SurgiMend® 1.0 2.0 3.0 4.0
Collagen Matrix for Soft Tissue Reconstruction

SurgiMend®-e
Collagen Matrix for Hernia Repair

POINTS OF STRENGTH for Hernia Repair

Proven Strength
Integration
Lasting Repair
Clinical Data
Source & Processing
Product Options
IMPORTANT OF STRENGTH

SurgiMend® is offered in thickness of 1mm, 2mm, 3mm and 4mm. Even at 1mm thickness, SurgiMend has been shown to have the strongest uniaxial tensile strength when compared to other major competitors.¹

An MD Anderson study comparing mechanical properties of ADMs derived from bovine and porcine dermis found 3mm and 4mm thick SurgiMend:

• To be as strong as the stainless steel suture²
• To have twice the suture retention of porcine dermal matrix (2mm thick)²
• To be more than twice as resistant to tearing as porcine dermal matrix²

<table>
<thead>
<tr>
<th>Tear Resistance</th>
<th>Thickness (mm), SD</th>
<th>Maximum Load (N), SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>PADM*</td>
<td>1.75 ± 0.14</td>
<td>19.66† ± 3.90</td>
</tr>
<tr>
<td>BADM** 2.0</td>
<td>1.85 ± 0.27</td>
<td>50.95† ± 11.79</td>
</tr>
<tr>
<td>BADM 3.0</td>
<td>3.23 ± 0.54</td>
<td>86.89† ± 15.34</td>
</tr>
<tr>
<td>BADM 4.0</td>
<td>3.83 ± 0.32</td>
<td>100.02† ± 14.28</td>
</tr>
</tbody>
</table>

* PADM: Porcine Acellular Dermal Matrix
** BADM: Bovine Acellular Dermal Matrix
† Significant difference from all other conditions by 1-way analysis of variance and Tukey post hoc analysis (P < 0.05).

• SurgiMend’s increased resistance to tearing is related to the bovine dermal source material²,³
• Bovine and porcine dermis have significant differences in collagen fiber weave pattern³
• Unlike bovine dermis, hair follicles perforate the entire dermis in porcine skin⁴
INTEGRATION & REVASCULARIZATION

SurgiMend is rapidly revascularized to support tissue building and healing for prolonged reinforcement.\textsuperscript{5,6}

11½ Months: Revascularized SurgiMend 11½ months after hernia repair in a patient undergoing a subsequent procedure unrelated to the original hernia repair.

6 Months: Revascularized SurgiMend 6 months after incisional hernia repair in a patient with Crohn’s disease during re-exploration for a second procedure unrelated to the original hernia repair.

SurgiMend revascularizing in a small animal intra-abdominal implant model. SurgiMend did not trigger a detrimental foreign-body inflammatory response that would lead to rapid degradation or encapsulation.\textsuperscript{7}
LONG LASTING HERNIA REPAIR\textsuperscript{8-10}

A persistent, thick, well-vascularized connective tissue was imaged more than two years post-operatively in SurgiMend reinforced hernia repairs.\textsuperscript{11}

\begin{itemize}
  \item Demonstrated maintenance of hernia reinforcement strength in a small animal model through 1 year\textsuperscript{6}
  \item Persistence of a host cell populated, well vascularized, connective tissue in a small animal model, consistent with clinical CT patient imaging\textsuperscript{6}
\end{itemize}

\textsuperscript{BFC: Bovine Fetal Collagen}

STRONG CLINICAL DATA
Numerous retrospective clinical studies have reported on hernia repair outcomes with SurgiMend reinforcement. Low hernia recurrence was shown with the use of SurgiMend.

<table>
<thead>
<tr>
<th>Study</th>
<th>SurgiMend Hernia Recurrence Rate</th>
<th>Materials Studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clemens et al.⁸</td>
<td>3.9%</td>
<td>SurgiMend, Strattice</td>
</tr>
<tr>
<td>Lineaweaver¹²</td>
<td>6.6%</td>
<td>SurgiMend, AlloDerm and Surgisis</td>
</tr>
<tr>
<td>Janafaza et al.¹³</td>
<td>5%</td>
<td>SurgiMend and FlexHD</td>
</tr>
<tr>
<td>Booth et al.⁹</td>
<td>5.8%</td>
<td>SurgiMend, Strattice and AlloDerm</td>
</tr>
<tr>
<td>Garvey et al.¹⁰</td>
<td>6.7%</td>
<td>SurgiMend, Strattice and AlloDerm</td>
</tr>
<tr>
<td>Soares et al.¹⁴</td>
<td>6%</td>
<td>SurgiMend and Prolene® with hybrid NPWT</td>
</tr>
</tbody>
</table>

INTRAOPERATIVE DEVICE FAILURES
A complex abdominal wall reconstruction study by MD Anderson found a 0% vs 10% intraoperative device failure rate when comparing SurgiMend acellular dermal matrix to a porcine acellular dermal matrix.⁸
PROPRIETARY SOURCE AND PROCESSING

The only biologic mesh composed of fetal or neonatal bovine dermal collagen, SurgiMend consists of an array of distinct interwoven collagen fibers with ample porosity to allow for rapid cell repopulation and vascularization.1,5,6,15

• Abundance of Type III Collagen (20-30%)16-20

• Type III Collagen is the first type of collagen synthesized during both embryonic development and wound healing16-20

Manufactured from fetal or neonatal bovine dermis using a patented processing method that:

**REMOVES** cells, lipids, carbohydrates, and other constituents that can induce inflammation

**PRESERVES** the beneficial properties of the natural collagen matrix in a native undamaged state

**STERILIZES** via exposure to ethylene oxide gas for a sterility assurance of $10^{-6}$ with undetectable ethylene oxide residuals

SurgiMend is readily populated by host cells upon implantation. Blood vessels (red, indicated by the arrows) also penetrate the collagen matrix (blue) to meet the metabolic requirements of the tissue.5,15
FLEXIBLE OPTIONS TO MEET PATIENTS NEEDS

SurgiMend is offered in 1.0mm, 2.0mm, 3.0mm, and 4.0mm thicknesses, providing surgeons with the widest flexibility to choose the most appropriate device thickness, strength, and size for each procedure, technique, and patient.

- Over 65 sizes and configurations
- Sizes up to 25cm x 40cm

The biological make-up of bovine dermis, including its inherent collagen fiber architecture, make SurgiMend particularly strong.\(^1\),\(^2\),\(^3\),\(^15\)

SurgiMend hydrates rapidly in room temperature saline. Trimming can be done in both its dry and hydrated state. Once fully hydrated, the material is pliable and compliant, readily conforming to the surgical site.
Description
SurgiMend is an acellular dermal tissue matrix derived from bovine dermis. The device is supplied sterile in a variety of sizes to be trimmed by the surgeon to meet the individual patient’s needs.

Indications
SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

SurgiMend is specifically indicated for:
- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias

Contraindications
- SurgiMend is not designed, sold, or intended for use except as indicated.
- SurgiMend should not be used in patients with a known history of hypersensitivity to collagen or bovine products.

Warnings and Precautions
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

- Consider the loading environment when selecting the product thickness; thicker product tends to have greater initial strength.
- Fenestrated product will stretch more than nonfenestrated product.
- SurgiMend should be used with caution where any pre-existing pathology may limit blood supply and compromise healing.
- Treat any existing infection appropriately with local and/or systemic antibiotics in an attempt to eliminate infection. If used in contaminated or infected wounds collagen-based implants can weaken or break down if exposed to bacterial enzymes.
- SurgiMend should be used with caution in surgical locations where the product may be exposed to stomach and/or intestinal contents. Collagen-based implants can be susceptible to degradation by digestive enzymes and conditions of acidic (low) pH.
- SurgiMend has not been evaluated in pregnant women.
- The patient’s medical condition may adversely impact healing of the deficient tissue. These conditions may include, but are not limited to: smoking, diabetes, insufficient blood supply at the implant site, and exposure of the implant site to radiotherapy.
- General risks may include, but are not limited to: infection, allergic reactions, pain, swelling or bruising, foreign body reaction, acute or chronic inflammatory reactions, adhesions, seroma, hematoma, and repair laxity. The patient should be made aware of these risks and others associated with general surgery and the use of anesthesia.

Availability of these products may vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

References