

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Scissor Tips:
Manufactured by SterilMed, Inc.
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Caution: Federal Law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

These devices are reprocessed scissor tips originally manufactured by Aesculap (Braun), Encision, Microline, and Snowden Pencer. Reprocessed scissor tips are intended to be used with a reusable hand piece and designed for minimally invasive and open surgical procedures to facilitate cutting, preparation, mobilization, and coagulation of tissue.

The OEM packaged an Instructions for Use (IFU) document with the original device. The health institution that wishes the device to be reprocessed should retain this original document.

DEVICE DESCRIPTION

SterilMed's reprocessed scissor tips are laparoscopic electric devices that are inserted into a reusable hand piece and are designed to be used in laparoscopic or open surgical procedures.

Reprocessed scissor tips have been cleaned, evaluated for continued integrity, and resterilized prior to use. These devices were shipped from a health facility, reprocessed, and returned for a single, subsequent use. Devices are tracked throughout the reprocessing steps to monitor the number of times reprocessed.

CONTRAINDICATIONS

- Not for use in contraceptive coagulation of fallopian tissue.
- Not for use when minimally invasive techniques are contraindicated

Note: These contraindications are not listed on the OEM Instructions for Use; however, they are listed on the SterilMed Instructions for Use for Laparoscopic Electric Instruments and therefore are included to be consistent with the practice of use of these devices.

ASSEMBLY AND DISASSEMBLY INSTRUCTIONS

Aesculap Assembly

1. Remove instrument from sterile packaging.
2. Leave tip protector in place and ensure jaw piece is closed.
3. Position jaw insert into handle.
4. Ensure proper functioning of instrument by opening and closing the tip.

Aesculap Disassembly

1. Close the jaws and replace the tip protector.
2. Detach jaw insert from handle.

Microline Assembly

1. Gently close the blades using your thumb and index finger to ensure blades are completely closed.
2. Position tip into shaft with tip blades and hand piece handles in their closed position.
3. Turn the rotation knob on the handpiece clockwise until the tip screwed on tight, while holding the blades.
4. Ensure proper functioning of the instrument by opening and closing the tip.

Microline Disassembly

1. Gently close the blades using your thumb and index finger and replace tip protector.
2. Turn the rotation knob on the handpiece counterclockwise until the tip is unscrewed, when holding the blades.
3. Remove tip from shaft.

Snowden Pencer Assembly

1. Remove scissor tips from sterile packaging.
2. Make sure tips are closed and tip protector is on.
3. Grasp device behind the tip.
4. Fully extend the center rod by opening the shaft handle (best achieved by placing shaft in vertical position with end down).
5. Position scissor tip slot over instrument rod by sliding into place.
6. Simultaneously push tip toward instrument and tighten scissor tips by turning clockwise.
7. Remove tip protector and ensure instrument is functioning properly by opening and closing the tip.

Snowden Pencer Disassembly

1. Close the tip and replace the tip protector.
2. Grasp scissor tip by black area below the assembly point and loosen by turning counterclockwise.
3. Separate scissor tip from the shaft by pulling.

Encision Assembly

1. Remove instrument from sterile packaging.
2. Leave tip protector in place and ensure jaw piece is closed.
3. Position scissor tip into insulation and handle.
4. Ensure proper functioning of instrument by opening and closing the tip.

Encision Disassembly

1. Close the jaws and replace the tip protector.
2. Detach scissor tip from handle.

WARNINGS AND PRECAUTIONS

- *Microline™ Tips* – Do not attach Microline™ tips to a handpiece if the “O” ring located on the distal end of the shaft appears worn, damaged, or missing.
- Procedures associated with the use of scissor tips should be performed only by persons having adequate training and familiarity with applicable techniques. Consult literature relative to techniques, complications and hazards prior to performing any procedure.
- Inspect the packaging and device prior to use. If sterility appears compromised or package/product appears damaged, do not use.
- SterilMed scissor tips are reprocessed for a *single use only*.
- Blades may not cut completely at the distal tip if they are not closed when inserted into the hand piece.
- Do not use in the presence of combustible/explosive gases.
- Activate the device only when in position to deliver energy to the target tissue to decrease the chance of capacitive coupling.
- Simultaneously activating an electrosurgical device with suction/irrigation may alter the path of the energy.
- Achieve proper cutting and coagulation by gradually increasing the power starting with the lowest possible power setting on the electrosurgical device.
- Inspect device insulation prior to use. Any insulation interruptions compromise safety and may cause electrical shocks or burns to the patient and user.
- Do not use the device if it performs poorly in an operational test. Ensure the jaws are closed completely before insertion through and removal from cannulas. Avoid mechanical shock and overstressing of the device. Properly grip and maneuver the device. Improper force applied to the handpiece may damage and cause a malfunction with the distal scissor mechanism

GENERAL INSTRUCTIONS AND INFORMATION

The directions are furnished for information purposes only.

Verify product upon receipt and ensure that owner’s name is appropriate on the label.

When needed for use, open product using appropriate sterile technique.

METHODS TO TEST REPROCESSED DEVICES

Devices have been tested to demonstrate biocompatibility following reprocessing as well as achievement of sterility. Validated methods are used for cleaning, packaging, and routine sterilization. Inspection and pre-release testing are used to ensure the device integrity and function of each device prior to release of product.

**Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product is processed in compliance with all applicable laws and regulations relating to EtO exposure, Proposition 65, a State of California voter initiative, requires the following notice:*

**Warning: This product and its packaging have been sterilized with ethylene oxide. The packaging may expose you to ethylene oxide, a chemical known to the State of California to cause cancer or birth defects or other reproductive harm.*

Instructions for Use can be found at www.SterilMed.com. Further questions or concerns by the health practitioner can be addressed directly by contacting your SterilMed Customer Service Associate and/or the SterilMed Quality Department at 1-888-541-0078.