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STERILE FO

Rx ONLY
Single use

Do not sterilize
Consume immediately
Bar code

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en Instructions for Use

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fr Istruzioni per l'uso

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no Bruksanvisning

sv Bruksanvisning

ru Инструкции по применению

zh 使用说明

en Edge™

REF E1455 Insulated Blade Electrode 2.75" (7.0 cm)

REF E1455-4 Insulated Blade Electrode 4" (10.16 cm)

REF E1455-6 Insulated Blade Electrode 6.5" (16.51 cm)

REF E1465 Insulated Needle Electrode 2.8" (7.2 cm)

REF E1465-4 Insulated Needle Electrode 4" (10.16 cm)

REF E1465-6 Insulated Needle Electrode 6.5" (16.51 cm)

Not made with natural rubber latex

Do not use if package is opened or damaged

For use with a max peak voltage of 5600 V.

Indications for Use

The Edge Coated Electrodes are intended as an alternative to uncoated stainless steel electrodes for use in conventional monopolar electro-surgical accessories. The coated electrodes are intended for use in situations where monopolar electro-surgical cutting and coagulation are normally used.

Warning

This product cannot be adequately cleaned and/or sterilized by the user in order to facilitate safe reuse, and is therefore intended for single use. Attempts to clean or sterilize these devices may result in bio-incompatibility, infection, or product failure risks to the patient.

Warning

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. Watch for enriched O₂ and N₂O atmospheres near the surgical site, especially during head and neck surgery. Enriched O₂ atmospheres may result in fires and burns to patients or surgical personnel.

Warning

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

- Oxidizing agents, such as N₂O atmospheres
 - Verify all anesthesia circuit connections are leak free before and during use of electro-surgery.
 - 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 electro-surgery.
- Alcohol-based skin prepping agents and tinctures
 - Activate the electro-surgical 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.

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Warning

Fire Hazard The sparking and heating associated with electro-surgery can provide an ignition source.

Observe fire precautions at all times:

- When using electro-surgery in the same room with gases or flammable substances, prevent pooling of fluids and the accumulation of gases under surgical drapes or near the surgical site.
- Tissue buildup (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen-enriched environments, such as in throat or mouth procedures. Eschar plus high oxygen may create embers. 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.

The electrode must fit completely and securely into the pencil. An incorrectly seated electrode may result in burns to the patient or surgical personnel.

Warning

Fire Hazard Always place the active electrode in a clean, dry, insulated safety holder when not in use.

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

• Electro-surgical 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.

• Confirm proper electro-surgical 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.

Warning

Some surgeons may elect to "buzz the hemostat" during surgical procedures. It is not recommended, and the hazards of such a practice probably cannot be eliminated. Burns to the surgeon's hands may result. To minimize the risk, take these precautions:

- Do not "buzz the hemostat" with a needle electrode.
- Do not lean on the patient, the table, or the retractors while buzzing the hemostat.
- Activate cut rather than coag. Cut has a lower voltage than coag.
- Use the lowest power setting possible for the minimum time necessary to achieve hemostasis.
- Activate the generator after the accessory makes contact with the hemostat. Do not arc to the hemostat.
- Firmly grasp as much of the hemostat as possible before activating the generator. This disperses the current over a larger area and minimizes the current concentration at the fingertips.

Warning

• "Buzz the hemostat" below hand level (as close as possible to the patient) to reduce the opportunity for current to follow alternate paths through the surgeon's hands.

• When using a coated or nonstick blade electrode, place the edge of the electrode against the hemostat or other metal instrument.

Precaution

Do not exceed maximum power limits as stated in instructions for use. Exceeding these power settings may result in patient injury or product damage.

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.

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Precaution

Pediatric applications and/or procedures performed on small anatomic structures may require reduced power settings. The higher the current flow and the longer the current is applied, the greater the possibility of unintended thermal damage to tissue, especially during use on small appendages.

Needle electrodes are fragile. Handle them with care to avoid damage to the needle and injury to hospital personnel.

Before use, examine the electro-surgical unit and accessories for defects. Do not use cables or accessories with damaged (cracked, burned, or taped) insulation or connectors.

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

Activate the electro-surgical unit only when ready to deliver electro-surgical current and the active tip is in view (especially if looking through an endoscope).

Deactivate the electro-surgical unit before the tip leaves the surgical site.

Precaution

The electrodes are intended for single use only. Safely discard after use to prevent injury to hospital personnel. These electrodes are not designed to withstand re-sterilization. Do not re-sterilize.

Notice

Needle electrodes are designed for precise low power use during monopolar electro-surgery. Using a needle at high power settings for extended periods of time may result in damage to the needles. Use low power settings for short periods of time to prevent needle damage.

This electrode has a coating to reduce sticking of eschar. Cleaning the electrode with a scratch pad or other abrasive object, scraping with a sharp object, or bending beyond 90 degrees may damage the electrode. If the electrode is damaged, discard it.

Notice

Using coated electrodes at high power settings may cause damage to the coating. If the coating is damaged, discard the electrode.

Electro-surgical generators (e.g., Force FX™ or Force E2™ generators) produce less surgical effects at lower power cut mode settings than conventional electro-surgical generators. The electrode coating may deteriorate when used with tissue response generators at higher power settings.

Important

Wipe the electrode often with moist gauze or other material.

Instructions for Use

1. Ensure the pencil is not connected to the generator.

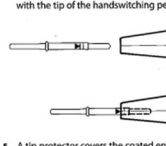


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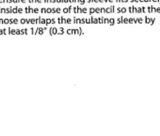
2. Grasp the insulating sleeve on the electrode and insert the electrode into the pencil.



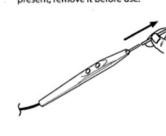
4. Hex electrodes have a depth indicator. The line on the depth indicator should be flush with the tip of the handswitching pencil.



3. Ensure the insulating sleeve fits securely inside the nose of the pencil so that the nose overlaps the insulating sleeve by at least 1/8" (0.3 cm).



5. A tip protector covers the coated end of some electrodes. If a tip protector is present, remove it before use.



Maximum Power

Maximum Power for Blades

The maximum power limits for E1455 series blades are as follows:

Mode	Power Setting
Coag	35 watts
Pure Cut or Blend	50 watts

Maximum Power for Needles

The maximum power limits for E1465 series needles are as follows:

Mode	Power Setting
Coag	25 watts
Pure Cut or Blend	30 watts