

Reprocessed by



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## Sustainability Solutions

### Instructions for Use Reprocessed Ethicon ENDOPATH® XCEL™ Bladeless 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

 Sterilized by Ethylene Oxide Gas

 Date of Reprocessing

 Use by Date

**REF** Product Code

 Do Not Reuse

 See Instructions For Use

# Reprocessed Ethicon ENDOPATH® XCEL™ Bladeless Trocar with OPTIVIEW® Technology

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## Reprocessed Ethicon ENDOPATH® XCEL™ Bladeless Trocar with OPTIVIEW® Technology

The Reprocessed ENDOPATH® XCEL™ Bladeless Trocar with OPTIVIEW® Technology, (hereinafter Reprocessed Bladeless Trocar) is a sterile single patient use instrument consisting of a radiolucent sleeve and obturator. The obturator contains a clear, tapered optical element. The 5 mm obturator accommodates an appropriately sized 0° endoscope and provides visibility of individual tissue layers during insertion. 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 Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar.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 Bladeless Trocar has applications in abdominal, thoracic, and gynecologic minimally invasive surgical procedures to establish a path of entry for endoscopic instruments. The trocar may be used with or without visualization for primary and secondary insertions.

### Contraindications for Use

Reprocessed Bladeless 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.
- 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, 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. 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 diameter smaller than specified for the Reprocessed Bladeless Trocar may result in desufflation of the abdominal cavity.
- The optical features in the obturator design are intended to minimize the likelihood of penetrating injury to intra-abdominal and intra-thoracic structures. However, the standard precautionary measures employed in all obturator insertions must be observed.
- Although the Reprocessed Bladeless Trocar has a blunt tip, 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;
  - Properly position the patient to help displace organs out of the area of penetration;
  - Note important anatomical landmarks;
  - Direct the trocar tip away from major vessels and structures;
  - Do not use excessive force.
- Once partial entry has been accomplished, very little pressure may be required to complete entry of the Reprocessed Bladeless Trocar. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.
- Once complete entry has been made into the abdominal or thoracic cavity, the Reprocessed Bladeless Trocar should not be advanced for additional penetration. Continued entry of the obturator device at this point could cause injury to intra-abdominal or intra-thoracic structures.
- 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 sleeve with integrated stability threads, additional stability devices should not be used.
- After removing the trocar from the 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 open instruments whether used or unused.
- This device is packaged and sterilized for single use only.

### Adverse Reactions

None

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## Directions for Use

Verify compatibility of all 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. The package label is detachable and may be affixed to the medical record of the patient.

## **IMPORTANT: The following instructions are recommended to ensure a thorough understanding of proper insertion technique for the Reprocessed Bladeless Trocar.**

- Success with the Reprocessed Bladeless Trocar depends upon recognizing and differentiating between tissue layers. Therefore, utilize the Reprocessed Bladeless Trocar as a secondary port following insufflation to gain experience visualizing the tissue layers.
- After achieving experience with the above technique, the Reprocessed Bladeless Trocar may be inserted as a primary port after insufflation.

## **Follow the steps below for 5 mm Reprocessed Bladeless Trocar insertion with the use of an endoscope.**

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. The trocar obturator and sleeve are packaged unassembled. 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 closed when the stopcock lever is parallel to the trocar sleeve.
3. Connect the appropriately sized 0° endoscope to the light supply and monitor as directed in the manufacturer's instructions. Verify proper connection of the endoscope and ensure the clarity of the picture on the monitor.
4. Insert the endoscope into the opening at the proximal end of the obturator until it reaches the distal tip of the obturator.
5. Rotate the endoscope as desired. Secure the endoscope in the obturator using the scope locking cam.
6. To provide a clear image on the monitor, insert the endoscope into the obturator, touch the tip of the optical element to a convenient soft surface, and focus the camera.
7. 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.
8. Introduce the obturator through the skin incision using a 30° to 90° rotation motion. Apply light and continuous but controlled downward pressure on the obturator.  
View the penetration of the obturator tip through the individual tissue planes by using the endoscope and video camera. The individual tissue planes may be seen as the obturator tip advances.
9. When the trocar is in the abdominal or thoracic cavity, press the locking buttons to remove the obturator and endoscope, leaving the sleeve in place. Release the scope locking cam and remove the endoscope from the obturator. 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.
10. 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.
11. Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

## **Follow the steps below for Reprocessed Bladeless Trocar insertion without the use of an endoscope.**

1. Using sterile technique, remove the instrument from the package. To avoid damage, do not flip the instrument into the sterile field.
2. The trocar obturator and sleeve are packaged unassembled. Assemble the trocar by inserting the obturator into the trocar sleeve until they lock securely together.  
Note: The trocar is packaged with the stopcock in the open position. Close the stopcock before use. The stopcock is closed when the stopcock lever is parallel to the sleeve.
3. 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.
4. Introduce the obturator through the skin incision using a 30° to 90° rotation motion. Apply light and continuous but controlled downward pressure on the obturator.
5. When the trocar is in the abdominal or thoracic cavity, press the locking buttons to remove the obturator and endoscope, 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.
6. 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.
7. 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.

XCEL™ is a trademark of Ethicon Endo-Surgery, Inc.  
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