

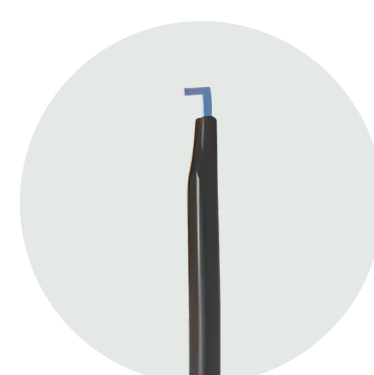


## Disposable SurgyCut Electrode with Handle

### Instructions for Use

#### Product Description

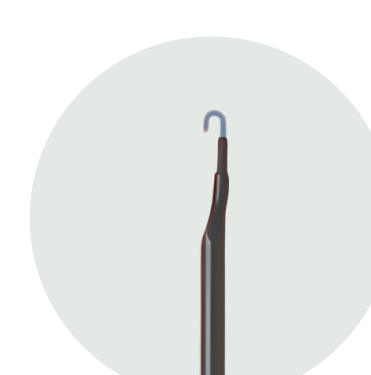
These fully disposable laparoscopic electrodes designed for electrosurgical procedures feature a handle electrode that connects directly to a monopolar cable while providing a comfortable and ergonomic grip. The device features a non-stick PTFE coating to reduce eschar buildup and tissue sticking, and because the insulation is entirely new with each device, it effectively reduces the risk of electrical arcing. To accommodate varying surgical preferences, the electrode is available in 35cm and 45cm shaft lengths and comes in various tip shapes, including L-Hook, J-Hook, L-Wire, J-Wire, and Spatula.



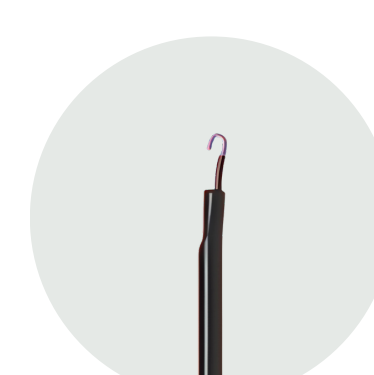
L - Hook



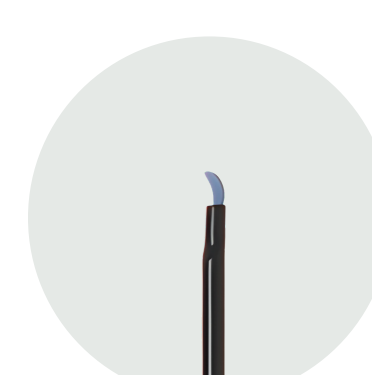
L - Wire



J - Hook



J - Wire



Spatula



Ergonomic Handle

#### Clinical Benefits

- **Controlled tissue cutting and coagulation:** Supports localized monopolar electrosurgical cutting and coagulation during laparoscopic procedures.
- **Hemostasis support:** Assists in controlling minor bleeding during tissue dissection and coagulation.
- **Reduced tissue sticking:** The PTFE/non-stick coating helps reduce eschar buildup and tissue adhesion to the electrode tip.
- **Improved procedural efficiency:** Helps reduce interruptions for cleaning the active tip and supports smoother electrosurgical performance.
- **Reduced risk of insulation-related issues:** Single-use electrodes provide new insulation for each procedure, reducing risks associated with worn or damaged reusable insulation.

#### Intended User

- All procedures should be performed only by physicians with adequate training and knowledge of these procedures.
- Users/physicians should consult medical literature regarding techniques, hazards, contraindications, and complications prior to performing these procedures.

#### Inspections

- **Pre-Use Inspection:** Before use, examine the electrosurgical unit and accessories for any defects.
- **Insulation check:** Remove the electrode with the handle from its sterile pouch and carefully observe for any insulation damage prior to use. Do not use cables or accessories with damaged, cracked, burned, or taped insulation or connectors.
- **Coating check:** Check for coating integrity. If the coating is damaged or scratched, the electrode must be discarded.

#### Patient Population

- **General Use:** Used on patients undergoing laparoscopic or electrosurgical procedures requiring cutting and coagulation.

#### Contraindication

Incidents which have been reported in connection with the use of these systems:

1. Alternating current paths leading to burns on spots where the patient or user comes into contact with components without insulation.
2. In the presence of flammable gases, liquids, and/or oxygen enriched environments.
3. Electrosurgery is potentially hazardous for patients with active implants such as pacemakers, AICDs and neuro stimulators.

#### Single-Use/ Disposable Product

- **Single-Use Only:** These electrodes are intended for single use only.

#### Disposal

- Following use, discard the Surgycut electrode in accordance with applicable hospital policies and local regulations.

#### Shelf Life, storage and Transportation

The product must be handled in a manner that preserves the sterile pouch and prevents damage to the electrode's delicate coating or insulation.

#### Performance Claims

- **Non-Stick Efficiency:** The specialized coating successfully reduces the sticking of eschar to the tip.
- **Output Efficiency:** When used with electrosurgical generators equipped with contact quality monitoring technology to control output power, the device produces the desired surgical effects at lower cut mode settings than conventional generators.

#### Undesirable Side Effects

- **Thermal Injury:** Potential for unintended burns or thermal damage to the patient or surgical personnel if settings are too high, if the electrode is incorrectly seated, or if it is placed close to flammable materials.

#### Precautions

- Before connecting devices to an electrosurgical unit, make sure that the unit has been switched off or is in standby mode. Disregarding these instructions may lead to burns and electrical shock. Leave device in holster when not in use. Never use the devices in the presence of flammable or explosive substances. Do not touch any other metallic instruments, trocar sleeves, optics or the likes during use. Always use monopolar devices with monopolar output of the generator.

▶ Warnings

- Do not use electrosurgery 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. 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 solution and tinctures have dissipated. The sparking and heating associated with electrosurgery can provide an ignition source.

Observe fire precautions at all times:

- When using electrosurgery in the same room with flammable substances, prevent pooling of fluids and the accumulation of gases under surgical drapes or near the surgical site.
- Tissue build up (eschar) on the tip of an active electrode poses a fire hazard, especially in oxygen enriched environment 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.
- Note: The electrode must fit completely and securely into the pencil. An incorrectly seated electrode may result in burns to the patient or surgical personnel. 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.

**Note:** 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.

**CAUTION:**

1. 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.
2. 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.

**NOTICE:**

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

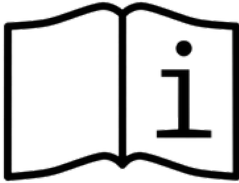
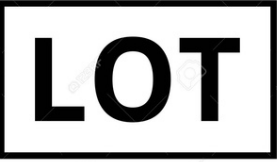
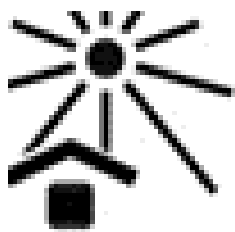
Electrosurgical generators with contact quality monitoring technology to control output power, produce desired surgical effects at lower cut mode settings than conventional electrosurgical generators. The electrode coating may deteriorate when used with contact quality monitoring generators at higher power settings.

**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.
- 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 (especially if looking through an endoscope).
- Deactivate the electrosurgical before the tip leaves the surgical site. 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.

▶ Preparation for Use

1. Ensure the cable is not connected to the generator.
2. Remove the electrode with handle from the sterile pouch.
3. Observe any insulation damage prior to use.
4. Grasp the insulating sleeve on the electrode.
5. A tip protector covers the coated end of some electrodes. If a tip protector is present, remove it before use.
6. Connect the cable to the RF post on the back of the handle electrode.
7. Wipe the electrode often with moist gauze or other non-abrasive material.

| Symbols                                                                               | Meaning                  |
|---------------------------------------------------------------------------------------|--------------------------|
|  | Latex Free               |
|  | Single Use               |
|  | Keep Dry                 |
|  | Sterile by EO            |
|  | See Instructions For Use |
|  | Humidity Limits          |
|  | Reference Number         |
|  | Batch Number             |
|  | Keep Away From Sunlight  |
|  | Temperature Limits       |