Insightra Medical®

Hernia Delivery Instrument Set

REF: FDIS

Instructions for Use

Description: The Insightra Medical Hernia Delivery Instrument Set is a non-sterile, reusable, instrument set designed for deploying hernia mesh implants. It can be sterilized using steam autoclave sterilization techniques. The set is comprised of two sizes of forceps type stainless steel instruments for grasping mesh implants and a stainless steel mesh flattening tool. The concave instrument tips are designed to avoid mesh implant damage.

Indications for Use: The Hernia Delivery Instrument Set is intended as a surgical tool to aide in the handling and implantation of hernia mesh implants.

Contraindications: Any hernias that are too small to accommodate the Delivery Instrument should not be treated using the Insightra Medical Hernia Delivery Instrument Set.

Warnings, Cautions and Symbols

Symbols	
REF	Catalog Number
LOT	Lot Number
⚠	Attention. See Instructions for Use
NON STERILE	The product is non sterile.
QTY	Quantity. Contents
	Manufacturer
℞	Caution: Federal (USA) law restricts this device to sale by or on the order of a Physician
LATEX	Contains no natural rubber latex
CE	EU – Conformity Symbol
EC REP	European Representative

DEFINITIONS

Warning: Could result in death or injury to the patient.
Caution: May result in minor injury to the patient.
Note: May result in property damage or advises on the proper use of the product.
Important Technique: Key instruction aiding the successful use of the product.

WARNINGS, CAUTIONS AND NOTES

Warning: Read Instructions For Use prior to using this device.

Warning: This product should only be used by physicians having adequate training and familiarity with surgical inguinal hernia repair using mesh plug implants. Clinical judgment and surgeon discretion must be used to determine the appropriateness of using this device with the hernia mesh implant.

Warning: Improper cleaning and resterilization may lead to patient infection or cross infection which in turn may result in patient injury, illness or death. Use proper hospital procedures for processing contaminated instruments and resterilization.

Caution: Before use, inspect the instruments to verify no damage to product has occurred during shipping, handling and resterilization.

Caution: Using an improper size of Delivery Instrument on the mesh implant may result in either damage to the implant or a poor therapeutic outcome.

Caution: Care must be taken when using the Mesh Flattening tool to prevent injury or perforation of the peritoneum.

Caution: Care must be taken when using the Delivery Instrument to not trap extraneous tissue in the jaw tips when closing the instrument while deployed in the body

BEFORE FIRST USE

Package Contents:

One (1) Delivery Instrument – 25mm
One (1) Delivery Instrument – 40mm
One (1) Mesh Flattening Tool

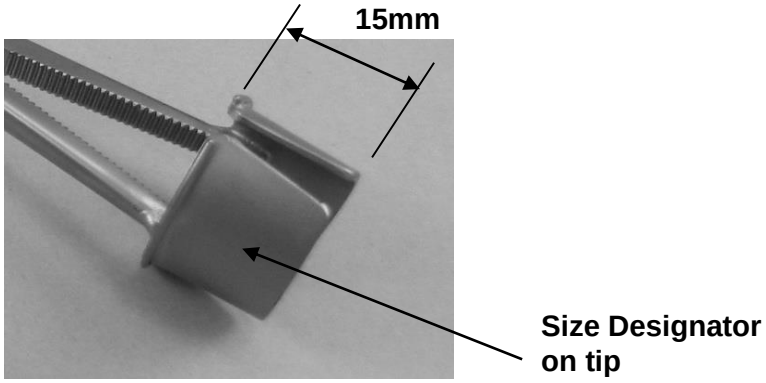

Figure 1

Inspect each component to ensure there are no cracks, bends or damage to the product. Verify proper hinge function and that the handle lock and tip travel stop are in place.

The set components are packaged NON STERILE and should be cleaned and sterilized using the instructions below:

INSTRUCTIONS FOR CLEANING

After opening a new kit and after each procedure, the Freedom Inguinal Hernia Dilator Kit should be manually cleaned using a standard enzymatic detergent (ENZOL® or equivalent prepared per manufacturer's instructions) using lukewarm tap water. The device tip travel stop should be disabled, tips opened and fully immersed in the detergent and allowed to soak for fifteen (15) minutes. Scrub with a soft brush to remove any visible debris. A syringe can be used as an aide to flush hard to reach areas. Rinse with deionized water for a minimum of one (1) minute and inspect. Repeat cleaning procedure if any visible debris remains.

Note: This product has not been qualified for use with automated cleaning systems.

INSTRUCTIONS FOR STEAM AUTOCLAVE STERILIZATION

Warning: Improper cleaning and resterilization may lead to patient infection or cross infection which in turn may result in patient injury, illness or death. Use proper hospital procedures for processing contaminated instruments and resterilization. The use of steam sterilization chemical indicators is recommended.

The Delivery Instrument Set components are non porous metal instruments and should be surface sterilized using the following recommended autoclave sterilization methods:

Sterilizer type:	Gravity displacement
Minimum Temperature:	250°F (121°C)
Pressure:	20 psi
Full Cycle Time:	30 minutes
Minimum Dry Time:	20 minutes
Wrapping:	Individually wrapped pieces

The use of alternate steam sterilizers is at the discretion and responsibility of each institution. If different equipment and/or parameters are used, each institution should use procedures that include biological indicators or appropriate validation methodologies to determine the effectiveness of the sterilization procedure.

REUSE LIFE

The Hernia Delivery Instrument Set has been designed to withstand multiple use cycles with proper care and handling. Instrument life is determined on its ability to perform its function, which is verified prior to each use by the operator. However, any visible deterioration such as damage resulting from use or handling is cause for retirement of the device from further use.

Standard procedures shall be followed for logging and recording sterilization cycles and use of this product as governed by local hospital and administrative procedures.

INSTRUCTIONS FOR USE

1. Carefully inspect the sterile packaging to ensure it is not damaged and sterility has not been compromised.

2. Open the sterile packaging and hand the Delivery Instrument Set to the operator using standard aseptic technique.

3. Inspect the product to ensure there are no cracks, breaks or signs of damage to the instruments.

Caution: Before use, inspect the instruments to verify no damage to product has occurred during shipping, handling and resterilization.

4. Verify that the handle lock and tip travel stop are functioning and that the hinge pivots freely on both Delivery Instruments.

5. Select the correct size of Delivery Instrument that is appropriate for the size of the mesh implant being used. Clinical judgement should be used to ascertain the correct size.

Caution: Mismatching sizes of the Delivery Instrument to the implant may result in either damage to the implant or a poor therapeutic outcome.

6. Place the implant inside the Delivery Instrument tips and close using the handle lock to secure the implant. The instrument tips should only be moved to the closed position while outside the body.

   Caution: Care must be taken when using the Delivery Instrument to not trap extraneous tissue in the jaw tips when closing the instrument while deployed in the body

7. Position the implant in the hernia defect using the Delivery Instrument. The flange on the tips serves as a visual and tactile indicator of 15 mm depth.

8. Use the Mesh Flattening tool to help position any sublay mesh into the preperitoneal plane when finger space is not available.
   Caution: Care must be taken when using the Mesh Flattening tool to prevent injury or perforation of the peritoneum.

Note: The Mesh Flattening tool should only be used on the top side of the sublay mesh and only to the edge of the mesh to avoid unintentional dissection or contact with the peritoneum.

9. Release the implant by opening the Delivery Instrument tips and spreading the surrounding tissue to allow the compressed implant to expand and be released. The Mesh Flattening tool can be used to stabilize the implant as the Delivery Instrument is withdrawn.

Tip fully open diameter
40mm Instrument = 36mm
25mm Instrument = 32mm

10. Inspect the implant to ensure no damage has occurred to its structure.

AFTER USE

All components of the Delivery Instrument Set should be checked for damage and then decontaminated, cleaned and sterilized using the instructions listed above.

Note: After use or after its useful life, this product should be considered a potential biohazard. Handle and recycle in accordance with accepted medical practice and applicable local, state and federal regulations.

Storage
Clean and sterilized product sets should be stored in a dry location.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Patent Pending

Manufacturer:
Insightra Medical, Inc.
9200 Irvine Center Drive
Irvine, CA 92618, USA
Phone (949) 215-1835

European Representative:
WMDE
Bergerweg 18
6085 AT Horn
The Netherlands