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# ABSTRACT

The purpose of this study is to provide objective evidence that the ZIP-PENTM Smoke Evacuation Pencil (15-foot cord length) satisfies defined customer requirements when used within actual or simulated-use environments in a manner consistent with the Package Insert. This study will focus on the nurse experience with the device. Questions 3-11 in table 1 are required to validate ZIP-PEN product codes 252510 (2525-10), 252510EC (2525-10EC), 252515 (2525-15), 252515EC (2525-15EC), 252510BN (2525-10BN), 252510ECBN (2525-10ECBN). The catalog numbers in parentheses are identical from a product perspective. The numbers with a hyphen are from the historical Megadyne Medical Products system whereas without a hyphen are for the Ethicon system. Questions 3-9 were satisfied in ENG-RPT-557 so this study will focus on questions 10 and 11 only.

**Table 1: ENG-RPT-557 Validated requirements for ZIP-PEN**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Validation Question** | **ZIP 15** | **ENG-RPT-557** |
| 3 | Did the device monopolar functionality perform as expected | X | Y |
| 4 | Rate the ability to evacuate smoke away from the surgical site | X | Y |
| 5 | Rate the ability to visualize the active electrode during the procedure | X | Y |
| 6 | Rate the ergonomics of the device | X | Y |
| 7 | Rate the amount of drag on your hand from the tubing | X | Y |
| 8 | Rate the tactile feel of the buttons | X | Y |
| 9 | Rate the security of the active electrode when cleaning | X | Y |
| 10 | Rate the ability to remove the active electrode | X | N |
| 11 | Rate the ability to insert the active electrode into the collet | X | N |

# REFERENCES

|  |  |
| --- | --- |
| ENG-PRT-452 | Design Validation Study with Nurses, Zip Pen |
| ENG-RPT-557 | Report, Design Validation Study with Surgeons, ACE BLADE 700 and Zip Pen |
| MKT-CMR-029 | CMR Smoke Evacuation Product Line |
| ENG-PS-007 | Smoke Evacuation and Accessories Product Spec |
| MKT-US-002 | Usability Specification – Smoke Evacuation Pencils and Universal ULPA Filter |

# METHODS AND SETUP

This evaluation was performed as a “piggy-back” to project Mantle (Cincinnati) Usability Study conducted in Cincinnati, OH on December 12, 2017. Matt Miller facilitated this study and a training record can be found in Attachment 2 of this report. The Nurse information was captured as part of the project Mantle study and is included in Table 2.

**Table 2: Nurse information**

|  |  |  |  |
| --- | --- | --- | --- |
| Gender | Female | Female | Female |
| Certification | RN | RN | RN |
| Currently Working in OR | Yes | Yes | Yes |
| Acting as Circulating Nurse | 40% | 80% | 40% |
| Acting as a Scrub Nurse | 40% | 20% | 40% |
| Performing Other Activities | 20% | 0% | 20% |
| # Years as Circulating Nurse | 6 | 22 | 9 |
| General Surgeries | 50+ | 30 | 50+ |
| Bariatric Surgeries | 0 | 0 | 0-1 |
| Colorectal Surgeries | 15-20 | 30 | 50+ |
| Thoracic Surgeries | 0 | 30 | 50+ |
| TOTAL | 70+ | 90 | 150+ |
| # Operating Rooms | 10 | 9 | 24 |
| Facility Type | Community Based, Teaching Hospital | Community Based, Non-Teaching Hospital | University Affiliated |

Table 3 lists the products that were used during the evaluation

**Table 3: Products used during the evaluation**

|  |  |  |
| --- | --- | --- |
| **Megadyne Catalog #** | **Description** | **Lot #** |
| 252515 | ZIP-Pen 15’ Smoke Evacuation Pencil with 2.5” EZ-CLEAN blade | S160050 |
| 0014 | 6.5” EZ-CLEAN Electrosurgical electrode | 174678 |
| 2560 | ZIP Pen Nozzle Extension 5.2” | 1507124 |

Each user will be provided with an IFU or copy of the IFU corresponding to the device they are validating prior to starting. The Nurse representative will be handed a ZIP-PEN 15’ and asked to remove the active electrode. It is acceptable for the nurse to use a surgical tool such as a hemostat to remove the electrode. After the active electrode is removed the Nurse representative will be asked to insert a 6.5” active electrode into the Zip-Pen. The Nurse will also be asked to attach a 5.2” extension Nozzle over the nozzle on the Zip-Pen.

After all tasks were completed, each Nurse was asked the following validation questions:

* Rate the ability to remove the active electrode
* Rate the ability to insert the active electrode into the collet
* Rate the ability to attach the Extension Nozzle to the pencil

# RESULTS

**Validation Question 1 - Rate the ability to remove the active electrode**

Summary: One participant rated the ability to remove the active electrode as acceptable. Two participants rated the ability to remove the active electrode as acceptable with comments. One participant commented that it was harder than normal and used a hemostat to remove the electrode and that she would typically use a 4x4 pad. One participant commented that it was hard to remove due to the low friction coating and used a hemostat to remove. The comments from the nurses were classified by them as a usability related or annoyances vs a safety hazard. A review of the ZIP-PEN complaint analysis (see ENG-RMF-045) shows there are no complaints related to the usability of the device. A line item has been added to the application section of ENG-RMF-045 (64-a) to document this item and the risk level is acceptable.

Detailed Responses:

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant** | **Acceptable** | **Acceptable w/Comments** | **Unacceptable** |
| 1 |  | X - Harder than normal. Used a hemostat, I wouldn't like it I usually use a 4x4 |  |
| 2 |  | X - Hard with friction of coating. Had to use a hemostat |  |
| 3 | X |  |  |
| **Total** | **1** | **2** | **0** |

**Validation Question 2 - Rate the ability to insert the active electrode into the collet**

Summary: Two of Three participants rated the ability to insert the active electrode into the collet as acceptable. One participant rated the ability to insert the active electrode into the collet as acceptable with comments. She commented that it was not as easy as she is used to.

Detailed Responses:

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant** | **Acceptable** | **Acceptable w/Comments** | **Unacceptable** |
| 1 |  | X - Not as easy as I am used to |  |
| 2 | X |  |  |
| 3 | X |  |  |
| **Total** | **2** | **1** | **0** |

**Validation Question 3 - Rate the ability to attach the Extension Nozzle to the pencil**

Summary: All Three participants rated the ability to attach the Extension Nozzle to the pencil as acceptable.

Detailed Responses:

|  |  |  |  |
| --- | --- | --- | --- |
| **Participant** | **Acceptable** | **Acceptable w/Comments** | **Unacceptable** |
| 1 | X |  |  |
| 2 | X |  |  |
| 3 | X |  |  |
| **Total** | **3** | **0** | **0** |

# CONCLUSION

A minimum of 3 individuals evaluated the devices which satisfies the requirements of the protocol.

The questions required to validate ZIP-PEN product codes 252510, 252510EC, 252515, 252515EC, 252510BN, 252510EC all received ratings of “Acceptable” and “Acceptable with Comments” (where comment was acceptably clarified) and are considered to satisfy the acceptance criteria for this study. There were no ratings of unacceptable or where a patient safety risk was identified within the nurses’s comments.

Completion of both ENG-PRT-453 and ENG-PRT-452 is sufficient to validate these product codes.

# ATTachments

## Attachment 1 - Moderator notes

## Attachment 2 - Training Record