FREEDOM – INGUINAL

Hernia Repair System
Instructions for Use

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INSIGHTRA® MEDICAL

Freedom™ Inguinal Hernia Implant (ProFlor™) Instructions for Use

Description: The Insightra Medical Freedom Inguinal Hernia Implant (ProFlor™) is a sterile implant device, constructed of polypropylene and designed for use in the open repair of inguinal hernias. It is designed for use with the Freedom Inguinal Hernia Disposable Deliver Device (REF: FIHR25mmD or FIHR40mmD)

Indications for Use: The Freedom Inguinal Hernia Implant is intended to be implanted to reinforce soft tissues where weakness for open repair of inguinal hernias exists.

Contraindications: Indirect or direct inguinal hernias, which are either too small or too large to accommodate the Freedom Inguinal Hernia Implant, should not be treated using the Freedom Inguinal Hernia Implant. The Freedom Inguinal Hernia Implant is not intended for inguinal hernia with hernia opening wider than 35 mm, Nyhus type IV or patients exceeding a BMI of 35.

Contraindications: There is a possibility for adhesion formation if device is placed in direct contact with the bowel.

Contraindications: Repair of femoral hernia with this device is contraindicated.

Contraindications: Use of the Freedom Inguinal Hernia Implant in recurrent hernia without the complete removal of a prior implant is contraindicated.

Warnings, Cautions and Symbols

Symbols	
REF	Catalog Number
LOT	Lot Number
2	Do not reuse. For single use only
⚠	Attention. See Instructions for Use
STERILE EO	Sterilized by ethylene oxide. The product is sterile if the product is not open or damaged.
QTY	Quantity. Contents
CE 0086	EU-Conformity Symbol
⧗	Use By
	Manufacturer
EC REP	European Representative
LATEX	Contains no natural rubber latex
Rx	Caution: Federal (USA) law restricts this device to sale by or on the order of a Physician

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

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 inguinal hernia repair using mesh plug implants.
Warning: The Freedom Inguinal Hernia Implant and Delivery Device require training for their proper use and implantation technique. Training options are listed on the package insert "Technique Guide" which also includes instructional steps and diagrams. It is recommended that the first 5 cases be supported by an authorized Insightra representative and proctored by a surgeon familiar with the device implant.

Warning: In the case of recurrent hernia where a previous implant is present, complete removal of the old implant is required prior to use of the Freedom Inguinal Hernia Implant Repair system.
Warning: The use of any nonabsorbable mesh, such as the Freedom Inguinal Hernia Implant, in a contaminated or infected wound could lead to infection, abscess, fistula formation and/or extrusion of the mesh.
Warning: Before use, inspect all packaging to verify that no damage has occurred during shipping or handling. Carefully inspect the packaging to ensure sterility has not been compromised and verify that the product has not expired.
Warning: The Freedom Inguinal Hernia is provided sterile and is intended for single use only. Do not resterilize. Opened packages and unused product should be discarded.
Warning: Reuse, reprocessing or resterilization may compromise the structural integrity of the device causing device failure and/or lead to patient infection or cross infection which in turn may result in patient injury, illness or death.
Warning: Potential adverse reactions are those typically associated with surgically implanted materials. These reactions include inflammation, adhesion formation, infection potentiation, fistula formation, and extrusion.
Warning: Surgical dissection and hernia repair in the inguinal region has been associated with certain risks. These would include, but are not limited to: swelling, seroma, sexual dysfunction, chronic groin pain, recurrence, excessive bleeding, injury to the intestines, nerve injury, vascular injury, vas deferens blockage, bowel blockage, spermatic cord injury, urinary complications and testicular injury. Care should be taken when preparing the surgical site.
Warning: The peritoneum should be inspected prior to insertion of the implant to ensure there are no openings. Peritoneal openings are to be closed by conventional surgical technique prior to implant insertion to avoid contact between the implant and the abdominal content. Failure to do this could lead to adhesions, fistula formation and bowel blockage or injury.
Warning: Do not apply excessive force to push the implant disk beyond the muscular wall. If excessive force or stretching is used and bleeding and/or other kind of injuries of the muscle fibers are detected, the Disposable Delivery Device and implant should be removed and the bleeding and/or muscular injury should be managed with proper surgical procedures.

CAUTIONS

Caution: Use standard sterile technique when opening product.
Caution: The Freedom implants should only be inserted using the Freedom Disposable Delivery Device or appropriately designed delivery instruments as the implant must be constrained for delivery.
Caution: Mismatching of the implant to the dilator may result in damage to the implant.
Caution: Clinical judgement should be used to ensure that the inguinal tissues are not over dilated. If you suspect over dilation may occur, **STOP** and change to a smaller Disposable Delivery Device & implant. If you are at the smallest size implant, the use of this device is contraindicated.
Caution: Once the implant disk is in the preperitoneal space and the Disposable Delivery Device is being pulled back towards the user, when any slight resistance is felt from the disk against the tissue is keeping it from retracting -**STOP**. Continuing to pull will prematurely dislodge the implant from the Disposable Delivery Device.
Caution: Pushing the Disposable Delivery Device Handle relative to the abdominal plane may cause the core of the implant to be pushed into the pre-peritoneal space. If this happens, the core of the implant can simply be adjusted using forceps to return it to the inguinal defect.
Caution: If a spermatic cord is present, carefully evaluate its position within the implant to ensure proper positioning. Clinical signs such as swelling, discoloration, and/or enlargement of the spermatic vein may indicate inappropriate placement. Clinical judgement should be used to decide if a clinical risk exists. If considered a risk, the implant should be removed by pulling it out using forceps and an alternate hernia repair technique should be used.
Caution: Good haemostasis should be achieved prior to closure to minimize post-operative hematoma.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

NOTES

Note: In the case of indirect inguinal hernia in the male patient, the implant loops should fold around the spermatic cord.
Note: See package insert “Technique Guide” included with the product which contains instructional steps and diagrams.
Note: After following the loading instructions of the implant, in the case of indirect inguinal hernia the “notch” of the Disposable Delivery Device should be aligned with the spermatic cord. This will allow the implant to deploy around the cord. If present, the cord must remain stretched laterally throughout the implantation procedure.
Note: Post operative implant assessment can be achieved with the use of ultrasound scans. Stable implant positioning within the previous inguinal defect confirms the lack of implant dislodgement or migration. Full obliteration of the defect confirms the lack of new hernia or recurrence.
Note: After use (if not implanted), this product should be considered a potential biohazard. Handle and recycle in accordance with accepted medical practice and applicable local, state and federal regulations.

PACKAGE CONTENTS

One (1) Inguinal Hernia Implant; size 25 mm (REF: FIHR25mm) or size 40 mm (REF: FIHR40mm)

INSTRUCTIONS FOR USE

USING THE IMPLANT WITH THE FREEDOM INGUINAL HERNIA DISPOSABLE DELIVERY DEVICE.

1. Select the correct size of implant corresponding to the intraoperatively measured defect size of the inguinal hernia. The following table serves as a guideline. Clinical judgement should be used to ascertain the correct size.

Intraoperatively Measured Hernia Defect Size	Classification	Implant Size
5mm – 20mm	Hernia to Nyhus type 1 and any inguinal hernia with diameter of hernia opening up to 20 mm	25 mm REF: FIHR25mm
21mm – 35mm	Nyhus type 2 to 3a and any inguinal hernia with diameter of hernia opening from 21 to 35 mm	40 mm REF: FIHR40mm

Warning: Before use, inspect all packaging to verify that no damage has occurred during shipping or handling. Carefully inspect the packaging to ensure sterility has not been compromised and verify that the product has not expired.

2. Open the sterile packaging and transfer the sterile implant holder to the sterile field using conventional/standard aseptic sterile technique.

3. On the sterile field, open the holder and remove the implant.

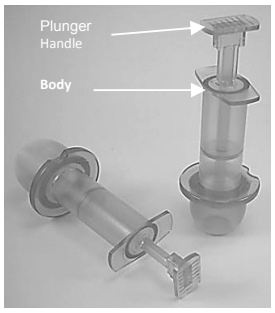
4. Inspect the implant to ensure it is not damaged. Verify that the implant disk is securely attached to the loop structures of the implant.

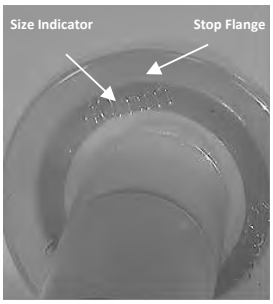
   Caution: The Freedom implants should only be inserted using the Freedom Disposable Delivery Device or appropriately designed delivery instruments as the implant must be constrained for delivery.

5. Select the proper size Disposable Delivery Device and transfer aseptically to the sterile field.

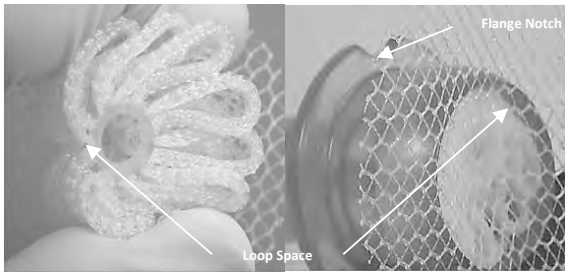
6. Ensure that the implant size selected matches the Hernia Dilator size. For the Disposable Delivery Device: The 25mm Device denoted by “25mm” on the dilator flange is intended for use with the 25 mm Implant and the 40mm Device denoted by “40mm” on the flange is intended for use with 40 mm Implant.

   Caution: Mismatching of the implant to the dilator may result in damage to the implant.





7. Prepare the Disposable Delivery Device to receive the implant by retracting the plunger handle and rotating counter clockwise on the body to the locked position.



8. The loops of the Freedom Hernia Implant should be folded around the central core of the implant. In the folded position, insert the loop structures of the implant into the distal end of the Disposable Delivery Device aligning the "space" between the loops with the "notch" on the flange of the Disposable Delivery Device.

   Note: This alignment is important in the case of indirect inguinal hernia as it helps the loops fold open around the spermatic cord.

9. The hernia defect should be prepared according to standard hernia technique.

   For **indirect hernia,** after skin incision and opening of the oblique externus aponeurosis, perform dissection and elevation of the cord, defining the hernia sac location and internal ring. Thoroughly remove the adhesions and scar tissue around the internal inguinal ring. Perform dissection of the sac, high ligation and excision of the sac. Before releasing the sac stump into the abdominal cavity, perform finger guided blunt dissection of the parietal peritoneum from the posterior abdominal wall as appropriate to accommodate the placement of the preperitoneal disc of the implant.

   For **direct hernia**, after opening the externus aponeurosis and elevation of the cord, perform dissection of the sac from the groin structures until the hernia opening arising through the fascia transversalis is reached. Thoroughly remove the adhesions and scar tissue around the hernia opening. After the hernia sac has been fully isolated, the trasversalis fascia should be breached as wide as necessary to detach the peritoneal sac with its content all around its posterior aspect. Before releasing the sac stump into the abdominal cavity, perform finger guided blunt dissection of the parietal peritoneum from the posterior abdominal wall as appropriate to accommodate the placement of the preperitoneal disc of the implant.

   Note: See package insert "Technique Guide" included with the product which contains instructional steps and diagrams.

10. The Disposable Delivery Device with the loaded implant can be inserted into the inguinal defect.

    Caution: Clinical judgement should be used to ensure that the inguinal tissues are not over dilated. If you suspect over dilation may occur, **STOP** and change to a smaller Disposable Delivery Device & implant. If you are at the smallest size implant, the use of this device is contraindicated.

    Note: After following the loading instructions of the implant, in the case of indirect inguinal hernia the "notch" of the Disposable Delivery Device should be aligned with the spermatic cord. This will allow the implant to deploy around the cord. If present, the cord must remain stretched laterally throughout the implantation procedure.

11. The implant disk will remain on the outside of the Disposable Delivery Device as it is advanced. The Disposable Delivery Device should be carefully advanced into the defect until the disk of the implant is fully behind the muscle wall in the preperitoneal space and the depth stop flange on the Disposable Delivery Device rests against the external border of the muscular wall.

    Warning: The peritoneum should be inspected prior to insertion of the implant to ensure there are no openings. Peritoneal openings are to be closed by conventional surgical technique prior to implant insertion to avoid contact between the implant and the abdominal content. Failure to do this could lead to adhesions, fistula formation and bowel blockage or injury.

    Warning: Do not apply excessive force to push the implant disk beyond the muscular wall. If excessive force or stretching is used and bleeding and/or other kind of injuries of the muscle fibers are detected, the Disposable Delivery Device and implant should be removed and the bleeding and/or muscular injury should be managed with proper surgical procedures.

12. Once the disk of the implant is in the preperitoneal space, the Disposable Delivery Device should gently be pulled back towards the user until a resistance from the disk is felt. This signifies the implant is ready to be deployed.

    Caution: Once the implant disk is in the preperitoneal space and the Disposable Delivery Device is being pulled back towards the user, when any slight resistance is felt from the disk against the tissue is keeping it from retracting -**STOP**. Continuing to pull will prematurely dislodge the implant from the Disposable Delivery Device.

13. Holding the Disposable Delivery Device body, turn the disposable plunger handle clockwise until it stops. The Disposable Delivery Device is now ready to deploy the implant.

14. Carefully pull back the Disposable Delivery Device while maintaining the position of the Disposable Delivery Device Handle relative to the abdominal plane. As you withdraw, gently deploy the plunger to release the implant. This will remove the Disposable Delivery Device from the defect, allowing the core of the implant to remain inside the defect.

    Caution: Pushing the Disposable Delivery Device Handle relative to the abdominal plane may cause the core of the implant to be pushed into the pre-peritoneal space. If this happens, the core of the implant can simply be adjusted using forceps to return it to the inguinal defect.

15. The Disposable Delivery Device can then be removed from the site. The Disposable Delivery Device and surgical site should be inspected to ensure that no part of the Disposable Delivery Device remains in the surgical site and that there is no bleeding due to over dilation.

    Following delivery of the implant: The core of the implant will be in the defect. The disk of the implant should be positioned in the preperitoneal space. See Figure 1. The loops of the implant should be positioned evenly around the defect to form a complete circle. This can be done using surgical forceps. If a spermatic cord is present, care must be taken to ensure it lies between two of the loops.

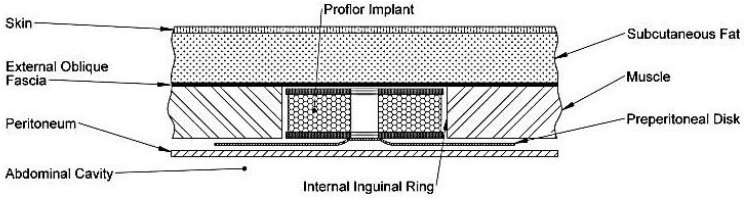


Figure 1

Caution: If a spermatic cord is present, carefully evaluate its position within the implant to ensure proper positioning. Clinical signs such as swelling, discoloration, and/or enlargement of the spermatic vein may indicate inappropriate placement. Clinical judgement should be used to decide if a clinical risk exists. If considered a risk, the implant should be removed by pulling it out using forceps and an alternate hernia repair technique should be used.

16. Using clinical judgement, a securing suture(s) may be placed between the loop(s) of the implant and the muscle wall. Monofilament, non-absorbable sutures are recommended. Use standard clinical techniques for mesh plugs.

17. Inspect the site for any signs of bleeding, nerve damage caused by dilation or deployment of the implant.

    Caution: Good haemostasis should be achieved prior to closure to minimize post-operative hematoma.

18. Perform wound closure using standard surgical technique.

Note: Post-operative implant assessment can be achieved with the use of ultrasound scans. Stable implant positioning within the previous inguinal defect confirms the lack of implant dislodgement or migration. Full obliteration of the defect confirms the lack of new hernia or recurrence.
Note: After use (if not implanted), 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: Products should be stored in a clean, cool, dry area, away from direct sunlight.
Shelf Life: A "Use By" date is referenced on the label.
Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Patents Pending

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