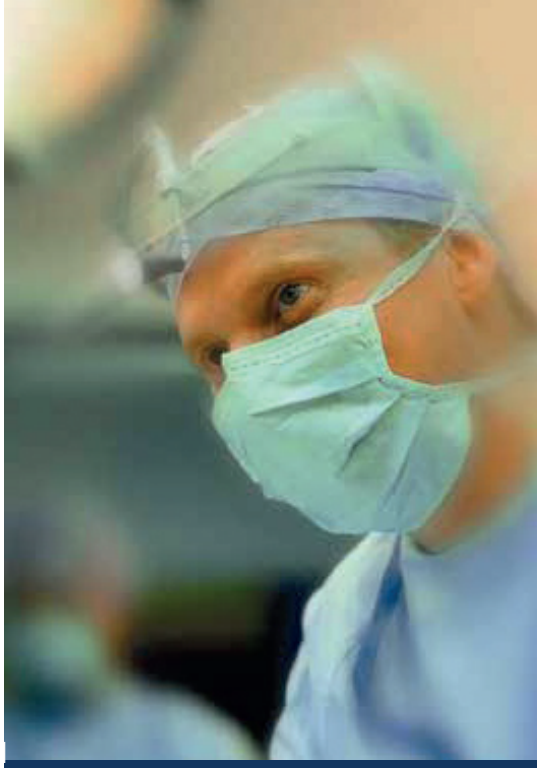
SurgiMend® 1.0 2.0 3.0 4.0

Collagen Matrix for Soft Tissue Reconstruction



Product Overview

SurgiMend is a unique acellular collagen matrix derived from fetal and neonatal bovine dermis. SurgiMend offers clear advantages over synthetic and other biologic products for soft tissue repair and reconstruction.

SurgiMend is the Strongest, Thickest Biologic Matrix

- The biological make-up of bovine dermis, including its inherent collagen fiber architecture, leaves SurgiMend unmatched in available thicknesses and mechanical strength
- 1.0, 2.0, 3.0 & 4.0 mm thicknesses and sizes up to 25 cm x 40 cm

SurgiMend Offers the Highest Levels of Type III Healing Collagen

- Type III collagen mediates tissue healing while inhibiting scarring
- SurgiMend is derived from young healthy tissue that contains three times more Type III collagen than other acellular dermal matrices

SurgiMend is Terminally Sterilized, Safe, and Consistent

- Free of potentially antigenic antibiotics and terminally sterilized
- Derived from only well-defined and characterized source tissue with respect to age, mechanical strength, structure, and composition

SurgiMend is Non-Inflammatory for Better Reinforcement

- Free of contaminants, artificial chemical crosslinks, & denatured proteins
- Pure collagen; No added preservatives
- Does not elicit an acute or chronic foreign body inflammatory response that leads to the implant's degeneration

SurgiMend Allows for Rapid Cell Repopulation and Vascularization

- Intraoperatively, SurgiMend is seeded with the patient's tissue-building cells and growth factors
- The microporous matrix is rapidly revascularized to support tissue-building and healing for prolonged reinforcement

SurgiMend for soft tissue repair, reinforcement & reconstruction.

- **Plastic & reconstructive surgery**
- **Muscle flap reinforcement**
- **Hernia repair**

The preferred choice of:

- *General Surgeons*
- *Trauma Surgeons*
- *Plastic & Reconstructive Surgeons*
- *Head & Neck Surgeons*

Q MEDICAL TECHNOLOGIES

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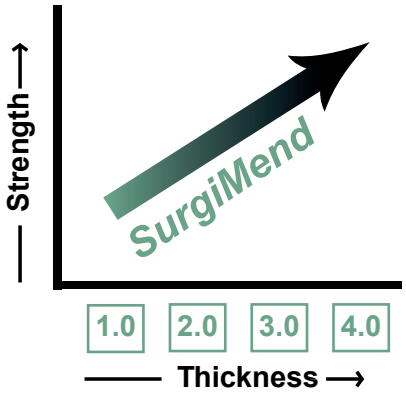
Collagen Matrix for Soft Tissue Reconstruction

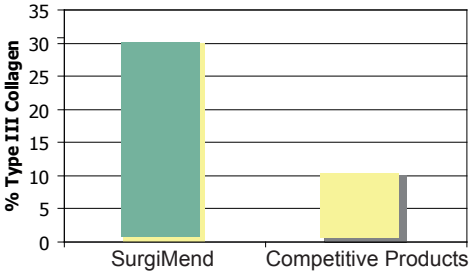
Strongest, Thickest Biologic Matrices

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. The biological make-up of bovine dermis, including its inherent collagen fiber architecture, leaves SurgiMend unmatched in available thickness and mechanical strength, making it the best choice to strengthen and reinforce the repairs required in the most challenging cases.



Highest Levels of Type III Healing Collagen

During tissue development and healing, a complex series of interactions amongst cells, regulatory factors, and the extracellular matrix occurs. When tissue is being generated, an abundance of Type III collagen is present in the extracellular matrix. Type III collagen mediates tissue healing and growth while inhibiting scarring.[1,2] SurgiMend, derived from fetal and neonatal bovine dermis, contains three times more Type III collagen than other acellular dermal matrices, which are derived from adult human or other animal tissues[3,4]



Terminally Sterilized, Safe, and Consistent

SurgiMend's source tissue is selected and processed in accordance with strict TEI, US, and International regulatory requirements. The TEI manufacturing process includes steps validated to ensure inactivation of potentially contaminating viruses and certified TSE safe by FDA, European Directorate for Quality of Medicines, and other International regulatory bodies. To assure consistency and optimal performance, SurgiMend is derived from only well-defined and characterized source tissue with respect to age, mechanical strength, structure and composition. SurgiMend is free of potentially antigenic antibiotics and terminally sterilized in a validated manner that leaves no ethylene oxide sterilization gas residuals.

[1] Larson et al. Scarless fetal wound healing: a basic science review" Plastic and Reconstructive Surgery 2010; 126:1172-1180.
[2] Volk et al. Dimished Type III collagen promotes myofibroblast differentiation and increases scar deposition in cutaneous wound healing. Cells Tissues Organs. 2011; 194:25-37.
[3] Smith LT, Holbrook KA, Madri J. Collagen types I, III and V in human embryonic and fetal skin. The American Journal of Anatomy 1986; 175:507-521.
[4] Ramshaw J. Distribution of type III collagen in bovine skin of various ages. Connective Tissue Research 1986: 14:307-314.

The Science of SurgiMend®

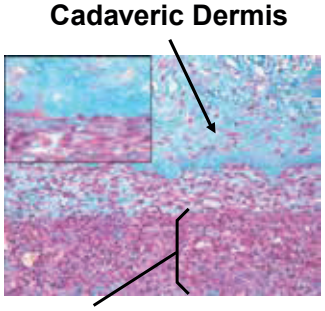
Non-Inflammatory for Better Reinforcement

Not all "Biologics" are the same. Other acellular matrix products are known to elicit an acute or chronic foreign body inflammatory response that leads to the implant's degeneration. The inflammatory response to a biologic matrix varies widely depending on source tissue composition, structure, method of processing, and the resulting uniformity and purity of the matrix to be implanted.[5,6,7]

TEI's proprietary manufacturing process preserves the beneficial properties of the natural collagen matrix while producing an acellular dermal matrix that is free of contaminants and artificial crosslinkers. When implanted, SurgiMend's purity and nativity minimizes detrimental foreign body inflammation to provide a matrix that is revascularized and repopulated with patient cells for prolonged reinforcement during healing.

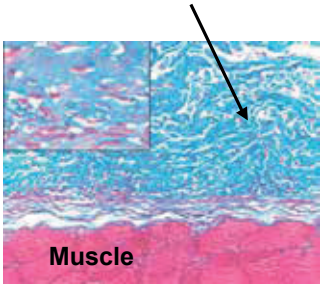
Inflammatory

Acellular Human Cadaveric Dermis



Non-Inflammatory

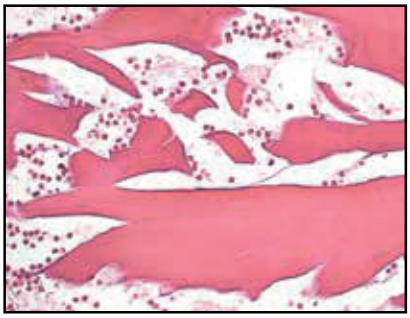
SurgiMend



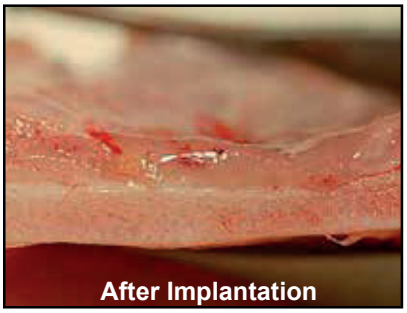
Upon implantation, a strong foreign body inflammatory response is observed with acellular human cadaveric dermis.[5] This inflammatory response has been shown to lead to degeneration of the matrix.Such a foreign body inflammatory response is not found with SurgiMend.[5,6]

SurgiMend Cell Repopulation and Revascularization

SurgiMend, prior to hydration: a highly porous, pure, non-chemically crosslinked acellular dermal matrix derived from fetal and neonatal bovine dermis, naturally rich in Type III healing collagen.



Upon implantation, the highly porous SurgiMend matrix soaks with blood, acting as a sponge to trap cells and growth factors (including VEGF) to seed the matrix.[8]



SurgiMend is rapidly repopulated with host cells and supporting vasculature. At week 26, SurgiMend maintains its thickness and its handling properties and shows no significant degradation.[8]

[5] Valentin JE, Badylak JS, McCabe GP, Badylak SF. Extracellular matrix bioscaffolds for orthopaedic applications. A comparative histologic study. The Journal of Bone and Joint Surgery. American Volume. 2006; 88(12):2673-86.

[6] Cornwell K et al. Extracellular matrix biomaterials for soft tissue repair. Clin Podiatr Med Surg. 2009; 26:507-523

[7] Blatnik J et al. Abdominal hernia repair with bridging acellular dermal matrix--an expensive hernia sac. American Journal of Surgery. 2008; 196(1):47-50.

[8] Cornwell K et al. A generative tissue fabricated with SurgiMend has a mesothelial lining limiting adhesion formation in a model of large ventral hernia repair. Presented at the meeting of the America Hernia Society, Orlando, FL, March 2010.

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Collagen Matrix for Soft Tissue Reconstruction

At a Glance

Composition	Native, non-denatured collagen			
Collagen source	Bovine dermis			
Appearance	Flat, dry sheet of uniform thickness and color			
Storage	Room temperature storage			
Chemical crosslinkers	None			
Rehydration	Approximately 60 seconds in room temperature saline			
Intraoperative handling	Can be trimmed to size wet or dry and placed in any orientation, with either side up			
Pyrogen and viral safety	Non-pyrogenic; manufacturing process includes validated viral-inactivation steps			
Transmissible Spongiform Encephalopathy (TSE) safety	TSE safety certification by European Directorate for the Quality of Medicines; source tissue selected and processed in accordance with strict US and International regulatory requirements			
Sterilization	Via exposure to ethylene oxide gas; sterility assurance level of 10^{-6} with undetectable ethylene oxide residuals			
Tensile Strength	1.0	2.0	3.0	4.0
	+	++	+++	++++

Ordering Information

Shape	Size (cm)	SurgiMend 1.0	SurgiMend 2.0	SurgiMend 3.0	SurgiMend 4.0
		0.75 - 1.54 mm	1.30 - 2.50 mm	2.40 - 3.50 mm	3.30 - 4.40 mm
Square	3 x 3	606-001-012*			
	10 x 10	606-001-005			
	20 x 20		606-200-019	606-300-019	
Rectangle	4 x 7	606-001-013*			
	4 x 12	606-001-014			
	5 x 6	606-001-002*	606-200-002	606-300-002	606-400-002
	6 x 12	606-001-004	606-200-004	606-300-004	606-400-004
	6 x 16	606-001-015			
	8 x 16	606-001-018			
	10 x 15	606-001-006	606-200-006	606-300-006	606-400-006
	10 x 25	E3 Fenestrated Product Code 606-300-002			
	10 x 25	E3 Non - Fenestrated Product Code 606-300-022			
	13 x 25	606-001-009	606-200-009	606-300-009	606-400-009
	16 x 20	606-001-008	606-200-008	606-300-008	
	20 x 25		606-200-020	606-300-020	
	20 x 30	606-001-017	606-200-017	606-300-017	606-400-017
	25 x 40	606-001-016	606-200-016	606-300-016	606-400-016

*** Thinner product (0.40 - 0.75 mm) is available.**

About TEI Biosciences

A leading, privately held biomedical company, TEI Biosciences has applied its expertise in regenerative medicine to develop and commercialize novel biologic products for a broad spectrum of soft tissue repair and reinforcement applications - from dura, tendon, and hernia repair to wound management and plastic and reconstructive surgery. TEI sells its products directly and through partnerships with some of the world's major medical device companies.

MEDICAL TECHNOLOGIES

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