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# References

|  |  |
| --- | --- |
| MKT-CMR-029 | CMR Smoke Evacuation Product Line |
| ENG-PRT-453 | Design Validation Study with Surgeons, ACE BLADE 700 and Zip Pen |
| ENG-RPT-557 | Report, Design Validation Study with Surgeons, ACE BLADE 700 and Zip Pen |
| ENG-PS-007 | Smoke Evacuation and Accessories Product Spec |
| MKT-US-002 | Usability Specification – Smoke Evacuation Pencils and Universal ULPA Filter |

# DEFINITIONS AND ACRONYMS

N/A

# scope

This study includes the validation of the following ZIP-PENTM product codes and accessories.

|  |  |
| --- | --- |
| 252510 | ZIP-Pen Smoke Evacuation Pencil (10 ft Cord Length) and Holster |
| 252510EC | ZIP-Pen Smoke Evacuation Pencil (10 ft Cord Length), 22mm Connector and Holster |
| 252515 | ZIP-Pen Smoke Evacuation Pencil (15 ft Cord Length) and Holster |
| 252515EC | ZIP-Pen Smoke Evacuation Pencil (15 ft Cord Length), 22mm Connector and Holster |
| 252510BN | ZIP-Pen Bulk Nonsterile (10 ft Cord Length) and Holster |
| 252510ECBN | ZIP-Pen Bulk Nonsterile (10 ft Cord Length), 22mm Connector and Holster |
| 2560J | ZIP Pen Extension Nozzle 5.2 inch (13.2 cm) |
| 2540J | ZIP Pen Extension Nozzle 2.7 inch (6.8 cm) |

A nurse representative may answer questions on behalf of both Scrub and Circulating nurse staff.

# PURPOSE

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, 252510EC, 252515, 252515EC, 252510BN, 252510ECBN. 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 |

# RISK ASSESSMENT

Any new risks identified will be assessed and added to the appropriate risk analysis document.

# Required tools and equipment

## ZIP-Pen 15’ with 22mm connector (252515)

## 2.5” EZ-CLEAN blade (0012, included with ZIP-Pen)

## ZIP Pen Extension Nozzle 5.2 inch (13.2 cm)

## 6.5” Extension electrodes

## A complete set of equipment used will be contained within the report if different from what is listed here.

# experimental design / sample size justification

This validation work is qualitative in nature. Statistical justification is not necessary given the nature of the study. There will be no statistical analysis of the study results. A small sample size will be used since the products being evaluated in the study or similar to products already on the market with a demonstrated performance record over the past 30 months.

# PROCEDURE

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.

Upon completion of the evaluation, the Scrub Nurse or representative will be asked to rate the tasks.

# acceptance criteria

Table 2 contains the 2 remaining requirements from ENG-PRT-453, and an additional requirement for the Nozzle extension, to validate and the related questions.

**Table 2: Scrub Nurse or equivalent validated requirements**

|  |  |
| --- | --- |
| Requirement | Questionnaire |
| Active electrode must be capable of being removed during the surgical procedure | Rate the ability to remove the active electrode |
| Nozzle to be designed so that the active electrode tip is easily insert able into the collet | Rate the ability to insert the active electrode |
| (Nozzle) Snap on easily and securely as not to fall off during use. | Rate the ability to attach the extension Nozzle to the pencil |

The moderator will ask questions from the questionnaire with and record user answers. Responses for all questions will be “Acceptable”, “Acceptable with Comments” or “Unacceptable”. In the event of responses of “Acceptable with Comments” or “Unacceptable”, the moderator shall ask specific clarifying follow up questions to the study participant in order to completely understand the logic behind their response and what aspect of the product or design caused the ranking response.

Response of “Acceptable” and “Acceptable with Comments” (where comment was acceptably clarified) will be considered responses that satisfy the acceptance criteria for this study.

Statistical methods will not be necessary for the interpretation of the data generated during this evaluation. Due to the design/nature of the study, statistical evaluation is not considered to be appropriate.

Deviations from this protocol will be documented in the final report. Relevant participant comments will be recorded for incorporation in the completion report.

# aTTACHMENTS

Attachment 1 Discussion Guide

……………………………………………………………………………………………………..

***Attachment 1: ZIP-PENTM Smoke Evacuation Pencil*** Design Validation Discussion Guide

……………………………………………………………………………………………………..

***Instrument Use and Evaluation: Scrub Nurse or Equivalent***

**This device has the ability to change active electrodes. For example if you needed a longer active electrode you could change during the procedure. Ask the scrub nurse to remove electrode. How would you remove it if the Surgeon wanted the electrode changed? (It is acceptable to use a tool to remove the electrode. A hemostat will be available to use as a removal tool)**

1. **A Zip Pen and Extension Nozzle IFU shall be provided to the user** **Rate the ability to remove the active electrode:**

Acceptable

Acceptable with Comments

Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

**Hand the scrub nurse the long electrode and ask to insert into device. Hand the scrub nurse the long nozzle and ask to insert over nozzle.**

1. **Rate the ability to insert the active electrode into the collet:**

Acceptable

Acceptable with Comments

Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

1. **Rate the ability to attach the extension Nozzle to the pencil:**

Acceptable

Acceptable with Comments

Unacceptable – (patient safety) (annoyance) (surgeon safety) (usability problem)

Comments:

**Device Information (Pen, Blade, Nozzle) :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Observer:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Nurse Representative:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Thank and dismiss.**