ENDOPATH® XCEL™

Universal Trocar Stability Sleeve



Please read all information carefully.

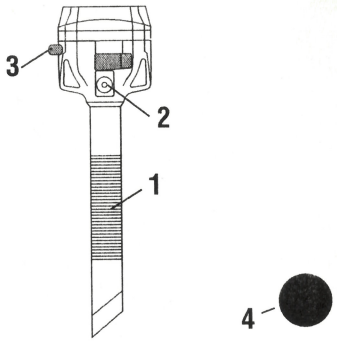
Failure to properly follow the instructions may lead to serious surgical consequences.

Important: This package insert is designed to provide instructions for use of the ENDOPATH® XCEL™ Universal Trocar Stability Sleeve. It is not a reference to trocar insertion techniques.

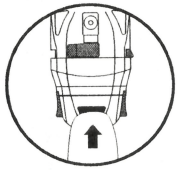
ETHICON ENDO-SURGERY, LLC
a Johnson & Johnson company

Instructions, Instructions, Gebrauchsanweisung, Istruzioni, Instruções, Instrucciones, Gebruiksaanwijzing, Brugsvejledning, Ohje, Οδηγίες, Bruksanvisning, Instrukcja, Utasítások, Návod k použití, Návod, 使用说明

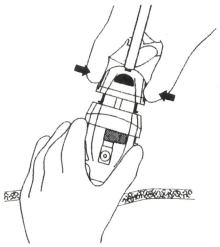
1



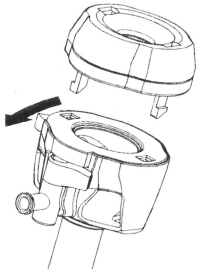
2



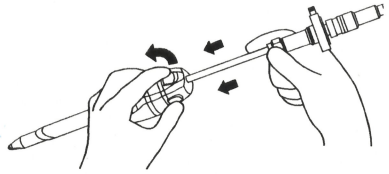
3



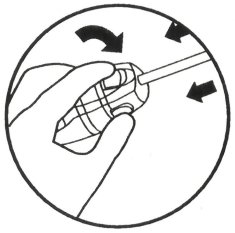
4



5



6



Indications
The ENDOPATH® XCEL™ Universal Trocar Stability Sleeve has applications in thoracic, gynecologic laparoscopy and other abdominal procedures to establish a path of entry for endoscopic instruments.

Contraindications
This device is not intended for use when minimally invasive techniques are contraindicated.

Device Description
The ENDOPATH® XCEL™ Universal Trocar Stability Sleeve is a sterile single patient use device with a radiolucent sleeve. The trocar sleeve for the 11 mm and 12 mm devices contains two seals, an outer integrated removable self-adjusting seal that accommodates instruments ranging from 5 mm to 12 mm in diameter where indicated and an internal seal. Together, these two seals minimize gas leakage when instruments are inserted or withdrawn through the trocar. The 5 mm trocar sleeve does not contain an integrated removable outer seal and accommodates only 5 mm instruments. 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.

Illustration and Nomenclature (Illustration 1)
1. Stability Threads
2. Stopcock
3. Outer Seal Release Lever
4. Universal Sleeve Symbol

Instructions 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.

Universal Sleeve For Use With ENDOPATH® XCEL™ Dilating Tip Surgical Trocars
NOTE: Refer to the ENDOPATH® XCEL™ Dilating Tip Surgical Trocar insert for additional Instructions for Use.

1 Using sterile technique, remove the trocar sleeve from the package. To avoid damage, do not flip the sleeve into the sterile field.

2 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 closed when the stopcock lever is parallel to the trocar sleeve.
Important: To allow retraction of the shield, push the reset button on the trocar obturator forward to the activated position until an audible click is heard. The trocar cannot be deactivated by forcing the red shield reset button to the original position. (Illustration 2).

3 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 (Illustration 3). 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 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 the entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.

4 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.

5 For specimen removal during the procedure, with the exception of the 5 mm sleeve, the outer seal can be removed by pushing the outer seal release lever in a counterclockwise direction and lifting off the outer seal. After removal of the specimen, replace the outer seal on the trocar. Orient the reducer cap so it is aligned correctly with the top of the trocar. Position the seal latches over the corresponding holes in the top of the trocar and press down to snap cap in place. (Illustration 4)
NOTE: The 5 mm trocar sleeve does not contain a removable outer seal.

6 Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

Universal Sleeve For Use With ENDOPATH® XCEL™ Bladeless Trocar
NOTE: Refer to the ENDOPATH® XCEL™ Bladeless Surgical Trocar insert for additional Instructions for Use.

1 Using sterile technique, remove the trocar sleeve from the package. To avoid damage, do not flip the sleeve into the sterile field.
NOTE: The obturator can be used for initial puncture or after insufflation.

2 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.

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 (Illustration 5).
NOTE: Follow these instructions for all Bladeless Trocar Obturators.

5 Rotate the endoscope as desired. Secure the endoscope in the obturator using the scope locking cam on the obturator (Illustration 6).

6 For specimen removal during the procedure, with the exception of the 5 mm trocar sleeve, the outer seal can be removed by pushing the outer seal release lever in a counterclockwise direction and lifting off the outer seal. After removal of the specimen, replace the outer seal on the trocar. Orient the reducer cap so it is aligned correctly with the top of the trocar. Position the seal latches over the corresponding holes in the top of the trocar and press down to snap cap in place.
NOTE: The 5 mm trocar sleeve does not contain a removable outer seal.

7 Upon completion of the procedure, remove the gas line. Open the stopcock to rapidly deflate the abdominal cavity.

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 Dilating Tip 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 electrosurgical 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 a minimally invasive instrument with a diameter smaller than specified for the Universal Trocar Stability Sleeve may result in desufflation of the abdominal cavity.
- During insertion of the obturator into the sleeve housing, the obturator should not be in the activated position.
- The incorporation of the shield feature in the Dilating Tip Trocar obturator 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 Dilating Tip Trocar is designed with a shield and the 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.
- Do not attempt to insert the Dilating Tip 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 of the Bladeless Trocar. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.
- If reactivation is necessary after partial entry has been made, the instrument should be removed, reactivated and then reinserted. 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.
- Once complete entry has been made into the abdominal or thoracic cavity, the Dilating Tip Trocar should not be reactivated or the 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 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 the stability sleeve, additional stability devices should not be used.
- After removing the 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.
- This device is packaged and sterilized for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.