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SurgyCut - Bugbee Electrode

Instructions for Use



Product Description

The SurgyCut Bugbee Electrode is a sterile packed, disposable, one-piece fulgurating electrode with a dome/ball tip. The electrode, cable and connector are integrated into one device; no cable assembly is required. Available in 5 Fr and 4 Fr sizes, both 58 cm in length. Compatible with most standard cystoscopes; specific scope-channel and generator compatibility must be verified before use.

Clinical Benefits

- **Precise Coagulation:** Ball-shaped tip enables targeted tissue coagulation and fulguration.
- **Effective Hemostasis:** Supports controlled management of localized bleeding during cystoscopic and endoscopic procedures.
- **Improved Maneuverability:** Flexible shaft facilitates access to confined anatomical areas.
- **Controlled Tissue Treatment:** Supports localized application of electrosurgical energy to minimize unnecessary tissue damage.
- **Reduced Cross-Contamination Risk:** Single-use design eliminates risks associated with inadequate reprocessing of reusable electrodes.
- **Procedural Efficiency:** Integrated electrode, cable, and connector eliminate assembly requirements and support streamlined surgical workflows.

Intended User

- Trained healthcare professionals competent in cystoscopy/endoscopy and electrosurgery.

Inspections

- Check the sterile package for integrity and confirm labeling, product reference and expiration before opening.
- Examine the dome/ball tip, electrode shaft, insulation, attached cable and connector for visible damage.
- Do not use a damaged device.
- Verify scope-channel fit and electrical-generator compatibility before proceeding.

Patient Population

The SurgyCut Bugbee Electrode is intended for adult and pediatric patients undergoing cystoscopic or other compatible endoscopic urological procedures requiring tissue coagulation, fulguration, or hemostasis, as determined by a qualified healthcare professional.

Contraindication

The SurgyCut Bugbee Electrode should not be used when monopolar electrosurgery is contraindicated, when the device is incompatible with the electrosurgical generator or endoscope, or when adequate visualization cannot be maintained. Use should be avoided when electrosurgical energy may cause unacceptable tissue injury, particularly in delicate or thin-walled anatomical structures.

Disposal

- After use, dispose of the device immediately as a contaminated sharp in accordance with hospital protocols and applicable local, state, and national regulations governing biohazardous and sharps waste.

Single-Use/ Disposable Product

- The electrode is supplied for single use and is not intended for cleaning, reprocessing, reuse or resterilization. Reuse or reprocessing may compromise device performance and create contamination or infection risks.

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Shelf Life, storage and Transportation

Store Surgycut Bugbee in its original unopened packaging in a clean, dry environment, away from direct sunlight and excessive humidity. The device should be maintained at 5 to 30 degree centigrade storage room temperature and has a shelf life of three years.

Performance Claims

- A dome/ball tip intended for controlled fulguration and precise tissue contact, and an integrated disposable cable and connector that eliminates assembly and reusable-cable reprocessing

Undesirable Side Effects

- Potential undesirable side effects associated with the use of the SurgyCut Bugbee Electrode may include thermal tissue injury, unintended burns, bleeding, infection, tissue perforation, hematoma, and patient discomfort. These complications may occur due to excessive electrosurgical energy, prolonged activation, or improper electrode positioning.

Precautions

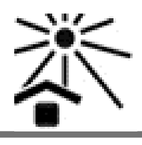
- Inspect the electrode, insulation, cable, and sterile packaging before use.
- Ensure compatibility with the cystoscope and electrosurgical generator.
- Use the lowest effective power setting and avoid prolonged activation to minimize unintended thermal injury.
- Maintain adequate visualization and avoid contact with unintended tissues.
- Ensure proper placement of the patient return electrode.
- Do not reuse, reprocess, or resterilize the device.

Warnings

- Single-use device. Do not reuse, reprocess or resterilize. Do not use if the sterile package has been opened or damaged.
- This is an electrosurgical accessory. Inappropriate use may cause unintended tissue injury or burns.
- Use only with compatible equipment and according to approved generator and endoscope instructions.
- Confirm the generator connector configuration, operating mode, permissible output limits and any required return-electrode arrangement before use.
- Do not energize the electrode during insertion or withdrawal.
- Follow institution-approved electrosurgical safety practices and applicable precautions for the clinical setting.
- Use only the lowest power setting. Use at higher settings may result in overheating, damage of insulation or injury.

Preparation for Use

- Verify that the package is intact and within the expiration date.
- Open the sterile package using aseptic technique.
- Inspect the device for defects or damage.
- Introduce the device through a compatible cystoscope according to standard clinical practice.
- Check the generator and current flow before usage at the targeted area.
- Upon completion of the procedure, carefully withdraw the device.
- Dispose of the device immediately in an approved sharps container.

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

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