**Post-Market Clinical Follow-up (PMCF) Plan**

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| **Title / Description** | Ace Blade |
| **PMCF Plan #** | SCN075317 |
| **Version** | 1.0 |
| **Date last modified** | 19 May 2020 |

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| **Approvals** | | | |
| **Role** | **Name & Title** | **Signature** | **Date** |
| Clinical Research | Jaime Connelly, MS, RAC  Franchise Clinical Platform Leader |  |  |
| Medical Affairs | Giovanni A. Tommaselli, MD  Medical Director |  |  |
| Post Market Surveillance | Katharine Seppa  Sr. Manager Post Market Surveillance |  |  |
| Biostatistics | N/A as no statistical elements |  |  |
| Epidemiology & Real-World Data Science | N/A as no Epidemiology data included |  |  |
| Regulatory Affairs | N/A not required per PMCF SOP |  |  |

**Scope**

This PMCF plan is generated in compliance with the Medical device regulation (EU) 2017/745 ANNEX XIV part B requirements. The product(s) and families covered can be found in Section 2.

**Post Market Clinical Follow-up (PMCF) Plan**

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| **Section 1. Manufacturer information** | |
| **Legal manufacturer** | Megadyne Medical Products, Inc |
| **Address** | 11506 State St, Draper, UT 84020 |
| **SRN:** | N/A |
| **Person Responsible for Regulatory Compliance (PRRC)** | Sharon Sussex  Sr. Director, Quality Engineering Energy |
| **PRRC E-Mail** | [Ssussex@its.jnj.com](mailto:Ssussex@its.jnj.com) |
| **PRRC Phone** | (904) 742-3723 |
| **PRRC Fax** | N/A |
| **Authorized Representative (If Applicable)** | N/A |
| **Address** | N/A |
| **Contact Person** | N/A |
| **E-Mail** | N/A |
| **Phone** | N/A |
| **Fax** | N/A |

| **Section 2. Device information** | |
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| **Device Trade Name(s) covered by PMCF Plan** | Ace Blade, Megadyne Ace Blade 700 Soft Tissue Dissector, Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector, Megadyne Telescoping Soft Tissue Dissector |
| **Basic UDI-DI(s)** | TBD |
| **Product Codes Covered by this plan** | Includes:   |  |  | | --- | --- | | Legacy Devices Megadyne Ace Blade 700 Soft Tissue Dissector | | | Product Code | Connector Type | | ME7251C | C Connector (Sterile) | | ME7251E | E Connector (Sterile) | | ME725M1C | Modified C Connector (Sterile) | | ME725M1E | Modified E Connector (Sterile) |  |  |  | | --- | --- | | Legacy ACE Blade | | | Product Code | Blade Length | | ACE12BN5 | 2.5 | | ACE12MBN5 | 2.5 | | ACE12A | 2.75 | | ACE14 | 6.5 | | ACE14A | 4 | | ACE12AM | 2.75 | | ACE14AM | 4.0 | | ACE14M | 6.5 |  |  | | --- | | Product Code | | ME7251ST | | ME725M1ST | | ME7251T | | ME725M1T | |
| **Device Description** | All devices in this plan use the original Ace blade. The blade has never changed the only thing that has changed is the pen in which it is pre-loaded.  Legacy   |  |  | | --- | --- | | **Product Code** | **Description** | | ME7251C | Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, C connector  (Sterile) | | ME7251E | Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, E connector  (Sterile) | | ME725M1C | Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, Modified, C connector (Sterile) | | ME725M1E | Megadyne ACE Blade™ 700 Soft Tissue Dissector, 2.5” Blade, Modified, E connector  (Sterile) | | ACE12BN5 | ACE Blade, I/C, Bulk, Non-Sterile 2.5” QTY (500) | | ACE12MBN5 | ACE Blade**, I**/C, Modified, Bulk, Non-Sterile 2.5” QTY (500) | | ACE12A | E-Z Clean ACE Blade 2.75in | | ACE14 | E-Z Clean ACE Blade 6.5in | | ACE14A | E-Z Clean ACE Blade 4.0in | | ACE12AM | E-Z Clean ACE Blade Mod 2.75in | | ACE14AM | E-Z Clean ACE Blade Mod 4.0in | | ACE14M | **E**-Z Clean ACE Blade Mod 6.5in |   The devices below are new products that are currently in development and don’t have regulatory approval. They will use equivalence to the device above to gain regulatory approval.   |  |  | | --- | --- | | **Product Code** | **Description** | | ME7251ST | Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector | | ME725M1ST | Megadyne Telescoping Smoke Evacuation Soft Tissue Dissector, Modified | | ME7251T | Megadyne Telescoping Soft Tissue Dissector | | ME725M1T | Megadyne Telescoping Soft Tissue Dissector, Modified | |
| **Intended purpose** | Legacy ACE Blade:  MEGADYNE ACE Blade electrosurgical electrodes are intended to conduct radio frequency (RF) current for monopolar cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and coagulation.  Legacy MEGADYNE ACE BLADE™ 700:  MEGADYNE ACE BLADE™ 700 electrosurgical electrodes are intended to conduct radio frequency (RF) current for monopolar cutting and coagulation from the RF electrosurgical generator to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and coagulation.  The devices below are new products that are currently in development and don’t have regulatory approval. They will use equivalence to the device above to gain regulatory approval.  (Rally Gem) MEGADYNE™ Telescoping Soft Tissue Dissector:  MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector is a monopolar device designed for general electrosurgical applications including cutting and coagulation (coag) and for removing smoke generated by electrosurgery when used in conjunction with a smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical unit (ESU) and delivers it to the target tissue to achieve the desired surgical effect.  The electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.  The electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU’s Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU’s Geometric Electron Modulation (GEM) mode.  (Refine) MEGADYNE™ Telescoping Soft Tissue Dissector:  MEGADYNE™ Telescoping Soft Tissue Dissector is a monopolar device designed for general electrosurgical applications including cutting and coagulation (coag). This device conducts an electrosurgical current from an electrosurgical unit (ESU) and delivers it to the target tissue to achieve the desired surgical effect.  The electrosurgical active electrodes are intended to conduct radio frequency (RF) current for cutting and coagulation from the ESU to target soft tissue in a broad range of surgical procedures requiring the use of electrosurgery for cutting and cauterization.  The electrosurgical active electrodes have a specific geometry that minimizes blanching and thermal damage in skin incisions when used in conjunction with the MEGADYNE™ ESU’s Advanced Cutting Effect (ACE) mode or the MEGADYNE™ ESU’s Geometric Electron Modulation (GEM) mode.  There are no known contraindications for the Megadyne Telescoping Pencils and the ACE Blade 700™ Soft Tissue Dissector. |

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| **Section 3. Reference to relevant parts of technical documentation including clinical evaluation report and risk management** | | |
|  | **Identifier** | **Title / Description** |
| **Post-market Surveillance (PMS) Plan and/or Report** | Plan # RA-REC-003, Rev. 001 | PMS Plan for ACE Blade Advanced Cutting System |
| Report RA-REC-004, Rev. 001 | PMS Report for ACE Blade Advanced Cutting System |
| Plan # 500453801 | PMS Plan for Megadyne Telescoping Pencils |
| Report # | Not applicable at this time |
| **Clinical Evaluation Plan and/or Report** | Report # RA-RPT-007 | Megadyne ACE Blade & ACE Blade 700™ Soft Tissue Dissector |
| Report # SCN074850 | Megadyne Telescoping Pencils |
| **Risk Management Report** | Report # ENG-RMF-055 | Risk Management Report |
| Report # ENG-RMF-088 | Risk Management Report |

| **Section 4. Evaluation of clinical data relating to equivalent or similar devices** |
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| **Mark all that apply:**  Evaluation of equivalent devices  Evaluation of similar devices  Not Applicable  **Describe:**  Legacy:  The Ace blade that was originally CE self-certified in 08 June 2009. That blade has remained unchanged and is being used in all of the products listed in the plan. Since the blade is the clinical piece of the device they have been all grouped together in one PMCF plan. All PMCF activities will provide further evidence on the Ace blade and not the pencils since they are following a non-clinical pathway.  The Zip Pen (pencil/blade holder), a component of the ACE Blade 700™ device serves only as an ergonomic hand-held electrical conduit which simply passes energy from the generator to the ACE blade. It should be duly noted that the ACE blade electrode is the point of clinical therapeutic action where cutting and coagulation of soft tissue occurs. Given that the Zip Pen (pencil) acts only as an ergonomic hand-held electrical conduit which houses the blade (electrode), the level of risk associated with these elements is commensurate with MDD, Annex X, 1.1d (non-clinical route of conformity) since there are no measurable clinical safety or performance attributes associated with the pencil blade holder itself. Conformity with applicable Essential Requirements is, therefore, correctly based on non-clinical data (bench testing and pre-clinical evaluation and conformity with all applicable harmonized electrical safety standards) given that there is no therapeutic function performed by the Zip Pen (pencil blade holder) itself.  MEGADYNE™ Telescoping Soft Tissue Dissector and MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector have essentially equivalent configurations of the electrosurgical pencils with smoke evacuation features when used with shorter electrodes/blades already exist in the Megadyne portfolio as Megadyne Ace 700 soft tissue dissector. There are two key features of Megadyne Telescoping Pencils: (1) the telescoping feature and (2) the (optional) smoke evacuation feature. The risk level of these two key features is considered low based on the intended purpose. The intended purpose of the telescoping pencil housing is to extend (telescope) the electrode/blade for reach and access, with this feature being equivalent to the surgeon changing from a shorter to a longer length electrode. Note that the electrodes/blades remain unchanged. Similarly, the smoke evacuation feature already exists on Megadyne electrode pencils, and this feature is intended to reduce surgical smoke. Therefore, in accordance with MDD Annex X clause 1.1.d, and the state of the art for clinical evaluation with respect to the state of the art guidance of MEDDEV 2.7/1 revision 4, the body of evidence includes non-clinical data to demonstrate conformity with applicable essential requirements (ERs). Clinical data are not required to confirm clinical safety and functionality of these features. Noting again the medical purposes detailed above, there are no clinical claims that would require supporting clinical data for these features of the Megadyne Telescoping Pencils. |

| **Section 5. Objectives to be addressed by PMCF** |
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| The objective of the PMCF Plan is to describe the methods and procedures to be undertaken for the subject device(s) and the associated accessories, within their intended purposes, for proactively collecting and evaluating clinical data.  **General Objectives of the PMCF:**  **Mark all that apply:**   1. Confirming the safety and performance of the device throughout its expected lifetime, 2. Identifying previously unknown side-effects and monitoring the identified side-effects and contraindications, 3. Identifying emergent risks on the basis of factual evidence, 4. Ensuring the continued acceptability of the benefit-risk ratio, 5. Identifying possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.   **Additional information regarding General Objectives (if applicable):**    **Specific Objectives of PMCF identified in the Clinical Evaluation Report**  **Indicate additional specific objectives to be addressed by the PMCF.**  **Mark appropriate specific objective(s) that apply:**   1. Clinical evaluation is based on equivalence; subject device data to be generated 2. Analyzing emergent risks and the occurrence of clinical events (e.g. delayed hypersensitivity reactions) 3. Confirmation of safety and performance in a specific patient population that may have different risk-benefit (e.g. pediatric populations) 4. Confirmation of safety and performance in high-risk anatomical locations 5. Confirmation of safety and performance in surgical approaches (e.g. open, laparoscopic) 6. Confirmation of safety and performance of the device **in** a larger and more varied population of patients 7. Confirmation of safety and performance of the device when used **by** a larger and more varied population (i.e. community hospitals) 8. Understanding interactions with specific other medical treatments 9. Other, describe: Post Market Clinical Survey   **Additional information regarding Specific Objectives (if applicable):**  To date, PMCF has not been conducted on the ACE Blades or the ACE Blade 700™ Soft Tissue Dissector given the established safety and performance profile that the ACE Blades have demonstrated over the past 10 years since its regulatory approval and CE Mark in 2005. The continued review of the post market surveillance data also supports the safety and performance of the subject device; however, in general, clinical publications on the use of ACE Blades is limited, given the long term (decades) history of electrosurgery and acceptability as “standard of care” devices in the majority of surgical procedures performed globally.  F 1: A Request for Proposal for an Investigator Initiated study has been posted on the JnJ website in order to obtain more information about any/all Megadyne products. This is to be completed as proactive monitoring and to demonstrate safety and performance of the ACE Blade.  F 2: The use of a chart review/data use agreement will be explored (within 6 months of launch of Rally Gem and Refine) to capture additional data on ace blade. It will be a single arm study looking at all products that contain an Ace blade when used in orthopedic and plastic procedures.  Other 1: A Post Market Clinical Survey (PMCS) will be conducted to further confirm the clinical safety and performance of the MEGADYNE System in the US and/or EU sites.  *Sites:*  6-10 sites in the US and EU.  *Patient Population:*  A minimum of 500 uses of both Megadyne Electrosurgical Generators (240 Megadyne Mega Power and 260 Megadyne Electrosurgical Generators)  *Performance Confirmation Variables*:   * Overall Performance of the Megadyne Mega Power and Ethicon Megadyne Electrosurgical Generators. * Overall Performance of any other Megadyne products used with the Megadyne Electrosurgical Generators including the ACE Blade 700TM Soft Tissue Dissector where applicable. * Overall Performance of Universal Megasoft Patient Return Electrode or disposable electrode(s) – Only the use of the generator is required. |

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| **Section 6a. General Methods and Procedures** | | | | |
| ID | Description of Activity | Objective(s) Addressed by the Activity | Methods or Procedures employed in the activity | Timelines of Activity |
| 1 | A Post Market Clinical Survey (PMCS) | Further confirm the clinical safety and performance of the MEGADYNE System in the US and/or EU sites (a-e) | Survey responses will be gathered over the next year. Data will be compiled and analyzed once all 500 surveys have been completed. | -Contract signed with 3rd party vendor- Actual 6 Jan 2020  -First Site Activated- Actual 4 May 2020  -First Survey Completed- Actual 18 May 2020  -Study completed- Feb 2021  -Data in house and being analyzed- Feb 2021  -Final report- Mar 2021 |
| 2 | Post Request For Proposal for Investigator Initiated Study | Determined by the Investigator (a-d) | Determined by the Investigator that submits the proposal to the portal. | Request for Proposal Posted April 2020 |

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| **Section 6b. General Methods and Procedures Rationale** | |
| ID | Rationale for Chosen Methods and Procedures |
| 1 | The questionnaires will address all aspects of the Proactive Monitoring of the device as it will provide additional evidence to support the long-term safety and performance of the device throughout its expected lifetime. The criteria for inclusion of the patient data will be that the Megadyne Mega Power and Ethicon Megadyne Electrosurgical Generators was used during surgery therefore ensuring that possible off label use is captured allowing the assessment of the suitability of the current labeling |
| 2 | The Investigator Initiated Study could potentially address all aspects of the Proactive Monitoring of the device as it will provide additional evidence to support the long-term safety and performance of the device throughout its expected lifetime. The study will assess known side effects and identify any new side effects which have not been previously reported. |

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| **Section 7a. Specific Methods and Procedures** | | | | |
| ID | Description of Activity | Objective(s) Addressed by the Activity | Methods or Procedures employed in the activity | Timelines of Activity |
| 1 | A Post Market Clinical Survey (PMCS) | Further confirm the clinical safety and performance of the MEGADYNE System in the US and/or EU sites (n) | Survey responses will be gathered over the next year. Data will be compiled and analyzed once all 500 surveys have been completed. | -Contract signed with 3rd party vendor- Actual 6 Jan 2020  -First site active- Actual 12 May 2020  -First Survey Completed- Actual 18 May 2020  -Study completed- Feb 2021  -Data in house and being analyzed- Feb 2021  -Final report- Mar 2021 |
| 2 | Post Request For Proposal for Investigator Initiated Study | Determined by the Investigator (f) | Determined by the Investigator that submits the proposal to the portal. | Request for Proposal Posted April 2020 |
| 3 | Explore data use agreement | (f) | • Product codes of Megadyne devices used during the procedure;  • Occurrence of blood transfusion (record the total required units of blood and rationale);  • Surgical procedure conducted (and technique used);  • Procedure duration;  • Hospital stay duration;  • Hematoma;  • Seroma; | Explore within 6 months of the launch or MEGADYNE™ Telescoping Soft Tissue Dissector and MEGADYNE™ Telescoping Smoke Evacuation Soft Tissue Dissector |

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| **Section 7b. Specific Methods and Procedures Rationale** | |
| ID | Rationale for Chosen Methods and Procedures |
| 1 | The questionnaires will collect data on all Megadyne devices used during a procedure. This will provide additional documented uses of the subject device. allow address all aspects of the Proactive Monitoring of the device as it will provide additional evidence to support the long-term safety and performance of the device throughout its expected lifetime. The criteria for inclusion of the patient data will be that the Megadyne Mega Power and Ethicon Megadyne Electrosurgical Generators was used during surgery therefore ensuring that possible off label use is captured allowing the assessment of the suitability of the current labeling. |
| 2 | The Investigator Initiated Study could potentially provide data on devices that have the ACE blade as the Request for Proposal states that the only requirement is that the study incorporates the use of Megadyne products. Since most of Megadyne products work as a system then it increases the likelihood that we will get data on devices that has an ACE blade and the pencil that is used. |
| 3 | The data use agreement will enable additional data to be extracted around Megadyne product codes. This will include all Megadyne codes including subject device data. |

| **Section 8. Reference to relevant common specifications, harmonized standards and guidance applicable to the PMCF Plan** |
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| **Mark all that apply:**   1. Medical Device Regulation 2017/745 2. MEDDEV 2.12/2 revision 2, Guidelines on Post Market Clinical Follow-Up Studies 3. MEDDEV 2.7/1 revision 4, Clinical Evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC 4. ISO 14971:2012 Application of risk management to medical devices 5. ISO 14155:2011 Clinical investigation of medical devices for human subjects – good clinical practice 6. Common specification, describe in comments 7. Harmonized standard, describe in comments 8. Other, describe in comments   **Additional Comments (if applicable):** |

| **Section 9. Attachments (if applicable)** | |
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| **#** | **Description** |
| 1 | A Post Market Clinical Survey (PMCS) Protocol |
| 2 | Approved Request for Proposal |

| **Section 10. PMCF Plan Revision history** | |
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| **Version** | **Description of changes made** |
| 1.0 | N/A |

| TV-eFRM-06302 Document Revision History | | | |
| --- | --- | --- | --- |
| Version Number | Section | Description of Change | Justification of Change |
| 1.0 | All | New document | New Form |
| 2.0 | All | Modified the document to reflect feedback from internal users and notified bodies. | To improve the content and readability of the document. |
| 3.0 | All | Added traceability matrix and Modified the document to reflect Draft Guidance from Medical Device Coordination Group (MDCG) to align to definitions of General and Specific PMCF. | To improve traceability from objectives, to activities, and their associated justifications. To ensure all activities in the PMCF plan meet the definition of PMCF. |