

#### INSTRUCTION FOR USE



**Eliro™**

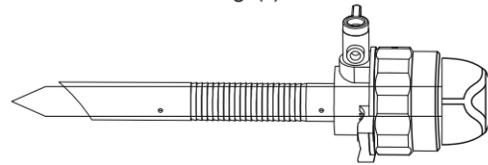
**Disposable Endoscopic Trocar**

Rev. 02 Rev. Dt. 2023/01 Document No.: ME/IFU/DET/003

Manufactured by:  
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#### CAREFULLY READ ALL INSTRUCTIONS PRIOR TO USE.

Fig. (1)



Please carefully read this manual before use  
Sterilized guaranteed Unless Package Opened or Damaged  
Sterilization period of validity: 3 Years  
Single patient use  
Sterilized by Ethylene Oxide

#### DESCRIPTION

The Disposable Endoscopic Trocar with or without integrated pistol handle is sterile single patient use instrument consisting of a sleeve and obturator in sizes 5mm, 10mm 12mm and 15mm diameter. The obturator contains a clear tapered optical element. The Trocar sleeves for the 5mm, 10mm 12mm and 15mm devices contain two seals. An outer integrated removable self-adjusting seal that accommodates instruments in all Trocar diameter where indicated and an internal seal. Together these two seals minimize gas leakage when instruments are inserted or withdrawn through the Trocar.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.

#### DIAGRAM

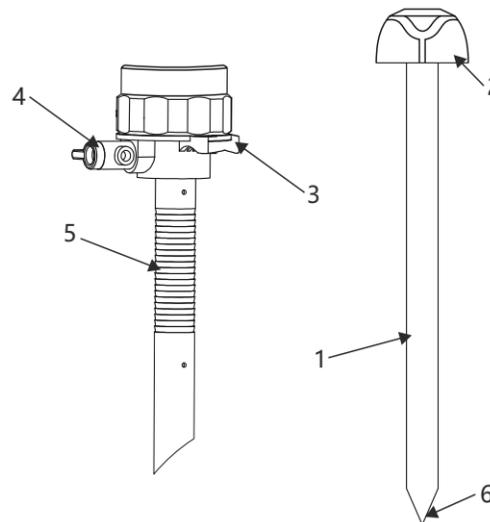


Fig. (2)

1. Obturator
2. Obturator Handle
3. Outer Seal
4. Stopcock
5. Trocar Threaded Sleeve
6. Bladeless Tip

#### INDICATION FOR USE :

The Disposable Endoscopic 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 :

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

#### PRECAUTIONS :

Verify compatibility of all instruments and accessories prior to using the instrument (refer to Warning).

#### INSTRUCTIONS FOR USE :

1. Creation of pneumoperitoneum in the abdomen is recommended prior to insert the trocar. Make an adequate incision on the skin of abdomen or chest cavity to accommodate the cannula diameter of the control of the trocar. Insufficient incision may increase penetration force and reduce the control of trocar during entry. Over size incision may increase the potential for port instability.

**CAUTION:** Insufficient pneumoperitoneum, inadequate incision, excessive force or incorrect insertion of trocar may increase the risk of injury to internal structure.

2. Assemble the trocar by inserting the obturator into the cannula while aligning the arrow on the top of the obturator with the arrow on the top of the cannula.

3. Lift up the lower abdomen, introduce the trocar at the appropriate angle to the abdominal wall through the skin incision. (Fig(3))

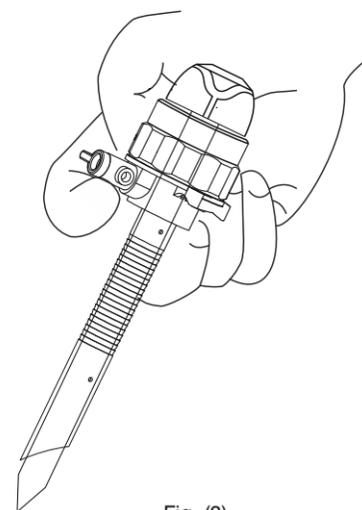


Fig. (3)

4. Keep compression on top of obturator and use continuous downward pressure to insert the trocar.

**CAUTION:** Excessive compression force may compromise surgeons' control trocar.

5. Remove the obturator from the cannula when the trocar is inserted into the desired position. Then the endoscope may be introduced through the cannula for initial inspection. (Fig(4))

**CAUTION:** Insert and remove the instruments carefully to avoid the damage to the seal.

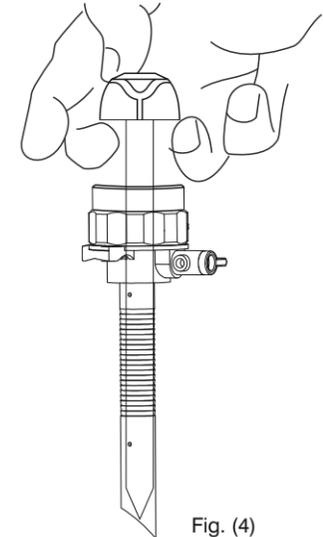


Fig. (4)

6. For 10mm-12mm trocar, 5mm converted is equipped for the accommodation of 5mm instrument. Push down the converter onto the top of cannula when necessary.

7. For removal of specimen, untwist the upper seal cap, then pull the specimen through the cannula. Make sure the specimen can be removed comfortably in this manner. (Fig(5))

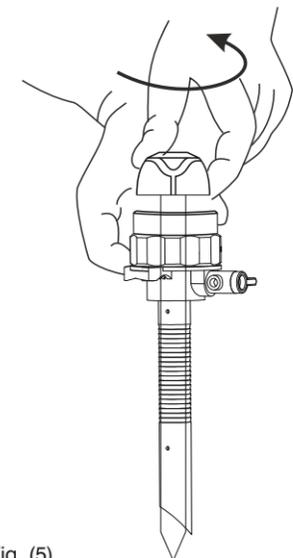


Fig. (5)

ARTWORK No.	REV.
ME/IFU/DET/003	02

**Revision History:**  
- New size 15mm Eliro trocar incorporated

Colour Shade	
	PANTONE 279 C
	PANTONE 1235 C
	BLACK

8. Open the stopcock to desufflate the abdomen when completing the surgery. Remove the cannula from the abdominal or chest cavity by a twisting motion. (Fig(6))

#### CAUTION

Always inspect the operative site for hemostasis when removing trocar from the abdominal or chest cavity. Bleeding can be controlled by electrocautery or manual sutures.

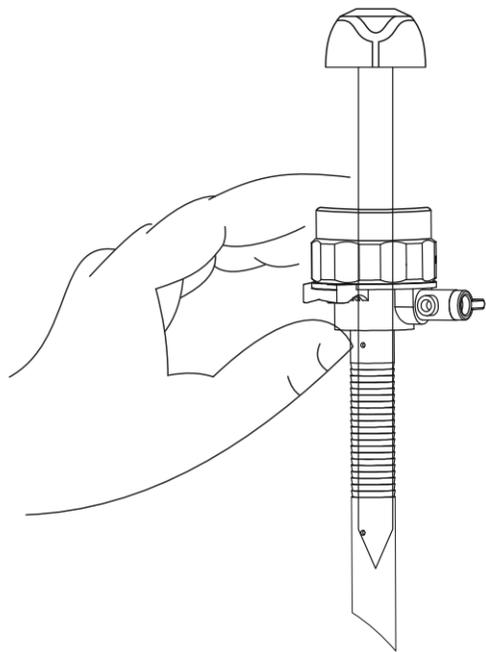


Fig. (6)

#### WARNING

1. 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.

2. 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.

3. A thorough understanding of the principles and techniques involved in laser, electro surgical, 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 electro surgical instruments in liquid unless the instruments are designed and labelled to be immersed.

4. Using minimally invasive instruments with a diameter smaller than specified for the Bladeless Trocar may result in desufflation of the abdominal cavity.

5. 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.

6. Although the Bladeless Trocar has a blunt tip, care must still be taken as with all trocars to avoid damaged 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 if penetration:
- Note important anatomical and marks:
- Direct the trocar tip away from major vessels and structures:
- Do not use excessive force.

7. Once complete entry had been made into the abdominal or thoracic cavity, 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.

8. Once partial entry has been accomplished, very little pressure may be required complete entry. Excessive pressure could cause injury to intra-abdominal or intra-thoracic structures.

9. Use caution when introducing or removing instruments through the trocar sleeve in order 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.

10. When using a sleeve with integrated threads, additional stability devices should not be used.

11. After removing the Bladeless Trocar from the cavity, always inspect the site for hemostasis. If hemostasis is not present appropriate techniques should be used to achieve hemostasis.

12. Instruments or devices which come into contact with body fluids may require special disposal handling to prevent biological contamination.

13. This device packaged and sterilized single use only. Do

not reuse, reprocess or resterilize. Reuse, reprocessing, or re-sterilization may compromise the structural integrity of device and/or lead to device failure which in turn may result in patient injury, illness or death. Also, reprocessing or re-sterilization 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.

#### SPECIFICATIONS

Sr. No.	Size	Description	Trocar Sleeve	Code
1	5mm	Disposable Endoscopic Trocar	Stability	ELR05
2	10mm		Stability	ELR10
3	12mm		Stability	ELR12
4	15mm		Stability	ELR15

#### STORAGE

Products must kept in cool and dry, aerated and non corrosive room, avoid instrument extrusion, abrasion and bump.

#### SHELF-LIFE

Eliro™ Trocar is valid for 3 years.

#### RISK OF REUSE

The product is intended to be used single time only. If used multiple time it may lead to cross contamination / infection, also it may not meet the intended use. Hence instruction for single use only is mentioned on label as well as IFU.

#### SYMBOLS USED ON LABELING

