMCF. See example below.   * Example: High risk target population, e.g., pediatrics * Sufficient data are present * Risks are appropriately accounted for in risk analysis and determined to be acceptable * Intended use is limited to skeletally mature individuals and while individuals younger than 18 are technically pediatric, some are already skeletally mature. (Cite appropriate reference defining skeletal maturity or documentation by author). * Conclusion: No need for additional specific PMCF |
|  |  | If specific PMCF is required, identify the PMCFP # and a high-level summary of activities described in the PMCFP and estimated completion so it is clear whether it will be expected in the next CER update. This can be in prose, a bulleted list, or tabular list (as desired). |
|  |  | All devices should have some form of ongoing activities to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment (i.e., general PMCF). Identify the PMSP or PMCF Plan (if different from that used to describe specific PMCF activities) and include a high-level summary of the general PMCF activities. |

While the devices have a well-established clinical history, an assessment based on guidance from MEDDEV 2.12-2 and MDCG 2020-7 (Appendix 9.6) was completed to determine whether any additional specific PMCF activities were warranted.

While the clinical data collected to date support that the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System, Femoral Recon Nailing System, and Retrograde Femoral Nail Advanced System are safe and performs in accordance with the intended purpose as stated in the IFU (MDD IFU: SE\_532126 and SE\_793149; and MDR IFU: SE\_833508), additional PMCF is deemed warranted to further investigate specific objectives to address open questions that remains after the Clinical Evaluation; namely: confirmation of safety and performance of the device in a larger and more varied population of patients for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System and Femoral Recon Nailing System; and to generate Retrograde Femoral Nail Advanced System data as clinical evaluation is based on equivalence. Therefore, additional specific post-market clinical follow-up (PMCF) activities have been planned and are ongoing (refer Table 178 for PMCF Plans) to address this objective to further substantiate the safety and performance of the subject devices through the therapeutic lifetime.

For continuous surveillance of the Expert Adolescent Lateral Femoral Nail System and Expert Lateral Femoral Nail System, a PMCF plan have been established (refer Table 178 for PMCF Plan). This plan provides proactive data sources (e.g., general PMCF) which will be incorporated into subsequent clinical evaluations as reports for the activities are completed to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment.

The planned and ongoing activities are summarized in Table 178. Refer to the PMCFP for more detail.

Table : Planned/Ongoing PMCF Activities

| Clinical Activity # from PMCFP | Specific or General PMCF | Clinical Activity Type | Objectives | Estimated Year of Completion |
| --- | --- | --- | --- | --- |
| Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (PMCFP: #500445872) | | | | |
| Investigator Initiated Study  DPS-TCMF-2018-034 | General | Retrospective study (e.g., chart review)  Other: Investigator Initiated Study | Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q2 2023 |
| AO Periprosthetic Registry  DPS-TCMF-2017-018 | General | Prospective observational study  Collecting general data from registries or public/ non-public databases | Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q1 2025 |
| Retrospective data collection | Specific  General | Retrospective study (e.g., chart review) | Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q4 2024 |
| Expert Adolescent Lateral Femoral Nail System and Expert Lateral Femoral Nail System (PMCFP: #500577392) | | | | |
| Retrospective data collection | General | Retrospective study (e.g., chart review) | Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q4 2025 |
| Femoral Recon Nailing System (PMCFP: #500566412) | | | | |
| Investigator Initiated Study  DPS-TCMF-2018-34 | Specific  General | Retrospective study (e.g., chart review) Other: Investigator Initiated Study | Confirmation of safety and performance of the device in a larger and more varied population of patients  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q2 2023 |
| Retrograde Femoral Nail Advanced System (PMCFP: #500441682) | | | | |
| AO Periprosthetic Registry  DPS-TCMF-2017-018 | Specific  General | Prospective observational study  Collecting general data from registries or public/ non-public databases | Clinical evaluation is based on equivalence; subject device data to be generated  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q1 2025 |
| Investigator Initiated Study  DPS-TCMF-2021-033 | Specific  General | Prospective observational study  Retrospective study (e.g., chart review) Other: Investigator Initiated Study | Clinical evaluation is based on equivalence; subject device data to be generated  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q4 2024 |
| Investigator Initiated Study  DPS-TCMF-2021-050 | Specific  General | Retrospective study (e.g., chart review) Other: Investigator Initiated Study | Clinical evaluation is based on equivalence; subject device data to be generated  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q4 2023 |
| Investigator Initiated Study  DPS-TCMF-2021-061 | Specific  General | Retrospective study (e.g., chart review) Other: Investigator Initiated Study | Clinical evaluation is based on equivalence; subject device data to be generated  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence,   Ensuring the continued acceptability of the benefit-risk ratio | Q4 2023 |
| Lower Extremity Shaft Nail Registry  Protocol Number: DST202103 | Specific  General | Prospective observational study World Evidence Study  Collecting general data from registries or public/ non-public databases | Clinical evaluation is based on equivalence; subject device data to be generated  Other:   * Confirming the safety and performance of the device throughout its expected lifetime, * Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, * Identifying emergent risks on the basis of factual evidence, * Ensuring the continued acceptability of the benefit-risk ratio | Q3 2024 |

## 

## CER Update Frequency Assessment

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete the CER Frequency Matrix.   * Identify best choice for each attribute by highlighting cell * After identifying risk classification for all attributes, evaluate an overall risk classification and justify the rationale for the CER update frequency |
|  |  | If there are different groups of devices covered in the CER, assess the CER frequency separately for the different groups (as warranted) and an overall frequency for the CER justified. Alternatively, assess the worst-case group (e.g., highest class or highest risk) and justify the CER Frequency. |
|  |  | State the minimum frequency of routine CER updates below along with rationale and reference to Appendix 9.11 for frequency assessment. |

Due to the class/risk evaluation of the subject devices, the frequency of CER updates will be at least every year (Refer to Appendix 9.11).

## Conclusion

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Provide a high-level summary of the performance and safety data available for each System/Device Group by intended use /indication/claim/patient target group (as appropriate) over the device lifetime and cross-reference data summaries in Sections 8.1.1 and , respectively. Include (at least) the following in the summary:   * Expected clinical benefits (required for MDR only, as stated in Sections 3.1.X) * Key performance and safety outcome parameters used to evaluate benefit-risk assessment * Type of included data (per Section 3.6.1) * Pertinent included data demographics (e.g., number of patients/publications, age range, length of follow-up range) * Whether any new or emerging harms identified in the review |
|  |  | State if the harms /adverse events /side-effects were judged to be acceptable and whether the benefits of the device outweighed the risks relative to the state of the art. |
|  |  | State if the contents of the IFU (i.e., description of the intended purpose, indications, patient target group(s), handling instructions, type and frequency of risks, warnings, precautions, contraindications) and any additional claims are supported by adequate clinical evidence and are in line with the risk analysis. |
|  |  | Identify if any actions are necessary as a result of the clinical evaluation, including a reference to an associated quality system reference. |
|  |  | Provide valid conclusion (based on entirety of CER) on whether sufficient clinical data are documented in the CER to help support the safety and performance of the subject device(s) when used as intended over the lifetime of the device(s) and, for MDR, whether the types of data included (per Section 3.6.1) meet the requirements of MDCG 2020-6. |
|  |  | Identify whether specific and/or general PMCF were determined to be warranted, including cross-reference to associated PMS/PMCF Plan(s) and Section 8.2. |
|  |  | Conclude whether the regulatory requirements of the Clinical Evaluation have been met by addressing the following:   * Whether a pre-market CI was completed, or an exemption duly justified (required only for class III and implantable devices). * Whether an SSCP was written and referenced in the CER (MDR class III and implantable devices only) with cross reference to Section 9.1.2. * If CI(s) was(were) conducted, whether the CI met the applicable requirements (e.g., MDR 745/2017), ethical studies (e.g., origin in Declaration of Helsinki), medical device standards (e.g., EN ISO 14155 or comparable standards). * If CE-marking was based on equivalence, whether a PMCFP is in place to collect sufficient clinical data on the subject device for the intended use/indications over the device lifetime. * Whether the compliance with relevant ERs/GSPRs has been adequately demonstrated. * End the section with a concluding statement substantiating that there are sufficient safety and performance data to support conformity of the devices subject to the evaluation with the relevant ERs of the MDD, and/or GSPRs of the MDR. |

### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

The clinical data used to assess safety and performance of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System is summarized in Table 179. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the state of the art (SOA) review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources. These data were used to assess the expected clinical benefits of the device.

Table : Summary of Clinical Data Sources and Outcomes – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Expected Clinical Benefits (when used according to instructions for use and recommended technique): | The expected clinical benefit of internal fixation devices such as Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices when used according to instructions for use and recommended technique is:   * Achievement of bone union (IFU: SE\_833508) |
| Clinical Claims (Beyond those identified in the Intended Use and Expected Clinical Benefits): | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: N/A  Medical Rationale: N/A |

Table : CER Final Conclusions – Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to a high outcome rates at final follow up and were seen across device types and clinical indications, which is indicative of good bone healing. In terms of safety outcomes, the rates for infection, nonunion, and revision were acceptable and consistent with those found in the state of the art when used as intended. Deaths in clinical literature were not attributed to the subject device. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Range Reported in Scientific Literature and PMCF Activities (%) | | Bone Union (%) at ≥ 6 months | 76.20 – 100.00% | |  | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range of Central Rates Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 0.0% | | Nonunion (%) | 0.0 – 24.0% | | Revision (%) | 0.0 – 13.0% | |  | | |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the device(s) |
| Acceptability of residual risks and known side-effects: | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support achievement of expected clinical benefits and associated clinical claims (if applicable): | Sufficient data have been documented to support the achievement of the expected clinical benefits  There are no associated clinical claims (beyond those identified in the Intended Use and expected clinical benefits) |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of subject devices and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | No known limitations were identified from the clinical data that introduce residual risks or ambiguity on long-term clinical performance or safety. Therefore, general PMCF is considered sufficient to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment.   * PMCF Plan: #500445872 |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Associated SSCPs: | One or more SSCPs are referenced in the CER, refer to Section 7.2 |
| SSCP Updates: | The CER conclusions/release trigger an update to a previously released SSCP or draft SSCP approved by the Evaluators, refer to Section 7.2 |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) and General Safety and Performance Requirements (GSPRs) of Regulation (EU) 2017 / 745 of the European Parliament and of the Council of 5 April on Medical Devices (MDR) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), completed PMCF (Section 6.2), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

### Expert Adolescent Lateral Femoral Nail System (System #2)

The clinical data used to assess safety and performance of the Expert Adolescent Lateral Femoral Nail System is summarized in Table 181. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the SOA review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources.

Table : Summary of Clinical Data Sources and Outcomes – Expert Adolescent Lateral Femoral Nail System (System #2)

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Clinical Claims (Beyond those identified in the Intended Use): | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: Femoral Shaft Fractures, Subtrochanteric fractures and Ipsilateral femoral neck/shaft fractures  Medical Rationale: All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions. |

Table : CER Final Conclusions Expert Adolescent Lateral Femoral Nail System (System #2)

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to a high outcome rates at final follow up and were seen across device types and clinical indications, which is indicative of good bone healing. In terms of safety outcomes, the rates for infection, nonunion, and revision were low and acceptable and consistent with those found in the state of the art when used as intended. No deaths were reported in the clinical literature and PMCF studies. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Rate Reported in Scientific Literature and PMCF Activities | | Bone Union (%) at ≥ 6 months | 100% | |  | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 0.0% | | Nonunion (%) | 0.0 – 0.0% | | Revision (%) | 0.0 – 3.6% | |  | | |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the devices |
| Acceptability of residual risks and known side-effects: | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Expert Adolescent Lateral Femoral Nail System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support associated clinical claims (if applicable): | There are no associated clinical claims (beyond those identified in the Intended Use) |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of Expert Adolescent Lateral Femoral Nail System and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | No known limitations were identified from the clinical data that introduce residual risks or ambiguity on long-term clinical performance or safety. Therefore, general PMCF is considered sufficient to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment.   * PMCF Plan: #500577392 |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), completed PMCF (Section 6.2), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

### Expert Lateral Femoral Nail System (System #3)

The clinical data used to assess safety and performance of the Expert Lateral Femoral Nail System is summarized in Table 183. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the SOA review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources.

Table : Summary of Clinical Data Sources and Outcomes – Expert Lateral Femoral Nail System (System #3)

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Clinical Claims (Beyond those identified in the Intended Use): | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: Femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures  Medical Rationale: All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions. |

Table : CER Final Conclusions Expert Lateral Femoral Nail System

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to improved outcome (50 – 100%) rates at final follow up and were seen across device types and clinical indications, which is indicative of bone healing. The low bone union rates is due to non-implant related factors. In terms of safety outcomes, the rates for infection, nonunion, and revision were low and acceptable and consistent with those found in the state of the art when used as intended. Deaths reported in clinical literature were not attributed to the subject device. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Range Reported in Scientific Literature and PMCF Activities | | Bone Union (%) at ≥ 6 months | 50\* – 100% | | \*See justification in Section 8.1.1. | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 0.0% | | Nonunion (%) | 0.0 – 5.0% | | Revision (%) | 0.0 – 5.0% | |  | | |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the devices |
| Acceptability of residual risks and known side-effects: | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Expert Lateral Femoral Nail System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support associated clinical claims (if applicable): | There are no associated clinical claims (beyond those identified in the Intended Use. |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of Expert Lateral Femoral Nail System and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | No known limitations were identified from the clinical data that introduce residual risks or ambiguity on long-term clinical performance or safety. Therefore, general PMCF is considered sufficient to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment.   * PMCF Plan: #500577392 |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), completed PMCF (Section 6.2), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

### Femoral Recon Nailing System (System #4)

The clinical data used to assess safety and performance of the Femoral Recon Nailing System is summarized in Table 185. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the SOA review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources.

Table : Summary of Clinical Data Sources and Outcomes – Femoral Recon Nailing System

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Clinical Claims (Beyond those identified in the Intended Use: | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: Femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures.  Medical Rationale: All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions. |

Table : CER Final Conclusions Femoral Recon Nailing System

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to improved outcome (50 – 100%) rates at final follow up and were seen across device types and clinical indications, which is indicative of bone healing. The low bone union rates is due to non-implant related factors. In terms of safety outcomes, the rates for infection, nonunion, and revision were acceptable and consistent with those found in the state of the art when used as intended. There were no deaths reported in clinical literature and PMCF for the subject device. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Range Reported in Scientific Literature and PMCF Activities | | Bone Union (%) at ≥ 6 months | 50\* – 100% | | \*See justification in Section 8.1.1. | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 13.5% | | Nonunion (%) | 0.0 – 10.8% | | Revision (%) | 0.0 – 7.1% | |  | | |
| Representation of data relative to target population: (Delete checkbox not selected) | The data are representative of the intended patient population |
| Representation of data relative to device indications: (Delete checkbox not selected) | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: (Delete checkbox not selected) | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: (Delete check box AND bullets that are not applicable) | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the devices |
| Acceptability of residual risks and known side-effects: (Delete checkbox not selected) | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: (Delete checkbox not selected) | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when Femoral Recon Nailing System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support associated clinical claims (if applicable): | There are no associated clinical claims (beyond those identified in the Intended Use. |
| Adequacy of Equivalence and Associated PMCF Plan: | Equivalence was appropriately demonstrated, based on a comparison of clinical, technical, and biological characteristic with the subject devices.  The associated PMCF plan is appropriate and includes post-market activities to adequately demonstrate the safety and performance of the subject device for all indications for which equivalence was demonstrated by collecting sufficient data on the identified key outcome parameters over the lifetime of the device. |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of Femoral Recon Nailing System and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | Some limitation was identified from the clinical data that introduces residual risks or ambiguity on long-term clinical performance and/or safety. Therefore, specific PMCF is considered warranted to further substantiate the safety and performance of the subject devices through the therapeutic lifetime.   * PMCF Plan: #500566412 |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), ongoing and completed PMCF (Section 6.2), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

### Retrograde Femoral Nail Advanced System (System #5)

The clinical data used to assess safety and performance of the Retrograde Femoral Nail Advanced System is summarized in Table 187. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the SOA review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources.

Table : Summary of Clinical Data Sources and Outcomes – Retrograde Femoral Nail Advanced System

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Clinical Claims (Beyond those identified in the Intended Use: | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: N/A  Medical Rationale: N/A |

Table : CER Final Conclusions Retrograde Femoral Nail Advanced System

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to a high outcome rates at final follow up and were seen across device types and clinical indications, which is indicative of good bone healing. In terms of safety outcomes, the rates for infection, nonunion, and revision were acceptable and consistent with those found in the state of the art when used as intended. Deaths in clinical data sources were not attributed to the subject device. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Range Reported in Scientific Literature and PMCF Activities | | Bone Union (%) at ≥ 6 months | 76.20 – 100% | |  | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range of Central Rates Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 10.0% | | Nonunion (%) | 0.0 – 24.0% | | Revision (%) | 0.0 – 13.0% | |  | | |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the devices |
| Acceptability of residual risks and known side-effects: | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Retrograde Femoral Nail Advanced System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support achievement of expected clinical benefits and associated clinical claims (if applicable): | Sufficient data have been documented to support the achievement of the expected clinical benefits  There are no associated clinical claims (beyond those identified in the Intended Use). |
| Adequacy of Equivalence and Associated PMCF Plan: | Equivalence was appropriately demonstrated, based on a comparison of clinical, technical, and biological characteristic with the subject devices.  The associated PMCF plan is appropriate and includes post-market activities to adequately demonstrate the safety and performance of the subject device for all indications for which equivalence was demonstrated by collecting sufficient data on the identified key outcome parameters over the lifetime of the device. |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of Retrograde Femoral Nail Advanced System and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | Some limitation was identified from the clinical data that introduces residual risks or ambiguity on long-term clinical performance and/or safety. Therefore, specific PMCF is considered warranted to further substantiate the safety and performance of the subject devices through the therapeutic lifetime.   * PMCF Plan: #500441682 |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), ongoing and completed PMCF (Section 6.2), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

### Expert Asian Femoral Nail System (System #6)

The clinical data used to assess safety and performance of the Expert Asian Femoral Nail System is summarized in Table 189. The data presented include information on the key outcome parameters (i.e., the parameters deemed most relevant to establishing the performance and safety of the device). These were selected based on the SOA review and input by internal clinicians and other clinical stakeholders. While other outcomes are reported in the clinical data sources, including the known potential device or procedural residual risks and undesirable effects identified in the IFU, they may not have been selected as key outcomes based upon device-relatedness, prevalence, patient impact, required medical intervention, or frequency of reporting in clinical data sources.

Table : Summary of Clinical Data Sources and Outcomes – Expert Asian Femoral Nail System

|  |  |
| --- | --- |
| Clinical Data Sources: | Device-specific Clinical Literature  Post-Market Clinical Follow-Up Activities |
| Key Outcome Measures Used to Assess Benefit / Risk: | Performance:   * Bone Union (%) at ≥ 6 months   Safety:   * Infection (%) * Nonunion (%) * Revision (%) |
| Other Outcomes that are Widely Reported but not Considered Key Outcomes: | None |
| Clinical Claims (Beyond those identified in the Intended Use: | None |
| Medical rationale for justifying consolidation of different clinical conditions/patient target groups/anatomical locations/etc.: | Clinical Conditions to be Merged: Femoral shaft fractures, subtrochanteric fractures, and femoral shaft in combination with femoral neck fractures.  Medical Rationale: All the indicated fractures fall under the category of femoral shaft fractures. The subject device treats the symptoms of such a category of fractures and therefore we do not need to stratify the category. The same outcomes measures are used for all clinical conditions |

Table : CER Final Conclusions Expert Asian Femoral Nail System

|  |  |
| --- | --- |
| Summary of Clinical Performance and Safety: | Reported performance outcome, bone union rates from all clinical data sources identified that the use of subject devices led to a high outcome rates at final follow up and were seen across device types and clinical indications, which is indicative of good bone healing. In terms of safety outcomes, the rates for infection, nonunion, and revision were acceptable and consistent with those found in the state of the art when used as intended. There were no deaths reported in clinical data sources. There were no new safety trends or harms reported in clinical data sources and post market surveillance activities. |
| Overall Summary of Key Performance Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Performance Outcome | Overall Range of Central Values Reported in Scientific Literature and PMCF Activities | | Bone Union (%) at ≥ 6 months | 90.0% (90.0 – 98.2) | |  | | |
| Overall Summary of Key Safety Outcomes from All Included Data Sources: | |  |  | | --- | --- | | Key Safety Outcome | Overall Range of Central Rates Reported in Scientific Literature and PMCF Activities (%) | | Infection (%) | 0.0 – 13.0% | | Nonunion (%) | 10.0% (2.0 – 10.0) | | Revision (%) | 10.0 – 13.0% | |  | | |
| Representation of data relative to target population: | The data are representative of the intended patient population |
| Representation of data relative to device indications: | The data are representative of all the device indications |
| Adequacy of the follow-up time to assess performance and safety: | The follow-up time is sufficient to assess performance and safety over the therapeutic lifetime for the included data |
| Identification of new / emerging potential risks: | None of the following parameters (which could potentially affect the benefit-risk assessment of the device) have been identified:   * New / emerging potential risks * Significant increases in the frequency or severity of events * Trends associated with the devices |
| Acceptability of residual risks and known side-effects: | The residual risks and known side effects are acceptable and consistent with the state of the art |
| Acceptability of the benefit-risk ratio: | Based on the review of the benefits and the possible harms identified from all data sources, it has been determined that when the Expert Asian Femoral Nail System is utilized according to the intended use, the occurrence of the risks have been reduced as far as possible and the benefits outweigh the possible residual risks over the lifetime of the device and are consistent with the state of the art |
| Sufficiency of data to support associated clinical claims (if applicable): | There are no associated clinical claims (beyond those identified in the Intended Use) |
| Adequacy of the IFU and data sufficiency for all device groups / variants: | The IFU correctly describes the intended purpose and residual risks of Expert Asian Femoral Nail System and is supported by sufficient clinical data for all indications over the lifetime of the device |
| Ongoing PMCF needs triggered by the CER: | No known limitations were identified from the clinical data that introduce residual risks or ambiguity on long-term clinical performance or safety. Therefore, general PMCF is considered sufficient to monitor the use of the device to address unknown areas of emerging risks posed by changes in the clinical environment.   * PMS Plan: The Expert Asian Femoral Nail is nearing the end of its product lifecycle. The safety and performance of the System will continue to be monitored through the reactive methods outlined in the Post-Market Surveillance Plan. |
| Justification for exemption of pre-market Clinical Investigation (CI): | CI exemption was duly justified |
| Compliance with the relevant Essential Requirements (ERs) of the European Medical Device Directive (MDD) 93/42/EEC (as amended by Directive 2007/47/EC) (Refer to Section 3.5): | The clinical evaluation has established that the devices in scope are state-of-the-art (Section 3.9), and based on safety and performance data obtained from nonclinical testing (Section 3.6.2), device-specific clinical literature (Section 4), post market surveillance data (Section 6.1), review of the benefit-risk ratio (Section 8.1), and the assessment for the need for additional PMCF (Section 8.2):  Compliance was adequately demonstrated for the subject devices for the intended use/indications over the device lifetime |

# APPENDICES

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Tabulate all key supporting documents referenced in the CER that are housed in the Quality System (e.g., PMSP/PMSR/PSUR, Risk documents, IFU, STG, PMCFP/PMCFR, DMR/FDR/IOVV/Trace Matrix, literature protocol/report, other [as applicable]). If CER does not contain both MDD and MDR codes, delete subsection that is not applicable.   * Note: The documents identified in the template tables below are REQUIRED documents per MDCG 2020-13 (if applicable). Add all other pertinent key documents, as appropriate. * If any of the key documents is an attachment to the CER, list it in Table 1 instead. |
|  |  | All document names must be **unique** per subsection. If there are multiple documents of the same type for different Device Groups / systems, include an additional descriptor in the Document Name. |

## Supporting References for Key Documents

### MDD Supporting References for Key Documents

Table : MDD Supporting References for Key Documents (Refer to Table 1 for all CER Attachments)

| Document Name | Document Number | Revision |
| --- | --- | --- |
| IFU/STG | | | |
| IFU: Intramedullary Nailing Implants | SE\_532126 | AL |
| IFU: Retrograde Femoral Nail Advanced | SE\_793149 | AC |
| STG: EXPERT Adolescent Lateral Femoral Nail | SE\_891211 | AA |
| STG: EXPERT Lateral Femoral Nail | SE\_846534 | AB |
| STG: Femoral Recon Nail System | DSEM/TRM/1117/0978 | 1 |
| STG: RFN-ADVANCEDTM Retrograde Femoral Nailing System | SE\_820613 | AE |
| STG: Expert A2FN | DSEM-TRM-1015-0537 | 2 |
| Nonclinical Testing | | | |
| Static Four-Point Bend Test of Expert R/AFN  Dynamic Four-Point Bend Test of Expert R/AFN | Windchill #0000259070 | A.17 |
| Interconnectivity and tolerance rationale of Expert R/AFN | Windchill #0000259076 | A.13 |
| Rationale for Validation Studies of Expert R/AFN | Windchill #0000259074 | A.10 |
| Synthes ALFN Recon Locking Fatigue | Windchill #0000258159 | A.9 |
| Drawing review for risk control for sharp edges (Implants) | Windchill #0000259039 | A.9 |
| Interconnectivity and Tolerance Analysis Rationale | Windchill #0000255375 | A.14 |
| Rationale for Validation Studies ALFN | Windchill #0000258162 | A.6 |
| Dynamic Fatigue Test  Finite Element Analysis | Windchill #0000254138 | A.20 |
| Rationale for Validation Studies LFN | Windchill #0000255376 | A.9 |
| Tolerance Analysis – Verification Analysis | Windchill #0000264921 | A.35 |
| Cross section analysis – Nail Shaft | Windchill #0000261710 | A.15 |
| Validation Report Anatomical Study | Windchill #0000269230 | A.32 |
| Endurance testing of 14MM FRN GT and 14MM FRN PF constructs with Recon Screws | Windchill #0000268621 | A.22 |
| MRI Mechanical Testing Report | Windchill #0000268373 | A.10 |
| Drawing Verification Analysis for Femoral Recon Nail Implants | Windchill #0000268343 | A.33 |
| Design Validation Report (Nurses User Group) – Femoral Recon Nail System | Windchill | A.13 |
| Validation Report Anatomical Study | Windchill #0000269230 | A.32 |
| Design Validation Method – Femoral Recon Nail System | Windchill #0000270986 | A.20 |
| Design verification: RFN LAW construct static test report | Windchill #0000293480 | A.31 |
| Design verification: RFNA Nail Static 4-Point Bend Design Verification Report | Windchill #0000293476 | A.49 |
| Design verification: RFNA Nail Static Torsion Design Verification Report | Windchill #0000293478 | A.36 |
| Design verification: Reaming rod ball tip tensile strength | Windchill #0000293487 | A.8 |
| Design verification: LAW static torque to failure | Windchill #0000293484 | A.13 |
| Design verification: Nail poly (inlay) axial push-out | Windchill #0000293479 | A.30 |
| Design verification: RFNA Nail Dynamic 4-point Bend | Windchill #0000293477 | A.38 |
| Poly Inlay Vibration/Transit Test | Windchill #0000293481 | A.9 |
| Galvanic corrosion study | Windchill #0000297100 | A.8 |
| Rational Polymer Debris | Windchill #0000293897 | A.13 |
| Retrograde Femoral Nail Design Validation Report | Windchill #0000293489 | A.28 |
| Periprosthetic Nail Entry Point Validation Rationale | Windchill #0000295114 | A.2 |
| Predicate Device/Reference Product Comparative Analysis | Windchill #0000295068 | A.11 |
| Predicate Device/Reference Product Comparative Analysis | Windchill #0000295056 | A.12 |
| RFN Nail Shape Comparison | Windchill #0000294764 | A.3 |
| Femoral Shaft Nailing Implants | Windchill #0000309156 | A.7 |
| Static 4-point bending test of Expert A2FN and AFN  Dynamic 4-point bending test of Expert A2FN and AFN | Windchill #0000258158 | A.14 |
| Design verification report | SE\_702711 | AA |
| Drawing review for risk control for sharp edges (Implants) | Windchill #0000259039 | A.9 |
| Interconnectivity and Tolerance Analysis Rationale | Windchill #0000255375 | A.14 |
| Rationale for Validation Studies Expert A2FN | Windchill #0000258161 | A.6 |
| Biocompatibility Documents | | | |
| F-S738: LRBSE CTP01051 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Non Sterile,  Biological Safety Evaluation | Windchill #500002123 | 4.3 |
| F-S738: LRBSE CTP01479 Monument TSP NS Anodize- TAN TAV (Ti Alloy)- Sterile | Windchill #500002143 | 5.3 |
| F-S738: LRBSE – CTP01277 – Elmira Neutral Salt Anodize (TAN) – Non-sterile | Windchill #500002446 | 3.7 |
| F-S738: LRBSE – CTP01489 – Elmira Neutral Salt Anodize (TAN) – Sterile, QMV-LRBSE | Windchill #500002447 | 3.3 |
| BSE01006 Mark Two Inc. Transfer to Mark Two Inc. Anodized End Cap, QMV-BSE | Windchill #500002521 | 2.2 |
| F-S738: LRBSE CTP01482 20% Nitric Passivation Monument-Sterile | Windchill #500002087 | 3.1 |
| F-S738 Washer Raron Titanium non sterile, Biological Safety Evaluation | Windchill #500004346 | 1.10 |
| F-S738 Washer Raron Titanium non sterile, Biological Safety Evaluation | Windchill #500004348 | 1.6 |
| F-S738 – BSE for Thermal Rinse Process at Monument | Windchill #500007485 | 2.10 |
| F-S738 – Final Cleaning Titan – Synthes Raron | Windchill #500015616 | 2.3 |
| F-S738 – A2FN/LFN nails – Mezzovico | Windchill #500020788 | A.14 |
| F-S738 Femoral Recon Nails – Implants | Windchill #500021703 | A.6 |
| F-S738 – TF10405 – Recon Femoral Nailing Implants, Biological Safety Evaluation | Windchill #500352712 | A.3 |
| F-S738 – LESN SRS – Screws, Nuts, Washers, Ends Caps – GRE, MON, RAR, BET.,  Biological Safety Evaluation | Windchill #500455440 | D.5 |
| BER – TF10620 Recon Femoral Nailing Implants, Biocompatibility Evaluation Report | Windchill #501083479 | A.5 |
| F-S738: BSE01008. Sterile, Mark Two Inc. & Monument, Material: TAN | BSE01008 | A.6 |
| QMV-LRBSE, Balsthal | SE\_555521 | AF |
| QMV-LRBSE, Balsthal | SE\_590581 | AF |
| QMV-LRBSE, Balsthal | SE\_590842 | AD |
| QMV-LRBSE, Balsthal | SE\_623321 | AI |
| QMV-LRBSE, Balsthal | SE\_623962 | AF |
| QMV-LRBSE, Balsthal | SE\_627958 | AB |
| F-S738 – LESN RFN, UHMWPE, LA Washer – MON, BRA, RAR, Biological Safety Evaluation | Windchill #500458847 | D.5 |
| Sterility | | | |
| Decision Finding Protocol – Sterile, Spiral Blade f/Expert™ Retrograde Femoral Nail-TAN – ELM / Früh | SE\_428388 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 9.0 mm-TAN – MON / Früh | SE\_428393 | AB |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 11.0 mm-TAN – MON / Früh | SE\_428398 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 13.0 mm-TAN – MON / Früh | SE\_428402 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 15.0 mm-TAN – MON / Früh | SE\_428408 | AC |
| Decision Finding Protocol – Sterile, Expert™ End Cap f/Spiral Blade Locking-TAN – Mark Two / Früh | SE\_428412 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 10.0 mm-TAN – MON / Früh | SE\_428535 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 12.0 mm-TAN – MON / Früh | SE\_430391 | AC |
| Decision Finding Protocol – Sterile, Expert™ Retrogr./Antegr. Femoral Nails Ø 14.0 mm-TAN – MON / Früh | SE\_430397 | AC |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 | AC |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 | AB |
| Endotoxin Risk Assessment, Invasive Implantable Medical Devices | SE\_744335 | AA |
| Sterilization Dose Equivalence Determination Form, LESN End Caps | Windchill #500402171 | A.9 |
| Sterilization Dose Equivalence Determination Form, Sterile Tube Packaging – Non-cannulated Screws TAN Mez/Früh | SE\_800399 | AB |
| Sterilization Dose Equivalence Determination Form, SRS – Recon Screw 04.046.660-730TS – GRE/FRU | SE\_805588 | AA |
| Sterilization Dose Equivalence Determination Form, Self Retaining Locking Recon Screw for Medullary Nail | SE\_836103 | AA |
| Risk based approach for X-ray sterilization, project scope specific SKU list | SE\_839375 | AC |
| Dose Mapping Equivalence Determination Form, LESN End Caps | Windchill #500402158 | B.3 |
| Dose Mapping Equivalence Determination Form, Sterile Tube Packaging – L Tubes | SE\_800281 | AB |
| Dose Mapping Equivalence Determination Form, Sterile Tube Packaging – L+ Tubes | SE\_800282 | AB |
| Dose Mapping Equivalence Determination Form, SRS – recon screw 04.046.660-730TS FRU31 | SE\_805593 | AA |
| Dose Mapping Equivalence Determination Form, Self Retaining Locking Recon Screw for Medullary Nail | SE\_836108 | AA |
| Decision Finding Protocol – Sterile, Hip Screws ø6.5 f/AFN TAN – BAL/ KKS / Früh | SE\_252744 | AC |
| Decision Finding Protocol – Sterile, Washer ø3.5/2.7 TAN – RAR / Collini / Früh | SE\_252752 | AC |
| Decision Finding Protocol – Sterile, Expert End Caps TAN f/ Femoral Nails – MEZ / Früh | SE\_387840 | AB |
| Decision Finding Protocol – Sterile, Hip Screws T25 Ø 6.5mm self-tapping TAN – MEZ / Früh | SE\_427592 | AB |
| Decision Finding Protocol – Sterile, End Caps f/Expert™ A2FN TAN – MEZ / Früh | SE\_427675 | AB |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø9.0mm and 10mm cannulated TAN – MEZ / SUZ/ Früh | SE\_427678 | AC |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø11.0mm and 12 mm cannulated TAN – MEZ / SUZ/ Paka Hänni / Früh | SE\_427701 | AC |
| Decision Finding Protocol – Sterile, Expert™ A2FN Ø13.0mm and 14mm cannulated TAN – MEZ / SUZ/ Paka Hänni / Früh | SE\_427709 | AC |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø9 TAN – MEZ / Paka Hänni / Früh | SE\_430361 | AB |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø12 TAN – MEZ / Paka Hänni / Früh | SE\_430367 | AB |
| Decision Finding Protocol – Sterile, Expert™ Lateral Femoral Nails ø14 TAN – MEZ / Paka Hänni / Früh | SE\_430369 | AB |
| Decision Finding Protocol – Sterile, Expert End Caps f/ Adolescent Lateral Femoral Nails TAN – Mark II / Früh | SE\_438287 | AB |
| Decision Finding Protocol – Sterile, Hip Screws Stardrive TAN – Bell Pro / MON / Früh | SE\_438348 | AB |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø8.2 TAN – MON / Früh | SE\_438355 | AB |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø9.0 TAN – MON / Früh | SE\_438360 | AB |
| Decision Finding Protocol – Sterile, Expert Adolescent LFN ø10.0 TAN – MON / Früh | SE\_438361 | AB |
| Decision Finding Protocol – Sterile, Femoral Recon Nails – BET/ Früh | SE\_698046 | AB |
| Clinical Processing Decision Finding Protocol For Non-Sterile Devices, LESN End Caps | Windchill #500401570 | B.3 |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 | AC |
| Decision Finding Protocol – Non-Sterile, Trauma Implants | SE\_634298 | AD |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 | AB |
| Decision Finding Protocol – Non-Sterile, Intramedullary Nails and Endcaps | SE\_657316 | AA |
| Decision Finding Protocol – Non Sterile, Femoral Recon Nails | SE\_697176 | AB |
| Decision Finding Protocol – Non-Sterile, Self Retaining Screw System – Recon Screw for Medullary Nail | SE\_825646 | AA |
| F-S380 Sterilization Dose Equivalence Determination, Retrograde Femoral Nail (RFN) | Windchill #500399828 | C.13 |
| Sterilization Dose Equivalence Determination Form, Locking Attachment Washer for RFN | Windchill #500399833 | A.13 |
| Sterilization Dose Equivalence Determination Form, LESN End Caps | Windchill #500402171 | A.9 |
| Dose Mapping Equivalence Determination Form, Locking Attachment Washer for RFN | Windchill #500399242 | B.2 |
| Dose Mapping Equivalence Determination Form, Retrograde Femoral Nail (RFN) | Windchill #500399752 | C.10 |
| Dose Mapping Equivalence Determination Form, LESN End Caps | Windchill #500402158 | B.3 |
| Clinical Processing Decision Finding Protocol For Non-Sterile Devices, LESN End Caps | Windchill #500401570 | B.3 |
| Decision Finding Protocol – Non-Sterile, Trauma Expert Implants | SE\_360722 | AC |
| Decision Finding Protocol – Non Sterile, Trauma Expert Implants | SE\_642930 | AB |
| Risk Management Documents | | | |
| Femoral Shaft Nailing Implants RMR | Windchill #0000259337 | A.34 |
| Femoral Shaft Nailing Implants DCRM | Windchill #0000257474 | A.40 |
| Femoral Shaft Nailing Implants DCRM for Generic Risks | Windchill #0000259158 | A.14 |
| Recon Femoral Nailing Implants RMR | Windchill #0000258778 | A.26 |
| Recon Femoral Nailing Implants DCRM | Windchill #0000257162 | A.45 |
| Recon Femoral Nailing Implants DCRM for Generic Risks | Windchill #0000258658 | A.12 |
| Femoral Recon Nail RMR | Windchill #0000077525 | A.75 |
| Femoral Recon Nail DCRM | Windchill #0000077523 | A.132 |
| Retrograde Femoral Nail and Locking Attachment Washer RMR | Windchill #0000273585 | A.30 |
| Retrograde Femoral Nail and Locking Attachment Washer DCRM | Windchill #0000216378 | A.116 |
| PMS Documents | | | |
| PMSP: Shaft and Distal Femur IM Nailing Implants (TN-005) | Windchill #0000244976 | G.3 |
| PMSR: Shaft and Distal Femur IM Nailing Implants (TN-005) | Windchill #0000250261 | A.44 |
| PMSP: Locking Screws and Bolts for IM Nailing (TN-008) | Windchill #0000244979 | G.5 |
| PMSR: Locking Screws and Bolts for IM Nailing (TN-008) | Windchill #0000250208 | A.34 |
| PMSP: Femoral Recon Nail (TN-009) | Windchill #500040369 | E.2 |
| PMSR: Femoral Recon Nail (TN-009) | Windchill #0000275810 | A.17 |
| PMSP: Retrograde Femoral Nail Advanced (TN-010) | Windchill #500444123 | D.2 |
| PMSR: Retrograde Femoral Nail Advanced (TN-010) | Windchill #500444124 | A.2 |
| PMSP: Self-Retaining Locking Screw System (TS-002) | Windchill #500443966 | D.5 |
| PMSR: Self-Retaining Locking Screw System (TS-002) | Windchill #500443971 | B.2 |
| PMCF Documents | | | |
| PMCFP: Retrograde Antegrade Femoral Nail (RAFN) | Windchill #500445872 | D.3 |
| PMCFER: Expert Retrograde Antegrade Femoral Nail (Expert RAFN) | Windchill #500939735 | A.2 |
| PMCF Study Report: RAFN | Adaptiv 10083084 | - |
| Expert RAFN DUA Data Report | Windchill #0000311162 | A.3 |
| Expert RAFN DUA Data Report | Windchill #0000311163 | A.4 |
| Expert RAFN DUA Data Report | Windchill #0000311164 | A.4 |
| PMCF Plan: EXPERT ALFN and EXPERT LFN | Windchill #500577392 | G |
| PMCFER: EXPERT ALFN and EXPERT LFN | Windchill #500775514 | F |
| Femoral Nailing Data Summary Report | Windchill #0000317835 | A.2 |
| Femoral Nailing Data Summary Report | Windchill #0000317838 | A.2 |
| PMCF Plan: Femoral Recon Nail | Windchill #500566412 | D.2 |
| PMCFER: Femoral Recon Nail | Windchill #500770504 | B.2 |
| PMCF Plan: Retrograde Femoral Nail Advanced | Windchill #500441682 | D.2 |
| PMCFER: Retrograde Femoral Nail Advanced | Windchill #500945925 | A.2 |

### MDR Supporting References for Key Documents

Table : Additional MDR Supporting References for Key Documents (Refer to Table 1 for all CER attachments)

| Document Name | Document Number | Revision |
| --- | --- | --- |
| IFU/STG | | |
| IFU: Expert™ Retrograde/Antegrade Femoral Nail (R/AFN)  Expert™ Retrograde Femoral Nail (RFN) | SE\_833508 | AA |
| STG: Expert R/AFN | SE\_831737 | AA |
| Claims Matrix | | |
| Femoral Shaft Nailing Implants Claims Matrix | 168325-210225 | 1 |
| Biocompatibility Documents | | |
| Femoral Shaft Nailing Implants, Biological Safety Evaluation | Windchill #500646101 | B.2 |
| Spiral Blades for Expert Retrograde Femoral Nails, Biocompatibility Evaluation Report | Windchill #501139530 | A.3 |
| Restricted Substances | | |
| RS: Femoral Shaft Nailing Implants | Windchill #0000308743 | A.5 |

## Product Codes

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Add sub-sections, if applicable, to delineate subject device codes from equivalent or reference device codes (or other stratification as appropriate). |
|  |  | If some codes comply with MDD and others comply with MDR, note this appropriately in this appendix.   * Note: If CER does not contain both MDD and MDR codes, delete subsection that is not applicable. |
|  |  | All descriptions must be unambiguous (i.e., unique versus other descriptions) |
|  |  | If GMDN / EMDN numbers and terms are the same for all devices within the subsection, this information can be captured in the banner row for the Device Group and the column deleted. |
|  |  | For MDR implants and class III devices (which require an SSCP), the Medical Device Nomenclature numbers and descriptions should indicate the European Medical Device Nomenclature (EMDN) if available. If not available, identify “not yet available”. |
|  |  | If there are multiple legal manufacturers, CE-Mark date should be identified by manufacturer |
|  |  | Table format shown is suggested but may be modified, as appropriate. |
|  |  | For MDR, the Basic UDI-DI value(s) needs to be reported for all devices except class I, Im, Ir, or Is. |

### MDD Subject Device Product Codes

Refer Product Codes spreadsheet in Attachment (referenced in Table 1).

### MDR Subject Device Product Codes

Refer Product Codes spreadsheet in Attachment (referenced in Table 1).

## Equivalence Table for Femoral Recon Nail

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete separate Equivalence Tables (in separate subsections) for EACH subject / equivalent device combination under evaluation. |
|  |  | Characterize the clinical, technical, and biological parameters for each device in parts A, B, and C, respectively.   * Match clinical parameters to IFU and/or other relevant documents and reference source documentation in applicable cells in the table * Detail material composition **with focus on materials coming in contact (directly or indirectly) with patient/user.** For example, if the material is titanium, then specify type such as titanium-6 aluminum-7 niobium (TAN) alloy (ISO 5832- 11) * Describe any manufacturing processes that affect biological characteristics (e.g., monofilament versus braid, cross-linking, sterilization process) |
|  |  | Identify all differences in characteristics between subject and equivalent device, summarize the potential clinical impact of these differences, and conclude whether each characteristic meets the definition of clinical, technical, or biological equivalence; respectively.   * For all parameters requiring the “same” characteristics, the assessment for the ‘potential clinical impact of differences’ must conclude that devices meet the definition of being the “same”. * Only parameters that allow “similar” characteristics can be different, by definition. * Cite any supporting reference by document number to provide objective evidence to substantiate the equivalence claim. * Refer to MEDDEV 2.7/1, Rev. 4 for additional considerations for MDD equivalence. * Refer to MDCG 2020-5 Guidance for additional considerations for MDR equivalence. |

Table : Equivalence Table for Femoral Recon Nail

| Equivalence Parameters | Subject Device: Femoral Recon Nail (Synthes GmbH) | Equivalent Device #1: Expert Lateral Femoral Nail (Synthes GmbH) | Potential Clinical Impact of Differences |
| --- | --- | --- | --- |
| Representative Device Image |  |  | Not Applicable – For illustration only |
| **A. Clinical Parameters -** | | | |
| Intended Purpose | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.  (IFU: SE\_532126) | Intramedullary Nailing Implants are intended to be used for temporary fixation and stabilization of long bones in various anatomical regions such as proximal femur, femoral shaft, tibia and humerus.  (IFU: SE\_532126) | 🗹 Clinically Equivalent   * The intended purpose for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| Indication(s) | Standard Locking Indications:  The Femoral Recon Nail with standard locking is indicated for fractures in the femoral shaft:   * 32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1)   Recon Locking Indications:  The Femoral Recon Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:   * 32-A/B/C combined with 31-B (double ipsilateral fractures   Additionally the Femoral Recon Nail is indicated for fractures in the subtrochanteric section:   * 32-A [1–3].1, 32-B [1–3].1 and 32-C [1–3].1   (IFU: SE\_532126 | Standard Locking Indications:  The Expert Lateral Femoral Nail with standard locking is indicated for fractures in the femoral shaft:  32-A/B/C (except subtrochanteric fractures 32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1)  Recon Locking Indications:  The Expert Lateral Femoral Nail with recon locking is indicated for fractures in the femoral shaft in case of combination with femoral neck fractures:  32-A/B/C combined with 31-B (double ipsilateral fractures).  Additionally, the Expert Lateral Femoral Nail is indicated for fractures in the subtrochanteric section:  32-A [1–3].1, 32-B [1–3].1, and 32-C [1–3].1  (IFU: SE\_532126) | 🗹 Clinically Equivalent   * The indications for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| Contraindication(s) | No contraindication specific to these devices.  (IFU: SE\_532126) | No contraindication specific to these devices.  (IFU: SE\_532126) | 🗹 Clinically Equivalent   * The contraindication for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| Anatomic Areas of Use | Femoral shaft, femoral neck, subtrochanteric section | Femoral shaft, femoral neck, subtrochanteric section | 🗹 Clinically Equivalent   * The anatomic area of use for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| Intended User | Surgeons | Surgeons | 🗹 Clinically Equivalent   * The intended user for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| Patient Population | Patients were growth plates have fused. | Patients were growth plates have fused. | 🗹 Clinically Equivalent   * The patient population for Femoral Recon Nail and Expert Lateral Femoral Nail are same. |
| Duration of Use | The therapeutic lifetime is six to nine months (time to bone healing).  Implant removal – if indicated – is performed after 1 or 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen as the remaining lifetime of the patient. | The therapeutic lifetime is six to nine months (time to bone healing).  Implant removal – if indicated – is performed after 1 or 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen as the remaining lifetime of the patient. | 🗹 Clinically Equivalent   * The duration of use for Femoral Recon Nail and Expert Lateral Femoral Nail is same. |
| **B. Technical parameters** | | | |
| Design / Specifications | | | |
| Design Parameters: Sidedness | Left and right nails | Left and right nails | 🗹 Technically Equivalent   * The diameter for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| Design Parameters: Diameter | Distal diameters: 9, 10, 11, 12 and 14 mm  Proximal diameters:   * 9 – 12 mm nails: 13 mm proximal diameter * 14 mm nail: 14 mm proximal diameter | * Distal diameters: 9.0–16.0 mm (1.0 mm increments)   Proximal diameters:   * 9.0–12.0 mm nails have a proximal diameter of 13.5 mm * 13.0–16.0 mm nails have a proximal diameter of 16.0 mm | 🗹 Technically Equivalent  All diameters of the Femoral Recon Nail fall within the boundaries of the Expert Lateral Femoral Nail. While the nail diameters are not exactly the same, all devices allow the surgeon to fit the patient to accommodate different anatomies.  There is no clinically significant difference in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the diameter of nails. |
| Design Parameters: Length | * 9, 10 mm distal diameter: 280–480 mm (20 mm increments) * 11, 12, 14 mm distal diameter: 300–480 mm (20 mm increments) | * 300–480 mm (20.0 mm increments) | 🗹 Technically Equivalent  All lengths of the Femoral Recon Nail fall within the boundaries of the Expert Lateral Femoral Nail except for one additional length in the Femoral Recon Nail that is 20 mm shorter giving the surgeon additional options. While the nail lengths are not exactly the same, all devices allow the surgeon to fit the patient to accommodate different anatomies.  There is no clinically significant difference in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the length of nails. |
| Design Parameters: Antegrade Proximal Locking Hole Angle | * 140° for Greater Trochanter Nails * 135° for Piriformis Fossa Nails | * 120° | 🗹 Technically Equivalent  While the antegrade proximal locking hole angle varies slightly between the Femoral Recon Nail and Expert Lateral Femoral Nail devices, the differences allow the use of the same insertion handle.  There is no clinically significant difference in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the antegrade proximal locking hole angle. |
| Specifications, Properties: Fatigue Strength (to failure) | Recon locking for Piriformis Fossa Nails: 1149.62 n (median)  (95% CI 1084.78 to 1214.46)  Standard locking for Piriformis Fossa Nails: 786.64 n (median)  (95% CI 748.32 to 824.96)  Recon for Greater Trochanter Nails: 1188.77 n (median)  (95% CI 1123.19 to 1254.36)  Standard locking for Greater Trochanter Nails: 781.00 n (median)  (95% CI 743.43 to 818.57) | Recon locking: 850.84 n (median)  (95% CI 742.77 to 958.91)  Standard locking: 680.83 n (median)  (95% CI 644.33 to 717.33) | 🗹 Technically Equivalent  The nail fatigue strength of Femoral Recon Nail worst-case constructs has been tested to be superior to that of the Expert Lateral Femoral Nail. The median Femoral Recon Nail fatigue-to-failure was superior to the Expert Lateral Femoral Nail comparator by 28.5% in recon locking mode and 13% in standard locking mode (set\_20170079, set\_20170081, and set\_20160256).  There is no clinically significant difference in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the fatigue strength. |
| Conditions of Use | Sterile operating room | Sterile operating room | 🗹 Technically Equivalent  The conditions for use for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| Principle(s) of Operation | | | |
| Preparation for Use | N/A – Implant is provided sterile | Implants are available as sterile and nonsterile package.   * Sterile Implants: N/A * Nonsterile Implants: Steam sterilization | 🗹 Technically Equivalent  Both the Femoral Recon Nail and Expert Lateral Femoral Nail are provided sterile ready to use while the Expert Lateral Femoral Nail product is also available as non-sterile, sterilization instructions are provided in the important information brochure (se\_023827). There are no differences in properties between the sterile and non-sterile devices.  There is no clinically significant difference (i.e., addition of new risks) in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the preparation of use. |
| Application | Device serves as an internal splint, providing relative stability without interfragmentary compression while allowing micromotion to assist in bony callus formation and remodeling. | Device serves as an internal splint, providing relative stability without interfragmentary compression while allowing micromotion to assist in bony callus formation and remodeling. | 🗹 Technically Equivalent  The application for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| Technique / Deployment Method | Antegrade approach for Piriformis Fossa:  The Femoral Recon Nail Piriformis Fossa is designed to insert into the in line with the medullary canal in the AP and lateral views. The point is posterior in the proximal femur, in the piriformis fossa, but varies with patient anatomy.  Antegrade approach for Greater Trochanter:  The Femoral Recon Nail Greater Trochanter is designed to insert into the bone on the tip or slightly lateral to the tip of the greater trochanter (5° lateral of the femoral shaft axis). In the lateral view, the entry point for the nail is centered in the greater trochanter and in line with the medullary canal.  The Femoral Recon Nail Piriformis Fossa and Greater Trochanter allows standard or recon locking options.  Recommended deployment steps:  Position patient  Reduce fracture  Determine nail length  Determine nail diameter  Open proximal femur:  Insert nail  Standard locking  Proximal locking – reconstruction locking  Distal locking  Insert end cap  Implant removal  (STG: DSEM/TRM/1117/0978) | Antegrade approach:  The Expert Lateral Femoral Nail is designed to insert into the bone 10° lateral to the axis of the medullary canal (depending on anatomy this is slightly lateral to the greater trochanter). In the lateral view the entry point is in line with the axis of the intramedullary canal.  The Expert Lateral Femoral Nail allows standard or recon locking options.  Recommended deployment steps:  Position patient  Reduce fracture  Confirm nail length and diameter  Approach  Determine entry point  Insert guide wire  Option: realign guide wire  Open medullary canal  Option: ream medullary canal  Insert nail  Proximal locking – standard  Proximal locking – recon (optional)  Distal locking  Insert end cap  Implant removal  (STG: SE\_846534) | 🗹 Technically Equivalent  Both device systems follow the same standard series of steps for antegrade entry to the greater trochanter.  The Femoral Recon Nail is indicated for two entry points (greater trochanter and piriformis fossa) versus the Expert Lateral Femoral Nail’s single entry point (lateral to greater trochanter). The addition of a second design of nails enables surgeons to determine the best approach based on the patient’s injuries and physical status.  While the Piriformis Fossa entry point is not available with the Expert Lateral Femoral Nail. Synthes has a long history using this entry point and provides evidence of its safety and performance. A piriformis fossa Synthes nail product line has been in clinical use since 2004 (Expert R/AFN system (which is also in scope of this CER).  There is no clinically significant difference in performance and safety of Femoral Recon Nail as compared to Expert Lateral Femoral Nail with respect to the technique / deployment method. |
| Mode of Action | Mechanical | Mechanical | 🗹 Technically Equivalent   * The mode of action for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| **C. Biological parameters** | | | |
| Materials (including consideration of sourcing characteristics) | Ti-6Al-7Nb (TAN)  per ASTM F1295 / ISO 5832-11 | Ti-6Al-7Nb (TAN)  per ASTM F1295 / ISO 5832-11 | 🗹 Biologically Equivalent  The device materials for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| Construction (including consideration of sourcing and manufacturing characteristics) | <e.g., Machined and anodized per XXX and sterilized via EtO > | TBD | TBD |
| Human Tissue or Body Fluids in Contact with the Device | Bone and soft tissue of the femur | Bone and soft tissue of the femur | 🗹 Biologically Equivalent  The human tissue or body fluids in contact with Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |
| Biological Response | Long-term clinical experience with use in a medical setting of the material used to manufacture the subject device (TAN) can be shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.  ISO 5832-11:2014 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 7-niobium alloy (Ti-6-Al 7-Nb) for use in the manufacture of surgical implants. The titanium alloy composition in scope for the subject devices in this CER has been in use as an ISO standard for over 2 decades (earlier ISO 5832-11:1994) and employed in implants that touch bone and tissue since that time. Due to the well characterized level of biological response exhibited by this alloy of titanium, TAN has been used as a control material in practice.  Biocompatibility of the devices was demonstrated when used as intended in the BSE (500021703). | Long-term clinical experience with use in a medical setting of the material used to manufacture the subject device (TAN) can be shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.  ISO 5832-11:2014 specifies the characteristics of, and corresponding test methods for, the wrought titanium alloy known as titanium 6-aluminium 7-niobium alloy (Ti-6-Al 7-Nb) for use in the manufacture of surgical implants. The titanium alloy composition in scope for the subject devices in this CER has been in use as an ISO standard for over 2 decades (earlier ISO 5832-11:1994) and employed in implants that touch bone and tissue since that time. Due to the well characterized level of biological response exhibited by this alloy of titanium, tan has been used as a control material in practice.  Biocompatibility of the devices was demonstrated when used as intended in the BSE (500021703). | 🗹 Biologically Equivalent   * The biological response exhibited for Femoral Recon Nail and Expert Lateral Femoral Nail is similar. |

## Equivalence Table for RFN-ADVANCED Femoral Nail

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete separate Equivalence Tables (in separate subsections) for EACH subject / equivalent device combination under evaluation. |
|  |  | Characterize the clinical, technical, and biological parameters for each device in parts A, B, and C, respectively.   * Match clinical parameters to IFU and/or other relevant documents and reference source documentation in applicable cells in the table * Detail material composition **with focus on materials coming in contact (directly or indirectly) with patient/user.** For example, if the material is titanium, then specify type such as titanium-6 aluminum-7 niobium (TAN) alloy (ISO 5832- 11) * Describe any manufacturing processes that affect biological characteristics (e.g., monofilament versus braid, cross-linking, sterilization process) |
|  |  | Identify all differences in characteristics between subject and equivalent device, summarize the potential clinical impact of these differences, and conclude whether each characteristic meets the definition of clinical, technical, or biological equivalence; respectively.   * For all parameters requiring the “same” characteristics, the assessment for the ‘potential clinical impact of differences’ must conclude that devices meet the definition of being the “same”. * Only parameters that allow “similar” characteristics can be different, by definition. * Cite any supporting reference by document number to provide objective evidence to substantiate the equivalence claim. * Refer to MEDDEV 2.7/1, Rev. 4 for additional considerations for MDD equivalence. * Refer to MDCG 2020-5 Guidance for additional considerations for MDR equivalence. |

Table : Equivalence Table RFN-ADVANCED Femoral Nail

| Equivalence Parameters | Subject Device: RFN-ADVANCED Femoral Nail (Synthes GmbH) | Equivalent Device #1: Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Synthes GmbH) | Potential Clinical Impact of Differences |
| --- | --- | --- | --- |
| Representative Device Image |  |  | Not Applicable – For illustration only |
| **A. Clinical Parameters -** | | | |
| Intended Purpose | The Retrograde Femoral Nail Advanced implants are intended to be used for temporary fixation and stabilization of the distal femur and femoral shaft.  (IFU: SE\_793149) | Bone Fixation Nails, including DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices, are intended for temporary fixation, correction and stabilization of bones.  (MDR IFU: SE\_833508) | 🗹 Clinically Equivalent  Both the RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail are intended to fix and stabilize the fractures in the distal femur and femoral shaft.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the intended purpose. |
| Indication(s) | The Retrograde Femoral Nail Advanced implants are intended to stabilize fractures of the distal femur and the femoral shaft, including:   * Supracondylar fractures, including those with intra-articular extension * Combination of ipsilateral condylar and diaphyseal fractures * Ipsilateral femur/tibia fractures * Femoral fractures in multiple trauma patients * Periprosthetic fractures * Fractures in the morbidly obese * Fractures in osteoporotic bone * Impending pathologic fractures * Malunions and nonunions   (IFU: SE\_793149) | Retrograde approach:   * Fractures of the distal end segment of the femur * Fractures of the middle and distal diaphyseal segment of the femur   Antegrade approach:   * Fractures of the middle and distal diaphyseal segment of the femur   (MDR IFU: SE\_833508) | 🗹 Clinically Equivalent  Supracondylar fractures and ipsilateral condylar and diaphyseal fractures are fundamentally similar to distal end segment fracture and fracture of middle and distal diaphyseal segment of the femur, respectively.  Ipsilateral femur/tibia fractures and fracture in multiple trauma patients are independent to the fracture being treated by the subject/equivalent device. Patients with ipsilateral fracture can be treated with either of the devices using a retrograde approach.  Although periprosthetic fracture is not described within the indication language for Expert R/AFN, the use of retrograde nails for treatment of periprosthetic fracture is well documented both within the patient body of literature, and specifically for the Expert R/AFN (Horneff 2013, Butler 2019). Periprosthetic fractures are not fundamentally different than the other fracture types identified under the indications for retrograde femoral nailing. Based on its principal mode of action, the Expert R/AFN is comparable to other retrograde intramedullary nails for which there is substantial literature to support use in periprosthetic fracture. In patients with an open-box prosthetic knee, the newly designed Retrograde Femoral Nail Advanced will be better able to meet the challenges presented by distal femoral fractures in the presence of a prosthetic.  Although not described in the indication language of Expert R/AFN, it is not contraindicated for use in osteoporotic bone, or impending pathologic fractures that result in a fracture pattern which is treated with a nail and therefore are comparable to RFNA.  Although fractures in morbidly obese patients are not explicitly mentioned as an indication for Expert R/AFN, its IFU (SE\_833508) provides that such condition may be considered provided that the physician consider the risks versus the benefits of the individual patient.  Although not described in the indication language of Expert R/AFN, malunions and non-unions are not contraindicated for use and, therefore, are inherently included as long as they are associated with the other indications.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the indications. |
| Contraindication(s) | No contraindication specific to these devices.  (IFU: SE\_793149) | Retrograde approach:   * Fractures of the proximal diaphyseal segment of the femur * Multifragmentary articular fractures of the distal end segment of the femur   Antegrade approach:   * Fractures of the proximal diaphyseal segment of the femur   (MDR IFU: SE\_833508) | 🗹 Clinically Equivalent  RFNA is indicated for Supracondylar fractures with only intra-articular extension  Although not described in the specific contraindications of RFNA, multifragmentary articular fractures of the distal end segment of the femur are not indicated for RFNA.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the contraindications. |
| Anatomic Areas of Use | Femur | Femur | 🗹 Clinically Equivalent  The anatomic area of use for RFN-ADVANCED Femoral Nail Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Intended User | The Retrograde Femoral Nail Advanced implants are intended to be used by qualified health care professionals e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.  All personnel handling the device should be fully aware of the instructions for use, the surgical procedures, if applicable, and/or the Synthes “Important Information” brochure as appropriate.  (IFU: SE\_793149) | This device is intended to be used by qualified health care professionals who are experienced in orthopedic surgery e.g. surgeons, physicians, operating room staff, and individuals involved in preparation of the device.  All personnel handling the device should be fully aware that these instructions for use do not include all the information necessary for selection and use of a device. Please read the instructions for use and the Synthes brochure “Important Information” carefully before use. Ensure that you are familiar with the appropriate surgical procedure.  (MDR IFU: SE\_833508 | 🗹 Clinically Equivalent  The intended user for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Patient Population | The Retrograde Femoral Nail Advanced implants are recommended for use in skeletally mature patients.  (IFU: SE\_793149) | The DePuy Synthes Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail devices are recommended for use in skeletally mature patients.  (MDR IFU: SE\_833508) | 🗹 Clinically Equivalent  The patient population for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Duration of Use | The therapeutic lifetime is six to nine months (time to bone healing).  Implant removal – if indicated – is performed after 1 or 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen as the remaining lifetime of the patient. | The therapeutic lifetime is six to nine months (time to bone healing).  Implant removal – if indicated – is performed after 1 or 2 years at the earliest. In terms of biological parameters, the post-therapeutic lifetime of the implant is therefore seen as the remaining lifetime of the patient. | 🗹 Clinically Equivalent  The duration of use for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| **B. Technical parameters** | | | |
| Design / Specifications | | | |
| Design Parameters | Intramedullary Nail, cannulated  Lengths: 160 to 480 mm  Diameters: 9 to 14 mm  Contains through holes for interlocking fixation to the bone distally and proximally  Implant component: Nails, Screws, Endcaps and Locking attachment washers  Inlay: The IM nail consists of poly inlay which helps in retaining the screws.  Flat edge design: The IM nail has flat edges to create maximum width to fit through the total knee replacement implant. | Intramedullary Nail, cannulated  Length: 160 to 480 mm  Diameters: 9 to 15 mm  Contains through holes for interlocking fixation to the bone distally and proximally  Implant component: Nails, Screws, Endcaps, and Spiral Blade | 🗹 Technically Equivalent  Both the nails are cannulated.  All lengths and diameters of the RFN-ADVANCED Femoral Nail fall within the boundaries of the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail. While the nail diameters are not exactly the same, all devices allow the surgeon to fit the patient to accommodate different anatomies.  Both systems are modular systems comprising intramedullary nail, screw and endcap. The Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail includes an additional blade option for fixation in the distal femur, while the RFN-ADVANCED Femoral Nail includes locking attachment washers.  The inlay and flat edges are generational design improvements. However, once implanted, both systems act as an internal splint that provides stress sharing, helps to limit damage to soft tissue in the vicinity of bone during surgery, and preserves periosteal blood supply to allow fracture healing.  The nonclinical testing suggests that the bending strength, bending stiffness (Windchill#0000293476) and torsional stiffness (Windchill #00000293478) of RFN-ADVANCED Femoral Nail provide outcomes matching acceptance criteria.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the design parameters. |
| Specifications, Properties: Static Bending | Bending strength = 107 ± 1.37 Nm  Bending structural stiffness = 32.9 ± 0.13 Nm2 | Bending Strength = 105 ± 2.99 Nm  Bending structural stiffness = 32.3 ± 0.22 Nm2 | 🗹 Technically Equivalent  Comparing the offset bending moment and bending structural stiffness, [ a two-sample t-test statistically significant for offset bending moment (p < 0.001, considering a confidence level of 90%) with a predetermined margin of non-inferiority of 13 Nm and bending structural stiffness (p < 0.001) with a predetermined margin of non-inferiority of 3.55 Nm2; therefore,] the acceptance criteria has been met.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the static bending. |
| Specifications, Properties: Torsional Stiffness | Torsional stiffness = 1.83 ± 0.04 Nm | Torsional stiffness = 1.72 ± 0.02 Nm | 🗹 Technically Equivalent  Comparing the torsional stiffness, [a two-sample, t-test is statistically significant for torsional stiffness (p < 0.001, considering a confidence level of 90%) with a predetermined margin of non-inferiority of 0.184 Nm); therefore, the acceptance criteria has been met.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the static bending. |
| Conditions of Use | Sterile operating room | Sterile operating room | 🗹 Technically Equivalent  The conditions for use for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Principle(s) of Operation | | | |
| Preparation for Use | Nails are provided sterile only for single use only. | Nails are provided sterile only for single use only. | 🗹 Technically Equivalent  The preparations for use for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is similar. |
| Application | Intramedullary Nails are rigid, nonabsorbable constructs for temporary fixation, correction or stabilization of the femur during the healing phase. The nails are permanently implanted unless otherwise selected for removal. | Intramedullary Nails are rigid, nonabsorbable constructs for temporary fixation, correction or stabilization of the femur during the healing phase. The nails are permanently implanted unless otherwise selected for removal. | 🗹 Technically Equivalent  The application for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is similar. |
| Technique / Deployment Method | Deployment by open or minimally invasive reduction and internal fixation using retrograde approach. | Deployment by open or minimally invasive reduction and internal fixation using both the antegrade and retrograde or retrograde approach. | 🗹 Technically Equivalent  The subject device and equivalent comparator device follow the same standard series of techniques for fixation of fractures of the femoral shaft and distal femur. RFN-ADVANCED Femoral Nail utilizes only a retrograde approach which is a sub-set of the deployment methods for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail.  The technique / deployment method for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is similar. |
| Mode of Action | Mechanical | Mechanical | 🗹 Technically Equivalent  The mode of action for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is similar. |
| **C. Biological parameters** | | | |
| Materials (including consideration of sourcing characteristics) | Nails: Ti-6Al-4V (TAV) Titanium Alloy (ISO 5832-3)  Inlay: UHWMPE (ISO 5834-2)  End Caps: Ti-6Al-7Nb (TAN) Titanium Alloy (ISO 5832-11)  Locking Attachment Washer: 316L Stainless Steel (ISO 5832-1) | Nails: Titanium Alloy (TAN): Ti-6Al-7Nb (ISO 5832-11/ ASTM F1295)  End Caps: Titanium Alloy (TAN): Ti-6Al-7Nb (ISO 5832-11/ ASTM F1295)  Spiral Blades: Titanium Alloy (TAN): Ti-6Al-7Nb (ISO 5832-11/ ASTM F1295) | 🗹 Biologically Equivalent  Both the nails and endcaps of Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail are manufactured using TAN, following the standard (ISO 5832-11).  RFNA nails are manufactured using TAV, following the standard (ISO 5832-3), while the RFN-ADVANCED Femoral Nail endcaps are manufactured using TAN, following the standard (ISO 5832-11). Both TAN and TAV are biocompatible titanium alloys and has been employed successfully for over 30 years in human implants and application in contact with bone and soft tissue.  It is important to note that the RFN-ADVANCED Femoral Nail has a distal inlay (thickness (distal): 1.26mm (6.72 OD/4.2 ID)) made of UHMWPE (ISO 5834-2) that is a biocompatible material and has been employed successfully for over 20 years in human implants and applications in contact with bone and soft tissue.  Moreover, addition of an inlay to the implant design will not significantly impact the safety and performance as it represents a minor subcomponent and would not change the overall biocompatibility of the system. This difference is a minor generational improvement and is a small subcomponent of the overall nail system.  Assuming the distal locking screws are used as intended and the end cap is used, the contact between the patient and the inlay should be minimal to non-existent. Rationale assessing polymer debris from RFNA with inlay (Windchill #0000293897) concluded that number, size, and shape of particles generated by the nail are comparable to MultiLoc Humeral nail.  The total number of PE particles generated from a MultiLoc nail represents less than 0.001% of the number of particles generated per year from a successful hip joint replacement. These amount of particles will not cause any local, intramedullary or systemic negative side effects beyond what is observed with joint replacement.  Considering this inlay provides additional stability in the locking between the screw and the nail, it is on the inside of the nail, and it does not generate clinically significant debris during insertion, this additional inlay should not negatively impact safety or performance.  RFN-ADVANCED Femoral Nail is offered with an optional locking attachment washer. The washer is manufactured using stainless steel (ISO-5832:1) which is a biocompatible material and has been employed successfully for over 30 years in human implants and applications in contact with bone and soft tissue. The corrosion testing (Windchill #0000297100) and the fretting testing (Windchill #0000293897) concluded that the difference in materials of RFNA nail and LAW construct with attached screws does not lead to accelerated corrosion or fretting rates.  The washer is an optional additional component to the system and does not impact the biocompatibility of the implant system; and it doesn’t come in contact with the nail except via the screws.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the materials. |
| Construction (including consideration of sourcing and manufacturing characteristics) | Machined and anodized as per ES0063 and sterilized via Gamma sterilization | Machined and anodized as per ES0063 and sterilized via Gamma sterilization | 🗹 Biologically Equivalent  The construction process used for RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Human Tissue or Body Fluids in Contact with the Device | Bone and soft tissue of the femur | Bone and soft tissue of the femur | 🗹 Biologically Equivalent  The human tissues or body fluids in contact with RFN-ADVANCED Femoral Nail and Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail is same. |
| Biological Response | Biological safety evaluation per ISO 10993-1 supports acceptable biological response. | Biological safety evaluation per ISO 10993-1 supports acceptable biological response. | 🗹 Biologically Equivalent  The RFNA (Nails: TAV and endcaps: TAN) and Expert R/AFN (Nails and endcaps: TAN) implants are manufactured and offered in titanium alloys TAV and TAN.  Manufacturing process strictly adheres to technical specification and testing outlined in ISO 5832-11 for TAN and ISO 5832-3 for TAV.  The RFNA inlay is manufactured using UHMWPE and the manufacturing process strictly adheres to technical specification and testing outlined in ISO 5834-2.  The RFNA locking attachment washer is manufactured using stainless steel and the manufacturing process strictly adheres to technical specification and testing outlined in ISO 5834-1.  The specific Biological Safety Evaluations for the subject devices were performed as per ISO 10993-1.  There is no clinically significant difference in performance and safety of RFN-ADVANCED Femoral Nail as compared to Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail with respect to the biological response. |

## Literature Search results

### Systematic SOA Search

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert the Systematic SOA Review search results from the full SOA Review Report described in Section 3.9.1 |

Refer to SOA Report – Internal Fixation of Femur Fractures – Distal Femur and Femoral Shaft (Table 1) for complete search details, including databases and search terms. The search included within the report covered the period of July 2017 through August 2022.

### 

### Systematic SOA Review Search Appraisal Summary

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert the Systematic SOA Search Appraisal Summary from the full SOA Review Report describe in Section 3.9.1. |

The following tables (Table 195 – Table 199) identify the number of publications and patients from the Systematic SOA Review Search that are of sufficient scientific validity and relevance to contribute to the SOA assessment.

Table : Included Secondary Benchmark Data for intramedullary nail fixation of adult femoral shaft fractures (TO # 1)

| Key Outcome Parameter | Appraisal Rank | Publication Type | Publication Reference (Author, Year) | # Patients | Reported / Pooled Mean / Rate | Mean Follow-Up (Months) | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Min | Max |
| Performance: | | | | | | | |
| Bone Union (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 94.5% | NR[[10]](#footnote-11) | NR |
| Systematic review | ([Saleeb et al., 2019](#_ENREF_30)) | 908 | 97% | 6 | 144 |
| **Bone Union (%) Range** | | | | **4,242** | **94.5 – 97%** | **6** | **144** |
| Safety: | | | | | | | |
| Non-union (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 6.1% | NR | NR |
| Systematic review | ([Mohan et al., 2019](#_ENREF_28)) | 173 | 0% | 20 | 48 |
| Retrospective Cohort | ([Dingemans et al., 2018](#_ENREF_7)) | 93 | 14% | NR | NR |
| Non-union (%) Range | | | | 3,600 | 0 – 14.0% | 20 | 48 |
| Infection (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 0.5% | NR | NR |
| Systematic review | ([Saleeb et al., 2019](#_ENREF_30)) | 908 | 6% | 6 | 144 |
| Infection (%) Range | | | | 4,242 | 0.5 – 6% | 6 | 144 |
| Revision (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 7.1% | NR | NR |
| Revision (%) Total | | | | 3,334 | 7.1% | NR | NR |

Table : Included Primary Benchmark Data for intramedullary nail fixation of adult femoral shaft fractures (TO # 1)

| Key Outcome Parameter | Appraisal Rank | Publication Type | Publication Reference (Author, Year) | Device Name and Mfr | # Patients | Mean / Rate | Mean Follow-Up (Months) | Pre- to Post-Op Significant Difference?  Yes/No  (p-value) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Performance: | | | | | | | |  |
| Bone Union (% of patients) | 6b | Comparative prospective study | ([Ekwunife et al., 2022](#_ENREF_9)) | NR | 50 | 100% | 48 hours to 18 weeks | Yes (*p* = 0.020)[[11]](#footnote-12) |
| Bone Union (%) Total | | | | | 50 | 100% | 48 hours to 18 weeks | Yes (*p* = 0.020) |
| Safety: | | | | | | | | |
| Infection (% of patients) | 6b | Comparative prospective study | ([Ekwunife et al., 2022](#_ENREF_9)) | NR | 50 | 11.5% | 48 hours to 18 weeks | NR |
| Infection (%) Total | | | | | 50 | 11.5% | 48 hours to 18 weeks | NR |
| Revision (% of patients) | 6c | Large cohort multivariate regression analysis | ([Yoon et al., 2017](#_ENREF_34)) | NR | 316 | 3.8% | NR | NR |
| Revision (%) Total | | | | | 316 | 3.8% | NR | NR |

Table : Included Secondary Benchmark Data for intramedullary nail fixation of Adult Distal Femoral Fracture

| Key Outcome Parameter | Appraisal Rank | Publication Type | Publication Reference (Author, Year) | # Patients | Reported / Pooled Mean / Rate | Mean Follow-Up (Months) | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Min | Max |
| Performance: | | | | | | | |
| Bone Union (% of patients) | 6a | Systematic review | ([Shah et al., 2020](#_ENREF_27)) | 1,188 | 71.4 – 100% | 6 | NR |
| Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 89.1% | NR | NR |
| **Bone Union (%) Range** | | | | **4,522** | **71.4 – 100%** | **6** | **NR** |
| Safety: | | | | | | | |
| Non-union (% of patients) | 6a | Meta-analysis | ([Byung-Ho et al., 2021](#_ENREF_3)) | 2156 | 4% | NR | NR |
| Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 5.4% | NR | NR |
| Systematic review and meta-analysis | ([Neradi et al., 2022](#_ENREF_29)) | 293 | 7.8% | 10.4 | 31.3 |
| Non-union (%) Range | | | | 5,783 | 4 – 7.8% | 10.4 | 31.3 |
| Infection (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 0.0% | NR | NR |
| Systematic review and meta-analysis | ([Neradi et al., 2022](#_ENREF_29)) | 293 | 7.14% | 10.4 | 31.3 |
| Infection (%) Range | | | | 3,627 | 0.0 – 7.14% | 10.4 | 31.3 |
| Revision (% of patients) | 6a | Systematic review and meta-analysis | ([Koso et al., 2018](#_ENREF_18)) | 3,334 | 10.9% | NR | NR |
| Systematic review | ([Shah et al., 2020](#_ENREF_27)) | 1,188 | 14.6% | 6 | NR |
| Revision (%) Range | | | | 4,522 | 10.9 – 14.6% | 6 | NR |

Table : Included Secondary Benchmark Data for intramedullary nail fixation of Adolescent Femoral Fractures

| Key Outcome Parameter | Appraisal Rank | | Publication Type | Publication Reference (Author, Year) | # Patients | Reported / Pooled Mean / Rate | Mean Follow-Up (Months) | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Min | Max |
| Performance: | | | | | | | | |
| Bone Union (% of patients) | 6a | | Review | ([John et al., 2017](#_ENREF_15)) | 1,705 | 100% | NR | NR |
| **Bone Union (%) Total** | | | | | **1,705** | **100%** | **NR** | **NR** |
| Safety: | | | | | | | | |
| **Revision (% of patients)** | 6a | | Registry | ([Madhuri et al., 2014](#_ENREF_24)) | **527** | **9.5%** | **12** | **93.6** |
| **Revision (% of patients) Total** | | | | | **527** | **9.5%** | **12** | **93.6** |
|  | |  |  |  |  |  |  | |
|  |  |
|  | | | | | | | | |
|  | |  |  |  |  |  |  |  |
|  | | | | |  |  |  |  |

Table : Included Primary Benchmark Data for intramedullary nail fixation of Adolescent Femoral Fractures

| Key Outcome Parameter | Appraisal Rank | Publication Type | Publication Reference (Author, Year) | Device Name and Mfr | # Patients | Mean / Rate | Mean Follow-Up (Months) | Pre- to Post-Op Significant Difference?  Yes/No  (p-value) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Performance: | | | | | | | |  |
| Bone Union (% of patients) | 6c | Retrospective analysis | ([Kruppa et al., 2017](#_ENREF_19)) | NR | 42 | 100% | 12 | NR |
| Retrospective review, case series | ([Del Balso et al., 2021](#_ENREF_6)) | Smith and Nephew (Memphis, Tennessee) Trigen Adolescent Trochanteric Antegrade Nail (TAN) | 64 | 100% | 27.4 ± 8.1 | NR |
| Bone Union (%) Total | | | | | 106 | 100% | 12 – 27.4 ± 8.1 | NR |
| Safety: | | | | | | | | |
| Non-union (% of patients) | 6c | Retrospective analysis | ([Kruppa et al., 2017](#_ENREF_19)) | NR | 42 | 11.1% | 12 | NR |
| Retrospective review, case series | ([Del Balso et al., 2021](#_ENREF_6)) | Smith and Nephew (Memphis, Tennessee) Trigen Adolescent Trochanteric Antegrade Nail (TAN) | 64 | 0.0% | 27.4 ± 8.1 | NR |
| **Non-union (%) Range** | | | | | **106** | **0.0 – 11.1%** | **12 – 27.4 ± 8.1** | **NR** |
| Infection (% of patients) | 6c | Retrospective analysis | ([Kruppa et al., 2017](#_ENREF_19)) | NR | 42 | 22.2% | 12 | NR |
| Retrospective review, case series | ([Del Balso et al., 2021](#_ENREF_6)) | Smith and Nephew (Memphis, Tennessee) Trigen Adolescent Trochanteric Antegrade Nail (TAN) | 64 | 0.0% | 27.4 ± 8.1 | NR |
| Infection (%) Total | | | | | 106 | 0.0 – 22.2% | 12 – 27.4 ± 8.1 | NR |
| Revision (% of patients) | 6c | Retrospective review, case series | ([Del Balso et al., 2021](#_ENREF_6)) | Smith and Nephew (Memphis, Tennessee) Trigen Adolescent Trochanteric Antegrade Nail (TAN) | 64 | 36.9% | 27.4 ± 8.1 | NR |
| Revision (%) Total | | | | | 64 | 36.9% | 27.4 ± 8.1 | NR |

### Device-Specific Systematic Literature Review Search

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert the Device-Specific Systematic Literature Review search results from the full Literature Review Report(s) describe in Section 4.1. |

Refer to Systematic Literature Review Report (Table 1) for complete search details, including databases and search terms. The search included within the report covered the period of January 1992 through August 2022.

### 

### Device-Specific Systematic Literature Appraisal Summary

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert the Device-Specific Systematic Literature Appraisal Summary from Section 2.4 of the full Literature Review Report(s) describe in Section . |

The following tables identify the number of publications and patients from the Systematic Literature Search (summarized in Section ) that are of sufficient scientific validity and relevance to either support safety and/or performance conformity (Table 200), to inform on the identification of safety trending or performance issues (Table 201), or inform on misuse / off-label trending (Table 202).

Table : Appraisal Rank of Publications of Sufficient Quality and Relevance to Support Safety and/or Performance Conformity Assessment

| Appraisal Rank | Type of clinical evidence | Number of Publications (Overall Search) | Number of Patients (Overall Search) | Associated References |
| --- | --- | --- | --- | --- |
| Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | |
| 2 | Results of high-quality clinical investigations with some gaps | 2 | 241 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified | 4 | 132 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Adolescent Lateral Femoral Nail System | | | | |
| 2 | Results of high-quality clinical investigations with some gaps | 1 | 15 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Lateral Femoral Nail System | | | | |
| 2 | Results of high-quality clinical investigations with some gaps | 3 | 51 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified | 1 | 154 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Asian Femoral Nail System | | | | |
| 2 | Results of high-quality clinical investigations with some gaps | 2 | 72 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified | 3 | 48 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Multiple Femoral Nail Systems | | | | |
| 4 | Outcomes from studies with potential methodological flaws but where data can still be quantified and acceptability justified | 1 | 8 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Total | All data types identified above | 17 | 721 | - |

Table : Appraisal Rank of Publications of Sufficient Quality and Relevance to Inform Safety and/or Performance Trending Assessment

| Appraisal Rank | Type of clinical evidence | Number of Publications  (Overall Search) | Number of Patients  (Overall Search) | Associated References |
| --- | --- | --- | --- | --- |
| Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 4 | 150 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 9 | Individual case reports, conference proceedings or technical notes with aggregated clinical data on the subject device | 8 | 8 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Adolescent Lateral Femoral Nail System | | | | |
| 7 | Data that provides information regarding indirect use e.g., mixed cohort publications, where the subject device is aggregated with non-similar devices or publications which report on device use but do not report on the key performance and safety outcomes | 1 | 53 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Lateral Femoral Nail System | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 4 | 358 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 9 | Individual case reports, conference proceedings or technical notes with aggregated clinical data on the subject device | 8 | 46 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Femoral Recon Nailing System | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 1 | 22 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Retrograde Femoral Nail Advanced System | | | | |
| 9 | Individual case reports, conference proceedings or technical notes with aggregated clinical data on the subject device | 3 | 3 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Asian Femoral Nail System | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 9 | 534 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| 9 | Individual case reports, conference proceedings or technical notes with aggregated clinical data on the subject device | 4 | 4 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Unspecified Femoral Nails | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 1 | 114 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Multiple Femoral Nail Systems | | | | |
| 6 | Mixed cohort publications where the acceptability cannot be justified but the subject device is aggregated with similar devices. | 2 | 152 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Total | All data types identified above | 45 | 1,444 | - |

Table : Appraisal Rank of Publications to Inform Off-Label / Misuse Trending Assessment

| Appraisal Rank | Type of clinical evidence | Number of Publications  (Overall Search) | Number of Patients  (Overall Search) | Associated References |
| --- | --- | --- | --- | --- |
| Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System | | | | |
| 13 | Data that cannot be used for the safety and performance conformity assessment e.g., exclusively off-label or misuse or data where the acceptability cannot be justified. | 4 | 245 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Adolescent Lateral Femoral Nail System | | | | |
| 13 | Data that cannot be used for the safety and performance conformity assessment e.g., exclusively off-label or misuse or data where the acceptability cannot be justified. | 4 | 23 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Lateral Femoral Nail System | | | | |
| 13 | Data that cannot be used for the safety and performance conformity assessment e.g., exclusively off-label or misuse or data where the acceptability cannot be justified. | 2 | 10 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Expert Asian Femoral Nail System | | | | |
| 13 | Data that cannot be used for the safety and performance conformity assessment e.g., exclusively off-label or misuse or data where the acceptability cannot be justified. | 8 | 716 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Unspecified Femoral Nails | | | | |
| 13 | Data that cannot be used for the safety and performance conformity assessment e.g., exclusively off-label or misuse or data where the acceptability cannot be justified. | 1 | 29 | Refer Literature Review Report (Table 1) or Appendix 9.7.3 |
| Total | All data types identified above | 19 | 1,023 | - |

## PMCF Activity Guide[[12]](#footnote-13)

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete Specific PMCF Activity Assessment for all devices.   * Create separate tables (in separate subsections), as warranted (e.g., by System / Device Group / Variant / indications / patient target group(s) / technique). If assessment is grouped for multiple Device Groups, explicitly state this and justify why. |
|  |  | Confirm that PMCF Activity Assessment aligns with PMCFP. |

Table : Specific PMCF Activity Guide for Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (adapted from MEDDEV 2.12/2 and MDCG 2020-7 PMCF Plan Guidance)

| Circumstances that may justify PMCF activities include, for example: | Applicable? |
| --- | --- |
| 1. Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel | Does not drive need for specific PMCF |
| 1. Significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed | Does not drive need for specific PMCF |
| 1. High product related risk e.g., based on design, materials, components, invasiveness, clinical procedures | Does not drive need for specific PMCF |
| 1. High risk anatomical locations | Does not drive need for specific PMCF |
| 1. High risk target populations e.g., pediatrics, elderly | Does not drive need for specific PMCF |
| 1. Severity of disease/treatment challenges | Does not drive need for specific PMCF |
| 1. Questions of ability to generalize clinical investigation results | Does not drive need for specific PMCF |
| 1. Unanswered questions of long-term safety and performance | Does not drive need for specific PMCF |
| 1. Results from any previous clinical investigation, including adverse events or from post-market surveillance activities | Does not drive need for specific PMCF |
| 1. Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g., hip implants in different ethnic populations | Does not drive need for specific PMCF |
| 1. Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product | Does not drive need for specific PMCF |
| 1. Risks identified from the literature or other data sources for similar marketed devices | Does not drive need for specific PMCF |
| 1. Interaction with other medical products or treatments | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of device when exposed to a larger and more varied population of clinical users | Does not drive need for specific PMCF |
| 1. Emergence of new information on safety or performance | Does not drive need for specific PMCF |
| 1. Where CE marking was based on equivalence | Does not drive need for specific PMCF |
| 1. Confirmation of safety and performance of the device **in** a larger and more varied population of patients | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of a device when utilized in different surgical approaches (e.g., open, laparoscopic). | Does not drive need for specific PMCF |
| 1. Other: N/A | Does not drive need for specific PMCF |

Table : Specific PMCF Activity Guide for Expert Adolescent Lateral Femoral Nail System and Expert Lateral Femoral Nail System (adapted from MEDDEV 2.12/2 and MDCG 2020-7 PMCF Plan Guidance)

| Circumstances that may justify PMCF activities include, for example: | Applicable? |
| --- | --- |
| 1. Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel | Does not drive need for specific PMCF |
| 1. Significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed | Does not drive need for specific PMCF |
| 1. High product related risk e.g., based on design, materials, components, invasiveness, clinical procedures | Does not drive need for specific PMCF |
| 1. High risk anatomical locations | Does not drive need for specific PMCF |
| 1. High risk target populations e.g., pediatrics, elderly | Does not drive need for specific PMCF |
| 1. Severity of disease/treatment challenges | Does not drive need for specific PMCF |
| 1. Questions of ability to generalize clinical investigation results | Does not drive need for specific PMCF |
| 1. Unanswered questions of long-term safety and performance | Does not drive need for specific PMCF |
| 1. Results from any previous clinical investigation, including adverse events or from post-market surveillance activities | Does not drive need for specific PMCF |
| 1. Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g., hip implants in different ethnic populations | Does not drive need for specific PMCF |
| 1. Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product | Does not drive need for specific PMCF |
| 1. Risks identified from the literature or other data sources for similar marketed devices | Does not drive need for specific PMCF |
| 1. Interaction with other medical products or treatments | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of device when exposed to a larger and more varied population of clinical users | Does not drive need for specific PMCF |
| 1. Emergence of new information on safety or performance | Does not drive need for specific PMCF |
| 1. Where CE marking was based on equivalence | Does not drive need for specific PMCF |
| 1. Confirmation of safety and performance of the device **in** a larger and more varied population of patients | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of a device when utilized in different surgical approaches (e.g., open, laparoscopic). | Does not drive need for specific PMCF |
| 1. Other: N/A | Does not drive need for specific PMCF |

Table : Specific PMCF Activity Guide for Femoral Recon Nailing System (adapted from MEDDEV 2.12/2 and MDCG 2020-7 PMCF Plan Guidance)

| Circumstances that may justify PMCF activities include, for example: | Applicable? |
| --- | --- |
| 1. Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel | Does not drive need for specific PMCF |
| 1. Significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed | Does not drive need for specific PMCF |
| 1. High product related risk e.g., based on design, materials, components, invasiveness, clinical procedures | Does not drive need for specific PMCF |
| 1. High risk anatomical locations | Does not drive need for specific PMCF |
| 1. High risk target populations e.g., pediatrics, elderly | Does not drive need for specific PMCF |
| 1. Severity of disease/treatment challenges | Does not drive need for specific PMCF |
| 1. Questions of ability to generalize clinical investigation results | Does not drive need for specific PMCF |
| 1. Unanswered questions of long-term safety and performance | Does not drive need for specific PMCF |
| 1. Results from any previous clinical investigation, including adverse events or from post-market surveillance activities | Does not drive need for specific PMCF |
| 1. Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g., hip implants in different ethnic populations | Does not drive need for specific PMCF |
| 1. Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product | Does not drive need for specific PMCF |
| 1. Risks identified from the literature or other data sources for similar marketed devices | Does not drive need for specific PMCF |
| 1. Interaction with other medical products or treatments | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of device when exposed to a larger and more varied population of clinical users | Does not drive need for specific PMCF |
| 1. Emergence of new information on safety or performance | Does not drive need for specific PMCF |
| 1. Where CE marking was based on equivalence | Does not drive need for specific PMCF |
| 1. Confirmation of safety and performance of the device **in** a larger and more varied population of patients | Consider need for specific PMCF |
| 1. Verification of safety and performance of a device when utilized in different surgical approaches (e.g., open, laparoscopic). | Does not drive need for specific PMCF |
| 1. Other: N/A | Does not drive need for specific PMCF |

Table : Specific PMCF Activity Guide for Retrograde Femoral Nail Advanced System (adapted from MEDDEV 2.12/2 and MDCG 2020-7 PMCF Plan Guidance)

| Circumstances that may justify PMCF activities include, for example: | Applicable? |
| --- | --- |
| 1. Innovation, e.g., where the design of the device, the materials, substances, the principles of operation, the technology or the medical indications are novel | Does not drive need for specific PMCF |
| 1. Significant changes to the products or to its intended use for which premarket clinical evaluation and re-certification has been completed | Does not drive need for specific PMCF |
| 1. High product related risk e.g., based on design, materials, components, invasiveness, clinical procedures | Does not drive need for specific PMCF |
| 1. High risk anatomical locations | Does not drive need for specific PMCF |
| 1. High risk target populations e.g., pediatrics, elderly | Does not drive need for specific PMCF |
| 1. Severity of disease/treatment challenges | Does not drive need for specific PMCF |
| 1. Questions of ability to generalize clinical investigation results | Does not drive need for specific PMCF |
| 1. Unanswered questions of long-term safety and performance | Does not drive need for specific PMCF |
| 1. Results from any previous clinical investigation, including adverse events or from post-market surveillance activities | Does not drive need for specific PMCF |
| 1. Identification of previously unstudied subpopulations which may show different benefit/risk-ratio e.g., hip implants in different ethnic populations | Does not drive need for specific PMCF |
| 1. Continued validation in cases of discrepancy between reasonable premarket follow-up time scales and the expected life of the product | Does not drive need for specific PMCF |
| 1. Risks identified from the literature or other data sources for similar marketed devices | Does not drive need for specific PMCF |
| 1. Interaction with other medical products or treatments | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of device when exposed to a larger and more varied population of clinical users | Does not drive need for specific PMCF |
| 1. Emergence of new information on safety or performance | Does not drive need for specific PMCF |
| 1. Where CE marking was based on equivalence | Consider need for specific PMCF |
| 1. Confirmation of safety and performance of the device **in** a larger and more varied population of patients | Does not drive need for specific PMCF |
| 1. Verification of safety and performance of a device when utilized in different surgical approaches (e.g., open, laparoscopic). | Does not drive need for specific PMCF |
| 1. Other: N/A | Does not drive need for specific PMCF |

## Bibliographies

### SOA Included Publications & General Publications

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert the bibliographic references from the Included Publications list from Section 3.9.2 of the SOAR. |
|  |  | These references should be inserted with EndNote using the Cell Style. |

Bishop, J.A., Buza, J., and Leucht, P. (2018). Ipsilateral Femoral Neck and Shaft Fractures. In Proximal Femur Fractures (Springer), pp. 129-139.

Butler, B.A., Harold, R.E., and Williams, J. (2019). Prosthesis-Engaging Retrograde Femoral Nail with Locking Plate for the Treatment of a Vancouver B1 Periprosthetic Femur Fracture Nonunion: A Case Report. JBJS Case Connect *9*, e0108.

Byung-Ho, Y., Keun, P.I., Kim, Y., Hyoung-Keun, O., Choo, S.K., and Yerl-Bo, S. (2021). Incidence of nonunion after surgery of distal femoral fractures using contemporary fixation device: a meta‐analysis. Archives of Orthopaedic and Trauma Surgery *141*, 225-233.

Chen, X., Lu, M., Xu, W., Wang, X., Xue, M., Dai, J., Zhang, Z., and Chen, G. (2020a). Treatment of pediatric femoral shaft fractures with elastic stable intramedullary nails versus external fixation: a meta-analysis. Orthopaedics & Traumatology: Surgery & Research *106*, 1305-1311.

Chen, Z., Han, D., Wang, Q., and Li, L. (2020b). Four interventions for pediatric femoral shaft fractures: Network meta-analysis of randomized trials. International Journal of Surgery *80*, 53-60.

Del Balso, C., Bartley, D., Cashin, M., Carey, T., and Lawendy, A.R. (2021). Rigid intramedullary nail fixation of traumatic femoral fractures in the skeletally immature. OTA International *4*.

Dingemans, S., Sier, M., Peters, R., Goslings, J., and Schepers, T. (2018). Two-stage treatment in patients with patients with high-energy femoral fractures does not lead to an increase in deep infectious complications: a propensity score analysis. European Journal of Trauma and Emergency Surgery *44*, 125-131.

Edwards, T.A., Daly, C., Donovan, R.L., and Whitehouse, M.R. (2021). Risk of complications following surgical fixation of femoral diaphyseal fractures in children aged 4 to 12 years: A systematic review and meta-analysis. Injury.

Ekwunife, R.T., Iyidobi, E.C., Enweani, U.N., Nwadinigwe, C.U., Okwesili, C.I., Ekwedigwe, H.C., and Obande, B.O. (2022). Comparative prospective study of early outcomes after osteosynthesis with locked intramedullary nailing or plating for closed femoral shaft fractures at the National Orthopaedic Hospital Enugu, Nigeria.

Grønhaug, K.M., Dybvik, E., Matre, K., Östman, B., and Gjertsen, J.-E. (2022). Intramedullary nail versus sliding hip screw for stable and unstable trochanteric and subtrochanteric fractures: 17,341 patients from the Norwegian hip fracture register. The Bone & Joint Journal *104*, 274-282.

Horneff, J.G., 3rd, Scolaro, J.A., Jafari, S.M., Mirza, A., Parvizi, J., and Mehta, S. (2013). Intramedullary nailing versus locked plate for treating supracondylar periprosthetic femur fractures. Orthopedics *36*, e561-566.

Huang, X.a., Chen, Y., Chen, B., Zheng, K., Lin, C., Lin, F., and Luo, X. (2022). Reamed versus unreamed intramedullary nailing for the treatment of femoral shaft fractures among adults: A meta-analysis of randomized controlled trials. Journal of Orthopaedic Science *27*, 850-858.

Imam, M.A., Negida, A.S., Elgebaly, A., Hussein, A., Ernstbrunner, L., Javed, S., Jacob, J., Churchill, M., Trikha, P., and Newman, K. (2018). Titanium elastic nails versus spica cast in pediatric femoral shaft fractures: a systematic review and meta-analysis of 1012 patients. The Archives of Bone and Joint Surgery *6*, 176-188.

Jin, Y.f., Xu, H.c., Shen, Z.h., Pan, X.k., and Xie, H. (2020). Comparing Augmentative Plating and Exchange Nailing for the Treatment of Nonunion of Femoral Shaft Fracture after Intramedullary Nailing: A Meta‐analysis. Orthopaedic Surgery *12*, 50-57.

John, R., Sharma, S., Raj, G.N., and Singh, J. (2017). Suppl 2: M4: Current concepts in paediatric femoral shaft fractures. The open orthopaedics journal *11*, 353.

Khan, A.M., Tang, Q.O., and Spicer, D. (2017). The Epidemiology of Adult Distal Femoral Shaft Fractures in a Central London Major Trauma Centre Over Five Years. The open orthopaedics journal *11*, 1277-1291.

Khoriati, A.-a., Jones, C., Gelfer, Y., and Trompeter, A. (2016). The management of paediatric diaphyseal femoral fractures: a modern approach. Strategies in Trauma and Limb Reconstruction *11*, 87-97.

Koso, R.E., Terhoeve, C., Steen, R.G., and Zura, R. (2018). Healing, nonunion, and re-operation after internal fixation of diaphyseal and distal femoral fractures: a systematic review and meta-analysis. International orthopaedics *42*, 2675-2683.

Kruppa, C., Wiechert, G., Schildhauer, T.A., and Dudda, M. (2017). Complications after operative treatment of femoral shaft fractures in childhood and adolescence. Orthopedic reviews *9*.

Liau, G.Z.Q., Lin, H.Y., Wang, Y., Nistala, K.R.Y., Cheong, C.K., and Hui, J.H.P. (2021). Pediatric femoral shaft fracture: an age-based treatment algorithm. Indian Journal of Orthopaedics *55*, 55-67.

Lindisfarne, E.A., and Ayodele, O. (2020). Non-accidental injury, femoral shaft and neck fractures in children. Surgery (Oxford) *38*, 568-580.

Liu, W., Gao, Q., Li, Q., and Jing, J. (2019). LOCKED COMPRESSION PLATE VERSUS RETROGRADE INTRAMEDULLARY NAIL FOR PERIPROSTHETIC FEMUR FRACTURES FOLLOWING TOTAL KNEE ARTHROPLASTY: A META-ANALYSIS. ACTA MEDICA MEDITERRANEA *35*, 1019-1024.

Lu, Y., Wang, Y., Song, Z., Wang, Q., Sun, L., Ren, C., Xue, H., Li, Z., Zhang, K., Hao, D.*, et al.* (2020). Treatment comparison of femoral shaft with femoral neck fracture: a meta-analysis. Journal of Orthopaedic Surgery *15*, 19.

Madhuri, V., Dutt, V., Gahukamble, A.D., and Tharyan, P. (2014). Interventions for treating femoral shaft fractures in children and adolescents. Evidence‐Based Child Health: A Cochrane Review Journal *9*, 753-826.

Makarewich, C.A., Talwar, D., Baldwin, K.D., and Swarup, I. (2020). Flexible intramedullary nailing of femoral shaft fractures in children weighing≥ 40 kg: a systematic review and meta-analysis. Journal of Pediatric Orthopaedics *40*, 562-568.

Medlock, G., Stevenson, I.M., and Johnstone, A.J. (2018). Uniting the un-united: should established non-unions of femoral shaft fractures initially treated with IM nails be treated by plate augmentation instead of exchange IM nailing? A systematic review. Strategies in trauma and limb reconstruction *13*, 119-128.

Mohamed, A., and Rajeev, A.S. (2017). Clinical outcomes and complications of titanium versus stainless steel elastic nail in management of paediatric femoral fractures-a systematic review. European journal of orthopaedic surgery & traumatologie *27*, 157-167.

Mohan, K., Ellanti, P., French, H., Hogan, N., and McCarthy, T. (2019). Single versus separate implant fixation for concomitant ipsilateral femoral neck and shaft fractures: a systematic review. Orthopedic Reviews *11*.

Neradi, D., Sodavarapu, P., Jindal, K., Kumar, D., Kumar, V., and Goni, V. (2022). Locked Plating Versus Retrograde Intramedullary Nailing for Distal Femur Fractures: a Systematic Review and Meta-Analysis. Archives of Bone and Joint Surgery *10*, 141.

Saleeb, H., Tosounidis, T., Papakostidis, C., and Giannoudis, P.V. (2019). Incidence of deep infection, union and malunion for open diaphyseal femoral shaft fractures treated with IM nailing: a systematic review. The Surgeon *17*, 257-269.

Saleh, A.M.G., Salama, A.M., Elhewala, T.A.E., and Khaled, M. (2021). Comparing Outcomes of Plating versus Flexible Nailing of Fracture Shaft Femur in children: Metaanalysis Study. European Journal of Molecular & Clinical Medicine *8*, 3335-3341.

Shah, J.K., Szukics, P., Gianakos, A.L., Liporace, F.A., and Yoon, R.S. (2020). Equivalent union rates between intramedullary nail and locked plate fixation for distal femur periprosthetic fractures–a systematic review. Injury *51*, 1062-1068.

Whiting, P.S., Amajoyi, O.V., and Sethi, M.K. (2018). Diaphyseal Femur Fractures. In Orthopedic Traumatology: An Evidence-Based Approach, M.K. Sethi, W.T. Obremskey, and A.A. Jahangir, eds. (Cham: Springer International Publishing), pp. 223-235.

Yoon, R.S., Gage, M.J., Galos, D.K., Donegan, D.J., and Liporace, F.A. (2017). Trochanteric entry femoral nails yield better femoral version and lower revision rates-A large cohort multivariate regression analysis. Injury *48*, 1165-1169.

### SOA Excluded Publications

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Insert or cross-reference the bibliographic references from the Excluded Publications list from of the SOAR and identify reason for exclusion. Alternatively, reference or attach SOA screening log. |
|  |  | If inserted, use the “Reference List” Style. |

Refer to SOA Report – Internal Fixation of Femur Fractures – Distal Femur and Femoral Shaft (Table 1) for a complete list of references excluded from the report, including reason for exclusion.

### Literature Included Publications

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | If CER includes device-specific systematic literature review, insert list of included publications by device group from the referenced Literature Report (Section 4.1).   * Create separate subsections for: * References of sufficient scientific validity/relevance to support performance / safety * References of sufficient scientific validity/relevance to inform performance / safety assessment for trending * References of sufficient scientific validity/relevance to support identification of off-label use / misuse |
|  |  | Use the “Reference List” Style. |

#### References of Sufficient Scientific Validity /Relevance to Support Performance / Safety Conformity Assessment

##### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (Device Group #1)

Rank 2

Flanagan, C. D.,Joseph, N. M.,Copp, J.,Romeo, N.,Alfonso, N.,Hirschfeld, A.. Weight-bearing status may influence rates of radiographic healing following reamed, intramedullary fixation of diaphyseal femur fractures. OTA international : the open access journal of orthopaedic trauma. 2021. 4:e154

Ru J.-Y, Niu Y.-F., Cong Y., Kang W.B., Cang H.-B., Zhao J.-N.. Exchanging reamed nailing versus augmentative compression plating with autogenous bone grafting for aseptic femoral shaft nonunion: a retrospective cohort study Publisher: Kare Publishing. Acta Orthopaedica et Traumatologica Turcica. 2015. 49:668-675

Rank 4

Ciftdemir M. Tuncel S.A. Ozcan M. Copuroglu C. Erem M.. Does electromagnetic-manual guided distal locking influence rotational alignment in antegrade femoral nailing?. International Orthopaedics. 2015. 39:507-512

Garala, K.,Ramoutar, D.,Li, J.,Syed, F.,Arastu, M.,Ward, J.,Patil, S.. Distal femoral fractures: A comparison between single lateral plate fixation and a combined femoral nail and plate fixation. Injury. 2022. 53(2):634-639

Oh, C. W.,Kim, J. W.,Park, K. H.,Oh, J. K.,Yoon, Y. C.,Chung, S. H.. The importance of reconstruction nailing for diaphyseal atypical femoral fractures: a comparative study with standard nailing. Archives of orthopaedic and trauma surgery. 2021. #volume#:#pages#

Spitler, C. A.,Bergin, P. F.,Russell, G. V.,Graves, M. L.. Endosteal Substitution With an Intramedullary Rod in Fractures of the Femur. Journal of Orthopaedic Trauma. 2018. 32:S25-S29

##### Expert Adolescent Lateral Femoral Nail System (System #2)

Liebs, T. R.,Messling, A.,Milosevic, M.,Berger, S. M.,Ziebarth, K.. Health-Related Quality of Life after Adolescent Fractures of the Femoral Shaft Stabilized by a Lateral Entry Femoral Nail. Children (Basel, Switzerland). 2022. 9:#pages#

##### Expert Lateral Femoral Nail System (System #3)

Ergisi, Y.,Kafa, N.,Tokgoz, M. A.,Demir, E.,Kanik, Z. H.,Sezgin, E. A.,Ataoglu, M. B.. Is gluteus medius injured in patients treated with a trochanter tip entry intramedullary nail? Clinical, electrophysiological and functional outcomes. Joint diseases and related surgery. 2020. 31 (2):312-319

Liodakis, E.,Kenawey, M.,Petri, M.,Zumrut, A.,Hawi, N.,Krettek, C.,Citak, M.. Factors influencing neck anteversion during femoral nailing: A retrospective analysis of 220 torsion-difference CTs. Injury. 2011. 42 (11):1342-1345

Prasarn, M. L.,Cattaneo, M. D.,Achor, T.,Ahn, J.,Klinger, C. E.,Helfet, D. L.,Lorich, D. G.. The effect of entry point on malalignment and iatrogenic fracture with the synthes lateral entry femoral nail. Journal of Orthopaedic Trauma. 2010. 24 (4):224-229

Volgas, D. A.,Burch, T.,Stannard, J. P.,Ellis, T.,Bilotta, J.,Alonso, J. E.. Fat embolus in femur fractures: a comparison of two reaming systems. Injury. 2010. 41 Suppl 2:S90-3

##### Femoral Recon Nailing System (System #4)

No article was included in this section.

##### Retrograde Femoral Nail Advanced System (System #5)

No article was included in this section.

##### Expert Asian Femoral Nail System (System #6)

Rank 2

Li, L.,Gao, F.,Huang, Q.,Li, Q.,Xie, L.,Zhang, B.. Midterm follow-up results on Asian femoral intramedullary nail for the treatment of segmental and comminuted femoral fractures. Zhongguo gu shang = China journal of orthopaedics and traumatology. 2016. 29 (6):522-525

Shin, W. C.,Jang, J. H.,Jung, S. J.,Moon, N. H.. Advantages and limitations of intramedullary nailing for the surgical treatment of ipsilateral intertrochanteric and femoral shaft fractures: a retrospective comparative study based on propensity score matching. European journal of trauma and emergency surgery : official publication of the European Trauma Society. 2020. #volume#:no pagination

Rank 4

Gavaskar, D. A.,Srinivasan, D. P.,J, D. B.,Raj, D. R. V.,Sagar, D. K.,P, D. K.. Retrograde entry portal for cephalomedullary nailing in difficult subtrochanteric fractures. Injury. 2021. 52(7):2010-2015

Oh, C. W.,Kim, J. W.,Oh, J. K.,Apivatthakakul, T.,Park, K. H.,Hong, W.. “Reverse miss-a-nail technique” of reconstruction nailing for successful fixation of the ipsilateral femoral neck and shaft fracture. Archives of Orthopaedic and Trauma Surgery. 2020. #volume#:no pagination

Yoon, Y. C.,Park, K. C.,Oh, C. W.,Kim, J. W.,Kim, J. W.,Park, K. H.,Kim, T. S.,Song, H. K.,Abdel Baki, S. W.. Intramedullary nailing of subtrochanteric fractures in elderly patients: Comparative study of helical blade cephalomedullary nail versus reconstruction nail. Injury. 2022. 53(4):1477-1483

##### Unspecified Femoral Nail Systems

No article was included in this section.

##### Multiple Femoral Nail Systems

Rank 4

Lu, V.,Zhang, J.,Zhou, A.,Krkovic, M.. Management of post-traumatic femoral defects with a monorail external fixator over an intramedullary nail. European Journal of Orthopaedic Surgery and Traumatology. 2022. 32(6):1119-1126

#### References of Sufficient Scientific Validity /Relevance to Inform Performance / Safety Assessment for Trending

##### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1)

Rank 6

Byun, S. E.,Cho, Y. H.,Lee, Y. K.,Park, J. W.,Kim, S.,Koo, K. H.,Byun, Y. S.. Straight nail insertion through a laterally shifted entry for diaphyseal atypical femoral fractures with bowing: good indications and limitations of this technique. International Orthopaedics. 2021. 45(12):3223-3232

Horneff, John G,ScolAro, John A,JafArI, S MehDI,MirzA, Amer,ParvIzI, JavAD,MehtA, SAMIr. Intramedullary nailing versus locked plate for treating supracondylar periprosthetic femur fractures. Orthopedics. 2013. 36:e561-e566

Oh, C. W.,Kim, J. W.,Park, K. H.,Oh, J. K.,Yoon, Y. C.,Chung, S. H.. The importance of reconstruction nailing for diaphyseal atypical femoral fractures: a comparative study with standard nailing. Archives of orthopaedic and trauma surgery. 2021. #volume#:#pages#

Yang, T. C.,Tzeng, Y. H.,Wang, C. S.,Lin, C. C.,Chang, M. C.,Chiang, C. C.. “Ratio of fracture site diameter to isthmus femoral canal diameter” as a predictor of complication following treatment of infra-isthmal femoral shaft fracture with antegrade intramedullary nailing. Injury. 2021. #volume#:no pagination

Rank 9

Butler, B. A.,Harold, R. E.,Williams, J.. Prosthesis-Engaging Retrograde Femoral Nail with Locking Plate for the Treatment of a Vancouver B1 Periprosthetic Femur Fracture Nonunion: A Case Report. JBJS case connector. 2019. 9 (4):e0108

Hak, P. T.,Jones, M. W.. Prophylactic femoral intramedullary nailing for impending fracture associated with bisphosphate use. American Journal of Case Reports. 2010. 11:155-158

Jasqui-Romano, S.,Jasqui-Remba, S.,Jasqui-Bucay, A.. Bilateral atypical femoral fractures due to a long-term bisphosphonate based therapy. Journal of Bone and Mineral Research. 2019. Conference:124

Keppler, A. M.,Zeckey, C.,Kammerlander, C.,Bocker, W.,Neuerburg, C.. [Peri-implant femoral fracture following hip arthrodesis in adolescence]. Der Unfallchirurg. 2018. #volume#:#pages#

Mellon, M. B.. Late recognition of an early catastrophic failure of a carbon fiber reinforced distal femoral plate: A case report. Trauma Case Reports. 2021. 34:no pagination

Ortmaier, R.,Resch, H.,Stiebock, C.,Stundner, O.,Arlt, E. M.. Purtscher’s retinopathy after intramedullary nailing of a femoral shaft fracture in a 20-year old healthy female – Report of a rare case and review of the literature. BMC Musculoskeletal Disorders. 2014. 15:no pagination

Sikka, R.,Fetzer, G.,Hunkele, T.,Sugarman, E.,Boyd, J.. Femur fractures in professional athletes: a case series. Journal of Athletic Training. 2015. 50:442-8

Tung, T.,Tufescu, T.. The cortical step sign fails to prevent malrotation of a nailed femoral shaft fracture: a case report. Case Reports in Orthopedics. 2014. 2014:301723

##### Expert Adolescent Lateral Femoral Nail System (System #2)

Rank 7

Rapp, M.,Kraus, R.,Illing, P.,Sommerfeldt, D. W.,Kaiser, M. M.. [Treatment of femoral shaft fractures in children and adolescents >/=50 kg : A retrospective multicenter trial]. Der Unfallchirurg. 2017. #volume#:#pages#

##### Expert Lateral Femoral Nail System (System #3)

Rank 6

Ferchaud, F.,Rony, L.,Ducellier, F.,Cronier, P.,Steiger, V.,Hubert, L.,Orthopedics,,Traumatology Society of Western, France. Reconstruction of large diaphyseal bone defect by simplified bone transport over nail technique: A 7-case series. Orthopaedics & traumatology, surgery & research. 2017. 1 WURL- <http://ac>.els-cdn.com/S1877056817301706/1-s2.0-S1877056817301706-main.pdf?\_tid=47d0a07e-9a59-11e7-9522-00000aacb362&acdnat=1505509570\_9a4f39c6ba4ab35d615d38974ba8602b:#pages#

Gargyan, I.,Dozsai, D.,Csonka, I.,Rarosi, F.,Bodzay, T.,Csonka, A.. Bisphosphonate therapy associated with bilateral atypical femoral fracture and delayed union. Joint diseases and related surgery. 2022. 33(1):24-32

Pavelka, T.,Sal, Asek M.. [Treatment of Subtrochanteric Fractures, Our Experience, Complications]. Acta Chirurgiae Orthopaedicae et Traumatologiae Cechoslovaca. 2020. 87:259-267

Weil, Y. A.,Greenberg, A.,Khoury, A.,Mosheiff, R.,Liebergall, M.. Computerized navigation for length and rotation control in femoral fractures: A preliminary clinical study. Journal of Orthopaedic Trauma. 2014. 28 (2):e27-e33

Rank 9

Bretschneider, T.,Michelitsch, C.,Frima, H.,Furrer, M.,Sommer, C.. Pathologic femur fractures following surgery and radiotherapy for soft tissue sarcomas: A case series. International journal of surgery case reports. 2021. 84:106062

Hidden, K. A.,Dahl, M. T.,Ly, T. V.. Management of a Broken PRECICE Femoral Nail at an Ununited Distraction Osteogenesis Site: A Case Report. JBJS case connector. 2020. 10 (1):e0267

Hopf, J. C.,Rommens, P. M.,Drees, P.,Traub, F.,Wagner, D.. [Atypical femoral fracture : Pitfalls in surgical treatment]. Der Unfallchirurg. 2022. #volume#:#pages#

Kubes, K.,Friedman, A.,Pyle, C.,Diaz, G.,Hargett, D.. Management of twenty centimeter segmental bone defect of femoral shaft secondary to infected non-union of fracture using masquelet technique: A case report. International Journal of Surgery Case Reports. 2021. 84:no pagination

Liodakis, E.,Claassen, L.,Hawi, N.,Wiebking, U.,Citak, M.,Krettek, C.. Navigated correction of a complex femoral deformity after false nailing technique. Archives of Orthopaedic and Trauma Surgery. 2014. Conference:445

Notarnicola, A.,Pesce, V.,MacCagnano, G.,Vicenti, G.,Moretti, B.. Klippel-Trenaunay syndrome: A rare cause of disabling pain after a femoral fracture. Archives of Orthopaedic and Trauma Surgery. 2012. 132 (7):993-996

Reynders, P.. New modular femoral nails does it matter?. Injury. 2013. Conference:S20

Yaish. Percutaneous management of ununited femoral fracture. Ann R Coll Surg Engl. 2011. 93:e83-6

##### Femoral Recon Nailing System (System #4)

No article was included in this section.

##### Retrograde Femoral Nail Advanced System (System #5)

Rank 9

Liporace, F.A. Menken, L.G. Yoon, R.S.. Complex Distal Femur Fracture A New and Novel Technique to Maximize Fixation and Promote Early Weight Bearing A Case Report. Journal of Orthopedic Trauma. 2021. #volume#:e1- e4

Liporace, F. A.,Tang, A.,Jankowski, J. M.,Yoon, R. S.. Distal femur: nail plate combination and the linked construct. OTA International. 2022. 5(3):E172

Shaath, M.K, Haidukewych, G.J. Fixation of Distal Femoral Periprosthetic Fracture With a Retrograde Nail and Locking Attachment Washer Combination A Case Report. Journal of Orthopedic Trauma. 2021. #volume#:e1- e4

##### Expert Asian Femoral Nail System (System #6)

Rank 6

Hung, W. C.,Hsu, C. J.,Kumar, A.,Tsai, C. H.,Chang, H. W.,Lin, T. L.. Perioperative Radiographic Predictors of Non-Union in Infra-Isthmal Femoral Shaft Fractures after Antegrade Intramedullary Nailing: A Case-Control Study. Journal of clinical medicine. 2022. 11:#pages#

Kim, J. W.,Oh, J. K.,Byun, Y. S.,Shon, O. J.,Park, J. H.,Oh, H. K.,Shon, H. C.,Park, K. C.,Kim, J. J.,Lim, S. J.. Incidence of Avascular Necrosis of the Femoral Head After Intramedullary Nailing of Femoral Shaft Fractures: A Multicenter Retrospective Analysis of 542 Cases. Medicine. 2016. 95:e2728

Kim, J. W.,Kim, H.,Oh, C. W.,Kim, J. W.,Shon, O. J.,Byun, Y. S.,Kim, J. J.,Oh, H. K.,Minehara, H.,Hwang, K. T.,Park, K. C.. Surgical outcomes of intramedullary nailing for diaphyseal atypical femur fractures: is it safe to modify a nail entry in bowed femur? WURL- <https://rd>.springer.com/content/pdf/10.1007%2Fs00402-017-2764-1.pdf. Archives of orthopaedic and trauma surgery. 2017. #volume#:#pages#

Kim, J. W.,Park, K. C.,Oh, J. K.,Oh, C. W.,Yoon, Y. C.,Chang, H. W.. Percutaneous cerclage wiring followed by intramedullary nailing for subtrochanteric femoral fractures: a technical note with clinical results. Archives of Orthopaedic & Trauma Surgery. 2014. 134:1227-35

Lim, S. J.,So, S. Y.,Yoon, Y. C.,Cho, W. T.,Oh, J. K.. A forward-striking technique for reducing fracture gaps during intramedullary nailing: A technical note with clinical results. Injury. 2015. 46:2507-11

Seong, Y. J.,Jang, J. H.,Jeon, S. B.,Moon, N. H.. Characteristics and Surgical Outcomes of Intertrochanteric or Subtrochanteric Fractures Associated with Ipsilateral Femoral Shaft Fractures Treated with Closed Intramedullary Nailing: A Review of 31 Consecutive Cases over Four Years at a Single Institution. Hip & pelvis. 2019. 31:190-199

Shin, J. S.,Kim, N. C.,Moon, K. H.. Clinical features of atypical femur fracture. Osteoporosis and Sarcopenia. 2016. 2 (4):244-249

Shin, W. C.,Jang, J. H.,Moon, N. H.,Jun, S. B.. Is open bone graft always necessary when treating aseptic subtrochanteric nonunion with a reamed intramedullary nail?. BMC Musculoskeletal Disorders. 2021. 22:no pagination

Shin, W. C.,Moon, N. H.,Jang, J. H.,Jeong, J. Y.,Suh, K. T.. Technical note and surgical outcomes of percutaneous cable fixation in subtrochanteric fracture: A review of 51 consecutive cases over 4 years in two institutions. Injury. 2018. #volume#:#pages#

Shin, W. C.,Lee, S. M.,Jang, J. H.,Kang, J. H.,Moon, N. H.. Importance of firm isthmic fixation in high-energy induced subtrochanteric fracture of the femur: retrospective observational study in a level I trauma center. European journal of trauma and emergency surgery : official publication of the European Trauma Society. 2022. 48(3):1807-1815

Yoon, Y. C.,Song, H. K.,Han, J. S.,Lee, K. C.. Antegrade nailing in femoral shaft fracture patients – comparison of outcomes of isolated fractures, multiple fractures and severely injured patients. Injury. 2021. 52(10):3068-3074

Rank 9

Fang C., Chau J.Y.-M., Woo S.-B., Lau T.-W., Kwan K., Leung F.. Propagation of Bisphosphonate-Related Femoral Stress Fractures Despite Femoral Nailing: A Cautionary Tale From 2 Cases. Geriatric Orthopaedic Surgery and Rehabilitation. 2014. 5:14-17

Hwang, P. X.,Anuwar, N. A.,Khaw, Y. C.,Hadizie, D.. Valgus malalignment due to internally malrotated trochanteric nail placement, with rotational malalignment in femoral shaft segmental fracture fixation, an underestimated avoidable technical error: A case report. Malaysian Orthopaedic Journal. 2020. 14 (1):74-77

Roh, Y. H.,Kim, K. H.,Yoon, K. S.,Ha, Y. C.,Yoo, S. J.,Nam, K. W.. Unique Form of Atypical Subtrochanteric Femoral Fracture at the Medial Cortex: A Report of 3 Cases. JBJS Case Connector. 2020. 10(3):1-5

Vaishya, R.,Agarwal, A. K.,Gupta, N.,Vijay, V.. Bilateral segmental pelvic and femoral fractures in a young female: A rare case report. Chinese Journal of Traumatology – English Edition. 2016. 19 (5):286-289

##### Unspecified Femoral Nail Systems

Rank 6

Brewster, J.,Grenier, G.,Taylor, B. C.,Carter, C.,Degenova, D.,Ebaugh, M. P.,Halverson, A.. Long-term comparison of retrograde and antegrade femoral nailing. Orthopedics. 2020. 43 (4):E278-E282

##### Multiple Femoral Nail Systems

Rank 6

Hwang, J.,Cannady, D. F.,Nino, S.,Koval, K. J.,Langford, J. R.,Parry, J. A.. Comparison of standard versus reconstruction proximal interlocking screw configurations for antegrade intramedullary nail fixation of femoral shaft fractures. Journal of clinical orthopaedics and trauma. 2021. 17:94-98

Kim, K. H.,Song, G.. Intramedullary Nailing for Atypical Femoral Fracture With Lateral Bowing: Does Medial Gap Matter?. Geriatric orthopaedic surgery & rehabilitation. 2022. 13:21514593211070130

#### References of Sufficient Quality/Relevance to Support Identification of Off-Label Use/Misuse

##### Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail System (System #1)

Rank 13

Bobak, P.,Polyzois, I.,Graham, S.,Gamie, Z.,Tsiridis, E.. Nailed cementoplasty: A salvage technique for rorabeck type II periprosthetic fractures in octogenarians. Journal of Arthroplasty. 2010. 25 (6):939-944

Fernandez-Arroyabe, N.,Garcia-Melendez, G.,De Castro-Almeida, A. R.,Escalona-Perez, F.,Perez-Lara, A.,Gonzalez-Quevedo, D.,Garcia-Quevedo, D.,Tamimi, I.. Non-union and use of proton pump inhibitors in the treatment of femoral and tibial shaft fractures: a nested case-control study. European journal of orthopaedic surgery & traumatology : orthopedie raumatology. 2021. #volume#:#pages#

Hatem, M.,Khoury, A. N.,Erickson, L. R.,Jones, A. L.,Martin, H. D.. Femoral Derotation Osteotomy Improves Hip and Spine Function in Patients With Increased or Decreased Femoral Torsion. Arthroscopy – Journal of Arthroscopic and Related Surgery. 2021. 37 (1):111-123

Woods, J. B.,Shinabarger, A. B.,Burns, P. R.. Periprosthetic fracture after femoral intramedullary nail use in two cases of tibiotalocalcaneal arthrodesis. Journal of Foot & Ankle Surgery. 2012. 51:266-9

##### Expert Adolescent Lateral Femoral Nail System (System #2)

Rank 13

Baumbach, S. F.,Hobohm, L.,Wozasek, G. E.. A treatment strategy for complex cases of osteomyelitis in children and its applicability on three exemplary cases. Journal of Pediatric Orthopaedics Part B. 2011. 20 (6):432-435

Hashem, J.,Krochak, R.,Culbertson, M. D.,Mileto, C.,Goodman, H.. Atypical femur fractures in a patient with pycnodysostosis: a case report. Osteoporosis International. 2015. 26:2209-12

Pailhe, R.,Bedes, L.,Sales de Gauzy, J.,Tran, R.,Cavaignac, E.,Accadbled, F. C. I. N. J. Pediatr Orthop B. Mar,Pmid. Derotational femoral osteotomy technique with locking nail fixation for adolescent femoral antetorsion: surgical technique and preliminary study. Journal of Pediatric Orthopaedics, Part B. 2014. 23:523-8

Reynolds, R. A.,Legakis, J. E.,Thomas, R.,Slongo, T. F.,Hunter, J. B.,Clavert, J. M.. Intramedullary nails for pediatric diaphyseal femur fractures in older, heavier children: early results. Journal of Childrens Orthopaedics. 2012. 6:181-8

##### Expert Lateral Femoral Nail System (System #3)

Rank 13

Biz, C.,Iacobellis, C.. Nailing treatment in bone transport complications. Strategies in trauma and limb reconstruction (Online). 2014. 9:89-96

Villatte, G.,Erivan, R.,Mondon, D.,Canavese, F.. A case of chronic osteomyelitis after flexible intramedullary nailing of the femur in 14-year-old boy. European Journal of Orthopaedic Surgery and Traumatology. 2012. 22 (SUPPL. 1):S167-S171

##### Femoral Recon Nailing System (System #4)

No article was included in this section.

##### Retrograde Femoral Nail Advanced System (System #5)

No article was included in this section.

##### Expert Asian Femoral Nail System (System #6)

Rank 13

Chen, F.,Wei, Y.,Xia, J.,Wu, J.,Wang, S.,Huang, G.,Chen, J.,Shi, J.. Double-level osteotomy and one-stage reconstruction with long intramedullary femoral nail to correct a severe proximal and diaphyseal femur deformity in a patient with polyostotic fibrous dysplasia: case report and literatures review. International journal of clinical and experimental medicine. 2015. 8:14188-95

Gao, Z.,Lv, Y.,Zhou, F.,Ji, H.,Tian, Y.,Zhang, Z.,Guo, Y.. Risk factors for implant failure after fixation of proximal femoral fractures with fracture of the lateral femoral wall. Injury. 2018. 49 (2):315-322

Kharbanda, Y.,Singh, R.,Mir, T.,Tanwar, Y. S.. Extensive Re-ossification and Reformation of the Proximal Femur After External Beam Radiotherapy in Metastatic Carcinoma Breast. Indian journal of surgical oncology. 2018. 9:394-397

Kim, J. W.,Cuellar, D. O.,Hao, J.,Herbert, B.,Mauffrey, C.. Prevention of inaccurate targeting of proximal screws during reconstruction femoral nailing. European Journal of Orthopaedic Surgery and Traumatology. 2016. 26 (4):391-396

Shon, O. J.,Yoon, J. Y.,Kim, J. W.. Clinical outcomes of using contralateral-side laterally bent intramedullary nails in atypical femur fractures with femoral bowing. Archives of Orthopaedic and Trauma Surgery. 2020. #volume#:no pagination

Yoon, B. H.,Park, S. B.. Insufficiency fracture occurring 3 years after union of an intertrochanteric hip fracture: A case report. JBJS Case Connector. 2017. 7 (1):e1

##### Unspecified Femoral Nail Systems

Popkov, A.,Pietrzak, S.,Antonov, A.,Parol, T.,Lazovic, M.,Podeszwa, D.,Popkov, D.. Combined lengthening for acquired leg length discrepancy: Are there advantages of hydroxyapatite-coated intramedullary nails?. Orthopaedics & traumatology, surgery & research : OTSR. 2021. #volume#:103101

##### Multiple Femoral Nail Systems

No article was included in this section.

### Literature Excluded Publications

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | If CER includes device-specific systematic literature review, insert or cross-reference list of excluded publications and reasons for exclusion from the referenced Literature Report (Section 4.1). |
|  |  | If inserted, use the “Reference List” Style. |

Refer to Systematic Literature Review Report (Table 1) for a complete list of references excluded from the report, including reason for exclusion.

## Acronyms

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Add any additional acronyms used in the CER in the table below in alphabetical order. |
|  |  | Delete any acronyms that are not applicable to the CER. |

Table : Acronyms Associated with CER

| Abbreviation | Definition |
| --- | --- |
| AVN | Avascular Necrosis |
| BSE | Biological Safety Evaluation |
| BER | Biocompatibility Evaluation Report |
| BUDI-DI | Basic Unique Device Identifier |
| CAPA | Corrective and Preventative Action |
| CEDR | Clinical Evaluation Data Route |
| CEP | Clinical Evaluation Plan |
| CER | Clinical Evaluation Report |
| CI | Clinical Investigation |
| CS | Common Specification |
| CV | Curriculum Vitae |
| DCRM | Design & Clinical Risk Management |
| DOI | Declaration of Interest |
| DUA | Data Use Agreement |
| EMDN | European Medical Device Nomenclature |
| ESIN | Elastic Stable Intramedullary Nailing |
| Expert ALFN | Expert Adolescent Lateral Femoral Nail |
| Expert LFN | Expert Lateral Femoral Nail |
| Expert A2FN | Expert Asian Femoral Nail |
| Expert R/AFN | Expert Retrograde/Antegrade Femoral Nail |
| Expert RFN | Expert Retrograde Femoral Nail |
| FRN | Femoral Recon Nailing |
| RFNA | Retrograde Femoral Nail Advanced |
| FSCA | Field Safety Corrective Action |
| FSN | Field Safety Notice |
| GMDN | Global Medical Device Nomenclature |
| GT | Greater Trochanter |
| IFU | Instructions For Use |
| IIS | Investigator Initiated Study |
| IMDRF | International Medical Device Regulators Forum |
| IMN | Intramedullary Nailing |
| LRR | Literature Review Report |
| MA | Medical Affairs |
| MDCG | Medical Device Coordination Group |
| MDD | Medical Device Directive |
| MDR | Medical Device Regulation |
| MRI | Magnetic Resonance Imaging |
| PEC | Product Experience Code |
| PF | Piriformis Fossa |
| PMCF | Post-Market Clinical Follow-up |
| PMCFP | Post-Market Clinical Follow-up Plan |
| PMCFER | Post-Market Clinical Follow-up Evaluation Report |
| PMS | Post-Market Experience and Surveillance |
| PMSP | Post-Market Experience and Surveillance Plan |
| PMSR | Post-Market Experience and Surveillance Report |
| RMR | Risk Management Report |
| RWE | Real World Evidence |
| SOA | State of the art |
| SOAR | State of the art Report |
| SSCP | Summary of Safety and Clinical Performance |
| STG | Surgical Technique Guide |

## Applicable Guidance References

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Identify applicable guidance that was considered when planning or executing the CER. |

Table : Guidance Considered During the Planning or Execution of the CER

| Reference | Description |
| --- | --- |
| European Council Directive 93/42/EEC | Medical Device Directive (MDD) as amended by 2007/47/EC |
| REGULATION (EU) 2017/745 | EU Medical Device Regulation (MDR) (Regulation (EU) 2017/745) |
| MEDDEV 2.7/1 | Clinical Evaluation: A Guide for Manufacturers and Notified Bodies |
| MDCG 2020-5 | Clinical Evaluation – Equivalence: A Guide for Manufacturers and Notified Bodies |
| MDCG 2020-6 | Clinical Evidence Needed for Medical Devices Previously CE Marked under Directives 93/42/EEC or 90/385/EEC: A Guide for Manufacturers and Notified Bodies |
| MDCG 2020-13 | Clinical Evaluation Assessment Report Template |

## CER Team

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | List only J&J personnel meeting the requirements within the procedure for CER Evaluator and primary CER Team Member.   * External Suppliers should not be included (CRO, etc). The internal CER Evaluators and CER Team are responsible for External Supplier output |

Table : CER Team Members

| Role | Name |
| --- | --- |
| Medical Affairs Evaluator / LRR Approver | Michael Blauth |
| Regulatory Affairs Evaluator | Kathryn LaRose |
| Medical Operations Evaluator / CER Author | Danielle Campbell |
| Medical Operations Literature Approver / LRR Author | Leanne Conneely |
| Post Market Surveillance | Bill Naylor, Amos Henderson, Chris Smith, Taylor Jonas |
| Clinical Research | Suzanne Hughson |
| Risk Management / Quality | Syeda Batool |
| R&D / Product Development | Iswarya M |
| Other: RA Associate | Boobalan |

## CER Update Frequency Assessment

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete the Frequency Matrix based on worst case devices. |

Table : Femoral Nail Systems CER Frequency Matrix

| CER Update Frequency - Risk Determination Matrix | | | | | |
| --- | --- | --- | --- | --- | --- |
| Attribute | Very Low | Low | | Med | High |
| \*Highest rating in any of the pink attribute categories mandates minimum update frequency | | | | | |
| Highest potential risk to patient as a result of device failure\*  (Characterizes patient health consequences associated with device failure) | Limited (transient, minor impairment, or complaints)  **OR** No adverse health consequences | Failure unlikely to cause or contribute to serious injury, or death under circumstances of normal use with results being temporary or reversible without medical intervention | | Failure likely to cause or contribute to serious injury, or death under circumstances of normal use that is likely reversible with medical / surgical intervention | Results in permanent impairment of body function or permanent damage to a body structure **OR** Life-threatening (death has or could occur) regardless of medical / surgical intervention |
| Complaint Rate\*  (Characterizes # of complaint events per determined volume associated with device to provide evidence if device is not safe or is not performing) | Negligible rate per time or volume | Low rate per time or volume | | Medium rate per time or volume | High/Very High rate per time or volume |
| Device Classification  (Characterizes general risk of device) | I | IIa | | IIb WET implant, IIb non-implant | III,  IIb Non-WET implant |
| Degree and Duration of Device Invasiveness  (Characterizes degree of device contact) | Non-Invasive Device No patient contact or exposure to device | Invasive Device (non-implantable, body orifice)  Transient / Short-Term patient contact or exposure (seconds / minutes / Hours) | | Surgically Invasive Device (non-implantable) Transient / Short-Term patient contact or exposure (seconds / minutes / Hours) | Surgical Implant  Extended time frame of contact or exposure to the device (partially implantable devices that are implanted >30 days and/or fully implantable devices) |
| Natural course and consequences of medical conditions if left untreated  (Characterizes state of health (i.e., patient motivation/risk), not about the device) | Limited (transient, minor impairment or pain)  **OR**  No adverse health consequences | Natural course unlikely to cause or contribute to serious injury, pain, or death | | Natural course could possibly cause or contribute to serious injury, pain, or death | Natural course likely causes or contributes to serious injury, pain, or death |
| Anatomical location where device used  (Characterizes risk by anatomic area / physiological functions) | No body contact | Body orifice, intact skin | | All other anatomical locations | CNS, CCS |
| Product Maturity of the Subject Device  (Characterizes how long (theoretically, how often) subject device used for the intended use.  Lower risk the longer the device is on market / more devices used. Worst case = devices with highest potential risk to patient as a result of device failure.) | | | | | |
| # Units of worst-case variant(s) sold / shipped since launch | x > 10,000 | 1000 < x < 10,000 | | 100 < x < 1000 | x < 100 |
| Time on Market – Implantable Device: | > 10 years | 5 - 10 years | | 3 - 5 years | < 3 years |
| Technological Maturity of Equivalent Device:  (Characterizes how long the equivalent device technology (design, mfg, materials) has been on the market) | | | | | |
| Time on Market – Implantable Device: | > 10 years | 5 - 10 years | | 3 - 5 years | < 3 years |
| Maturity of Clinical Science  (Characterizes how well established the clinical science is (i.e., how long clinicians have been using similar devices for the intended use / technique) | | | | | |
| Time of Clinical Use: | > 10 years | | 5 - 10 years | 3 - 5 years | < 3 years |
| Clinical Data Sufficiency for Conformity Assessment  (Characterizes the Safety / Performance evidence for intended use / technique across lifetime) | | | | | |
| Clinical Data Quantity / Quality | Clinical data were deemed not necessary (e.g., MDD - Annex X, 1.1d; MDR Article 61[10]). | Ample data on subject / associated device across all indications / therapeutic lifetime. Subject device is not expected to carry significant risks. | | Sufficient data on subject / associated device across all indications / therapeutic lifetime. No significant known risks and uncertainties or unanswered questions relative to subject device, in the medium or long term. | Sufficient data on equivalent device across all indications / therapeutic lifetime. Potential for risks and uncertainties or unanswered questions relative to subject device, in the medium or long term. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| CER Update Frequency - Risk Determination Matrix | | | | |
| Attribute | Very Low | Low | Med | High |
| CER Update Frequency Guide: | Every 5th Year | Every 4th Year | Every 2nd Year | Every Year |
| Background and Justification for Selection:   * Femoral Nail Systems have been in clinical use for over 18 years and based on the available clinical data, the technology is considered state of the art. * Data on current clinical data sources (PMCF and device-specific literature) is supportive of the efficacy of the devices in addressing the clinical indications as described in labeling. * There are no uncertainties or unanswered questions related to the device or its intended use. * No significant risks or harms were identified in data sources that would impact the use of the device in real world settings. | | | | |

## CER Revision History

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Complete revision history for CER. Recommended order is initial revision at the top followed by all subsequent revisions.   * **All revisions listed should be for current CER #.** If CER # changed from previous related CER, reference previous version in footnote for traceability. * Where possible history should denote WHAT changed (e.g., routine update; scope reduced to remove XXX; scope expanded to add XXX; edits to sections X, Y, and Z to fix typos; annual update to section 6.4, 7, and 8). All changes should be referenced. Scope changes must be specifically referenced. * Note: Detail on historical changes may not be available * For current revision, recommend denoting “See document header” or similar for quality system release date and potentially revision / version if not known upon uploading. |

Revision history for CER #500404346

|  |  |  |
| --- | --- | --- |
| Revision Number | Date  (DD Month YYYY) | Description of Change |
| A.3 | 18 September 2020 | Routine CER update for Expert A2FN, Expert ALFN, Expert LFN, Expert R/AFN and FRN. Updated literature and PMS data added to the CER. New product codes added to the FRN under the LESN project. Pre-marketing CER for RFNA.  Previous CER number: 0000233097 |
| B.3 | 22 September 2020 | Administrative update: Correction to attachments. No change to CER content. |
| C.4 | 15 July 2021 | This is a routine annual update of the CER #500404346 with no changes to the devices in scope. In addition, the Expert R/AFN Implants (Nails only) have added compliance to MDR in this update. |
| D.4 | 27 July 2021 | Administrative update to remove redline changes that were inadvertently left in. |
| E.3 | 3 November 2021 | Sections 2.2 and 7.2 updated to address Notified Body Feedback |
| F.3 | 20 January 2022 | Updated to address Notified Body Feedback |
| G.3 | 04 May 2022 | Administrative updates and Section 3 updated to address Notified Body Feedback |
| See Windchill for Revision Number | See Windchill for Approval Date | This CER is updated to the latest template, with the following content changes:   * Added initial MDR conformity to the Spiral Blade for Expert Retrograde/Antegrade Femoral Nail (Device Group #3)   Routine annual update to   * Sustain MDR compliance to the Expert Retrograde/Antegrade Femoral Nail and Expert Retrograde Femoral Nail (Device Group #1) * Sustain MDD compliance for all the remaining device groups. |

## CER Approval Signatures (E-Signatures)

| This section should include the following content (as appropriate): | | |
| --- | --- | --- |
| ✓ | N/A | Action |
|  |  | Enter name and title of CER Evaluators. |

Refer to CHANGE MANAGEMENT SYSTEM for e-signature and approval date for each Evaluator (Table 211).

Table : CER Approvers/Authors

| **Approver Roles** | **Name & Title** |
| --- | --- |
| Medical Affairs Evaluator: | * Name: Michael Blauth * Title: Medical Director, Medical Affairs |
| Regulatory Affairs Evaluator: | * Name: Kathryn LaRose * Title: Director, Regulatory Affairs |
| Medical Operations Evaluator / CER Author: | * Name: Danielle Campbell * Title: Senior Manager, Medical Operations |

Refer to Table 1 for Attachment numbers for Curriculum Vitae (CV) & Declaration of Interest (DOI) for each Evaluator

1. The CER Sections are named in accordance with the naming identified in the MDCG 2020-13 Template for an EU Clinical Evaluation Assessment Report (CEAR) for ease of review. References are made throughout to the associated Sections. [↑](#footnote-ref-2)
2. https://surgeryreference.aofoundation.org/orthopedic-trauma/adult-trauma/femoral-shaft [↑](#footnote-ref-3)
3. The infections were mostly superficial wound infections that resolved within two weeks post-operatively except for one case of deep wound infection in each comparative group that persisted at 18-week follow-up period. [↑](#footnote-ref-4)
4. A total of 24 patients out of 65 traumatic diaphyseal femur fractures (36.9%) underwent reoperation. Fifteen patients underwent isolated distal locking screw removals. Nine patients underwent nail removal. No complications occurred in any of the 24 patients during or after reoperation. [↑](#footnote-ref-5)
5. Implantable devices that do not require an implant card and class III devices that are not intended to be used directly by patients do not require a Part B section for patients. [↑](#footnote-ref-6)
6. Note: The Expert Retrograde/Antegrade Femoral Nail is used for the treatment of femoral shaft fractures and distal femur fractures. However, the study with 8 patients considered under this Section 8.1.1.7 did not report on the use of Expert Retrograde/Antegrade Femoral Nail for distal femur fractures. [↑](#footnote-ref-7)
7. Note: The Expert Retrograde/Antegrade Femoral Nail is used for the treatment of femoral shaft fractures and distal femur fractures. However, the study with 8 patients considered under this Section 8.1.1.7 did not report on the use of Expert Retrograde/Antegrade Femoral Nail for distal femur fractures. [↑](#footnote-ref-8)
8. Only explicit reports of safety events were included in this assessment. If the authors did not report that zero events occurred, this was not assumed. [↑](#footnote-ref-9)
9. The Expert Asian Femoral Nail is nearing the end of its product lifecycle. The safety and performance of the System will continue to be monitored through the reactive methods outlined in the Post-Market Surveillance Plan (complaints monitoring). [↑](#footnote-ref-10)
10. Studies under consideration were historic data and publications from years 2000 to 2015. [↑](#footnote-ref-11)
11. The overall better early outcome of those that had nailing compared to those that had plating is probably due to the excellent recovery of knee range of motion; significantly higher number of patients in the intramedullary nailing group had excellent outcome (x2 = 9.734; p = 0.020). [↑](#footnote-ref-12)
12. The Expert Asian Femoral Nail is nearing the end of its product lifecycle. The safety and performance of the System will continue to be monitored through the reactive methods outlined in the Post-Market Surveillance Plan (complaints monitoring). [↑](#footnote-ref-13)