A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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Summary

1. TissueMend Soft Tissue Repair Matrix is an acellular, collagen membrane designed to reinforce tendon repair and facilitate tissue remodeling.

2. A clinical safety record of 99.9% was demonstrated with over 8,500 implantations.

3. A unique collagen composition and structure makes TissueMend an excellent biologically inspired scaffold for tissue remodeling.

4. Strength and ease of handling are designed to handle the surgical demands of tendon repair.

Introduction

The TissueMend Soft Tissue Repair Matrix is an acellular, collagen membrane designed to reinforce soft tissues where weakness exists. It also serves as a biologically inspired scaffold for cellular and vascular ingrowth that is gradually remodeled into new tissue.

Produced from fetal bovine dermis through a proprietary process, TissueMend possesses a unique combination of biologically inspired and physical properties, helping to satisfy the surgical demands of massive rotator cuff repair.

Unique Features

Clinically Proven Safety

- Depleted of all known immunogens, e.g., lipids and carbohydrates
- Terminally sterilized
- Demonstrated lack of inflammation and foreign body reaction
- Achieved a 99.9% clinical safety rate with over 8,500 implantations

Histological staining of pre-processed TissueMend. Note the native collagen fibers (in red) and intact cells (in blue).

Histological staining of post-processed TissueMend. Note the native collagen fibers (in red) and lack of intact cells.
**Biological Scaffold for Remodeling**

- Derived from fetal tissue and contains a high amount of type III collagen, which has been shown to facilitate tissue remodeling and support tendon repair$^{4-7}$
- Non-artificially cross-linked and contains active native collagen$^{8-10}$
- Designed to maintain the native collagen structure and pore size for better cell and vascular infiltration$^{8,9}$

![Scanning Electron Micrograph (SEM) of TissueMend scaffold showing the native collagen fiber structure.](image)

A schematic diagram depicting the scaffold remodeling process:

- **Step 1:** Infiltration of host cells after implantation
- **Step 2:** Breakdown of the implant matrix and synthesis of the new matrix proteins (e.g., type III and I collagens) by host cells
- **Step 3:** Formation of host derived matrix mimicking the repair tissue

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**Improved Strength for Load Sharing**

- Validated suture pull-out strength of 35.5 N$^3$
- Demonstrated 107% of improvement on load to failure$^{11}$

![Graph showing improved load to failure](image)

**Repairs of Achilles tendon rupture were performed on six matched pairs of sheep with either interlocking Krackow loops alone using #2 Ethibond suture or TissueMend circumferentially wrapped around the sutured tendon.$^9$**

**Better Physical and Handling Property**

- Room temperature storage with a shelf life of 3 years
- Hydrates in less than a minute
- Highly conforming once hydrated

* Information found in package insert

![Hydrated TissueMend](image)
TissueMend is a soft tissue matrix that possesses the unique combination of biologically inspired and physical properties for excellent tendon repair.

<table>
<thead>
<tr>
<th>Product</th>
<th>Safety</th>
<th>Strength</th>
<th>Remodeling</th>
<th>Ease of use</th>
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<td></td>
<td>Lack of Inflammation</td>
<td>Terminal Sterilization</td>
<td>Failure Load (&gt;70 N)</td>
<td>Fetal Origin &gt; 25% Col III Content</td>
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1. Information gathered from companies’ websites
2. Information gathered from Sales Brochures

Richard M. Seldes, MD
University Place Orthopaedics, New York, NY

“I have been using TissueMend for tissue augmentation for massive rotator cuff tears for the last 3 years. I perform an arthroscopic insertion technique after an arthroscopic rotator cuff repair. I have performed approximately 40 arthroscopic insertions. I have also used it for delayed reconstructions of quadriceps and Achilles tendon ruptures.

“I have evaluated and used most of the other tissue augments and I prefer TissueMend because of its handling and suturing characteristics and its lack of an inflammatory response or tissue reactions. Additionally, it is easy to store on the shelf and hydrates in less than a minute in the OR. It is one of the few tissue augments that, in my opinion, may be inserted arthroscopically.

“I am currently using it in all of my cases of large to massive rotator cuff repairs. I have had excellent results with using TissueMend in these difficult cases.”

References: