

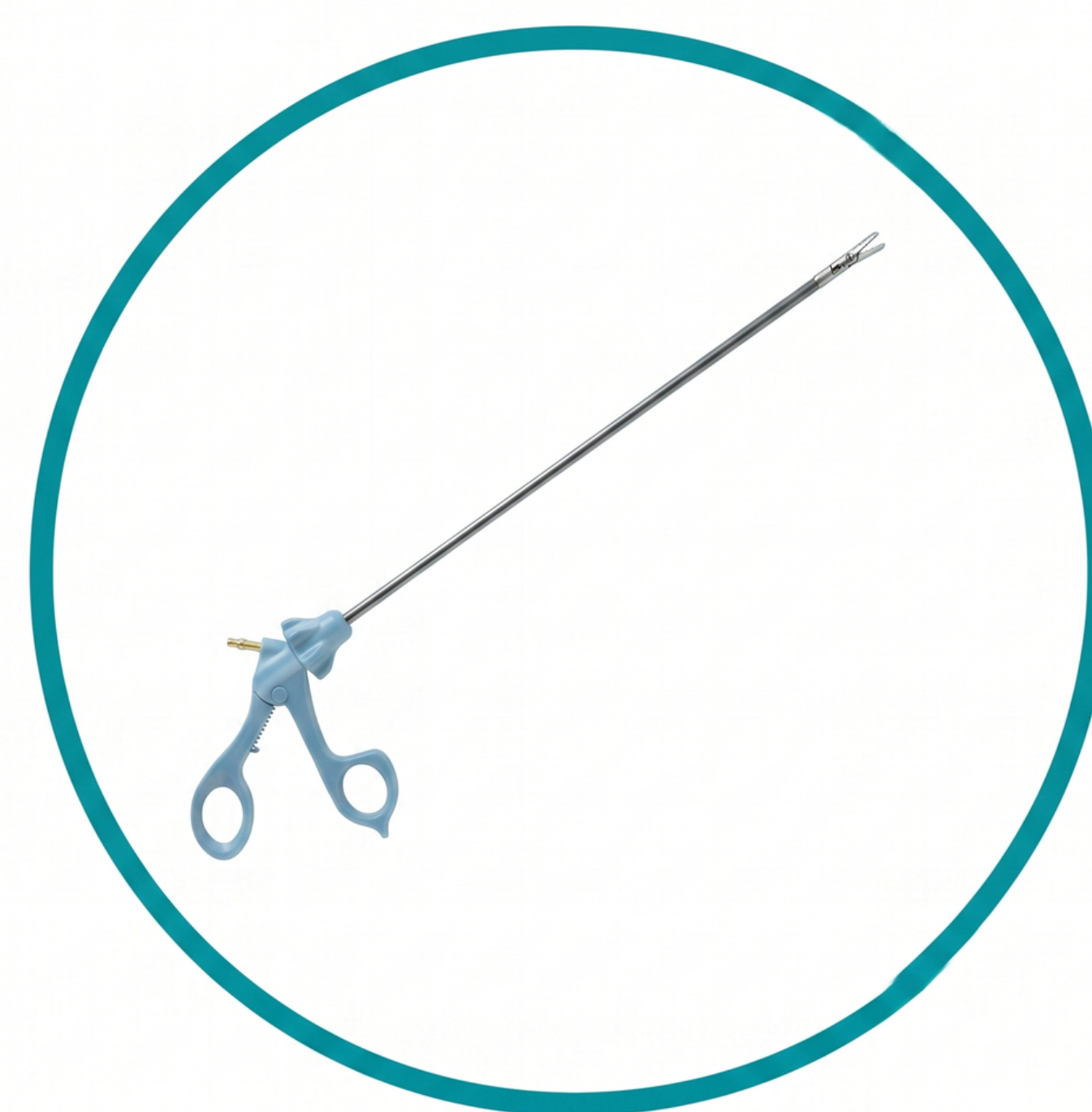


# Disposable SurgyCut Graspers

## Instructions for Use

### ► Product Description

The SurgyCut Fully Disposable Laparoscopic Grasper is a sterile, single-use, monopolar electrosurgical instrument sold as a pre-assembled, "all-in-one" device consisting of a comfortable, lightweight handle, an insulated shaft with a 5mm diameter, and an active tip or jaw. For diverse procedural needs, the device is available in both 35 cm and 45 cm lengths and features various jaw patterns, including Maryland, Clinch, Fenestrated, Claw, Bowel, Babcock, Allis, and Mixer.



### ► Clinical Benefits

- **Precision and Control:** Features a lightweight handle design with smooth control tailored for precise movements during long surgeries.
- **Secure Grip:** A specialized jaw design gives a firm, steady hold on tissues and prevents slipping.
- **Streamlined Workflow:** Supplied clean, sterile, and ready to use, which saves time and ensures smooth procedures.
- **Elimination of Cross-Contamination:** Being single-use and sterile-packed eliminates any chance of patient-to-patient cross-contamination.

### ► Intended User

- This device is intended to be used by trained medical professionals/surgeons performing minimally invasive endoscopic or laparoscopic surgical procedures.

### ► Inspections

- **Packaging Inspection:** Before opening, inspect the sterile packaging. If the package is opened, damaged, or wet, the device must not be used.
- **Visual Inspection:** Using aseptic technique upon removal, visually inspect the instrument for any loose parts, cracked insulation on the shaft or handle, or damage to the jaws.
- **Functionality Check:** Fully open and close the handle to verify smooth actuation and proper jaw closure. For ratcheted handles, engage and disengage the ratchet mechanism to verify it holds and releases securely.
- **Electrosurgical Check:** Prior to use, examine the insulation of the shaft and handle for breaks or cracks to prevent accidental operator or patient burns. If electrosurgery is used, ensure the monopolar cable is fully seated on the RF post with no metal exposed.

### ► Patient Population

- **General:** Suitable for use in both adult and pediatric patient populations.

### ► Contraindication

Not intended for use when laparoscopic electrosurgical techniques are contraindicated.

### ► Single-Use/ Disposable Product

- **Sterility:** Supplied sterile via Ethylene Oxide (EO) gas.
- **Single-Use Only:** Strictly for one-patient use. Do not reuse, reprocess, or re-sterilize.



► Disposal

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

► Shelf Life, storage and Transportation

Transport and store all products safely at ambient temperatures of 5°C to 30°C and relative humidity of 35% to 65 % (non-condensing). Handle with care.

► Performance Claims

- The grasper is intended to successfully grasp, manipulate, dissect, and/or cauterize soft tissue during minimally invasive surgeries.
- It claims to offer high performance, anti-slip reliability, smooth actuation, and reliable tissue retention via its ratcheted or non-ratcheted handle configurations.

► Undesirable Side Effects

- Accidental electrosurgical tissue burns to the patient or operator may occur if the insulation is compromised or broken.
- Device failure, cross-contamination, or patient infection can occur if the device is improperly reused or reprocessed.

► Warnings

- This device utilizes Monopolar Energy; ensure the patient is properly grounded with a return electrode.
- Keep the active jaw in view at all times when electrosurgical energy is applied.
- Defective or cracked insulation can result in accidental burns to the patient or operator.
- Do not use the device if the packaging is compromised (open, damaged, or wet).
- Never reuse or re-sterilize the device.

► Preparation for Use

- Verify that the sterile packaging is completely sealed and dry.
- Using aseptic technique, remove the instrument from the package.
- Complete a full visual and functional check (insulating shaft inspection, jaw movement, and ratchet mechanism testing).
- Ensure the jaws are fully closed before inserting the device through a compatible trocar cannula to prevent damage to the trocar seal or patient tissue.
- If electrosurgery is required, connect a compatible monopolar cable to the RF post on the handle, ensuring the cable is fully seated and no metal is exposed.

| 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       |