



PRECAUTIONS

Contraindications

The ENTceps is not to be used as a fallopian tube sterilization device.

Compliance with Standards

When used with the UPS, device complies with IEC60601-1 requirements for type CF applied part, and meets electromagnetic compatibility requirements of IEC60601-1-2.



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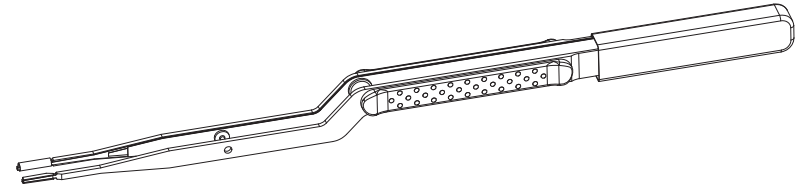


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ENTceps

Model #110-005D



INSTRUCTIONS FOR USE

For use only with

Starion PowerPack™ Dual Control Footswitch (REF 309-004R) and Starion PowerPack™ UPS (Universal Power Supply) (REF 200-003R) or Starion UPS (Universal Power Supply) (REF 200-004R, 200-006R)

Device Description

The ENTceps is a footswitch-activated, hand-held surgical instrument that is powered by a Universal Power Supply (UPS). The ENTceps contain a heating element at the distal tip of the instrument. The heating element is activated by means of the reusable PowerPack Dual Control Footswitch. The ENTceps power cable extends from the handle of the instrument and terminates at the Instrument connector for electrical connection to the UPS.

Intended Use

The ENTceps is a single use device and is intended to be used once only for a single patient. The ENTceps is intended for the simultaneous cutting and cauterization of soft tissue during surgery. The ENTceps may also be used for cutting natural or synthetic, non-metallic, sutures during surgery.

Symbol Definition



Means: Attention — Read and follow indicated Instructions For Use, Precautions, Warnings, etc.



Means: For single use only, do not reuse.



Means: Sterilized by gamma irradiation.



Means: Authorized Representative



Means: Type CF applied part.



Means: Variable Power.



Means: High Power.



INSTRUCTIONS FOR USE

1. Remove the ENTceps from its sterile packaging.

Note: Follow the appropriate Instructions For Use for the PowerPack Dual Control Footswitch and UPS used for the procedure.

2. Insert the connector from the PowerPack Dual Control Footswitch (non-sterile) into the Footswitch connector receptacle of the UPS unit as per Footswitch Instructions For Use. Ensure the connector plugs key properly into the receptacles. Uncoil the ENTceps power cord, pass the connector end of the power cord off the sterile field. Insert the connector of the power cord firmly into the instrument connector receptacle of the UPS. Ensure connector plugs key properly into receptacle. The ENTceps is now ready for use.

3. Pre-check the Starion system for correct set-up and operation. Set-up the UPS and PowerPack Dual Control Footswitch following the applicable Instructions for Use. Place the ENTceps tips in a small amount of sterile saline. Close the device and activate the device on high power by use of the PowerPack Dual Control Footswitch. There should immediately be an audible hissing sound as the saline is heated by the element, and the UPS will emit a high pitch audible signal tone. Repeat with the PowerPack Dual Control Footswitch operated on variable and the control knob on the UPS turned to the number 8 position. A lower pitch audible signal tone will be emitted. Repeat pre-check by attempting to activate the device by closing the forceps without stepping on the foot pedal. If there is a hissing sound as the saline is heated by the element, do not use the Starion system. Contact your Starion representative for repair or replacement.

Note: The heating element and tone will not operate unless the ENTceps are fully closed, the PowerPack Footswitch is connected to the UPS, and a pedal is depressed.

Note: The footswitch variable power output is adjustable when the ENTceps and PowerPack Footswitch are connected to the UPS and the footswitch is activated with the left footpedal. (See UPS Instructions for Use)

4. To seal/cut tissue, grasp the desired tissue between the tip of the ENTceps. Squeeze the handle grips fully together to apply pressure to the tissue. Depress either pedal of the footswitch. Depressing the left footpedal will activate the heating element at the tip of the ENTceps on variable power. (See Note above) An audible low-frequency tone will accompany the activation of the heating element. Depressing the right pedal on the footswitch will activate the heating element of the tip of the ENTceps on high power. An audible high-frequency tone will accompany the activation of the heating element. Generally, lower heat ranges increase the sealing capabilities and increase the time to cut tissue. Higher heating ranges decrease the time to cut and may decrease seal integrity.

5. After the desired sealing/cutting of the tissue, open the ENTceps and then release the pedal of the footswitch. This deactivates the heating element.

Note: After removing the ENTceps, examine tissue for hemostasis. If hemostasis is not present, use appropriate techniques to achieve hemostasis.

6. If desired, progress to a new region of tissue to be sealed/cut.



INSTRUCTIONS FOR USE

Note: It may be desirable to clean the tips of the ENTceps during the surgical procedure. A saline-moistened surgical gauze or sponge may be applied gently along length of the tips of the forceps to remove buildup of coagulated blood and tissue debris. Avoid twisting or pulling on tips. Applying excess pressure can bend the tips or cause tip misalignment.

7. At the end of the surgical procedure, disconnect and discard the ENTceps.



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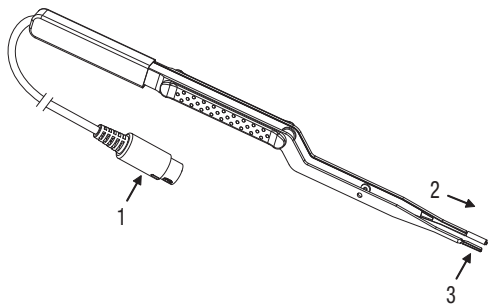
- Device is not designed for reuse or reuse decontamination processes. Reuse of single-use devices creates a potential risk of patient or user infections, injury, illness or death.
- Do not use if the instrument or the cord is damaged.
- Do not use a scalpel or other sharp metal instrument to clean the ENTceps. Doing so may damage the tips and could prevent the ENTceps from functioning properly.
- Refrain from unnecessary activation of the heating element while there is no tissue grasped within the ENTceps. This activity may result in premature degradation of the ENTceps. Device is not intended for continuous use. A typical duty cycle of approximately five (5) seconds on, ten (10) seconds off is recommended.
- Do not immerse the ENTceps handle in liquids.
- Do not touch electrosurgical (Bovie) electrode to ENTceps.
- Use the ENTceps only with the Starion PowerPack Dual Control Footswitch and UPS Unit. Use of any other power supply may damage the ENTceps and could prevent it from functioning properly during use.
- Procedures using instruments for sealing/cutting should be performed only by persons having adequate training and familiarity with these surgical techniques. Consult the medical literature relative to techniques, complications and hazards prior to performance of any procedure. Surgeons using this device should be familiar with the specific anatomy of the region in which they intend to perform the procedure.
- There are no unusual risks associated with the proper disposal of this equipment. Follow any local regulations regarding proper disposal of used surgical equipment.
- Store in a cool, dry place.

Warning

- Do not use in the presence of flammable materials (e.g. alcohol, flammable anesthetics).
- Always disconnect the instrument before discarding; the PowerPack Dual Control Footswitch and UPS are reusable.

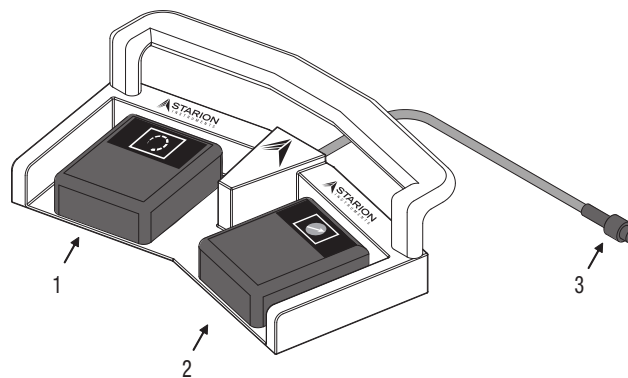
1 ENTceps (sterile)

- 1 - Instrument Connector (Connects to the power supply)
- 2 - Tip Cleaning Direction
- 3 - Heating Element



2 Dual Control Footswitch (non sterile)

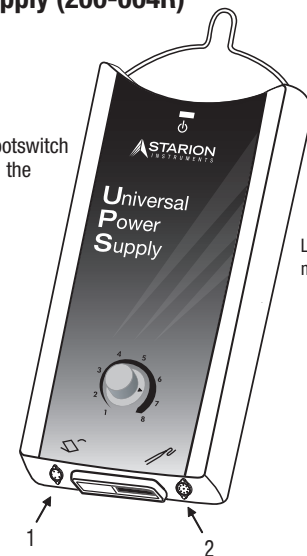
- 1 - Left Pedal (Variable Power)
- 2 - Right Pedal (High Power)
- 3 - Footswitch Connector (Connects to the power supply)



3 Universal Power Supply (200-004R) (non sterile)

- 1 - Footswitch Receptacle
- 2 - Instrument Receptacle

Note: The instrument and footswitch lights will not illuminate until the ENTceps are activated.



Label graphics may vary