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***ACE BLADE 700 and ZIP-PENTM Smoke Evacuation Pencil*** Design Validation Discussion Guide

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***Instrument Set-up: Circulating Nurse or Equivalent***

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

***Moderator Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_***

***Device Used:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**Set-up:**

**After being provided with the IFU (attachment 2 of the protocol) The participant will be asked to connect the In-Line filter to the wall vacuum and the suction canister per the protocol.**

1. **Rate the ability to connect the In-Line filter to the wall and suction canister:**

Acceptable

Acceptable with Comments

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

Comments:

**The participant will be asked to connect the C connector on the Zip-Pen to the canister using a 2145 connector and surgical tubing per the protocol.**

1. **Rate the ability to connect the Zip-pen to the suction canister:**

Acceptable

Acceptable with Comments

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

Comments:

***Instrument Use and Evaluation: Surgeon***

***Surgeon Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date:\_\_\_\_\_\_\_\_\_\_\_***

***Device Used:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Surgeon Information is captured in Hurricane Discussion Guide and will be referenced in the report corresponding to this protocol.***

**Greeting** (2 min):

I will be the moderator of today’s session….

*Provide Surgeon with IFU of the device being used*

**Ex-Vivo Model:**

**In this portion of the lab I’d like to give you the chance to use the device for a period of time to assess the overall performance.**

**Do you use monopolar electrosurgical devices in your practice?**

Yes  No

**If no, thank and dismiss.**

**Describe device (monopolar with smoke evacuation).**

* **Demonstrate how the tube zips from the handle for a more different hand positioning.**
* **Ask surgeon to use most comfortable configuration.**
* **Ask surgeon to use cut and coag functions of the device on the tissue model**

1. **Did the device monopolar functionality perform as expected:**

Acceptable

Acceptable with Comments

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

Comments:

1. **Rate the ability to evacuate smoke away from the surgical site:**

Acceptable

Acceptable with Comments

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

Comments:

1. **Rate the ability to visualize the active electrode during the procedure:**

Acceptable

Acceptable with Comments

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

Comments:

1. **Rate the ergonomics of the device:**

Acceptable

Acceptable with Comments

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

Comments:

1. **Rate the amount of drag on your hand from the tubing:**

Acceptable

Acceptable with Comments

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

Comments:

1. **Rate the tactile feel of the buttons:**

Acceptable

Acceptable with Comments

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

Comments:

**Ask the surgeon to clean electrode with gauze or 4x4 sponge.**

1. **Rate the security of the active electrode when cleaning:**

Acceptable

Acceptable with Comments

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

Comments:

**Thank and dismiss Surgeon.**

***Instrument Use and Evaluation: Scrub Nurse or Equivalent (only applicable if testing the Zip-Pen)***

**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.**

1. **Rate the ability to remove the active electrode:**

**(If the scrub nurse has difficulty, demonstrate technique to remove.) If scrub nurse still has difficulty ask if they would use a tool (Hemostat?) to remove.**

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:

***Instrument Clean-up: Circulating Nurse or Equivalent***

**Clean-up:**

**The participant will be asked to disconnect the In-Line filter to the wall vacuum and the suction canister per the protocol.**

1. **Rate the ability to disconnect the In-Line filter to the wall and suction canister:**

Acceptable

Acceptable with Comments

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

Comments:

**The participant will be asked to disconnect the ACE BLADE 700 or Zip-Pen from the canister.**

1. **Rate the ability to disconnect the ACE BLADE 700 or Zip-pen to the suction canister:**

Acceptable

Acceptable with Comments

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

Comments:

**Thank and dismiss.**