

Dermal Tip Electrodes; Non-Sterile

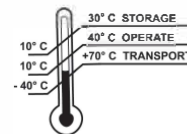
Instruction for Use

Shaft Length ~7cm

R_x ONLY



Not Made With Natural
Rubber Latex



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

Electrodes have a standard 2.4 mm (3/32 in.) diameter stainless steel shaft and plastic insulator, and fit most electrosurgical pencils.

WARNINGS:

Danger – Explosion Hazard: Do not use electro-surgery in the presence of flammable anesthetics.

Fire Hazard: Both oxygen (O₂) and Nitrous Oxide (N₂O) support combustion. Avoid O₂ and N₂O enriched atmospheres. Enriched atmospheres may result in fires and burns to patients or surgical personnel.

The metal shaft of the electrode must fit completely and securely into the pencil. If metal is visible, do not use the electrode. Exposed metal may result in electric shock or burn to the patient or surgical personnel.

Confirm proper electrosurgical settings prior to and during a procedure. Use the lowest power settings to achieve the desired effect. If increased power settings are requested, check the patient return electrode and all accessory connections before major power setting adjustments.

Fire Hazard: Always place the active Electrode in a clean, dry, insulated safety holster when not in use.

Electrosurgical accessories that are activated or hot from use can cause unintended burns to the patient or surgical personnel.

Electrosurgical accessories may cause fire or burn if placed close to or in contact with flammable materials such as gauze or surgical drapes. Place longer electrodes such as extended electrodes away from the patient and drapes.

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Fire/Explosion Hazard: The following substances contribute to increased fire and explosion hazards in the operating room:

- Oxygen enriched environments
- Oxidizing agents such as nitrous oxide (N₂O) atmospheres
 - * Verify all anesthesia circuit connections are leak free before and during use of electrosurgery.
 - * Verify endotracheal tubes are leak free and that the cuff seals properly to prevent oxygen leaks.
 - * If an uncuffed tube is in use, pack the throat with wet sponges around the uncuffed tube.
 - * If possible, stop supplemental oxygen at least one minute before and during use of electrosurgery.
- Alcohol-based skin prepping agents and tinctures
- * Activate the electrosurgical unit only after vapors from skin prep solutions and tinctures have dissipated.
- * Naturally occurring flammable gases (such as methane) that may accumulate in body cavities.

Fire Hazard: The sparking and heating associated with electrosurgery can provide an ignition source.

Observe fire precautions at all times:

- When using electrosurgery in the presence of gases or flammable substances, prevent pooling of fluids and the accumulation of gases under surgical drapes. Tent drapes to allow vapors to mix with room air before using electrosurgery.
- Tissue buildup (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen enriched environments. With sufficient heating, eschar can become a glowing ember and pose a fire hazard both as an ignition source and as a fuel. Keep the electrode clean and free of all debris.
- Facial and other body hair is flammable. Water soluble surgical lubricating jelly may be used to cover hair close to the surgical site to decrease flammability.

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. This can happen as a result of either direct coupling with the active electrode or capacitive coupling between the active electrode and the external surface of the electrode insulation. Therefore, to prevent unintended burns in the presence of conductive fluids:

- Always keep the external surface of the active electrode away from adjacent tissue while activating the electrosurgical generator.
- Clear conductive fluid from the electrode before activating the electrosurgical pencil.

CAUTIONS:

Federal (USA) law restricts this device to sale by or on the order of a physician.

Use aseptic techniques to open packaging.

Before beginning the procedure, verify compatibility of all instruments and accessories. Generators and electrical accessories complying with IEC60601-1-1 and IEC60601-2-2 standards are deemed to be compatible.

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

During electrosurgery, follow general instructions for each surgical procedure.

Device is rated for 4k Vpeak.

Always use the lowest power setting that achieves the desired surgical effect. Use the active electrode for the minimum time necessary in order to reduce the possibility of unintended burn injury.

Do not contact or arc the activated electrode to metal surfaces. Dermal tip breakage may result.

Confirm that the active electrode is properly connected to the active accessory, and that the accessory is firmly connected to the correct power output receptacle on the electrosurgical generator.

Before use, examine the electrosurgical unit and accessories for defects. Do not use cables or accessories with damaged (cracked, burned, or taped) insulation or connectors. Localized burns to the patient or physician may result.

Do not modify or add to the insulation of active electrodes.

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.

The electrodes are intended for single use only. Discard after use in a puncture resistant container to prevent injury.

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

When applying the patient return electrode, ensure that the entire pad adheres to the patient. Do not reuse single use patient return electrodes. Do not use the return electrode if the packaging is damaged, or if the gel / adhesive material has dried.

If the patient has moved or is repositioned after the patient return electrode is applied, ensure that the return electrode firmly contacts the skin and that all connections are intact.

Avoid spilling any solutions on the return electrode. If this occurs, remove the return electrode, dry the skin, and apply a new return electrode. A moist environment may cause the return electrode to peel off.

Operating Principal

Bovie Electrodes are used for cutting and coagulation of Tissue

Site of use

- No Restrictions

Site Condition

- Aseptic

Intended User Profile

- Education
 - Restricted for use by or on the order of a physician
- Knowledge
 - Understands electrosurgery and electrosurgical techniques
 - Reads and understands the supplied Instruction for Use or Device Labeling
 - Understands hygiene
- Experience
 - Some training on techniques or training under surveillance/supervision
- Permissible impairments
 - Mild reading vision impairment or corrected vision to 20/20

Intended Conditions for Use

- Doctor office, Surgery center or Hospital, intended for professional use only
- Lit, clear and unobstructed view at point of use
- Ambient Temperature 10° C to 40° C

Frequency of Use

- Single Use - Single patient multiple activation
- Reusable – see Cleaning and Sterilization Instructions

Disposal

- Biohazard – Dispose of electrode according to facility procedures

Notice:

Do not modify the electrode tip. Modifications to the tip may result in tip breakage or other damage.

Important:

Clean the electrode often with moist gauze or other material appropriate for the electrode type.

Install the Electrode



Maximum Power

Notice:

Exceeding maximum power settings may result in patient injury or product damage.

The following maximum power settings are recommended:

		<u>Power</u>
<u>Electrode</u>	<u>Mode</u>	<u>Setting</u>
Dermal tip	Coag or Blend	55 W

1. Ensure the pencil is not connected to the generator, or the generator is Off or in the Standby mode, if available.
2. Grasp the insulating sleeve on the electrode. Remove tip protector. Insert the electrode into the pencil.
3. Ensure the electrode is fully inserted into the pencil. The shank and insulating sleeve should fit securely into the pencil. If the shank and/or insulating sleeve does not fit, or the insulation will not insert 3.2 mm (1/8 in.), do not use this electrode/pencil combination.
4. Refer to the generator instruction manual for proper procedures for connecting the active accessory to the generator.

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.