

BioBridge® Collagen Matrix

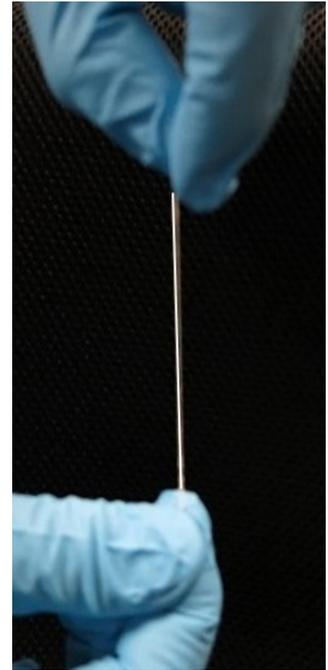
Engineered for Patient Care

The BioBridge® Collagen Matrix is a new sterile implantable surgical mesh designed for use in soft tissue support and repair.

This novel medical device is made of highly purified collagen and is fabricated using Fibralign's patented Nanoweave® technology to deliver the mechanical properties needed to provide support to weaknesses and deficiencies in soft tissue and aids in "bridging" a connection between healthy soft tissues.

Proven Performance and Safety

- Bioengineered native tissue structure produced from only highly purified Type 1 porcine atelocollagen (pepsin treated)
- Biocompatible — minimizes patient immunogenic response
- Absorbable — design to integrate into tissue and safely fully absorb
- Suturable, high biomechanical strength (30 MPa)
- Versatile — narrow ribbon form factor provides flexibility in use
- Ready to use, provided in single-use sterile packaging (e-beam)
- Highly porous multilumenal structure, promotes capillary flow;
- Zero length cross linking technology (EDC)
- Pre-clinical data shows BioBridge helps to promote angiogenesis and tissue repair, enhancing the natural maintenance process



BioBridge is a novel surgical mesh made of highly purified collagen engineered to support and repair soft tissue



Fibralign BioBridge[®] Collagen Matrix

BioBridge[®] Collagen Matrix is a sterile, thin collagen ribbon made of highly purified pepsin treated Type 1 porcine collagen. It is provided in single-use packaging with five devices included in each package. BioBridge cannot be resterilized.

Indications

The BioBridge Collagen Matrix is intended to reinforce soft tissue where weakness and deficiencies exist, specifically, for reinforcement of soft tissue repaired by sutures or suture anchors in tendon repair, including small tendons, ligaments; and general surgical procedures for tissue repair where weakness exists, including muscle flap reinforcement.

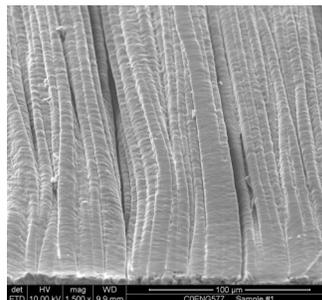
BioBridge is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair.

Contraindications

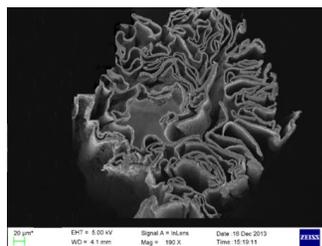
BioBridge is contraindicated for use in any patient with known sensitivity to porcine products.

Use of this product in applications other than those indicated has the potential for serious complications, such as suture pullout or failure of the repair.

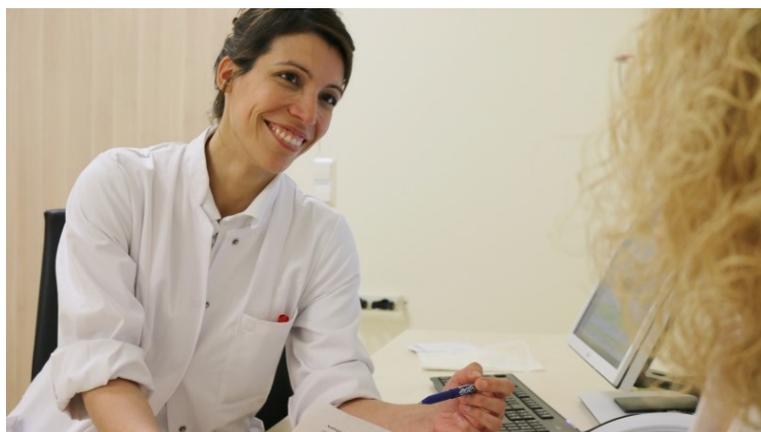
Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure used based on the medical training and experience, along with the specific patient condition. Strict aseptic techniques should be followed.



BioBridge up close (1500x magnification): Fibralign's Nanoweave technology enables the formation of a scaffold with native tissue structure from highly purified atelocollagen —providing the mechanical properties needed for the application while minimizing the immunogenic response.



Cross-section (magnified): BioBridge's thin ribbon structure provides a highly porous matrix with very high surface area, making it ideal for cell attachment and excellent tissue integration.



Fibralign Corporation
32930 Alvarado-Niles Rd., Suite 350
Union City, CA 94587
(555) 555-0123
info@fibralignbio.com
www.fibralignbio.com

Fibralign
Enabling Regenerative Medicine

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician. For complete instructions for use, storage, warnings, indications, contraindications, precautions, adverse reactions, and disclaimer of warranties, please refer to the insert accompanying each Fibralign product.

BioBridge and Nanoweave are registered trademark of Fibralign Corp. U.S. Patent include 8,513,382.

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