Use Specification

**Approvals:**

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| --- | --- | --- | --- |
| **Function** | **Name** | **Signature** | **Date** |
| **NPD / Lifecycle Design Engineer** | Gracie Brooks | see e-Sig in EpiCenter | see e-Sig in EpiCenter |
| **NPD / Lifecycle Quality Engineer** | Scot Harris | see e-Sig in EpiCenter | see e-Sig in EpiCenter |
| **Industrial Design / Human Factors** | Racquel Redwood | see e-Sig in EpiCenter | see e-Sig in EpiCenter |

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| **Project Name** | Smoke Evacuation Pencil and Accessories |
| **Design Plan / Design Change Number** | ENG-IOM-004 (ME7251C, ME7251E, ME725M1C, ME725M1E)  ENG-IOM-012 (2540, 2560, 2540J, 2560J, 252510, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 252510EC)  ENG-IOM-018 (251010EC, 251010ECBN, 251015EC, 251015ECBN) |

**REVISION HISTORY**

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| --- | --- | --- |
| **Revision** | **Date** | **Summary of Change** |
| A | 31July 2020 | Original Issue |

# Device/System Identification

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| **Applicable Product Code(s)** | 252510, 252510EC, 2525-15, 252515, 252515EC, 2525-15EC, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 2540, 2560, 2540J, 2560J, 251010EC, 251010ECBN, 251015EC, 251015ECBN, 2250R, ACE12BN5, ACE12MBN5, ME7251C, ME7251E, ME725M1C, ME725M1E, ECVV120, ECVV220 |

# Part A: Identify Context of Use

| **Factors for Consideration** | | **Response / Comment** |
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| **Intended Use/Purpose** | | |
| 1. | What is the intended use of the device/system and how is the device/system to be used?  Identify any associated factors, including:   * Device/system’s role relative to diagnosis, prevention, monitoring, treatment, alleviation of disease, compensation for injury / handicap, or replacement / modification of anatomy * Indications for use * Whether the device/system sustains or supports life * Whether intervention is necessary in the case of failure of the device/system | **MEGADYNE ACE BLADE™ 700** *(ME7251C, ME7251E, ME725M1C, ME725M1E)*  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. Some tip configurations have a specific geometry that minimize blanching and thermal damage in skin incisions when used in conjunction with the Mega Power™ generator’s Advanced Cutting Effect (ACE) mode.  **Telescoping and Zip Pen Smoke Evacuation Electrosurgical Pencil** *(251010EC, 251010ECBN, 251015EC, 251015ECBN, 252510, 252510EC, 2525-15, 252515, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN,* *2525-15EC, 252515EC)*  MEGADYNE™ Telescoping Smoke Evacuation Pencil and Zip Pen Smoke Evacuation Electrosurgical Pencil are 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.  MEGADYNE™ PTFE coated 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.  **Zip Pen Extension Nozzle** *(2540, 2560, 2540J, 2560J)*  Zip Pen Nozzle Extension is an accessory for use only with the Zip Pen Pencil.  **MiniVac™ Smoke Evacuator** *(ECVV120, ECVV220)*  MEGADYNE® MiniVac™ Smoke Evacuation Systems are intended to evacuate and filter surgical smoke plume and aerosols created by the interface surgical tools with tissue, examples being lasers, electrosurgery systems, and ultrasonic devices. |
| 2. | If the device/system is intended to contact the patient or other persons, describe the location of the intended contact or type of tissue applied to/interacted with and the nature of the intended contact (e.g. surface contact, invasive contact) and the period and frequency of contact for each. | N/A  The disposable smoke evacuation pencil and extension nozzles are not intended to contact the patient but can come in contact with the patient’s skin and/or tissue during the procedure. The device is held by the gloved surgeon. Patient infection or reaction may occur if not sterile nor biocompatible. The smoke evacuator or filters are not intended to come in contact with the patient.  **MEGADYNE ACE BLADE™ 700** *(ME7251C, ME7251E, ME725M1C, ME725M1E)*  The ACE blade is intended for invasive contact with skin and tissue for intermittent periods of time during surgical procedure.  **Telescoping and Zip Pen Smoke Evacuation Electrosurgical Pencil** *(251010EC, 251010ECBN, 251015EC, 251015ECBN, 252510, 252510EC, 2525-15, 252515, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN,* *2525-15EC, 252515EC)*  These devices are intended for direct contact with target tissue. |
| 3. | If the device/system is intended for single use, identify whether it is obvious that the device/system has been used. If the device has a signal that it has been used, identify that signal. | N/A  **MEGADYNE ACE BLADE™ 700** *(ME7251C, ME7251E, ME725M1C, ME725M1E)* **Telescoping and Zip Pen Smoke Evacuation Electrosurgical Pencil** *(251010EC, 251010ECBN, 251015EC, 251015ECBN, 252510, 252510EC, 2525-15, 252515, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN,* *2525-15EC, 252515EC)*  These devises are intended for single use only, discard after use.  **Zip Pen Extension Nozzle** *(2540, 2560, 2540J, 2560J)*  These are single devices, discard after use.  **Zip Pen Smoke Evacuation Electrosurgical Pencil** *(252510, 252510EC)*  These devices are intended for single use only. |
| 4. | If the device/system is intended to be reusable (i.e. routinely cleaned and disinfected)   * Identify whether device/system requires assembly/disassembly for cleaning, and if so are instructions required. | N/A |
| **Intended Patient Populations** | | |
| 5. | Who are the intended patient populations?  Identify characteristics of each patient population. May include age, weight range, physical activity or condition, health, etc. | General |
| **Intended User Group Profiles** | | |
| 6. | Identify all users of the device/system and describe the profile for each user group (e.g. education, experience, procedure volume, etc.). For the profile, consider characteristics that would cause different behaviors or patterns of use among the user groups.  Consider whether the device/system will be used by:   * Persons with mental and/or physical limitations (e.g. handicapped persons, the elderly, or children). * Individuals with differing skill levels and educational backgrounds * People with different cultural backgrounds * People who use a variety of devices and systems (e.g. from different manufacturers) * Surgeons with varying surgical approaches and techniques (e.g. Bariatric vs. Colorectal)  |  |  |  | | --- | --- | --- | | **Groups** | **User of Device/**  **System?** | **User Group Profile**  **May be left blank if answer to “User of Device/System?” is no.** | | Surgeons | Yes  No | Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.  Age ranges from medical school residents in their early twenties to retirement age.   * Gender is split depending upon specialty: typically, more heavily male in general, but the female population is rising. * Primary responsibility is to perform the surgical procedure,and have a thorough working knowledge of all instruments / devices being used. | | Scrub technicians/nurses | Yes  No | * Primary responsibilities are to assist the surgeon by handing off / taking back surgical devices and having the proper devices / materials immediately available as needed. * The scrub nurse may be involved in troubleshooting of the device and reading the IFU. * Age ranges from entry level college students to retirement age. The current average age is in the 40’s; a reflection of the generally aging nurse population. * Gender may be male or female. Gender is significantly female. | | Circulating nurses | Yes  No | * Primary responsibilities include ensuring the availability of all instruments and equipment needed to perform the procedure. The circulating nurse is not scrubbed in and not part of the sterile staff. * The circulating nurse is often the one responsible for pulling a device for a procedure in case a surgeon calls out for a specific size/type device and may rely on package graphics to identify devices. * Same general age, gender, and education profile as scrub nurse. Gender is significantly female. * Nurses are typically college-educated. * Although having received intensive overall training in nursing school, the nurses typically require additional training (“in-service”) from the surgical equipment manufacturer for the proper use of technical equipment. * Circulating nurses tend to not have extensive knowledge of technology, and greatly appreciate equipment that is simple and intuitive to use. Their primary focus is on patient care. * There is relatively high turnover in the nursing staff, in terms of new nurses coming on board or nurses from other specialties “covering” for each other during certain times of the day. | | Nurse Practitioners (NP) | Yes  No | Primary responsibility is to ensure availability of instruments needed in surgical procedures and have a thorough working knowledge of all instruments / devices being used.  Age ranges from graduate school in their mid-twenties to retirement age.  Gender is split depending upon specialty: typically, more heavily male in general, but the female population is rising. For Wound closure after surgery, there is an increase chance that the surgeon may ask a less experienced or younger surgeon/NP/PA or even resident to operate the device. | | Physician’s Assistants (PA) | Yes  No | Primary responsibility is to assist surgeon in surgical procedure and have a thorough working knowledge of all instruments / devices being used.  Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.  Age ranges from graduate school in their mid-twenties to retirement age.  Gender is split depending upon specialty: typically, more heavily male in general, but with the female population is rising. | | Central processing personnel | Yes  No |  | | Technicians  (e.g. Radiology, IVD Lab, dialysis, reprocessing) | Yes  No |  | | Therapists (physical, respiratory, etc.) | Yes  No |  | | Servicing personnel (e.g. biomedical technicians, etc.) | Yes  No |  | | Imaging personnel (e.g. for diagnostics, pre-operative templates, etc.) | Yes  No |  | | Pharmacists | Yes  No |  | | Emergency response personnel | Yes  No |  | | Lay people (e.g. patients, care givers) | Yes  No |  | | Other | Yes  No  n/a |  | | |
| **Use Environments** | | |
| 7. | Identify all use environments and describe the characteristics of each use environment that could affect use of the device. Important characteristics might include: lighting, noise level, distraction, work surface height, space limitations, procedure type, tissue type, access/visualization, etc.   |  |  |  | | --- | --- | --- | | **Environments** | **Device/**  **System Use Environment?** | **Use Environment Characteristics**  **May be left blank if answer to “Device/System Use Environment?” is no.** | | Operating room (OR) | Yes  No | * There is a distinct possibility of distractions, mainly from an audio perspective, from other instruments and pieces of equipment in the OR. There is noise from the various machines beeping and humming as well as the general noise from surgeons & nurses talking, sometimes music playing, instruments clanking, and various devices are used. While feedback from some other monitoring systems may employ an audible component, it will not be limited to just audio. * Typically, a dimly lit OR with task-specific lighting which can make it challenging to perform the operating procedures | | Catheterization lab | Yes  No |  | | Central processing | Yes  No |  | | Patient room | Yes  No |  | | Doctor’s office | Yes  No |  | | Other procedure room | Yes  No |  | | Home | Yes  No |  | | Other: | Yes  No  n/a |  | | |

# Part B: Identify Operating Principle and User Interface Characteristics

| **Factors for Consideration** | | **Response / Comment** |
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| **Operating Principle** | | |
| 1. | How will information for safe use be provided (IFU, surgical technique guide, user manual, quick start up guide, quick reference guide, maintenance manual, etc.)?  Identify the following (if known):   * Whether information will be provided directly to the end user or if it will involve the participation of third parties such as installers, sales reps, care providers, health care professionals or pharmacists and whether this will have implications for training * Commissioning and handing over to the end user and whether it is likely/possible that installation can be carried out by people without the necessary skills (for capital equipment only) * Based on the expected life of the device/system, whether re-training or re-certification of operators or service personnel is required (for capital equipment only) | IFU: 3000336-01 & 3000312-01 IFU Zip Pen Smoke Evac Pencil (252510, 2525-15, 252515, 252510EC, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 2525-15EC, 252515EC)  3000313-01 (2540, 2560, 2540J, 2560J)  3000307-01 (251010EC, 251010ECBN, 251015EC, 251015ECBN)  3000317-01 & 3000318-01 (ME7251C, ME7251E, ME725M1C, ME725M1E)  902413 (User’s Manual ECVV120, ECVV220)  provide instructions, warnings and precautions. An in-service training with an Ethicon Sales representative may occur and Ethicon.com includes information for safe use that is assessible by users.  These devices are not capital equipment. |
| 2. | Describe any potential problems associated with patient compliance. | N/A |
| 3. | If the device/system is intended for use in conjunction with medicines or other medical technologies, list the medicines/technologies that are necessary to use the specific device/system (such as imaging systems). | N/A |
| 4. | If applicable, list the consumables, connecting parts, or accessories associated with the use of the device/system. Examples of consumables, connecting parts, or accessories include bone biopsy needle, trocars, batteries, other implant systems or surgical devices/instruments which are to be used with the device/system, etc. | N/A  **MEGADYNE ACE BLADE™ 700** *(ME7251C, ME7251E, ME725M1C, ME725M1E)*  Megadyne recommends use of the MEGADYNE ACE BLADE™ 700 with the Mega Power Electrosurgical Generator and Megadyne accessory devices (i.e. electrosurgical pencils and return electrodes).  **Zip Pen Smoke Evacuation Electrosurgical Pencil** *(252510, 252510EC)*  Megadyne recommends the use of the smoke evacuation pencil with the E-Z Clean® active electrode with the Mega Power® electrosurgical generator (MAX 300 Watts Cut, 120 Watts Coag), Mega VacTM/Mega VacTM Plus, or comparable  smoke evacuators rated up to 708 LPM,\* and other Megadyne products. |
| 5. | If maintenance and/or calibration are necessary, identify whether:   * Maintenance or calibration are to be carried out by the operator/user or by a specialist * Special substances or equipment are necessary for proper maintenance or calibration | N/A |
| 6. | If the device/system contains software, identify whether software is intended to be installed, verified, modified, or exchanged by the operator or user or by a specialist. | N/A |
| 7. | If use or installation of the device/system requires special training, describe the training and whether the training is required for sale of the device.  For example, special training for health care professionals may go beyond general medical expertise learned in their course of training that will otherwise affect/impact the outcome of the procedure. Such training may be required prior to the purchase/receipt of the device/system. | N/A |
| **User Interface** | | |
| 8. | If the device/system has a control interface (e.g. handles, grip points, foot pedals, knobs, dials, graphical user interface, menus, etc.), briefly describe the control interface.  Factors to consider when designing the device/system control interface include, but are not limited to visibility, modes of feedback, direction of activation or change, whether the controls are continuous or discrete, spacing, grouping, mapping, and the reversibility of settings or actions. | IFU: 3000336-01 & 3000312-01 IFU Zip Pen Smoke Evac Pencil (252510, 2525-15, 252515, 252510EC, 252510BN, 252510ECBN, 2525-10BN, 2525-10ECBN, 2525-15EC, 252515EC)  3000313-01 (2540, 2560, 2540J, 2560J)  3000307-01 (251010EC, 251010ECBN, 251015EC, 251015ECBN)  3000317-01 & 3000318-01 (ME7251C, ME7251E, ME725M1C, ME725M1E)  902413 (User’s Manual ECVV120, ECVV220)  provide instructions, warnings and precautions. An in-service training with an Ethicon Sales representative may occur and Ethicon.com includes information for safe use that is assessible by users.  These devices are not capital equipment. |
| 9. | If the device/system displays information (e.g. using instrument markings, perceptual cues and feedback, graphical user interface, etc.), identify any known factors affecting use including visibility in various environments, orientation, the visual capabilities of the user, populations and perspectives, clarity of the presented information, units, color coding, and the accessibility of critical information. | N/A  “CHANGE FILTER” light illuminates on the smoke evacuator’s front panel. |
| 10. | If the device/system is intended to be mobile or portable (e.g. cases, trays, packaging, capital equipment, etc.), identify how it is transported. Also identify any necessary features (e.g. grips, handles, wheels, brakes, mechanical stability, and durability) for mobility and portability. | N/A |

**TEMPLATE FRM003984 REVISION HISTORY**

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| **REV** | A | **Summary** |
| **ECN** | ECN021673 | Original Issue |