

OnePort® Surgical Trocar System DIRECTIONS FOR USE



Product Description

The OnePort® Surgical Trocar System from ContMed® is a broad range of surgical trocars and accessories intended for use as the means for providing abdominal access for various instruments during laparoscopic surgery. The OnePort® Surgical Trocar System is available in 4 configurations:

- Fully Disposable w/Bladed Trocar
- Fully Disposable w/Dilating Trocar
- Reposable Cannula w/Bladed Trocar
- Reposable Cannula w/Dilating Trocar (reusable cannula & obturator, disposable seal)

Each configuration is available in numerous diameters and lengths with either smooth or ribbed cannula for additional abdominal retention. Multi-Use Cannulae and Dilating Obturators are supplied non-sterile and must be sterilized prior to use [Refer to "Reprocessing of Multi-Use Components"]. Also, see the OnePort® sales literature for a complete listing of available sizes.

Bladed Trocars

OnePort® bladed trocars are available in both disposable and reposable versions and contain a bilateral cutting blade designed to provide a simple, linear abdominal incision that minimizes application of force to gain abdominal entry. These trocars are also equipped with a locking shield, which is designed to cover the cutting edges once the body cavity has been entered.

Dilating Trocars

OnePort® dilating trocars use a conical blunt tipped obturator to gain entry through the abdominal wall. These trocars are available in both disposable and reposable configurations.

Open Trocars (Hasson style)

This device has a blunt obturator tip designed to atraumatically enter the abdominal cavity through the incision made by the surgeon. The device is equipped with a tapered plug to externally seal the incision and prevent the loss of pneumoperitoneum. The plug is equipped with arms to secure the plug with suture and a friction fit so that the depth of the sleeve may be adjusted.

Accessory Trocar Sleeves and Seal Bodies

Also available are OnePort® trocar cannulae packaged without obturators. This allows the surgeon to reuse an existing OnePort® trocar obturator to introduce additional cannulae (of the same size) in the same patient.

When the trocar of choice is the OnePort® Reposable, then replacement single-use seal bodies are required for use with the OnePort® Multi-Use cannulae. These replacement seal bodies are available individually packaged and sterile.

Refer to OnePort® sales literature for a complete listing of OnePort® Trocar products.

Indications

The OnePort® Surgical Trocar has applications in a variety of endoscopic procedures to provide a means of abdominal entry and access for endoscopic instruments. Surgeons should be thoroughly familiar with trocar placement techniques and follow all clinically indicated precautions and procedures for trocar placement.

Contraindications

The OnePort® Surgical Trocar System should only be used by surgeons trained in surgical endoscopy and the methods of safe trocar placement.

Method of Use

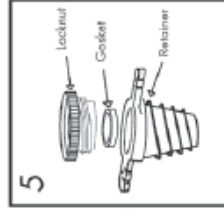
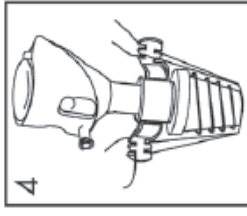
Assembly of Multi-Use Cannula

Note: If no Multi-Use components are being used, proceed to the appropriate category below.

1. Assembly: Attach the OnePort® Seal Body to the Multi-Use Cannula by

Open (Hasson style) Trocars

1. Insert the obturator through the Seal Body, into the cannula, as shown in Illustration 1. As necessary, position the cone-shaped retainer onto the cannula.
2. Using standard technique, carefully perform a mini-laparotomy to accommodate the OnePort® cannula.
3. Apply two fascial sutures - one to each side of the incision. These sutures are used to secure the trocar and can also be used for post-operative wound closure.
4. Introduce the trocar through the incision into the peritoneal cavity.
5. Position the cone-shaped retainer and trocar into the incision and secure the fascial sutures to the retainer. See Illustration 4.
6. The single-use cannula position can be adjusted by holding the retainer firmly with one hand and sliding the cannula in and out with the other hand. The Multi-Use Cannula position can be adjusted by turning the Locknut counterclockwise, holding the Retainer firmly with one hand and sliding the cannula in and out with the other hand. Tighten the Locknut securely before proceeding.
7. Remove the obturator by rotating the obturator cap and withdrawing the obturator from the Seal Body. See Illustration 2.
8. Where applicable, use insufflation tubing with a threaded luer type connector, and attach it to the integral stopcock. Open the stopcock to enable gas flow by rotating the lever so it aligns with the stopcock.
9. Desufflation and intra-operative venting can be achieved by rotating the stopcock lever downward.
10. In seal bodies equipped with a removable seal, these seals may be removed during a procedure by turning the seal counterclockwise into the unlocked position and pulling up. Reverse this procedure to reinstall the seal. See Illustration 3.



Reprocessing of Multi-Use Components

Prior to initial use, and subsequent reuse, the OnePort® Multi-Use Cannula and OnePort® Multi-Use Dilating Trocar must be decontaminated and resterilized before reuse. The Multi-Use Hasson Retainer must be disassembled, decontaminated and resterilized before reuse.

Decontamination

Scrub the outer and inner surface of the component thoroughly using a soft brush and an enzymatic detergent. Continue process until there is no visible discoloration of the cleaning fluid. Rinse with clean distilled water. Soak in enzymatic detergent solution for a minimum of two minutes. Rinse with clean distilled water and dry. It is recommended that the component be ultrasonically cleaned after decontamination. Verify that all traces of blood and debris have been removed.

Resterilization

It is imperative that all OnePort® Multi-Use components be thoroughly cleaned, using the above process, and properly wrapped prior to sterilization. The sterilization process should be carried out in accordance with sterilizer-specific instructions and hospital protocol.

Sterilizer Settings

Pre-Vacuum

Saturated Steam: Time 4 minutes Temperature 270 - 273° F (132 - 135° C)

Gravity Steam: Time 10 minutes Temperature 270 - 273° F (132 - 135° C)

The useful life span of a reusable surgical instrument is largely dependent on the care and handling of the instrument. For optimal product life, protect all OnePort® Multi-Use components from contact with other instruments during decontamination and resterilization. Allow components to cool and dry prior to handling.