

INSTRUCTIONS FOR USE

SterilMed, Inc.
Reprocessed Endoscopic Trocars
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 endoscopic trocars from various original equipment manufacturers (OEM). Endoscopic trocars are designed to provide a pathway for entry of minimally invasive instruments to a body organ or cavity during general, abdominal, thoracic, gynecologic or other minimally invasive surgical procedures such as observation, dissecting, cutting, repairing, and removal or manipulation of internal tissues and/or organs.

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

DEVICE DESCRIPTION

The reprocessed endoscopic trocar systems consists of two main components:

1. Trocar/Obturator
2. Sleeve/Cannula

Components of the Reprocessed Trocars:

The obturator/trocar consists of a sharp flat blade tip or blunt pyramidal tip to reduce the likelihood of injury to internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered. The obturator may or may not have a safety shield.

The sleeve/cannula has an inner and outer gasket to maintain pneumoperitoneum when instrumentation is inserted and withdrawn through the cannula during a surgical procedure. Some trocar sleeve housings are provided with a stopcock for insufflating the operative space. The trocar sleeve may be supplied smooth or threaded.

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Devices are reprocessed under contract with the health institution that previously used the device; the devices are used by the health institution, sent to SterilMed for reprocessing, and returned for reuse.

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

CONTRAINDICATIONS

1. The instrument is not intended for use when endoscopic techniques are contraindicated.

WARNINGS AND PRECAUTIONS

1. The user of the device should have adequate training and a thorough understanding of the use and applications of endoscopic trocars.
2. The device and packaging should be inspected prior to use. Do not use if sterility appears compromised or the package/product appears damaged.
3. Equipment may vary with each manufacturer. Verify appropriate compatibility of all equipment and accessories prior to use.
4. The trocar should not be inserted into other endoscope annuals.
5. The trocar should not be introduced into the cannula at an angle.

Prior to Use

6. Identify patients at greater risk of injury from use of a trocar (for example, thin patients, or patients who have had prior abdominal surgeries) and consider alternative methods of abdominal entry (such as open laparotomy).
7. Ensure that the patient is positioned (for example, placed in the Trendelenburg position) so that organs and other important structures are not directly in the trocars' intended path.
8. Ensure that a vascular surgeon or a general surgeon familiar with minimally invasive surgical injuries is immediately available to address major vessel repairs if laceration should occur.
9. Due to the variability in diameter of minimally invasive instruments from one manufacturer to another, it may be necessary to verify compatibility when using the instruments and accessories together in a procedure.

During Insertion

10. Ensure that the incision is large enough to accommodate the trocar shield.
11. Do not allow anyone but the user to arm the trocar; do not arm the trocar until just before insertion.
12. The trocar should be inserted slowly, steadily, and at the correct angle. Do not twist the trocar unless the tip is free to rotate.

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13. Avoid gripping the trocar too tightly, placing heavy finger pressure on the shaft of the cannula, or touching the shield indicator or arming button during insertion.
14. Do not rely on a tip shield to prevent injury.
15. Withdraw the trocar, and remove it from service if unusual resistance is felt during insertion.
16. Be aware that loss of blood pressure may signal vascular injury.
17. Be aware that reinserting an armed shielded trocar through an open trocar hole may cause failure of the shield.
18. Save suspect trocars for later inspection; do not inspect such devices during surgery.
19. Care must be taken with all trocars/obturators, to avoid damage to major vessels and other anatomic structures. To minimize risk of such injury, be sure to:
20. Direct the trocar/obturator tip away from major vessels and structures
21. Do not use excessive force.
22. When introducing or removing instruments through the trocar sleeve, use caution to prevent damage to the gaskets.

POTENTIAL ADVERSE EVENTS

The following potential risks may be associated with endoscopic procedures. The frequency and severity of these adverse events can vary, and may necessitate additional medical intervention, including surgery.

1. Bleeding
2. Vascular injury
3. Burns
4. Torn gaskets
5. Chipping of trocar
6. Cracking
7. Leakage
8. Malfunction
9. Perforation
10. Splitting of seals
11. Tubing fracture
12. Breakage of trocar

GENERAL INSTRUCTIONS AND INFORMATION

Verify product receipt and ensure that owner's name is appropriate on the label. Inspect package and product for signs of damage or sterility compromise.

Remove the device from the sterile packaging using proper sterile technique.

Use of this reprocessed device should be limited to those physicians trained in use of this device and associated equipment. For specific information on clinical studies,

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individualization of treatment, patient counseling, and procedural use of this reprocessed device, refer to the medical literature and rely upon appropriate training and experience. for this device.

If additional reprocessing of the product is desired, wipe the device a with a moist sponge to remove any visible blood or tissue, package product, label as "biohazard", and ship product back to SterilMed.

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, routine sterilization, and functionality testing. Inspection and pre-release testing are used to ensure appropriate device integrity and function of each device prior to release of product for reuse.

**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.

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