

Reprocessed by



Instructions for Use Reprocessed Endoscopic Trocars and Cannulas

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- **STERILE**

Explanation of Icons

 Sterilized by Ethylene Oxide Gas



Date of Reprocessing



Use by Date

REF

Ascent Product Code



Do Not Reuse



See Instructions For Use

Reprocessed Endoscopic Trocars and Cannulae

Endoscopic Trocar and Cannula Description

Trocars and cannulae are designed to establish a port of entry for endoscopic instruments used during minimally invasive surgery.

Trocar Cannulae is available with smooth or threaded sleeve in sizes 5-15mm inner diameter and 70 – 150mm length. Cannulae are equipped with a sealing system for maintenance of pneumoperitoneum during insertion and withdrawal of instruments and with a luer stopcock port for insufflation and desufflation of the operative cavity. Some models are provided with stability anchors inserted over the cannula sleeve to help seal the incision site and maintain cavity pressure.

Trocar Obturator is available in bladed and bladeless configurations sized 5-15 mm. Bladed obturators are equipped with a safety shield designed to expose the blade during insertion but to retract over the tip once the operative cavity has been penetrated, so as to reduce the risk for vascular or visceral injury. Bladeless optical obturators are equipped with a clear tip and a videolaparoscopy channel to allow trocar insertion under direct visual guidance and minimize the risk for internal injury.

Indications for Use

Reprocessed Endoscopic Trocars are indicated for use to establish a port of entry for endoscopic instruments in patients requiring minimally invasive surgical procedures.

Contraindications for Use

Endoscopic Trocars are contraindicated for the following uses:

- Any uses generally contraindicated for minimally invasive techniques.

Warnings

- These instruments are only intended for use by individuals with adequate training and familiarity with minimally invasive techniques. For further information about techniques, complications and hazards, consult the medical literature.
- Prior to use, read and follow the instructions of this insert as well as those of the instruments to be used during the procedure. Damage to the instrument can lead to patient injuries. Always inspect instrument carefully for overall integrity before use.
- Improper use of this product can result in life-threatening injury to internal organs and vasculature. Use extreme caution during trocar insertion.
- To avoid any patient and operator burn and shock hazard or instrument damage, it is essential to have a complete understanding of laser laparoscopy and electro surgical procedures.
- Do not attempt secondary trocar punctures until the primary site and recommended pneumoperitoneum (typically 12-18 mmHg) are established.
- Peritoneal pressures exceeding 20 mmHg can pose a risk for increased venous pressure, tachycardia, and hypertension.
- Always keep the trocar straight relative to the cannula when inserting or removing. Introducing or removing the trocar at an angle relative to the cannula can damage the cannula and result in desufflation.
- Although many trocar models are blunt or have safety features, care must be taken when introducing to avoid damage to major vessels and other anatomic structures.
- Keep organs out of reach of trocar penetration by ensuring a suitable positioning of the patient's body.
- Direct the trocar away from major vessels and other anatomic structures.
- Do not use excessive force.
- Special care should be taken during insertion of bladed instruments so as not to damage the cannula valve, and/or seal resulting in desufflation of the operative cavity.
- Using an instrument with a diameter smaller than the trocar may result in desufflation of the body cavity. A reducer cap or valve should be used to seal the opening into the body cavity and allow access of instruments through the cannula.
- Instruments with a diameter ranging from 5mm to 12mm can be supported by the VERSAPORT™ Bladeless self-adjusting seal. The usage of instruments with a diameter smaller than 5mm can result in loss of pneumoperitoneum.
- Unless at least a limited intrapleural space exists (air or fluid filled), thoracoscopy is not indicated. Therefore, prior to inserting the trocar, needle aspiration through the selected site is indicated.
- After removing the instruments from the cavity, inspect the surgical site for hemostasis and take appropriate steps to achieve hemostasis as needed.
- For incisions made with a 10-15mm trocar, suture the underlying fascia at the end of the procedure to reduce the risk

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for incisional herniation For Endopath® Xcel™ Bladeless trocars fascial suturing may not be routinely required. This applies to 11mm and 12mm, and does not apply to 15mm trocars.

Precautions

- If using instruments from different manufacturers, verify compatibility of instruments before use to avoid complications during surgery.
- The Versaport™ Bladeless and Versaport™ Plus Bladeless fixation sleeves are not compatible with other Autosuture™ trocar systems.
- Become familiar with specific model of trocar and cannula prior to employing it in a surgical procedure to avoid damage to patient, to operator or to instrument.
- Careful handling of instruments is necessary to avoid damage or breakage.
- Care should be taken when removing instruments not to prematurely dislodge the cannula.
- All precautions applicable to minimally invasive procedures should be observed at all times.
- Use a trocar that is intended for the procedure and that has all the desired attributes. For example, never use a trocar that is intended to be introduced into an air- or fluid-filled cavity if a pleural space is not present in the body cavity. Never use a trocar that does not ensure a gas seal if a gas seal is needed.
- Incorrect perpendicular trocar insertion during abdominal procedures may result in an aortic puncture.

Adverse Reactions

- Superficial lesions
- Bleeding
- Peritonitis
- Injury to the abdominal wall
- Injury to internal vessels
- Hematoma
- Infection

Directions for Use

1. The package label is detachable and may be affixed to the medical record of the patient.
2. Before beginning the procedure, verify overall compatibility of all instruments and accessories and confirm that grounding or electrical isolation are not jeopardized.
3. Inspect the instrument and package before opening. The contents of the package are sterile if the packaging has not been compromised. If the package is damaged or if it was opened and the instrument was not used, return the instrument and packaging to Ascent Healthcare Solutions for resterilization by ethylene oxide (EtO) gas.
4. Do not attempt to resterilize.
5. Remove the instrument from the package and place it in a sterile work area using aseptic technique. Avoid contact with exposed sharp edges of the trocar.
6. Inspect the instruments for any damage. Do not use the instrument if any damage is noted. Return the instrument and packaging to Ascent Healthcare Solutions if it is not in acceptable condition for surgery.
7. If present, remove the plastic tip protector that shields the trocar blade.
8. Select and follow a suitable endoscopic and/or thoracoscopic protocol.
9. The trocar is packaged with the stopcock in its open position. To prevent desufflation during insertion, close the valve prior to use.
10. If a stability anchor is used, lock it into position near the cannula proximal end.
11. Establish the primary puncture site and insufflate the operative cavity using recommended procedures.
12. Make a small incision where the instrument will be introduced. A larger, deeper incision may be necessary for blunt trocar models.
13. Create a secondary incision of adequate size to accommodate the trocar sleeve.
Note: Greater trocar insertion force will be required if the incision is too small. Furthermore, too large of an incision, may increase possible port instability.
14. Insert the trocar and cannula assembly through the incision by applying continuous downward pressure until the body cavity has been completely penetrated.
15. For bladed trocars, the safety shield should re-engage over the obturator blade as soon as the tip has penetrated the cavity. There is an audible click once the shield is re-engaged. **DO NOT DISENGAGE THE SAFETY SHIELD WITH THE OBTURATOR IN THE CAVITY.**
16. Position the cannula as desired and, if used, slide the stability anchor down the sleeve into the incision. Lock the anchor in place and secure the sutures from the skin flaps around the anchor posts to ensure the seal.
17. To insufflate, attach a gas line to the trocar port and open its valve.
18. Remove the obturator and insert appropriately sized instruments. Apply an appropriately sized reducer cap as needed for smaller diameter instruments.
19. When retrieving a tissue sample through a cannula with a reducer cap, detach the cap and slide up the instrument

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shaft until the specimen has been removed.

20. At the end of the procedure, leave the laparoscope in place during desufflation and removal of the trocar cannula.

Exteriorization of the cavity contents can occur if the laparoscope is first pulled from the cannula.

21. Detach the stability anchor (if used), remove the cannula, and suture the incision site.

Storage and Handling

Store in controlled environment, not exceeding 130 F (54° C), away from chemical fumes.

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Warranty

Ascent Healthcare Solutions (**ASCENT**) will reprocess medical instruments, including cleaning, testing, and sterilization, as appropriate. Such activities will be conducted in compliance with the FDA Quality System Regulations and the ISO 13485:2003 standard for medical devices and the Canadian Medical Device Regulation designation.

ASCENT warrants the sterility of reprocessed medical instruments unless the packaging of the medical instrument has been opened or damaged, or the expiration date has been exceeded. ASCENT warrants the functionality of reprocessed medical instruments until such medical instruments have been used in one medical procedure. Medical Facility has sole responsibility for deciding to use any reprocessed Medical Device, and the obligation to use the same, if at all, in accordance with such Device's instructions for use.

ASCENT shall indemnify and hold harmless MEDICAL FACILITY, PHYSICIANS AND CLINICIANS against claims, demands and liability for sums which MEDICAL FACILITY, PHYSICIANS AND CLINICIANS shall become legally obligated to pay as damages caused by bodily injury to patients as a result of ASCENT's negligent performance of services under this Agreement. This indemnity and hold harmless obligation shall not apply to damages arising out of misuse of medical instruments which are the subject of this Agreement. ASCENT shall only be liable to Medical Facility for incidental or consequential damages arising out of or related to any act or omission of ASCENT and ASCENT makes no warranty, express or implied, other than such warranties as expressly described in this Agreement.

Ascent does not warrant reprocessed (in full or in part) Medical Devices that have been or will be resold, modified or treated by Medical Facility or any other party.

This Warranty is in lieu of and excludes all other warranties not expressly set forth herein.

Only Ascent Healthcare Solutions bears the responsibility for this device. The OEM information listed on the label is provided as device ID prior to reprocessing and may contain the trademarks of unrelated third parties that do not sponsor this device.

Sterilization: This product and its packaging have been sterilized with ethylene oxide gas (EtO). Even though the product then 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.