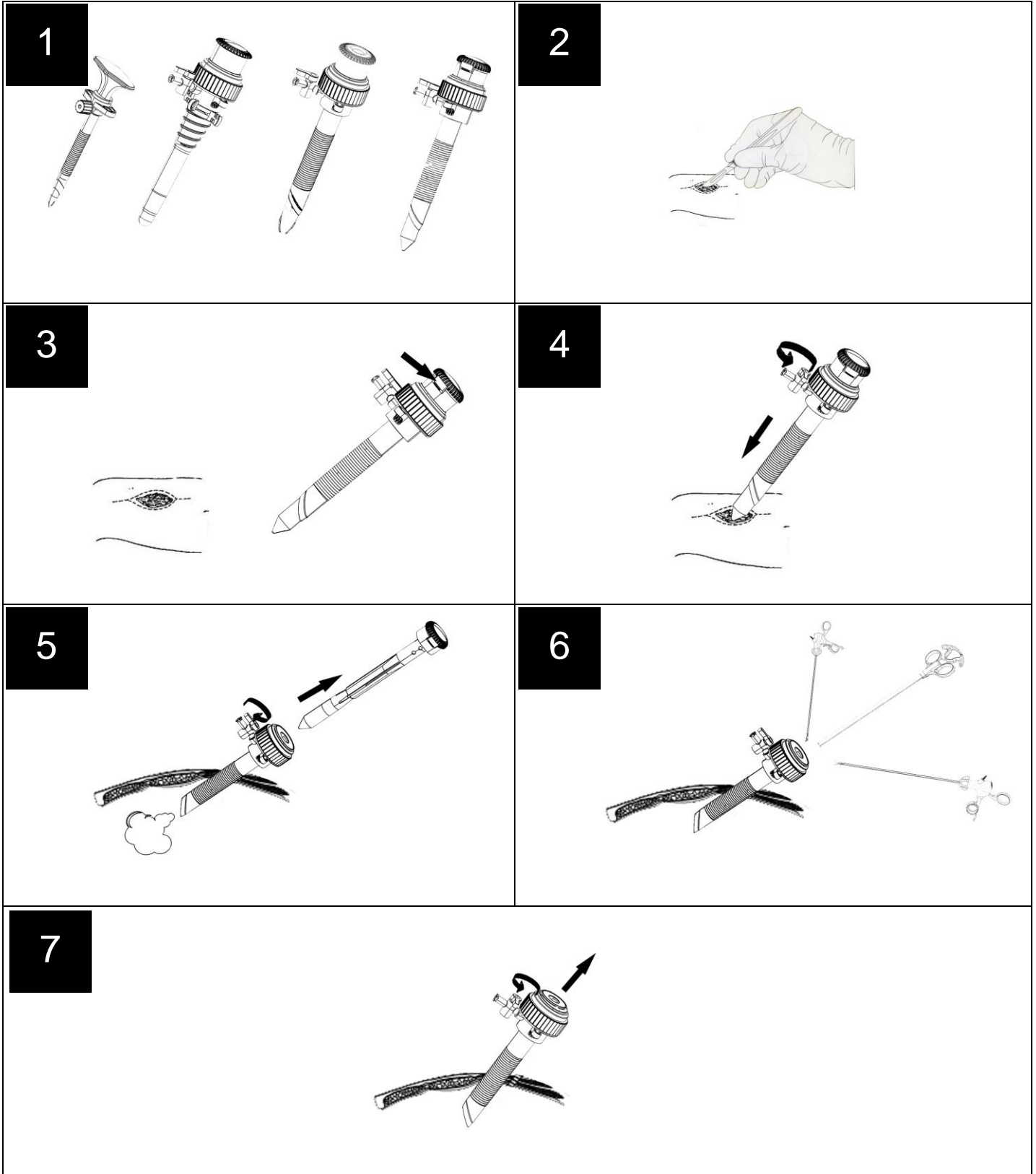


Single Use Trocar

Instructions for use



BEFORE USING THIS PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

IMPORTANT

- This booklet is designed to assist using this product. It is not a reference to surgical techniques.
- This device was designed, tested and manufactured for single use patient use only.
- Reuse of this device may lead to its failure and subsequent patient injury.
- Reprocessing and/or re-sterilization of this device may create risk of contamination and patient infection.
- Do not reuse, reprocess or re-sterilize this device

INTENDED USE

Single Use trocars are intended to establish a port of entry for laparoscopic instruments used during laparoscopic procedures.

CONTRAINDICATIONS

- Endoscopic trocars are contraindicated whenever endoscopic surgical techniques are contraindicated for any reason.
- The use of VHMED laparoscopic products is contraindicated whenever laparoscopic surgical techniques are contraindicated for any reason.

DESCRIPTION

- Trocar Cannula is made with a sealing system for maintaining pneumoperitoneum during insertion and withdrawal of instruments and with a Luer stopcock port for insufflation and exsufflation of operative cavity.
- Trocar Obturator is available in Auto Shield, bladeless, bladeless optical, and Hasson configurations. Auto Shield 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. Bladeless obturators have dilating tips which largely reduce the insertion force and prevent unwanted damage. Bladeless optical obturators are equipped with a clear tip and a video laparoscopy channel to allow trocar insertion under direct visual guidance to minimize the risk for internal injury during insertion. Hasson trocar is designed with a blunt tip obturator, a smooth cannula, and a cannula anchoring device for surgeon who prefers open technique on a laparoscopic procedure.
- Shelf life: 3 years.

WARNINGS AND PRECAUTIONS

- These instruments should be performed only by physicians with adequate training and familiarity with minimally invasive techniques. For further information about the techniques, complications and hazards, please consult the medical literature.
- Verify compatibility of all instruments and accessories from different manufacturers before utilizing together in the procedures to avoid complications.
- Prior to use, read and follow the instructions of all the instruments to be used during the procedure. Always inspect instruments carefully for overall integrity before use.
- Improper use of this product can result in life-threatening injury to internal organs and vasculature. Exercise caution during trocar insertion.
- Keep the obturator 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 exsufflation.
- Keep organs out of reach of trocar penetration by ensuring proper positioning of the patient's body.
- Direct the trocar away from major vessels and other anatomic structures.
- For the second and additional punctures of the trocar into the abdominal or thoracic cavity, inspect the tip of the trocar obturator.













- Instruments should not be opened while inside the cannula.
- After removing the instruments from the cavity, take appropriate steps to achieve hemostasis as needed.
- For Auto Shield trocars---The incorporation of the shield feature in the trocar design is intended to minimize the possibility 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 insertions must be observed.
- For Auto Shield trocars---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.
- Special care should be taken during insertion of bladed instruments so as not to damage the cannula seal, resulting in exsufflation of the operative cavity
- Remove the trocar and cannula by using continuous upward force while gentle rotating the cannula in alternating clockwise and counterclockwise directions until they are completely visible.
- Do not use excessive force or in a manner not consisting with normal instrumentation use. That may compromise its functionality and safety.
- Careful handling of instrument is necessary to avoid damage or breakage.
- Retrieve the trocar obturator slowly from the cannula. Retrieve it violently may damage the seal.
- The instrument is not intended for use when laparoscopic techniques are contraindicated.
- This instrument is intended for single patient use ONLY. DO NOT RESTERILIZE. Dispose of all used product as standard hospital practices for biohazard control.

POTENTIAL COMPLICATIONS FOR ALL VHMED PRODUCTS

Potential complications associated with the use of laparoscopic devices include but are not limited to organ or vessel damage / perforation, hemorrhage, hematoma, trocar site hernia, and septicemia / infection.

GENERAL INSTRUCTIONS FOR USE

1. The trocar obturator and cannula are packaged unassembled. Assemble the trocar by inserting the obturator into the trocar cannula until a complete match. Select and follow a suitable endoscopic and / or laparoscopic protocol. Establish the primary puncture site and insufflate the operative cavity using recommended procedures. **Refer to picture 1**
2. Make a small incision where instrument will be introduced. Ensure there is no blood vessel or grume in the incision area. **Refer to picture 2**
3. Unlock the blade shield lock. **Refer to picture 3**
4. Close the insufflation valve. Penetrate the trocar from the incision site to the cavity until the audible click is heard while the percutaneous access is obtained and the blade shield is re-engaged. **Refer to picture 4**
5. To insufflate, attach a VHMED Green Box insufflation tube to the trocar port and turn on the valve. Remove the obturator. **Refer to picture 5**
6. Insert appropriately sized instruments. When retrieving a tissue sample through a cannula with a top housing, detach the top housing and slide up the instrument shaft until the specimen has been removed. **Refer to picture 6**
7. At the end of procedure, leave the laparoscope in place during exsufflation and remove the trocar cannula. Exteriorization of the cavity contents can occur if the laparoscope is first pulled out from the cannula. Remove the cannula, and suture the incision site with the assistance of a VHMED port closure device if necessary. **Refer to picture 7**

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