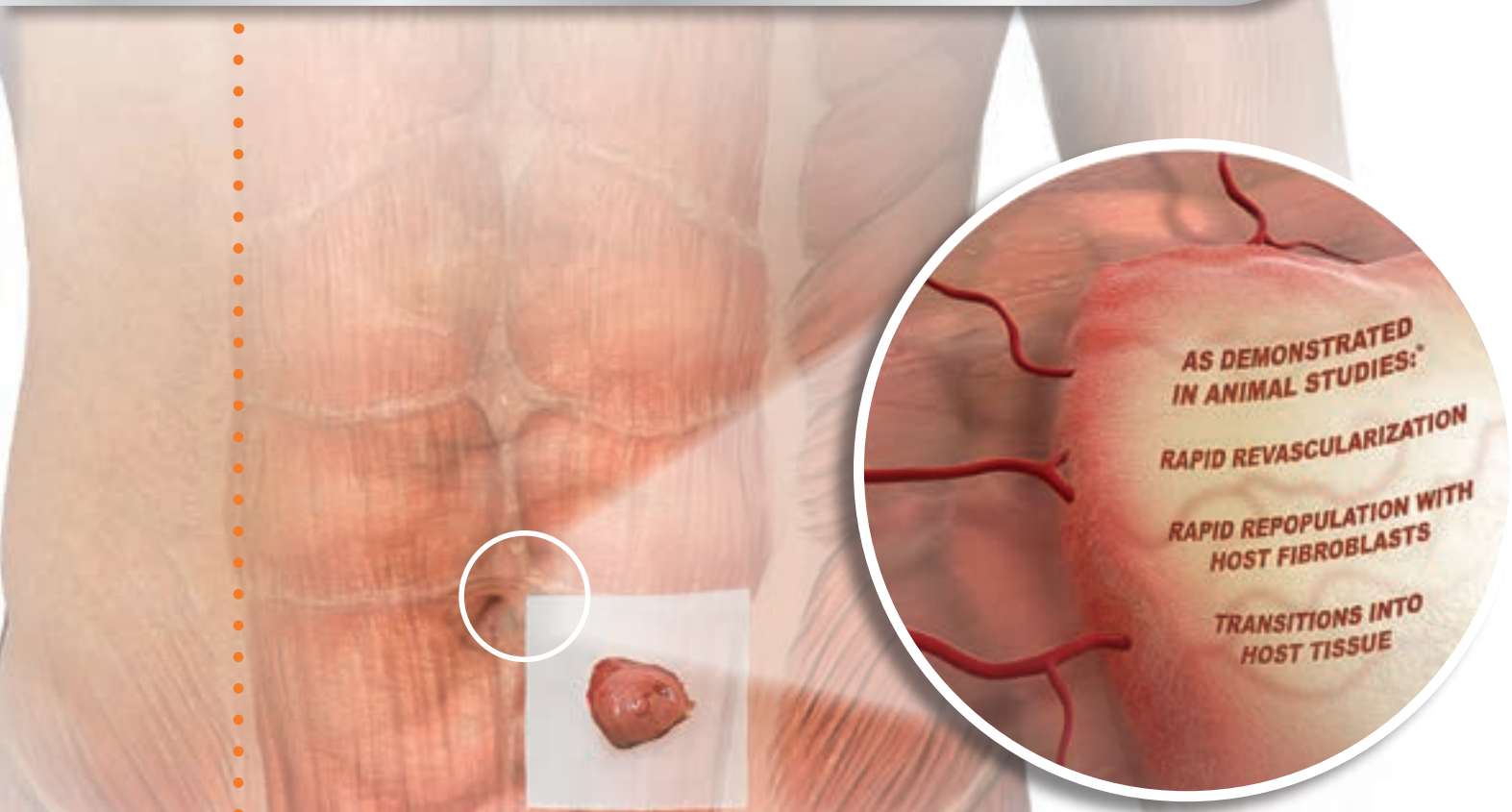
LifeCell™
An Acelity Company

Strattice™ Reconstructive Tissue Matrix for parastomal hernia repair

Every matrix has a story.



Ours is based on outcomes.

Strattice™
RECONSTRUCTIVE TISSUE MATRIX

* Correlation of these results to results in humans has not been established.

Because Outcomes Matter

Because Complexity Matters

Consider the challenges of parastomal hernias:

- Surgical repair is indicated in 11-70% of patients with a parastomal hernia[1]
- Up to 76% recurrence rate for primary-suture-only parastomal hernia repair[2]
- Up to 100% recurrence rate when multiple repairs are required[2]
- Recurrence rates of up to 86% have been reported after stoma relocation[1,2]
- After a relocation, patients are left with 3 defects in their abdomen (original stoma location, mid-line incision and new stoma)

Parastomal Hernia

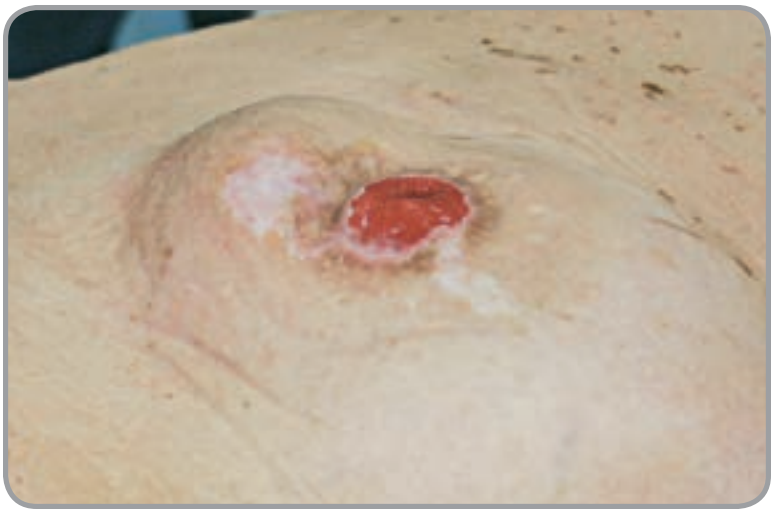


Photo courtesy of Alfredo M. Carbonell, DO, Greenville, South Carolina

Consider the challenges of stoma takedown or relocation:

- There is a larger and generally longer-term risk of an incisional hernia at the stoma site following the reversal procedure[4]
- This incidence may be as high as 12%[5]
- A mesh repair can reduce the rate of re-occurrence of hernia compared to suture repair[6]

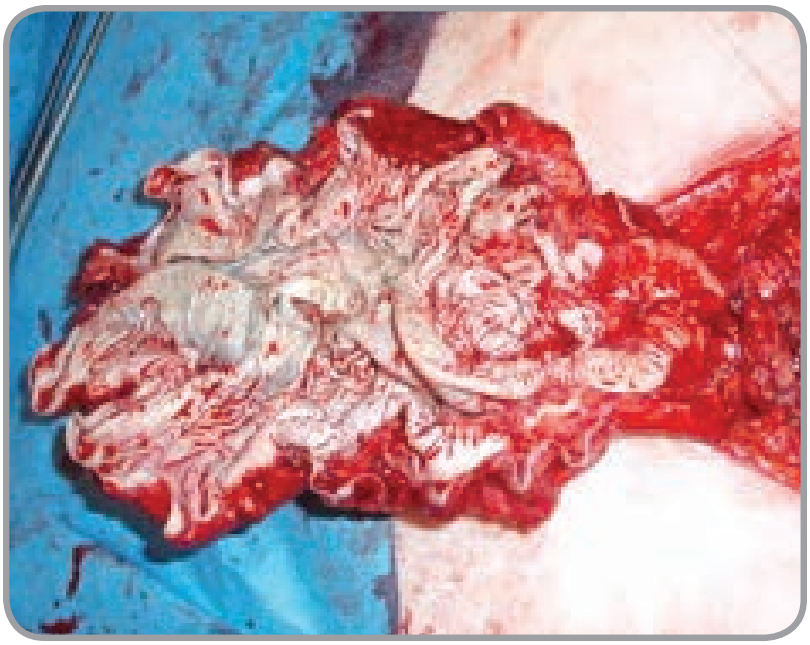
Because the Right Matrix Matters

Patient challenges of parastomal hernia repair include:

- Obesity, immunosupression, steroid therapy, local radiation treatment, infection and malnutrition[7]
- Emergency parastomal hernia repair is indicated for bowel obstruction or perforation[8]
- Multiple comorbidities, prior hernia repairs, intraoperative challenges, and postoperative complications may lead to a higher risk of poor surgical outcomes[9,10]

Potential issues associated with synthetic (plastic) mesh include:

- Infection of synthetic (plastic) mesh may require mesh explant[11]
- Chronic foreign body response, mesh erosion, shrinkage or migration[12]



Shrinkage of a synthetic mesh

Photo courtesy of Dr. Bhanot. Dr. Bhanot is a paid consultant to LifeCell Corporation, Washington, DC.

Why Strattice™ Tissue Matrix Matters

Benefits of Strattice™ Reconstructive Tissue Matrix:

- Provides support to the weakened tissue near the primary suture repair
- Provides strong repair supported by its excellent biomechanical strength

As shown in animal models*:

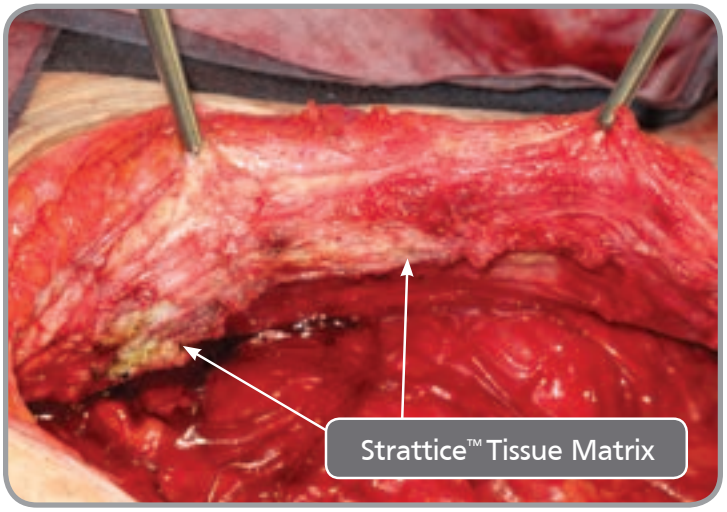
- Supports rapid revascularization, cell re-population, and white cell migration which may lead to increased resistance to infection at surgical site[13]
- Positive recognition in which the body recognizes it and transitions into host tissue[13]

*Correlation of these results to results in humans has not been established.

At 10 months post-implantation, Strattice™ Tissue Matrix reinforced the abdominal wall and provided for a long lasting repair.

"The retrorectus Strattice™ Tissue Matrix was distinctly identifiable as visually it appeared fascia-like."†

Photo courtesy of Omar Guerra, MD, FACS, St. Louis, MO from clinical case study, LifeCell™, Data on file. Dr. Guerra is a paid consultant to LifeCell Corporation.



†Results may not be typical and individual results may vary.

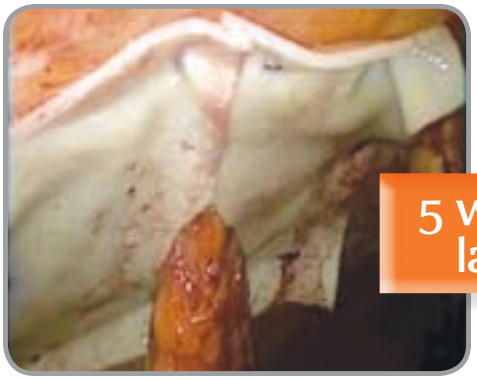
Because Outcomes Matter

Rapid revascularization

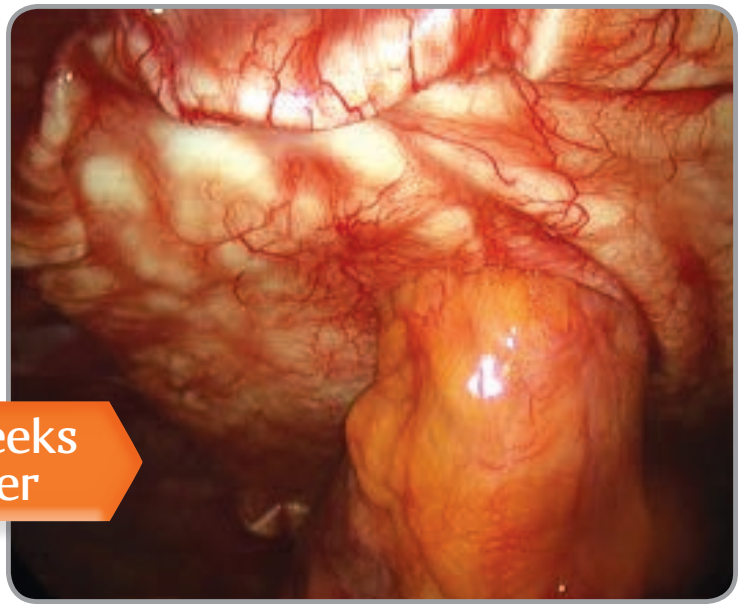
In a complex patient, Strattice™ Tissue Matrix revascularized in 5 weeks post op.

The revascularization of Strattice™ Tissue Matrix using the keyhole technique.*

Photos courtesy of Virgilio George, MD. Indianapolis, IN. Dr. George is a paid consultant to LifeCell Corporation.



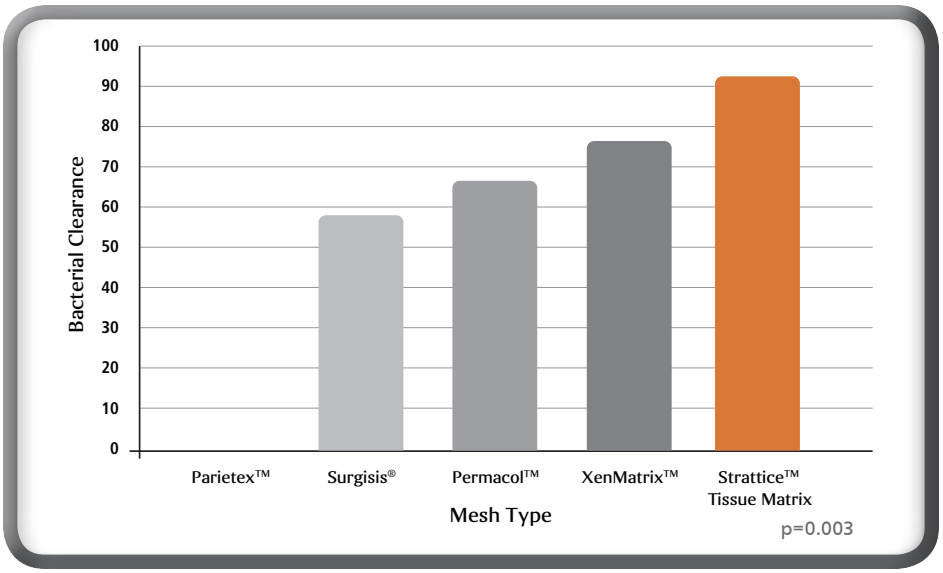
5 weeks later



Clearance of bacteria

In a small animal model, Strattice™ Tissue Matrix allowed for 92% of animals in the study to clear Staphylococcus aureus[3†] (p=0.003)

Strattice™ Tissue Matrix cleared S. aureus better than a synthetic material.



Reproduced with permission from the article "Bacterial clearance of biologic grafts used in hernia repair: an experimental study" : Surgical Endoscopy, Vol.25:Issue 7, page 2227; figure 1, July 2011, © 2012 Springer Science+Business Media, New York.

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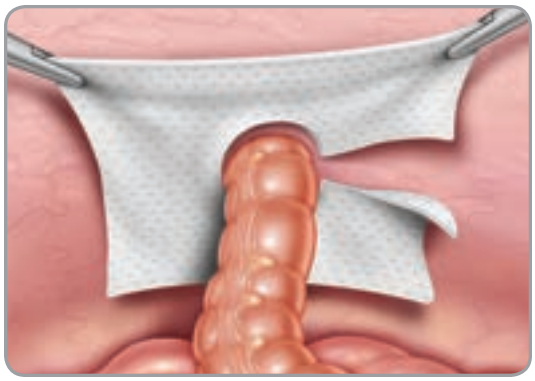
*Results may not be typical and individual results may vary.

Techniques for Parastomal Hernia Repair

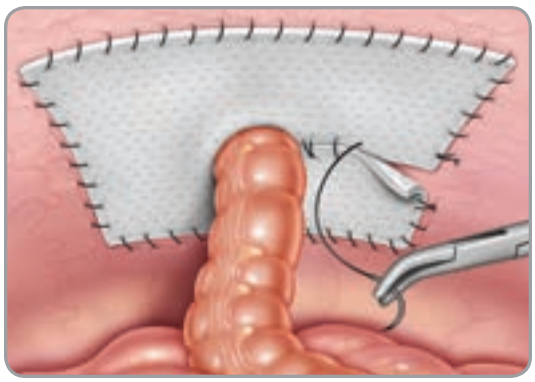
Keyhole Technique*

In the Keyhole technique, the Strattice™ Tissue Matrix is placed ventral to the bowel, below the stomal opening, with a slit and a hole created in the mesh to accommodate the existing bowel.

After removal of the adhesions to the hernia sac and reduction of the redundant loops of bowel, the stoma is pushed as far laterally as possible in the fascial defect.

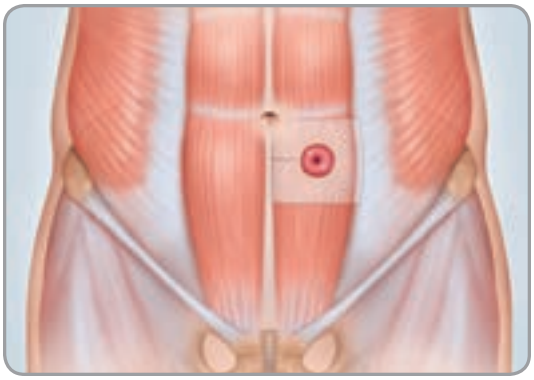


After primary closure of the fascial defect, a Strattice™ Tissue Matrix is sutured over the defect and around the stoma from the intraperitoneal side. Running sutures are placed at the overlap of keyhole.



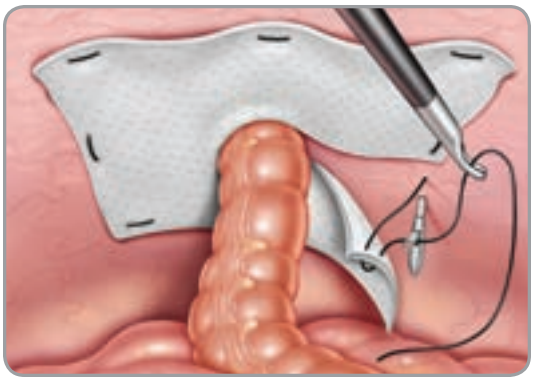
Orient keyhole laterally and place cut end towards the mid-line to improve the ease of fixation.

Overlap tails to get a more secure matrix. Then secure with sutures or tackers.



Laparoscopic tips & techniques:

With Strattice™ Tissue Matrix Laparoscopic, you may fixate with tackers† or you may presuture the tissue matrix then use a suture passer to secure it.



† Strattice™ Reconstructive Tissue Matrix Laparoscopic has NOT been validated with all tackers currently on the market. ProTack™, AbsorbaTack™, and SorbaFix™/PermaFix™ fixation devices have been validated with the product. The choice of fixation device and fixation method should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation.

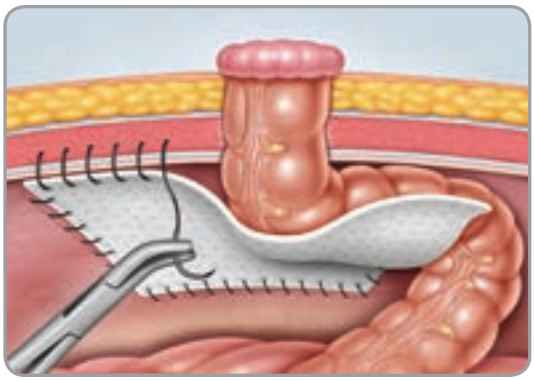
*Illustrations are artist renderings

Techniques for Parastomal Hernia Repair

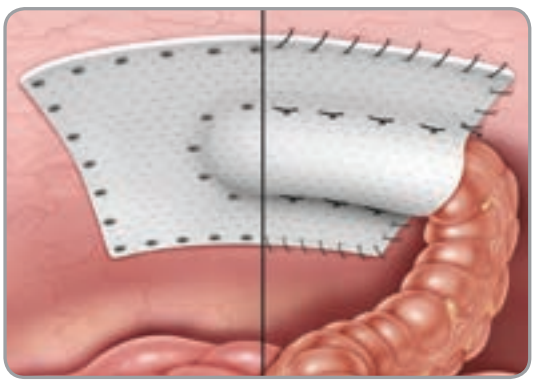
Sugarbaker Technique*

After the adhesions are removed and the hernia is reduced, the bowel is run laterally against the abdominal wall.

The Strattice™ Tissue Matrix is deployed within the abdomen, onto the parastomal hernia defect, allowing for significant mesh-defect overlap dorsal to the hernia defect. The lateral and superior portions of the tissue matrix are sutured to the abdominal wall.



The bowel courses above the tissue matrix, which is sutured to cover the defect and secure the bowel to the lateral abdominal wall. This repair exploits the same intra-abdominal forces which potentiate hernia formation to actually hold the matrix in place.



*Illustrations are artist renderings

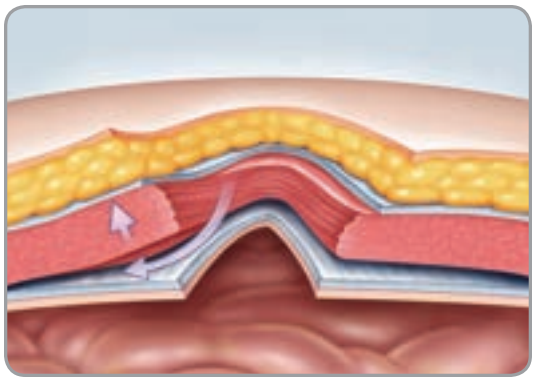
Takedown Site Reinforcement*

Reinforcement of original site of relocations decreases the likelihood of recurrences.

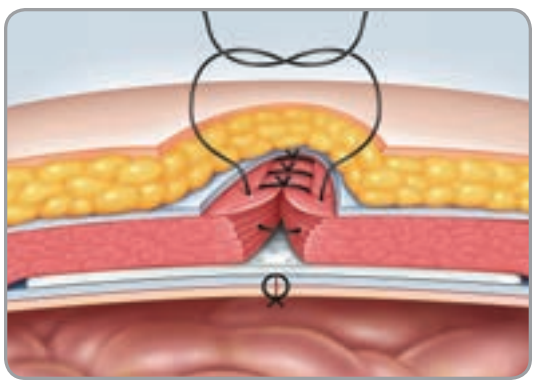
There may be up to a 35% hernia rate at takedown site.[14]

Rectus Abdominis Technique

After takedown, dissect the peritoneum from the rectus abdominis muscle to create a space to accommodate the appropriately sized Strattice™ Tissue Matrix.



Suture the peritoneum and place the tissue matrix in the pocket place. Next, suture the rectus abdominis and anterior fascia and close.



Strattice™
RECONSTRUCTIVE TISSUE MATRIX

Ordering Information

Product Code	Product Size	Version	Coverage (sq cm)
0606002	6 x 6 cm	Firm	36
0808002	8 x 8 cm	Firm	64
0610008	6 x 10 cm	Firm	60
1010002	10 x 10 cm	Firm	100
0616002	6 x 16 cm	Firm	96
1020002	10 x 20 cm	Firm	200
1025002	10 x 25 cm	Firm	250
1620002	16 x 20 cm	Firm	320
1525002	15 x 25 cm	Firm	375
1530002	15 x 30 cm	Firm	450
2020002	20 x 20 cm	Firm	400
2025002	20 x 25 cm	Firm	500
2030002	20 x 30 cm	Firm	600
2040002	20 x 40 cm	Firm	800
2540002	25 x 40 cm	Firm	1000
1016005	10 x 16 cm	Firm (Laparoscopic)	160
1620005	16 x 20 cm	Firm (Laparoscopic)	320
2020005	20 x 20 cm	Firm (Laparoscopic)	400

Essential Prescribing Information for Strattice™ Reconstructive Tissue Matrix

Indications for use

Strattice™ Tissue Matrix is intended for use as a soft-tissue patch to reinforce soft-tissue where weakness exists and for the surgical repair of damaged or ruptured soft-tissue membranes. Indications for use include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

Strattice™ Tissue Matrix is supplied sterile and is intended for single patient one-time use.

Contraindications

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- This device contains Polysorbate 20.

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

WARNING

- Do not resterilize. Discard all open and unused portions of the device.
- Do not use if the package is opened or damaged. Do not use if seal is broken or compromised.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Precautions

- Discard device if mishandling has caused possible damage or contamination, or the device is past its expiration date.
- Ensure that device is soaked in room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation in the body.
- Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- Strattice™ Tissue Matrix product should be hydrated and moist when the package is opened. If Strattice™ Tissue Matrix is dry, do not use.

Storage

- Strattice™ Tissue Matrix is a sterile medical device that should be stored in a clean, dry location at room temperature.
- It is to be stored in its original packaging.

Before use, physicians should review all risk information, which can be found in the Instructions for Use attached to the packaging of each LifeCell™ Tissue Matrix graft.

References:

1. Israelsson LA. Parastomal hernias. Surg Clin N Am. 2008;88:113-125.
2. Rubin Ms, et al. Parastomal hernia: is stomal relocation superior to fascial repair? Arch Surg. 1994;129:413-419.
3. Harth KC, et al. Bacterial clearance of biologic grafts used in hernia repair: an experimental study. Surg Endosc 2011;25(7):2224-9.
4. Saha AK, et al. Morbidity and mortality after closure of loop ileostomy. Colorectal Dis. 2009 Oct;11(8):866-71.
5. Kaidar-Person O, et al. Complications of construction and closure of temporary loop ileostomy. J Am Coll Surg. 2005 Nov;201(5):759-73. Epub 2005 Sep 6.
6. Luijendijk RW, et al. A comparison of suture repair with mesh repair for incisional hernia. N Engl J Med. 2000 Aug 10;343(6):392-8.
7. Lo Menzo EL, et al. Use of biologic mesh for a complicated paracolostomy. Am J Surg. 2008 Nov;196(5):715-9.
8. Brand MI, et al. Preoperative considerations and creation of normal ostomies. Clin Colon Rectal Surg. 2008 Feb;21(1):5-16. doi: 10.1055/s-2008-1055316.
9. Patel KM, et al. Indications and outcomes following complex abdominal reconstruction with component separation combined with porcine acellular dermal matrix reinforcement. Ann Plast Surg. 2012;69(4):394-398.
10. Hawn MT, et al. Predictors of mesh explantation after incisional hernia repair. Am J Surg. 2011;202(1):28-33.
11. Cobb W IV, et al. Incisional herniorrhaphy with intraperitoneal composite mesh: A report of 95 cases. Am Surg. 2003;69:784.
12. Klinge U, et al. Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg. 1999;165(7):665–673.
13. Connor, et al. Retention of structural and biochemical integrity in a biological mesh supports tissue remodeling in a primate abdominal wall model. Regen Med 2009; 4(2):185-195
14. Sharp SP, Francis JK, Valerian BT, Canete JJ, Lee EC. Incidence of Ostomy Site Incisional Hernias after Stoma Closure. Poster presented at: Annual Scientific Meeting of the American Society of Colon and Rectal Surgeons; 2013 Apr 27 – May 1; Phoenix, AZ, USA.

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