

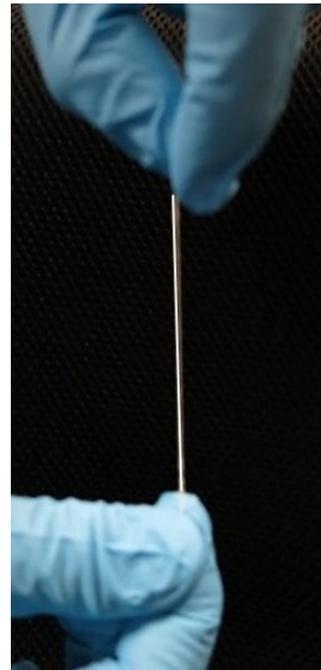
BioBridge® Collagen Matrix

Engineered for Patient Care

The BioBridge® Collagen Matrix is a new sterile implantable surgical mesh designed to provide support for the surgical treatment of lymphedema.

This novel thread-like 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, "bridging" a connection between healthy lymphatic tissue and restoring lymphatic function. BioBridge is implanted using minimally invasive techniques and is designed to safely fully resorb after it completes its function.

While BioBridge is a new breakthrough treatment option, it has already been used in over 50 surgical cases where it has been proven to be safe and effective in addressing both upper and lower limb lymphedema. These case studies have shown significant reduction in limb volume, with many patients returning to normal range.



Lower Limb Lymphedema Before and After Surgery with LNT and BioBridge
Preop Vdiffer = 35% - Postop Vdiffer = 7%



Upper Limb Lymphedema Before and After Surgery with LNT and BioBridge
Preop Vdiffer = 21% - Postop Vdiffer = 9%

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



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BioBridge[®] Collagen Matrix (PRT-0070)

Proven Performance and Safety

- Bioengineered native tissue structure produced from only highly purified Type 1 porcine atelocollagen (pepsin treated)
- Biocompatible, minimizes patient immunogenic response
- Design to integrate into tissue and safely fully resorb
- Highly porous multiluminal structure, promotes capillary flow
- Ready to use, provided in single-use sterile packaging

Indications

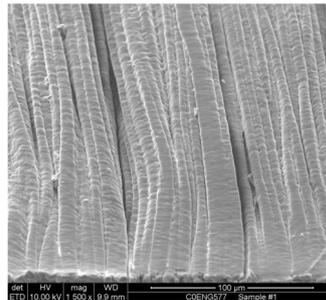
The BioBridge[®] Collagen Matrix is intended to reinforce soft tissue where weakness and deficiencies exist, specifically lymphatic tissue repair after or in conjunction with surgical procedures used to address lymphedema (lymph node transfer, lymphaticovenous anastomosis).

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

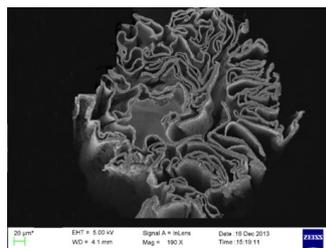
Contraindications

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

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 nanostructure from highly purified atelocollagen — providing the mechanical properties needed for lymphatic repair while minimizing the immunogenic response.



Cross-section (190x 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.



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BioBridge is only available for purchase 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 Instructions for Use (IFU) insert accompanying each Fibralign product.

BioBridge and Nanoweave are registered trademarks of Fibralign Corp.

Protected by U.S. and international patents, including U.S. Patent 8,513,382.

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Enabling Regenerative Medicine