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Sustainability Solutions

Instructions for Use
Reprocessed Ethicon Endopath® XCEL™ Bladed 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 Symbols

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

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Ethicon XCEL™ Bladed 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 5-12mm inner diameter and 75 – 100mm 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.

Trocar Obturator is available in a bladed configuration, sized 5-12 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.

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

Reprocessed 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.
- 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.
- 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.
- Special care should be taken during insertion of bladed instruments so as not to damage the cannula valve, 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.
- 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 11-12mm 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.

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 Stryker Sustainability 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 Stryker Sustainability Solutions if it is not in acceptable condition for surgery.
7. 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.
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. Establish the primary puncture site and insufflate the operative cavity using recommended procedures.
11. 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.
12. Insert the trocar and cannula assembly through the incision by applying continuous, controlled downward pressure until the body cavity has been completely penetrated.
13. 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.
14. When the trocar is in the abdominal or thoracic cavity, press the locking buttons to remove the obturator handle assembly, leaving the sleeve in place. The internal seal in the sleeve automatically closes as the obturator is withdrawn. The seal system maintains insufflation in the absence of an instrument in the sleeve.
    Important: If entry into the abdominal or thoracic cavity is incomplete or the surgeon is uncertain whether entry is complete, the instrument must be reactivated. In order to reactivate the instrument, it should first be removed. After removing the instrument, push the red shield reset button forward to the activated position. The shield will again be free to retract when pressure is applied. Reinsert the instrument to complete entry.
    WARNING: Since partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.

15. To insufflate, attach a gas line to the trocar port and open its valve.
16. Remove the obturator and insert appropriately sized instruments. Apply an appropriately sized reducer cap as needed for smaller diameter instruments.
17. When retrieving a tissue sample through a cannula with a reducer cap, detach the cap and slide up the instrument shaft until the specimen has been removed.
18. 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.
19. 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.

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.

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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