Strattice™
RECONSTRUCTIVE TISSUE MATRIX

Strattice™ Reconstructive Tissue Matrix

A clinically proven approach to challenging abdominal wall repair.

Now that's
Biological

Artist's Rendering

LifeCell™
An Acelity Company

A clinically proven option for complex patients

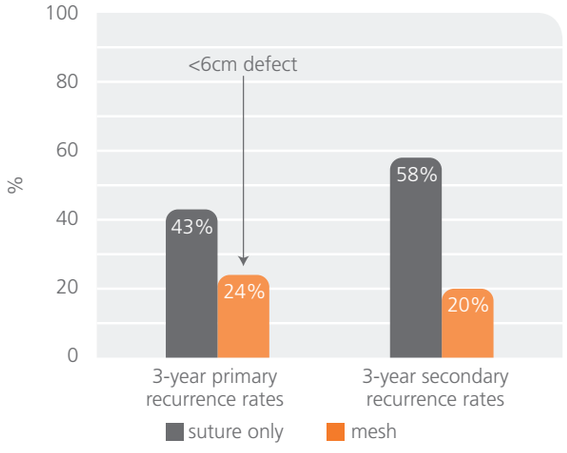
Now you can perform single-stage abdominal repair even with challenging patients, depending on risk profile.

Traditional methods may not always be sufficient.[1]

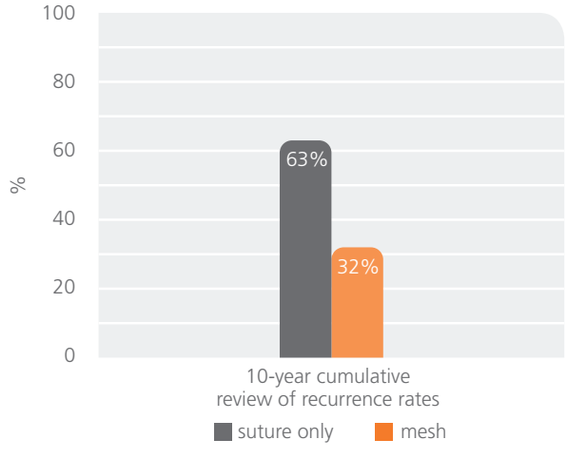
Not all repairs can be conducted the same. Advanced techniques in combination with Strattice™ Reconstructive Tissue Matrix can provide the option of single-stage repair. [11,19, 20]

>> Suture repair only

Data shows suture alone is not sufficient even in simple repairs. [2,3]



[2.] Luijendijk RW,, et al. NEJM 2000



[3.] Burger JW, et al. Am Surg 2004

>> Synthetic mesh

While synthetic mesh shows decreased recurrence, it may not be appropriate due to the risk of infectious complications.[1,6,7,8]

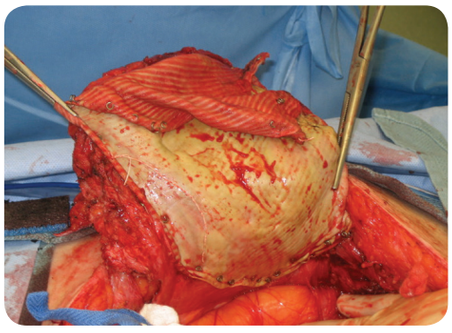
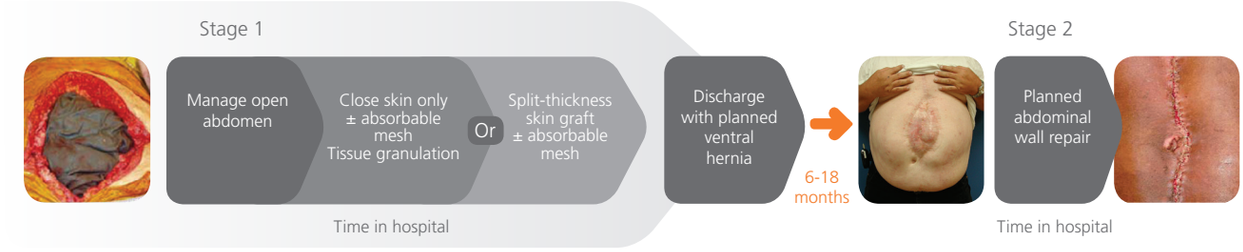


Photo courtesy of Richard Miller, MD, Nashville, Tennessee, USA

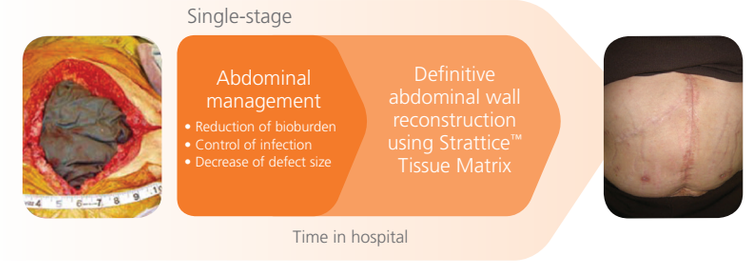
>> Two-stage repair when synthetics are not appropriate‡ [1, 22, 30, 31]

A two-stage repair is a temporary solution for a challenging situation. The second complex surgery carries additional risks.



Strattice™ (TM) offers more options to address unique needs

>> Single-stage with Strattice™ Tissue Matrix‡



Discharge with functional abdominal wall

‡ Photos courtesy of Richard Miller, MD, Nashville, Tennessee, USA; Michael Rosen, MD, Cleveland, Ohio, USA; Dan Vargo, MD, Salt Lake City, Utah, USA; Joe Patton, MD, Detroit, Michigan, USA; Bradford Scott, MD, Houston, Texas, USA. Photos are examples only and do not represent individual patients.

Identifying the Strattice™ Tissue Matrix patient

Abdominal Wall Defects Grading System[1]

Infected mesh commonly results in a second procedure for removal[4]

Grade 4: Infected
Active infection • Infected mesh

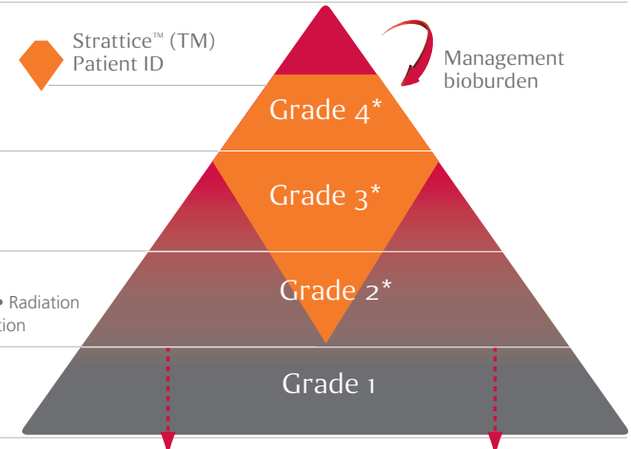
Open incisional hernias are 10x more likely to have infection than a clean surgical case[5]

Grade 3: Contaminated
Stoma present • Violation of GI tract
History of mesh infection • Existing open wound

Patients with comorbid conditions have up to 4x increase in wound-infection rates[6,7]

Grade 2: Increased risk
Smoker • Immunosuppressed • Obese • Diabetic • Radiation
History of mesh infection • Hypoxemia • Malnutrition

Grade 1: Low risk
Healthy • Uncomplicated • No history of infection



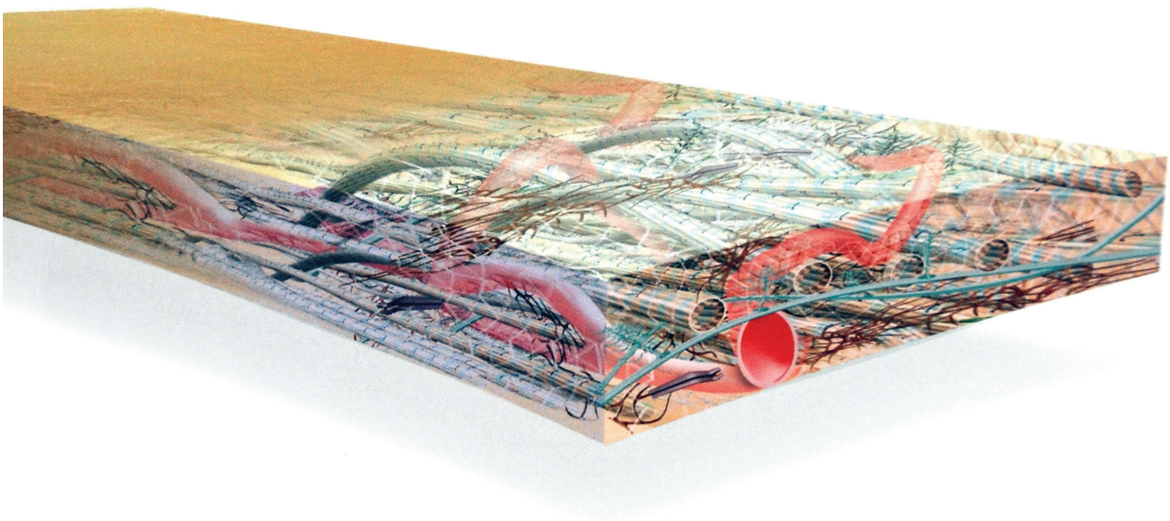
The ideal repair material provides

Reduced risk of infection • Strong repair

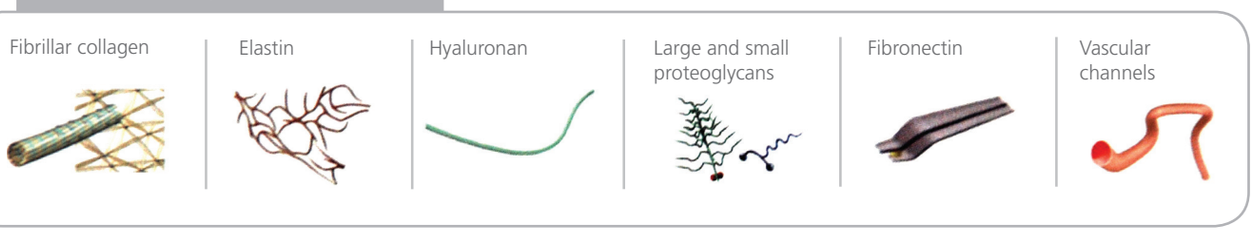
The biological benefits

Preservation of intact extracellular matrix is key to supporting regeneration.

Strattice™ Tissue Matrix is derived from porcine dermis and undergoes non-damaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response (alpha- 1,3-Gal epitope).[9] It has been shown to provide single-stage definitive repair in the face of contamination or infection.[11,19,20]



Key components:



"The use of permanent prosthetic mesh in the presence of contaminated operative fields yields a significant increase in mesh explantation and subjects patients to further operations to treat mesh complications." – M.T. Hawn et al., 2011[8]

Benefit: Allows rapid revascularization, cell repopulation and white cell migration[9]

2 weeks[9]

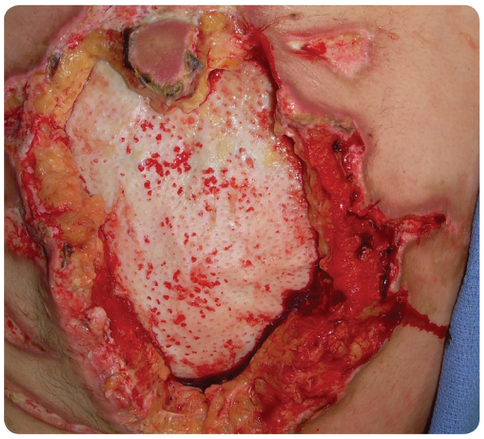
Vessel formation and cell repopulation observed

6 months[9]

Mature vascular structure observed

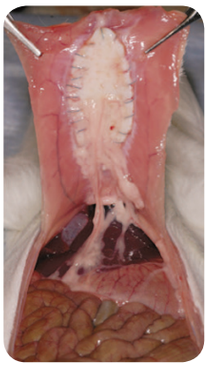
H&E stain 200x. Explant assessment histology of primate model. Correlation of these results to results in humans is not established.[9,14]

Benefit: Allows for local treatment in the setting of infection and implant exposure[11]

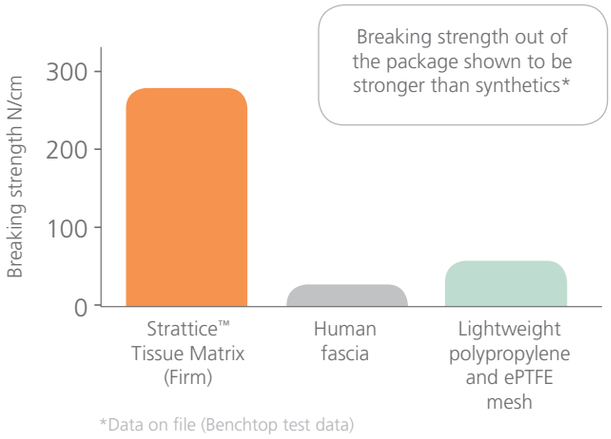


Strattice™ Tissue Matrix in a human patient was vascularized as evidenced by its bleeding when rubbed with forceps two weeks post implantation. Note: Patient results may vary. Photo courtesy of Ronald Silverman, MD, Baltimore, Maryland.

Benefit: Minimizes adhesions to implant[12]



Representative repair after 4 weeks after repair with Strattice™ Tissue Matrix in a guinea pig model



*Data on file (Benchtop test data)

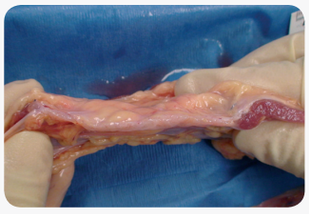
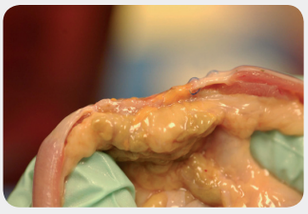
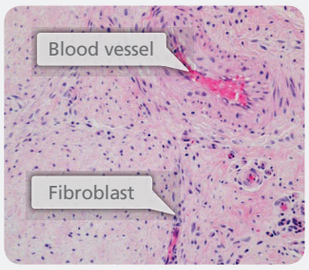
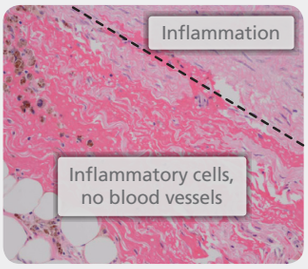
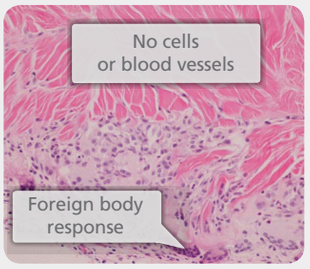
Benefit: Provides for strong repair supported by its excellent biomechanical strength[9,10]

The science

Strattice™ Tissue Matrix is unique among other biologics[13,14]

Old World Primate Study, which are 92% genomically homologous to humans

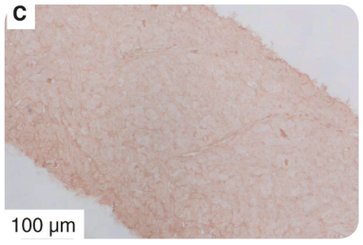
Mechanisms of action

	Strattice™ Reconstructive Tissue Matrix	Denatured porcine tissue	Cross-linked porcine tissue
Immunologic response	Positive recognition[14] (Body recognizes as self)	Negative recognition[13] (Body recognizes as foreign)	
Mechanisms of action	**Regeneration** Body accepts and integrates the intact tissue matrix as part of the host through rapid revascularization, white cell migration and cell repopulation.	**Resorption** Body attacks the damaged tissue to break it down and eliminate it.	**Encapsulation** Body attacks the cross-linked tissue to extrude or wall it off from the host.
6-month gross observations and histology			
			
Study outcomes	Rapid revascularization strong repair	Resorbs leading to contracture and scarring	Does not incorporate into surrounding tissue

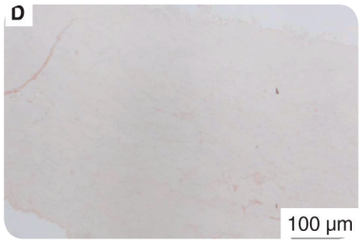
H&E stain 200x. Explant histology and gross observation of cross-sectional view of abdominal wall explant in animal model. Correlation of these results to results in humans is not established.

Minimized immune response due to significant reduction of the alpha-1,3-Gal epitope[9]

Porcine dermis

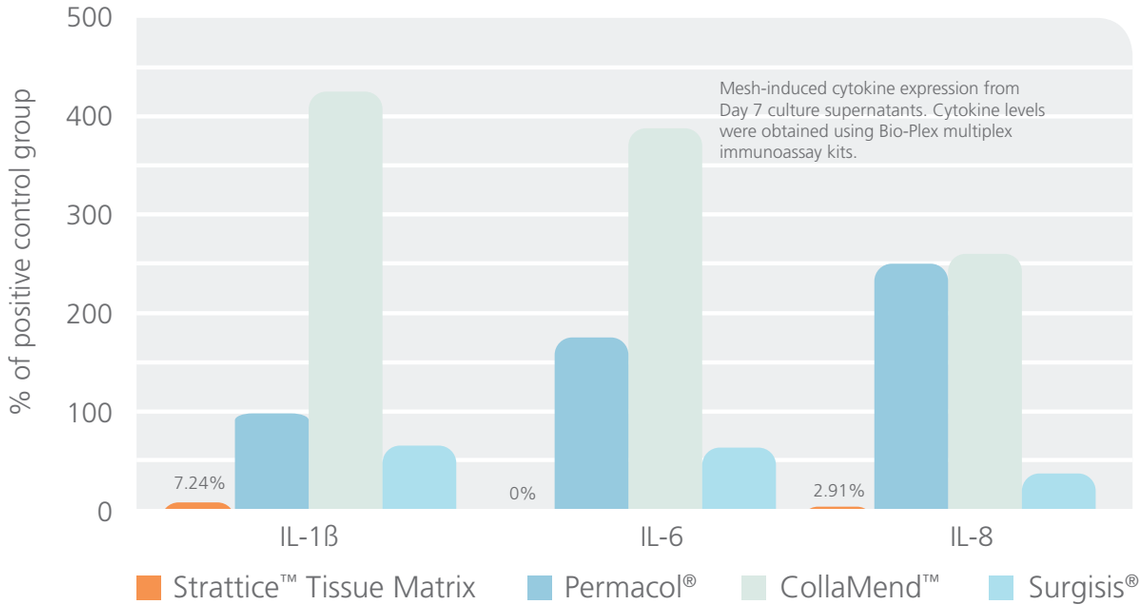


Strattice™ (TM)



[13] Sandor M et al., 2008 / 9. Connor et al., 2009. Correlation of primate study results to results in humans has not been established.

In-vitro monocyte activation[27]



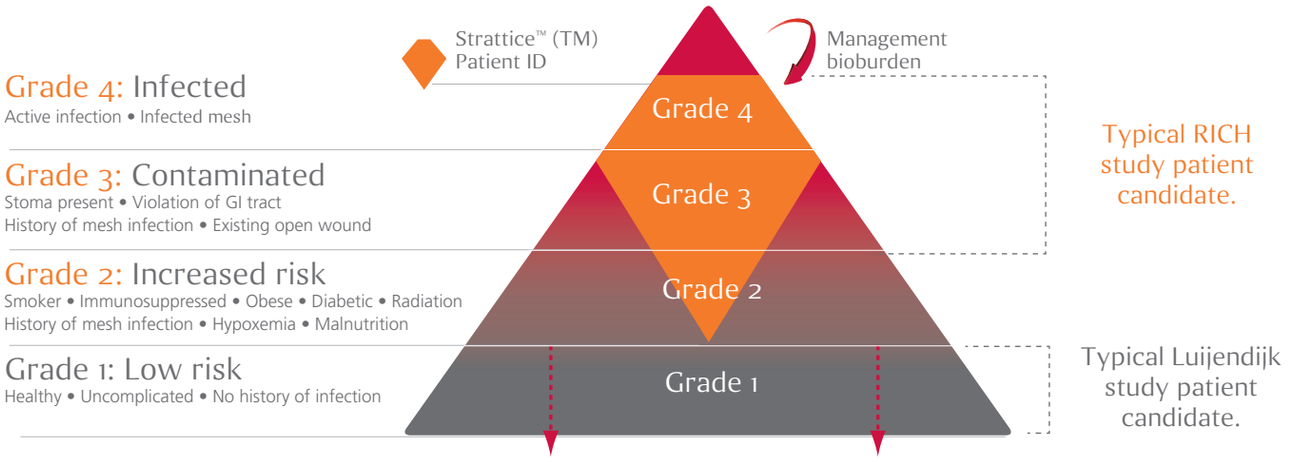
The data above have been normalized to the positive control group. Samples of four acellular porcine-derived meshes, Strattice™ Tissue Matrix (LifeCell™), Permacol® (TSL/Covidien), CollaMend™ (C.R. Bard/Davol), and Surgisis® (Cook® Biotech), were exposed to mononuclear cells derived from the peripheral blood of six healthy subjects. Following a seven-day incubation period, supernatants were assayed for interleukin-1beta (IL-1b), interleukin-6 (IL-6) and interleukin-8 (IL-8) using a multiplex bead-based immunoassay system. The groups were compared using analysis of variance (ANOVA) and Student's t-test.[27]

"...in vivo results observed for these mesh products are a direct consequence of specific manufacturing processes that yield modified collagen matrices. The resulting loss of biological and structural integrity elicits a foreign body response while hindering normal healing and tissue integration." – Sandor, et al[13]

Proven Clinically[11,17,19,20,28]

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.[1] 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

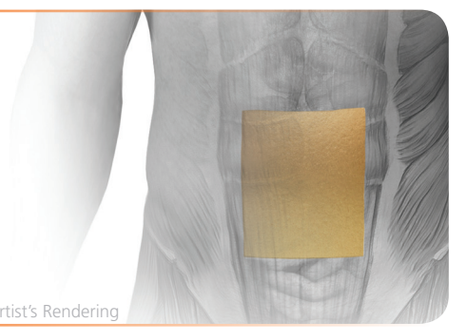
	Luijendijk, et al.[2]	The RICH study[11]
Number of prior repairs	0-1	1-6
BMI median	26.2	30.9
Hernia defect median (cm^2)	24	220
Signs of contamination or infection	excluded	required
Recurrence rate at 12 months	**17%**	**19%**

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.[2] study of relatively small, clean hernia defects.

RICH study[11]

"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™ (TM) explanted."

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


Artist's Rendering

** Quotes from interviews with RICH study investigators 2010

Clinically proven techniques

Strattice™ Tissue Matrix provides a clinically proven option for challenging patients.

Single-stage definitive repair leads to improved patient quality of life, compared to delayed reconstruction[21,22]

Fig 1 Patient presented with a large hernia

Fig 2 The large defect could not be closed primarily

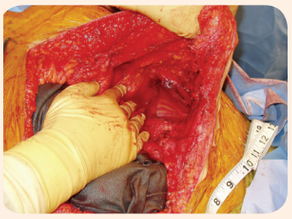


Fig 3 Component separation performed on patient's left side

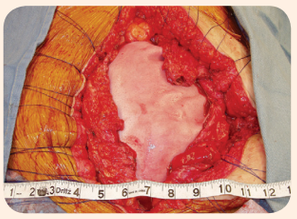


Fig 4 Strattice™ Tissue Matrix sutured in place as an underlay with interrupted mattress sutures

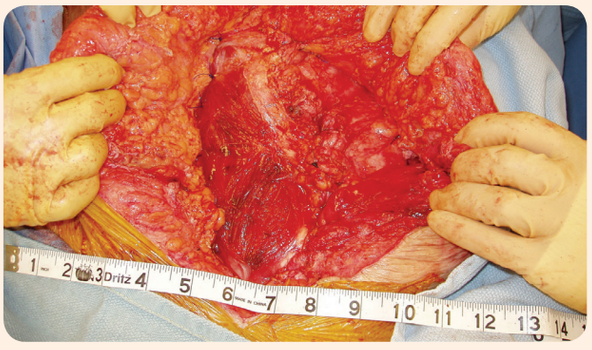


Fig 5 Midline reapproximation accomplished without tension

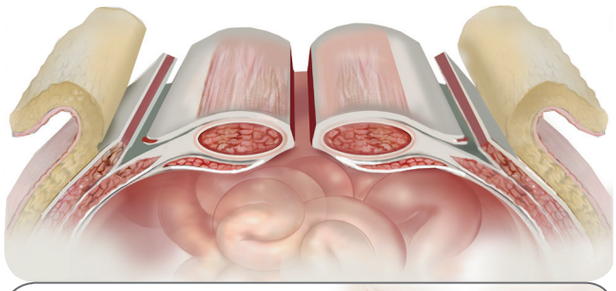
Fig 6 The patient was examined at months 1, 2, and 3 and healing progressed well

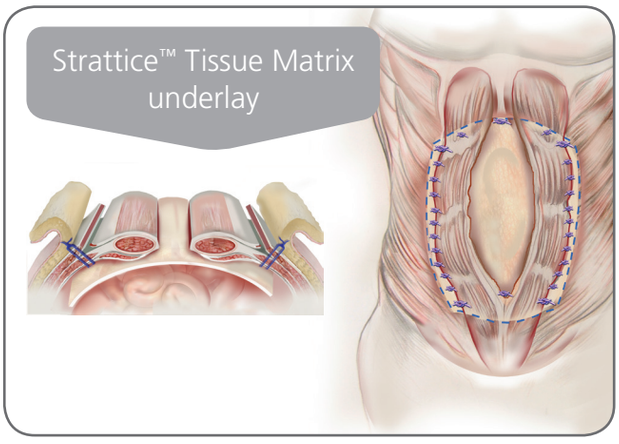
Courtesy of Michael Rosen, MD - Cleveland, Ohio, US. Case report (MLC 934)

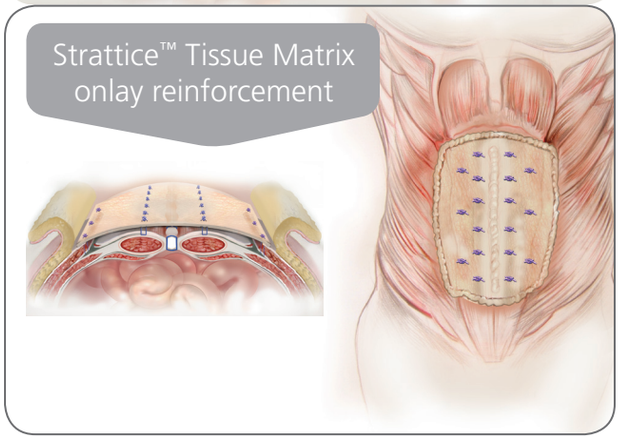
Clinically proven techniques to restore structure, function, and physiology[18,26]

Component separation – Ramirez Technique

- Can allow up to 10 cm mobility on each side[18]
- Can help centralize rectus muscles to allow for primary closure or significantly decrease size of defect







Considerations

- Use bioburden-reducing techniques to minimize contamination levels at the surgical site
- Reapproximate rectus muscles to midline whenever possible and use Strattice™ Tissue Matrix as an onlay or underlay to relieve tension and reinforce primary fascial closure.
- At a minimum, reduce the size of the defect as much as possible
- If primary closure is not achievable underlay Strattice™ Tissue Matrix at least 3-5 cm or as far as required to reach healthy tissue
- Suture Strattice™ Tissue Matrix under physiologic tension to ensure laxity is removed
- Use permanent sutures
- Liberal use of drains is recommended (e.g. three drains to maximize contact with vascular tissue)

Ordering information

	Product size	Product code	Product size	Product code
Strattice™ Reconstructive Tissue Matrix Firm	6x16 cm 16x20 cm 10X25 cm 20x25 cm	0616002EU 1620002EU 1025002EU 2025002EU	10x16 cm 20x20 cm 15x25 cm	1016002EU 2020002EU 1525002EU
Strattice™ Reconstructive Tissue Matrix STOMA/Firm	6x6 cm (X-cut) 6x10 cm	0606008EU 0610008EU	8x8 cm (X-cut) 10x10 cm	0808008EU 1010002EU

Strattice™ Reconstructive Tissue Matrix offers you a clinically proven option to manage your challenging abdominal wall repair patients.

Strattice™ Tissue Matrix demonstrated low recurrence rate and no graft removal in challenging abdominal wall repairs,[11] allowing for a safe and effective alternative for suture or staged repair and without the complications associated with synthetic mesh

References:

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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.

LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
USA
Tel: +1 908 947 1100

www.lifecell.com

LifeCell EMEA Ltd.
4650 Kingsgate
Cascade Way
Oxford Business Park South
Oxford OX4 2SU, United Kingdom
Tel: 00800 200 80 400
Email: contact@lifecell.com

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