

INSTRUCTIONS FOR USE: ELECTROSURGICAL TIP ELECTRODE – STERILE

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

DESCRIPTION

The Xodus Medical ElectroSurgical (ES) Tip Electrode is a single-use electrosurgical device. It is used to deliver monopolar RF electrosurgical energy to a surgical site to cut and/or coagulate soft tissue.

INDICATIONS

The ES Tip Electrode is a single use, sterile device to be used in surgical procedures.

INTENDED PURPOSE AND USER

This device is intended for use by trained healthcare professionals only to cut and coagulate tissue.

CONTRADICTIONS

This device is not designed, sold, or intended for use except as indicated.

KNOWLEDGE AND USE

Professional use requires knowledge of this instruction for use. Device use limited to surgical operating room in a hospital or surgery center.

CLINICAL BENEFITS

Provides cutting and coagulation effects of tissue during surgical procedures.

PREPARATION AND USE

1. Confirm that the ES pencil is NOT connected to the electrosurgical generator.
2. Prior to use, confirm that the ES tip Electrode supplied is fully inserted in the electrosurgical pencil. The insulating
3. If changing the ES Tip Electrode, insert the ES Tip Electrode into the accessory until it stops.
4. DO NOT USE the ES Tip Electrode if it does not fit securely into the accessory..
5. Remove the ES Tip Electrode protector (if one is present) prior to use.
6. PTFE ES Tip Electrodes are coated with blue PTFE which reduces the buildup of eschar on the tip during procedures. These tips need only to be wiped clean with a damp sponge to remove any eschar buildup during a procedure.

DISPOSAL

- After use, the ES Tip Electrode should be disposed of in accordance with hospital policy.

WARNINGS

- This device was designed, test and manufactured for single patient use only. Reuse or reprocessing of this device may lead to its failure or subsequent injury.
- Reprocessing and/or resterilization of this device may create the risk of contamination and patient infection.
- Do not reuse, reprocess or resterilization this device.
- After use, the ES Tip Electrode should be disposed of in accordance with hospital policy.
- The ES Tip Electrode should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.
- Please visually inspect for breaches of packaging integrity prior to use. Do not use if damaged, opened or breached as sterility cannot be guaranteed.
- Do not use a Cautery Tip Cleaner or scratch pad on these tips. This may result in damage to the PTFE coating.
- Do not use the electrode if the coating is damaged, it should be discarded.
- Bending the blade is not recommended, it may damage the PTFE coating and/or electrode.
- To avoid unintended tissue damage, only activate electrode in contact with or in close proximity to target tissue.
- Electrodes should be stored in an electrically insulated container when not in use.

- Keep hot/activated cautery tips away from flammable materials substances. (e.g. drapes, flammable gases, endotracheal tubes, etc.).
- Use the lowest power settings possible to achieve desired effect.
- Use the active electrode for the minimum time necessary.
- Using coated electrodes at high power settings may cause damage to the coating.
- Do not modify or add to the insulation of active electrodes.
- Deactivate the electrosurgical before the tip leaves the surgical site.
- Electrosurgery should not be used to perform circumcisions.
- USA Federal law restricts this device to sale by or on the order of a physician.

PRECAUTIONS

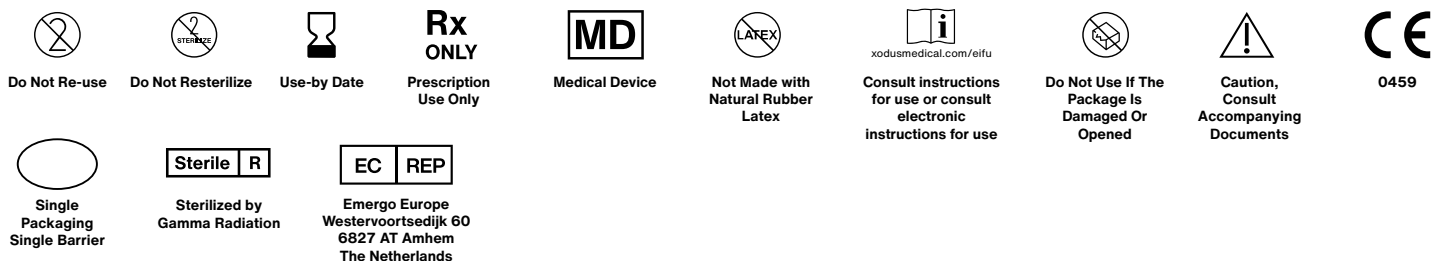
- The ES Tip Electrode should be used in accordance with the instructions for use and any contraindications, warnings or precautions provided by the manufacturer of the associated instrument.
- Xodus Medical recommends the use of gamma radiation for sterilization.
- ES Tip Electrode is compatible with gamma radiation and EO methods of sterilization.
- User should have a complete understanding of the principles of electrosurgical procedures to avoid shocks, burns or other injury to the patient.
- Notice to the User and/or patient that any serious incident that has occurred in relation to the device should be reported and the competent authority of the Member State in which the user and/or patient is established, as well as, Xodus Medical and its Authorized Representative.

TECHNICAL SPECIFICATIONS

- Finished product sterilized by gamma radiation
- Materials of manufacture include:
 - » Stainless Steel
 - » Polyolefin
 - » Kynar
 - » PTFE
- Shelf Life – 4 years

STORAGE, TRANSPORT, AND OPERATIONAL CONDITIONS

- ES Tip Electrode should be stored in a clean, dry location at room temperature prior to use. Avoid prolonged exposure to elevated temperatures.



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FDA REGISTERED
ISO 13485 CERTIFIED

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