Dome Switch Protocol

**Projects: Dome Switch Supplier ChangeProtocol: ENG-PRT-660**

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| **REVISION** | **DATE** | **SUMMARY OF CHANGE** |
| 001 | 12/03/2019 | Original Release |

Approval List:

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| --- | --- | --- | --- |
| **Function** | **Name** | **Signature** | **Date** |
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1. **Purpose**

The purpose of this questionnaire is to evaluate a new dome switch design in the ZIP, ACE, Rally, and Rally GEM products with representative users to determine the acceptability of the buttons for use in their procedures.

1. **Study Design**

Surgeons will be asked to evaluate the tactile feedback of each button on each pencil (inclusive of force to activate and “feel” of the button).

Please note: Because the ZIP and ACE pencils are currently released on the market, this study will focus on the new dome switch. All other components of the devices are unchanged and are therefore outside the scope of this evaluation. Additionally, the Rally and Rally GEM devices are evaluated in a separate design validation study (see ENG-PRT-654). Only the new dome switch will be within the scope of this protocol.

The questionnaire will be administered following the completion of ENG-PRT-654 and therefore will not affect the results of that study.

1. **Participants**

This evaluation will incorporate the expected variation in user experience, technique, and ability.

This study will utilize the same participants recruited for the Rally/Refine Design Validation Study (ENG-PRT-654). Please see ENG-PRT-654 for more detail on recruitment criteria.

1. **Materials**

All ZIP, ACE 700, Rally and Rally GEM devices used in this evaluation will be representative of finished goods and will be produced using documented manufacturing, sterilization, and handling processes. Any differences between the study devices and final devices built using a validated process will be documented and addressed in the completion report of this protocol. The completion report will document the serial number or lot number of the released products used in this study. See Table 1 for the devices to be used in this evaluation:

**Table 1: Megadyne Products Used in Evaluation**

|  |  |  |  |
| --- | --- | --- | --- |
| Product Code | Product Name | Project Name | Build Protocol |
| 1000 | MEGADYNE™ MEGA POWER™ Electrosurgical Generator | n/a (released product) | n/a (released product) |
| 2100J | MEGADYNE™ Mega Vac Smoke Evacuator | n/a (released product) | n/a (released product) |
| X252510N | ZIP PEN, ELECTROSURGICAL PENCIL W/E-Z CLEAN, HOLSTER, 10 FT. TUBING | Dome Switch Supplier Change | X6020350/A |
| XME725M1CN | ACE BLADE 700, 2.5 MODIFIED ZIP PEN, "C"CONNECTOR, 10 FT. TUBING | Dome Switch Supplier Change | X6020351/A |
| X251010JN | ULTRA VAC 2, ELECTROSURGICAL PENCIL W/E-ZCLEAN, HOLSTER, 10 FT. TUBING | Dome Switch Supplier Change | X6020348/A |
| XME725M1STN | MEGADYNE ACE BLADE 700, 2.5” BLADE, MODIFIED, SMOKE EVACUATION TELESCOPING PENCIL, 10 FT. | Dome Switch Supplier Change | X6020349/A |

1. **Subject & Location**

Evaluations will be in a market research or approved laboratory facility to be documented in the completion report.

1. **Evaluations**
   1. Trained Ethicon associates or independent contractors will oversee all evaluations as moderator. The moderator will read the introductory statement (Attachment 1) and be responsible for going through the questionnaire following the evaluation. Surgeons will be asked to activate the buttons (see Section 6.2) and to evaluate the statement in Table 3 for each device. The surgeon will be asked to provide a rating as detailed in Table 4. Relevant participant comments will be recorded and included in the completion report. Appropriate protocol training records will be completed and included with the completion report. Deviations from this protocol will be documented in the final report.

**Table 3: Requirements for New Dome Switches**

|  |
| --- |
| 1. Rate the tactile feedback of the device buttons |

|  |  |
| --- | --- |
| **Result** | **Definition** |
| **Acceptable (A)** | You can work with the device without causing problem in your workflow. |
| **Acceptable with Comments (AC)** | You can work with the device, but it may be a challenge in your workflow. |
| **Unacceptable (UA)** | You cannot work with device because it leads to undesirable outcomes. |
| **Not Applicable (N/A)** | An outcome may be N/A if the user does not normally complete the task, or in case of unanticipated use- related hazards, or system malfunctions or breakage. |

**Table 4: Customer Marketing Requirement (CMR) Rating Evaluation Scale**

* 1. Procedure for Evaluation
     1. Study Introduction Statement: The moderator will read the study introduction statement to the participant (Attachment 1).
     2. Surgeon Evaluation of Device Buttons: Participants will have an opportunity to actuate the devices buttons and will have access to excised tissue if they want to evaluate the buttons while activating energy. The surgeon will be handed each device one at a time and then asked to evaluate the tactile feedback of each button.
     3. Closing statement: Moderator will thank participant and end the study.

1. **Acceptance Criteria**

Surgeons will be asked to evaluate the requirement listed in Table 3 for each of the devices. Participant responses and qualitative feedback in the form of verbal comments will be recorded and analyzed. In the event of responses of “Acceptable with Comments” or “Unacceptable”, the Moderator will ask specific clarifying follow-up questions to the study participant 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. Ranking responses of “Acceptable with Comments” (where comment was not acceptably clarified) and “Unacceptable” shall be discussed in greater detail by the team and satisfaction of the acceptance criteria for these items will be judged at that time. Corrective action will be taken where appropriate.

Due to the design/nature of the study, statistical evaluation is not considered to be appropriate.

1. **Attachment**

Attachment 1 – New Dome Switch Moderation Guide

*ZIP, ACE-700, Rally, Rally GEM*:

Design Validation for New Dome Switch Moderation Guide

|  |  |
| --- | --- |
| **Participant** |  |
| **Date / Location of Evaluation** |  |
| **Moderator** |  |
| **Notetaker Name** |  |
| **Notetaker Signature & Date** |  |

**Introduction**: We will ask you to evaluate the tactile feel and force to activate the buttons on several monopolar pencils. If you would prefer, we can connect these pencils to the generator, and you can activate on excised tissue. You may also evaluate the button feel without connecting the devices to the generator.

*[Moderator to hand the surgeon one device at a time.]*

Using the following scale, please categorize your responses for my questions as:

Acceptable, Acceptable with Comments or Unacceptable *[show printed scale]*

|  |  |  |
| --- | --- | --- |
| **Participant:** | | |
| **MEGADYNE ZIP Pen Electrosurgical Pencil (ZIP)** | | |
| **Question:** | **A, AC, UA** | **Comments:** |
| Rate the tactile feedback of the device buttons. |  |  |
| **MEGADYNE ACE Blade 700 ZIP Pen, C-Connector Electrosurgical Pencil (ACE-700)** | | |
| **Question:** | **A, AC, UA** | **Comments:** |
| Rate the tactile feedback of the device buttons. |  |  |
| **MEGADYNE Telescoping Smoke Evacuation Electrosurgical Pencil (Rally)** | | |
| **Question:** | **A, AC, UA** | **Comments:** |
| Rate the tactile feedback of the device buttons. |  |  |
| **MEGADYNE Telescoping Smoke Evacuation Soft Tissue Dissector Pencil (Rally GEM)** | | |
| **Question:** | **A, AC, UA** | **Comments:** |
| Rate the tactile feedback of the device buttons. |  |  |

Any other comments?  None

This completes the study. Thank you!