

Strattice™ Reconstructive Tissue Matrix Laparoscopic (TML)

.....Expanding the possibilities
in ventral hernia repair

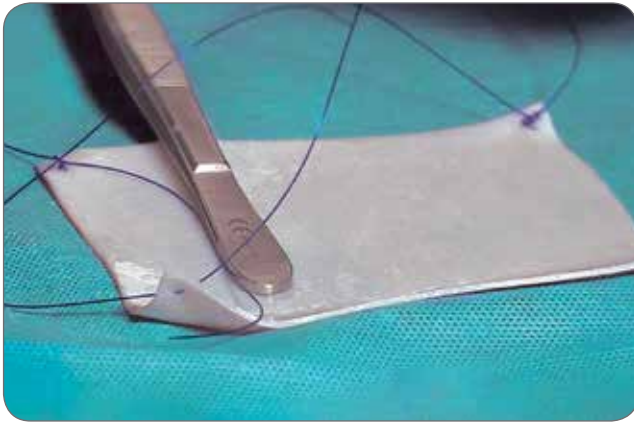


 **Strattice™**
RECONSTRUCTIVE TISSUE MATRIX

Because Outcomes Matter

Strattice™ Reconstructive Tissue Matrix Laparoscopic (TML)

You asked for a biologic tissue matrix designed to address the challenges of laparoscopic ventral hernia repair...



Strattice™ Tissue Matrix Laparoscopic was designed with a thickness profile to meet your specific needs in laparoscopic ventral hernia repair.

Because ease of use matters
Because strength matters
Because performance matters

- Strattice™ Tissue Matrix Laparoscopic has a thickness profile designed to optimize laparoscopic handling:
 - Designed to facilitate placement through a trocar or incision site
 - Ease of fixation to the abdominal wall, as demonstrated in an animal model^{1,*}
- Provides out-of-package strength¹
- No permanent synthetic mesh left in the abdominal space

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

.....Because outcomes matter

- When a minimally invasive approach is the technique of choice for your challenging ventral hernia patient...



In peer-reviewed publications, laparoscopic ventral hernia repair has been demonstrated to:

- Decrease length of hospital stay^{2,3}
- Reduce postsurgical complications^{2,3}

According to literature, laparoscopic approach may be appropriate for the following patient types^{4,5}:

- Patients who may require additional abdominal procedures⁴
- Patients with elevated risk for postsurgical complications associated with an open procedure⁵

..... Because ease of use matters

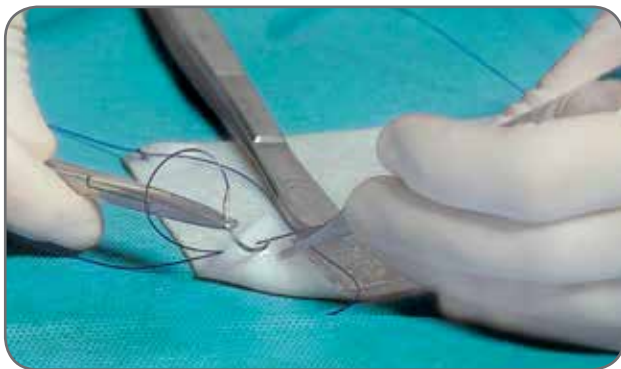
..... An optimized thickness profile facilitates:

..... Ease of Placement



| Ease of placement through trocar and/or incision site

..... Ease of Fixation



| Ease of fixation with sutures and tackers for confidence in a secure, well-implanted matrix*

When implanting a biologic matrix, achieving primary fascial closure ensures an optimal repair^{6,7}

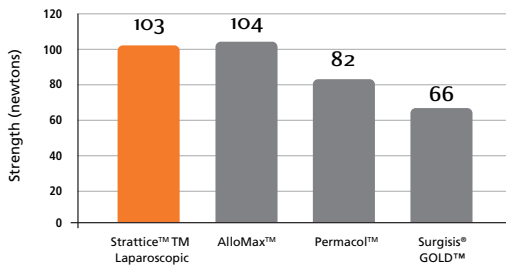
*Strattice™ Reconstructive Tissue Matrix Laparoscopic has NOT been validated with all tackers currently on the market. ProTack™, AbsorbaTack™, and SorbaFix™/PermaFix™ fixation devices have been validated with the product. The choice of fixation device and fixation method should be determined by surgeon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

Because strength matters

Versus biologics!

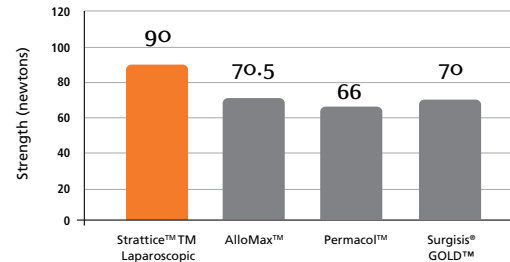
Comparable Tensile Strength

Out-of-Package Tensile Strength*



Greater Suture Retention Strength

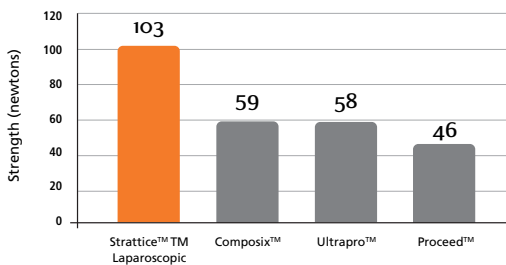
Out-of-Package Suture Retention Strength*



Versus synthetics!

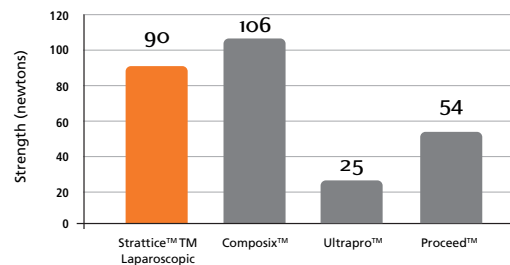
Greater Tensile Strength

Out-of-Package Tensile Strength*

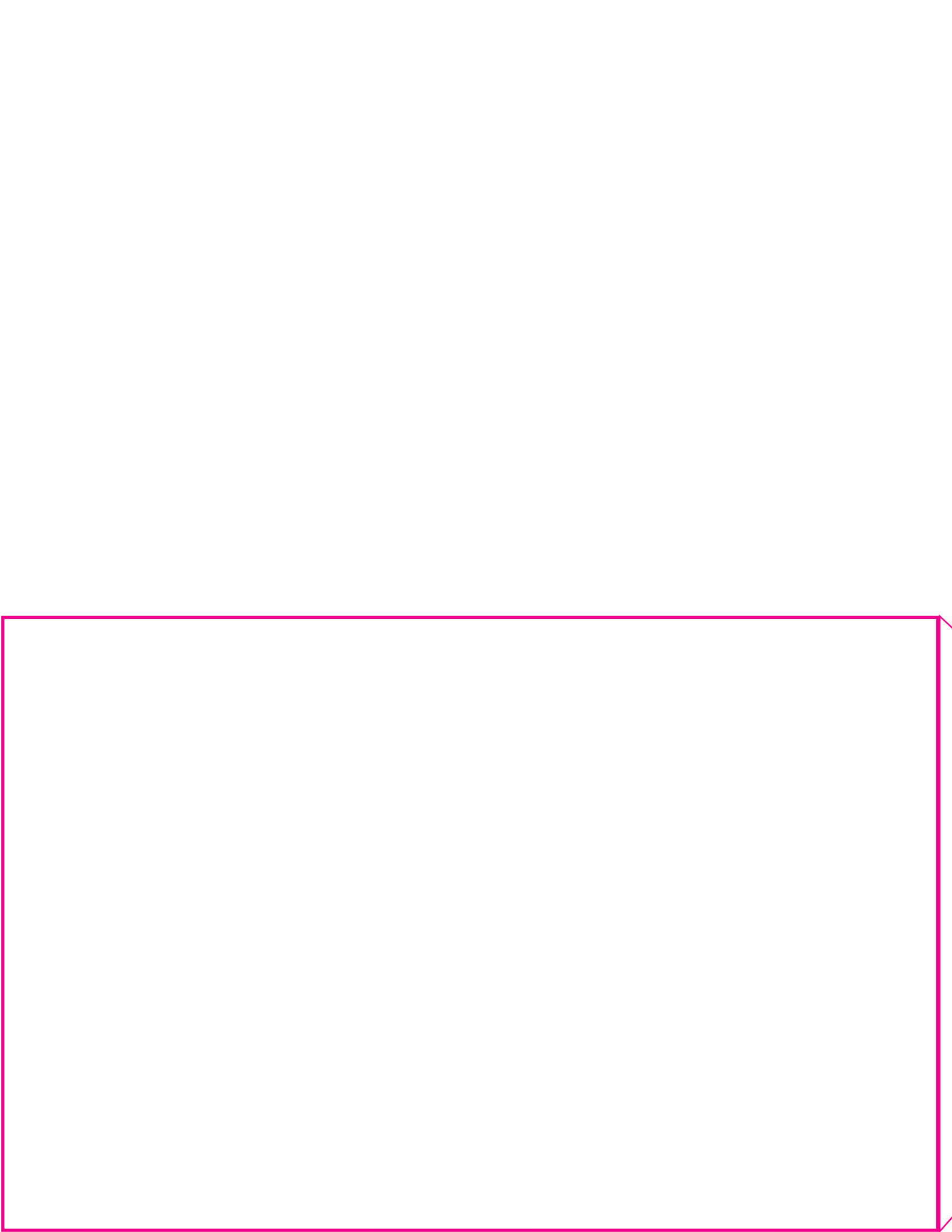


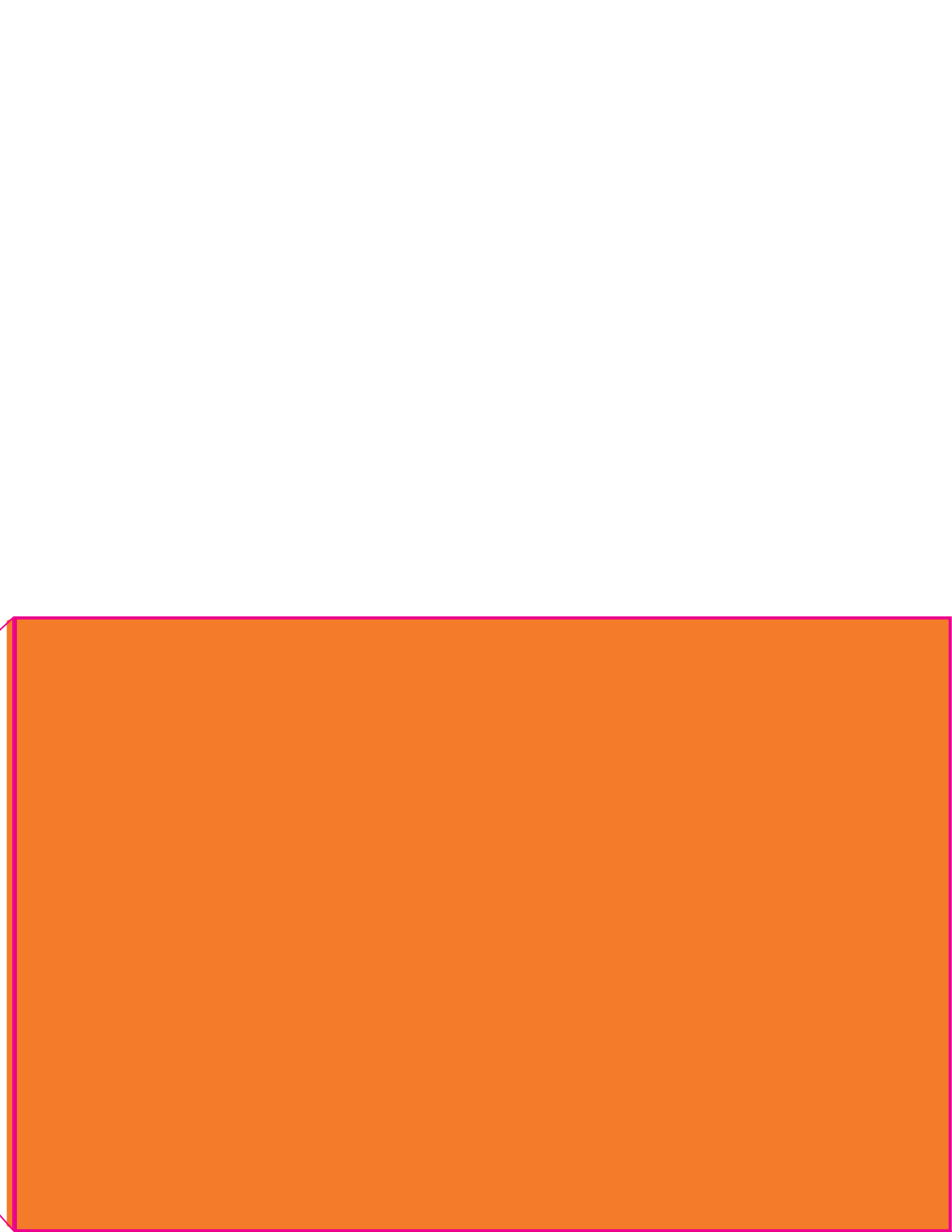
Comparable to Synthetics

Out-of-Package Suture Retention Strength*



*Strength parameters shown in newtons.





Every matrix has a story

Ours is based on outcomes

Ordering information

Product code	Product size	Coverage (sq cm)
0608005	6 x 8 cm	48
1010005	10 x 10 cm	100
1016005	10 x 16 cm	160
1620005	16 x 20 cm	320
2020005	20 x 20 cm	400

References:

1. Data on file. LifeCell Corporation.
2. Salvilla SA, Thusu S, Panesar SS. Analysing the benefits of laparoscopic hernia repair compared to open repair: a meta-analysis of observational studies. *J Minim Access Surg.* 2012;8(4):111-117.
3. Kavic SM, Kavic SM. Adhesions and adhesiolysis: the role of laparoscopy. *JSL.* 2002;6(2):99-109.
4. Stocchi L. Current indications and role of surgery in the management of sigmoid diverticulitis. *World J Gastroenterol.* 2010;16(7):804-817.
5. Heniford BT, Park A, Ramshaw BJ, Voeller G. Laparoscopic repair of ventral hernias: nine years' experience with 850 consecutive hernias. *Ann Surg.* 2003;238(3):391-400.
6. Patel KM, Nahabedian MY, Gatti M, Bhanot P. 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.
7. Butler CE, Campbell KT. Minimally invasive component separation with inlay bioprosthetic mesh (MICSIB) for complex abdominal wall reconstruction. *Plast Reconstr Surg.* 2011;128(3):698-709.

Essential Prescribing Information for Strattice™ Reconstructive Tissue Matrix Laparoscopic

Indications for use

Strattice™ Reconstructive Tissue Matrix Laparoscopic 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 during open or laparoscopic procedures.

Strattice™ Reconstructive Tissue Matrix Laparoscopic is intended for single patient one-time use only.

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.
- Soak the device for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the mesh.
- Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- Strattice™ Reconstructive Tissue Matrix Laparoscopic product should be hydrated and moist when the package is opened. If Strattice™ Reconstructive Tissue Matrix Laparoscopic is dry, do not use.
- A bridged hernia defect may result in an increased risk of hernia recurrence.
- Refrain from using excessive force if inserting the mesh through the trocar.

Storage

- Strattice™ Reconstructive Tissue Matrix Laparoscopic 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.
- Expiration date of the product is indicated as year (4 digits) and month (2 digits). The product expires after the last day of the month indicated.

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.

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