



Edge™

Insulated Blade and Needle Electrodes

REF E1455, E1455-4, E1455-6, E1465, E1465-4, E1465-6

Instructions for Use

Rx **CE**
ONLY 2797

Symbols

STERILE EO

Sterilized using ethylene oxide



Not made with natural rubber latex



Do not reuse

Rx
ONLY

For prescription use only



Do not resterilize



Do not use if package is damaged



Consult the instructions for use



Caution! Read all warnings and cautions in instructions for use



Product is a medical device



Single sterile barrier system



Transport

Transport temperature limitations



Storage/Operation

Storage and operation temperature limitations



Keep product dry



GOST-R



CE Mark, Notified Body



Authorized Representative in the European Community



Catalog number



Manufacturer



Use by Date



Lot number



Package quantity (50)

Figure 1. Pencil disconnected from the generator

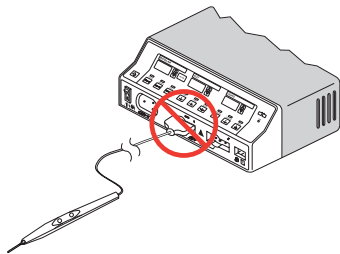


Figure 2. Inserting the electrode

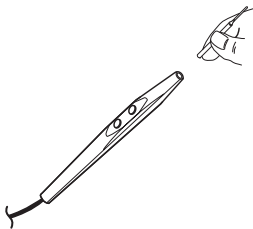


Figure 3. Depth Indicator

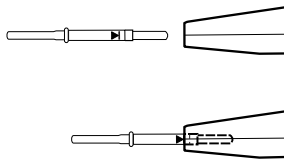
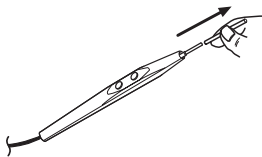


Figure 4. Tip Protector



Edge™

E1455 Insulated Blade Electrode, 7.00 cm (2.75 in.)

E1455-4 Insulated Blade Electrode, 10.16 cm (4.00 in.)

E1455-6 Insulated Blade Electrode, 16.51 cm (6.50 in.)

E1465 Insulated Needle Electrode, 7.20 cm (2.80 in.)

E1465-4 Insulated Needle Electrode, 10.16 cm (4.00 in.)

E1465-6 Insulated Needle Electrode, 16.51 cm (6.50 in.)

1. Indications for Use

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

2. Compatible Equipment

These devices are designed for use with a maximum peak voltage of 4500 V.

These devices are compatible with handswitching or footswitching electrosurgical pencils with a 2.36 mm (0.093 in.) insertion diameter.

2.1. Maximum Power

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

Table 1. Maximum Power for Blades

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

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

Table 2. Maximum Power for Needles

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

3. Handling and Operating Conditions

Condition	Ambient temperature	Relative humidity
Operation	10°C to 40°C (50°F to 104°F)	15% to 90% non-condensing
Transport	-30°C to 60°C (-22°F to 140°F)	5% to 90% non-condensing
Storage	10°C to 40°C (50°F to 104°F)	5% to 90% non-condensing

4. Clinical Benefits

The electrosurgical devices used in combination with compatible generators and accessories (adapters, footswitches, cords) will provide monopolar or bipolar energy for cutting and coagulating soft tissue. This

provides the capability for the surgeon to balance tissue dissection and hemostatic effects as needed during a given surgical case.

5. General Warnings and Cautions

Read all instructions, warnings, and cautions before performing electrosurgery using Covidien equipment or accessories.

5.1. Warnings

- **Warning:** This device is for use only by trained, licensed physicians. Do not use electrosurgical equipment unless properly trained to use the device in the specific procedure being undertaken. Use of this device without such training can result in serious, unintended patient injury.
- **Warning:** The sparking and heating associated with electrosurgery can provide an ignition source.

Observe fire precautions at all times:

- Do not use in the presence of flammable anesthetics or oxidizing gases, such as nitrous oxide (N₂O) and oxygen (O₂).
- Do not use in close proximity to volatile solvents (such as ether or alcohol), as explosion may occur.
- Be aware of naturally occurring flammable gases (such as methane) that may accumulate in body cavities.
- When using electrosurgery 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 in the presence of oxygen-rich atmospheres 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.
- **Warning:** 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.
- **Warning:** 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.
- **Warning:** Do not exceed maximum power limits as stated in [Table 1](#) and [Table 2](#), located in [Section 2](#). Exceeding these power settings may result in patient injury or product damage.
- **Warning:** Do not modify or add to the insulation of active electrodes.
- **Warning: For coated electrodes** – The 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.

5.2. Caution and Notes

- **Caution:** Do not use the electrode beyond its expiration date.
- **Note:** Needle electrodes are designed for precise low power use 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 settings for short periods of time to prevent needle damage.
- **Note:** Using coated electrodes at high power settings may cause damage to the coating. If the coating is damaged, discard the electrode.
- **Note:** Electrosurgical generators (for example, Force FX™ or Force EZ™ generators) produce desired surgical effects at lower power cut mode settings than conventional electrosurgical generators. The electrode coating may deteriorate when used with tissue response generators at higher power settings.

6. Before Surgery

6.1. Warnings

- **Warning:** Due to concerns about the carcinogenic byproducts (such as tissue smoke plume and aerosols), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used.
- **Warning:** 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. Tip modifications may result in breakage or other damage. Discard any damaged electrode.
- **Warning:** 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:** Ensure that the patient electrode is appropriate, properly applied to the patient, and connected to the generator for monopolar use. Confirm that the active electrode is connected to the active generator port.
- **Warning:** Do not use in patients who have electronic implants such as cardiac pacemakers without first consulting a qualified professional (for example, cardiologist). A possible hazard exists because interference with the action of the electronic implant may occur, or the implant may be damaged.

6.2. Setup Instructions

1. Apply the return electrode to the patient according to the manufacturer's instructions.
2. Connect the return electrode to the generator.
3. Inspect sterile packaging. Discard electrodes with damaged sterile packaging.
4. Transfer the electrode aseptically into the sterile field.
5. Inspect the electrode for insulation damage and coating damage.
6. Ensure the pencil is not connected to the generator. Refer to [Figure 1](#).
7. Grasp the insulating sleeve on the electrode. Insert the electrode into the pencil. Refer to [Figure 2](#).

8. Ensure the electrode is fully inserted into the pencil. Ensure the insulating sleeve fits securely inside the nose of the pencil so that the nose overlaps the insulating sleeve by at least 0.3 cm (1/8 in.).
9. Hex electrodes have a depth indicator. The line on the depth indicator should be flush with the tip of the handswitching pencil. Refer to [Figure 3](#).
10. A tip protector covers the end of some electrodes. If a tip protector is present, remove it before use. Refer to [Figure 4](#).
11. Confirm that all power settings on the generator are appropriate for the procedure to be performed. Verify that the generator output does not exceed the rated accessory voltage (both return electrode and pencil electrode).

7. During Surgery

7.1. Warnings

Warning: 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.

Warning: Some surgeons may elect to “buzz the instrument” 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 instrument” with a needle electrode.
- Do not lean on the patient, the table, or the retractors while buzzing the instrument.
- 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 instrument. Do not arc to the instrument.
- Firmly grasp as much of the instrument as possible before activating the generator. This disperses the current over a larger area and minimizes the current concentration at the fingertips.

- “Buzz the instrument” 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 instrument or other metal instrument.

7.2. Cautions and Note

- **Caution:** Needle electrodes are fragile. Handle them with care to avoid damage to the needle and injury to hospital personnel.
- **Caution:** Activate the electrosurgical unit **only** when ready to deliver electrosurgical current and the active tip is in view (especially if looking through an endoscope).
- **Caution:** Deactivate the electrosurgical unit **before** the tip leaves the surgical site.
- **Caution:** Do not activate the instrument while cleaning the electrode. Injury to the operating room personnel may result.
- **Note:** Wipe the electrode often with moist gauze or other material.

8. After Surgery

Warning: This product cannot be cleaned 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 a bioincompatibility, infection, or product failure risks to the patient.

Caution: Single use only. Discard biologically contaminated devices in accordance with your institution’s hazardous medical waste and sharps procedures and local regulatory requirements.

8.1. Instructions

1. After the procedure, turn off the electrosurgical generator.
2. Disconnect the pencil and electrode assembly from the generator.
3. Disconnect the electrode from the pencil.

9. Residual Risk Summary

While every attempt has been made to reduce patient and user risks, all surgeries using this instrument carry some residual risk, even when used by trained physicians. The potential adverse events associated with the use of electrosurgery includes, but are not limited to, the following risks:

- Airway obstruction
- Bleeding
- Burn (including thermal and bowel)
- Electric shock
- Foreign body in patient
- Infection
- Tissue trauma

Note: Any serious incident that has occurred in relation to the device should be reported to the manufacturer and necessary regulatory authority (if European Union, the competent authority of the Member State) in which the user or patient is established.

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