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Sustainability Solutions

Instructions for Use
Reprocessed Ethicon ENDOPATH® XCEL™
Dilating Tip Trocar with OPTIVIEW® Technology

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
	Do Not Reuse
	See Instructions For Use

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Reprocessed Ethicon ENDOPATH® XCEL™ Dilating Tip Trocar with OPTIVIEW® Technology
The Reprocessed Ethicon ENDOPATH® XCEL™ Dilating Tip (Bladed) Trocar with OPTIVIEW® Technology, (hereinafter Reprocessed Dilating Tip Trocar) is a sterile, single patient use instrument consisting of a radiolucent sleeve and obturator. The obturator has a sharp, flat-bladed tip and spring-loaded shield. The shield is designed to cover the flat-bladed tip to protect internal structures from puncture or laceration once the abdominal or thoracic cavity has been entered. The trocar sleeve contains two seals that accommodate instruments 5 mm in diameter. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. A stopcock valve is compatible with standard luer lock fittings and provides attachment for gas insufflation and desufflation. The stopcock is in the closed position when it is parallel to the sleeve.

Indications for Use
The Reprocessed Dilating Tip Trocar has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Contraindications for Use
Reprocessed Dilating Tip Trocars are contraindicated for the following uses:
- Any uses generally contraindicated for minimally invasive techniques.

Warnings and Precautions
- Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive techniques. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure. The presence of the shield on the obturator is not a substitute for proper endoscopic techniques.
- Minimally invasive instruments may vary in diameter from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
- A thorough understanding of the principles and techniques involved in laser, ultrasonic and elctrosurgical procedures is essential to avoid shock and burn hazards to both patient and medical personnel and damage to the device or other medical instruments. Ensure that electrical insulation or grounding is not compromised. **Do not** immerse electrosurgical instruments in liquid unless the instruments are designed and labeled to be immersed.
- Using minimally invasive instruments with a smaller diameter than specified for the Reprocessed Dilating Tip Trocar may result in desufflation of the abdominal cavity.
- 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 briefly unprotected prior to shield advancement, the standard precautionary measures employed in 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, exposing internal structures to injury.
- Although the Reprocessed Dilating Tip Trocar is designed with a shield, care must still be taken, as with all trocars, to avoid damage to major vessels and other anatomic structures (such as bowel or mesentery).
  To minimize the risk of such injury, be sure to:
  - Establish adequate pneumoperitoneum, in order to secure enough space in the abdominal or thoracic cavity;
  - 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 trocar visually by monitor and note important anatomical landmarks each time;
  - Direct the trocar tip away from major vessels and structures;
  - Do not use excessive force.
- Do not attempt to insert the trocar if the red shield reset button does not stay in the activated position.
- Once partial entry has been accomplished, very little pressure may be required to complete entry. Excessive pressure from the tip of the trocar could cause injury to intra-abdominal or intra-thoracic structures.
- Once complete entry has been made into the abdominal or thoracic cavity, the Reprocessed Dilating Tip Trocar should not be reactivated. Continued entry of the exposed flat-bladed tip at this point could cause injury to intra-abdominal or intra-thoracic structures.
- During insertion of the obturator into the sleeve housing, the obturator should not be in the activated position.
- Use caution when introducing or removing instruments or prosthetic mesh through the trocar sleeve in order to prevent inadvertent damage to the seals which could result in loss of pneumoperitoneum. Special care should be used when inserting sharp or angled edged endoscopic instruments to prevent tearing the seal.
- When using a Reprocessed Dilating Tip Trocar, additional stability devices should not be used.
- After removing the Reprocessed Dilating Tip Trocar from the abdominal or thoracic cavity, always inspect the site for hemostasis. If hemostasis is not present, appropriate techniques should be used to achieve hemostasis.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- This device is packaged and sterilized for single use only.

Adverse Reactions
None

Directions for Use
Verify compatibility of all minimally invasive instruments and accessories prior to using the instrument (refer to **Warnings and Precautions**).

Prepare the patient in accordance with proper surgical techniques prior to insertion of the trocar.
1. The package label is detachable and may be affixed to the medical record of the patient.
2. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
3. The trocar obturator and sleeve are packaged unassembled. To assemble, remove the protective tip covering from the obturator and trocar sleeve and discard. Assemble the trocar by inserting the obturator into the trocar sleeve until they lock securely together.
   NOTE: The trocar sleeve is packaged with the stopcock in the open position. Close the stopcock before use. The stopcock is in the closed position when the stopcock lever is parallel to the sleeve.
4. **Important:** To allow retraction of the shield, push the reset button forward to the activated position until an audible click is heard. The trocar cannot be deactivated by forcing the reset button to the original position.
5. Create an incision using standard surgical procedure which allows the trocar to be introduced.
   NOTE: An inadequate incision may cause increased resistance to insertion, increasing the required penetration force, and possibly resulting in a loss of control during entry.
6. Introduce the trocar through the skin incision, applying continuous but controlled downward pressure on the trocar. When this pressure is applied, the shield will begin to retract. As the shield retracts, the sharp flat-bladed tip is exposed to create the passage through the abdominal or thoracic wall. Once the retracted shield has passed through the abdominal or thoracic wall, it will advance forward and cover the exposed flat-bladed tip. As the shield retracts, the red shield reset button will return to the original position.
   NOTE: Shield retraction is activated by tissue resistance. When there is insufficient tissue resistance, the shield reset button will remain in the activated position and the shield will be free to retract when the pressure is applied.
7. 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. Instruments of appropriate size can be easily introduced through the sleeve of the trocar.
   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 the 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.
8. To insufflate, attach a gas line to the stopcock on the trocar sleeve and open the stopcock. The seal system maintains insufflation in the absence of an instrument in the sleeve.
9. Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

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.

XBT Rev A 01-2014 RM702131