Strattice™

Artist's rendering

Count on STRATTICE™

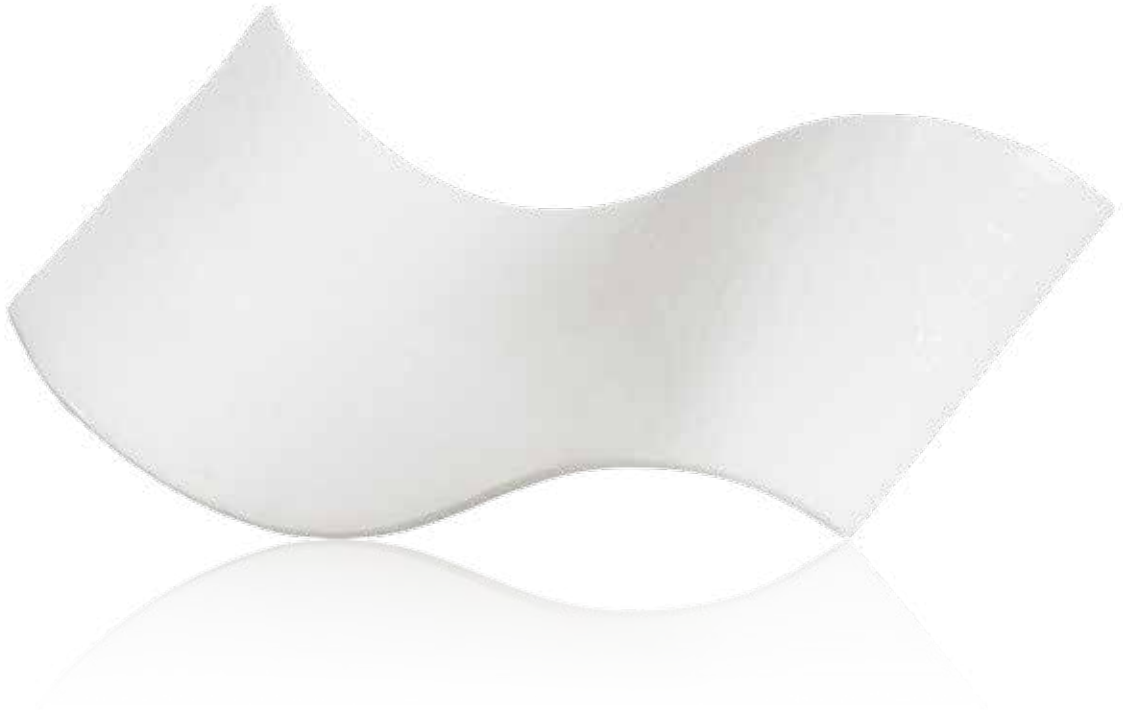
The Most Clinically Studied Biological Mesh for Complex Abdominal Wall Repair†

GD medical

Allergan

Count on STRATTICE™

#1 Biological Mesh**



<0.3%

Average explantation rate reported in all Complex AWR publications tracking explantations*,††

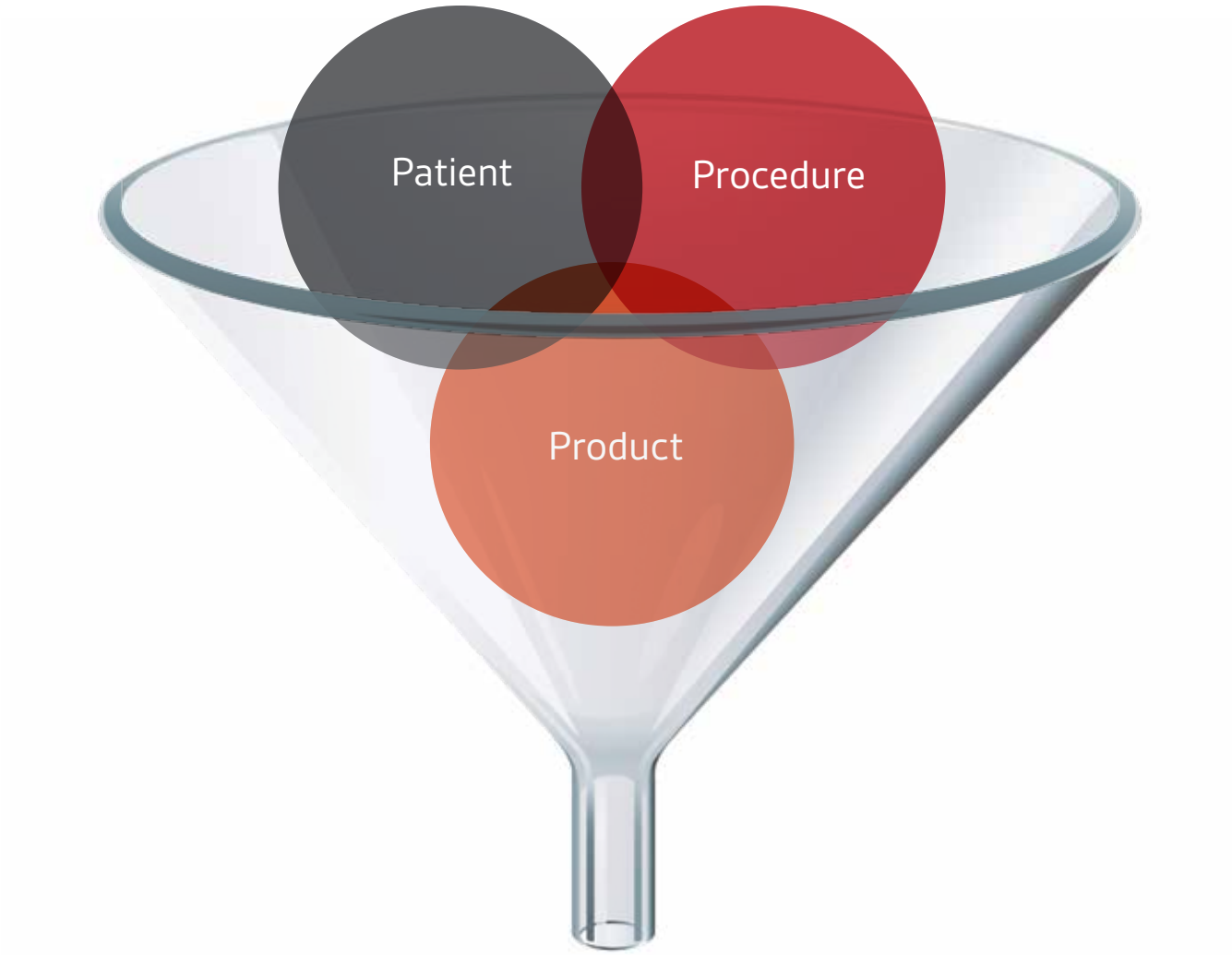
90+

Peer-reviewed Articles†

*Average explantation rate based on cumulative figures from 90 peer-reviewed articles which demonstrated six cases of explantation in a total STRATTICE patient population of 2,066 patients (6 explants/2,066 patients=.29%).
**Total U.S. Procedure Volumes of Biologics as reported by IMS CDM for Ventral/Incisional Procedures. December, 2015.
†Searches performed on PubMed, Google, Google Scholar and ScienceDirect® in June, 2016.
††Each study was considered independent during calculation. Studies may contain overlapping populations. Percentage based on weighted average.

Ventral Hernia Repair

Patients can be complex. Procedures can be complex. Product selection doesn't have to be...



VHR OUTCOME

Multiple variables can affect outcomes in Ventral Hernia Repair. When considering patient quality of life, recovery times and risk of SSOs, the product chosen for repair must be carefully considered.

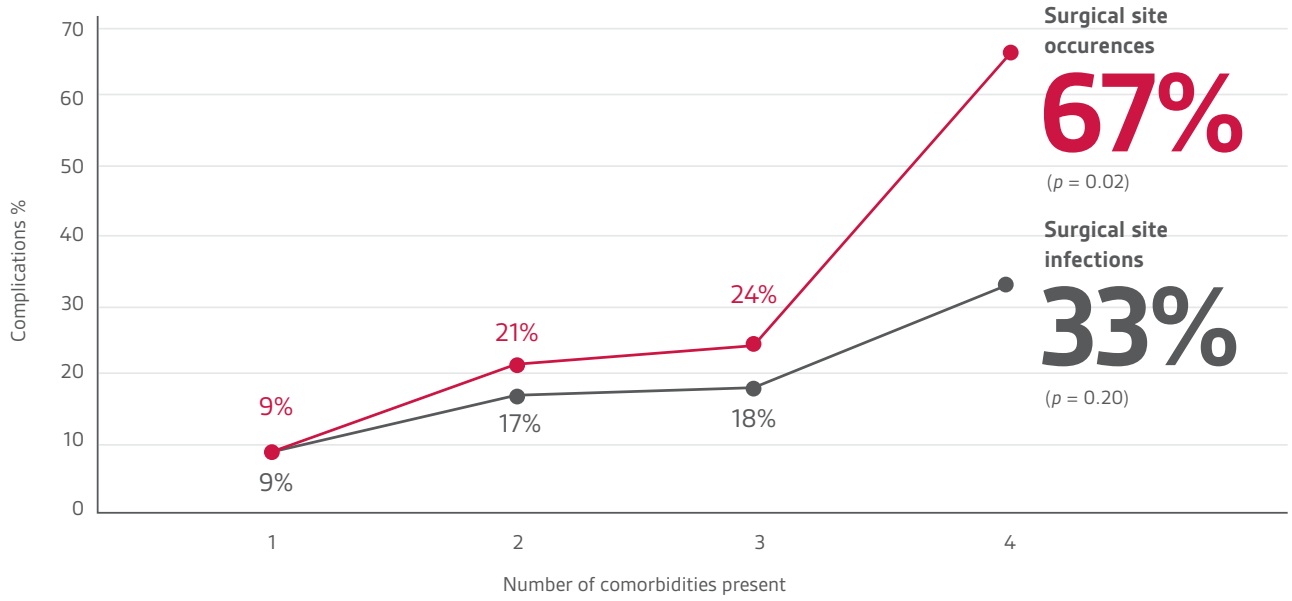
Patients can be complex

Multiple Comorbidities, Prior Hernia Repairs, Intraoperative Challenges, and Postoperative Complications May Lead to a Higher Risk of Poor Surgical Outcomes[1]

Studies have demonstrated that there is an increased risk of postoperative complications in patients with[1]:

- Smoking history
- Prior hernia repair
- Overweight/obesity
- Stoma/ostomy presence
- Chronic obstructive pulmonary disease
- Steroid use
- Diabetes

Probability of SSO and SSI based on number of comorbidities present*,[2]

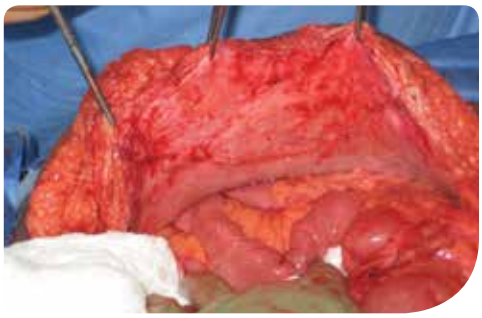


Reprinted from *Surgery*, 153(1), Krpata DM, Blatnik JA, Novitsky YW, Rosen MJ, Evaluation of high-risk, comorbid patients undergoing open ventral hernia repair with synthetic mesh, Pages 120-5, ©2013 with permission from *Elsevier.*

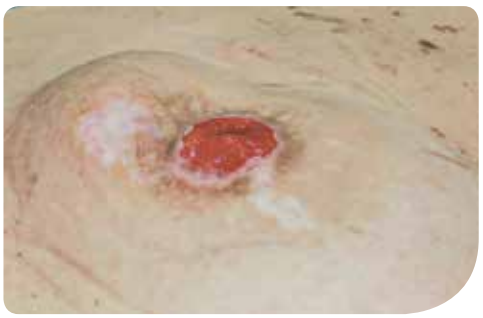
* Surgical site occurrences were defined in this study as infections, clinically relevant seroma requiring intervention, dehiscence, or formation of an enterocutaneous fistula.

Complex patients often times lead to complex procedures that require additional measures to complete a successful repair.

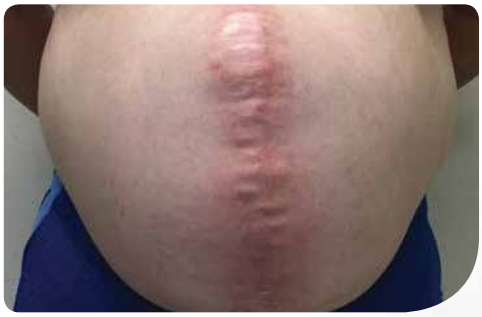
Procedures can be complex



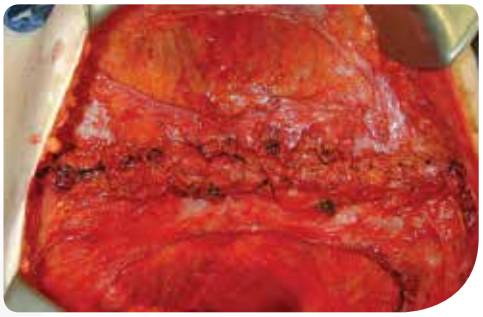
Large skin flaps
Photo courtesy Michael K. Liang, MD
Houston, TX



Stoma
Photo courtesy of Alfredo M. Carbonell, DO
Greenville, SC



Incidental hernia
Photo courtesy Devinder Singh, MD
Baltimore, MD



Fascial release
Photo courtesy Ron Silverman, MD
Baltimore, MD

Procedural variables have been shown to increase the occurrence of postoperative wound complications[3]

Overall risk of SSI was 25% and increased with risk factors[3]

58.6% ← **Elevating skin flaps**

Fascial release → **43.2%**

55% ← **Incidental hernia**

Concomitant procedures → **27%**

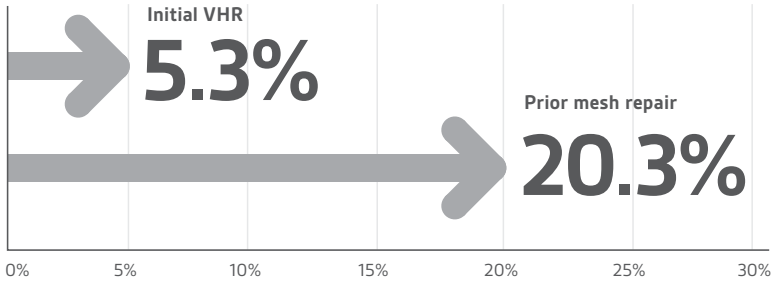
Artist rendering

Choosing the right product for repair from the start is paramount to reaching a favorable outcome.

Improper product selection can impact your VHR procedure

The incidence of enterotomy or unplanned bowel resection was 5.3% in primary ventral hernia repairs, but was 20.3% ($p<0.01$) if the patient had a prior mesh repair[4]

Incidence of enterotomy or unplanned bowel resection[4]



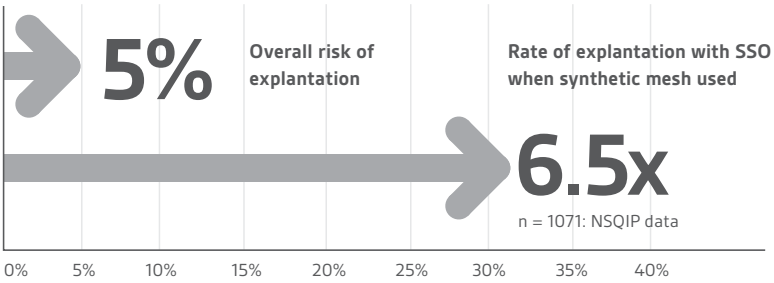
Use of synthetic mesh may result in unintended consequences including:[5]

Complication rates associated with synthetic mesh over 18 months[5]

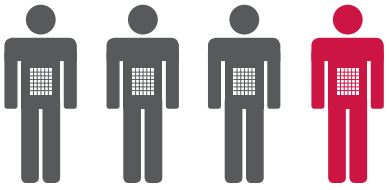
- Post-op surgical site infection
- Infection requiring explantation
- Small bowel obstruction
- Mesh contraction and migration increasing the risk of recurrence
- Bowel adhesions
- Gastrointestinal fistula

If a postoperative wound complication develops in a patient with synthetic mesh, it is a serious problem, often leading to explantation.[6]

Explantation rates

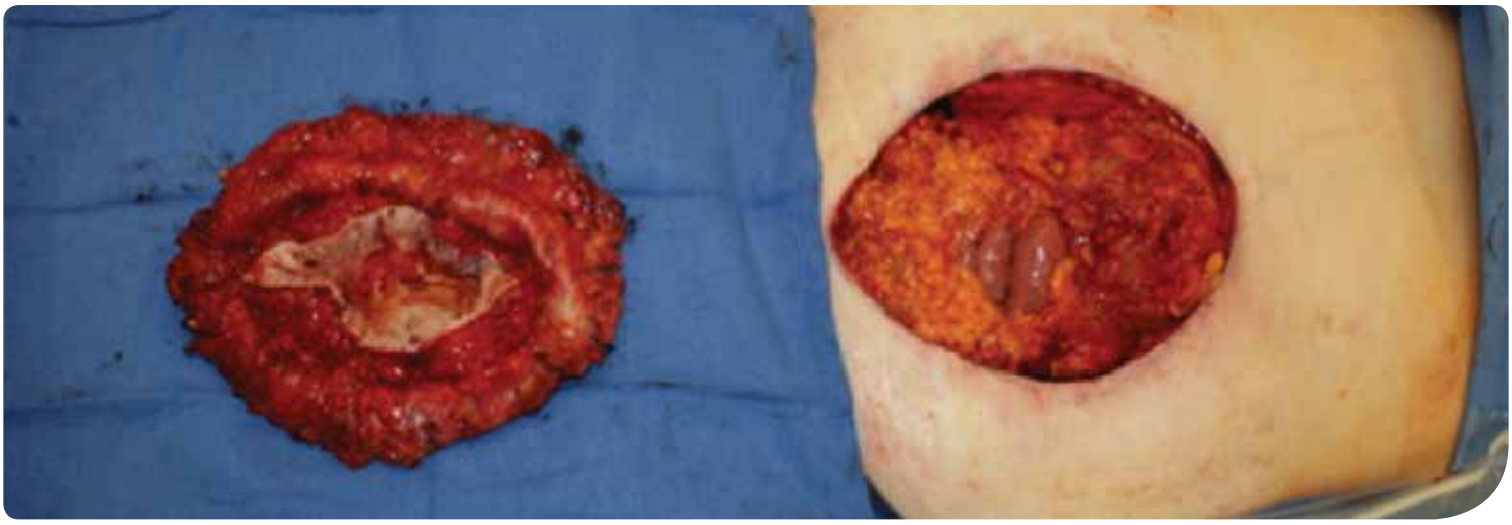


Synthetic mesh removal rates



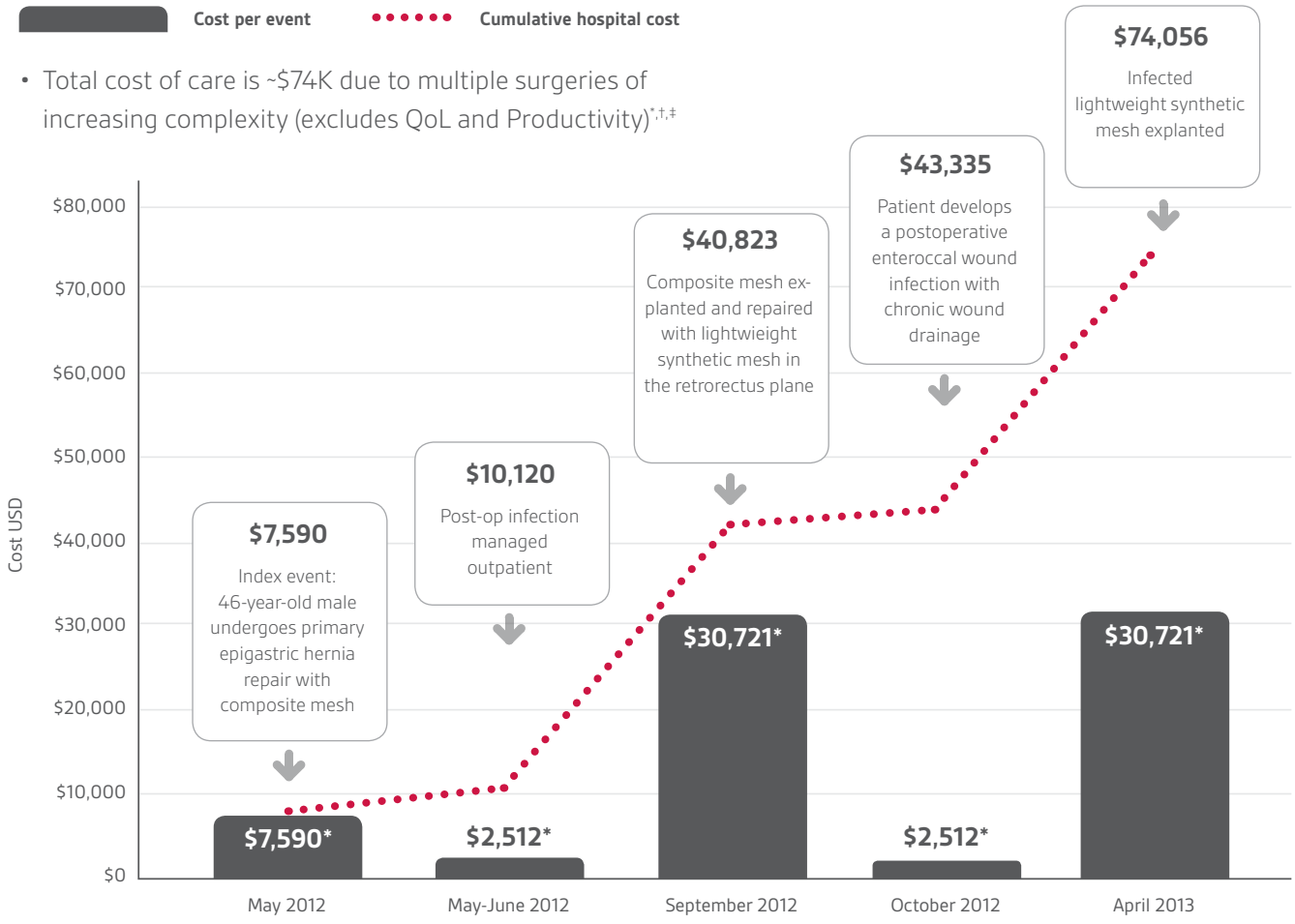
Approximately 1 in 4 CAWR patients with synthetic mesh will have infected mesh removal*,5

* LifeCell™ data on file based on a longitudinal analysis of private and public insurance claims from the Truven MarketScan® Database. Patients were followed from their initial procedure in 2007 for 18 months. (n =740).



Synthetic mesh explantation
Photo courtesy of George DeNoto III, MD FACS
NY, NY

The economic impact of lightweight synthetic mesh



Case example provided by George DeNoto III, MD FACS, Roslyn, NY

* Raynolds, et al. Financial implications of ventral hernia repair a hospital analysis. *J Gastrointest Surg*. 2013 Jan;17(1):159-66.

† LifeCell data on file. Analysis of 2008-2011 public and private insurance claims from Thomson Reuters MarketScan® Database. N=13,463 patients.

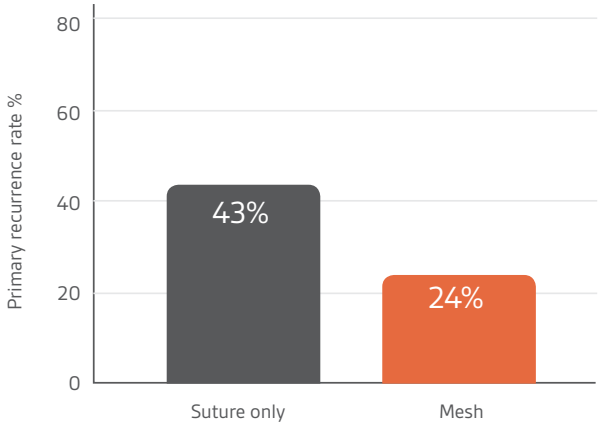
‡ LifeCell data on file based on a longitudinal analysis of private and public insurance claims from the Truven MarketScan® Database. Patients were followed from their initial procedure in 2007 for 18 months. Dollar amounts reflect 2013 dollars (n=740).

Product selection impacts Ventral Hernia Repair outcomes

Landmark clinical trials have clearly demonstrated even the smallest hernia repairs should be reinforced.[6,7]

Luijendijk RW, et al. A comparison of suture repair with mesh repair for incisional hernia. *NEJM*. 2000;343(6):392-398[7]

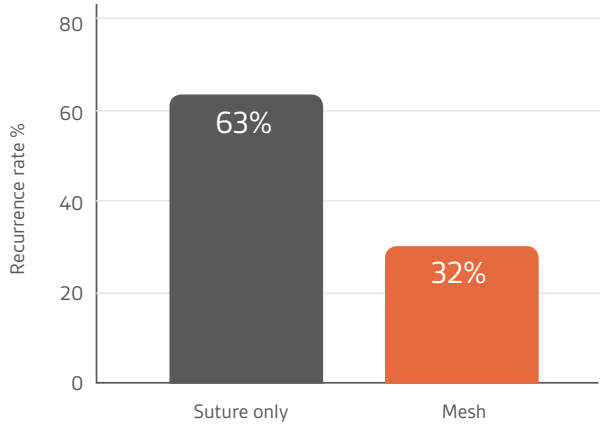
3-year primary recurrence rates



Clean wounds < 6cm² defects

Burger JW, et al. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. *J Ann Surg*. 2004;240(4):578-583[8]

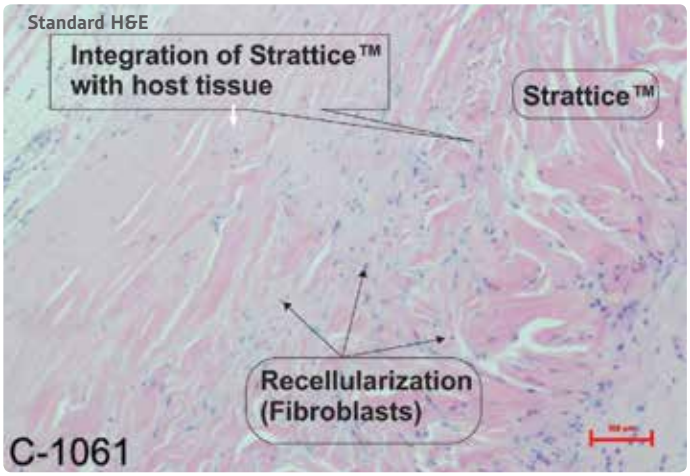
10-year cumulative review of recurrence rates



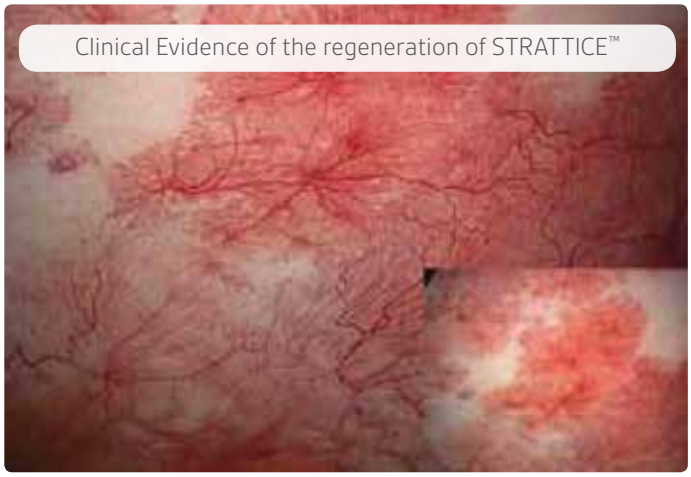
Clean wounds < 6cm² defects

STRATTICE™ Tissue Matrix regenerates and continues to reinforce over time

STRATTICE™ Tissue Matrix provided a reinforced repair up to 38 months post-implantation as demonstrated in histopathologic results.[17]



Histopathology for patient 1 showed robust recellularization and remnants of STRATTICE™ Tissue Matrix, 31 months post-implantation.



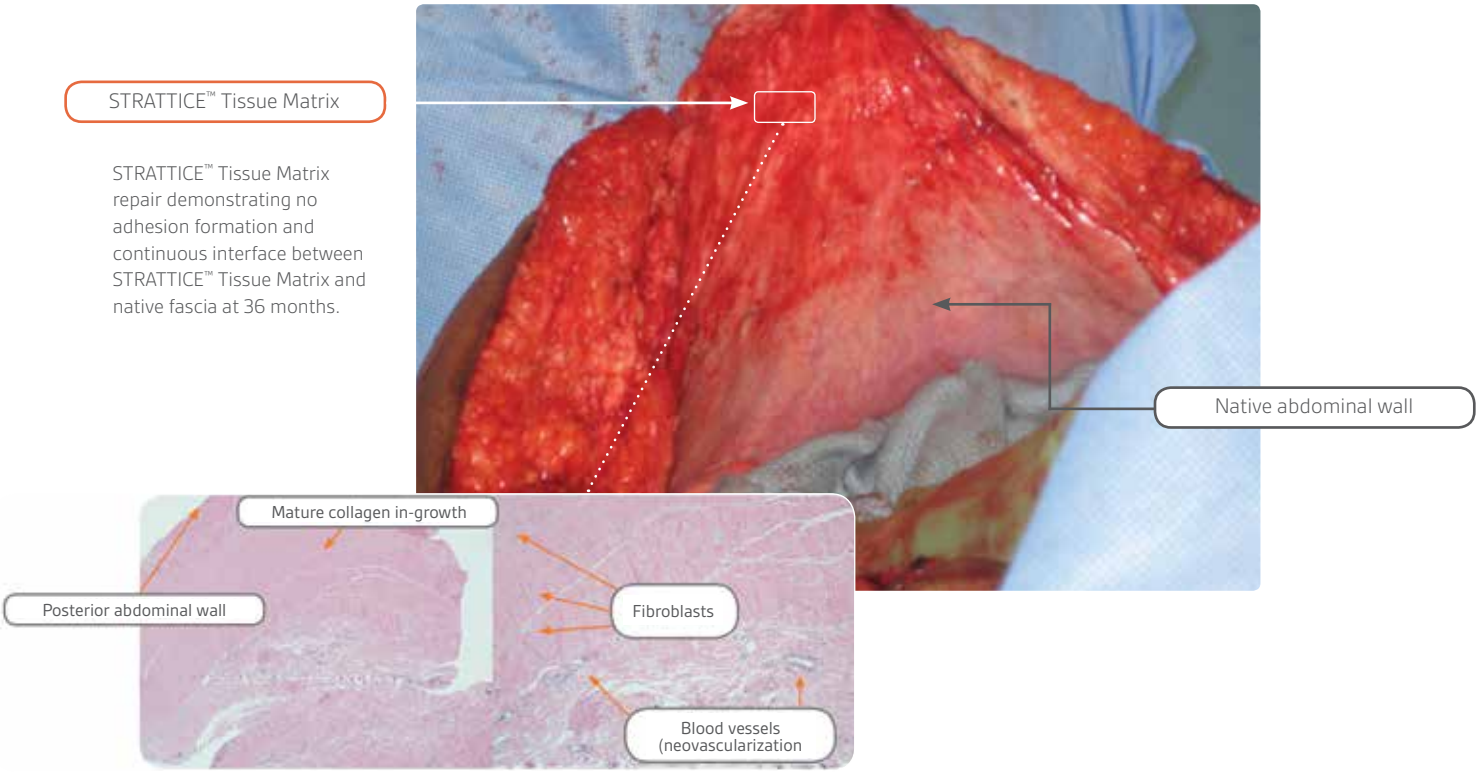
Centripetal budding pattern of vascularity on STRATTICE™ TM.

Images courtesy of W. Scott Helton, MD, FACS

Biopsies taken from STRATTICE™ Tissue Matrix demonstrated neovascularization and collagen deposition with minimal foreign body reaction after 36 months.[18]

STRATTICE™ Tissue Matrix

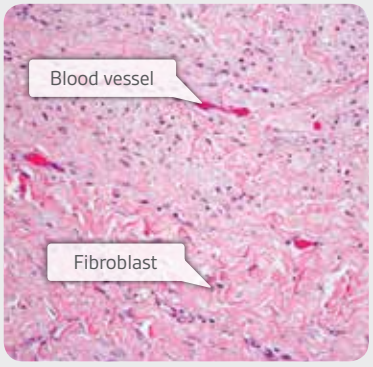
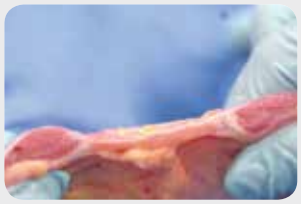
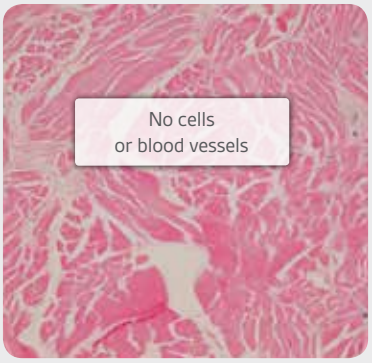
STRATTICE™ Tissue Matrix repair demonstrating no adhesion formation and continuous interface between STRATTICE™ Tissue Matrix and native fascia at 36 months.



STRATTICE™ TM and native abdominal wall interface 36 months postoperative at 40x and 100x magnification.

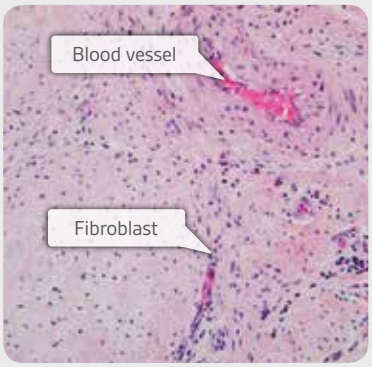
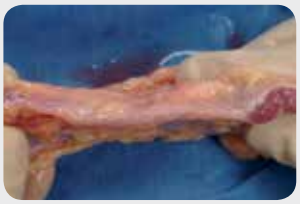
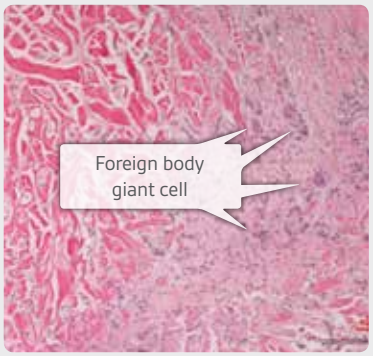
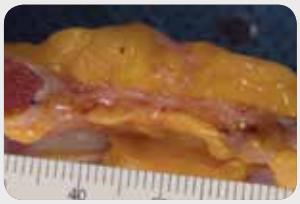
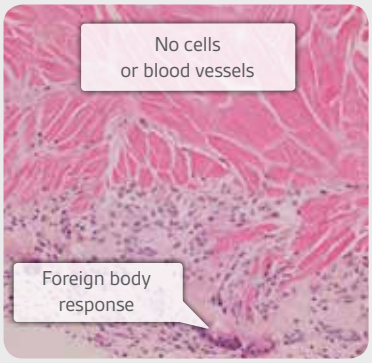
Not all biological tissue matrices perform equally

Since 1994, LifeCell has been a pioneer and is today a leader in the science of regenerative medicine. Our dedication to the science and characterization of tissue properties has enabled us to develop a process specifically designed to retain the biochemical and biomechanical integrity of the tissue, which is critical for

Immunologic response	Mechanism of action	1-month histology and gross observation*,**,†
Positive Recognition[19,†] (Body recognizes as self)	**Regeneration** Body accepts and integrates the intact tissue matrix as part of the host through rapid revascularization, white cell migration and cell repopulation.	STRATTICE™ Reconstructive Tissue Matrix  
Negative Recognition[20,†] (Body recognizes as foreign)	**Resorption** Body attacks the damaged tissue to break it down and eliminate it.	Denatured porcine tissue  
	Encapsulation Body attacks the cross-linked tissue to extrude or wall it off from the host.	Cross-linked porcine tissue  

†Correlation of these results to results in humans has not been established.
*H&E stain 200x. Explant histology and gross observation of cross-sectional view of abdominal wall explant in primate model.
**Data on File

regeneration and essential for successful clinical outcomes. The end result is a biologically intact scaffold that supports and enables tissue regeneration by promoting rapid revascularization, white cell migration and cell repopulation.†

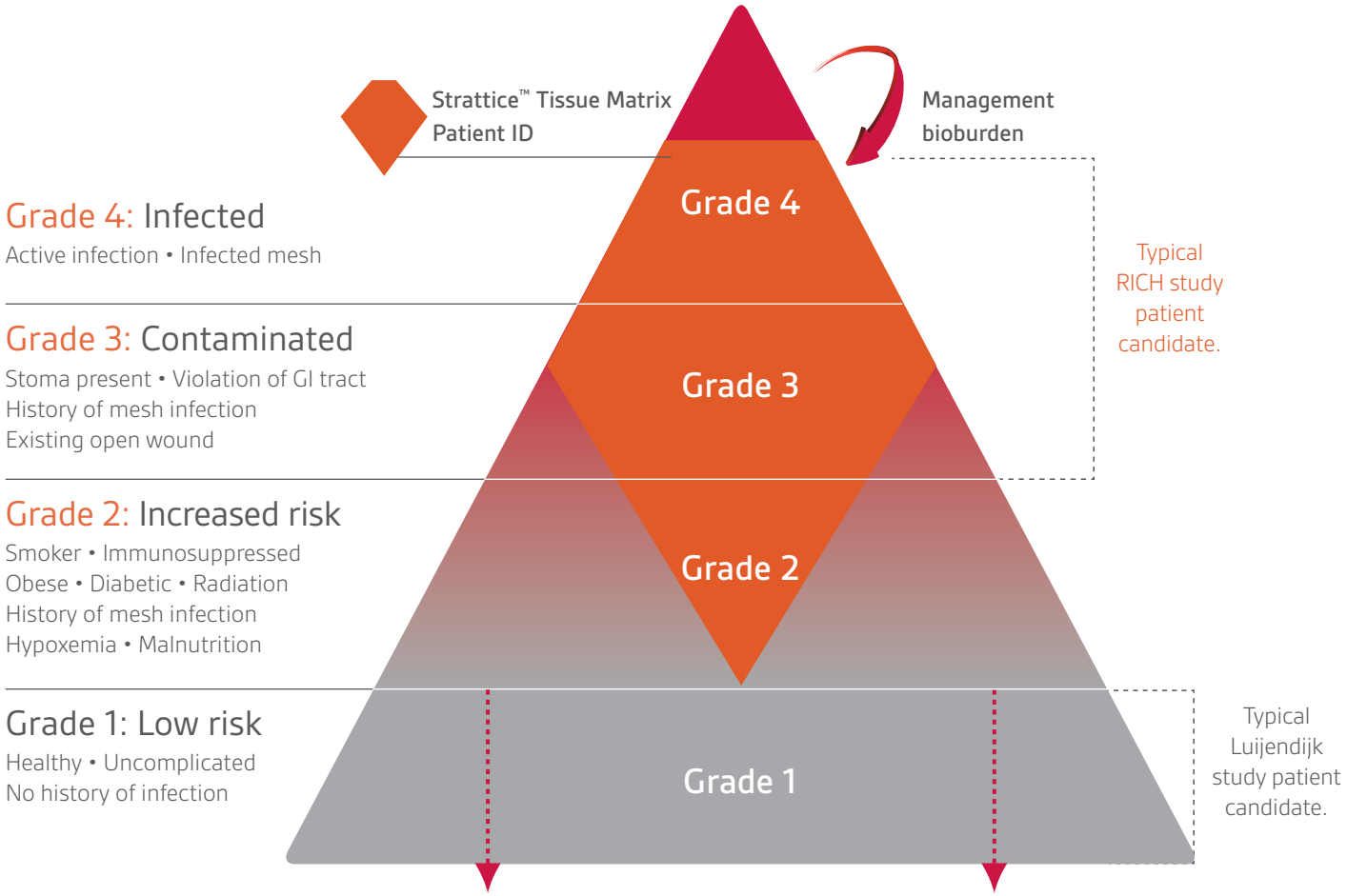
6-month histology and gross observation**,†		Tissue processing	Biologic performance
		Extracellular matrix is preserved and intact	Rapid revascularization Strong repair Cell repopulation Minimal inflammatory response
		Altered matrix Foreign antigens	Similar to resorbable synthetics • Inflammation • Infiltration with inflammatory cells • Replacement with scar
		Chemically cross-linked	Similar to permanent synthetics • Inflammation • No cell infiltration • Contraction

†Correlation of these results to results in humans has not been established.
*H&E stain 200x. Explant histology and gross observation of cross-sectional view of abdominal wall explant in primate model.
**Data on File

Proven Clinically[1,21,22,23,24]

The STRATTICE™ Repair of Contaminated and Infected Hernias (RICH) study

Defects can be classified as Grade 3 (n=60) or 4 (n=20) according to the Ventral Hernia Working Group System.[21] There are very few alternatives for hernia repair in such a patient population. Patients are often closed in a 2-stage "planned hernia," for which synthetic mesh is inappropriate due to the high risk of postoperative infection, bowel erosion, and fistula formation when placed in a contaminated field.



Comparing 12-month results

	Small Clean Defects	Large Infected/ Contaminated Hernias
	Luijendijk, et al.[7]	The RICH study[22]
Number of prior repairs	0-1	1-6
BMI median	26.2	30.9
Hernia defect median (cm2)	24	220
Signs of contamination or infection	excluded	required
Recurrence rate at 12 months	**17%**	**19%**

The 12-month recurrence rate observed in the STRATTICE™ RICH Study looking at the open repair of large contaminated and infected hernias is comparable to the rates seen in the Luijendijk, et al.[7] study of relatively small, clean hernia defects.

RICH study[22]

"The main finding, in my opinion from this study is that despite having infected and contaminated patients, none of the patients had to have the STRATTICE™ Tissue Matrix explanted."

R. Silverman, MD, FACS, Baltimore
RICH study data safety monitor**

Artist's Rendering

**Quotes from interviews with RICH study investigators 2010.
Dr. Silverman is Chief Medical Officer for LifeCell Corporation

STRATTICE™ Tissue Matrix a proven product in VHR

STRATTICE™ Reconstructive Tissue Matrix is the industry leader for biological meshes in Complex Abdominal Wall Reconstruction.

Studied in more than

2,000

patients*,†

Clinical experience

90+

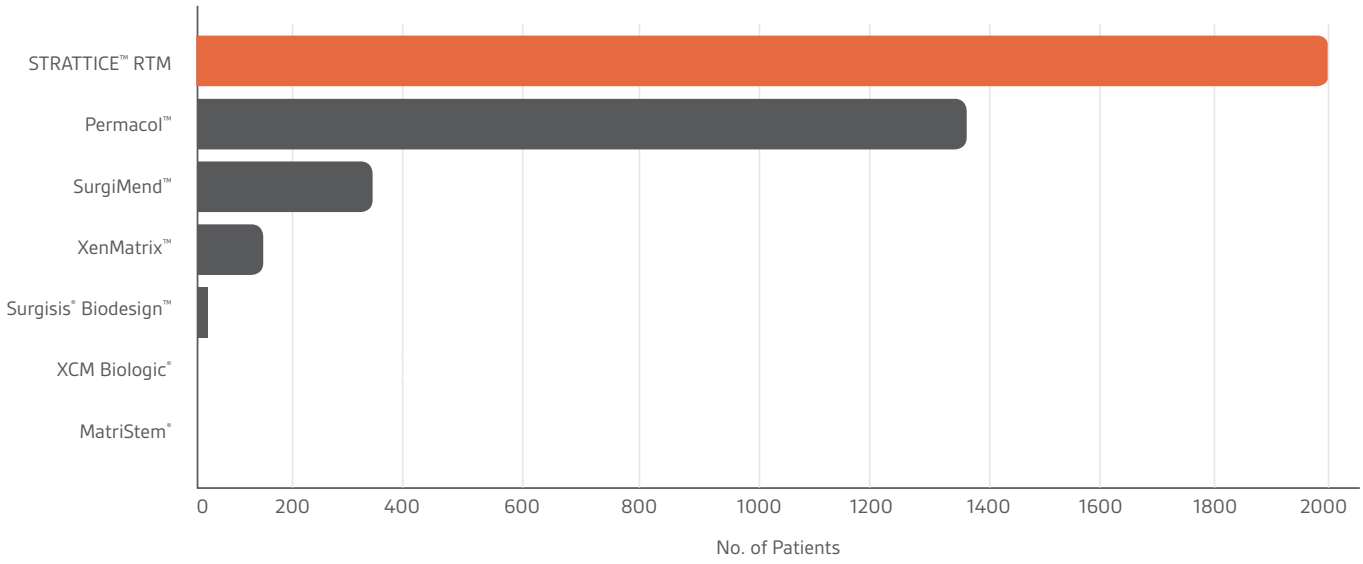
peer-reviewed publications*,†

<0.3%

Average explantation rate reported in all peer-reviewed Complex AWR publications tracking explantations*,†

And the most studied

Number of Complex Abdominal Wall Reconstruction patients reported in peer-reviewed articles*,†



* Searches performed on PubMed, Google, Google Scholar and ScienceDirect® in June 2016.

† Each study was considered independent during calculation. Studies may contain overlapping patient populations. Percentage based on weighted average.

If you are concerned about your patient developing a postoperative wound complication, you know you can count on...

References:

1. 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 Oct;69(4):394-8.
2. Krpata DM, Blatnik JA, Novitsky YW, Rosen MJ. Evaluation of high-risk, comorbid patients undergoing open ventral hernia repair with synthetic mesh. *Surgery*. 2013;153(1):120-125.
3. Liang et al, 2015: External Validation of the Ventral Hernia Risk Score for Prediction of Surgical Site Infections, SURGICAL INFECTIONS 16,1, 2015
4. Gray SH et al. Risk of Complications From Enterotomy or Unplanned Bowel Resection During Elective Hernia Repair, *Arch Surg*. 2008
5. DeNoto G III, Nancy Reaven, Susan Funk, Ventral hernia: retrospective cost analysis of primary repair, repair with synthetic mesh, and repair with acellular xenograft implant. Open Access Surgery. 30th May 2013.
6. Hawn MT, Gray SH, Snyder CW, Graham LA, Finan KR, Vick CC. Predictors of mesh explantation after incisional hernia repair. *Am J Surg*. 2011;202(1):28-33
7. Luijendijk RW, et al. A comparison of suture repair with mesh repair for incisional hernia. *NEJM*. 2000;343(6):392-3982
8. Burger JW, et al. Long-term follow-up of a randomized controlled trial of suture versus mesh repair of incisional hernia. *J Ann Surg*. 2004;240(4):578-583
9. Booth JH, Garvey PB, Baumann DP, Selber JC, Nguyen AT, Clemens MW, Liu J, Butler CE. Primary facial closure with mesh reinforcement is superior to bridged mesh repair for abdominal wall reconstruction. *J Am Coll Surg*. 2013 September.
10. Condé-Green A, Chung TL, Holton LH 3rd, Hui-Chou HG, Zhu Y, Wang H, Zahiri H, Singh DP. Incisional Negative-Pressure Wound Therapy versus Conventional Dressings Following Abdominal Wall Reconstruction: A Comparative Study. *Ann Plast Surg*. 2013 Oct;71(4):394-397.
11. Golla, D, Russo, C. Outcomes following Placement of Non-Cross-Linked Porcine-Derived Acellular Dermal Matrix in Complex Ventral Hernia Repair. *Int Surg* 2014;99:235–240.
12. Guerra O, Maclin MM. Non-crosslinked porcine-derived acellular dermal matrix for the management of complex ventral abdominal wall hernias: a report of 45 cases. *Hernia*. 2013 Aug 10.
13. Liang MK, Berger RL, Nguyen MT, Hicks SC, Li LT, Leong M Outcomes with PADM versus Synthetic Mesh and Suture in Complicated OVHR. *S Inf*. 2014 Sept.
14. Patel KM, Albino FP, Nahabedian MY, Bhanot P. Critical analysis of STRATTICE performance in complex abdominal wall reconstruction: intermediate-risk patients and early complications. *Int Surg*. 2013 Oct-Dec;98(4):379-84.
15. Richmond B,Ubert A, Judhan R, King J, Harrah T, Dyer B, Thompson S. Component separation with porcine acellular dermal reinforcement is superior to traditional bridged mesh repairs in the open repair of significant midline ventral hernia defects. *Am Surg* 2014 Aug;80(8):725-31.
16. Skipworth JR, Vyas S, Uppal L, Floyd D, Shankar A. Improved Outcomes in the Management of High-Risk Incisional Hernias Utilizing Biological Mesh and Soft-Tissue Reconstruction: A Single Center Experience. *World J Surg*. 2014
17. 2014 American Hernia Society Abstract "Histological Profile of a Porcine Acellular Dermal Matrix (STRATTICE™) 31 and 38 Months After Implantation: Two Clinical Case Reports" M. Sawyer, Comanche County Hospital, Lawton, OK and P.G. De Deyne, LifeCell Corporations, Branchburg, NJ.
18. STRATTICE™ Reconstructive Tissue Matrix clinical case study: Gross and histologic examination of STRATTICE™ Reconstructive Tissue Matrix three years postimplantation. Mike K. Liang, MD, University of Texas Health Sciences Center, Houston, TX, MLC3819-R1/4065/11-2013.
19. Connor J, et al. Retention of structural and biochemical integrity in a biological mesh supports tissue remodeling in a primate abdominal wall model. *Regenerative Medicine*. 2009 4(2), 185-195.
20. Sandor M, et al. Host response to implanted porcine-derived biologic materials in a primate model of abdominal wall repair. *Tissue Eng Part A*. 2008 Dec;14(12):2021-31.
21. Breuing K. et al, Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. *Surgery*. 2010 Sep;148(3):544-58.
22. Itani K, et al. Prospective Clinical Study Evidence of Safe, Single-Stage Repair of Infected/Contaminated Abdominal Incisional Hernias Using STRATTICE™ Reconstructive Tissue Matrix. *Hernia*. 2009;13(1):S1-S32):S28.
23. Rosen M.J., et al. A novel approach for the simultaneous repair of large midline incisional and parastomal hernias with biological mesh and retrorectus reconstruction. *The American Journal of Surgery* (2010) 199,416-421.
24. Skipworth JRA, et al. Mesh repair of complex, incisional hernias, utilizing soft tissue reconstruction & biological mesh insertion: a consecutive, single-team experience. *Hernia* (2011) 15 (Suppl 2): S37-S66, P066
25. McCullough JA, et al. Component separation supported by STRATTICE mesh in the repair of contaminated ventral hernias. Colorectal Disease. The Association of Coloproctology of Great Britain and Ireland. 13(Suppl. 6), 28-62, P253

Essential Prescribing Information for STRATTICE™ Reconstructive Tissue Matrix

Device Description

STRATTICE™ Reconstructive Tissue Matrix (STRATTICE™ Tissue Matrix or STRATTICE™ surgical mesh) is a surgical mesh that is derived from porcine skin and is processed and preserved in a patented aqueous phosphate buffered solution containing matrix stabilizers. STRATTICE™ TM is intended to perform as a surgical mesh for soft tissue repair while presenting a scaffold to the patient's tissue. The structural properties minimize tissue attachment to the mesh. The STRATTICE™ surgical mesh consists of a sterilized sheet of processed porcine dermis provided in prescribed different sizes, dimensions, and thicknesses and packaged in a double pouch.

Use of the surgical mesh provides for a strong and biocompatible implant and will incorporate into the patient's tissue with associated cell and microvascular ingrowth.

Animal studies show a low incidence of adhesion to the STRATTICE™ surgical mesh based on observation of minimal visceral tissue attachment.

Indications

STRATTICE™ surgical mesh 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.

It is indicated to be used to reconstruct, to recontour and to reform the host's human soft connective tissue particularly where loss of tissue has occurred and as a supporting tissue in surgical procedures such as abdominal wall hernia repairs and breast reconstruction.

STRATTICE™ surgical mesh is supplied sterile and is intended for single patient one-time use.

Contraindications

- This surgical mesh is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- Polysorbate 20 is a component of the aqueous phosphate buffered solution and therefore STRATTICE™ surgical mesh should not be used in patients with a known sensitivity to this material.

Warnings

- Do not resterilize.
- Do not use if the package is opened or damaged. Do not use if seal is broken or compromised. Do not use if the temperature monitoring device does not display "OK".
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practices and applicable national and regional environmental laws on disposal of packaging and biological materials.
- STRATTICE™ surgical mesh cannot be reused once it has been removed from the packaging and/or is in contact with a patient without increased risk of patient-to-patient contamination and subsequent infection.

Precautions

- Discard surgical mesh if handling has caused possible damage or contamination.
- Discard surgical mesh if it is past the use-by-date of the product (indicated as 4 digit year, 2 digit month, and 2 digit day [YYYY-MM-DD]).
- Ensure that the surgical mesh is put into a sterile basin and covered with room temperature sterile saline or room temperature sterile lactated Ringer's solution for a minimum of 2 minutes prior to implantation.
- Place surgical mesh in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- The STRATTICE™ surgical mesh should be hydrated and moist when the package is opened. If the STRATTICE™ surgical mesh is dry, do not use.
- In significantly contaminated or infected cases, utilize bioburden-reducing techniques to minimize contamination levels at the surgical site, including, but not limited to, appropriate drainage, debridement, negative pressure therapy, and/or antimicrobial therapy prior and in addition to implantation of the STRATTICE™ surgical mesh. (Presence of a significant microbial load may impact overall performance of the surgical mesh.)
- Large hernia defects and a bridging mesh technique are risk factors for hernia recurrence. Likewise, in large abdominal wall defect cases where midline fascial closure cannot be obtained, with or without separation of components techniques, utilization of STRATTICE™ Tissue Matrix in a bridged fashion is associated with a higher risk of hernia recurrence than when used to reinforce fascial closure.
- Certain considerations should be made in order to reduce the risk of adverse events when performing surgical procedures using a surgical mesh such as STRATTICE™ Tissue Matrix. Please see the following sections for more information: Product/Patient Selection, Technique Guidance, and Post-Operative Care.

Adverse Events

Potential adverse events are those typically associated with surgical mesh materials and/ or their implantation procedures including, but not limited to, infection, foreign body response, hematoma, seroma formation, failure to integrate, recurrence of tissue defect, bulging, fistula formation, lack of tissue perfusion, inflammation, wound dehiscence and adhesion formation.

Storage

- The STRATTICE™ surgical mesh is a sterile medical device that should be stored in a clean, dry location at -8°C to 30°C.
- Refer to the temperature monitor located on the product carton to ensure that product has been stored within its temperature limits. Only use the product if the included temperature monitor displays "OK" on the screen. If screen displays anything other than "OK," do not use the product*.
- It is to be stored in its original packaging.
- The use-by-date of the product is indicated as 4 digit year, 2 digit month, and 2 digit day (YYYY-MM-DD).

Ordering Information

Product Code	Product Size	Version	Coverage (sq cm)
1010002EU	10x10cm	Firm	100
1016002EU	10x16cm	Firm	160
1025002EU	10x25cm	Firm	250
1620002EU	16x20cm	Firm	320
1525002EU	15x25cm	Firm	375
2020002EU	20x20cm	Firm	400
2025002EU	20x25cm	Firm	500
2030002EU	20x30cm	Firm	600
2040002EU	20x40cm	Firm	800
1530002EU	15x30cm	Firm	450
2540002EU	25x40cm	Firm	1000

STRATTICE™ Reconstructive Tissue Matrix (STOMA)

Product Code	Product Size	Coverage (sq cm)
0606008EU	6x6cm (X-cut)	36
0610008EU	6x10cm	60
0808008EU	8x8cm (X-cut)	64

medical

Allergan