SurgiMend 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
	+	++	+++	++++

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.
- Treat any existing infection appropriately 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.
- 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.
- 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.

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

Ordering Information

Shape	Size	SurgiMend 1.0 1 mm*	SurgiMend 2.0 2 mm*	SurgiMend 3.0 3 mm*	SurgiMend 4.0 4 mm*
Square	3 x 3cm	606-001-012**	–	–	–
	10 x 10cm	606-001-005	–	–	–
	20 x 20cm	–	606-200-019	606-300-019	–
Rectangle	0.3 x 25cm	606-003-001	–	–	–
	0.5 x 20cm	–	–	–	606-403-001
	0.6 x 25cm	606-003-002	–	–	–
	1.0 x 25cm	606-003-003	–	–	–
	4 x 7cm	606-001-013**	–	–	–
	4 x 12cm	606-001-014	–	–	–
	4 x 16cm	606-001-010	–	–	–
	5 x 6cm	606-001-002**	606-200-002	606-300-002	606-400-002
	6 x 12cm	606-001-004	606-200-004	606-300-004	606-400-004
	6 x 16cm	606-001-015	–	–	–
	8 x 16cm	606-001-018	–	–	–
	10 x 15cm	606-001-006	606-200-006	606-300-006	606-400-006
	10 x 20cm	606-001-007	–	–	–
	13 x 25cm	606-001-009	606-200-009	606-300-009	606-400-009
	16 x 20cm	606-001-008	606-200-008	606-300-008	–
	20 x 25cm	–	606-200-020	606-300-020	–
	20 x 30cm	606-001-017	606-200-017	606-300-017	606-400-017
	25 x 40cm	606-001-016	606-200-016	606-300-016	606-400-016
Ellipse	10 x 25cm	–	–	606-300-022	606-400-018
		–	–	606-304-002 (f)	606-404-001 (f)

* Nominal ** Thinner product is available (f) Fenestrated

[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.
[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 American Hernia Society, Orlando, FL, March 2010.
[9] Deeken CR, Eliason BJ, Pichert MD, et al. Differentiation of Biologic Scaffold Materials Through Physicomechanical, Thermal, and Enzymatic Degradation Techniques. Ann Surg. 2012; 00(0)
[10] Cornwell, K, Zhang F, Lineaweaver W. Bovine fetal collagen reinforcement in a small animal model of hernia with component repair. Journal of Surgical Research. 2015 Nov; 0(0)

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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Manufacturer:
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7 Elkins Street
Boston, MA 02127 ▪ USA

Product Summary

SurgiMend® 1.0 2.0 3.0 4.0

Collagen Matrix for
Soft Tissue Reconstruction

Because we are committed to limiting uncertainty, Integra offers SurgiMend in 1, 2, 3 or 4 mm thicknesses and in over sixty configurations, providing the most appropriate device thickness, strength, and size for each procedure, technique, and patient.

INTEGRA®
LIMIT UNCERTAINTY

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 [9]

- 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 and 4.0 mm thicknesses and sizes up to 25 cm x 40 cm

SurgiMend Offers an Abundance of Type III Healing Collagen [3,4]

- 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

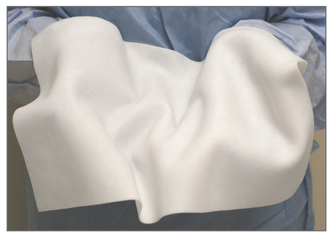
- Free of potentially antigenic antibiotics and terminally sterilized
- Derived from only well-defined and characterized source tissue with respect to age, mechanical strength, structure, and composition

SurgiMend is Non-Inflammatory for Better Reinforcement

- Does not elicit an acute or chronic foreign body inflammatory response that leads to the implant's degeneration; SurgiMend is without preservatives, denatured proteins, artificial chemical crosslinks, cells, lipids, carbohydrates and other constituents
- Type I and Type III Healing Collagen; No added preservatives

SurgiMend Allows for Rapid Cell Repopulation and Vascularization [8,10]

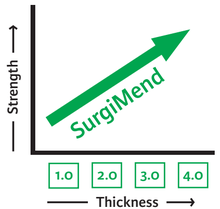
- Intraoperatively, patient tissue-building cells and growth factors are sequestered within SurgiMend [8]
- The microporous matrix is rapidly revascularized to support tissue-building and healing for prolonged reinforcement [10]



Sizes up to 25cm x 40cm

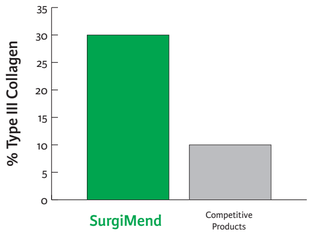
Strongest, Thickest Biologic Matrices [9]

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 thicknesses and mechanical strength, making it the best choice to strengthen and reinforce the repairs required in the most challenging cases.



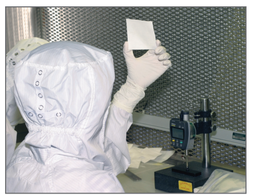
High Levels of Type III Healing Collagen

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

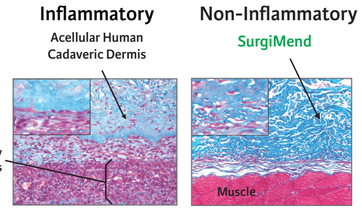
SurgiMend's source tissue is selected and processed in accordance with strict Integra, US, and International regulatory requirements. The manufacturing process includes steps validated to ensure inactivation of potentially contaminating viruses and certified TSE safe by FDA, European Directorate for 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 undetectable ethylene oxide sterilization gas residuals.



Non-Inflammatory for Better Reinforcement

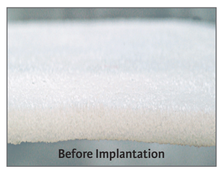
Not all "biologics" are the same. Other acellular matrix products are known to elicit an acute or chronic foreign body inflammatory response that leads to the implant's degeneration. The inflammatory response to a biologic matrix varies widely depending on source tissue composition, structure, method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

Integra's proprietary manufacturing process preserves the beneficial properties of the natural collagen matrix while producing an acellular dermal matrix that is without preservatives, denatured proteins, artificial chemical crosslinks, cells, lipids, carbohydrates and other constituents, all of which can induce inflammation. 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.

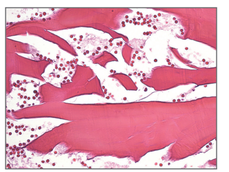


Upon implantation, a strong foreign body inflammatory response is observed with acellular human cadaveric dermis.[5] This inflammatory response has been shown to lead to degeneration of the matrix. Such a foreign body inflammatory response is not found with SurgiMend.[5,6]

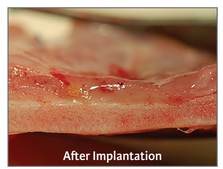
SurgiMend Cell Repopulation and Revascularization



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).[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.[8,10]