XCM Biologic Tissue Matrix.
Regenerative matrix for reinforcement and repair of soft tissue.

Hydrated, ready-to-use

Allows for cellular infiltration

Strength without crosslinking
XCM Biologic Tissue Matrix

XCM Biologic Tissue Matrix is a sterile non-cross-linked 3-D matrix derived from porcine dermis. Dermis is composed of cells and extracellular matrix (ECM), a combination of proteins, proteoglycans, glycosaminoglycans, and other biological materials produced by cells that form the structures of all the tissues in the body.

XCM Biologic Tissue Matrix is manufactured by Kensey Nash Corporation and available through Synthes CMF.

XCM Biologic Tissue Matrix undergoes Kensey Nash’s proprietary Optrix process, which has been developed to be strong enough to disinfect the tissue, inactivate viruses, and remove the cells, yet gentle enough to maintain the bulk of the natural ECM components and minimize damage to the tissue architecture.

The result is a strong biologic implant with the properties needed to facilitate soft tissue healing. XCM Biologic Tissue Matrix is ready-to-use, right out of the package. No hydrating or rinsing is required. Once the tissue matrix is implanted, it provides a structure that can be infiltrated by the body’s cells.
XCM Biologic Tissue Matrix provides reinforcement and repair of soft tissue during healing.

- Hydrated and ready-to-use out of the package
- Structurally allows for cellular infiltration
- Strength without crosslinking
- Can be stored at room temperature
- No risk of human disease transmission
- No prestretching required
- Large sizes available
- Consistent thickness
- No orientation required
- Terminally sterilized
Clinical applications
Clinical applications include, but are not limited to the following:
- Hernia repair
- Defects of the thoracic wall
- Suture line reinforcement
- Muscle flap reinforcement
- Plastic and reconstructive procedures
  - Breast reconstruction
  - Abdominal wall reconstruction
  - Orofacial reconstructive procedures

* Immunohistochemical stains courtesy of Vacanti Laboratory for Tissue Engineering and Organ Fabrication, Massachusetts General Hospital
Indications and Contraindications

Indications
XCM Biologic Tissue Matrix is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to; defects of the thoracic wall, suture line reinforcement, and muscle flap reinforcement; hernia repair; soft tissue reconstructive procedures including but not limited to plastic and reconstructive surgical applications such as breast reconstruction, abdominal wall reconstruction, and orofacial reconstructive procedures; and for reinforcement of the soft tissues, which are repaired by suture or suture anchors. XCM Biologic Tissue Matrix is intended for one time use.

Contraindications
This device is derived from a porcine source and should not be used for patients with known sensitivity to porcine material. The device is contraindicated for patients known to be undergoing desensitization injections to meat products, as these injections can contain porcine collagen.

Abdominal wall
XCM Biologic Tissue Matrix placement options for abdominal wall reconstruction and hernia repair.
Device Properties

Biomechanical Testing

XCM Biologic Tissue Matrix has been subjected to biomechanical testing to characterize its physical properties.

Tensile testing was conducted according to internationally recognized standard procedures, which subjects a dogbone-shaped sample to tensile forces at 50 mm per minute and measures the maximum tensile force.* All forces are normalized to the width of the dogbone. XCM Biologic Tissue Matrix demonstrates an average tensile strength of 130 N/cm, greater than leading products made from PTFE, heavyweight macroporous polypropylene, and midweight macroporous prolene/cellulose/PDS, and well in excess of normal human fascia.¹

Testing was conducted to determine the ability of the tissue matrix to withstand suture pull-out forces. A #2 suture was placed 2 mm from the edge of the device. XCM Biologic Tissue Matrix demonstrates a suture retention strength of 54 N, far in excess of PTFE and midweight macroporous prolene/cellulose/PDS.

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* Data on file at Kensey Nash Corporation

¹ Native Fascia strength=16 N/cm

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![Tensile strength graph]

![Suture pull-out strength graph]
Kensey Nash is a regenerative medicine company with more than 20 years of experience in processing biologic materials. Kensey Nash has drawn from this experience to develop the Optrix cleansing process. This tissue cleansing process removes antigenic components from biologic materials while maintaining the native collagen structure and key extracellular matrix molecules used in tissue reconstruction.\(^2\) The result is a strong, acellular biologic graft that facilitates soft tissue healing.*

Key features of the Optrix process used in the manufacturing of XCM Biologic Tissue Matrix include:*

- Removal of cells and DNA
- Inactivation and clearance of viruses
- Maintenance of intact collagen structure for excellent strength and durability without crosslinking
- Preservation of natural fibrous architecture that provides a scaffold for cell in-growth and proliferation
- Retention of beneficial extracellular matrix molecules resulting in a scaffold that allows revascularization and tissue regeneration

* Data on file at Kensey Nash Corporation

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Results of Pico Green testing measuring the amount of DNA in a test sample. XCM Biologic tissue matrix is reduced to background levels of residual DNA.
Immunohistochemical evaluation of XCM Biologic Tissue Matrix confirms that the major components of the extracellular matrix are preserved after processing.4

XCM Biologic Tissue Matrix was evaluated for proteins such as collagen. Collagen is the most abundant structural protein found in mammals and plays an important role in tissue organization and biomechanical support.3 Utilizing immunohistochemical assays, various collagen types have been confirmed to be present in XCM Biologic Tissue Matrix including types 1, 3, 4 and 7 collagen.** Types 1 and 3 collagens are produced by fibroblasts and are the essential structural elements of most soft tissues.4 Types 4 and 7 collagens provide attachment sites for epithelial, endothelial, and mesothelial cells.2 Maintenance of the natural collagen architecture as demonstrated in the XCM Biologic Tissue Matrix is an important property of tissue regeneration scaffolds.5

The presence of elastin was confirmed through Van Gieson staining.2 Elastin is another important structural protein required for proper biomechanical function of various soft tissues.5 As elastin is degraded, its fragments become matrikines which are chemotactic for numerous cell types.7

* Data on file at Kensey Nash Corporation
7 Immunohistochemical stains courtesy of Vacanti Laboratory for Tissue Engineering and Organ Fabrication, Massachusetts General Hospital
Immunohistochemistry was used to confirm the presence of glycoproteins such as fibronectin and laminin. Fibronectin plays a vital role in cell adhesion, cell differentiation, and is highly involved in tissue reconstruction. Laminin is an important molecule for the adhesion of epithelial, endothelial, and mesothelial cells, and a key factor in tissue maintenance.

Alcian blue staining and spectrophotometric analysis by Blyscan assay confirmed the presence of sulfated glycosaminoglycans (GAG). Immunohistochemistry confirmed the presence of non-sulfated GAGs (hyaluronic acid). GAGs are highly charged molecules that are important for cell-cell signaling and cell-matrix interaction. GAGs sequester water for structural support and play important roles in the regulation of many tissue functions, such as tissue repair.

* Data on file at Kensey Nash Corporation
* Immunohistochemical stains courtesy of Vacanti Laboratory for Tissue Engineering and Organ Fabrication, Massachusetts General Hospital
A 4 x 4 cm window defect was created in sheep fascia lata and abdominal wall fascia and repaired with XCM Biologic Tissue Matrix. After 6 and 12 weeks, the implant sites were harvested and subjected to mechanical testing and histological analysis.

The implant sites appeared to be well integrated with the surrounding tissue at both 6 and 12 weeks. There was no evidence of bulging of the underlying muscle. Based on tactile feel, the repaired tissue felt identical to the native host tissue.*

The tissue matrix was fixed upon explantation, sectioned, and stained by hematoxylin and eosin to assess cell penetration and tissue repair. Histology showed excellent incorporation with the surrounding tissues and cell infiltration.*

* Data on file at Kensey Nash Corporation
Biomechanical testing was conducted by cutting dogbone-shaped samples from the repaired tissue at the center of the implant. The test samples were subjected to tensile testing at 24 mm per minute. The biomechanical testing proved that the repair sites implanted with XCM Biologic Tissue Matrix maintained strengths greater than normal fascia throughout the healing process.*

![Histology at 6 weeks (left) and 12 weeks (right). Note cell infiltration at 6 weeks, and repair tissue at 12 weeks.](image)

**Surgical Site Strength over Time**

![Surgical Site Strength over Time graph](image)

Biomechanical testing of surgical sites after healing. XCM Biologic Tissue Matrix maintains strengths greater than native tissue throughout the healing process.

* Data on file at Kensey Nash Corporation
### XCM Biologic Tissue Matrix, sterile, hydrated

**Dimensions**

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Additional sizes may be available. Please contact your Synthes Sales Consultant for details.

**Note:** For additional information, please refer to package insert.
References


