

REUSABLE ELECTROSURGICAL ELECTRODES

- Store in a cool, dry place.
- Device is rated for 4kVpeak

INDICATIONS FOR USE: The instrument is used for coagulating tissue at the surgical site.

WARNING: Do not use in the presence of flammable gases/materials or in oxygen rich environments. Do not place active accessories near or in contact with flammable material (gauze, surgical drapes, etc.) Fire could result.

WARNING: Tissue buildup (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen enriched environments. Keep the electrode clean and free of all debris.

WARNING: Conductive fluids (e.g., blood or saline) in direct contact with an active electrode or in close proximity to any active accessory may disperse electrical current and cause unintended burns to the patient.

WARNING: Improper electrode installation may result in injury to the patient or operating room personnel by arcing at the electrode pencil connection.

WARNING: Accessories and electrodes should be placed in a clean, dry, nonconductive and highly visible area when not in use.

WARNING: Keep active electrodes away from the patient when not in use. Inadvertent patient contact may result in unwanted burns.

WARNING: Do not bend or reshape electrodes; damage to the insulation or electrode may result. Do not use an electrode with visible insulator damage. Using damaged electrodes may result in unwanted burns.

CAUTION: This product is sold NON-STERILE. Sterilize prior to use.

CAUTION: Needles are fragile and should be handled with care to avoid damage to the needle and injury to hospital personnel.

CAUTION: Always refer to the instruction manuals of a high frequency generator.

CAUTION: During electrosurgery, follow general instructions for each surgical procedure.

CAUTION: Activate the electrosurgical unit only when you are ready to deliver electrosurgical current and the active tip is in view and near target tissue. Deactivate the electrosurgical unit before the tip leaves the surgical site.

CAUTION: For monopolar electrosurgical procedures, ensure that the patient return electrode is appropriately selected, properly applied to the patient, and connected to the electrosurgical generator.

Instructions for Electrode Setup:

Bovie Medical Corporation electrodes have a standard 2.36 mm (3/32") diameter stainless steel shaft and plastic insulator, and fit Bovie® and most other electrosurgical pencils.

1. Prior to use, check the electrode/pencil connection to ensure proper fit and compatibility.
2. Examine all accessories for damage before connecting to the electrosurgical generator. After connection, ensure that they are functioning as intended.
3. Before inserting or changing an electrode be sure that the generator is in the OFF/STANDBY position and that the active accessory is not connected.
4. For devices with insulators, the shank and insulators must fit securely into the active accessory. Insert the round shank into the electrosurgical accessory until electrode is fully inserted.
5. Confirm proper electrosurgical settings before proceeding with surgery. Use the lowest possible setting to achieve the desired effect.
6. **CAUTION:** Needle electrodes are for use with precise low power settings during monopolar electrosurgery. Using a needle at high power settings for extended periods of time may result in damage to the needle. Use low power for short periods of time to prevent damage to needle tip.

CONTRAINDICATIONS: This device is not intended for use except as indicated.

Medical Purpose/ Indication

Electrode is used for coagulation of tissues

Operating Principle

Electrodes provide a point source transfer of RF energy to tissue

Patient Population

No restriction

Site of Use and Site Conditions

Site of use – No restriction

Site conditions – Aseptic

Intended User Profile

This device is intended to be used by trained physicians or individuals familiar with electrosurgery.

Intended Conditions for Use

Environment

- Doctor Office, Surgery Center, or Hospital
- Clear and unobstructed view at point of use

Frequency of use

Single patient multiple activation

Disposal

- Biohazard – Dispose of electrode according to facility procedures

Procedures Where Visualization May Be Impaired:

For procedures where visualization may be impaired be alert to these potential hazards.

- The electrode may remain hot enough to cause burns after the electrosurgical current is deactivated.
- Inadvertent activation or movement of the activated electrode outside the field of vision may result in injury to the patient.
- Localized burns to the patient or physician may result from electrical currents carried through conductive objects (such as a speculum) or conductive fluids. Electrical current may be generated in conductive objects by direct contact with the active electrode.

Cleaning Instructions:

1. Remove all gross matter (blood, tissue) by wiping the electrode using a gauze pad or soft cloth dampened with warm tap water until all visible debris is removed.

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Cleaning Instructions:

1. Remove all gross matter (blood, tissue) by wiping the electrode using a gauze pad or soft cloth dampened with warm tap water until all visible debris is removed.

2. Soak the electrode in an enzymatic detergent mixture diluted according to the manufacturer's instructions. The electrodes may also be cleaned using a soft bristled cleaning brush to remove any visible debris.
3. **IMPORTANT:** Abrasive material should not be used in the area of the barcode when cleaning the electrode.
4. Remove cleaning agents from electrode by wiping with tap water dampened cloth.
5. Dry electrode thoroughly.

Sterilization Instructions:

NUMBER OF USES WHEN STERILIZED BY STEAM AUTOCLAVE: 5 uses for Loop Electrodes and 25 uses for all other Electrodes.

1. Steam autoclave 250° F. (121°C.; gravity) for 30 minutes using an autoclavable pouch or wrapped cloth method. Consult the AAMI recommended practice for steam sterilization using the wrapped cloth method. Allow the product to cool at least 30 minutes.
2. Flash autoclaving is not recommended.

Storage and Handling:

Device must be stored in a clean, cool and dry place.

It must be handled with care to avoid damage to the packaging and its content during transportation and storage.

Instrument must not be in contact with acids or other corrosive liquids.

R_x ONLY



Read Instructions Before Use

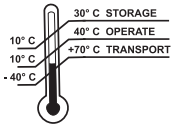


Do Not Use if Packaging is Damaged or Opened



Non Sterile

Not Made With Natural Rubber Latex



STORAGE
10 to 75 % non-condensing
OPERATE
30 to 75 % non-condensing
TRANSPORT
10 to 100 % including condensation

R_x ONLY



Read Instructions Before Use

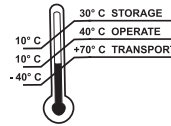


Do Not Use if Packaging is Damaged or Opened




Non Sterile

Not Made With Natural Rubber Latex



STORAGE
10 to 75 % non-condensing
OPERATE
30 to 75 % non-condensing
TRANSPORT
10 to 100 % including condensation

Bovie[®]

 **Bovie Medical Corporation**
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2023-05-30

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