

InnoPort®

Laparoscopic Access Port

INSTRUCTIONS FOR USE

INTRODUCTION

The InnoPort Laparoscopic Access Port is a sterile, single use laparoscopic access device comprised of flexible polymer and a rigid plastic plate. The polymer is formed into a “flowerpot” shaped, hollow cone approximately 5 cm long (not including ports), with three individual laparoscopic, self-lubricating instrument ports at the larger end. A fourth port connects to the insufflation system to provide intra-abdominal pneumoperitoneum, and a fifth port may be used for intra-procedural smoke removal. The working ports are designed to accommodate full maneuverability of 5 mm rigid (either straight or curved) or articulating laparoscopic instruments without loss of pneumoperitoneum. The plastic plate provides a fulcrum for instrument manipulation and wings to suture the device in place. The complete device is intended to be inserted into a single incision in the abdominal cavity for the duration of surgery.

Users should be well familiarized with the device by training prior to use.

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1 InnoPort packaged in Mounting Card

STORAGE

Identical to conditions used for conventional trocars and other Single Port Access (SPA) devices – store at controlled room temperature and avoid excessive heat.

INDICATIONS FOR USE

The InnoPort is a sterile, single use device intended for use as a multiple instrument and/or camera port during minimally invasive laparoscopic abdominal surgery.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

1. Rx only: Federal law (USA) restricts this device to sale by, or on the order of, a physician.
2. After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.
3. Minimally invasive procedures should be performed only by persons having adequate training and familiarity with minimally invasive procedures.
4. Minimally invasive instruments may vary in diameter among manufacturers. When minimally invasive instruments from different manufacturers are employed together in a procedure, verify compatibility prior to initiation of the procedure.
5. A thorough understanding of the 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.
6. Patients with very thick abdominal walls may present difficulty in creating continuity between the InnoPort access ports and the abdominal cavity.
7. Although the end of the port is soft and flexible, care must still be taken to avoid damage to major vessels and other anatomic structures (such as the bowel or mesentery). To minimize the risk of injury be sure to:
 - Properly position the patient to help displace organs out of the area of penetration.
 - Note important anatomical landmarks.
 - Avoid use of excessive force.
8. Excessive pressure could cause injury to intra-abdominal structures.
9. The use of rigid tools in SPA procedures may limit the surgeon’s ability to triangulate on the surgical site.
10. Be careful to avoid kinking the insufflation tube which may limit CO₂ flow to the abdomen.

11. Use caution when introducing or removing instruments through the ports in order to prevent inadvertent damage to the seals, which could result in loss of pneumoperitoneum. Special care should be taken to prevent damaging the ports when introducing sharp or angled edged endoscopic instruments.
12. Also use caution when introducing or removing instruments through the ports in order to prevent inadvertent damage to the InnoPort body; instruments should be angled so as to pass directly through the open end of the device and not contact the wall of the device. Articulating instruments should be straightened prior to removal. Instruments with sheaths should be sheathed prior to removal. Instruments with curved or angled ends, such as cautery electrodes, should be rotated so that the curved/angled surface does not catch on the wall of the device. Energized instruments should be allowed to cool before withdrawal.
13. After removing the InnoPort, inspect the incision site for hemostasis. If hemostasis is not present, appropriate techniques should be used to establish hemostasis.
14. Inspect the InnoPort after removal to check for device integrity (tearing, pieces cut away, etc.).
15. Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
16. 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.

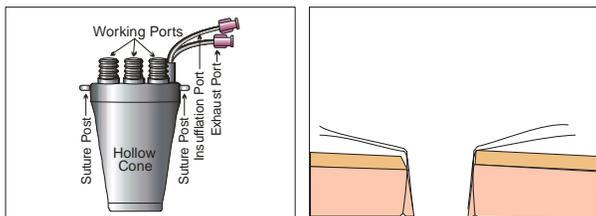
STERILIZATION

The InnoPort is sterile upon receipt. It is sterilized by EtO sterilization per ISO 11135 guidelines. Contents will remain sterile unless package is opened or damaged outside a sterile field. Should the device be inadvertently rendered non-sterile, or should the package be opened and/or damaged outside a sterile field, discard the device.

INSTRUCTIONS FOR USE

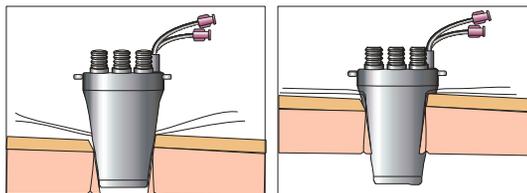
User must be properly trained on the use of the device prior to use.

1. Verify compatibility of all instruments and accessories prior to using the device (refer to Warnings and Precautions).
2. Select the device and inspect the packaging for any damage to the seals or the sterile barrier. If damage is evident, do not use the device.
3. Prepare the surgical site per routine procedure.
4. Elevate the abdominal wall at the anticipated insertion position.
5. Use a sterile surgical ruler and pen to draw a line 2.5 cm long along the desired incision line. Make a 2.5 cm incision along this line using standard surgical technique. **Note: An incision shorter than 2.5 cm may increase insertion resistance, possibly result in a loss of control during entry. An incision substantially longer than 2.5 cm may cause difficulty maintaining pneumoperitoneum or device pop-out under high angulation.**
6. Place a finger into the incision to ensure that the free abdominal cavity has been entered. Pass size 0 resorbable sutures through each fascial edge. (sutures not provided.) Hold the sutures upward and apart.



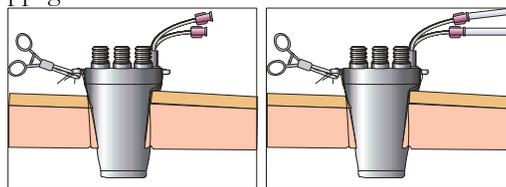
The InnoPort (left), sutures anchored through fascia (right)

7. Using sterile technique, remove the InnoPort from sterile packaging onto sterile field. It is recommended that the InnoPort be removed from the Mounting Card by first dismounting the InnoPort suture wings, then the insufflation tube. Do not pull on the InnoPort body to dismount the device insufflation tube from the Mounting Card.
8. Inspect the device for damage. If damage is evident, do not use the device.
9. Insert the device into the incision. Use an alternating, rotating motion to facilitate insertion. When fully inserted, the tapered section should be in the incision and the straight section, which ends about 1cm below the suture posts, should be above the skin.



Device insertion; partial (left), near complete (right)

10. Maintain tension and wrap one suture 2 – 4 times around the nearest suture post, pinching the suture into the crevice between the InnoPort body and the wing. Repeat on the opposite wing. The suture can be grasped with a hemostat to prevent slippage.



Sutures wrapped around wing, secured with hemostat (left); inflow/outflow tubes attached to insufflation/suction (right)

11. Connect the insufflation supply line to a CO₂ source. Be careful to avoid kinking or applying excessive tension to the insufflation tubing during procedure as this may impair the ability to maintain pneumoperitoneum.
12. As desired, connect the outflow port to a negative pressure source to evacuate intra-abdominal smoke during the procedure, such as from cautery. When

not in use, keep this port closed to prevent loss of pneumoperitoneum.

13. Use caution when introducing or removing instruments through the ports in order to prevent inadvertent damage to the InnoPort. Ensure that all instruments are in the closed position when passing through a port. Instruments should be angled so as to pass directly through the open end of the device and not contact the walls of the device. Articulating instruments should be straightened prior to removal. Instruments with sheaths should be sheathed prior to removal. Instruments with curved or angled ends, such as cautery electrodes, should be rotated so that the curved/angled surface does not catch on the wall of the device. Energized instruments should be allowed to cool before withdrawal.
14. Upon completion of the procedure, remove the insufflation line to allow deflation of the abdominal cavity. Detach the sutures from the suture wings and remove the device. To remove large specimens, remove the InnoPort, then remove the specimen. Properly close the abdominal incision.
15. Dispose of InnoPort in accordance with hospital, administrative, and/or local government policy.

DO NOT RESTERILIZE

For questions or comments, please contact:

Innova

Innovia LLC

12415 Southwest 136 Avenue, Suite 3

Miami, FL 33186 USA

Phone: (305) 378-2651

Fax: (305) 378-2652

innovia@innovia-llc.com

www.innovia-llc.com

www.theinnoport.com