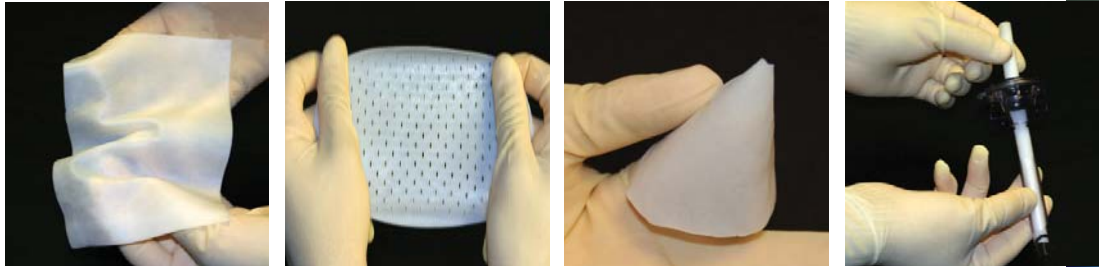


# SurgiMend<sup>®</sup>

## Inguinal Hernia Repair Matrix

Collagen Matrix for Soft Tissue Reconstruction



# TEI

## BIOSCIENCES

Repair | Reinforce | Regenerate

### Product Overview

TEI Biosciences' SurgiMend Inguinal Hernia Repair Matrix offers clear advantages over synthetic and other collagen products for inguinal hernia repair. Intrinsically strong, yet soft and supple when rehydrated, SurgiMend handles like natural tissue; it readily conforms to the surgical site, and is easily sutured or stapled. 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.

SurgiMend is appropriate for use in open or laparoscopic inguinal hernia repair; it can be cut, shaped, and sutured in place to fashion three-dimensional plug-type hernia repair devices. It may also be easily key-holed for use in tension-free, Liechtenstein repairs. For laparoscopic procedures, hydrated SurgiMend may be easily rolled and delivered through a cannula.

Unlike synthetic meshes, SurgiMend is not encapsulated. The biologic matrix is capable of being remodeled into native tissue, and does not promote the formation of adhesions or scars.



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

### Inguinal hernia repair

- Open
- Laparoscopic



## SurgiMend at a Glance

Composition	Native, non-denatured collagen
Collagen source	Fetal bovine dermis
Appearance	Flat, dry sheet of uniform thickness and color
Dry thickness	0.40 - 1.00 mm
Pyrogens	Non-pyrogenic
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
Rehydration	Approximately 60 seconds in room temperature saline
Viral safety	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 <sup>-6</sup> with undetectable ethylene oxide residuals

## Ordering Information

Size (cm)	Description	Fenestrations	Quantity	Product Number
8 x 12	Oval	Yes	1-pack	606-005-001
8 x 12	Oval	Yes	3-pack	606-005-101
8 x 12	Rectangle	No	1-pack	606-005-003
8 x 12	Rectangle	No	3-pack	606-005-103
10 x 15	Oval	Yes	1-pack	606-005-002
10 x 15	Oval	Yes	3-pack	606-005-102
10 x 15	Rectangle	No	1-pack	606-005-004
10 x 15	Rectangle	No	3-pack	606-005-104

Specifications subject to change without notice.

## 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.



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## Features & Benefits

- Acellular collagen matrix derived from fetal bovine dermis – rich in Type III collagen, the active collagen found in developing and healing tissues
- Biocompatible and cell-friendly with no artificial chemical crosslinking – promotes rapid revascularization and integration with host tissue
- Does not encapsulate, nor promote formation of adhesions or scars
- Can be remodeled into native host tissue
- Soft and supple

### Open repair

- Easily trimmed with scissors while retaining its structural integrity
- Readily formed into three-dimensional shapes

### Laparoscopic repair

- Oval-shaped to facilitate delivery through a cannula
- Fenestrated to permit rapid integration and fluid exchange

## 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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