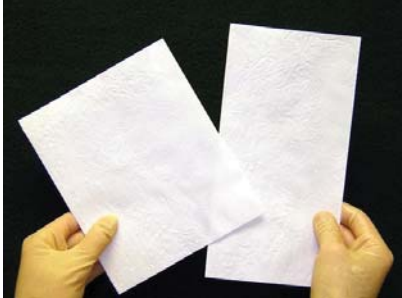


SurgiMend®

Collagen Matrix for Soft Tissue Reconstruction



SurgiMend provides a sound structural support during healing and promotes the regeneration of new, native tissue.

TEI
BIOSCIENCES
Repair | Reinforce | Regenerate

Product Overview

SurgiMend offers clear advantages over synthetic and other collagen products for soft tissue repair and reconstruction applications. Inherently strong, yet soft and supple when rehydrated, SurgiMend handles like natural tissue; it readily conforms to the surgical site, and is easily sutured. The product's biochemistry and microporosity facilitate rapid cell penetration and revascularization. Ultimately, SurgiMend acts as a scaffold that can be naturally and progressively integrated, remodeled, and eventually replaced by functional host tissue.

TEI Biosciences manufactures SurgiMend using a patented process designed to remove cellular components and potentially infectious agents from the raw material, while preserving the biological properties and structure of native collagen.

Indications

SurgiMend is intended for implantation to reinforce weak or damaged soft tissues. The product is specifically indicated for:

- Plastic and reconstructive surgery
- Muscle flap reinforcement
- Hernia repair including abdominal, inguinal, femoral, diaphragmatic, scrotal, umbilical, and incisional hernias

Soft tissue reconstruction

Hernia repair

Breast reconstruction

Plastic surgery

Muscle flap reinforcement

SurgiMend at a Glance

Composition	Native, non-denatured collagen
Collagen source	Fetal bovine dermis
Appearance	Flat, dry sheet of uniform thickness and color
Storage and shelf life	Room temperature storage for up to three years
Chemical crosslinkers	None
Intraoperative handling	Can be trimmed to size wet or dry and placed in any orientation, with either side up
Nominal tensile strength	~29 MegaPascals
Nominal suture pull-out force	~36 Newtons
Rehydration	Approximately 60 seconds in room temperature saline
Pyrogen and viral safety	Pyrogen-free; 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 European regulatory requirements
Sterilization	Via exposure to ethylene oxide gas; sterility assurance level of 10 ⁻⁶ with undetectable ethylene oxide residuals

Coding and Reimbursement

C-9358 - Effective July 1, 2008: CMS has approved SurgiMend for Transitional Pass-Through Payment, with a C-code specific to SurgiMend. Transitional pass-through status allows certain drugs and biologics to be reimbursed separately from other procedures for a period of two to three years, during which time CMS gathers cost data to help determine final payment for the procedure utilizing the new drug/biologic.

Ordering Information

Size (cm)	Thickness (mm)	Product Number
3 x 3	0.75 - 1.54	606-001-012
4 x 7	0.75 - 1.54	606-001-013
5 x 6	0.75 - 1.54	606-001-002
4 x 12	0.75 - 1.54	606-001-014
4 x 16	0.75 - 1.54	606-001-010
6 x 12	0.75 - 1.54	606-001-004
6 x 16	0.75 - 1.54	606-001-015
10 x 10	0.75 - 1.54	606-001-005
10 x 15	0.75 - 1.54	606-001-006
10 x 20	0.75 - 1.54	606-001-007
16 x 20	0.75 - 1.54	606-001-008
13 x 25	0.75 - 1.54	606-001-009
25 x 40	0.75 - 1.54	606-001-016
3 x 3	0.40 - 0.75	606-002-005
4 x 7	0.40 - 0.75	606-002-002
5 x 6	0.40 - 0.75	606-002-003
0.3 x 25	0.75 - 1.54	606-003-001
0.6 x 25	0.75 - 1.54	606-003-002
1.0 x 25	0.75 - 1.54	606-003-003



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Features & Benefits

- Biologic, acellular collagen matrix derived from fetal bovine dermis – rich in Type III collagen, the active collagen found in developing and healing tissues
- Superior handling characteristics
- Available in several sizes, with select sizes offered in two different thicknesses
- Three-year shelf life
- Room temperature storage
- Minimal preparation time – rehydrates in about 60 seconds
- Biocompatible and cell-friendly with no artificial chemical crosslinking – promotes rapid revascularization and integration with host tissue
- Terminally sterilized



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.

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 PN 606-999-016 v02