

Reprocessed by




Instructions for Use
Reprocessed Applied Medical
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**
- **LATEX-FREE**

Explanation of Icons


 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

 Ascent Product Code

 Do Not Reuse

 See Instructions For Use

Reprocessed Applied Medical Endoscopic Trocars and Cannulas

Endoscopic Trocar System 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 cones 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.

Universal[®] Seal is available with a 5-12mm port.

Stability Cones are available in conductive and non-conductive configurations sized for 10-12mm cannula.

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 including thoracic, gynecologic laparoscopy and other abdominal 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.
- 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.
- Keep the trocar straight relative to the cannula when inserting or removing. If the trocar is at an angle relative to the cannula, it 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 proper positioning of the patient's body.
- *For bladed trocars* – The incorporation of the shield feature in the trocar design is intended to minimize the likelihood of penetrating injury to intra-abdominal or intra-thoracic structures. However, because the trocar tip will be temporarily unprotected before shield advancement, the standard precautionary measures for all trocar insertions must be observed.
- *For bladed trocars* – Adhesions, anatomical anomalies, or other obstructions, if present, may prevent or delay advancement of the shield, leaving the tip uncovered and exposing internal structures to injury.
- Direct the trocar away from major vessels and other anatomic structures.
- Properly position the patient to help displace organs out of the area of penetration.
- For the second and additional punctures of the trocar into the abdominal or thoracic cavity, inspect the tip of the trocar visually by monitor and note important anatomical landmarks each time.
- Do not use excessive force.
- Use moderate, controlled pressure when placing access port.
- Special care should be taken during insertion of bladed instruments so as not to damage the cannula valve, resulting

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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.
- 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 for incisional herniation

Precautions

- Verify compatibility of all instruments before use to avoid complications during surgery.
- 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.
- For Kii® Access System instruments, practice care when inserting angular and asymmetrical instruments (such as “J” hooks and clip appliers). Center the instruments axially when inserting through the seal for easier insertion.
- Highly textured surfaces of the Kii® Access System instruments should be coated with a sterile lubricant prior to insertion to minimize eversion of the seal.

Adverse Reactions

- Superficial lesions
- Bleeding
- Injury to the abdominal wall
- Peritonitis
- 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.
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 (EO) 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.

Kii®Access System Trocars

1. The trocar is packaged with the seal attached to the cannula and the stopcock in the open position. In case the seal and the cannula are disassembled, to reassemble, simply align the seal axially over the opening of the cannula with the slots of the seal lining up with the latches on the cannula. Press down on the seal until it snaps securely in place.
2. Insert the obturator through the seal into the cannula until the tip is exposed. Ensure the seal and obturator are locked in place.
3. Place an appropriate sized laparoscope through the opening in the shaft of the obturator when using the Kii Optical access system to visualize insertion. The scope will freely rotate while in position. The Optical access system utilizes an optical element to visualize tissue layers during insertion.
Note: The system may be used without visualization for primary or secondary insertions.
4. At the placement site make an incision in the skin of minimal length to just accept the tip and the cannula of the Trocar.
5. Insert the trocar into the abdominal wall by applying continuous downward force while gently rotating the trocar in alternating clockwise and counterclockwise directions, until the cannula is placed as desired.
6. To remove the obturator, press the release tabs to remove from seal.
7. To remove the seal, simultaneously squeeze tabs on side of cannula and pull up on seal.

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Note: The seal can be removed from the cannula for desufflation, specimen removal, or per physician need.

Applied Medical Endoscopic Trocars and Cannulas

1. The trocar obturator and sleeve may be packaged unassembled. Assemble the trocar by inserting the obturator into the trocar sleeve until they lock securely together.
2. Seals and cannulas may be packaged separately. To assemble, align the seal axially over the opening of the cannula and rotate clockwise onto the pins to secure the unit in place.
3. Select and follow a suitable endoscopic and/or thoracoscopic protocol.
4. The trocar is packaged with the stopcock in its open position. To prevent desufflation during insertion, close the valve prior to use.
5. If a stability cone is used, lock it into position near the cannula proximal end.
6. Establish the primary puncture site and insufflate the operative cavity using recommended procedures.
7. Make a small incision where the instrument will be introduced. A larger, deeper incision may be necessary for blunt trocar models. Note: Greater trocar insertion force will be required if the incision is too small. This could result in loss of control during entry.
8. Insert the trocar and cannula assembly through the incision by applying continuous, controlled downward pressure until the body cavity has been completely penetrated.
9. 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.**
10. Position the cannula as desired and, if used, slide the stability cone down the sleeve into the incision. Lock the stability cone in place and secure the sutures from the skin flaps around the cone posts to ensure the seal.
11. To insufflate, attach a gas line to the trocar port and open its valve.
12. Remove the obturator and insert appropriately sized instruments. Apply an appropriately sized reducer cap as needed for smaller diameter instruments.
13. When retrieving a tissue sample through a cannula with a reducer cap, detach the cap and slide the instrument shaft until the specimen has been removed.
14. 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.
15. Detach the stability cone (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.

Recommended Decontamination

1. **Segregation of Devices** - At the completion of each procedure, single-use devices to be reprocessed by Ascent Healthcare Solutions should be physically segregated from other devices. All devices to be reprocessed should be moved from the operating room suite to an adequate decontamination area within the facility.
2. Devices should **not** be allowed to dry prior to collection.
3. **Clean** – Wipe down the device with lukewarm water.
4. **Collection and Staging** - Devices to be reprocessed should be placed in the appropriate collection container system and staged for pick-up.

The user facility is responsible for providing personal protective equipment (PPE) for all service personnel. Such equipment must comply with OSHA regulations, and can include protective gloves, liquid-resistant clothing, face shields, and surgical face masks. PPE should be worn whenever an individual is performing collection and initial decontamination procedures.

Additionally, personnel who might be exposed to infectious agents should receive training on how to recognize potentially unsafe conditions, when and how to use safety equipment, and how to decontaminate surfaces when this is practical. As an additional safety measure, the user facility should offer hepatitis B vaccinations to their service staff. Any questions regarding these instructions should be forwarded to the Ascent Healthcare Solutions Account Service Representative or the Ascent Healthcare Solutions corporate office at 1.888.888.3433.

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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.

Universal[®] Seal and Kii[®] are registered trademarks of Applied Medical Resources Corporation.