



The Electrosurgical Authority®

DOCUMENT NUMBER: MKT-US-002

DOCUMENT TITLE: Usability Specification - Smoke Evacuation Pencils and Universal

DOCUMENT NOTES:

Adding Zip ACE, all Zip product codes in Scope. Clarifying wording of tubing related

Document Information

Revision: 002

Vault: MEG-Rel

Status: Release

Document Type: MKT-US

Date Information

Effective Date: 13 Feb 2018

Expiration Date:

Release Date: 13 Feb 2018

Next Review Date:

Control Information

Author: MGLASSETT

Owner: MKT-APPR

Previous Number: 1360002-10

Change Number: 2017-MKT-DCO-098

Signature Manifest**Document Number:** MKT-US-002**Revision:** 002**Title:** Usability Specification - Smoke Evacuation Pencils and Universal ULPA Filter

All dates and times are in Mountain Standard Time.

Zip Usability Spec**Change Request**

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		14 Dec 2017, 10:26:17 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Rob Farnsworth (RFARNSWORTH)		09 Jan 2018, 09:18:34 AM	Complete
Mike Hintze (MHINTZE)		09 Jan 2018, 03:57:07 PM	Complete
Mark Glassett (MGLASSETT)		10 Jan 2018, 08:03:23 AM	Complete
Paul Borgmeier (PBORGMEIER)		12 Jan 2018, 02:56:28 PM	Complete
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	31 Jan 2018, 05:30:55 PM	Complete
Christian Crook (CCROOK)		08 Feb 2018, 08:49:03 AM	Complete
Darlene Hull (DHULL)	Regulatory	08 Feb 2018, 05:52:58 PM	Complete
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Document Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		12 Feb 2018, 08:18:27 AM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	12 Feb 2018, 11:06:27 AM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
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MKT-Approval

Name/Signature	Title	Date	Meaning/Reason
Mike Hintze (MHINTZE)		12 Feb 2018, 09:41:38 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		13 Feb 2018, 07:30:48 AM	Approved

Printed on: 22 Jan 2020, 04:08:56 am; Printed by: .

Final Release

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		13 Feb 2018, 07:31:13 AM	Approved

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1. REFERENCES

ENG-RMF-043	Risk Management Plan, Smoke Evacuation Pencils
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
IEC 62366	Medical Devices – Application of usability engineering to medical devices
IEC 60601-1-6	Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance- Collateral standard: Usability

2. APPENDIX

Not Applicable

3. SCOPE

This usability specification applies to Megadyne Zip-Pen™ Smoke Evacuation Pencils (2525-10 (252510), 2525-15 (252515), 2525-10EC (252510EC), 2525-15EC (252515EC), 2525-10BN (252510BN), 2525-10ECBN (252510ECBN), ME7251C, ME7251E, ME725M1C, ME725M1E), Extension Nozzles (2540, 2560), and Universal ULPA Filter (2211).

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. The old and new catalog numbers are interchangeable as it relates to referencing a product.

4. PURPOSE

The purpose of this document is to specify the usability requirements for the Zip-Pen smoke evacuation pencils, Extension Nozzles and Universal ULPA Filter in compliance with IEC 62366 and IEC 60601-1-6 specifications.

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5. DEFINITIONS AND ACRONYMS

DMR	Device Master Record
MDD	Medical Device Directive (93/42/EEC)
URS	Usability Requirements Specification

6. RESPONSIBILITIES

- 6.1. The Engineering Department is responsible for this document.

7. UNIQUE IDENTIFIERS

Unique usability specification identifiers are used in this document for ease of tracking the requirements throughout the project. These identifiers are in the form of URS XXXX followed by a requirement title and requirement description. Any requirement without an identifier does not need to be tested during design verification.

8. USABILITY INPUTS

- 8.1. Intended Medical Indication:

8.1.1. Zip-Pen™ smoke evacuation electrosurgical pencil is a monopolar device designed for general electrosurgical applications including cutting and coagulation and for removing smoke generated by electrosurgery when used in conjunction with an effective smoke evacuation system. This device conducts an electrosurgical current from an electrosurgical generator and delivers it to the target tissue to achieve the desired surgical effect.

8.1.2. Extension Nozzles are accessories to the Zip-Pen™ smoke evacuation pencils and are designed to remove surgical smoke when extended length electrodes are used with the Zip-Pen™ Pencil.

8.1.3. Universal ULPA Filter is an accessory to the Mega Vac and Mega Vac Plus Smoke Evacuation Systems and is designed to filter surgical smoke when attached to the system.

- 8.2. Intended patient population

8.2.1. Zip-Pen™ Smoke Evacuation Pencils, Extension Nozzles and Universal ULPA Filter are for use on general population.

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8.2.2. There is no patient age limit for the usage of Zip-Pen™ Smoke Evacuation Pencils, Extension Nozzles and Universal ULPA Filter.

8.3. Intended part of the body or type of tissue applied to or interacted with Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles.

8.3.1. Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles are used wherever general electrosurgery is used. Zip-Pen™ Smoke Evacuation Pencils can be used on any part of the body or tissue where it is necessary to perform surgery as deemed by the surgeon. This includes tissues of all impedance levels (low, medium or high).

8.3.2. Universal ULPA Filter is an accessory that is attached to the Mega Vac or Mega Vac Plus and does not contact the patient.

8.4. Intended User Profile

8.4.1. Electrosurgery is a specialized process and is performed only by trained surgical professionals and is restricted to use by or on the order of a physician.

9. APPLICATION SPECIFICATION

9.1. Intended condition of use:

9.1.1. Sterile / non-sterile: The Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles are intended to be used sterile and are marked accordingly. The Universal ULPA filter is non-sterile.

9.1.2. Single use or reusable: Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles are single use and are marked accordingly. The Universal ULPA filter is reusable (limited reuse and no reprocessing).

9.1.3. Single patient vs. multiple patients: The Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles are disposable accessories are intended for use on a single patient. The Universal ULPA filter may be used with multiple patients.

9.1.4. Hospital vs. home use: Zip-Pen™ Smoke Evacuation Pencils, Extension Nozzles, and the Universal ULPA filter are NOT intended for home use. Use is restricted by or on the order of a physician.

9.1.5. Ambulance use, in hospital transport or wall mounted: Zip-Pen™ Smoke Evacuation Pencils, Extension Nozzles and the Universal ULPA filter are

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intended to be used in surgical settings and hence are not meant for usage in ambulances or in hospital transport.

9.1.6. General ward vs. operating theatre use: Zip-Pen™ Smoke Evacuation Pencils, Extension Nozzles and the Universal ULPA filter are intended to be used in operating theatre or surgical settings only.

9.1.7. Permanent implant or less than one hour contact: Zip-Pen™ Smoke Evacuation Pencils and Extension Nozzles are NOT intended for permanent implant and are meant for transient use only. However, the usage can vary based on the procedure being performed. The Universal ULPA filter has no patient contact

9.2. Frequently used functions for Zip-Pen™ Smoke evacuation pencil

9.2.1. Remove from sterile packaging and place on the sterile field.

9.2.2. Plug the pencil into an electrosurgical generator and connect to a smoke evacuation device.

9.2.3. Gripping/holding the device

9.2.4. Removing the tip protector

9.2.5. Pressing the coag button

9.2.6. Pressing the cut button

9.2.7. Changing an electrode

9.2.8. Attaching the Extension Nozzle

9.3. Primary Operating Functions Zip-Pen™ Smoke evacuation pencil and Extension Nozzles

9.3.1. All of the frequently used functions identified in previous section are also primary operating functions.

9.4. Frequently Used Functions for Universal ULPA Filter

9.4.1. Remove from packaging

9.4.2. Attach to Mega Vac or Mega Vac Plus

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9.4.3. Attach Zip-Pen™ Smoke evacuation pencil tubing to Universal ULPA Filter

9.4.4. Disposal of Universal ULPA Filter

9.5. Primary Operating Functions

9.5.1. All of the frequently used functions for the Universal ULPA Filter identified in the previous section are also primary operating functions

10. HAZARDS RELATED TO USABILITY

10.1. Identification of hazards and hazardous situations specific to usability

10.1.1. All hazards and hazardous situations related to usability, identification of known or foreseeable hazards and hazardous situations, the severity associated with the identified hazard, the probability of occurrence of the hazard, appropriate actions taken to mitigate the hazard are all identified in appropriate columns under “Pre risk mitigation” section of the FMEA document ENG-RMF-045 (Smoke Evacuation Accessories Risk Analysis). The risks associated with usability are identified in the usability section with a description in the “Application Step” column of the FMEA.

10.2. Risk Control:

10.2.1. Risk control measures taken to mitigate the risks associated with usability are identified in columns under “Risk Control” as identified in the FMEA contained in document ENG-RMF-045 (Smoke Evacuation Accessories Risk Analysis) document. The residual risk is assessed and documented in columns under “Residual Risk”

10.3. Usability hazards for the Zip-Pen™ Smoke evacuation pencil include but are not limited to the following:

10.3.1. Hot electrode or inadvertently activated electrode could burn the patient.

10.3.2. Hot electrode or inadvertently activated electrode could cause a fire in the presence of flammable materials.

10.3.3. Damage to tissue could occur if electrosurgery is used on body parts with relatively small cross sectional area.

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10.4. Usability hazards for the Universal ULPA Filter include but are not limited to the following

10.4.1. Biohazardous fluid in the Universal ULPA Filter could spill out when the filter is changed.

11. THINGS THAT COULD GO WRONG

11.1. During Normal Use

11.1.1. Fluid in one of the electrical switch's causing inadvertent activation

11.1.2. The smoke tubing could be broken

11.1.3. The electrode could become dislodged.

11.1.4. Tubing could become unplugged from the smoke device.

11.1.5. Plug could become unplugged from the ESU.

11.1.6. Tubing could become kinked.

11.1.7. The suction feature could become occluded

11.1.8. The Extension Nozzle could fall off.

11.2. Use Errors

11.2.1. Pressing the wrong button

11.2.2. Dropping on the floor

11.2.3. Mechanical failure due to prying with the pencil or nozzle

11.2.4. Excessive pull strength on tubing could dislodge the tubing from the smoke pencil housing.

11.2.5. Could pull on the tubing/cord so hard that it dislodges from the smoke evacuation unit

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12. USABILITY SPECIFICATION REQUIREMENTS

Megadyne has marketed electrosurgical pencil for many years. Design features that are common to electrosurgical pencils and items that are dictated by standards have been purposely omitted from the list of requirements. The usability specification requirements only contain items that are new features based on the unique design features of the Zip-Pen™ Smoke Evacuation Pencil.

The Universal ULPA Filter is a direct replacement for an existing device. The only difference with this new device is the connector accepts multiple tubing connectors.

URS Number	Title	Requirement
URS1001	Grip	The IFU will provide graphics showing the options for gripping the device.
URS1002	Hot electrode	Provide a holster that will insulate the device from the patient when not in use both thermally and electrically
URS1003	Dislodged electrode	The collet will have an extraction force that insures the electrode will not fall out of the pencil
URS1004	Pencil Plug comes unplugged	The pencil plug will have an extraction force that insures it remains attached during use
URS1005	Smoke Tubing comes unplugged	The smoke tubing connector will have adequate removal force to insure it stays connected to the filter during typical use
URS1006	Kinked tubing	The IFU will provide warning to not kink the tubing
URS1008	Tubing dislodged	The smoke tubing connector will have adequate removal force to insure it stays connected to the filter during typical use
URS1011	Nozzle falls off	The Extension Nozzles will securely attach to the pencil
URS2001	Connector mates with Zip-Pen tube connector	The smoke tubing connector will have removal force in a range that insures that it stays connected to the tubing during use

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13. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-058-01	Initial Release	2014-05-05
B	14-086-01	Update the intended use statement and change name from E-Z Clear to Zip-Pen	2014-08-19
See MasterControl for subsequent revisions			

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