Patients can be complex, procedures can be complex...

Why would you risk using anything other than Strattice™ Reconstructive Tissue Matrix in your Complex Abdominal Wall Repair patients?
With a risk of surgical site complications, explantation and recurrence...

Why would you risk using anything other than Strattice™ Reconstructive Tissue Matrix in your Complex AWR patients like us?
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 outcomes¹

Studies have demonstrated that there is an increased risk of postoperative complications in patients with¹:

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

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

---


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

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

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$^3$.

- **Large skin flaps**
  - Photo courtesy Michael K. Liang, MD
  - DeBakey VA Medical Center

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

- **Incidental hernia**
  - Photo courtesy Devinder Singh, MD
  - University of Maryland, Baltimore, MD

- **Fascial release**
  - Photo courtesy Ron Silverman, MD
  - University of Maryland, Baltimore, MD

- **58.6%**
  - Elevating skin flaps

- **55%**
  - Incidental hernia

- **43.2%**
  - Fascial release

- **27%**
  - Concomitant procedures

Choosing the right product for repair from the start is paramount to reaching a favorable outcome.
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 repair⁴

Use of synthetic mesh may result in unintended consequences including: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 explantation⁶

* 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).
The economic impact of lightweight synthetic mesh

Cost per event

$7,590

Index event: 46-year-old male undergoes primary epigastric hernia repair with composite mesh

$40,823

Composite mesh explanted and repaired with lightweight synthetic mesh in the retrorectus plane

$10,120

Post-op infection managed outpatient

$43,335

Patient develops a postoperative enterococcal wound infection with chronic wound drainage

$74,056

Infected lightweight synthetic mesh explanted

$30,721*

Composite mesh explanted and repaired with lightweight synthetic mesh in the retrorectus plane

$2,512*

Post-op infection managed outpatient

$30,721*

Post-op infection managed outpatient

$2,512*

Post-op infection managed outpatient

$7,590*

Index event: 46-year-old male undergoes primary epigastric hernia repair with composite mesh

May 2012

May-June 2012

September 2012

October 2012

April 2013

Case example provided by George DeNoto III, MD FACS, Chief Division of General Surgery at St. Francis Hospital, Roslyn, NY & Clinical Associate Professor of Surgery, Hofstra North Shore-Long Island Jewish School of Medicine.

‡ 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\(^6,7\)


---

**Strattice™ TM reinforcement combined with primary fascial closure reported an average hernia recurrence rate <10% in 446 CAWR patients up to 34 months post-implantation in 8 recent articles\(^9-16\)**

---

**3-year primary recurrence rates**

- Suture only: 43%
- Mesh: 24%

Clean wounds < 6cm\(^2\) defects

**10-year cumulative review of recurrence rates**

- Suture only: 63%
- Mesh: 32%

Clean wounds < 6cm\(^2\) defects

---

**Table:**

<table>
<thead>
<tr>
<th>Study</th>
<th>N = patients</th>
<th>Follow-up (months)</th>
<th>Recurrence rate</th>
<th>Defect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Booth(^9)</td>
<td>120 pts (&gt;80% primary fascial closure)</td>
<td>31 mean</td>
<td>8%*†</td>
<td>14.05cm</td>
</tr>
<tr>
<td>Condé-Green(^10)</td>
<td>56 pts (100% primary fascial closure)</td>
<td>15 mean</td>
<td>7%</td>
<td>NR</td>
</tr>
<tr>
<td>Golla(^11)</td>
<td>47 pts (100% primary fascial closure)</td>
<td>34 median</td>
<td>6%</td>
<td>NR</td>
</tr>
<tr>
<td>Guerra(^12)</td>
<td>44 pts (&gt;90% primary fascial closure)</td>
<td>17 mean</td>
<td>5%*</td>
<td>NR</td>
</tr>
<tr>
<td>Liang(^13)</td>
<td>40 pts (&gt;90% primary fascial closure)</td>
<td>34 median</td>
<td>7.5%</td>
<td>NR</td>
</tr>
<tr>
<td>Patel(^14)</td>
<td>41 pts (&gt;90% primary fascial closure)</td>
<td>15 mean</td>
<td>0%</td>
<td>14.30cm</td>
</tr>
<tr>
<td>Richmond(^15)</td>
<td>40 pts (88% primary fascial closure)</td>
<td>33.1 median</td>
<td>13.2%</td>
<td>16.80cm</td>
</tr>
<tr>
<td>Skipworth(^16)</td>
<td>58 pts (90% primary fascial closure)</td>
<td>17 mean</td>
<td>5%</td>
<td>13.67cm</td>
</tr>
</tbody>
</table>

* Recurrences reported are in pts with primary fascial closure only
† Recurrence rate reported for all products (Strattice n 120/220)  
‡ Outcomes from matched PADM vs Synthetic cohort only
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\textsuperscript{17}

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

Biopsies taken from Strattice™ Tissue Matrix demonstrated neovascularization and collagen deposition with minimal foreign body reaction after 36 months.\textsuperscript{18}

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.
Since 1994, LifeCell has been a pioneer and is today the market 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 critical biochemical and biomechanical integrity of biological tissue.

**Immunologic response**

<table>
<thead>
<tr>
<th>Positive Recognition&lt;sup&gt;19&lt;/sup&gt;</th>
<th>Negative Recognition&lt;sup&gt;19&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Body recognizes as self)</td>
<td>(Body recognizes as foreign)</td>
</tr>
</tbody>
</table>

**Mechanism of action**

<table>
<thead>
<tr>
<th>Encapsulation</th>
<th>Resorption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body attacks the cross-linked tissue to extrude or wall it off from the host.</td>
<td>Body attacks the damaged tissue to break it down and eliminate it.</td>
</tr>
</tbody>
</table>

**Regeneration**

Body accepts and integrates the intact tissue matrix as part of the host through rapid revascularization, white cell migration and cell repopulation.

**Denatured porcine tissue**

<table>
<thead>
<tr>
<th>Foreign body giant cell</th>
</tr>
</thead>
</table>

**Cross-linked porcine tissue**

<table>
<thead>
<tr>
<th>No cells or blood vessels</th>
</tr>
</thead>
</table>

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.*
Matrices perform equally of the tissue, which is critical for regeneration and leads to 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

**Blood vessel**

**Fibroblast**

**Foreign body giant cell**

**No cells or blood vessels**

**Foreign body response**

### Tissue processing

- Extracellular matrix is preserved and intact

### Clinical outcomes/Biological performance

- Rapid revascularization
- Strong repair

- Damaged matrix
- Foreign antigens

- Chemically cross-linked

- Similar to resorbable synthetics
  - Inflammation
  - Infiltration with inflammatory cells
  - Replacement with scar

- 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.*
Strattice Tissue Matrix
a proven product in VHR

Strattice™ Reconstructive Tissue Matrix is the industry leader for biologics in Complex Abdominal Wall Reconstruction

Studied in more than
1700 patients*†

Clinical experience
>70 peer reviewed publications*†

Explantation reported
<1%
in all peer-reviewed Complex AWR publications*†

And the most studied

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

<table>
<thead>
<tr>
<th>Product</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strattice™ TM</td>
<td>1600</td>
</tr>
<tr>
<td>Permacol™</td>
<td>1300</td>
</tr>
<tr>
<td>SurgiMend™</td>
<td>500</td>
</tr>
<tr>
<td>XenMatrix™</td>
<td>170</td>
</tr>
<tr>
<td>Surgisis® Biodesign™</td>
<td>100</td>
</tr>
<tr>
<td>XCM Biologic®</td>
<td>50</td>
</tr>
<tr>
<td>MatriStem®</td>
<td>20</td>
</tr>
</tbody>
</table>

* Searches performed on PubMed, Google, Google Scholar and ScienceDirect® in September 2014.
† Each study was considered independent during calculation. Studies may contain overlapping patient populations.
If you are concerned about your patient developing a postoperative wound complication, strengthen your odds with...

**STRATTICE™ RECONSTRUCTIVE TISSUE MATRIX**

References:


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 StratticeTM Reconstructive Tissue Matrix three years postimplantation. Mike K. Liang, MD, University of Texas Health Sciences Center, Houston, TX, MLC3819-R1/4065/11-2013.

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 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.
<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Size</th>
<th>Version</th>
<th>Coverage (sq cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5510009</td>
<td>5.5 x 10 cm</td>
<td>Pliable (Pre-Shaped)</td>
<td>47.5</td>
</tr>
<tr>
<td>0608001</td>
<td>6 x 8 cm</td>
<td>Pliable</td>
<td>48</td>
</tr>
<tr>
<td>0613009</td>
<td>6 x 13 cm</td>
<td>Pliable (Pre-Shaped)</td>
<td>70</td>
</tr>
<tr>
<td>0516001</td>
<td>5 x 6 cm</td>
<td>Pliable</td>
<td>80</td>
</tr>
<tr>
<td>0815009</td>
<td>8 x 15 cm</td>
<td>Pliable (Pre-Shaped)</td>
<td>107</td>
</tr>
<tr>
<td>0816001</td>
<td>8 x 16 cm</td>
<td>Pliable</td>
<td>128</td>
</tr>
<tr>
<td>0606002</td>
<td>6 x 6 cm</td>
<td>Firm</td>
<td>36</td>
</tr>
<tr>
<td>0610008</td>
<td>6 x 10 cm</td>
<td>Firm</td>
<td>60</td>
</tr>
<tr>
<td>0808002</td>
<td>8 x 8 cm</td>
<td>Firm</td>
<td>64</td>
</tr>
<tr>
<td>0616002</td>
<td>6 x 16 cm</td>
<td>Firm</td>
<td>96</td>
</tr>
<tr>
<td>1010002</td>
<td>10 x 10 cm</td>
<td>Firm</td>
<td>100</td>
</tr>
<tr>
<td>1016002</td>
<td>10 x 16 cm</td>
<td>Firm</td>
<td>160</td>
</tr>
<tr>
<td>1020002</td>
<td>10 x 20 cm</td>
<td>Firm</td>
<td>200</td>
</tr>
<tr>
<td>1025002</td>
<td>10 x 25 cm</td>
<td>Firm</td>
<td>250</td>
</tr>
<tr>
<td>1620002</td>
<td>16 x 20 cm</td>
<td>Firm</td>
<td>320</td>
</tr>
<tr>
<td>1525002</td>
<td>15 x 25 cm</td>
<td>Firm</td>
<td>375</td>
</tr>
<tr>
<td>2020002</td>
<td>20 x 20 cm</td>
<td>Firm</td>
<td>400</td>
</tr>
<tr>
<td>1530002</td>
<td>15 x 30 cm</td>
<td>Firm</td>
<td>450</td>
</tr>
<tr>
<td>2025002</td>
<td>20 x 25 cm</td>
<td>Firm</td>
<td>500</td>
</tr>
<tr>
<td>2030002</td>
<td>20 x 30 cm</td>
<td>Firm</td>
<td>600</td>
</tr>
<tr>
<td>2040002</td>
<td>20 x 40 cm</td>
<td>Firm</td>
<td>800</td>
</tr>
<tr>
<td>3030002</td>
<td>30 x 30 cm</td>
<td>Firm</td>
<td>900</td>
</tr>
<tr>
<td>2540002</td>
<td>25 x 40 cm</td>
<td>Firm</td>
<td>1000</td>
</tr>
</tbody>
</table>

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

**CONTRAINDICATIONS**
Strattice is derived from a porcine source and should not be used in patients with known sensitivity to porcine material, or in patients with a known sensitivity to Polysorbate 20.

Visit [www.lifecell.com](http://www.lifecell.com) and contact your LifeCell representative for more information.