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

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| **Title / Description** | Mega Power Generator and Electrosurgical Generator |
| **PMCF Plan #** | SCN075391 |
| **Version** | 1.0 |
| **Date last modified** | 11 May 2020 |

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| **Approvals** | | | |
| **Role** | **Name & Title** | **Signature** | **Date** |
| Clinical Research | Jaime Connelly, MS, RAC  Franchise Clinical Platform Leader | See NON-electronic Signature Files Tab in EPI | |
| Medical Affairs | Giovanni A. Tommaselli, MD  Medical Director | See NON-electronic Signature Files Tab in EPI | |
| Post Market Surveillance | Katherine Seppa  Sr. Manager Post Market Surveillance | See NON-electronic Signature Files Tab in EPI | |

**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** | Megadyne Mega Power® Electrosurgical Generator and Ethicon Megadyne Electrosurgical Generator |
| **Basic UDI-DI(s)** | TBD |
| **Product Codes Covered by this plan** | Includes:   |  | | --- | | Product Code | | 1000 | | MEGEN1 | |
| **Device Description** | |  |  | | --- | --- | | **Product Code** | **Description** | | 1000 | Megadyne Mega Power Electrosurgical Generator |   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** | | MEGEN1 | Ethicon Megadyne Electrosurgical Generator | |
| **Intended purpose** | Megapower Generator  Megadyne Mega Power Electrosurgical Generator  Electrosurgical Generator  Ethicon Megadyne Electrosurgical Generator  Both Megadyne generators are intended as a general-purpose electrosurgical generator designed to produce radio frequency (RF) current for cutting and coagulation to be delivered to the target tissue through an accessory electrode during open and laparoscopic surgical procedures.  There are no known contraindications for the Mega Power® and Electrosurgical generator. |

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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-012 | PMS Plan for Mega Power Electrosurgical Generator |
| Report #  RA-REC-013 | PMS Report for Mega Power Electrosurgical Generator |
| Plan # 500453821 | PMS Plan for Ethicon Megadyne Electrosurgical Generator and Footswitch |
| Report # | Not applicable at this time. |
| **Clinical Evaluation Plan and/or Report** | Report # SCN073157 | Megadyne Electrosurgical Generators |
| **Risk Management Report** | Report # ENG-RMF-055 | Risk Management Report |
| Report # ENG-RMF-088 | Risk Management Report |
| Plan # QA-SOP-15 | Ethicon Megadyne Electrosurgical Generator |
| Report # ENG-RMF-077 |

| **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:**  The body of evidence includes clinical data on the existing Megadyne Mega Power Electrosurgical Generator and will also serve as the equivalent subject device for the new Ethicon Megadyne Electrosurgical Generator, following the literature route of conformity. The equivalence rationale between the existing Megadyne Mega Power Electrosurgical Generator and the new Ethicon Megadyne Electrosurgical Generator is duly justified in regard to clinical, technical, and biological characteristics -the subject devices are 83% identical and 17% highly similar or equivalent with no impact on clinical safety and performance outcomes.  There are several types of clinical benefits, including but not limited to, the impact of the subject device on clinical management, patient health, and patient satisfaction in the target population, such as significantly improving patient management and quality of life, reducing the probability of death, aiding improvement of patient function, reducing the probability of loss of function, and providing relief from symptoms. Therefore, the clinical benefits on the subject devices have been substantiated via evidence from the appraised data (clinical and non-clinical). |

| **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):**  PMCF has not been conducted on the Megadyne Mega Power Electrosurgical Generator given the established safety and performance profile that the generator has demonstrated over the past 15 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 the Megadyne Mega Power Electrosurgical Generator are limited, given the long term (decades) history of electrosurgery and acceptability as a “standard of care” device 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 Megadyne Generators.  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. * 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  -Study start up activities- Nov 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  -Study start up activities- Nov 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 |

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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 Megadyne generators 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 the use of Megadyne generators. |

| **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** |
| A | 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. |