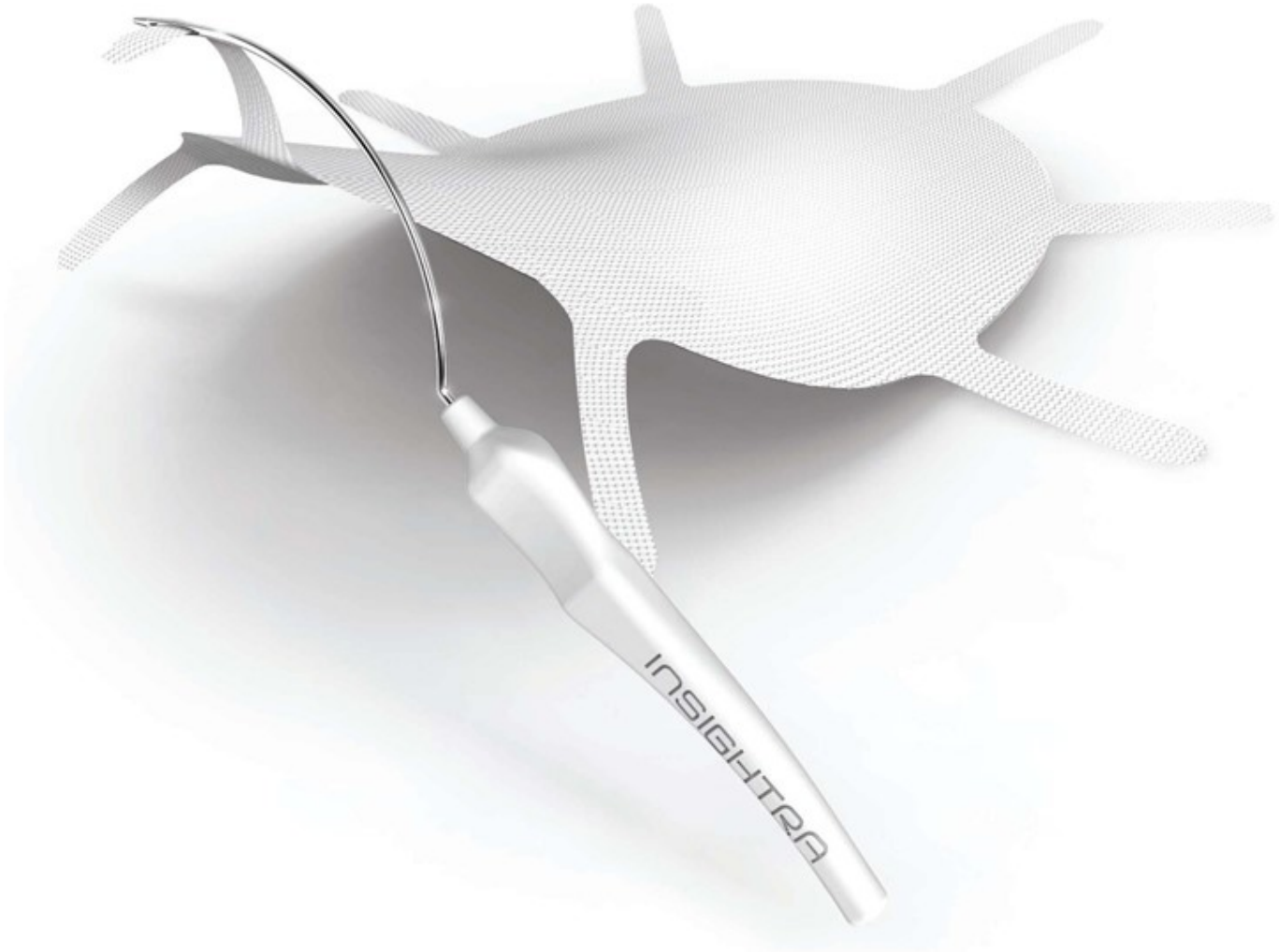
FREEDOM - OCTOMESH

Ventral Hernia Repair System



TECHNIQUE GUIDE

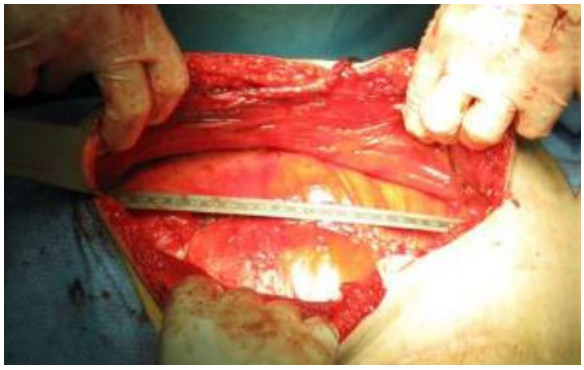
INSIGHTRA® MEDICAL

The following describes the open surgical implantation technique for the Freedom Ventral Hernia Repair System.

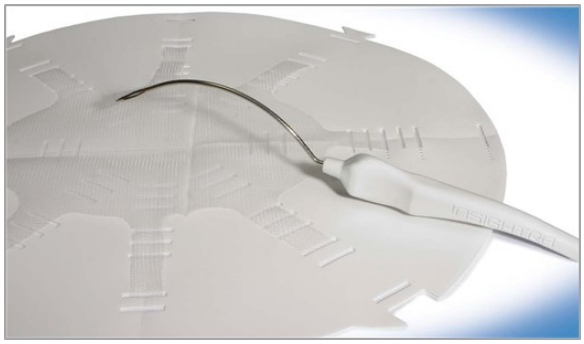
Note: The surgeon must determine the appropriateness of use based on their experience and the individual patient condition and circumstances.

Note: The initial site preparation is typical of open ventral hernia mesh repair with preperitoneal mesh placement or retromuscular sublay technique which the surgeon must be familiar.

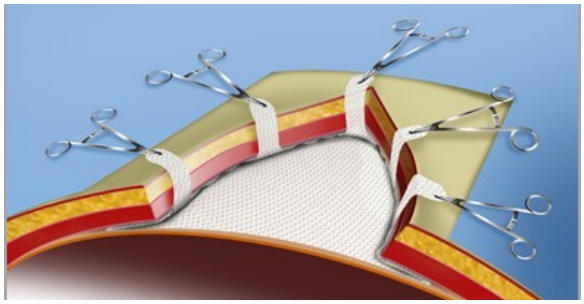
1) Prepare the implantation site for preperitoneal sublay or retromuscular placement per the Instructions for Use provided with the product adhering to all Warnings, Cautions and Notes.
2) The incision utilized in preparation for implanting is standard for conventional, open ventral hernia repair methods, centered over the defect.
3) The width of the dissected preperitoneal/retromuscular space must be measured with a sterile ruler in order to choose the right size of the implant.



4) Select the correct size of implant corresponding to the size of the ventral/incisional hernia. **A 5 cm minimum overlap** of the hernia defect is recommended to ensure a broader overlap from hernia edges and tension free implant placement.
5) Open the sterile packaging and transfer the tray to the sterile field using conventional/ standard aseptic sterile technique.
6) On the sterile field, remove and discard the tray lid. Unfold and carefully remove the implant from its carrier. Remove each strap individually. Do not attempt to pull the implant straps simultaneously or strap damage may occur. Inspect the implant to ensure it is not damaged.

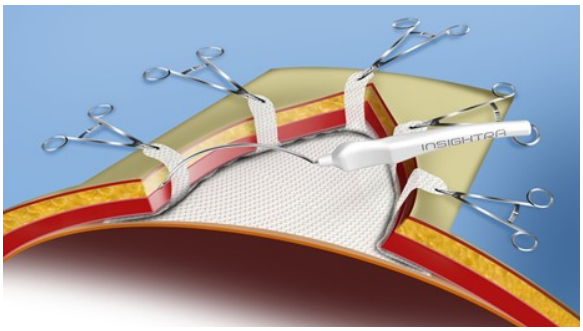


7) Remove the strap passer from the kit tray. The Freedom hernia implants should only be inserted using the strap passer provided.
8) Place the mesh body into the hernia defect above the peritoneum. Care should be taken to ensure that any holes in the peritoneum have been closed. Clamps should be used to keep the anchoring straps exposed and organized.

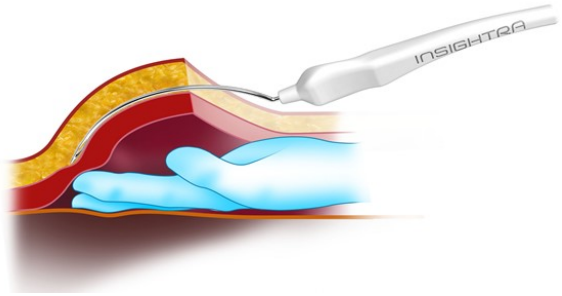


9) Using the strap passer, penetrate the subcutaneous layer just anterior to the abdominal fascial plane and below the fat, starting at the desired strap exit point. Countertraction of the fascia using grasping forceps will facilitate passer penetration.

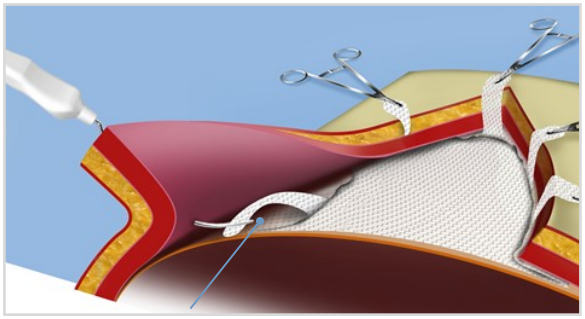
   Passer entry can be transcutaneous (through a small skin incision <3 mm) or subcutaneous at the discretion of the surgeon. In case the passer is being inserted in the subcutaneous layer, it should be tunneled above the fascia until the lateral abdominal muscle layer (external + internal oblique and transverse muscles) is reached. In both cases the passer must traverse the lateral abdominal wall musculature to ensure adequate tissue friction.



10) As the passer is tunneled, the passer tip should be felt by the surgeon through the posterior wall of the abdominal structures and guided to the point of perforation.

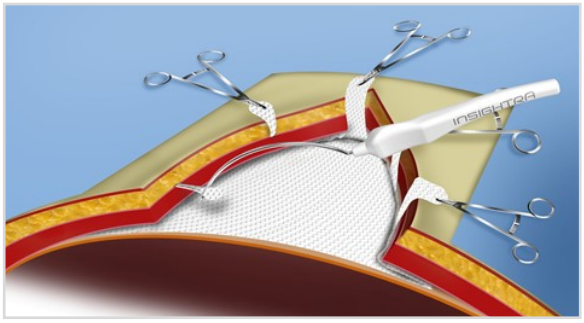


11) When the lateral extremity is reached, the passer should be tunneled gently through the muscles towards the posterior aspect of the abdominal wall, using finger guidance.
12) Once through the posterior aspect of the abdominal wall, the passer tip should be turned and pointed toward the operator so that the strap can be inserted under direct visualization.

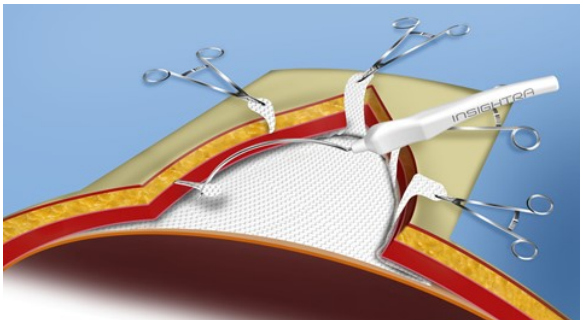


Note: Do not thread more than 1.5cm of strap through the passer eyelet for proper retrieval through the tissues.

13) The passer should be gently pulled back through the tunnel using one continuous motion, carefully dragging the mesh strap into the tunnel where it will grip through friction.
14) When the passer tip is free of the tissue, the passer should be carefully pulled away from the strap; releasing it.



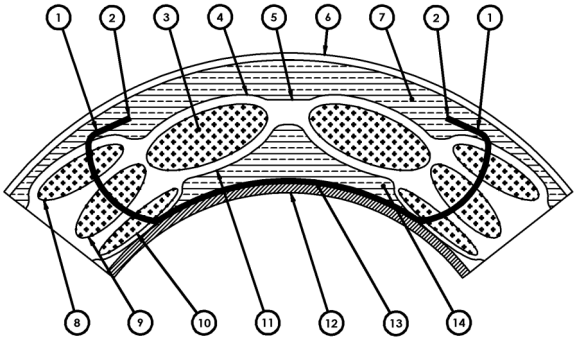
15) The tip of the strap should be grabbed with forceps and gently pulled until the body of the mesh contacts the underside of the abdominal wall. Tension will be felt on the strap. Care should be taken to ensure the body of the mesh remains relatively flat, without tension or folds.
16) Clamps should remain on all straps after they have been tunneled.
17) Closure of the fascia and muscle with suture technique at surgeon's discretion.
18) After closure of the fascia, all 8 mesh straps are tensioned again for final centering of the implant body and then trimmed flush at the exit points of the subcutaneous tissue using scissors. The edge of the trimmed strap should lie in the subcutaneous layer at the tunnel entry point, below the level of the skin. The trimmed straps will relax to a tension free state but provide adequate friction to fixate the mesh body.



19) Placement of drains is at the discretion of the surgeon.
20) The subcutaneous layer should be sutured and the skin closed by standard surgical technique.
21) Post operative care and recovery should use standard of care practices for conventional open ventral hernia repair methods.

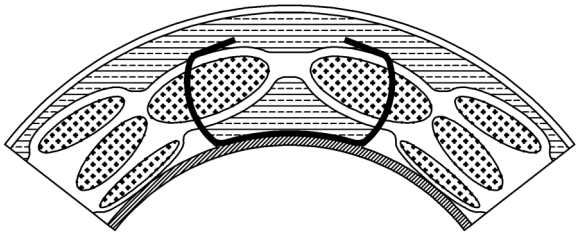
Additional placement information for various hernia types

1) The diagrams below illustrate the placement of the implant body and mesh straps based on implant size. Also shown is the implant position relative to preperitoneal versus retromuscular sublay techniques.

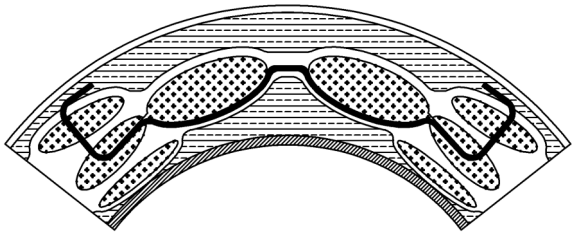


Large Implant Placed in preperitoneal sublay

1	Strap	**8**	External Oblique
2	Trimmed Strap	9	Internal Oblique
3	Rectus Muscle	10	Transverse Muscle
4	Anterior Rectus Fascia	11	Posterior Rectus Fascia
5	Linea Alba	12	Peritoneum
6	Skin	13	Body of Mesh
7	Subcutaneous Fat	14	Preperitoneal Fat

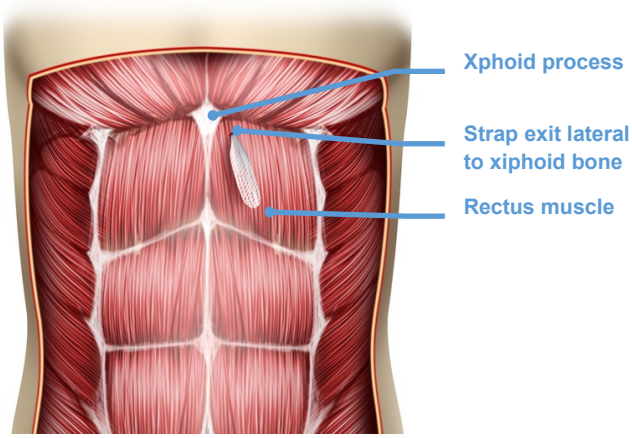


Small implant placed in preperitoneal sublay

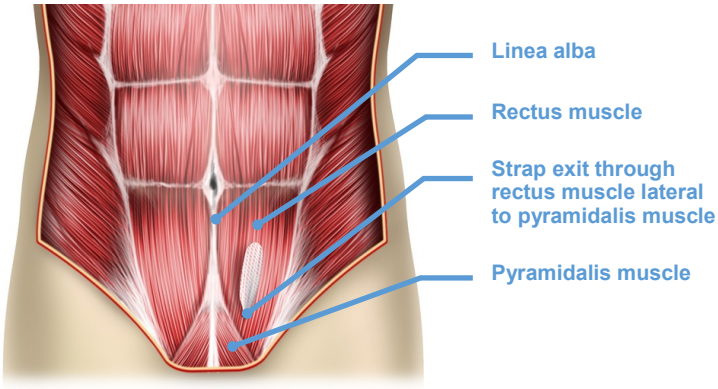


Implant placed in retromuscular sublay

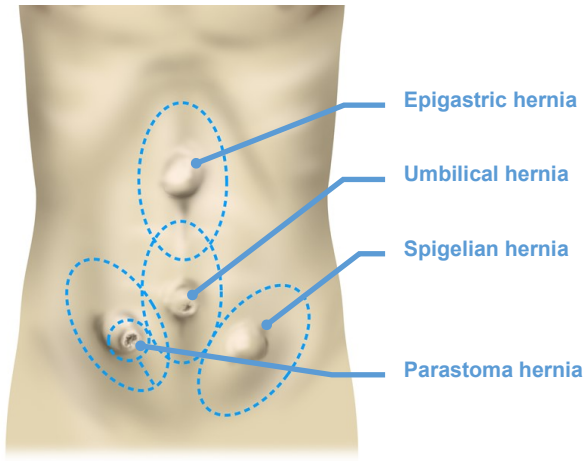
2) High abdominal wall placement such as Epigastric hernia where the preperitoneal mesh placement is at or under the xiphoid process, the upper strap is tunneled across the rectus muscle and its sheaths, lateral to the xiphoid bone.



3) Low abdominal wall placement such as Spigelian hernia where the preperitoneal mesh placement is close and above the pubic bone, the lowest strap must be delivered lateral to the pyramidalis muscle across the lowest fibers of the rectus and its sheaths. The implant is placed extraperitoneally in either a sublay, retrorectus or preperitoneal position, deep to the rectus abdominis muscle, above, across or below the arcuate line. The surgeon must determine the appropriateness of use based on their experience and the individual patient condition and circumstances which includes proximity of incisions known to be associated with muscle atrophy and incision position and is consistent with their clinical practice.



4) Anterior views of mesh placement for umbilical, epigastric, parastomal and Spigelian hernias



Follow Up Examination

Strap incorporation has been studied in the porcine model showing individual strap tensile strengths exceeding 3.0 Kg at four weeks. These results are in line with the return to work recommendations reported by Forbes (1) and Olmi (2) of 4-6 weeks. Consideration must be given to the patient's occupation and pain experience. If there are concerns for mesh migration, recurrence or new hernia, high resolution CT is a useful modality for follow up.

Animal Testing and Clinical Experience with Freedom Ventral Hernia Octomesh™ Repair System

Animal Testing

The ventral hernia repair mesh with eight radiating straps was evaluated in a porcine model using a preperitoneal sublay technique. The study objectives were to evaluate mesh placement stability and strap incorporation into the surrounding tissue. The implant device was marked at each strap using titanium Ligaclips® so that their position could be followed by x ray. Strap incorporation was evaluated by physical tensile testing of straps and histological studies of the strap-tissue interface. Data was collected at 2, 4 and 8 weeks.

Multiple straps from each animal were tensile tested. Individual strap tensile force values exceeded 3.0 Kg at four weeks. Histological samples were harvested from the transabdominal strap sites. At two weeks the mesh straps and body mesh were fully integrated by a reactive fibrous response and inflammation. The instrument track created during the procedure was completely filled by the organizing fibrous response to the mesh strap. By four and eight weeks the system demonstrated a marked degree of mature fibrosis integrated throughout the mesh straps and implant body. The porcine animal model demonstrated a normal healing response and normal incorporation of the mesh straps and body mesh. The study concluded no mesh migration and demonstrated signs of early incorporation with substantial anchoring forces to stabilize the mesh.

Additional bench testing of the implant using pig abdominal wall was performed to simulate implant stability immediately post op. A one square inch through and through defect of the wall was created. After strap passage, a 9.74 lbf load was placed on the mesh over the defect. This represented 2x the worst case intraabdominal pressure measured during jumping of 252 mmHg reported by Cobb (3). Despite this load placed over unsupported mesh, the straps did not move. Evidence from these animal studies show that the straps, used in this manner, provided an equivalent method of securing the mesh to the implantation site as compared to using sutures, staples, or tissue anchors for mesh attachment to the muscle tissue.

Clinical Experience

Study 1

The Insightra Freedom Ventral Hernia Repair underwent evaluation in the clinical setting from November 2008 to November 2012. Results of these investigator lead studies are reported herein from multiple centers and countries. Clinical evaluation of this device in the initial 22 patients of this group was also reported by Amato, et. al (4).

Participants: The following investigator sponsored evaluation studies of the Freedom Ventral Hernia Repair are reported.

Prof. G. Amato - Palermo, Italy (n=13)
Drs. P. Aulakh, B. Bhalla, P. Jain – Punjab, India (n=3)
Dr. D. Jindel – Jaipur, India (n=20)
Prof. V. Paolucci - Offenbach, Germany (n=19)
Dr. S. Singh - Chandigarh, India (n=2)
Dr. D. Venditti - Rome, Italy (n=3)
Dr. S. Venkatraman – Chennai, India (n=5)

Design: A total of 65 patients were implanted with the Freedom Ventral Hernia Repair device. These clinical studies followed cohorts of sequential patients at each institution that met the following inclusion/exclusion criteria:

Inclusion Criteria:

- Scheduled to undergo routine ventral hernia repair
- Competent to give consent
- Clinically relevant ventral hernia (Incisional hernia: location- median, lateral, upper abdomen, lower abdomen; Ventral hernia: type- epigastric, umbilical, stomal, spigelian
- Male or female
- Over 18 years old to 80 years old
- Life expectancy of at least 12-months
- Diagnosed with primary ventral or incisional hernia

Exclusion Criteria:

- Signs of obvious local or systemic infection
- Hernia is not in the abdominal wall area
- Hernia not identified as incisional or ventral, abdominal wall hernia
- 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

The studies used the following objectives:

Primary Efficacy Objectives:

- Ability to successfully deploy the implant into the abdominal hernia defect by a modified RIVES technique in sublay preperitoneal or retromuscular
- Time of placing the arms of the implant starting from closure of the peritoneum to the closure of the fascia.
- Ultrasound follow up with evidence of the straps inserted in the abdominal wall structures as an indication of mesh displacement, beside the presence of other pathological evidences, such as seroma
- Freedom from hernia recurrence at the designated time points of (1, 2, 6, 12, 18, 24, 36 months)

Secondary Complications Objectives :

- Collection of data on any peri-operative/postoperative complications;
    - Bleeding, seroma, infection / abscess, hematoma, wound complications, wound dehiscence, chronic pain syndrome, discomfort from the mesh body or straps.

Patient cohort and results are described in the following table:

Study	Post market evaluation of the Freedom™ Ventral Hernia Repair Device
Number of centers/ investigators	9 centers/9 investigators
Study Enrollment Period	November 2008 to November 2012
Number of patients enrolled	N= 65
Number of implants per mesh size	XS: n=10 S: n=23 M: n=23 L: n=6 XL: n=3

Patient demographics	• Male =31/Female = 34
	• BMI (Kg/m2) = Mean 28.82 (range 16-40 Kg/m2)
	• Age = Mean 51.78 years, (range 26 – 84)
	• Hernia types*: Incisional=42, Umbilical=11, Epigastric= 6, Ventral= 10, Stomal= 2
	*Some mixed
	• Hernia size: Mean 9.75 x 12.07 cm (range 3 x 4cm – 15.2 x 25.4cm)
	• Recurrent hernia: n=15
	• Comorbidities:
	  • Diabetes: n=8
	  • Hypertension: n=8
	  • Divarication recti: n=1
	  • Myocardial Ischemic disease: n=4
	  • Ischemic cardiomyopathy: n=4
	  • BPCO: n=1
	  • Aortic stenosis: n=1

Operative procedure specifics	• Anesthesia: General = 92%, Regional = 8% • Procedure duration: Mean 75.74 minutes (range 35 -180) • Defect measurement: Intra operative measurement of the dissected space using surgical ruler for implant sizing; 5 cm margin coverage goal • Strap Tunneling: Passer entry at subcutaneous fat level along midline incision; transmuscular penetration at measured margin borders, trimmed strap lengths at subcutaneous exit point after final cinching • Note: This procedure and implant was not used for bridging repair in this cohort. No experience for this type of repair using this product has been reported

Patient Follow up Outcomes/Adverse events	• Initial Follow up: Mean 15.91 months (n=65, range 1 – 43)
	• Months 1-10; n=36
	• Months 11-20; n=8
	• Months 21-30; n= 6
	• Months 31-40; n= 12
	• Months >40; n=3
	Complications
	• Early complications
	  • Seroma: n=4
	  • Wound dehicence: n=1
	  • Infection/abscess: n=1
	• Late complications – None
	• Recurrences or reoperations – None
	• Supplemental Follow up (N=41); Mean 36 months (range 12-72)
	  • Recurrences: None
	  • Reoperatons: None
	  • Infections: None
	  • Complications due to surgery: None
	  • Pain: Mean = 0.12 Range 0-5;
	  • 0= No Pain; n=37
	  • 1= Very Little; n=3
	  • 2= Some pain; n=1
	  • 3=Medium painful; n=0
	  • 4=Very painful; n=0
	  • 5=Extreme pain; n=0

Ultrasound findings - 20 patients consented to ultrasound examination at 1, 3 and 12 months	All mesh implants were confirmed to be properly positioned and all straps in their correct anatomical space not having moved from their original location.
CT scan findings – patient scans were reviewed for mesh placement, strap dislodgements, strap hernia and recurrence	• Patients scanned: n = 25 • Follow up: Mean 10.67 months (range 0.75- 46) • Mesh migration: n = 0 • Strap dislodgements: n = 0 • Strap microhernia formation: n = 1* • Hernia recurrences: n = 1** *Clinically insignificant ** Asymptomatic, formed under mesh repair

Procedure: Each implant size was chosen after measuring the space prepared for mesh placement. The standard 5 cm overlap margin objectivewas usedThe devices were implanted in a preperitoneal sublay or retromuscular sublay using open repair while passing the straps through the abdominal muscle. After dissection and prior to placement it was required that the peritoneum was fully closed and intact. After passage, the straps were trimmed below the skin. There was a routine use of drains as standard of care for abdominal wall surgery. Drains were generally removed after 48 hours with a few cases requiring 4-5 days. Local or systemic infection or skin infection near the surgical site was an exclusion criteria and was strictly adhered to. Any infection near the surgical site was resolved prior to hernia surgery. Since the straps are tunneled just anterior to the muscle fascia, the straps are well below the dermis under the subcutaneous fat. Due to this technique, the straps did not affect even low BMI patients in any way and there was no concern for the use of this device in these patients. No patients complained of any discomfort from the straps. Procedure duration had a mean of 75.74 minutes with the shortest operation taking only 35 minutes.

Discussion: A subset of patients (n=20) consented to ultrasound examination follow up at 1, 3 and 12 months. This was not a required follow up for these studies. The Freedom Ventral Hernia implant is a polypropylene mesh which is hyperechoic with ultrasound. The strap locations and implant edges can be readily identified with ultrasound which provides a positional mapping of the implant. At each of the one month ultrasound examinations, all eight straps were identified and verified that there were no notable shifts of the implant or strap dislodgements. No further changes were found in the subsequent 3 and 12 months exams. These ultrasound scans provided further evidence that the strap fixation stabilized the implant until tissue incorporation occurred. One limitation of ultrasound for this patient cohort is the inability to examine the strap passage sights for the presence of parastrap microhernias. The strap material can cast an ultrasonic shadow causing an anechoic region that precludes examination of tissue behind the strap.

A different subset of patients (n=25) consented to computed tomography (CT) examination. A high resolution (2mm slice minimum), inspiration, and no contrast protocol was used to obtain post implant scans. These scans were obtained at a mean of 10.67 follow up months (range .75-46) to gain a broad span of data points. The primary purpose was to examine for the presence of parastrap microhernias that could possibly form due to the straps penetrating the fascia and muscle tissue. Secondarily, the scans were examined for strap dislodgements, mesh migration and recurrences. Polypropylene is radiolucent therefore the scans were analyzed for the scarring and fibrosis caused by the straps and mesh. Once those artifacts were located, the surrounding tissue could be inspected. Not all straps could be identified due to interfering surgical artifacts which is a limitation of CT. Of the 175 identified straps, one 2mm microhernia defect was found which represented a 0.57% rate of occurrence. The patient was asymptomatic and defect was deemed clinically insignificant by two certified radiologists. One patient was found to have a new hernia, lateral to and not related to the previous repair. One recurrent hernia was identified under the midline mesh repair. The patient was asymptomatic and the mesh repair was serving its intended purpose.

Results: There were no reports of chronic pain or recurrence of the hernia in this cohort of 65 patients, indicating that the straps successfully stabilized the implant body in place until it was incorporated by the tissue. As evidenced by the ultrasound examinations, the implant and anchoring straps remained stable at one month. These results are in line with the return to work recommendations reported by Forbes (3) and Olmi (4) of 4-6 weeks. Consideration must be given to the patient's occupation and pain experience. The CT scans confirmed the straps did not introduce any unreasonable risk of new microhernia. If there are concerns for mesh migration, recurrence or new hernia, high resolution CT is a useful modality for follow up. Complications reported during the follow up period were wound infections (n = 1[1.5%]) and seroma (n = 3 [4.6%]). All complications reported were resolved successfully and did not require mesh removal. There were no reports of patient discomfort with the straps placed in the subcutaneous space.

A secondary follow up was conducted focusing on the collection of long term results in terms of recurrences, reoperations, infections, complications and chronic pain. Data were collected from forty one (41) of the sixty five (65) patients. The mean follow up was 36 months (range 12-72). There were no recurrences or complications reported and only one patient with some pain during coughing. The rest reported very little (n=3) or no pain (n=37).

Conclusions: The Freedom Ventral Hernia repair was an effective repair in terms of recurrence, acute and chronic pain. It is a time efficient repair system that enables broad margin coverage in the preperitoneal sublay and retromuscular sublay position.

Study 2

The Insightra Freedom Ventral Hernia Repair underwent a second study in the clinical setting from December 2013 to May 2014. Results of these investigator lead studies are reported herein from multiple centers.

Participants: The following investigator sponsored evaluation studies of the Freedom Ventral Hernia Repair are reported.

Dr. Ashwin Porwal – Sharada Cliinic, Pune, India (n=30)

Dr. Pradeep Kumar Jadhav – Healing Hands Clinic, Pune, India (n=25)

Design: A total of 55 patients were implanted with the Freedom Ventral Hernia Repair device and 51 reported on. These clinical studies followed cohorts of sequential patients at each institution that met the following inclusion/exclusion criteria:

Inclusion Criteria:

- Scheduled to undergo routine ventral hernia repair
- Competent to give consent
- Clinically relevant ventral hernia (Incisional hernia: location- median, lateral, upper abdomen, lower abdomen; Ventral hernia: type- epigastric, umbilical, stomal, spigelian
- Male or female
- Over 18 years old to 80 years old
- Life expectancy of at least 12-months
- Diagnosed with primary ventral or incisional hernia
- Diagnosed with recurrent abdominal wall hernia

Exclusion Criteria:

- Signs of obvious local or systemic infection
- Hernia is not in the abdominal wall area
- Hernia not identified as incisional or ventral, abdominal wall hernia
- 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
- Peritoneum cannot be closed
- Requires concurrent abdominoplasty

The studies used the following objectives:

Primary Efficacy Objectives

- Evaluate the implant mesh for clinically significant migration greater than 5 cm.
- Determine if there are new strap hernia formations after ventral hernia

Secondary Complications Objectives

- Collection of data on any peri-operative/postoperative complications and adverse events;
  - Bleeding, seroma, infection / abscess, hematoma, wound complications, wound dehiscence, chronic pain syndrome, discomfort from the mesh body or straps

Patient cohort and results are described in the following table:

Study	**Post market evaluation of the Freedom™ Ventral Hernia Repair Device**
Number of centers/ investigators	2 centers/2 investigators
Study Enrollment Period	December 2013 to May 2014
Number of patients enrolled	N= 55; 4 lost to follow up
Number of implants	XS: n=39 S: n=9 M: n=3 L: n=0 XL: n=0

Patient demographics	• Male =19/Female = 32
	• BMI (Kg/m2): Mean = 25.4 (range 19-31.2 Kg/ m2)
	• Age: Mean = 46.3 years, (range 25-64)
	• Hernia types: Incisional=11, Umbilical=34, Epigastric= 2 Spigelian=1, Mixed=3
	• Hernia size: Mean 6.0 cm x 6.3 cm (range 3-10 cm x 3-10 cm)
	• Recurrent hernia: n=4
	• Comorbidities:
	  • Diabetes: n=8
	  • Hypertension: n=4
	  • Smoking: n=1

Operative procedure specifics	• Anesthesia: General = 0%, Regional = 100% • Procedure duration: Mean = 106 minutes (range 40-140 min) • Defect measurement: Intra operative measurement of the dissected space using surgical ruler for implant sizing; 5cm margin coverage goal • Ligaclips® installed at each strap location on the mesh body for x ray monitoring of mesh migration during healing period of two months • Implant preperitoneal sublay placement • Strap Tunneling: Passer entry at subcutaneous fat level along midline incision; transmuscular penetration at measured margin borders, trimmed strap lengths at subcutaneous exit point after final cinching • Note: This procedure and implant was not used for bridging repair in this cohort. No experience for this type of repair using this product has been reported
Patient Follow up Outcomes/Adverse events Follow up x rays at one and two months were compared to post op x ray High resolution CT scans at two months were performed with Valsalva maneuver and oral contrast	• Patients enrolled = 55 • Patients followed = 51; 4 lost to follow up • Month 1 X ray: No migration • Month 2 X ray: No migration • Month 2 CT scan: Two recurrences, one new hernia; one 3mm defect identified at instrument site along linea alba* but no hernia formation * Strap passage through linea alba is contraindicated Complications • Seroma: n=4 (8%) • Infection/abscess: n=2 (4%) • Pain: None • Recurrences: n=2 (4%)

Procedure: Each implant size was chosen after measuring the space prepared for mesh placement. The sizing guideline objective was to achieve at least a 5 cm margin beyond the defect. Each implant was prepared with Ligaclips® positioned at the implant border adjacent to each strap for future x ray monitoring. Any mesh migration would be assessed by movement of these clips with respect to the postoperative x ray. The devices were implanted in a preperitoneal sublay using open repair while passing the straps through the abdominal muscle. After dissection and prior to placement it was required that the peritoneum was fully closed and intact. After passage, the straps were trimmed at the midline incision, below the skin. There was a routine use of drains as standard of care for abdominal wall surgery. Local or systemic infection or skin infection near the surgical site was an exclusion criteria and was strictly adhered to. Since the straps are tunneled just anterior to the muscle fascia, the straps are well below the dermis under the subcutaneous fat. Due to this technique, the straps did not affect even low BMI patients in any way and there was no concern for the use of this device in these patients. No patients complained of any discomfort from the straps. Procedure duration had a mean of 106 minutes with the shortest operation taking 40 minutes.

Discussion: All patients consented to computed tomography (CT) examination at the two month follow up. A high resolution (2mm slice minimum), Valsalva maneuver, oral contrast protocol was used to obtain post implant scans. The primary purpose was to examine for the presence of parastrap microhernias that could possibly form due to the straps penetrating the fascia and muscle tissue. Secondarily, the scans were examined for strap dislodgements, mesh migration and recurrences. Polypropylene is radiolucent therefore the scans were analyzed for the scarring and fibrosis caused by the straps and mesh. Once those artifacts along with the radiopaque clips were located, the surrounding tissue could be inspected.

Results: X rays from post op, one month and two months were compared for mesh migration. A limit of 5 cm was established since that is the widely recommended margin coverage based on the literature. Loss of this overlap margin could therefore introduce risk of recurrence. Five patients had one strap with a shift of less than 1.5 cm from post op baseline to one month. However no patients had any mesh migration or strap movement approaching the 5 cm limit. One month to two month comparison showed only one strap of all patients had shifted 1 cm. Final mesh positioning as indicated by the clips collectively showed the implants to be properly placed and stable. These results are in line with the return to work recommendations reported by Forbes (1) and Olmi (2) of 4-6 weeks. Consideration must be given to the patient's occupation and pain experience.

All but two of the 408 straps in this study were identified on CT. Of the identified straps, one defect of approximately 3mm was identified at the strap passer site which had penetrated the linea alba. There was no adipose tissue, abdominal organs or peritoneum involved in or around the area of the defect. This represented an occurrence rate of 2%. The patient was asymptomatic and defect was deemed clinically insignificant by two certified radiologists. Strap passage through the linea alba or xiphoid is not recommended and should be placed laterally in the rectus muscle as shown in this guide. One patient was found to have a recurrence of a difficult lateral hernia repair and one patient had a recurrence that was concurrent with a large mesh abscess. This represented a recurrence rate of 4%. The CT scans confirmed the straps did not introduce any unreasonable risk of new microhernia. If there are concerns for mesh migration, recurrence or new hernia, high resolution CT is a useful modality for follow up. Complications reported during the follow up period were wound infections (n =2 (4%)) and seroma (n =4 (8%)). There were no reports of patient discomfort with the straps placed in the subcutaneous space.

Conclusions: The Freedom Ventral Hernia repair was an effective repair in terms of recurrence, migration and acute pain. It is a time efficient repair system that enables broad margin coverage in the preperitoneal sublay and retromuscular sublay position.

References

1) Forbes J, Fry N, Hwang H, Karimuddin A, Timing of return to work after hernia repair: Recommendations based on a literature review, www.bcmj.org , Vol. 54 No. 7, September 2012

2) Olmi S., Scaini A., Cesana G., Erba L., Croce E., Laparoscopic versus open incisional hernia repair-An open randomized controlled study, Surg. Endosc (2007) 21:555-559

3) Cobb W, Kercher K, Heniford T. The argument for lightweight polypropylene mesh in hernia repair. Surgical Innovation, Vol 12, No 1 (March), 2005: pp 63-69

4) Amato G, Romano G, Goetze T, Salamone G, Agrusa A, Gulotta G, Paolucci V, New mesh shape and improved implantation procedure to simplify and standardize open ventral hernia repair: a preliminary report, Hernia, 2011 Dec; 15(6): 659-65. Epub 2011 Jul 8.

For Surgeons and their Patients - Warnings & Cautions for the use of Polypropylene Implants:

The Insightra Medical Freedom Ventral Octomesh implant is a long term - permanent polypropylene implant. When patients are considering hernia surgery with such implants they should carefully consider the positive and negative aspects of such implants. Please read this advice from the FDA and consult fully with your patient.

Please follow this link to the FDA

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm142636.htm#hernia

Information from FDA on Surgical Mesh for Hernia Repairs

FDA wants to inform you about complications that may occur with the surgical mesh that is sometimes used to repair hernias, and to provide you with questions you may want to ask your surgeon before having this procedure. This is part of our commitment to keep the public informed about the medical products we regulate.

Hundreds of thousands of hernia repair operations are performed each year both with and without surgical mesh, and patients generally recover quickly and do well after surgery.

However, FDA has received reports of complications associated with the mesh. The complications include adverse reactions to the mesh, adhesions (when the loops of the intestines adhere to each other or the mesh), and injuries to nearby organs, nerves or blood vessels. Other complications of hernia repair can occur with or without the mesh, including infection, chronic pain and hernia recurrence.

Most of the complications reported to us so far have been associated with mesh products that have been recalled and are no longer on the market. For further information on the recalled products, please visit the FDA Medical Device Recall website.

We are continuing to analyze and evaluate incoming reports of adverse events, and are speaking with patients, surgeons and researchers. We will inform the public as new information becomes available.

Talking to your doctor

Before having a hernia operation, be sure to let the surgeon know if you've had a past reaction to materials used in surgical mesh or sutures, such as polypropylene.

There are also certain questions you should consider asking your surgeon:

- What are the pros and cons of using surgical mesh in my particular case?
- If surgical mesh will be used, is there special patient information that comes with the product, and can I have a copy?
- If surgical mesh will be used, what's been your experience with this particular product, and with treating potential mesh complications?
- What can I expect to feel after surgery and for how long?

Reporting complications to Insightra Medical

In order for Insightra to provide the highest quality product and most current information to our customers, it's important that both physicians and patients report complications that may be associated with this product. You can contact Insightra Medical at the following;

Insightra Medical
9200 Irvine Center Drive, Ste. 200
Irvine, CA 92618 USA
www.insightra.com
Customer Service Toll Free (in the U.S.A.): 888 709 5939
International: +1 949 215 1835
Fax: +1 949 625 8625
info@insightra.com

Reporting complications to the FDA

In order to help FDA learn more about possible problems with surgical mesh, it's important that both physicians and patients report complications that may be associated with this product.

You can report any problems to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by FAX.

Online : MedWatch Online Voluntary Reporting Form (3500)
Regular Mail : use postage-paid FDA form 3500 available at: MedWatch Forms
Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
FAX: 1-800-FDA-0178

Surgeon Training

Insightra Medical provides multiple training resources for the Freedom Ventral 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 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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