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INSPECTION POINTS	REQUIREMENT	REQUIREMENT DETAILS
	Stock:	Printer/Copier Paper
IQC/A	**Stock Color:**	White
	Stock Size:	A4
	Adhesive:	N/A
	Liner:	N/A
	Printing (check one):	☒ In house ☐ Supplier
IQC/B	**Print Color:**	Black (No Color)
	Printing Method: **(for in-house printed labeling only)**	Laser Printer (No Photocopying); Double Sided
IQC/C	**Content:** **(include below or as an attached page(s) to this document)**	This Page is NOT part of the IFU. Only the pages following this page are part of the IFU.
IQC/D	**Print Quality:**	Print must be legible, free of smear/smudges and must not be missing text.
IQC/E	**Page Numbering:**	100% inspect the lot to ensure that each sheet has page numbers printed on both sides.
IQC/F	**Finish:**	100% inspect to ensure the IFU is folded in half along the long side (REF: Final size 11” x 4.25”) with the “Fibralign Logo” visible after folding.

BioBridge® Collagen Matrix

CE 0344

The Fibralign BioBridge® Collagen Matrix is a sterile, thin collagen ribbon made of highly purified pepsin treated Type 1 porcine collagen and features Fibralign's Nanoweave® technology. It is provided in single use packaging with five devices included in each package.

INDICATIONS

The BioBridge® Collagen Matrix is intended to reinforce soft tissue where weakness and deficiencies exist, specifically, in support of 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.

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.

POTENTIAL COMPLICATIONS

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.

PRECAUTIONS

DO NOT use BioBridge Collagen Matrix if the outer plastic package is damaged or torn. Damaged packaging may result in degradation or contamination of the product.

BioBridge is designed and intended for single use only; do not reuse devices. Open packaging using strict aseptic techniques and dispose of any unused devices after completing procedure. DO NOT save or repurpose devices for other patient procedures because it may result in serious patient harm. Reuse and repurposing may cause device failure or procedural complications including device damage, compromised device biocompatibility, and lead to cross-infection and contamination.

Do not use product beyond indicated expiration date.

ADVERSE REACTIONS

Possible adverse reactions may include, but are not limited to, contamination, infection, inflammation, adhesion, and tissue encapsulation.

If an infection or allergic reaction occurs, the entire matrix may have to be revised or removed.

STERILITY

The BioBridge Collagen Matrix is supplied **STERILE.** Provided that the package is not compromised in any way, the package will serve as an effective barrier until the "Use By" (expiration) date printed on the label. Immediately return damaged product to Fibralign Corporation.

The box and outer plastic tray and lid cannot be placed in a sterile field. The inner tray and tubes containing BioBridge are intended for sterile field where it can be opened to remove devices.

DO NOT RE-STERLIZE. Re-sterilization may damage the product.

STORAGE CONDITIONS

Do not use if this product has not been stored in accordance with the following storage conditions: Product must be stored in a clean, cool and dry environment in temperature below 37°C

This product has an expiration date and should be used before the "use by" (expiration) date marked on the box.

RECOMMENDED TECHNIQUES

HANDLING

Use strict aseptic techniques when preparing and handling the product.

To open the package, hold the base outer tray and peel back the lid so that the inner tray can be removed by grasping the lip. Place inner tray in sterile environment and gently remove the tubes holding each individual BioBridge Collagen Matrix. Each device can be removed from its plastic tube by removing the cap and sliding it out.

MAINTAINING ASEPSIS

To help maintain asepsis during surgery, special precautions and extremely careful preoperative site preparations are necessary. When operative infection is suspected, dissection of involved tissues should be considered. Any post operative infection should be aggressively treated at the earliest possible time. An unresolved infection may require removal of the material.

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Exposure of the BioBridge Collagen Matrix to the external environment during healing should be avoided. If the BioBridge device should become exposed during healing, treat to avoid contamination and allow secondary healing with tissue flap coverage, if possible.

SIZING

Trim the BioBridge Collagen Matrix to the desired size by using sharp surgical scissors. Avoid cutting too small because excessive tension may be placed on the suture line, which could result in recurrence of the original, or development of an adjacent tissue defect.

SUTURING

To ensure the optimal conditions for the tissue repair, the BioBridge Collagen Matrix should retain its configuration in the designated location. It is recommended to suture the BioBridge to the surrounding soft tissue. Although Fibralign cannot recommend a particular surgical technique suitable for all patients, non-resorbable or absorbable sutures should be used within 11-0 to 5-0 size range, depending on the application. It is advised that sutures in the size range of 10-0 to 11-0 be used to place the stitches though BioBridge, and 5-0 to 8-0 sutures be used to secure BioBridge by tying the suture around the device and making a knot.

WARNINGS

The BioBridge Collagen Matrix is designed for single use only; do not reuse device.

Strict aseptic techniques should be followed. If an infection develops, it should be treated aggressively. An unresolved infection may require removal of the material. Use appropriately sized material for the repair. Check product integrity after implantation. If the BioBridge is cut too small for the repair, excessive tension may be placed at the fixation points, which may lead to pull-out. Inadequate fixation may allow the material to migrate and not adequately support repair.

DISPOSAL

After use, handle and dispose of any unused portions of the matrix in accordance with accepted medical practice and applicable laws and regulations.

DEFINITIONS

Symbol	Definition	Symbol	Definition
	Do not Re-Sterilize	37°C	Storage temperature limitation
	Do not Re-Use		Manufacturer
	Use by		Caution
CE	This product fulfils the requirements of Directive 93/42/EC on Medical Devices		Keep Dry
REF	Part number		Do not use if package is damaged
LOT	Batch Code	STERILE R	Sterilized using radiation
EC REP	Authorized Representative in the European Community		Read instruction for use
5x	Five devices per package		

Manufacturer: Fibralign Corporation
32930 Alvarado-Niles Road,
Suite 350
Union City, CA 94587
+1-510-489-8109

EC REP Mectalent Medical Services Oy
Veistämötie 15
90620 Oulu, Finland

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