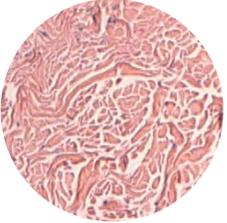
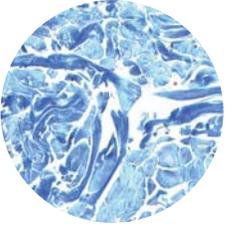


# SurgiMend™

*Collagen Matrix for Soft Tissue Reconstruction*



Why SurgiMend?

Structure and Composition

Significance of Fetal Collagen

Appearance & Dimensions

Intraoperative Handling

## 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.

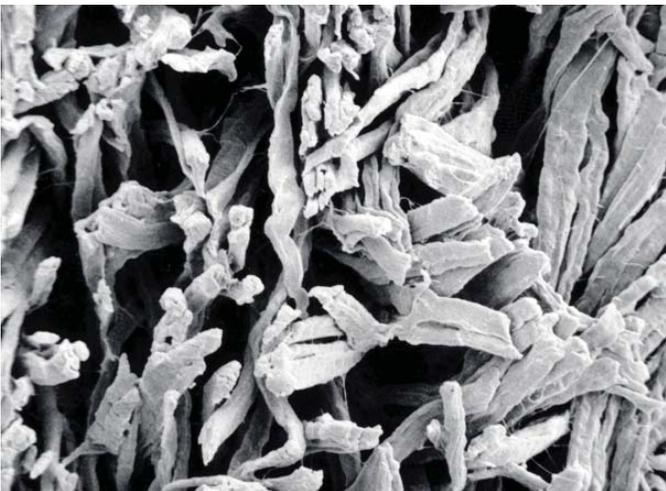
Intrinsically strong, SurgiMend handles and can be sutured in place like natural tissue. The product's biochemistry and microporosity facilitate rapid cell penetration and revascularization. SurgiMend participates in the healing of soft tissue defects by providing the requisite structural support as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

## Structure and Composition

Composed of fetal bovine dermal collagen, SurgiMend consists of a random 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 tissue contains significantly more Type III collagen, the first type of collagen synthesized during both embryonic development and wound healing.<sup>1-4</sup>

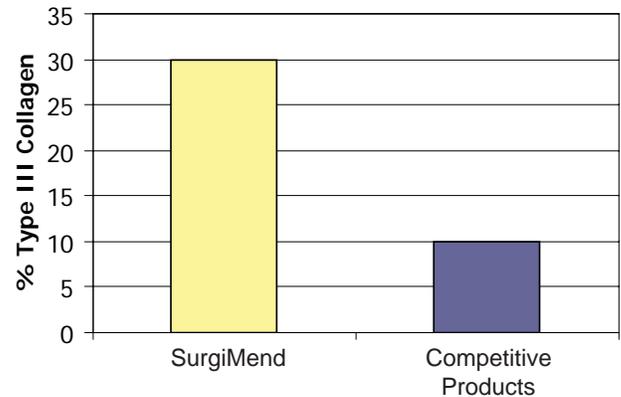
## Significance of Fetal Collagen

The product's collagen source distinguishes SurgiMend as it is the only biologic mesh on the market derived from a fetal tissue. In an effort to mimic the body's natural tissue development and healing processes, TEI Biosciences chose this source material in part because of its unique biochemistry.



*The microporosity of SurgiMend allows for rapid penetration of host cells and blood vessels upon implantation.*

Reference	Species	% Type III Collagen	
		Fetal	Adult
Ramshaw, 1986 <sup>5</sup>	Bovine	30	5 - 10
Smith, 1986 <sup>3</sup>	Human	18-21	8 - 11



*Percentages of Type III collagen found in mammalian dermis. Developing, fetal 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 Active, Native Collagens

The unique biochemistry of the active, native collagens found in fetal 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>7,9,10</sup>

### *Promoting Tissue Development & Regeneration*

Fetal dermis naturally contains the protein building blocks specific for tissue development and maturation. Like adult tissue, fetal 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 dermis than in adult skin.<sup>3,5,6</sup>

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.<sup>11-13</sup> 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.<sup>1,14</sup>

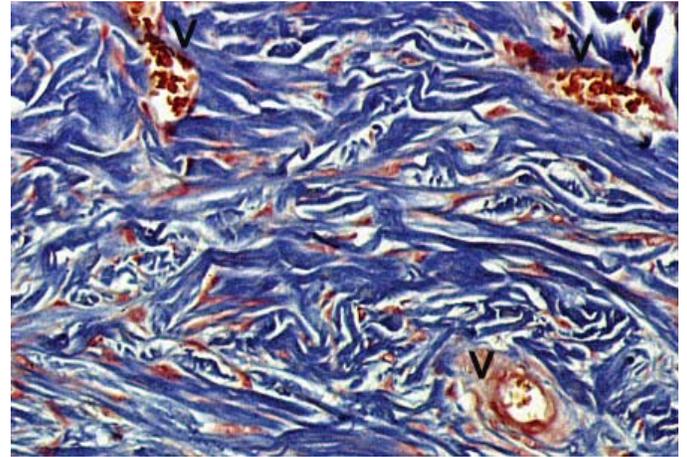
The comparatively high Type III collagen content of fetal bovine skin may be beneficial in terms of its ability to heal soft tissue defects. The biochemical composition of fetal collagen is specific for development and maturation, effectively acting as a signal to the body to integrate and remodel the 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 populated and acted upon by host cells (fibroblasts and macrophages) which, over time, progressively break down the implant collagen and replace it with new host collagen. This is an ongoing cellular process that naturally occurs throughout the body, allowing for repair of damaged tissues.

### *Additional Advantages of Fetal Bovine Dermis*

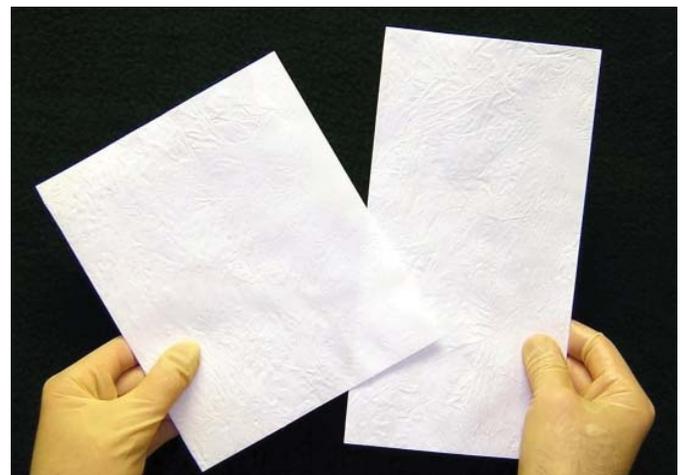
Not only is the source material for SurgiMend unique, it is readily available and more predictable and controlled than other source materials, for example, cadaveric dermis. Another advantage of fetal bovine dermis over other tissue sources is its comparatively large area allowing for larger product 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.<sup>15</sup> The density and structure of fetal bovine dermis allow for effective cleansing and removal of all cellular components.



*SurgiMend is readily populated by host cells upon implantation. Blood vessels (V) also penetrate the collagen matrix (blue) to meet the metabolic requirements of the tissue.*

### **Appearance & Dimensions**

Provided in sheet form in sizes as large as 325 cm<sup>2</sup>, SurgiMend is packaged dry and can be trimmed (wet or dry) and sutured by the surgeon to meet the individual patient's needs. The material is available in two thickness ranges (0.75 - 1.54 mm and 0.40 - 0.75 mm) and is free of holes or other defects. Refer to the Ordering Information insert for a complete list of available product sizes.



*SurgiMend is available in large sizes including 13 x 25 cm and 16 x 20 cm.*

### **Intraoperative Handling**

SurgiMend hydrates in room temperature saline in approximately 60 seconds. 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 (nominal tensile strength: ~29 MegaPascals) and easily sutured (nominal suture pull-out force: ~36 Newtons). SurgiMend can be placed in any orientation, with either side up.

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