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1. REFERENCES

EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
QA-SOP-015*	Risk Management of Medical Devices
ENG-RMF-044	Mega Soft Pad Family Hazard Assessment Summary
ENG-DMR-012	Megadyne Smoke Evacuation Pencil and Accessories, Device Master Record
100583575	Franchise Global Complaint Trending and Signal Detection PMS Procedure
RA-RPT-005	Megadyne Family of products Clinical Evaluation Report
RA-RPT-007	Megadyne ACE Blade & ACE Blade 700™ Soft Tissue Dissector Clinical Evaluation Report (Product Codes: ME7251C, ME7251E, ME725M1C, ME725M1E)

*Note: This document follows QA-SOP-015 Rev 005. Per QA-SOP-015 section 2.4.1, "Risk documentation for devices implemented under revisions prior to Rev 006 of QA-SOP-015 can be maintained according to the version of QA-SOP-015 in effect when the document was created."

2. SCOPE

This Risk Analysis applies to Smoke Evacuation Accessory products. The products covered by this document are established in the Device Master Record ENG-DMR-012 and Megadyne's Design History File.

This Risk Analysis pertains to the Zip Pen products, including cat numbers 2525-10 (252510), 2525-10EC (252510EC), 2525-10BN (252510BN), 2525-10ECBN (252510ECBN), 2525-15EC (252515EC), and 2525-15 (252515), ME7251C, ME7251E, ME725M1C, ME725M1E. This document also pertains to the Extension Nozzle cat numbers 2540 (2540J) and 2560 (2560J), Charcoal Filter 2220 (2220J), and ULPA Filter 2211 (2211J). The catalog numbers in parentheses are new catalog numbers referring to the same product, due to transition of product information from Megadyne Medical Products to Ethicon Endo Surgery. This document will refer to the original catalog numbers.

3. PURPOSE

The document summarizes the risks associated with these devices and establishes how they have been addressed.

4. COMPLAINT HISTORY

4.1. Summary

This complaint history includes updated reported complaints received from JULY 2018 through JUNE 2020 completed as a periodic review of the risk management file. Complaint numbers are presented, as are complaint frequencies. The frequency of complaints is expressed as the number of complaints versus the number of units distributed during the above time frame. All of the data for the periodic review (JULY 2018 – JUNE 2020) was obtained from the PQSS DRB MMP Rates and Signals spreadsheet. The complaint classification codes, and their obtained Rates are presented in the below table.

Smoke Evacuation- 252510, 2525-10, 252510EC, 2522510-EC				
Product Experience Code (PEC)	No. of Complaints	Opportunities	CPMO	Complaint rate
ACTIVATION FAILURE	3	145657	20.6	0.0021%
SWITCH BUTTON ISSUE	3	145657	20.6	0.0021%
COAG ISSUE	3	145657	20.6	0.0021%
TISSUE EFFECT ISSUE	2	145657	13.7	0.0014%
ASPIRATION ISSUE	2	145657	13.7	0.0014%
DAMAGED PRODUCT	2	145657	13.7	0.0014%
SELF ACTIVATION	1	145657	6.9	0.0007%
FLAKING ISSUE	1	145657	6.9	0.0007%
CAUTERY ISSUE	1	145657	6.9	0.0007%
FLAME FLASH FIRE	1	145657	6.9	0.0007%
NOT SPECIFIED	1	145657	6.9	0.0007%
CUTTING ISSUE	0	145657	0	0%

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Smoke Evacuation ACE 700 - ME7251C, ME7251E, ME725M1C, ME725M1E				
Product Experience Code (PEC)	No. of Complaints	Opportunities	CPMO	Complaint Rate
ASPIRATION ISSUE	4	23969.5	166.9	0.017%
DAMAGED PRODUCT	4	23969.5	166.9	0.017%
CAUTERY ISSUE	3	23969.5	125.2	0.013%
ACTIVATION ISSUE	3	23969.5	125.2	0.013%
TISSUE EFFECT ISSUE	2	23969.5	83.4	0.008%
NOT SPECIFIED	2	23969.5	83.4	0.008%
HEMOSTASIS CONTROLLABLE	2	23969.5	83.4	0.008%
COAG ISSUE	2	23969.5	83.4	0.008%
ASSEMBLY DISASSEMBLY ISSUE	1	23969.5	41.7	0.004%
SWITCH BUTTON ISSUE	1	23969.5	41.7	0.004%
CUTTING ISSUE	1	23969.5	41.7	0.004%
UNINTENDED THERMAL INJURY LESS THAN 2ND DEGREE	1	23969.5	41.7	0.004%
UNRETRIEVED DEVICE FRAGMENT	1	23969.5	41.7	0.004%
CUSTOMER DISSATISFACTION	1	23969.5	41.7	0.004%
IGNITION OF DEBRIS OR FLAMMABLE CONDITION	1	23969.5	41.7	0.004%
FLAME FLASH FIRE	1	23969.5	41.7	0.004%
FLAKING ISSUE	0	23969.5	0	0%

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Smoke Evacuation Accessory – 2220, 2220J, 2140J, 2255J				
Product Experience Code (PEC)	No. of Complaints	Opportunities	CPMO	Complaint rate
PACKAGING IDENTIFICATION	101	75223	1342.7	0.134%
PACKAGING DEVICE ISSUE	5	75223	66.5	0.007%
NOT SPECIFIED	1	75223	13.3	0.001%

5. CLINICAL EVALUATION

The review of scientific literature is documented in RA-RPT-005 & RA-RPT-007. Megadyne believes, and the literature supports, the Smoke Evacuation accessories are safe products, with no unacceptable risks.

6. RISK SUMMARY

Risk analysis study of this product family was conducted according to QA-SOP-015 Risk Management of Medical Devices. A copy of the detailed Failure Mode and Effect Analysis (FMEA) for the Smoke Evacuation accessories follows in Section 8. All identified risks have been deemed acceptable or as low as possible (see Notes / Justification column of FMEA).

None of the risks identified in the Risk Analyses are of a nature that they are confined to Megadyne's Smoke Evacuation family of devices. All smoke evacuator manufacturers face approximately the same set of risks and have addressed them in very similar ways.

Megadyne's Smoke Evacuation devices present no risks to patients or users that are unacceptable or unreasonable when weighed against the benefits to the patient.

7. RISK BENEFIT ANALYSIS

Megadyne's Smoke Evacuation family of accessories is similar in many ways to existing smoke evacuation accessories that have a well-established history of safety and reliable performance through use in millions of cases in thousands of operating rooms throughout the world. Many of these devices have been in general distribution for decades. Some of the benefits provided by the Megadyne devices when compared with other competitive products as follows:

- the Zip-Pen Smoke Evacuation Pencil has ergonomic design for ease of surgeon use
- the smoke nozzle is contoured for improved surgeon visibility
- the Zip-Pen Smoke Evacuation Pencil incorporates swivels for tubing attachment to minimize drag on the surgeon's hand.

These devices are intended for use by or on the order of a physician who is trained in the associated risks of electrosurgery. The anticipated clinical benefits of using these high-frequency surgical devices as compared to other surgical techniques outweigh the residual and overall risks identified in the FMEA. As with other electrosurgical smoke evacuation devices on the market, these products meet international standards for safety. This family of devices presents no risks to patients or users that are unacceptable or unreasonable when weighed against the benefits to the patient. Risks of electrosurgery are reviewed with patients by the physician prior to through informed consent.

8. FMEA

The Failure Mode and Effect Analysis (FMEA) for the smoke evacuation product family are detailed in the following table:

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Zip-Pen aFMEA

Risk Analysis						Risk Estimation			Risk Evaluation	Risk Control						Risk Estimation of Residual Risk			Risk Evaluation of Residual Risk		
Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered? Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes, No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis / Notes**
1-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Inner bag gets contaminated (recognized) and contaminates sterile field	Causes a delay, must re-establish sterile field	1	1	1	NA	DFS	Package designed with same sealant as existing packaging and with chevron tab for intuitive opening. See footnote 1	Not Practical	Verification Plan: Verify that the package drawing indicates “OPEN HERE” on tab. Validation Plan: ENG-PRT-290, Ensure IFU includes opening instructions.	See ENG-DMR-012	Report ENG-RPT-418	1	1	1	NA	NA	NA
1.5-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Inner bag gets contaminated (recognized) and contaminates sterile field	Causes a delay, must re-establish sterile field	1	1	1	NA	IFS	Package says “OPEN HERE” on tab. See footnote 1	Not Practical	Verification Plan: Verify that the package drawing indicates “OPEN HERE” on tab. Validation Plan: ENG-PRT-290, Ensure IFU includes opening instructions	See ENG-DMR-012	Report ENG-RPT-418	1	1	1	NA	NA	NA
2-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Inner bag gets contaminated (not recognized) and contaminates sterile field	Non-sterile product used on patient resulting in infection	10	1	10	Yes	DFS	Package designed with same sealant as existing packaging and with chevron tab for intuitive opening. See footnote 1	Not Practical	NA	See ENG-DMR-012	NA	10	1	10	No	N/A	See footnote 4
2.5-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Inner bag gets contaminated (not recognized) and contaminates sterile field	Non-sterile product used on patient resulting in infection	10	1	10	Yes	IFS	Package says “OPEN HERE” on tab See footnote 1	Not Practical	Verification Plan: Verify that the package drawing indicates “OPEN HERE” on tab, Ensure See ENG-PRT-290, IFU includes opening instructions	See ENG-DMR-012	Report ENG-RPT-418	10	1	10	No	N/A	See footnote 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered? Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control?	Additional Risk Control (if applicable)	Risk Benefit Analysis / Notes
3-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Can break seal on wrong end, inner bag gets contaminated (recognized) and contaminates sterile field	Causes a delay, must re-establish sterile field	1	1	1	Yes	DFS	Package designed with same sealant as existing packaging and with chevron tab for intuitive opening. See footnote 1	Not Practical	Validation Plan: ENG-PRT-290	See ENG-DMR-012 and label drawings	Report ENG-RPT-418	1	1	1	No	N/A	Risk is as low as possible.
3.5-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Can break seal on wrong end, inner bag gets contaminated (recognized) and contaminates sterile field	Causes a delay, must re-establish sterile field	1	1	1	Yes	IFS	Package says “OPEN HERE” on tab See footnote 1	Not Practical	Verification Plan: Verify that the package drawing indicates “OPEN HERE” on tab.	See ENG-DMR-012 and label drawings	Report ENG-RPT-418	1	1	1	No	N/A	Risk is as low as possible.
4-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Can break seal on wrong end, inner bag gets contaminated (not recognized) and contaminates sterile field	Non-sterile product used on patient resulting in infection	10	1	10	Yes	DFS	Package designed with same sealant as existing packaging and with chevron tab for intuitive opening. See footnote 1	Not Practical	NA	See ENG-DMR-012 and label drawings	NA	10	1	10	No	N/A	See footnote 4
4.5-a	Break seal to open outer Pencil package	To deliver aseptic product to sterile field	Package difficult to open, defective package or package materials	Can break seal on wrong end, inner bag gets contaminated (not recognized) and contaminates sterile field	Non-sterile product used on patient resulting in infection	10	1	10	Yes	IFS	Package says “OPEN HERE” on tab See footnote 1	Not Practical	Verification Plan: Verify that the package drawing indicates “OPEN HERE” on tab.	See ENG-DMR-012 and label drawings	Report ENG-RPT-418	10	1	10	No	N/A	See footnote 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered? Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control?	Additional Risk Control (if applicable)	Risk Benefit Analysis / Notes
5-a	Scrub removes (picks) inside pouch from outer packaging	To deliver aseptic product to sterile field	The opening on the inside pouch is not oriented correctly	Can drop the product on floor	Non sterile product	1	1	1	NA	DFS	Ensure the flap is on the pouch side and not the top Tyvek side so the flap stays in the package when peeled open	Not Practical	Verify that the packaging design indicates correct pouch placement inside the outer package Validation Plan: ENG-PRT-290	Bag is long enough to fold over creating a flap, Drawing shows flap with correct orientation See ENG-DMR-012	Report ENG-RPT-418	1	1	1	NA	NA	NA
6-a	Pull Pencil out of inside bag	To deliver aseptic product to sterile field	Tubing unfurls	Drop product	Non sterile product	1	1	1	NA	DFS	Product is delivered to the sterile field inside of a secondary pouch to contain the tubing until technician is ready to connect tubing	Not Practical	Verify that the packaging design indicates correct pouch placement inside the outer package Validation Plan: ENG-PRT-290	See ENG-DMR-012	Report ENG-RPT-418	1	1	1	NA	NA	NA
7-a	Hand connecting ends to non-sterile person for connection to ESU and smoke box	Use ESU and smoke box	Tangled cable and tubing Cable not secured	Product contamination (recognized)	Causes a delay, need to replace the product	1	1	1	NA	DFS	The cable is contained in paper cohesive tape so it will not get tangled with the tubing	Not practical	NA	NA	NA	1	1	1	NA	NA	NA
8-a	Hand connecting ends to non-sterile person for connection to ESU and smoke box	Use ESU and smoke box	Tangled cable and tubing Cable not secured	Product contamination (not recognized)	Non-sterile product used on patient resulting in infection	10	5	50	Yes	DFS	The cable is contained in paper cohesive tape so it will not get tangled with the tubing	Not practical	Ensure product is packaged per drawing Validation Plan: ENG-PRT-290	See drawings 6020190-01and 6020303-01, First Article	Report ENG-RPT-418	10	1	10	No	N/A	See footnote 4
9-a	Pencil Use	Evacuate smoke URS1006	Tangled cable and tubing	Tubing is kinked or wrapped around the product, smoke not evacuated.	Possible user exposure to potential carcinogens, and infectious by-products	5	1	5	Yes	DFS	See footnote 1 and Designed similar to standard electrosurgical pencil	Not practical	Validation Plan: ENG-PRT-290	NA	Usability test report ENG-RPT-418	5	1	5	NA	NA	See footnote 3 and 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered? Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control?	Additional Risk Control (if applicable)	Risk Benefit Analysis / Notes
9.5-a	Pencil Use	Evacuate smoke URS1006	Tangled cable and tubing	Tubing is kinked or wrapped around the product, smoke not evacuated.	Possible user exposure to potential carcinogens, and infectious by-products	5	1	5	Yes	IFS	NA	Not practical	Verify the warning is captured in IFU Validation Plan: ENG-PRT-290	Warning listed in Zip IFU, Zip Ace IFU	NA	5	1	5	NA	NA	See footnote 4
10-a	Pencil Use	Activation of pencil	Use error	Buzzing hemostat	Shock to clinician	1	5	5	Yes	DFS	See footnote 1 and Designed similar to standard electrosurgical pencil	Not practical	Validation plan: Review history of clinical use of pencil	NA	See footnote 2	1	5	5	No	N/A	Risk is as low as possible.
10.5-a	Pencil Use	Activation of pencil	Use error	Buzzing hemostat	Shock to clinician	1	5	5	Yes	IFS	NA	Not practical	Verify the caution to “Activate pencil at target tissue” is in IFU	Caution listed in Zip IFU, Zip Ace IFU	See footnote 2	1	5	5	N	N/A	Risk is as low as possible.
11-a	Pencil Use	Activation of pencil	Use error such as inappropriate contact of insulated shaft with off target tissue	Capacitive coupling Corona effect	Patient burn	10	1	10	Yes	DFS	See footnote 1 and Designed similar to standard electrosurgical pencil	Not practical	NA	NA	See footnote 2	10	1	10	No	N/A	See footnote 4
11.5-a	Pencil Use	Activation of pencil	Use error such as inappropriate contact of insulated shaft with off target tissue	Capacitive coupling Corona effect	Patient burn	10	1	10	Yes	IFS	NA	Not practical	Verify the caution to “Activate pencil at target tissue” is in IFU.	Caution listed in Zip IFU, Zip Ace IFU	See footnote 2	10	1	10	No	N/A	See footnote 4
12-a	Pencil Use	Between activations URS1002	Use error such as failure to store device in holster	Contact with hot tip or inadvertent activation when electrode not in holster	Patient or user burn	10	5	50	Yes	DFS	Holster provided with each device. See footnote 1 Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)5)	Not practical	Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)5)	NA	See footnote 2 UL Test Report ENG-RPT-059	10	5	50	No	N/A	See footnote 3 and 4

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12.5-a	Pencil Use	Between activations URS1002	Use error such as failure to store device in holster	Contact with hot tip or inadvertent activation when electrode not in holster	Patient or user burn	10	5	50	Yes	IFS	Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)5)	Not practical	Ensure labeling restricts use to physicians Ensure IFU states that when not in use, store active electrode in an electrically insulated container. Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)5)	Labeling appropriately restricts the use of the device. Zip IFU, Zip Ace IFU warning meets IEC 60601-2-2 clause 201.7.9.2.2.101 a)5)	See footnote 2 UL Test Report ENG-RPT-059	10	5	50	No	N/A	See footnote 3 and 4
13-a	Pencil Use	Insert pencil into ESU	Plug into ESU upside down in non-Megadyne unit.	No COAG activation	User dissatisfaction Delay in surgery	3	5	15	Yes	DFS	Application of industry standards to product design	Not practical	Ensure device meets requirements of IEC 60601-1 for safety of electrosurgical accessories	The Handpiece is tested and certified for compatibility with Megadyne ESU. See UL report ENG-RPT-058	UL Test Report ENG-RPT-059	3	1	3	No	N/A	See footnote 3 and 4
14-a	Pencil Use	Activation of pencil	Used in oxygen rich environment, with flammable anesthetics, materials, or gases, or by coming in contact with drape while activated.	Electrode starts fire in surgical field	Patient / User injury (burn)	10	1	10	Yes	IFS	See footnote 1 Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	Not practical	Ensure labeling restricts use to physicians Ensure IFU states that activated or hot electrodes should not be placed near or in contact with flammable materials or substances. Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	Labeling appropriately restricts the use of the device. Zip IFU, Zip Ace IFU warning meets IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	See footnote 2 UL Test Report ENG-RPT-059	10	1	10	No	N/A	See footnote 3 and 4
14.5-a	Pencil Use	Activation of pencil	Used in oxygen rich environment, with flammable anesthetics, materials, or gases, or by coming in contact with drape while activated.	Electrode starts fire in surgical field with no property damage or patient injury	Delay of surgery, User dissatisfaction	3	1	3	Yes	IFS	See footnote 1 Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	Not practical	Ensure labeling restricts use to physicians Ensure IFU states that activated or hot electrodes should not be placed near or in contact with flammable materials or substances. Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	Labeling appropriately restricts the use of the device. Zip IFU, Zip Ace IFU warning meets IEC 60601-2-2 clause 201.7.9.2.2.101 a)9)	See footnote 2 UL Test Report ENG-RPT-059	3	1	3	No	N/A	NA

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered? Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control?	Additional Risk Control (if applicable)	Risk Benefit Analysis / Notes
15-a	Pencil Use	User performs electrosurgery with disposable smoke pencil	Contamination from improper sanitizing and sterilization	Product used for more than 1 procedure	Patient injury	10	5	50	Yes	DFS	Product designed to ISO 15223 and IEC 60601-2-2 See footnote 1	Not practical	NA	NA	UL Test Report ENG-RPT-059	10	5	50	No	N/A	See footnote 3 and 4
15.5-a	Pencil Use	User performs electrosurgery with disposable smoke pencil	Contamination from improper sanitizing and sterilization	Product used for more than 1 procedure	Patient injury	10	5	50	Yes	IFS	NA	Not practical	Ensure pencil is designated as single use in IFU and on labeling.	Labeling appropriately restricts the use of the device.	UL Test Report ENG-RPT-059	10	5	50	No	N/A	See footnote 3 and 4
16-a	Pencil Use	User performs surgery with small cross-sectional area with monopolar output.	Use error of monopolar energy	Unwanted tissue damage	Patient injury	10	1	10	Yes	DFS	See footnote 1	Not practical	NA	NA	UL Test Report ENG-RPT-059	10	1	10	No	N/A	See footnote 3 and 4
16.5-a	Pencil Use	User performs surgery with small cross-sectional area with monopolar output.	Use error of monopolar energy	Unwanted tissue damage	Patient injury	10	1	10	Yes	IFS	Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)6) See footnote 1	Not practical	Ensure labeling restricts use to physicians Ensure IFU states electrosurgery should not be used on body parts with relatively small cross-sectional area. Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)6)	Labeling appropriately restricts the use of the device. Zip IFU, Zip Ace IFU warning meets IEC 60601-2-2 clause 201.7.9.2.2.101 a)6)	UL Test Report ENG-RPT-059	10	1	10	No	N/A	See footnote 3 and 4
17-a	Pencil Use	Activation of electrosurgical pencil.	Failure to use the lowest power setting to achieve the desired effect	Excessive tissue damage	Patient injury	10	1	10	Yes	DFS	Megadyne ESU defaults to null power setting on start up, See footnote 1	Not practical	NA	NA	UL Test Report ENG-RPT-059, See complaint analysis.	10	1	10	No	N/A	See footnote 3 and 4 Occurrence based upon complaint analysis

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered? Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis / Notes**
17.5-a	Pencil Use	Activation of electrosurgical pencil, PRS 1701 – 1720, PRS 1901 – 1920	Failure to use the lowest power setting to achieve the desired effect	Excessive tissue damage	Patient injury	10	1	10	Yes	IFS	Megadyne ESU defaults to null power setting on start up . Ensure IFU states that the lowest power setting to achieve the desired effect should be used. Label according to IEC 60601-2-2 See footnote 1	Not practical	Ensure labeling restricts use to physicians Ensure IFU states that the lowest power setting to achieve the desired effect should be used. Label according to IEC 60601-2-2 clause 201.7.9.2.2.101 a)6) and ISO 15223. Validation Plan: Monitor customer complaints.	Labeling appropriately restricts the use of the device. Zip IFU, Zip Ace IFU warning meets IEC 60601-2-2 clause 201.7.9.2.2.101 a)7)	UL Test Report ENG-RPT-059, See complaint analysis.	10	1	10	No	N/A	See footnote 3 and 4 Occurrence based upon complaint analysis
18-a	Pencil Use	Activate electrode for tissue dissection.	User error. Cleaned PTFE with an abrasive cleaner.	Excessive eschar on tip.	Reduced performance of tip	1	1	1	NA	IFS	NA	NA	Ensure labeling restricts use to physicians Ensure IFU states not to use a scratch pad or abrasive material to clean the tip	Labeling appropriately restricts the use of the device and includes the warning	NA	1	1	1	NA	NA	NA
19-a	Pencil Use	Activate electrode	Failure to inspect the tip for damage.	Damaged Electrode	Patient / User Injury	10	1	10	Yes	IFS	See footnote 1 Include caution statement in IFU	Not practical	Ensure labeling includes caution to inspect electrode Ensure labeling restricts use to physicians	Labeling appropriately restricts the use of the device and includes caution	See footnote 2	10	1	10	No	N/A	See footnote 4
20-a	Pencil Use	Activate bent electrode	Use error. Bent electrode past 60 degrees	Coating/electrode is damaged.	Patient / User injury	10	1	10	Yes	IFS	See footnote 1 Include caution statement in IFU	Not practical.	Ensure labeling restricts use to physicians Ensure IFU states not to bend electrode past 60 degrees.	Verified instructions are listed in the Zip IFU, Zip Ace IFU	See footnote 2	10	1	10	No	N/A	See footnote 4
21-a	Pencil Use	Activation away from intended target tissue	Use error. Activated electrode when not in contact with tissue	Unintended injury	Patient / User injury	10	1	10	Yes	IFS	See footnote 1 Include warning statement in IFU	Not practical.	Ensure labeling restricts use to physicians Ensure IFU states appropriate caution	Verified instructions are listed in the Zip IFU, Zip Ace IFU	See footnote 2	10	1	10	No	N/A	See footnote 4

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22-a	Pencil Use	Placement of pencil cable on surgical field	Use error. Failure to position cable correctly. Smoke pencil cables are coiled or fastened with metal clips	Capacitive coupling injury due to cable contact with the patient or other leads.	Patient / User injury	10	1	10	Yes	IFS	Design to IEC 60601-2-2 Include warning statement in IFU See footnote 1	Not practical	Ensure labeling restricts use to physicians Ensure IFU cautions cable placement.	Verified instructions are listed in the Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059	10	1	10	No	N/A	See footnote 3 and 4
58-a	Pencil Use	Protect electrode from damage when pencil not in use	Use Error	Tip protector not removed	Delay of Surgery	3	1	3	Yes	IFS	Provide information to user See footnote #1	Not Practical	Ensure IFU instructs the user to remove tip protector	Zip IFU, Zip Ace IFU includes instructions	NA	3	1	3	No	N/A	See footnote 4 Occurrence determined by complaint analysis
59-a	Pencil Use	Intuitive Hand Grips	Pencil is non-intuitive	User unable to grip pencil as intended	User dissatisfaction	1	3	3	Yes	IFS	User Validation, Instructions in IFU. See footnote 1	NA	ENG-PRT-453 Validation, Ensure Zip-Pen IFU provides visual guide	Zip IFU, Zip Ace IFU	ENG-RPT-557	1	3	3	No	NA	NA
60-a	Pencil Use	Evacuation of smoke	Nozzle becomes occluded	Poor smoke capture	Potential user exposure to carcinogens and infectious by-products	5	1	5	Yes	DFS	Angled nozzle design, wider than predicate UltraVac	NA	Demonstrate outcome of full occlusion in ENG-PRT-280	Demonstrate outcome of full occlusion in ENG-RPT-403	NA	5	1	5	No	N/A	See footnote 3 and 4 Occurrence based upon complaint analysis

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61-a	Pencil Use	Holster holds pencil	User places pencil with extension nozzle in holster	Product falls on the floor	Delay of procedure	3	1	3	Yes	DFS	NA	Not Practical	Test per protocol ENG-PRT-344	Test report ENG-RPT-401	Test report ENG-RPT-401	3	1	3	No	N/A	See footnote 3 and 4 occurrence based upon complaint analysis
62-a	Pencil Use	Activate electrode on targeted tissue	Pencil with tubing has too much drag	User Fatigue	Delay of procedure	3	3	9	Yes	DFS/ IFS	Swivels are part of the design to reduce drag as well as allowing for different grips, see IFU.	Not Practical	Zip-Pen IFU provides visual guide Test Protocol ENG-PRT-290	Zip IFU, Zip Ace IFU Test Report ENG-RPT-418	Test Report ENG-RPT-418	3	3	9	NA	NA	occurrence based upon complaint analysis
68-a	Pencil Use	Proper use of device per Intended Use	Use of device on main vessels in central circulatory system	Unintended use of device	Bleeding / Hemorrhage	10	1	10	Yes	IFS	See footnote #1	Specify intended user of device	Ensure IFU contains warning about device not being evaluated in the central circulatory system.	IFU contains required statement. Labeling has symbol to consult IFU. CER (RA-RPT-007)	See Footnote #2	10	1	10	No	NA	See Footnote #4
69-a	Pencil Use	Proper use of device per Intended Use	Use of device on the central nervous system	Unintended use of device	Nerve injury- permanent and significant sensory or motor loss that will affect acts of daily living	10	1	10	Yes	IFS	See footnote #1	Specify intended user of device	Ensure IFU contains warning about device not being evaluated in the central nervous system	IFU contains required statement. Labeling has symbol to consult IFU. CER (RA-RPT-007)	See Footnote #2	10	1	10	No	NA	See Footnote #4
70-a	Pencil Use	Proper use of device per Intended Use	User activates energy device near patient's implant (Inadequate filtering/ shielding)	Interference with patient implanted devices (e.g.: pacemaker) during activation	Impedes implant from functioning correctly	10	1	10	Yes	IFS	See footnote #1	Specify intended user of device	Ensure IFU contains warning about device being used with implants.	IFU contains required statement. Labeling has symbol to consult IFU. CER (RA-RPT-007)	See Footnote #2	10	1	10	No	NA	See Footnote #4

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23-a	Button	Pencil activation PRS 1105	Button too small	Sore finger	User dissatisfaction	3	1	3	NA	DFS	Design for adequate button size	NA	Verification protocol ENG-PRT-290 Validation Plan: Protocol ENG-PRT-453	Test report ENG-RPT-418	Report ENG-RPT-557	3	1	3	NA	NA	See footnote 3 and 4
24-a	Pencil Body	Handle of electrosurgical device PRS 1103 PRS 1104	Branding not on product	User not aware of product brand	None	1	1	1	NA	DFS	Design with branding on the product	NA	Verification protocol ENG-PRT-290	Test report ENG-RPT-418	NA	1	1	1	NA	NA	NA
25-a	Cable	Connects the ESU Generator to the Zip pen	Cable in close proximity to other equipment or other equipment cables	Causes electromagnetic interference (EMI) or radio frequency interference (RFI) in other equipment	Disrupt other equipment -customer dissatisfaction	3	3	9	Yes	DFS	See footnote 1	Not Practical	Ensure device meets requirements of IEC 60601-1	Similar cable tested for EMC, see report ENG-RPT-052	Equivalent product tested to IEC 60601-1 Clause 17, see report ENG-RPT-052	3	2	6	No	N/A	See footnote 4
25.5-a	Cable	Connects the Zip pen to the ESU Generator	Cable in close proximity to other equipment or other equipment cables	Causes electromagnetic interference (EMI) or radio frequency interference (RFI) in other equipment	Disrupt other equipment - Customer Dissatisfaction	3	3	9	NA	IFS	Label product as required by standards	Not Practical	Ensure IFU instructs the user on properly positioning cables	IFU instructs user on proper routing of cables. Labelling appropriately restricts the use of the device. Zip IFU	UL EMC Test report ENG-RPT-052	3	3	9	NA	N/A	See footnote 4
26-a	Handpiece Assembly	Allows electrode to be fully inserted Insulates electrode shaft	Practitioner doesn't fully insert electrode into handpiece.	Electrode not fully inserted into handpiece (exposed uninsulated electrode shaft)	Patient or user burns	10	1	10	Yes	IFS	Product designed to IEC 60601-2-2 See footnote 1	Not Practical	Ensure device meets requirements of IEC 60601-1. Ensure IFU instructs the user to fully insert the electrode into the handpiece	Labeling appropriately restricts the use of the device according to standard – IEC 60601-2-2. IFU instructs the user on how to insert the electrode and states to fully insert electrode into the handpiece.	UL Report ENG-RPT-059	10	1	10	No	N/A	See footnote 4

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27-a	Multivac Packaging for Pencil	To maintain sterile barrier protect ES pencil during shipping and storage condition	Ineffective packaging for this application	Product damaged	Patient injury.	10	1	10	Yes	IFS	Product designed to ISO 15223 and IEC 60601-2-2 See footnote 1	Not Practical	Ensure IFU includes instructions to discard if pouch is damaged.	Labeling appropriately restricts the use of the device according to standards ISO 15223	Labeling appropriately restricts the use of the device according to standards ISO 15223	10	1	10	No	N/A	See footnote 4
27.5-a	Multivac Packaging for Pencil	To maintain sterile barrier protect ES pencil during shipping and storage condition	Ineffective packaging for this application	Product damaged	User dissatisfaction	1	1	1	Yes	IFS	Product designed to ISO 15223 and IEC 60601-2-2 See footnote 1	Not Practical	Ensure IFU includes instructions to discard if pouch is damaged.	Labeling appropriately restricts the use of the device according to standards ISO 15223	Labeling appropriately restricts the use of the device according to standards ISO 15223	1	1	1	No	N/A	NA
28-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Using on patient with electronic implant	Interaction with electronic implants	Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
29-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Use device in presence of flammable anesthetics or oxidizing gases or in close proximity to volatile solvents.	Explosion / Fire	User / Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
30-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Use with hybrid trocar	Capacitive coupling	Patient / User injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
31-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Failure to inspect product prior to use	Damaged insulation or cables	Patient / User injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4

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32-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Use device without aspirating fluids from the area.	Activating in conductive fluids	Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
33-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Activate device when not on target tissue resulting in capacitive coupling.	Alternate site injury	Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
34-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Lack of use of protective equipment / lack of smoke evacuation	Smoke inhalation	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	5	1	5	No	N/A	See footnote 4
35-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Attach device to ESU when unit is on.	Burn / Fire / electrical shock	User / Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
36-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	User does not use ESU with CQM and a compatible monitoring neutral electrode, No CQM alarm.	Neutral electrode site burn	Patient Injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	See complaint analysis	10	1	10	No	N/A	See footnote 4

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36.2-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	User does not use ESU with CQM and a compatible monitoring neutral electrode, No CQM alarm.	Reduced electrosurgical effect	User Dissatisfaction	3	1	3	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	See complaint analysis	3	1	3	No	N/A	See footnote 4
36.5-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Insufficient contact of neutral electrode	Neutral electrode site burn	Patient Injury	10	1	10	Yes	IFS	Label product as required by standards	CQM Alarm	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
36.7-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Insufficient contact of neutral electrode	Reduced electrosurgical effect	User Dissatisfaction	3	1	3	Yes	IFS	Label product as required by standards	CQM Alarm	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	3	1	3	No	N/A	See footnote 4
37-a										REDUNDANT CONTENT– SEE 17-A, 17.5-A											
38-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Allow eschar or other material to build up on active electrode.	Reduced electrosurgical effect	Patient injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4
39-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Activating device away from target tissue (such as during cleaning)	Accidental activation	Patient / User injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis	10	1	10	No	N/A	See footnote 4

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40-a	Zip-Pen IFU	Provide information for the user PRS 1701 – 1720, PRS 1901 – 1920	Not following recommended ESU duty cycle and/or RF voltage rating	Hot electrode	Patient / User injury	10	5	50	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059	10	5	50	No	N/A	See footnote 4
63-a	Zip-Pen IFU	Provide information for user	Use Error due to user not reviewing manuals of equipment necessary for use of Zip Pen	Devices used incorrectly	Patient / User Injury	10	1	10	Yes	IFS	See footnote 1 Include caution statement in IFU	Not practical	Ensure labeling includes caution to review ESU, smoke evacuator, neutral, and active electrode use instructions.	Zip IFU, Zip Ace IFU, Labeling appropriately restricts the use of the device and includes caution 2	NA	10	1	10	No	N/A	See footnote 4
41-a	Pencil and Nozzle Extension Labeling	Provide information for the user PRS 1701 – 1720, PRS 1901-1920	Product not labeled per Standards requirement	Use wrong product Use expired product Re-use the product	Patient Injury	10	5	50	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2	See label drawings	Drawings meet Standards - ISO 15223 and IEC 60601-2-2	10	5	50	No	N/A	See footnote 4
42-a	Pencil and Nozzle Extension IFUs	Use Instructions PRS 1001 URS 1001	Intended use not stated in IFU	Improper use of device	Patient Injury	10	1	10	Yes	IFS	Provide proper Instructions, Warnings, and Cautions in IFU according to ISO 15223 and IEC 60601-2-2.	Not Practical	Ensure IFU is compliant with ISO 15223 and IEC 60601-2-2	Labeling appropriately restricts the use of the device. See IFUs: Zip IFU, Zip Ace IFU (pencil) and nozzle extension	Drawings meet Standards - ISO 15223 and IEC 60601-2-2	10	1	10	No	N/A	See footnote 4
43-a	Nozzle Extension (4.0"and 6.5")	Install Nozzle and electrode	Use error, not following IFU	Incorrect Electrode to Nozzle size (Electrode too short)	Cannot do surgery without removing nozzle, delay of surgery	3	1	3	NA	IFS	Put compatibility statement in IFU	NA	Ensure compatibility is in IFU	Zip IFU, Zip Ace IFU	IFU 3000313-01	3	1	3	NA	NA	NA

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44-a	Nozzle Extension (4.0”and 6.5”)	Install Nozzle and electrode	Use error, not following IFU	Incorrect Electrode to Nozzle size (Electrode too long), Poor smoke capture	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	NA	IFS	Put compatibility statement in IFU	NA	Ensure compatibility is in IFU	Zip IFU, Zip Ace IFU	IFU 3000313-01	5	1	5	NA	NA	See footnote 4
45-a	Nozzle Extension (4.0”and 6.5”)	Install Nozzle	Nozzle not correctly installed or fully installed	Nozzle loose or falls off	Nozzle falls into patient	5	1	5	Yes	DFS	Visual and tactile confirmation of correct placement	Not practical	NA	Usability Test Report ENG-RPT-418 identified that nozzle was acceptable and was easy to attach	Usability Test Report ENG-RPT-418	5	1	5	No	N/A	See footnote 3 and 4
45.5-a	Nozzle Extension (4.0”and 6.5”)	Install Nozzle	Nozzle not correctly installed or fully installed	Nozzle loose or falls off	Nozzle falls into patient	5	1	5	Yes	IFS	NA	Not practical	Ensure installation instruction is in IFU Usability Test Protocol ENG-PRT-290	Zip IFU, Zip Ace IFU	Usability Test Report ENG-RPT-418	5	1	5	No	N/A	See footnote 3 and 4
46-a	Nozzle Extension (4.0”and 6.5”)	Install Nozzle	Nozzle not correctly installed or fully installed	Installed upside down or incorrectly	Nozzle falls into patient	5	1	5	Yes	DFS	Visual and tactile confirmation of correct placement	Not practical	NA	Usability Test Report ENG-RPT-418 identified that nozzle was acceptable and was easy to attach	Usability Test Report ENG-RPT-418	5	1	5	No	N/A	See footnote 3 and 4
46.5-a	Nozzle Extension (4.0”and 6.5”)	Install Nozzle	Nozzle not correctly installed or fully installed	Installed upside down or incorrectly	Nozzle falls into patient	5	1	5	Yes	IFS	NA	Not practical	Ensure installation instruction is in IFU Usability Test Protocol ENG-PRT-290	Zip IFU, Zip Ace IFU	Usability Test Report ENG-RPT-418	5	1	5	No	N/A	See footnote 3 and 4
47-a	Nozzle Extension (4.0” and 6.5”)	Install Nozzle and electrode	Use error, not following IFU	Install Nozzle first and cannot get electrode installed properly	Delay of surgery	1	1	1	NA	IFS	IFU gives instructions to install electrode prior to extension Nozzle	NA	Ensure installation instruction is in IFU Usability Test Protocol ENG-PRT-290	Usability Test Report ENG-RPT-418 identified that nozzle was acceptable and was easy to attach	Usability Test Report ENG-RPT-418	1	1	1	NA	NA	NA
48-a	Use pencil with extension nozzle	Perform electrosurgery with extension nozzle	Use error	Nozzle used for more than 1 procedure	Patient infection	10	5	50	Yes	IFS	Product designed to ISO 15223 and IEC 60601-2-2 See footnote 1	Not practical	Verify labeling designates nozzle as single use	Labeling appropriately restricts the use of the device according to standards ISO 15223	Labeling appropriately restricts the use of the device according to standards ISO 15223	10	5	50	No	N/A	See footnote 4

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49-a	Use pencil with extension nozzle	Attach nozzle	Use error Nozzle attached with foreign material	Decreases visibility Product damage Reduced smoke evacuation	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	NA	IFS	NA	NA	Verify labeling restricts the use to physicians and includes caution to not use foreign material to secure nozzle	Labeling cautions not to secure nozzle with foreign material	NA	5	1	5	NA	NA	See footnote 4
50-a	Use ULPA filter	Use filter to filter smoke PRS 1201 PRS 1202	Use error. Improper use of filter	Filter clogged (with fluid and/or tissue) Filter operation affected by environmental conditions	User dissatisfaction	1	1	1	NA	IFS	NA	NA	Ensure IFU cautions user not to use filter as primary fluid / tissue collector Ensure IFU includes shipping, storage, and use conditions	IFU	IFU 3000190-01	1	1	1	NA	NA	NA
51-a	Use ULPA filter	Use filter to filter smoke	Use error. Did not put cap on.	Biohazard materials spill out of ULPA filter during disconnection or disposal.	Potential for biohazard exposure	10	1	10	Yes	DFS	Connector designed above fluid level. Cap provided for used filter.	Clear material design provides visual indication of fluid presence.	Verify design provides connector above fluid level, the material is clear and the cap is provided	ENG-RPT-418 Usability Report	NA	10	1	10	No	N/A	See footnote 4
51.5-a	Use ULPA filter	Use filter to filter smoke	Use error. Did not put cap on.	Biohazard materials spill out of ULPA filter during disconnection or disposal.	Potential for biohazard exposure	10	1	10	Yes	IFS	NA	NA	Ensure IFU cautions user to install cap prior to disposal.	IFU	IFU	10	1	10	No	N/A	See footnote 4
52-a	Use filters (ULPA/ Charcoal filter)	Use to filter smoke PRS 1114	Use of damaged filters	Filter does not attach. Does not work properly.	User dissatisfaction	1	1	1	NA	IFS	Include instructions in IFU to not use damaged filter	NA	Ensure IFU cautions against use of damaged filters	See IFU	NA	1	1	1	NA	NA	NA

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53-a	Use filters (ULPA/ Charcoal filter)	Use to filter smoke	Cleaning or otherwise sterilizing filters	Damaged filters	User dissatisfaction	1	1	1	NA	IFS	Include instructions in IFU to not clean or otherwise sterilize filters	NA	Ensure IFU cautions against cleaning or otherwise sterilizing filters	See IFU	NA	1	1	1	NA	NA	NA
54-a	Charcoal Filter	Filter odors and residual chemicals PRS 1318	Overuse of filter	Charcoal absorption depleted	Odor/chemical removal inadequate, User dissatisfaction	1	1	1	NA	IFS	Source from approved supplier Identify requirements for replacement in IFU	NA	Ensure IFU restricts to use by physician and includes instruction on conditions that require filter change.	Required information contained in the IFU	NA	1	1	1	NA	NA	NA
55-a	ULPA and Charcoal Filter Labeling	Provide information for the user PRS 1721 – 1733, PRS 1921 – 1935	Product not labeled per Standards requirement	Use wrong product Re-use the product	User injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings	UL Test Report ENG-RPT-059, See complaint analysis.	10	1	10	No	N/A	See footnote 4
56-a	RF Sensor	Detect Pencil Activation	Defective / damaged sensor Not properly installed/ connected to unit or pencil	Not sensing activation	Customer dissatisfaction	1	1	1	NA	DFS	Design, material selection, and in process inspection See footnote 1	NA	Verify certificate of conformance is required on receipt	Drawing requires Certificate of Conformance	NA	1	1	1	NA	NA	NA
56.5-a	RF Sensor	Detect Pencil Activation	Defective / damaged sensor Not properly installed/ connected to unit or pencil	Not sensing activation	Customer dissatisfaction	1	1	1	NA	IFS	Provide information to user See footnote 1	NA	Verify IFU includes installation instruction	IFU ICM-001-0866 includes instruction	NA	1	1	1	NA	NA	NA
57-a	Handpiece Assembly	Provide information for user	Supplier defect Use Error	Cut/Coag buttons fall out, Fractures or pieces breakoff, etc.	Patient/User Injury	10	1	10	Yes	DFS	Design, material selection, and in process inspection See footnote 1	Not Practical	Ensure device meets IEC 60601-2-2 Verify certificate of conformance is required on receipt	Drawing requires Certificate of Conformance	UL Test Report ENG-RPT-059 See footnote 2	10	1	10	No	N/A	See footnote 3 and 4

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57.2-a	Handpiece Assembly	Provide information for user	Supplier defect Use Error	Device damage such as Cracked or damaged components	Customer dissatisfaction	1	1	1	Yes	DFS	Design, material selection, and in process inspection See footnote 1	Not Practical	Ensure device meets IEC 60601-2-2 Verify certificate of conformance is required on receipt	Drawing requires Certificate of Conformance	UL Test Report ENG-RPT-059 See footnote 2	1	1	1	No	N/A	See footnote 3 and 4
57.5-a	Handpiece Assembly	Provide information for user	Supplier defect Use Error	Cut/Coag buttons fall out, Fractures or pieces breakoff, etc.	Patient / User Injury	10	1	10	Yes	IFS	Provide information to user See footnote 1	Not Practical	Verify IFU includes proper use instruction including to inspect for damage	IFU & ICM-001-0866 includes instructions	UL Test Report ENG-RPT-059 See footnote 2	10	1	10	No	N/A	See footnote 3 and 4
57.7-a	Handpiece Assembly	Provide information for user	Supplier defect Use Error	Device damage such as Cracked or damaged components	Customer dissatisfaction	1	1	1	Yes	IFS	Provide information to user See footnote 1	Not Practical	Verify IFU includes proper use instruction including to inspect for damage	IFU & ICM-001-0866 includes instructions	UL Test Report ENG-RPT-059 See footnote 2	1	1	1	No	N/A	See footnote 3 and 4
64-a	Electrode	Electrode removal	Unable to grasp electrode to remove electrode for the purpose of swapping in a different electrode type	Electrode stuck in Zip Pen	Delay of surgery	3	5	15	Yes	DFS	Use of common tools found in surgical suite	NA	ENG-PRT-452	NA	ENG-RPT-559	3	1	3	No	NA	See footnote 3 and 4, Occurrence based on complaints analysis

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65-a	Electrode	Electrode removal	Re-inserting or adjusting electrode after removal with a tool	Significant coating / insulation damage, resulting in significant eschar build up and reduced surgical effect	Patient Injury	10	1	10	Yes	IFS	Label product as required by standards	Not Practical	Ensure label drawings meet Standards - ISO 15223 and IEC 60601-2-2 Validation Plan: Monitor customer complaints	See label drawings Zip IFU, Zip Ace IFU	UL Test Report ENG-RPT-059, See complaint analysis.	10	1	10	NA	NA	See footnote 4 Occurrence based on complaints analysis
66-a	Electrode	Electrode removal	Re-inserting or adjusting electrode after removal with tool	Electrode bent past 60 degrees	Patient / User injury	10	1	10	Yes	IFS	See footnote 1 Include caution statement in IFU	Not practical.	Zip IFU 3000312-01, Zip Ace IFU 3000317-01	Zip IFU, Zip Ace IFU	NA	10	1	10	No	N/A	See footnote 4 Occurrence based on complaints analysis
67-a	Electrode	Electrode removal	Removing electrode with metal instrument	Activating while removing with metal instrument	User injury	10	1	10	Yes	IFS	Caution statement in IFU	Not practical.	Zip IFU 3000312-01, Zip Ace IFU 3000317-01 Caution 9	Zip IFU, Zip Ace IFU	NA	10	1	10	No	N/A	See footnote 4 Occurrence based on complaints analysis
71-a	Perform Electrosurgery	Proper use of device per Intended Use	Use of Electrosurgery - Do not activate in contact with Metal instrument or device	Unintended monopolar energy is applied to critical structure	Patient / User injury (burn)	10	1	10	Yes	IFS	See footnote 1	Specify intended user of device	Ensure labeling restricts use to physicians familiar with electrosurgery Verify potential distraction for user relative to printed image on electrode insulation & Ensure IFU specifies electrode to be in contact or in close proximity to target tissue prior to activation	IFU contains required statement. Labeling has symbol to consult IFU. CER (SCN070741)	See Footnote 2	10	1	10	No	NA	See footnote 4

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Zip-Pen DESIGN FMEA

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1-d	Circuit Board	Cut mode activates when distal switch depressed PRS 1101 PRS 1402 PRS 1403 PRS 1409 PRS 2001	Incorrect tracings on circuit board. Incorrect cable lead position on circuit board	Coag mode activated when distal (cut) switch depressed (will not cut properly)	Practitioner dissatisfaction, wrong effect, patient tissue damage	5	5	25	Yes	DFS	Material and supplier selection and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	5	1	5	No	N/A	See footnote 3 and 4
2-d	Circuit Board	Coag mode activates when proximal switch depressed PRS 1101 PRS 1402 PRS 1403 PRS 1409 PRS 2001	Incorrect tracings on circuit board. Incorrect cable lead position on circuit board.	Cut mode activated when proximal (coag) switch depressed (will not coag properly)	Practitioner dissatisfaction, wrong effect	5	5	25	Yes	DFS	Material and supplier selection and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	5	1	5	No	N/A	See footnote 3 and 4
3-d	Circuit Board	Coag mode activates when proximal switch depressed PRS 1101 PRS 1402 PRS 1403 PRS 1409 PRS 2001	Cable leads not connected to circuit board properly	Both “cut” and “coag” modes activate simultaneously or unintentional/ self-activation	Practitioner dissatisfaction, wrong effect	5	5	25	Yes	DFS	Material and supplier selection and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	5	1	5	No	N/A	See footnote 3 and 4

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3.5-d	Circuit Board	Coag mode activates when proximal switch depressed PRS 1101 PRS 1402 PRS 1403 PRS 1409 PRS 2001	Cable leads not connected to circuit board properly	Self-activation	Patient injury	10	5	50	Yes	DFS	Material and supplier selection and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	10	1	10	No	N/A	See footnote 3 and 4
4-d	Circuit Board	Deliver current from ESU to electrode. PRS 1101 PRS 1402 PRS 1403 PRS 1409 PRS 2001	Incorrect tracings on circuit board.	No ES current at electrode (inoperable unit)	Practitioner dissatisfaction (inconvenience), Delay of surgery	3	1	3	NA	DFS	Material and supplier selection and product validation	NA	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	3	1	3	NA	NA	NA
5-d	Dome Switches	Activate ESU to provide signal to electrode Provide tactile response to user PRS 1101 PRS 1301 PRS 2001	Incorrect geometry (or material type) of dome switch	Switches too hard to depress	User dissatisfaction	1	1	1	NA	DFS	Material and supplier selection and product validation	NA	Verify button force is validated, include button force test in Mechanical Protocol	Mechanical Test Report ENG-RPT-329 Dome Switch Force Test Report 500433702	Mechanical Test Report ENG-RPT-329 Use Test Report ENG-RPT-779	1	1	1	NA	NA	NA
6-d	Dome Switches	Activate ESU to provide signal to electrode Provide tactile response to user PRS 1101 PRS 1301 PRS 2001	Incorrect geometry (or material type) of dome switch	Switches too soft (no tactile response, but operable)	User dissatisfaction	1	1	1	NA	DFS	Material and supplier selection and product validation	NA	Verify button force is validated, include button force test in Mechanical Protocol	Mechanical Test Report ENG-RPT-329 Dome Switch Force Test Report 500433702	Mechanical Test Report ENG-RPT-329 Same design as disposable pencils, see footnote 2 Use Test Report ENG-RPT-779	1	1	1	NA	NA	NA

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7-d	Dome Switches	Activate ESU to provide signal to electrode Provide tactile response to user PRS 1101 PRS 1301 PRS 2001	Incorrect geometry (or material type) of dome switch	Switches too soft (always activated)	Potential user or patient injury	10	5	50	Yes	DFS	Material and supplier selection and product validation	Not Practical	Verify button force is validated, include button force test in Mechanical Protocol	Mechanical Test Report ENG-RPT-329 Dome Switch Force Test Report 500433702	Mechanical Test Report ENG-RPT-329 Same design as disposable pencils, see footnote 2 Use Test Report ENG-RPT-779	10	1	10	No	N/A	See footnote 3 and 4
8-d	Dome Switches	Activate ESU to provide signal to electrode Provide tactile response to user PRS 1101 PRS 1301 PRS 2001	Incorrect geometry (or material type) of dome switch	Switches fail during surgery	Patient Injury	10	5	50	Yes	DFS	Material and supplier selection and product validation	Not Practical	Verify button force is validated, include button force test in Mechanical Protocol	Mechanical Test Report ENG-RPT-329 Dome Switch Force Test Report 500433702	Mechanical Test Report ENG-RPT-329 Same design as disposable pencils, see footnote 2	10	1	10	No	N/A	See footnote 3 and 4
9-d	Electrical Connection/ Collet	Provide secure mechanical and electrical connection for electrode PRS 1101 PRS 1302 PRS 1306 PRS 2001 URS 1002	Collet diameter out of tolerance	Electrode falls out (possibly during procedure)	Foreign object in patient (potential injury)	10	5	50	Yes	DFS	Material and supplier selection and product validation	Detect electrode under X-Ray	Validate collet retention force per standards.	Mechanical Test Report ENG-RPT-329	Tested to IEC 60601-2-2 clause 201.15.4.1.012	10	1	10	No	N/A	See footnote 3 and 4
10-d	Electrical Connection/ Collet	Provide secure mechanical and electrical connection for electrode PRS 1101 PRS 1107 PRS 1302 PRS 1303 PRS 1306 PRS 2001 URS 1002	Loose Collet, electrode not installed properly	Electrode falls out (possibly during procedure), electrode falls on floor (becomes non-sterile), no electrical contact	Delay of surgery	1	1	1	NA	DFS	Design, material and supplier selection and product validation	NA	Validate collet retention force per standards	Mechanical Test Report ENG-RPT-329	Tested to IEC 60601-2-2 clause 201.15.4.1.012	1	1	1	NA	NA	NA

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11-d	Electrical Connection/ Collet	Provide secure mechanical and electrical connection for electrode PRS 1101 PRS 1302 PRS 1303 PRS 1306 PRS 1319 PRS 1409 PRS 2001	Insufficient contact area between electrode and electrical connector.	Pencil overheats and melts	Potential user or patient injury	10	5	50	Yes	DFS	Material and supplier selection and design, product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Thermal Test Report ENG-RPT-395 Fluid Ingress Test Report 500433702	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Tested to IEC 60601-2-2 clause 201.11.6.5 b and IEC 60601-1 Clause 11.1.2.2	10	1	10	No	N/A	See footnote 3 and 4
12-d	Electrical Connection/ Collet	Provide secure mechanical and electrical connection for electrode PRS 1101 PRS 1302 PRS 1303 PRS 1306 PRS 1409 PRS 2001	Detached or damaged collet	No continuity	Practitioner dissatisfaction	1	1	1	NA	DFS	Material and supplier selection and design, product validation	NA	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555 Tested to IEC 60601-2-2 clause 201.11.6.5 b	1	1	1	NA	NA	NA
13-d	Buttons / Rocker	User interface for ESU activation on the pencil PRS 1106	Incorrect production or assembly	Both switches are the same color	User dissatisfaction	1	1	1	NA	DFS	Part designed for two shot color. Designed for oriented assembly. With yellow button nearest the active electrode	NA	Design does not allow buttons to be assembled incorrectly	Drawing 5800097-01, 6020190-01 and 6020191-01	NA	1	1	1	NA	NA	NA

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14-d	Buttons / Rocker	User interface for ESU activation on the pencil PRS 1101 PRS 2001	Switch components binding	ES pencil remains activated after switch is released.	Potential user or patient injury	10	5	50	Yes	DFS	Design for proper clearances Material and supplier selection and product validation	Not Practical	Verify button force is validated	Mechanical test report ENG-RPT-329	Mechanical test report ENG-RPT-329	10	1	10	No	N/A	See footnote 3 and 4
15-d	Pencil Nozzle	Provides port for smoke capture PRS 1101 PRS 1108 PRS 1304 PRS 1501 PRS 1502 PRS 1503 PRS 2001 URS 1007	Incorrect design or material Not a gamma stable material Opaque nozzle Inadequate design for flow	Fractures leaving material in patient Falls off into patient	Foreign body reaction or additional surgical intervention, patient injury	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test for mechanical strength Test for flow volume	Mechanical test report ENG-RPT-329	Tested per ISO 10993-1:2009 clauses 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-327 See test report ENG-RPT-329	10	1	10	No	N/A	See footnote 3 and 4
15.5-d	Pencil Nozzle	Provides port for smoke capture PRS 1101 PRS 1108 PRS 1304 PRS 1501 PRS 1502 PRS 1503 PRS 2001 URS 1007	Incorrect design or material Not a gamma stable material Opaque nozzle Inadequate design for flow	Transparency obstructs surgeons view Air flow not adequate, poor smoke evacuation	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	Yes	DFS	Design, material selection, and product validation	Not Practical	Test for mechanical strength Test for flow volume	Mechanical test report ENG-RPT-329	Tested per ISO 10993-1:2009 clauses 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-327 See test report ENG-RPT-329	5	1	5	No	N/A	See footnote 3 and 4
16-d	Housing / Handle	“Splash proof” – protect internal components from splashed liquids PRS 1101 PRS 1409 PRS 2001	Fluid enters housing, causing short circuits to internal components	Self-activation (without switches pressed)	Potential user or patient injury	10	5	50	Yes	DFS	Design specifies material and assembly to prevent fluid ingress	Not Practical	Ensure that material requirements and assembly are defined. The test for fluid ingress will be performed as part of product validation. ENG-PRT-439	Material and assembly requirements are defined on drawing. Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	10	1	10	No	N/A	See footnote 3 and 4

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63-d	Housing / Handle	"Splash proof" – protect internal components from splashed liquids PRS 1101 PRS 1409 PRS 2001	Fluid enters housing	Device circuit non-functional	Delay of surgery	3	1	3	Yes	DFS	Design specifies material and assembly to prevent fluid ingress	Not practical	Ensure that material requirements and assembly are defined. The test for fluid ingress will be performed as part of product validation. ENG-PRT-439	Material and assembly requirements are defined on drawing. Fluid Ingress Test Report ENG-RPT-555 Fluid Ingress Test Report 500433702	Tested to IEC 60601-2-2 clause 201.11.6.5 b	3	1	3	No	NA	See footnote 3 and 4
17-d	Housing / Handle	Electrical connection from cable to electrode Electrically insulates external surfaces from internal conductors. PRS 1101 PRS 1407 PRS 1408 PRS 2001	Insufficient amount and/or dielectric strength of housing material, or inner conductors too close to housing walls.	Burn holes through housing	Potential user or patient injury	10	5	50	Yes	DFS	Handpiece design, material and supplier selection and product validation	Not Practical	Ensure that material requirements and assembly are defined. The test for dielectric withstand will be performed as part of product validation.	Material and assembly requirements are defined on drawing. Dielectric Test Reports ENG-RPT-328 and ENG-RPT-412. Verified post EO sterilization in test report ENG-RPT-476 Dielectric Test Report 500433702	IEC 60601-2-2 Clauses 201.8.8.3.103 and .104 UL Test Report ENG-RPT-059 See test reports ENG-RPT-328, ENG-RPT-412, and ENG-RPT-476.	10	1	10	No	N/A	See footnote 3 and 4
18-d	Electrode	Connects to the distal end of the pencil body and provides electrosurgical activation at the tissue interface PRS 1101 PRS 1102 PRS 1601 PRS 1603 PRS 1604 PRS 1803 PRS 2001	Electrode punctures the cap which then punctures package	Electrode punctures package	Patient infection	10	5	50	Yes	DFS	Application of industry standards to package design	Not Practical	Test pouches after sterilization and shipping	Shipping test reports ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-535, and ENG-RPT-585	Tested per ISO 11607-1 See test reports ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-535, and ENG-RPT-585	10	1	10	No	N/A	See footnote 3 and 4

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19-d	Electrode	Connects to the distal end of the pencil body and provides electrosurgical activation at the tissue interface	**SEE ANY AND ALL ELECTRODE RISK ANALYSIS DOCUMENTS, SUCH AS: E-Z Clean Electrodes Risk Analysis (ENG-RMF-008) ACE Blade User FMEA (ENG-RMF-009) ACE Process FMEA (PROP-RMF-003) ACE Blade Design FMEA (PROP-RMF-004) Resposable and LERIS Risk Analysis (ENG-RMF-010) LLETZ Loops FMEA (ENG-RMF-012) SS Electrode Risk Analysis (ENG-RMF-016)**																			
20-d	Cable	Connects the ESU plug connectors to the PCB of the Pencil Body Electrical and mechanical wire protection PRS 1101 PRS 1307 PRS 1308 PRS 1309 PRS 1404 PRS 1405 PRS 1406 PRS 2001	Insufficient wire insulation Insufficient cable strain relief in pencil.	Shock or burn to user	Patient or user injury	5	5	25	Yes	DFS	Design, material selection, and product validation Design and test Cable Strain Relief to meet standard	Not Practical	Test dielectric properties of cable during validation Check strain relief properties of cable during validation	Dielectric Withstand Test Report ENG-RPT-328 and ENG-RPT-412 Mechanical Test Report ENG-RPT-329. Dielectric and Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	IEC 60601-2-2 Clauses 201.8.8.3.102, .103, .104 & 201.8.10.4.2 See test reports ENG-RPT-328, ENG-RPT-412 and ENG-RPT-329. Dielectric and Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	5	1	5	No	N/A	See footnote 3 and 4

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21-d	Cable	Connects the ESU plug connectors to the PCB of the Pencil Body Electrical and mechanical wire protection PRS 1101 PRS 1110 PRS 1307 PRS 1308 PRS 1309 PRS 2001	Incorrect wire insulation Insufficient cable strain relief in pencil	Cable pulled from handpiece, possibly exposing bare conductors	Practitioner and/or patient injury	5	5	25	Yes	DFS	Design cable inside of tubing for first 64", material selection, and product validation Design and test Cable Strain Relief to meet standard	Not Practical	Check strain relief properties of cable during validation	Mechanical Test Report ENG-RPT-329, and ENG-RPT-418. Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	IEC 60601-2-2 Clause 201.8.10.4.2 See test reports ENG-RPT-329, and ENG-RPT-418. Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	5	1	5	No	N/A	See footnote 3 and 4
22-d	Cable	Connects the ESU plug connectors to the PCB of the Pencil Body Electrical and mechanical wire protection PRS 1101 PRS 1307 PRS 1308 PRS 1309 PRS 2001	Incorrect geometry of cable / pencil housing junction and/or incorrect cable material resulting in damaged cord	Open circuit and / or intermittent connection	Delay of surgery	5	5	25	Yes	DFS	Design, material selection, and product validation	Not Practical	Check strain relief properties of cable during validation	Mechanical Test Report ENG-RPT-329. Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	IEC 60601-2-2 Clause 201.8.10.4.2 See test report ENG-RPT-329. Mechanical requirements met post EO sterilization. See test report ENG-RPT-452	5	1	5	No	N/A	See footnote 3 and 4
23-d	Cable	Connects the ESU plug connectors to the PCB of the Pencil Body Electrical and mechanical wire protection	Cable in close proximity to other equipment or other equipment cables	Causes electromagnetic interference (EMI) or radio frequency interference (RFI) in other equipment	Disrupt other equipment	5	5	25	Yes	DFS	Cables are designed to meet requirements for HF applications	Not Practical	Ensure device meets requirements of IEC 60601-1.	Similar cable tested for EMC, see report ENG-RPT-052	Tested to IEC 60601-1 Clause 17, see report ENG-RPT-052	5	1	5	No	N/A	See footnote 3 and 4

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24-d	Plug	Electrical connection between ESU and pencil cable PRS 1101 PRS 1401 PRS 1409 PRS 2001	Cable leads not connected to plug pins	No ES current at electrode (inoperable unit)	Practitioner dissatisfaction (inconvenience)	1	1	1	NA	DFS	Design, material selection, and product validation	NA	Check cut and coag continuity, prior to and after plug strain relief test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555	IEC 60601-2-2 Clauses 201.8.8.3.104 and 201.11.6.5 b See test reports ENG-RPT-329 and ENG-RPT-555	1	1	1	NA	NA	NA
25-d	Plug	Electrical connection between ESU and pencil cable PRS 1101 PRS 1310 PRS 1401 PRS 2001	Plug pin(s) broke off in generator socket	Unable to plug in connector	Practitioner dissatisfaction (inconvenience)	1	1	1	NA	DFS	Design and material selection	NA	Ensure that material requirements and assembly are defined	Mechanical Test Report ENG-RPT-329	IEC 60601-2-2 Clause 201.8.8.3.104 See test report ENG-RPT-329	1	1	1	NA	NA	NA
26-d	Plug	Electrical connection between ESU and pencil cable PRS 1101 PRS 1401 PRS 1409 PRS 2001	Incorrect wire connections to plug pins Pin or cable resistance too high (does not activate ESU)	No ES current at electrode (inoperable unit)	Patient injury Practitioner dissatisfaction	5	5	25	Yes	DFS	Design, material selection, and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555	IEC 60601-2-2 Clauses 201.8.8.3.104 & 201.11.6.5 b See test reports ENG-RPT-329 and ENG-RPT-555	5	1	5	No	N/A	See footnote 3 and 4
27-d	Plug	Electrical connection between ESU and pencil cable PRS 1101 PRS 1310 PRS 1401 PRS 1409 PRS 2001	Cable leads not connected to correct plug pins Plug pins broke off in generator	cut switch activates coag or coag switch activates cut	Practitioner dissatisfaction, wrong effect	5	5	25	Yes	DFS	Design, material selection, and product validation	Not Practical	Check cut and coag continuity, prior to and after cable flex test and fluid ingress test during validation	Mechanical Test Report ENG-RPT-329 Fluid Ingress Test Report ENG-RPT-555	IEC 60601-2-2 Clauses 201.8.8.3.104 & 201.11.6.5 b See test reports ENG-RPT-329 and ENG-RPT-555	5	1	5	No	N/A	See footnote 3 and 4

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28-d	Plug	Electrical connection between ESU and pencil cable	Exposed pins of plug not fully inserted into the ES generator.	Exposed plug pins at ES generator.	User burn	5	5	25	Yes	DFS	Generators that comply with IEC 60601-1 are required to prevent electrical contact if pins are accessible	Not Practical	Ensure material, assembly, and inspection requirements are defined.	UL Testing to IEC 60601-1 and IEC 60601-2-2	CB Test Report ENG-RPT-059	5	1	5	No	N/A	See footnote 3 and 4
28.5-d	Plug	Electrical connection between ESU and pencil cable	Exposed pins of plug not fully inserted into the ES generator.	Exposed plug pins at ES generator.	User burn	5	5	25	Yes	IFS	Generators that comply with IEC 60601-1 are required to prevent electrical contact if pins are accessible	Not Practical	Ensure IFU instructs the user to fully insert the plug into the ESU	Zip IFU 3000312 01, Zip Ace IFU 3000317 01	NA	5	5	25	No	N/A	See footnote 3 and 4
29-d	Plug	Electrical connection between ESU and pencil cable PRS 1101 PRS 1310 PRS 2001 URS 1004	Wrong pin design or wrong ESU socket	Difficult to insert in ES generator Too loose – won't stay plugged in	Delay of procedure	1	1	1	NA	DFS	Design plug to be compatible with Megadyne and other common ESU's	NA	Test insertion / extraction force in Mechanical Protocol ENG-PRT-228	Mechanical Test Report ENG-RPT-329	See test report ENG-RPT-329	1	1	1	NA	NA	NA
30-d	Convoluted Tubing	Lightweight / strong tubing to convey smoke from handpiece to smoke evac unit PRS 1101 PRS 2001 URS 1008 URS 2001 URS 1005	Improper tubing material specified	Disconnects from fitting Tubing web tears, No smoke collection	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	Yes	DFS	Design, material selection, and product validation	NA	Test mechanical pull strength of tubing from connectors	Mechanical Test Report ENG-RPT-329 Tubing verified to maintain integrity post EO sterilization and after 3 yr. accelerated aging per ENG-PRT-466	See test report ENG-RPT-329 and ENG-RPT-585	5	1	5	NA	NA	See footnote 3 and 4

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31-d	Swivel Connectors	Swivel to increase mobility of pencil body for ease of use PRS 1101 PRS 2001 URS 2001 URS 1005	Incorrect tubing design or material	Disconnects from pencil or tubing, poor smoke collection	Possible user exposure to potential carcinogens and infectious by-products	5	1	5	Yes	DFS	Design and material selection	NA	Test mechanical pull strength of tubing from swivel	Mechanical Test Report ENG-RPT-329 Tubing verified to maintain integrity post EO sterilization and after 3 yr. accelerated aging per ENG-PRT-466	See test report ENG-RPT-329 and ENG-RPT-585	5	1	5	NA	NA	See footnote 3 and 4
32-d	Proximal Filter Connector	Designed for connection to a variety of smoke boxes PRS 1101 PRS 2001 URS 2001	Customer does not use Megadyne smoke evacuator	Connector does not fit or disconnects easily, poor smoke collection	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design universal Connector or provide adapter	Not Practical	Test with protocol	Mechanical Test Report ENG-RPT-329	See test report ENG-RPT-329	5	1	5	No	N/A	See footnote 3 and 4
33-d	Tubing Connector	Designed for connection to a variety of smoke boxes PRS 1101 PRS 2001 URS 2001	Improper set-up	Connector compatible with other equipment, No smoke collection	Possible user exposure to potential carcinogens and infectious by-products, Customer dissatisfaction	5	1	5	NA	DFS	Design Connector to industry standards accepted	NA	Compare to predicate.	Mechanical Test Report ENG-RPT-329	See test report ENG-RPT-329	5	1	5	NA	NA	See footnote 3 and 4
34-d	Pencil Assembly	Sterile electrosurgical instrument PRS 1101 PRS 1501 PRS 1502 PRS 1503 PRS 1504 PRS 2001	Materials not biocompatible	Patient reaction	Patient injury/ Infection/ reaction	10	5	50	Yes	DFS	Material selection	Not Practical	Ensure material requirements are defined. Biocompatibility testing	Biocompatibility Test Report ENG-RPT-337	Tested per ISO 10993-1:2009 clauses 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-337	10	1	10	No	N/A	See footnote 3 and 4

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35-d	Pencil Assembly	Sterile electrosurgical instrument PRS 1101 PRS 1402 PRS 1403 PRS 1404 PRS 1405 PRS 1407 PRS 1408 PRS 2001	Materials have insufficient insulation properties after sterilization	Adversely affected by Gamma and Pencil housing and/or cable material breaks down	Patient or user gets burned	10	5	50	Yes	DFS	Design and material selection to withstand gamma	Not Practical	Test product for dielectric withstand after sterilization	Dielectric Test report ENG-RPT-328 and ENG-RPT-412 Dielectric Test Report 500433702	IEC 60601-2-2 Clauses 201.8.8.3.102, .103, .104, & 201.8.10.4.2 See test report ENG-RPT-338 and ENG-RPT-412	10	1	10	No	N/A	See footnote 3 and 4
35.1-d	Pencil Assembly	Sterile electrosurgical instrument PRS 1101 PRS 1402 PRS 1403 PRS 1404 PRS 1405 PRS 1407 PRS 1408 PRS 2001	Materials have insufficient insulation properties after sterilization	Adversely affected by EtO and Pencil housing and/or cable material breaks down	Patient or user gets burned	10	5	50	Yes	DFS	Design and material selection to withstand gamma	Not Practical	Test product for dielectric withstand after sterilization	Dielectric Test report ENG-RPT-452 (Cable) and ENG-RPT-476 (Housing and Holster) Dielectric Test Report 500433702	IEC 60601-2-2 Clauses 201.8.8.3.102, .103, .104, & 201.8.10.4.2 See test report ENG-RPT-452 (Cable) and ENG-RPT-476 (Housing and Holster)	10	1	10	No	N/A	See footnote 3 and 4
36-d	Pencil Assembly	Sterile electrosurgical instrument PRS 1101 PRS 2001	Sterilization Validation not performed on worst case configuration	Bioburden	Patient reaction	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test 15 ft. assembly as worst case for bioburden.	See Sterilization Validation test reports in DHF See DHF: Gamma Sterilization: New Dean Protocol P170829-E. EtO Sterilization: ENG-PRT-435, ENG-PRT-493, and ENG-PRT-489	ISO 11137-2 See test reports in DHF See DHF: Gamma Sterilization: New Dean Report: R171106-E EtO Sterilization: ENG-RPT-545, ENG-RPT-593, and ENG-RPT-594	10	1	10	No	N/A	See footnote 3 and 4

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37-d	Finished Device Assembly	Designed for smoke removal from the surgical site. PRS 1101 PRS 1311 PRS 2001	Improper flow path design	Does not remove smoke adequately	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design and product validation	Not Practical	Test with protocol	Mechanical Test Report ENG-RPT-329	See test report ENG-RPT-329	5	1	5	No	N/A	See footnote 3 and 4
38-d	Holster	Attaches securely to drape. Holds ES pencil when not in use Protects patient from burns when ES pencil is accidentally activated.	Inadequate design of drape attachment feature	Holster disconnects from drape and pencil falls on floor	Customer dissatisfaction Delay of surgery	3	5	15	Yes	DFS	Design to specification	Not Practical	Ensure design requirements are defined.	Holster design requirements are defined in drawing 5800100-01	N/A	3	1	3	No	N/A	See footnote 3 and 4
39-d	Holster	Attaches securely to drape. Holds ES pencil when not in use Protects patient from burns when ES pencil is accidentally activated. PRS 1101 PRS 2001	Inadequate dielectric strength of holster	Holster does not protect patient from accidental activations (when ES pencil stored in holster).	Patient burns	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test dielectric strength of holster per protocol	Dielectric Test report ENG-RPT-328, ENG-RPT-412, and ENG-RPT-476, Drawing: 5800100-01	See test report ENG-RPT-328 and ENG-RPT-412	10	1	10	No	N/A	See footnote 3 and 4
40-d	NOT USED																				
41-d	Holster	Holster holds pencil PRS 1109	Incorrect design	Product falls on the floor	Delay of procedure	3	5	15	Yes	DFS	Design for use and ensure color is Pantone 427, and Validation test	Not Practical	Test per protocol ENG-PRT-344	Test report ENG-RPT-401, drawing 5800100-01	Test report ENG-RPT-401	3	1	3	No	N/A	See footnote 3 and 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
42-d	Pencil Multivac Packaging	To maintain sterile barrier protect ES pencil during shipping and storage condition PRS 1101 PRS 1102 PRS 1601 PRS 1603 PRS 1604 PRS 1803 PRS 2001	Ineffective packaging for this application	Product unsterile (sterile barrier broken) Holes in packaging	Patient infection	10	5	50	Yes	DFS	Material Selection	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229, ENG-PRT-425, and ENG-PRT-441	Material requirements are defined in drawing 2525-10, 2525-15, 2525-10EC, 2525-15EC, ME7251E, ME7251C, ME725M1C, and ME725M1E. See ENG-DMR-012 See test report ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-546, and ENG-RPT-535 (EtO Sterilization)	Tested per ISO 11607-1, see test report ENG-RPT-330, ENG-RPT-413, ENG-RPT-546, and ENG-RPT-535 (EtO Sterilization).	10	1	10	No	N/A	See footnote 3 and 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
42.5-d	Pencil Multivac Packaging	To maintain sterile barrier protect ES pencil during shipping and storage condition PRS 1101 PRS 1102 PRS 1601 PRS 1603 PRS 1604 PRS 1803 PRS 2001	Ineffective packaging for this application	Product damaged	User dissatisfaction	1	5	5	Yes	DFS	Material Selection	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229, ENG-PRT-425, and ENG-PRT-441	Material requirements are defined in drawing See ENG-DMR-0122525-10, 2525-15, 2525-10EC, 2525-15EC, ME7251E, ME7251C, ME725M1C, and ME725M1E. See test report ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-546, and ENG-RPT-535 (EtO Sterilization)	Tested per ISO 11607-1, see test report ENG-RPT-330, ENG-RPT-413, ENG-RPT-546, and ENG-RPT-535 (EtO Sterilization).	1	1	1	No	N/A	NA

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
43-d	Inner bag/pouch	To contain and protect product	Inner bag/pouch opens unexpectedly	Product is contaminated	Unusable product delay of surgery	3	5	15	Yes	DFS	Design bag flap to be on the pouch side so flap stays in the package when peeled open	Not Practical	Ensure design requirements are defined. See ENG-PRT-425 and ENG-PRT-441	Material requirements are defined in drawings See ENG-DMR-012 2525-10, 2525-15, 2525-10EC, 2525-15EC, 2525-10BN, and 2525-10ECBN. For ME7251E, and ME7251C See ENG-RPT-546. For ME725M1E and ME725M1C See ENG-RPT-535.	Test report ENG-RPT-546 and ENG-RPT-535	3	1	3	No	N/A	See footnote 3 and 4
44-d	Inner bag/pouch	To contain and protect product PRS 1101 PRS 1501 PRS 1502 PRS 1503 PRS 2001	Improper material selection	Bag material is cytotoxic	User injury	10	5	50	Yes	DFS	Vendor selection and part approval with testing for cytotoxicity	Not Practical	Test product for biocompatibility, see test protocol ENG-PRT-235	Biocompatibility Report ENG-RPT-337	Tested per ISO 10993-1:2009 clause 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-337	10	1	10	No	N/A	See footnote 3 and 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
45-d	Pencil Shipping Box	Protect product during shipment PRS 1101 PRS 1102 PRS 1601 PRS 1603 PRS 1604 PRS 1801 PRS 1802 PRS 1803 PRS 2001	Box sized incorrectly – does not protect product adequately	Damaged pencil fails in use.	Practitioner and/or patient injury	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test according to protocol ENG-PRT-229 for 2525-10, ENG-PRT-327 for 2525-15, ENG-PRT-425 for ME7251C and ME7251E, and ENG-PRT-441 for ME725M1C and ME725M1E. Drawings 2525-10, 2525-15, 2525-10EC, 2525-15EC, 2525-10BN, 2525-10ECBN, ME7251E, ME7251C, ME725M1E, and ME725M1C.	Shipping test report ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-546, and ENG-RPT-535.	Tested per ISO 11607-1, see test reports ENG-RPT-330, ENG-RPT-413, ENG-RPT-503, ENG-RPT-546, and ENG-RPT-535. Drawings 2525-10, 2525-15, 2525-10EC, 2525-15EC, 2525-10BN, 2525-10ECBN, ME7251E, ME7251C, ME725M1E, and ME725M1C.	10	1	10	No	N/A	See footnote 3 and 4
46-d	Packaged Pencil Product	For electrosurgical use in the sterile field PRS 1101 PRS 1102 PRS 1201 PRS 1202 PRS 1601 PRS 1603 PRS 1604 PRS 1803 PRS 2001	Transport and storage out of accepted limits	Pencil material breakdown chemically / physically from exposure to extreme shipping / storage conditions (Temp and/or Humidity)	Patient or user injury	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229 for 2525-10, ENG-PRT-327 for 2525-15, and ENG-PRT-425 for ME7251C.	Material requirements are defined in drawing 2525-10, 2525-15, 2525-10EC, 2525-15EC, 2525-10BN, 2525-10ECBN, ME7251E, and ME7251C. Test Reports ENG-RPT-330, ENG-RPT-413 and ENG-RPT-503	Tested per ISO 11607-1, see test reports ENG-RPT-330, ENG-RPT-413 and ENG-RPT-503	10	1	10	No	N/A	See footnote 3 and 4

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
46.2-d	Packaged Pencil Product	PRS 1720 PRS 1920	Label print material not compatible with sterilization and shipping conditions	Product label information incomplete or illegible	Product not identifiable	1	1	1	Yes	IFS	Design material selection and product verification	Not Practical	Verify clarity and legibility post sterilization	After Gamma Sterilization see ENG-PRT-229. After EtO Sterilization see ENG-PRT-465.	After Gamma Sterilization see ENG-RPT-330. After EtO Sterilization see ENG-RPT-581.	1	1	1	No	N/A	See footnote 3 and 4 This is a potential regulatory compliance issue
47-d	Extension Nozzles	Extend smoke capture when using extended electrodes in pockets or deep tissue areas PRS 1101 PRS 1111 PRS 1113 PRS 1201 PRS 1202 PRS 1305 PRS 1313 PRS 1501 PRS 1502 PRS 1503 PRS 2001 URS 1011	Incorrect design or material Not a gamma stable material Opaque nozzle Wrong electrode exposure length	Fractures leaving material in patient Falls off into patient	Foreign body reaction or additional surgical intervention	10	5	50	Yes	DFS	Design, material selection, and product validation	Detect under X-ray	Test for mechanical strength	Mechanical test report ENG-RPT-329	Tested per ISO 10993-1:2009 clause 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-337 See test report ENG-RPT-329	10	1	10	No	N/A	See footnote 3 and 4
47.5-d	Extension Nozzles	Extend smoke capture when using extended electrodes in pockets or deep tissue areas PRS 1101 PRS 1111 PRS 1113 PRS 1201 PRS 1202 PRS 1305 PRS 1313 PRS 1501 PRS 1502 PRS 1503 PRS 2001 URS 1011	Incorrect design or material Not a gamma stable material Opaque nozzle Wrong electrode exposure length	Transparency obstructs surgeon's view. Poor smoke capture	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design, material selection, and product validation	Not Practical	Test for mechanical strength	Mechanical test report ENG-RPT-329	Tested per ISO 10993-1:2009 clause 6.2.2.2, 6.2.2.3, & 6.2.2.4 See test report ENG-RPT-337 See test report ENG-RPT-329	5	1	5	No	N/A	See footnote 3 and 4

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
48-d	Extension Nozzles	Extend smoke capture when using extended electrodes in pockets or deep tissue areas PRS 1101 PRS 1312 PRS 2001	Improper flow path design	Does not remove smoke adequately	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design and product validation	Not Practical	Flow test per protocol ENG-PRT-280	Flow Test Report ENG-RPT-403	See test report ENG-RPT-403	5	1	5	No	N/A	See footnote 3 and 4
49-d	Extension Nozzle Packaging	To maintain sterile barrier protect pencil extension during shipping and storage condition PRS 1101 PRS 1102 PRS 1112 PRS 1602 PRS 1603 PRS 1604 PRS 1803 PRS 2001	Ineffective packaging for this application	Product unsterile (sterile barrier broken) Holes in packaging	Patient infection	10	5	50	Yes	DFS	Material Selection	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229	Material requirements are defined in drawing 2540 and 2560 Test with Protocol ENG-RPT-329	Tested per ISO 11607-1, see test report ENG-RPT-329	10	1	10	No	N/A	See footnote 3 and 4
49.5-d	Extension Nozzle Packaging	To maintain sterile barrier, protect pencil extension during shipping and storage condition PRS1101 PRS1102 PRS1112 PRS1602 PRS1603 PRS1604 PRS1803 PRS2001	Ineffective packaging for this application	Product Damaged (noticed before surgery)	User dissatisfaction	1	5	5	Yes	DFS	Material Selection	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229	Material requirements are defined in drawing 2540 and 2560 Test with Protocol ENG-RPT-329	Tested per ISO 11607-1, see test report ENG-RPT-329	1	1	1	No	N/A	NA

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
49.7-d	Extension Nozzle Packaging	To maintain sterile barrier, protect pencil extension during shipping and storage condition PRS1101 PRS1102 PRS1112 PRS1602 PRS1603 PRS1604 PRS1803 PRS2001	Ineffective packaging for this application	Product Damaged (noticed during surgery)	Delay of surgery	3	5	15	Yes	DFS	Material Selection	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-229	Material requirements are defined in drawing 2540 and 2560 Test with ReprotENG-RPT-329	Tested per ISO 11607-1, see test report ENG-RPT-329	3	1	3	No	N/A	NA
50-d	Extension Nozzle Shipping/unit Box	Protect product during shipment PRS 1101 PRS 1102 PRS 1602 PRS 1603 PRS 1604 PRS 1801 PRS 1802 PRS 1803 PRS 2001	Box sized incorrectly – does not protect product adequately	Product unsterile (sterile barrier broken) due to holes in packaging	Practitioner and/or patient injury	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test according to protocol ENG-PRT-229 Drawings 2540, 2560	Shipping test report ENG-RPT-329 Drawings 2540, 2560	Tested per ISO 11607-1, see test report ENG-RPT-329	10	1	10	No	N/A	See footnote 3 and 4
50.5-d	Extension Nozzle Shipping/unit Box	Protect product during shipment PRS 1101 PRS 1102 PRS 1602 PRS 1603 PRS 1604 PRS 1801 PRS 1802 PRS 1803 PRS 2001	Box sized incorrectly – does not protect product adequately	Product Damaged (noticed before surgery)	User dissatisfaction	1	5	5	Yes	DFS	Design, material selection, and product validation	Not Practical	Test according to protocol ENG-PRT-229 Drawings 2540, 2560	Shipping test report ENG-RPT-329 Drawings 2540, 2560	Tested per ISO 11607-1, see test report ENG-RPT-329	1	1	1	No	N/A	NA

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
50.7-d	Extension Nozzle Shipping/unit Box	Protect product during shipment PRS 1101 PRS 1102 PRS 1602 PRS 1603 PRS 1604 PRS 1801 PRS 1802 PRS 1803 PRS 2001	Box sized incorrectly – does not protect product adequately	Product Damaged (noticed during surgery)	Delay of surgery	3	5	15	Yes	DFS	Design, material selection, and product validation	Not Practical	Test according to protocol ENG-PRT-229 Drawings 2540, 2560	Shipping test report ENG-RPT-329 Drawings 2540, 2560	Tested per ISO 11607-1, see test report ENG-RPT-329	3	1	3	No	N/A	NA
51-d	Expiration Life	3-year expiration date PRS 2002	Unstable product	Does not meet DMR after 3 years	Patient injury	10	5	50	Yes	DFS	Design for 3-year real time aging	Not Practical	Test per protocol ENG-PRT-227 ENG-PRT-228 ENG-PRT-229 ENG-PRT-439 ENG-PRT-239 ENG-PRT-327 ENG-PRT-466	Test report ENG-RPT-328 ENG-RPT-329 ENG-RPT-330 ENG-RPT-413 ENG-RPT-555 ENG-RPT-344 ENG-RPT-503 ENG-RPT-585 (after EtO sterilization)	Test report ENG-RPT-328 ENG-RPT-329 ENG-RPT-330 ENG-RPT-413 ENG-RPT-555 ENG-RPT-344 ENG-RPT-503 ENG-RPT-585 (after EtO sterilization)	10	1	10	No	N/A	See footnote 3 and 4
52-d	ULPA Filter	Primary smoke filter and fluid trap PRS 1316	Incorrect sizing of locking feature	Filter will not lock into box port	User dissatisfaction	3	5	15	Yes	DFS	Design port access feature to lock into smoke box port connection 1st article measurements on Mold part feature	Not practical	Test according to Protocol ENG-PRT-238 force to insert and shear force tests and for 1st article measurements.	See Report ENG-RPT-340	See footnote 2	3	1	3	No	N/A	See footnote 3 and 4

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Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification/ Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
53-d	ULPA Filter	Primary smoke filter and fluid trap PRS 1316 PRS 1317	Incorrect sizing of connecting features	Filter will not insert into box port Pencil will not connect to filter	User dissatisfaction	1	1	1	NA	DFS	Design port access features to fit smoke box port connection and pencil connections 1st article measurements on Mold part features	NA	Test according to Protocol ENG-PRT-238 force to insert and shear force tests and for 1st article measurements	See Report ENG-RPT-340	See footnote 2	1	1	1	NA	NA	NA
54-d	ULPA Filter	Primary smoke filter and fluid trap	Wrong filter media	Reduced or no smoke capture (little to no suction)	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design using correct ULPA filter media. Certificate of filter media performance	Not practical	Test according to Protocol ENG-PRT-238 for flow.	See Report ENG-RPT-340	See footnote 2	5	1	5	No	N/A	See footnote 3 and 4
55-d	ULPA Filter	Primary smoke filter and fluid trap	Inadequate material used for housing	Unable to connect box or smoke pencil to filter (connection features are broken off)	User dissatisfaction	1	1	1	NA	DFS	Design and specify appropriate material	NA	Test according to Protocol ENG-PRT-238 for flow Specify correct material	See Report ENG-RPT-340	See footnote 2	1	1	1	NA	NA	NA
56-d	ULPA Filter	Primary smoke filter and fluid trap PRS 1314 PRS 1315	Inadequate material and/or weld joint design	Filter leaks fluid	Bio-hazard	10	5	50	Yes	DFS	Design and specify appropriate material and weld joint design	Not practical	Test according to Protocol ENG-PRT-238 for Leak test. Specify correct material and weld joint design	See Report ENG-RPT-340	See footnote 2	10	1	10	No	N/A	See footnote 3 and 4
56.5-d	ULPA Filter	Primary smoke filter and fluid trap PRS 1314 PRS 1315	Inadequate material and/or weld joint design	Filter leaks smoke	Possible user exposure to potential carcinogens and infectious by-products	5	5	25	Yes	DFS	Design and specify appropriate material and weld joint design	Not practical	Test according to Protocol ENG-PRT-238 for Leak test. Specify correct material and weld joint design	See Report ENG-RPT-340	See footnote 2	5	1	5	No	N/A	See footnote 3 and 4

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Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification/ Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
57-d	Charcoal Filter	Capture odors and residual chemicals PRS 1114	Threads on muffler damaged	Charcoal Filter will not thread to box port	Increased noise reduced filtration, User dissatisfaction	1	1	1	NA	DFS	Design packaging to protect filter threads	NA	Test according to Protocol ENG-PRT-238 for ship test	See Report ENG-RPT-340	See footnote 2	1	1	1	NA	NA	NA
58-d	ULPA and Charcoal Filters	Filter air for surgical smoke evacuation PRS 1605	Shipping Damage	Filter Failure	Biohazard	10	5	50	Yes	DFS	Design adequate packaging	Not practical	Test according to Protocol ENG-PRT-238 for ship test	See Report ENG-RPT-340	See footnote 2	10	1	10	No	N/A	See footnote 3 and 4
59-d	Filter Shipping Box	Protect product during shipping, handling, and storage PRS 1801 PRS 1802 PRS 1803	Box sized incorrectly – does not protect product adequately	Damaged filter fails in use.	Biohazard	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Test according to protocol ENG-PRT-238 See drawings 2211, 2220	Shipping test report ENG-RPT-340	See test report ENG-RPT-340 See drawings 2211, 2220	10	1	10	No	N/A	See footnote 3 and 4
60-d	Filter Packaged Product	Protect filters during shipping, handling, and storage PRS 1201 PRS 1202 PRS 1803	Transport and storage out of accepted limits	Filter material breakdown chemically / physically from exposure to extreme shipping / storage conditions (Temp and/or Humidity)	Biohazard	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Ensure material requirements are defined. Test according to protocol ENG-PRT-238	Material requirements are defined in drawing 2211 and 2220 Test Report ENG-RPT-340	See test report ENG-RPT-340	10	1	10	No	N/A	See footnote 3 and 4
61-d	Applied and non-applied part intended to supply heat to the patient	Deliver RF energy PRS 1319 PRS 1320	RF Energy	Heat exceeding 41 C degrees	Patient Burn	10	5	50	Yes	DFS	Design, material selection, and product validation	Not Practical	Ensure material requirements are defined. Testing to standards IEC 60601-1	Material requirements are defined in drawing.	Test Report ENG-RPT-395	10	1	10	No	N/A	See footnote 3 and 4
62-d	Instructions for use	Provide IFU with device	Do not provide IFU with device	Customer unable to use the device	Customer dissatisfaction	1	1	1	NA	IFS	NA	NA	NA	NA	NA	1	1	1	NA	NA	NA

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Zip-Pen PROCESS FMEA resides with NDT (vendor)

Zip-Pen Megadyne EO Sterilization Process FMEA (applies to ME725M1E and ME725M1C)

Risk Analysis						Risk Estimation			Risk Evaluation	Risk Control						Risk Estimation of Residual Risk			Risk Evaluation of Residual Risk		
Item#	Application	Intended Use or Characteristic (Function)	Initiating Events / Circumstances / Causes	Potential Failure Mode (Hazard)	Potential Effects (Harm)	Severity	Probability of Occurrence	RPN	Risk reduction considered (Yes/No)	Options	Preventive Measures	Detection Measures	Verification / Validation Plan	Verification	Validation	Severity	Probability of Occurrence	RPN	Additional Risk after Risk Control? (Yes/No)	Additional Risk Control (if applicable)	Risk Benefit Analysis/ Notes
1-p	Receive Gaylord requiring sterilization	Sterilize Product	Product not marked as awaiting EO sterilization.	Not identifiable as product awaiting EO Sterilization	Use of non-sterile product (intended to be sterile).	10	2	20	Yes	Training and Traveler.	Traveler OPER-FRM-134	Non-Sterile Product awaiting sterilization tape found on gaylords.	Validation of process traveler OPER-FRM-134 per protocol ENG-PRT-474	See ENG-RPT-586	See ENG-RPT-586	10	1	10	No	N/A	See footnote 3
2-p	Transfer Gaylord to back building.	Product is not damaged.	Product dropped/damaged in transit.	Damaged Product – no sterility breach.	Damaged product not identified and used in surgery. Increased thermal damage to tissue, especially during plastic surgery.	5	2	10	Yes	DFS, Training and SOPs	Design, material selection, and process validation	QA-SOP-008	Test according to protocol ENG-PRT-441 and validate process per ENG-PRT-474.	See ENG-RPT-535 and ENG-RPT-586	See ENG-PRT-535 and ENG-RPT-586	5	1	5	No	N/A	See footnote 3
3-p	Transfer Gaylord to back building.	Product is not damaged.	Product dropped/damaged in transit.	Damaged Product – sterility breach.	Use of non-sterile product (intended to be sterile).	10	2	20	Yes	DFS, Training and SOPs	Design, material selection, and process validation	QA-SOP-008	Test according to protocol ENG-PRT-441 and validate process per ENG-PRT-474.	See ENG-RPT-535 and ENG-RPT-586	See ENG-RPT-535 and ENG-RPT-586	10	1	10	No	N/A	See footnote 3
4-p	Re-Palletize Product for sterilization	Sterilize Product	Product not properly palletized for sterilization.	Product not sterilized per validated process/cycle	Use of non-sterile product (intended to be sterile).	10	2	20	Yes	Training. Work instruction, and Traveler.	Traveler OPER-FRM-134 and OPER-WI-048	Not Practical	Validation of process traveler OPER-FRM-134 per ENG-PRT-474 and update to OPER-WI-048	See ENG-RPT-586	See ENG-RPT-586	10	1	10	No	N/A	See footnote 3

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Risk Analysis						Risk Estimation			Risk Evaluation	Risk Control						Risk Estimation of Residual Risk			Risk Evaluation of Residual Risk		
Item#	**Application**	**Intended Use or Characteristic (Function)**	**Initiating Events / Circumstances / Causes**	**Potential Failure Mode (Hazard)**	**Potential Effects (Harm)**	**Severity**	**Probability of Occurrence**	**RPN**	**Risk reduction considered (Yes/No)**	**Options**	**Preventive Measures**	**Detection Measures**	**Verification / Validation Plan**	**Verification**	**Validation**	**Severity**	**Probability of Occurrence**	**RPN**	**Additional Risk after Risk Control? (Yes/No)**	**Additional Risk Control (if applicable)**	**Risk Benefit Analysis/ Notes**
5-p	Re-Palletize Product for Sterilization	Prepare product for Sterilization. Product not damaged.	Product dropped/damaged during palletization	Damage to product packaging – no sterility breach	Cosmetic damage to packaging	1	2	2	Yes	Training and Work Instructions	OPER-WI-048	Not Practical	Validation of process traveler OPER-FRM-134 per ENG-PRT-474	See ENG-RPT-586	See ENG-RPT-586	1	1	1	No	N/A	See footnote 3 and 4
6-p	Final Release of Product for Distribution	Release product for distribution to customers	Incorrect handling	Final Release occurs without sterilization	Use of non-sterile product (intended to be sterile).	10	2	20	Yes	Training. Work instruction, and Traveler.	Traveler OPER-FRM-134	Not Practical	Validation of process traveler OPER-FRM-134 per ENG-PRT-474	See ENG-RPT-586	See ENG-RPT-586	10	1	10	No	N/A	See footnote 3 and 4

The risk assessment was reviewed and updated by Kiran Kumar (Lifecycle Quality Engineer) and Scot Harris (Lifecycle Quality Engineer Lead) on September 29, 2020.

Smoke Evacuation Pencil & Accessories IFU's

Product Code	MOD	IFU P/N
252510* 2525-10 252510EC* 2525-10EC, 252515* 2525-15 252515EC* 2525-15EC	00	3000312-01
	01	3000343-01
ME7251C ME7251E ME725M1C ME725M1E	01	3000317-01
	02	3000336-01
	00	3000313-01

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2540J*, 2540, 2560, 2560J*	01	3000344-01
2211, 2211J*	00	3000190-01
	01	3000346-01
2220J*, 2220	00	3000191-01
	01	3000347-01

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Table 1. Severity Risk Ranking

Description	Impact	Rank
Critical	The potential problem could result in death or serious injury to the patient or user, such as alternate current site injury, patient burn, or infection.	10
Important	The potential problem could result in a non-serious injury to the patient or user that requires medical intervention, such as reduced or no surgical effect, pressure sore, or allergic reaction.	5
Minor	The potential problem could result in a non-serious injury to the patient or user that does not require medical intervention, such as a delay in the procedure.	3
Negligible	There is no risk of injury to the patient or user.	1

Table 2. Probability of Occurrence Risk Ranking

Qualitative Description	Quantitative Description	Rank
Continual (expected to occur)	≥ 10%	5
Frequent (likely to occur)	> 1% and < 10%	3
Occasional (can occur)	> 0.1% and ≤ 1%	2
Rare (unlikely to occur)	≤ 0.1%	1

Probability of Occurrence Risk Ranking

Determination of RPN

			Severity Risk Ranking			
			Negligible	Minor	Important	Critical
		Ranking	1	3	5	10
Probability of Occurrence Risk Ranking	Continual	5	**5**	**15**	**25**	**50**
	Frequent	3	**3**	**9**	**15**	**30**
	Occasional	2	**2**	**6**	**10**	**20**
	Rare	1	**1**	**3**	**5**	**10**

FOOTNOTES

#1	This medical device is restricted to use by a physician.
#2	A review of clinical experience (as noted in complaint analysis section) reveals that the Probability of Occurrence levels actually fall within the range listed in the Post Risk Control section.

#3	Residual risk is deemed acceptable through verification / validation testing.
#4	The risk is reduced ALAP (As Low As Possible). The risk is associated with the use of electrosurgery regardless of the medical device used. The benefit derived from the use of the medical device is greater than the risks associated with its use. The risks associated with electrosurgery are accepted by the patient through informed consent. The surgeons are trained in the proper application of electrosurgery and the prevention of injuries.