Integra®
SurgiMend® Collagen Matrix

SurgiMend®
Collagen Matrix for Soft Tissue Reconstruction

SurgiMend®-e
Collagen Matrix for Hernia Repair

SurgiMend® PRS
Collagen Matrix for Plastic & Reconstructive Surgery

INTEGRA
LIMIT UNCERTAINTY
Why SurgiMend?
In cases where primary repair is not possible and synthetic meshes are not ideal, surgeons often turn to biologic meshes. Today, there is a superior choice: SurgiMend offers clear advantages over synthetic and other collagen products for soft tissue repair and reconstruction.

Instrinsically strong, SurgiMend handles and can be sutured in place like natural tissue. The product’s biochemistry and microporosity facilitate rapid cell penetration and revascularization. SurgiMend participates in the healing of soft tissue defects by providing the requisite structural support as well as the scaffold that can be naturally and progressively integrated, and remodeled.

Structure and Composition
Composed of fetal and neonatal bovine dermal collagen, SurgiMend consists of an array of distinct interwoven collagen fibers with ample porosity to allow for cell and blood vessel penetration. While both fetal and adult dermal tissues are predominantly composed of Type I collagen, fetal and neonatal tissue contains significantly more Type III collagen (20-30%), the first type of collagen synthesized during both embryonic development and wound healing.1-5

Significance of Fetal & Neonatal Collagen
The product’s collagen source distinguishes SurgiMend, as it is the only biologic mesh on the market derived from a fetal and neonatal tissue. In an effort to mimic the body’s natural tissue development and healing processes, this source material was chosen in part because of its unique biochemistry.

<table>
<thead>
<tr>
<th>Reference</th>
<th>Species</th>
<th>% Type III Collagen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ramshaw, 1986</td>
<td>Bovine</td>
<td>30</td>
</tr>
<tr>
<td>Smith, 1986</td>
<td>Human</td>
<td>18-21</td>
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Percentages of Type III collagen found in mammalian dermis. Developing, fetal and neonatal tissues contain significantly higher concentrations of Type III collagen than do adult tissues. Effectively acting as a signal to the body to initiate remodeling, Type III collagen may be beneficial in terms of its ability to promote rapid healing of soft tissue defects.

Composed of Native Collagens
The unique biochemistry of the native collagens found in fetal and neonatal tissue is preserved during the manufacture of SurgiMend. Unlike other products where the source collagen may be exposed to artificial chemical crosslinking agents which alter normal molecular structure, the SurgiMend processing technology succeeds in producing a collagen scaffold that can invoke a natural healing response similar to transplanted fascia and other soft tissue autografts.

Chemical crosslinking can improve mechanical stability; however, it decreases the ability of the scaffold to be remodeled. Although the biology of this deficit in remodeling is not known, crosslinking does create a barrier, possibly preventing cells from penetrating and adhering to the matrix.7 Experimental models have demonstrated that crosslinked dermal collagen does not integrate well with surrounding soft tissues and can elicit strong local inflammation with signs of foreign body reaction.8 Chemical crosslinking is known to increase the resistance of collagen to cellular enzymes, e.g., collagenase, which must be able to act normally and efficiently if natural tissue development and remodeling are to proceed.7,9,10

The microporosity of SurgiMend allows for rapid penetration of host cells and blood vessels upon implantation.
High Content of Type III Collagen
Fetal and neonatal dermis naturally contain the protein building blocks specific for tissue development and maturation. Like adult tissue, fetal and neonatal dermis is primarily composed of large, well-structured fibers of Type I collagen that offer the tissue significant tensile strength. However, biochemical studies have shown that Type III collagen is three to five times more concentrated in fetal and neonatal dermis than in adult skin.3,5,6

Type III collagen is known to signal the movement of fibroblasts and to perform dynamic functions including regulation of Type I/III collagen fibril growth, control of fibril diameter, and interactions with other essential constituents of developing tissues.11-13 The abundance of Type III collagen in granulation and scar tissues indicates its importance in wound healing as well. Dermal wounds in the early stages of healing resemble fetal skin in that Type III collagen is present in high proportions compared to Type I.1,14

The comparatively high Type III collagen content of fetal and neonatal bovine skin may be beneficial in terms of its ability to heal soft tissue defects. The biochemical composition of fetal and neonatal collagen is specific for development and maturation, effectively acting as a signal to the body to integrate and remodel the SurgiMend implant.

Encouraging Tissue Remodeling
SurgiMend is not acted upon as a foreign body (encapsulated) nor does it dissolve via hydrolysis like synthetic copolymer meshes designed to provide temporary support during wound healing. Instead, it is repopulated by patient cells and supporting vasculature to generate a new structural connective tissue capable of undergoing normal remodeling processes.

Additional Advantages of Fetal & Neonatal Bovine Dermis
Not only is the source material for SurgiMend unique, it is readily available and more predictable and controlled than other source materials, for example, cadaveric dermis. Another advantage of fetal and neonatal bovine dermis over other tissue sources is its comparatively large area allowing for larger product pieces with sufficient thickness. Inflammatory responses to other biologic meshes have been associated with implanted remnant animal cells erroneously left in the product during processing.15 The density and structure of fetal and neonatal bovine dermis allow for effective cleansing and removal of all cellular components.

Appearance & Dimensions
SurgiMend is offered in 1.0 mm, 2.0 mm, 3.0 mm, and 4.0 mm thicknesses, providing surgeons with the widest flexibility to choose the most appropriate device thickness, strength, and size for each procedure, technique, and patient. Provided in sheet form in sizes as large as 1,000 cm², SurgiMend is packaged dry and is free of holes or other defects.

Intraoperative Handling
SurgiMend hydrates in room temperature saline in approximately 60 seconds. 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. With handling properties very similar to native tissue, it is strong and easily sutured. SurgiMend can be placed in any orientation, with either side up.
Indications
SurgiMend is intended for implantation to reinforce soft tissue where weakness exists and for 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 for 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 non-fenestrated product.
- Meshing of fenestrated product is not recommended.
- Do not expose to chemicals or substances other than sterile, room temperature 0.9% saline.
- Excessive heat can damage collagen. Do not hydrate in 0.9% saline warmed above room temperature.
- If, when hydrated, the product shrinks in size, DO NOT use the product as it may be damaged.
- SurgiMend should be used with caution where any pre-existing pathology may limit blood supply and compromise healing.
- Postoperative infection in the vicinity of the implant may necessitate implant removal to prevent implant-related infection.
- Do not resterilize as this may damage SurgiMend.
- 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.
- Do not use 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.
- Do not resterilize as this may damage SurgiMend.
- SurgiMend is for single patient use only and is to be implanted surgically.
- 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.
- Do not use product past the date of expiration.

References


Availability of these products might 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.

For more information or to place an order, please contact:

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