



SurgyCut Repposable Laparoscopic Scissors IFU Legal

Instructions for Use

Product Description

These repposable laparoscopic surgical scissors combine a durable, reusable handle with a detachable, sterile-packed disposable shaft insert. The two components connect seamlessly using an innovative ball-and-socket connection mechanism. For enhanced surgical functionality, the system features an integrated RF post for electrosurgical energy transmission alongside a specialized rotation cone designed for precise shaft orientation.

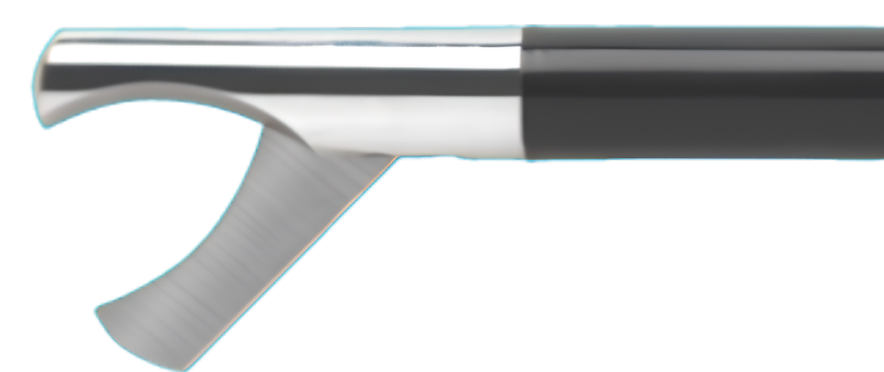
To accommodate varying surgical preferences and procedural needs, the disposable shaft inserts are supplied in lengths of 35cm and 45cm. Additionally, they are available in multiple distinct blade profiles, including Standard Metz, Mini Metz, and Hook styles.



Standard Metz



Mini Metz



Hook Tip

Clinical Benefits

- **Tissue cutting and dissection:** Enables controlled cutting, dissection, and manipulation of soft tissue during laparoscopic procedures.
- **Electrosurgical cauterization:** Allows monopolar energy delivery for coagulation/cauterization, supporting control of minor bleeding during tissue division.
- **Minimally invasive access:** Facilitates surgical tissue management through laparoscopic access, helping reduce the need for larger surgical exposure.
- **Improved procedural efficiency:** Combines mechanical scissor cutting with electrosurgical functionality in one instrument, reducing the need for frequent instrument exchange.
- **Tip orientation control:** Shaft rotation assists the surgeon in positioning the scissor tip accurately during laparoscopic procedures.

Intended User

- Licensed, trained surgical staff, laparoscopic surgeons, and operating room professionals familiar with endoscopic electrosurgical techniques and reprocessing guidelines.

Inspections

- **RF Post Verification:** Users must thoroughly inspect the integrated RF post for any structural damage before clinical use. Ensure that the connector assembly can be fully and securely covered.
- **Component and Assembly Check:** Prior to attachment, verify the reusable handle has undergone proper cleaning and sterilization cycles. Check the sterile packaging of the shaft insert for breaches before opening. Ensure the connection nut threads tightly and the insert ball seats fully into the socket.

Patient Population

- **Target Population:** Patients undergoing minimally invasive surgery, including general, vascular, gynecological, thoracic, or endoscopic/laparoscopic procedures where soft tissue division, manipulation, or electrosurgical cauterization is required.

Contraindication

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

Single-Use/ Disposable Product

- **Disposable Shaft Component:** The SurgyCut scissor shaft inserts are strictly single-use, sterile-packaged components. They are intended to be thrown away after one use and are not designed to withstand subsequent cleaning or re-sterilization.
- **Reusable Handle Component:** Conversely, the SurgyCut handle is a multi-use component explicitly built to be reprocessed and steam-sterilized between cases.



► Disposal

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

► Shelf Life, storage and Transportation

Product Maintenance: Shaft inserts must remain sealed within their original sterile packaging until the point of care. Reusable handles must be stored in a clean, dry environment post-sterilization.

► Performance Claims

- Cutting Precision:** Delivers peak sharpness, smooth cutting actions, and reliable tactile feedback without the tissue tearing or crushing typically caused by worn, degraded reusable scissor edges.
- Validated Reprocessing:** The reusable handle's sterilization pathways are fully compliant with international parameters, including AAMI TIR 12:2004 and BS EN 285:2006 standard frameworks.

► Undesirable Side Effects

- Thermal Accumulation:** Potential for localized heat buildup or collateral thermal tissue damage if unintended electrical energy transfers through an unapproved or hybrid cannula setup.

► 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

- Warning:** Sterilization using any other method may damage the device. Consult your local suppliers if you wish to use an alternative method.

► INSTRUCTIONS FOR USE:

- Ensure the handle is cleaned and sterilized in accordance to the cleaning & sterilization section below.
- Open the sterile packaged Surgycut shaft insert and remove from packaging.
- Ensure the scissor tip is closed and the protective cap is on.
- Fully open the handle. The connection socket will now be exposed.
- Locate the insert ball at the end of the shaft (A) and connect the ball into the handle socket.
- Close the handle to secure the connection.
- Hold the shaft rotation cone and tighten the connection nut (B) clockwise into the thread to secure the connection.
- Remove the protective cap on the shaft. The scissor is ready for use.

Using the RF Post:

Warning: Inspect the RF post for damage and make sure the connector is fully covered before use.

Caution: The use of hybrid plastic and/or metal cannula is not recommended. Take special care to prevent heat buildup.

Cleaning and Sterilization:

- Remove the insert and dispose.
- Immerse the Surgycut handle in a detergent based warm water solution. Use a brush to dislodge any tissue or blood. Alternatively, an instrument washing/drying system may be used.

Compliant with AAMI TRI 12:2004 and BS EN 285:2006 Dynamic Air Removal

Steam Sterilization: Porous Load

- Surgycut handles should be wrapped
- Exposure time: 3 minutes minimum
- Exposure Temperature: 132°C – 137°C

Gravity Displacement Steam Sterilization: Non-Porous Load

- Surgycut handles should be unwrapped
- Exposure time: 3 minutes minimum
- Exposure Temperature: 132°C – 137°C

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

