FREEDOM INGUINAL

Hernia Repair System

TECHNIQUE GUIDE

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The following describes the open surgical preparation and implantation technique for the Freedom Inguinal Hernia Repair System.

1) Anesthesia can be general, local or regional at the physician's discretion
2) Perform skin incision (4 –8cm.)
3) Two opposing retractors should be used. Use additional retractors at 90 degrees to increase visibility as needed.
4) Perform dissection through Scarpa's fascia, to external oblique aponeurosis
5) Gain exposure of external inguinal ring and external oblique aponeurosis.
6) Perform dissection and elevation of the spermatic cord while defining the hernia sac location and internal ring.
7) 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.
8) 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 sacculation 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.
9) Inspect the peritoneum prior to insertion of the implant to ensure there are no openings. Peritoneal openings must be closed to avoid contact between the implant and the abdominal content.
10) Select the appropriate sized Freedom Inguinal Hernia Repair implant in accordance with the recommended sizing instructions located in the instructions for use. Measure the dissected hernia defect using a sterile ruler to determine implant size requirements.

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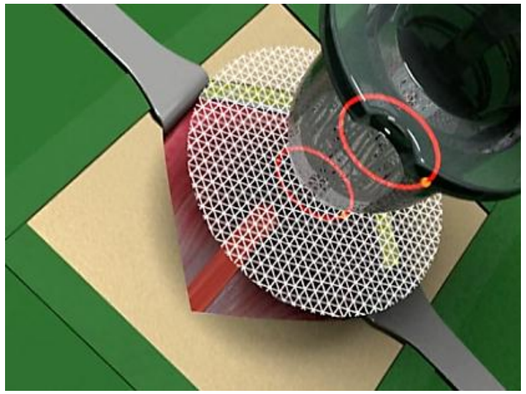
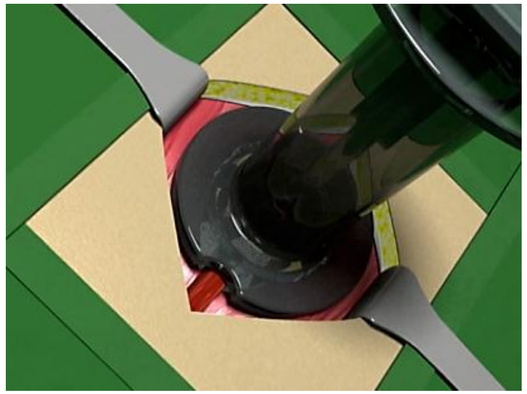
11) Load the implant into the delivery device aligning the lamella with the flange notch indicator as per the device instructions.	12) Insert the loaded delivery device into the hernia defect aligning the flange notch indicator with the spermatic cord	13) Insert delivery device until the stop flange is flush with anterior aspect of the inguinal canal (indirect) or abdominal muscle (direct)
		

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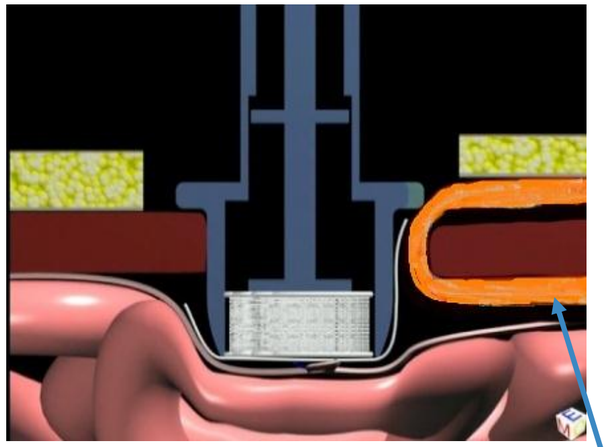
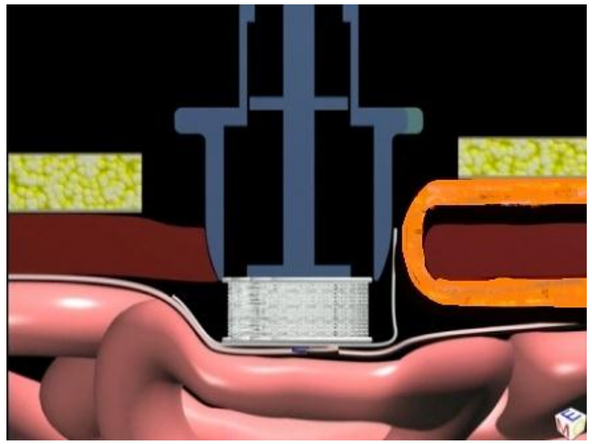
14) Using the plunger, deploy the implant while retracting the delivery device from the defect





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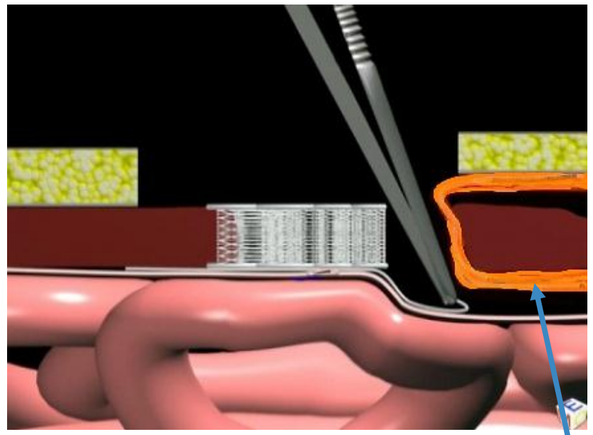
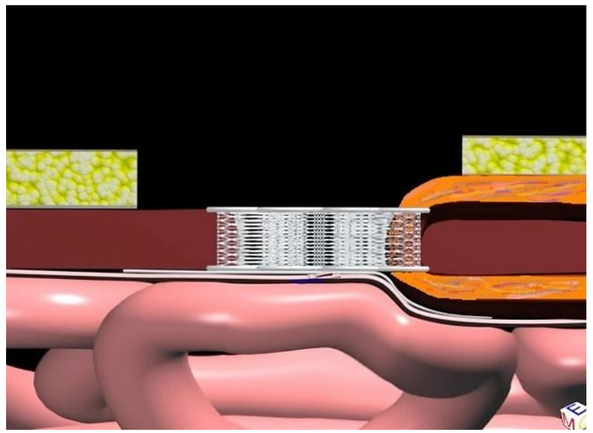
15) After delivery if needed, forceps guided adjustment can be used to position any protruding mesh disk material fully into the preperitoneal space.





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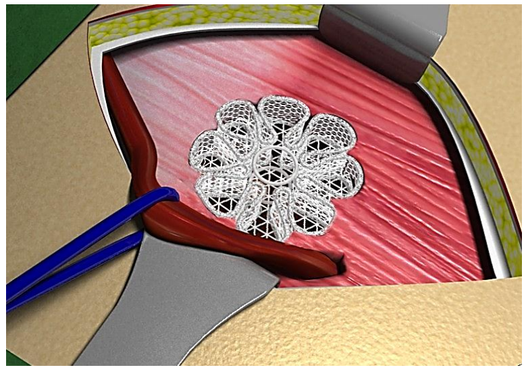
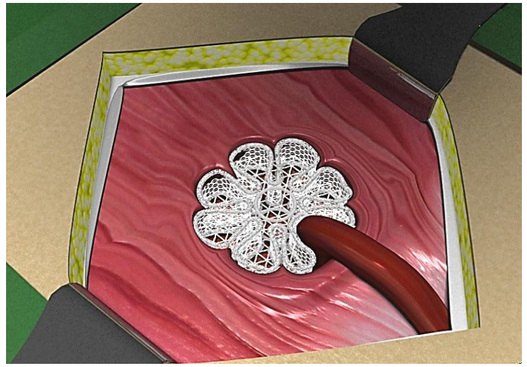
Note: Prior to closure proper implant positioning and stability should be confirmed by patient cough test (local anesthesia) or tugging of implant (general anesthesia). Coughing will expel an improperly placed or sized implant. Under general anesthesia, resistance to light pulling force with forceps will indicate whether the implant is secure.

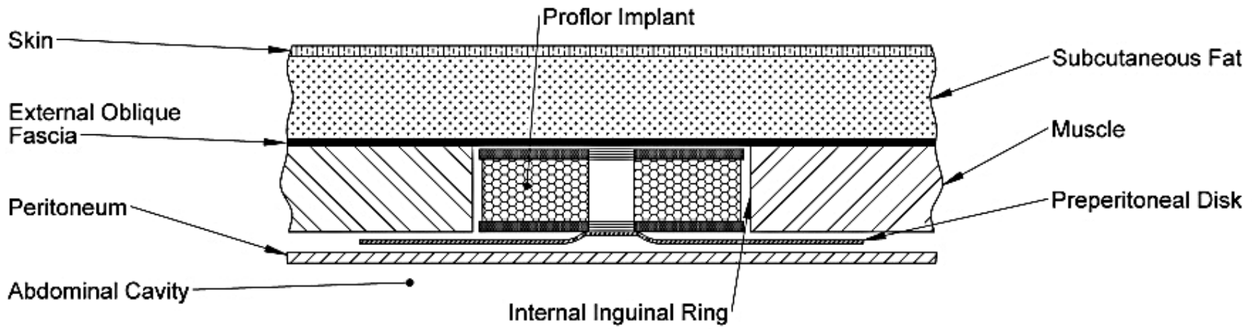
Surgical View of Placement with Spermatic Cord



Direct



Indirect



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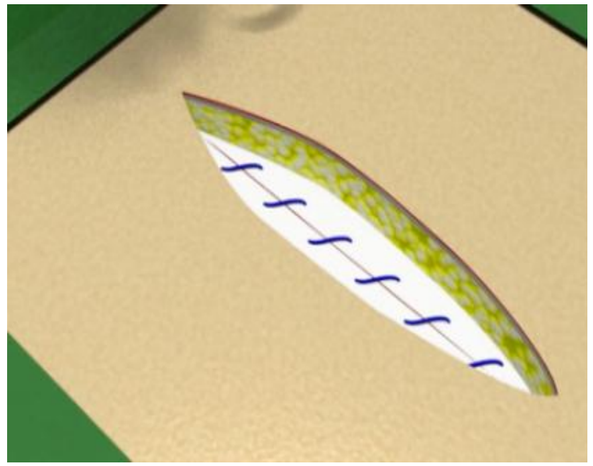
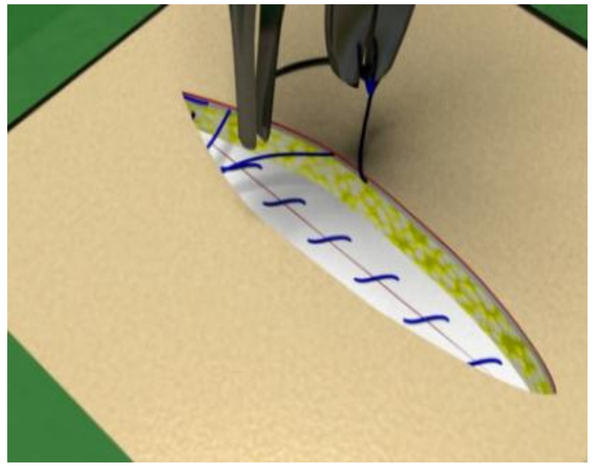
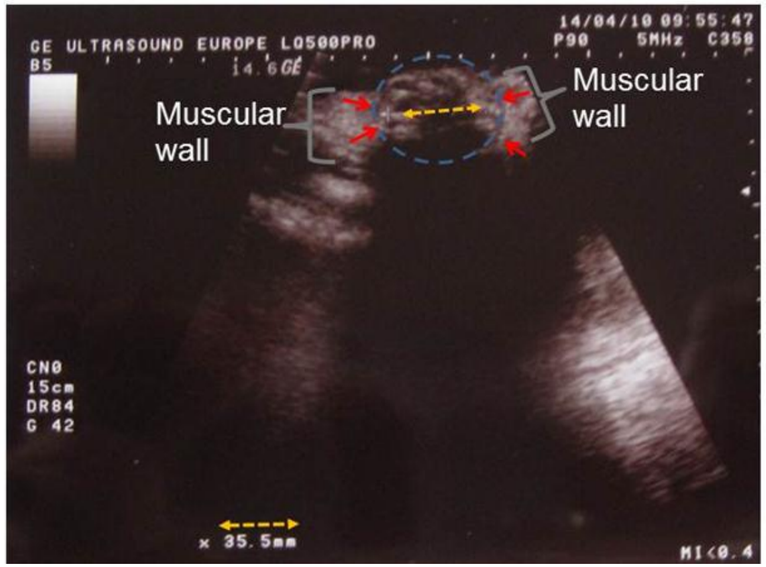
16) Closure of external oblique and subcutaneous layer. Skin closure to be subdermal. Avoidance of wound drains.





17) This exemplary image shows the aspect of a well positioned Freedom Inguinal implant obliterating the hernia defect. The implant is slightly compressed within the hernia frame, thus its lateral edges fully obliterate the hernia defect. An even horizontal reflection of the implant features indicates positioning in the proper tissue plane. An uneven view or shadowing by muscle may indicate that the implant is not in the plane of the defect and possibly dislocated. The position of the implant above or beyond the hernia opening indicates incorrect placement and can be source of recurrence.

Ultrasound image of Freedom Inguinal Hernia Implant



Hernia opening obliterated (blue dotted circle). Groin muscles grip & compress the implant (red arrows). Initial diameter of the implant (40mm) is compressed to 35.5mm.

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Clinical Results

Two investigator sponsored studies were performed by Prof. G. Amato in Palermo, Italy and Doctors G. Petrella and D. Venditti in Rome, Italy. These clinical studies followed cohorts of patients (total n=54) that met the following inclusion/exclusion criteria:

Inclusion Criteria:	Exclusion Criteria:
• Scheduled to undergo routine inguinal hernia repair • Competent to give consent • Clinically relevant inguinal hernia (classification: NYHUS I, II, IIIa, IIIb) • Male or female • Over 18 years old to 85 years old • Life expectancy of at least 12-months • Diagnosed with direct, indirect or mixed inguinal hernia, unilateral or bilateral • Primary or recurrent hernia	• Signs of obvious local or systemic infection • Hernia was not in the inguinal area • Presenting with unstable angina or NYHA class of IV • Pregnant • Active drug user • Immunosuppression, prednisone>15 mg/day, active chemotherapy • End stage renal disease • Abdominal ascites • Skin infection in area of surgical field • BMI > 35
Both Studies used the Following objectives	
Primary Efficacy Objectives	**Secondary Complications Objectives**
• Procedural success is defined as the ability to successfully deploy the implant into the inguinal hernia defect • Freedom from hernia recurrence at the time points of 1, 6, 12, 24, 36 months	• Collection of data on any perioperative/postoperative complications (1, 6, 12, 24, 36 months) • Bleeding, swelling or hematoma from hernia defect dilation or improper delivery or implantation technique • Seroma, infection/abscess, testicular or spermatic cord injury in males, wound complications, symptomatic pain or chronic pain syndrome.

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Clinical Results

Amato Study	Prospective study of a single operator case series of a modified plug technique and new 3D hernia implant
Number of centers/investigators	1 center/ 1 investigators
Study Enrollment Period	June 2009 to August 2011
Number of patients	30
Number of implants*	25mm: n=12 40mm: n=22 *Four cases were double unilateral hernias
Patient demographics	Male = 30/Female = 0 BMI (Kg/m2) = 28.4 (21,7 – 34,9) Age = 50.23 mean, range 23-82 Hernia types: Indirect=17, Direct=13 Hernia size: Mean 32 mm (range 20 – 37,7) Hernia type: NYHUS Type 1 = 5 NYHUS Type 2 = 13 NYHUS Type 3a = 12 NYHUS Type 3b = 4
Operative procedure specifics	Anesthesia: Local = 63% Spinal = 17% General = 20% Procedure duration: Mean 29 minutes (range 22 – 38) Defect measurement: Intra operative measurement of the dissected flaccid defect using surgical scale for implant sizing
Patient Follow up Outcomes/adverse events	Follow up: Mean = 25.23 months (range 11.0 - 36.5) Outcomes/Adverse: no long term complications or recurrences at this time
Additional Outcomes – Two patients in this cohort received onlay mesh patches	In two exceptional cases, an additional flat polypropylene mesh was deployed to cover the inguinal floor, over the Freedom Inguinal implant that obliterated the hernia opening. This further reinforced the inguinal canal at the hernial protrusion when the groin structures appeared obviously weak. Patient #1 – Male, 82 yrs, Double unilateral hernia – Rt Indirect, Rt Direct, 25mm and 40mm implants used, Nyhus 2 & 3a. BMI: 29. Comorbidities: Myocardial ischemic disease, hypertension. Non recurrent hernias. Follow up = 18.2 mos. Patient #2 – Male, 75 yrs, Lf Mixed hernia, 40mm implant, Nyhus 3b. BMI: 26. Comorbidities: BPCO, myocardial insufficiency, hypertension. Non recurrent hernia. Follow up = 18.2 Results of these two procedures to date have had no complications or unusual symptoms. Patient #1 reported occasional discomfort during the early postoperative stage but self resolved after 5 months post op.
Ultrasound findings in cohort of patients	Full and stable obliteration of twelve patients examined at 3, 6 and 12 months.

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Clinical Results

Petrella/Venditti Study	Prospective single arm study of the ProFlor Inguinal hernia Device
Number of centers/investigators	1 center/ 2 investigators
Study Enrollment Period	Dec 2011 to present
Number of patients	24 enrolled; Target enrollment = 80
Number of implants	25mm: n=5 40mm: n=19
Patient demographics	Male = 22/Female = 2 BMI (Kg/m^2) = 25.2 (19,4 – 35,2) Age = 52.3 mean, range (31 – 73) Hernia types: Indirect=20, Direct=4 Hernia size: 15mm<Hernia size>40mm NYHUS Type 2 = 20 NYHUS Type 3a = 4
Operative procedure specifics	Local anesthesia Procedure duration: 24 min mean, (20-30) Defect measurement: Intra operative measurement of the dissected flaccid defect using surgical scale for implant sizing
Patient Follow up Outcomes/adverse events	Follow up: Mean = 4.5 months (range 3.0 – 6.0) Outcomes/Adverse: None observed
Ultrasound findings in cohort of patients	Ultrasound scans were not a requirement of the study and were not performed for this cohort

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Surgeon Training

Insightra Medical provides multiple training resources for the Freedom Inguinal Hernia Repair System.

- **Training Centers -** Our surgical training programs are conducted around the world and have welcomed world renowned hernia surgeons to a hands on, multiple day program that includes the entire Freedom Hernia product line.
- **Surgeon Collaboration and Proctoring –** Other surgeons are willing to share their knowledge and experience of the Insightra Medical Freedom Hernia Products.
- **Inservice Training –** Insightra Medical authorized representatives are available for in house training and product support during initial cases.
- **Support Materials –** Clinical videos and product animations are available for viewing on the Insightra Medical website at www.insightra.com

Contact your local Insightra Medical representative or visit our website at www.insightra.com for further details and information

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