Reprocessed by

Sustainability Solutions

Instructions for Use
Reprocessed ENDOPATH® XCEL™ Bladeless 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

STERILE EO	Sterilized by Ethylene Oxide Gas
	Date of Reprocessing
	Use by Date
REF	Product Code
2	Do Not Reuse
	See Instructions For Use

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Reprocessed ENDOPATH® XCEL™ Bladeless Endoscopic Trocars and Cannulas

Endoscopic Trocar and Cannula Description
The Reprocessed Endoscopic Bladeless Trocar is an instrument consisting of a radiolucent cannula and obturator in sizes 5,11, and 12 mm in diameter. The obturator has a clear, tapered optical element and can be used with an endoscope to provide visibility of individual tissue layers during insertion. The Reprocessed Blunt Tip Trocar consists of a radiolucent cannula and obturator sized 12mm in diameter. The Reprocessed Blunt Tip Trocar has an obturator that has a blunt plastic tip that gently moves aside any internal viscera that may be adjacent to the abdominal or thoracic wall. The trocar cannula consists of two seals, an outer integrated removable self-adjusting seal that may accommodate instruments ranging from 5mm to 12mm in diameter, and an internal seal. These seals minimize gas leakage when instruments are inserted or withdrawn through the seal. Please note that the 5 mm trocar cannula does not have the outer integrated self-adjusting seal and only accommodates 5 mm instruments. The stopcock valve provides attachment for gas insufflation and desufflation.

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 and accessories to be used during the procedure. Damage to the instrument can lead to patient injuries. Always inspect instrument carefully for overall integrity before use.
- Minimally invasive instruments may differ in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together, verify compatibility prior to initiation of the procedure.
- A comprehensive understanding of the principles and techniques involved in laser, electrosurgical, and ultrasonic procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Make certain that the electrical insulation or grounding is not compromised. Do not submerge instruments in liquid unless the instruments are designed and labeled to be immersed.
- Bladeless trocar models and blunt tip trocars have a blunt tip, care must be taken when introducing to avoid damage to major vessels and other anatomic structures (such as bowel or mesentery).
- Keep organs out of reach of trocar penetration by ensuring a suitable positioning of the patient's body.
- Establish adequate pneumoperitoneum.
- Note important anatomical landmarks to help minimize the risk of injury during trocar insertion.
- Direct the trocar tip away from major vessels and other anatomic structures.
- Do not use excessive force.
- The Bladeless Trocar should not be advanced for additional penetration once complete entry has been made into the operative cavity. Possible injury to the internal structures could result due to continued entry of the obturator.
- Very little pressure may be required to complete entry once partial entry has been obtained. Excessive pressure could cause injury to the internal structures.
- Using an instrument with a diameter smaller than the trocar may result in desufflation of the body cavity.
- After removing the trocar from the cavity, inspect the surgical site for hemostasis and take appropriate steps to achieve hemostasis as needed.
- Additional stability devices should not be used when using a sleeve with stability threads.
- Special disposal handling may be required to prevent biological contamination for instruments or devices that come into contact with bodily fluids.

Precautions

- 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.
- The obturator is designed with the optical feature to minimize the risk of penetrating injury to intra-abdominal and intra-thoracic structures. Observe standard precautionary measures for all obturator insertions.
- Care should be taken when introducing or removing instruments through the cannula sleeve in order to prevent damage to the seals that may result in loss of pneumoperitoneum.
- Special precaution should be used when inserting sharp or angled edged endoscopic instruments to prevent accidental tearing of the seal.
- All precautions applicable to minimally invasive procedures should be observed at all times.

Directions for Use

1. Before beginning the procedure, verify overall compatibility of all instruments and accessories.
2. 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 Stryker Sustainability Solutions for resterilization by ethylene oxide (EtO) gas.
3. Do not attempt to resterilize.
4. Remove the instrument from the package and place it in a sterile work area using aseptic technique.
5. Inspect the instruments for any damage. Do not use the instrument if any damage is noted. Return the instrument and packaging to Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
6. Proper insertion techniques are provided below for Bladeless Trocars to ensure a thorough understanding of insertion techniques for success:
   - To gain experience recognizing and differentiating between the different tissue layers utilize the Bladeless Trocar as a secondary port following insufflation.
   - Once experience has been gained with the above technique, insert the Bladeless Trocars as the primary port after insufflation.
   - The Bladeless Trocar may be inserted without pneumoperitoneum when proficiency with the device has been achieved.
7. If present, remove the plastic tip protector from the obturator and cannula sleeve and discard.
8. The trocar can be assembled by inserting the obturator into the cannula sleeve until they lock securely together.
9. The trocar is packaged with the stopcock in its open position. To prevent desufflation during insertion, close the valve prior to use. The stopcock is in the closed position if the stopcock lever is parallel to the cannula sleeve.
10. If using an endoscope connect the appropriately sized, 0º endoscope to the light supply. Following manufacturer's instructions, monitor as directed. Verify proper connection of the endoscope and the clarity of the picture on the monitor. The endoscope may be inserted into the opening at the proximal end of the obturator until it reaches the distal tip of the obturator.
11. The endoscope can be rotated as desired. The endoscope may be secured in the obturator by using the scope locking cam. To obtain a clear image on the monitor, insert the endoscope into the obturator and touch the tip of the optical element to a soft surface and focus the camera.
12. Establish the primary puncture site and using standard surgical procedure create an incision which allows the trocar to be introduced.
13. Loss of control during entry may possibly result if the incision is inadequate, due to the increasing resistance of insertion and required penetration force.
14. **H12LP Trocars Only:** Ensure that the operative cavity has been entered by placing a finger into the incision. Pass two size 0, polyglactin 910 sutures, one through each fascial edge and tag them. The sutures should be held upward and apart. The trocar can be inserted into the incision with the adjustable plug secured against the bottom of the trocar sleeve housing. The adjustable plug can slide down the trocar sleeve and into the incision. Secure the sutures firmly around the suture tie posts on the adjustable plug, forcing the plug firmly into the incision. This will help to seal the site and minimize gas leakage later in the procedure. Position the cannula by sliding it up or down until the desired position. Secure the adjustable plug to the cannula by pushing down the locking cam. Skip steps 15 and 16 below.
15. Insert the obturator through the incision using a 30º to 90º rotating motion. Apply continuous but controlled downward pressure on the obturator.
16. The penetration of the obturator tip through the individual tissue planes may be viewed using the endoscope and video camera. As the obturator tip advance, the individual tissue planes may be seen.

17. With the Trocar positioned in the operative cavity, the locking buttons may be pressed to remove the obturator and endoscope (if used), leaving the trocar sleeve in place. If using an endoscope, release the scope locking cam and remove the endoscope from the obturator. When the obturator is withdrawn the internal seal in the sleeve automatically closes.
18. Insufflation is maintained by the seal system in the absence of an instrument in the sleeve.
19. To insufflate, attach a gas line to the trocar port and open its valve.
20. When retrieving a tissue sample the outer seal can be removed by pushing the outer seal release lever in a counterclockwise direction and lifting off the outer seal (not applicable to the 5mm trocar sleeve). Replace the outer seal of the trocar after tissue sample removal. The reducer cap should be oriented so it is aligned correctly with the top of the trocar. Snap the reducer cap in place by positioning the seal latches over the corresponding holes in the top of the trocar and pressing down to snap the cap into place.
21. At the end of the procedure, remove the gas line, and open the stopcock to rapidly deflate the abdominal cavity.

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

Warranty

Reprocessed Products

Stryker warrants all reprocessed products, subject to the exceptions provided herein, to be free from defects in reprocessing and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for one use in accordance with the instructions for use of such product.

STRYKER SHALL NOT BE LIABLE FOR ANY DAMAGES TO THE EXTENT CAUSED BY ANY DEFECT IN MATERIAL, WORKMANSHIP OR DESIGN BY THE ORIGINAL MANUFACTURER OF THE PRODUCT OR ANY ACT OR OMISSION OF THE ORIGINAL MANUFACTURER OF THE PRODUCT.

Products for which Stryker is the Original Manufacturer

Stryker warrants all products for which it is the original manufacturer, subject to the exceptions provided herein, to be free from defects in design, materials and workmanship and to substantially conform to the product specifications contained in the documentation provided by Stryker with the products for a period of one year from the date of purchase.

General Warranty Terms Applicable to All Products

TO THE FULLEST EXTENT PERMITTED BY LAW, THE EXPRESS WARRANTY SET FORTH HEREIN IS THE ONLY WARRANTY APPLICABLE TO THE PRODUCTS AND IS EXPRESSLY IN LIEU OF ANY OTHER WARRANTY BY STRYKER, EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL STRYKER'S LIABILITY ARISING IN CONNECTION WITH THE SALE OF THE PRODUCT (WHETHER UNDER THE THEORIES OF BREACH OF CONTRACT, TORT, MISREPRESENTATION, FRAUD, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR ANY OTHER THEORY OF LAW) EXCEED THE PURCHASE PRICE, CURRENT MARKET VALUE OR RESIDUAL VALUE OF THE PRODUCTS, WHICHEVER IS LESS. STRYKER SHALL NOT BE LIABLE FOR INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES RESULTING FROM ANY BREACH OF WARRANTY OR UNDER ANY OTHER LEGAL THEORY.

This warranty shall apply only to the original end-user purchaser of products directly from Stryker or a Stryker authorized distributor. This warranty may not be transferred or assigned without the express written consent of Stryker.

This warranty does not apply to: (1) products that have been misused, neglected, modified, altered, adjusted, tampered with, improperly installed or refurbished; (2) products that have been repaired by any person other than Stryker personnel without the prior written consent of Stryker; (3) products that have been subjected to unusual stress or have not been maintained in accordance with the instructions in the user manual or as demonstrated by a Stryker representative; (4) products on which any original serial numbers or other identification marks have been removed or destroyed; or (5) products that have been repaired with any unauthorized or non-Stryker components.

If a valid warranty claim is received within thirty (30) days of the expiration of the applicable warranty period, Stryker will, in its sole discretion: (1) replace the product at no charge with a product that is at least functionally equivalent to the original product or (2) refund the purchase price of the product. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property. In any event, Stryker's liability for breach of warranty shall be limited to the replacement value of the defective or non-conforming part or component.

If Stryker determines in its reasonable discretion that the claimed defect or non-conformance in the product is excluded from warranty coverage as described hereunder, it will notify the customer of such determination and will provide an estimate of the cost of repair of the product. In such an event, any repair would be performed at Stryker's standard rates.

Products and product components repaired or replaced under this warranty continue to be warranted as described herein during the initial applicable warranty period or, if the initial warranty period has expired by the time the product is repaired or replaced, for thirty (30) days after delivery of the repaired or replaced product. When a product or component is replaced, the item provided in replacement will be the customer's property and the replaced item will be Stryker's property. If a refund is provided by Stryker, the product for which the refund is provided must be returned to Stryker and will become Stryker's property.

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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.

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