
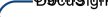




Adverse Events and Device Deficiency Sheet

Study ID: H-34 Q1 2022

[illegible]

| | Role | Requested to: |
|--|------|---|
| Written by: Lisa Ciuffarin | AJCL | DocuSigned by:  DocuSigned by: Lisa Ciuffarin Signing Name: Lisa Ciuffarin Signing Reason: I am the author of this document Signing Time: 30/3/2022 12:27 CEST DocuSigned by: 2D5C1223BA1F4EDB9C6206245B0C4464 Federica Azzimonti |
| Approved by: Federica Azzimonti | RMCL | DocuSigned by:  DocuSigned by: Federica Azzimonti Signing Name: Federica Azzimonti Signing Reason: I approve this document Signing Time: 30/3/2022 14:41 CEST F76117269A994B43A353A3F6CBA0F6D9 |
| The present document does not report handwritten signatures because the approval is electronically mediated. | | |

| Adverse Events | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|----------------|-------------|---------------------|-------------|---------------|--------------------------|--------------------------------------|-------------------------|----------------------|---------------------------------|--|-------------------------------------|---|----------------------------|----------|--------|---|---|---|------------------------------------|-----------------------------|---|--|---|---|--|----------|---|--|--------------|---|---|-------------------------------------|---------------------------------------|---------------------------------------|---------------------------------|--|--------------------|--------------|-------------------|---------------|--------|---------------------|---------------------|--------------|---------------|----------------------------------|--|-----------|------------------------------|---|--|--|--|
| Patient ID | Report type | Initial Report Date | Report Date | Date of Onset | Date of Study Team Aware | Time team became aware (24 hr clock) | Title of clinical study | Protocol ID | Name of the healthcare facility | Name of the Principal Investigator | Name of the medical device involved | Components involved | ID number of study subject | Age | Gender | Attribution within the clinical investigation | Adverse Event (diagnosis, if known, or signal/symptoms) | Event narrative | Admission date (dd/mm/yyyy) | Discharge date (dd/mm/yyyy) | Classification of the adverse event | Outcome of the event | Relevant concomitant drugs and date of administration | Detail all possible and suspected causes including relevant medical history | Current clinical status | Severity | Causality: relationship to study medical device | Causality: relationship to study procedure | Expectedness | Action taken | Detailed treatment | Was the device permanently removed? | Attachments: Relevant Medical History | Attachments: Relevant Medical Records | Attachments: Laboratory results | Attachments: Imaging Methods (e.g. X-ray, CT-scan) | Attachments: Other | Submitter | Name of submitter | Notes | Status | Initial / Follow-up | communicated to PMS | If Yes, date | Date of reply | Device relationship for PMS dept | Relationship to Procedure for PMS Dept | Complaint | Further evaluation performed | Final decision/communication on relationship and expectedness | | | |
| 101 | 9 | Initial & Final | 07/12/2021 | 07/12/2021 | 01/12/2021 | 01/12/2021 | 08:00 | DELTA Revision study | H-34 | Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP | Jerzy Bialecki | Delta Revision Cup, Hemispherical module, Bone screws, insert | 101 - 9 | 60 | Male | Treatment Group | Cup loosening | Early postoperative cup loosening. | 19-Nov-2021 | 19-Nov-2021 | Medical or surgical intervention required to prevent any of the above | Ongoing | None | Probable cause is technical mistake at first operation with Delta Revision implantation. Too proximal cup implantation and not sufficient cup hook stabilization at the iliacal bone. Second cause could be wrong position of stable stem, various position in femur. | Patient undergone revision surgery at 2021-12-01, with cup and stem removal. Reimplantation Trident Multipole cup with augment and Restoration stem. | Severe | Not Related | Not Related | N/A | Not pharmacological | Revision surgery with cup and stem removal. Reimplantation Trident Multipole cup with augment and Restoration stem. | Yes | None | None | None | Available | None | Investigator | Pawel Bartosz | N/A | Valid | Initial | Yes | 09/12/2021 | 10/12/2021 | | | | | | | | |
| 101 | 10 | Initial | 19/01/2022 | 19/01/2022 | 14/01/2022 | 14/01/2022 | 08:51 | DELTA Revision study | H-34 | Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP | Jerzy Bialecki | N/A | N/A | 101 - 10 | 76 | Male | Treatment Group | Dyspnoea, fluid collection in lungs | Chronic heart failure exacerbation | 30-Dec-2021 | 30-Dec-2021 | Hospitalization or prolongation of hospitalization | Ongoing | Paracetamol 40mg 2x/day from 14.01.2022. | Chronic heart failure | Good | Moderate | Not Related | Not Related | N/A | Pharmacological | | No | None | None | None | None | None | Investigator | Pawel Bartosz | N/A | Draft | Initial | No | | | | | | | | | |
| 101 | 5 | Initial | 03/02/2022 | 03/02/2022 | 20/10/2021 | 20/10/2021 | 00:00 | DELTA Revision study | H-34 | Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP | Jerzy Bialecki | Revision Hip /Anca Stem17mm/20 0mm | 101 - 5 | 76 | Female | Treatment Group | Intraoperative fracture of femur shaft | The femur shaft was weakened because of previous use of metal loop. | 18-Oct-2021 | 27-Oct-2021 | Hospitalization or prolongation of hospitalization | Ongoing | NA | The femur shaft was weakened because of previous use of metal loop, 25 years ago TKA of both hips, 2011 - revision of right hip/coll; | On the first control visit 22-Nov-2021 patient is walking with 2 crutches | Severe | Not Related | Not Related | Anticipated | Other intraoperative reduction and fixation of the fracture | | No | None | None | None | None | None | Investigator | Julia Macias | N/A | Draft | Initial | No | | | | | | | | | | |

Role: Date: Signature:

Written by: Lisa Ciuffarin AJCL 30/3/2022 | 12:30 CEST

Approved by: Federica Azzimonti RMCL 30/3/2022 | 14:42 CEST

DocuSigned by:

Lisa Ciuffarin

Signer Name: Lisa Ciuffarin

Signing Reason: I am the author of this document

Signing Time: 30/3/2022 | 12:28 CEST

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Signer Name: Federica Azzimonti

Signing Reason: I approve this document

Signing Time: 30/3/2022 | 14:41 CEST

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