XenMatrix™ Surgical Graft
Regenerative Collagen Matrix


SOFT TISSUE REPAIR
Right Procedure. Right Product. Right Outcome.
Demonstrated Performance

XenMatrix™ Grafts are created using the patented AquaPure™ Process which effectively removes cells while maintaining the structure and strength of the graft. The resulting open collagen scaffold allows early cellular infiltration and revascularization without a significant loss of strength during the early healing period.¹

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**Structure**
- Acellular non-cross-linked porcine collagen scaffold
- Open collagen structure allows early cellular infiltration and revascularization¹

**Strength**
- Demonstrated mechanical strength²
- Maintains strength throughout the initial healing period¹

**Performance**
- Peer-reviewed clinical data
- 31 articles published in peer-reviewed journals since 2009³

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¹ Preclinical clinical data on file, results may not correlate to clinical performance.
³ Literature Search: Clinical publications with XenMatrix Surgical Graft, published in last 5 years through 8/13, performed on Google Scholar and PubMed. Inclusion criteria, all preclinical and clinical studies published in peer-reviewed journals.

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Unique XenMatrix™ Surgical Graft open collagen scaffold.

Representative Illustration
Demonstrated Porous Structure

XENMATRIX™ Surgical Graft has almost 3x more open space than Strattice™ Firm.¹

![XENMATRIX™ Surgical Graft, H&E Stain 40x, 47% open space](image1)

![Strattice™ Firm, H&E Stain 40x, 16% open space](image2)

Repairing the abdominal wall with a strong, open collagen scaffold allows early remodeling.

Demonstrated Mechanical Strength

Mechanical test data confirmed the performance of the XENMATRIX™ Surgical Graft was above the threshold set by Deeken et al., for absorbable and nonabsorbable barrier composite meshes.²,³,⁴

Peer-Reviewed Data Demonstrated⁵

<table>
<thead>
<tr>
<th>Mesh Type</th>
<th>Thickness (mm)</th>
<th>Suture Retention Strength (N)</th>
<th>Tear Resistance (N)</th>
<th>Ball Burst Strength (N/cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>XENMATRIX™†</td>
<td>1.95 ± 0.012</td>
<td>99.74 ± 7.7</td>
<td>24.5 ± 1.9</td>
<td>377 ± 41.34</td>
</tr>
<tr>
<td>Strattice™ Firm†</td>
<td>1.76 ± 0.012</td>
<td>63.76 ± 4.8</td>
<td>27.54 ± 1.9</td>
<td>270.5 ± 48.91</td>
</tr>
<tr>
<td>SurgiMend™</td>
<td>0.84 ± 0.024</td>
<td>87.85 ± 4.9</td>
<td>27.86 ± 1.0</td>
<td>432.4 ± 14.19</td>
</tr>
<tr>
<td>Veritas™</td>
<td>0.80 ± 0.017</td>
<td>23.92 ± 2.4</td>
<td>15.06 ± 2.2</td>
<td>128.6 ± 8.52</td>
</tr>
</tbody>
</table>

Threshold values suggested as suitable properties for hernia repair applications²,³:

- Suture Retention Strength >20N
- Tear Resistance >20N

Demonstrated Process Impacts Structure and Strength¹,⁵,⁶

AQUAPURE™ Process

TISSUE HARVESTING → TISSUE CLEANSING → CELLULAR MATERIAL REMOVAL → VIRAL INACTIVATION → E-BEAM STERILIZATION

The patented AQUAPURE™ Process effectively transforms raw dermis into an extracellular matrix while maintaining the structure and strength of the graft. XENMATRIX™ Surgical Grafts are the only porcine dermis product for hernia repair that are created using this patented process.

¹ Davol Internal Reports. Bench data may not correlate to clinical use. N=minimum of 10 samples.
⁷ Non-cross-linked porcine dermis.
Demonstrated Preclinical Performance

Study Type
Preclinical Study – 24 male Sprague-Dawley rats* (400-450g)

Objective
Assess the strength over time of the XenMATRIX™ Surgical Graft

Study Design
Central, full thickness 0.5 cm incisional surgical defect was created in the ventral abdominal wall. A 38 mm circular XenMATRIX™ Surgical Graft was fixated directly over the defect with five interrupted 5-0 polypropylene sutures.

Ball burst testing was conducted at T=0, 2 weeks, 8 weeks and 12 weeks.

Results
Confirmed remodeling: XenMATRIX™ Grafts 2 weeks post-implantation in a preclinical model:*

• Early cellular infiltration
• New collagen deposition
• Early blood vessel formation

* Preclinical clinical data on file, results may not correlate to clinical performance.
Demonstrated Remodeling

Preclinical testing confirmed early tissue ingrowth, vascular integration, and incorporation into the ventral abdominal wall.*

Representative necropsy photographs of XenMatrix™ Surgical Grafts at 2, 8 and 12 weeks post-implantation demonstrated tissue ingrowth, vascular integration and incorporation into the ventral abdominal wall.7

Representative histology photographs of XenMatrix™ Surgical Graft at 2, 8 and 12 weeks post-implantation demonstrated early tissue remodeling.7

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Demonstrated Strength Over Time

In preclinical testing the XenMatrix™ Surgical Graft maintains a significant amount of strength during the critical early healing period suggesting it may be well suited for the demands of abdominal wall repair.7

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* Preclinical clinical data on file, results may not correlate to clinical performance.
Published Clinical Performance

**Am J Surg. 2010 Jan;199(1):22-7.**

**Use of a Non-Cross-Linked Porcine Dermal Scaffold in Abdominal Wall Reconstruction.**

Pomahac B, Aflaki P.
Division of Plastic Surgery, Brigham and Women's Hospital, Harvard Medical School, MA 02115, USA.

**Key Points:**
“Because [the XenMatrix™ graft] is non-cross-linked, it facilitates tissue ingrowth and remodeling, while minimizing the risks of encapsulation and fibrotic tissue formation commonly associated with synthetics and biosynthetics.”

**Am Surg. 2011 Feb;77(2):144-50.**

**Repair of High-Risk Incisional Hernias and Traumatic Abdominal Wall Defects with Porcine Mesh.**

Byrnes MC, Irwin E, Carlson D, Campeau A, Gipson JC, Beal A, Croston* JK.
Department of Trauma, North Memorial Medical Center, Robbinsdale, Minnesota 55422, USA.

**Key Points:**
“Complex ventral hernias can be repaired with a low recurrence rate. Our technique in combination with the XenMatrix™ biologic mesh provides for a durable repair.”

**Hernia. 2013 Feb.**

**Abdominal Wall Reconstruction Using a Non-Cross-Linked Porcine Dermal Scaffold: A Follow-Up Study.**

Diaz-Siso JR, Bueno EM, Pomahac B.
Division of Plastic Surgery, Brigham and Women's Hospital, Harvard Medical School, MA 02115, USA.

**Key Points:**
“Our findings suggest that XenMatrix™ is an effective adjunct in the reconstruction of complex abdominal wall defects, resulting in satisfactory outcomes at an average follow-up time of 40.1 months and yielding a low rate of surgical complications.”

**Hernia. 2013 Feb. [Epub ahead of print].**

**Onlay ventral hernia repairs using porcine non-cross-linked dermal biologic mesh.**

Alicuben ET, DeMeester SR.
Department of Surgery, Keck School of Medicine, The University of Southern California, 1510 San Pablo St, Suite 514, Los Angeles, CA 90033, USA.

**Key Points:**
“Porcine non-cross-linked biologic mesh (XenMatrix™) overlay has excellent short-term results. No patients required mesh removal, and there have been no recurrent hernias in patients with primary fascial closure. Biologic bridging is not effective for long-term abdominal wall reconstruction.”

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†Davol Inc. provided financial support in the form of a research fellow salary.

††Data on file at Davol but not published in this study.

*Dr. Croston is a paid consultant for Davol Inc. Brennen Medical LLC, the former manufacturer of the XenMatrix™ Surgical Graft provided support for this study.
## Documented Clinical Results

<table>
<thead>
<tr>
<th>Published in peer-reviewed journal</th>
<th>Population</th>
<th>Types of cases</th>
<th>BMI</th>
<th>Biologic graft placement</th>
<th>Average defect sizes</th>
<th>Comorbidities</th>
<th>Component separation &amp; bridging</th>
<th>Average follow-up</th>
<th>ASA score range</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pomahac XenMATRIX™ Surgical Graft</td>
<td>Yes</td>
<td>clean</td>
<td>Average BMI 27.5</td>
<td>Underlay</td>
<td>Average area repaired: 440 cm²</td>
<td>Heart disease 31.3%</td>
<td>CST 44%; bridging 19%</td>
<td>16.5 months</td>
<td>1-4</td>
<td>1 (7%) recurrence, 1 (7%) superficial wound dehiscence, 3 (21%) seromas (Note: Recurrence was 12 months post-op due to disattachment along right costal margin; repaired by reattaching. Graft noted to be completely revascularized and incorporated into host tissue)</td>
</tr>
<tr>
<td>Diaz-Siso/Pomahac XenMATRIX™ Surgical Graft</td>
<td>Yes</td>
<td>clean contaminated</td>
<td>Average BMI 29</td>
<td>Underlay</td>
<td>Average area repaired: 435 cm²</td>
<td>Heart disease 22.5%</td>
<td>CST 45%; bridging 20%</td>
<td>40.1 months</td>
<td>1-4</td>
<td>3 (7.9%) recurrence, 2 (5.2%) seromas (21%) seromas (2.6%) recurrent fistula (5.2%) early deaths unrelated to graft</td>
</tr>
<tr>
<td>Byrnes/Croston* XenMATRIX™ Surgical Graft</td>
<td>Yes</td>
<td>contaminated</td>
<td>Average BMI 31.7; 8 patients &gt;40</td>
<td>Underlay</td>
<td>Average area repaired: 180 cm²</td>
<td>Smokers 29% Insulin dependent diabetes 27%</td>
<td>Not reported</td>
<td>30.6 months</td>
<td>1-4††</td>
<td>4 (7.2%) recurrences = early technical failures 3 VAC drying graft 1 disrupted suture 2 (3.5%) early deaths unrelated to graft 0 (0%) Mesh infections 0 (0%) Fistula 0 (0%) Symptomatic seromas</td>
</tr>
<tr>
<td>Alicuben/DeMeester XenMATRIX™ Surgical Graft</td>
<td>Yes</td>
<td>contaminated</td>
<td>Average BMI 26</td>
<td>Onlay</td>
<td>Average area repaired: 532 cm²</td>
<td>Not reported</td>
<td>CST 73%; bridging 4.5%</td>
<td>7 months (median)</td>
<td>Not reported</td>
<td>1 (4.5%) recurrence, patient’s defect was bridged 2 (9%) wound infections, both treated successfully with VAC Therapy 6 (27%) seromas</td>
</tr>
</tbody>
</table>

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1† Data on file at Davol but not published in this study.
* Dr. Croston is a paid consultant for Davol Inc. Brennen Medical LLC, the former manufacturer of the XenMatrix™ Surgical Graft provided support for this study.
Indications
Intended for implantation to reinforce soft tissue where weakness exists and for surgical repair of damaged or ruptured soft tissue, including: abdominal plastic and reconstructive surgery; muscle flap reinforcement; hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias.

Contraindications
XenMatrix™ Surgical Graft should not be used on patients with known sensitivity to porcine products. Not for reconstruction of cardiovascular defects. Not for reconstruction of central nervous system or peripheral nervous system defects. Use of this product in applications other than those indicated has the potential for serious complications.

Warnings
If an infection develops, it should be treated aggressively. An allergic reaction, which is unrelated to other therapy, is an indication to consider removal of XenMatrix™ Surgical Graft.

Precautions
Place device in maximum possible contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling. When unable to close skin over the XenMatrix™ Surgical Graft, ensure that the implant remains moist. Avoid drying of the implant through "continued suction devices" as this may negatively impact the performance of the implant. Only physicians qualified in the appropriate surgical techniques should use this surgical graft.

The surgeon should thoroughly understand the surgical procedure and the performance characteristics of the surgical graft.

Adverse Reactions
Potential complications with the use of any prosthesis may include, but are not limited to, allergy, seroma, infection, inflammation, adhesion, fistula formation, hematoma and recurrence of tissue defect.

Please consult package insert for more detailed safety information and instructions for use.

To learn more, contact your local BARD representative or call 1.800.556.6275