MiroFlex®
Biologic Matrix

MIROFLEX® BIOLOGIC MATRIX INSTRUCTIONS FOR USE

CAUTION - RX ONLY
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
This product is intended for use by trained medical professionals.

DEVICE DESCRIPTION

MiroFlex Biologic Matrix is a non-crosslinked acellular surgical matrix that is derived from the highly vascularized porcine liver and is processed and stored in a phosphate buffered aqueous solution. MiroFlex Biologic Matrix is supplied sterile, packaged in an inner sterile pouch and outer non-sterile pouch, and is intended for one-time use. In clinical use, the device should be placed in maximum possible contact with healthy, well-vascularized tissue to assist in initiating cell ingrowth and tissue remodeling.

MiroFlex is available in six sizes listed in Table 1. Each device is packaged individually.

TABLE 1: MIROFLEX SIZE OFFERINGS

Size (dimensions)	Model Number	Quantity
6 cm x 8 cm	BLM-100-01-0608	1
8 cm x 8 cm	BLM-100-01-0808	1
10 cm x 10 cm	BLM-100-01-1010	1
8 cm x 16 cm	BLM-100-01-0816	1
10 cm x 16 cm	BLM-100-01-1016	1
10 cm x 20 cm	BLM-100-01-1020	1

INDICATIONS FOR USE

The MiroFlex Biologic Matrix is intended to be implanted to reinforce soft tissue and is also intended for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery.

CONTRAINDICATIONS

This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

WARNINGS

- MiroFlex Biologic Matrix is supplied sterile for single use only. Reuse of a single-use device creates a potential risk of patient user infections and may compromise the device functionality, which may lead to illness or serious injury.
- Do not resterilize as the safety and performance has not been evaluated for this scenario. MiroFlex is a single use only device.
- Do not use a device past the expiration date as the safety and performance has not been evaluated.
- Do not use if the package or seal is opened, damaged, or compromised. A damaged package could result in a breach of sterility or device damage.
- Do not use the product if the heat indicator has been activated as the safety and performance of the device has not been evaluated for that scenario.
- After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. This is a single-use device. Reuse of this device creates a potential risk of patient infections.

PRECAUTIONS

- Discard device if mishandling has caused possible damage or contamination as it may have resulted in breach of sterility or compromised device functionality.
- MiroFlex Biologic Matrix should be hydrated and moist when the package is opened. If the device is dry, do not use as it may compromise device functionality.
- If passing MiroFlex Biologic Matrix through a trocar for a laparoscopic procedure, ensure that the inner diameter is adequately sized to prevent tearing or other damage to the matrix.

POTENTIAL ADVERSE EVENTS

- Abscess
- Adhesion
- Biological response
- Dehiscence
- Dysphagia
- Erosion
- Fistula
- Hematoma
- Infection
- Laxity
- Necrosis
- Obstruction
- Pain
- Recurrence
- Seroma

STORAGE

- MiroFlex Biologic Matrix is a sterile medical device that should be stored in a clean, dry location at room temperature, in its original package. Avoid prolonged exposure to elevated temperatures as it may compromise device functionality.
- The product expiration date is indicated as year (4 digits) and month (2 digits). The product expires after the last day of the month indicated.

STERILIZATION

This product has been sterilized with electron beam irradiation and is provided sterile.

MR SAFETY INFORMATION

The MiroFlex Biologic Matrix is MR safe.

INSTRUCTIONS FOR USE

The MiroFlex Biologic Matrix should be used by physicians trained on the procedures for which the device is intended. The techniques and procedures described do not represent ALL medically acceptable protocols, nor are they intended as a substitute for the physician's experience and judgment in treating any specific patient. All available data, including the patient's signs and symptoms and other diagnostic test results, should be considered before determining a specific treatment plan.

PACKAGE CONTAINS: ONE (1) MIROFLEX BIOLOGIC MATRIX DEVICE IN A PHOSPHATE BUFFERED AQUEOUS SOLUTION

REQUIRED MATERIALS NOT PROVIDED

- Sterile forceps.
- Soaking solution: room temperature sterile saline or room temperature sterile lactated Ringer's solution.
- One sterile basin per piece of MiroFlex Biologic Matrix.

PRODUCT PREPARATION INSTRUCTIONS

1. Check the heat indicator on the carton. Do not use the product if the heat indicator is activated.
2. Open the carton and remove the foil pouch.
3. Inspect the outer foil pouch. Do not use if the outer pouch is damaged or if the seals are compromised.
4. Peel open the outer foil pouch and remove the inner foil pouch using aseptic technique. The inner foil pouch is sterile and may be placed directly into the sterile field.
5. Peel open the inner foil pouch and remove the product using aseptic technique. Always use sterile gloved hands or forceps when handling the product.
6. Soak the device for a minimum of 2 minutes using a sterile basin and room temperature sterile saline or room temperature sterile lactated Ringer's solution to cover the matrix and prevent it from drying out.
7. Store the device in the room temperature sterile solution until ready for implantation.

IMPLANTATION INSTRUCTIONS

1. Prepare the graft site using standard surgical techniques.
2. Using aseptic technique, MiroFlex Biologic Matrix may be trimmed or cut as desired to fit the surgical site, ensuring allowance for overlap.
3. MiroFlex Biologic Matrix should be placed in maximum possible contact with healthy, well-vascularized tissue to assist in initiating cell ingrowth and remodeling.
4. Suture MiroFlex Biologic Matrix in place. When suturing, place the sutures at least 3 mm from the edge of the MiroFlex Biologic Matrix.

5. Complete the standard surgical procedure per institutional protocol.
6. Discard any unused portion of the MiroFlex Biologic Matrix product and package in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

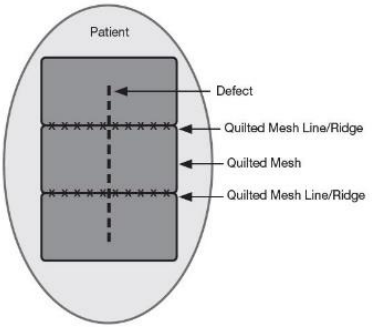
INSTRUCTIONS FOR QUILTING (I.E., SUTURING TOGETHER) TWO OR MORE MIROFLEX BIOLOGICS MATRICES

NOTE: If a larger size of MiroFlex Biologic Matrix is needed, multiple MiroFlex Biologic Matrices may be sutured together to a maximum size of 20 cm x 30 cm quilted matrix using the instructions below.

WARNING

THE RESULTING QUILTED MATRIX LINE MUST BE PLACED PERPENDICULAR TO THE DEFECT AS DESCRIBED BELOW AND SHOWN IN FIGURE 1 FOR QUILTED MATRICES.

Figure 1: Orientation and Placement Diagram for Three Quilted Matrices



QUILTING PRECAUTIONS

- Quilting multiple pieces of MiroFlex Biologic Matrix is not recommended for any bridging procedures.
- Do not allow the matrices to dry out while suturing them together.
- When trimming quilted matrices, do not cut or remove the suture knots.

ADDITIONAL REQUIRED MATERIALS FOR SUTURING TWO OR MORE MIROFLEX BIOLOGIC MATRICES – NOT INCLUDED

- CT-1 surgical needle with non-absorbable suture (such as PROLENE®) Size 0, minimum length of 30"
- Sterile ruler

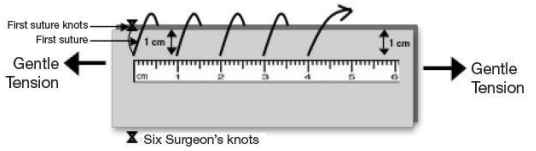
SUTURING INSTRUCTIONS:

1. Using aseptic technique, align and stack two MiroFlex Biologic Matrices along edges of equal length per Figure 2. Place a sterile ruler along the matrices 1 cm from the edge of the top MiroFlex Biologic Matrix as a suture guide. All running sutures require a 1 cm bite (Figure 2).

NOTE: It may be helpful to apply gentle tension on opposite ends of the stacked matrices during quilting to keep the matrices from moving.

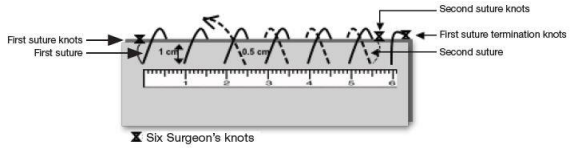
2. Anchor a suture on one end of the stacked MiroFlex Biologic Matrices with a minimum of six surgeon's knots and suture the two pieces together with a running suture every 1 cm (Figure 2). Suture line should be pulled taut during suturing process to ensure uniform tension along the line. Once the edge of the stacked matrices has been reached, secure the suture with a minimum of six surgeon's knots. Cut the suture to leave a tail of appropriate length. **NOTE:** The surgeon may add additional throws to each knot as necessary.

Figure 2: Diagram of Two Stacked Matrices with the First Running Suture



3. Beginning at the opposite end of the stacked MiroFlex Biologic Matrices, anchor another suture with a minimum of six surgeon's knots and **suture the two matrices together with a running suture in the opposite direction every 1 cm in between the spaces formed by the first running suture resulting in a final suture spacing of 0.5 cm (Figure 3)**.
Secure with a minimum of six surgeon's knots at the opposite end. Cut the suture to leave a tail of appropriate length. **NOTE:** The surgeon may add additional throws to each knot as necessary.

Figure 3: Diagram of Two Stacked Matrices with Both Running Sutures



4. The resulting quilted line will have a crisscross appearance to the sutures and a 0.5 cm spacing between the sutures (Figure 4 & 5).

Figure 4: Diagram of Finished Matrices

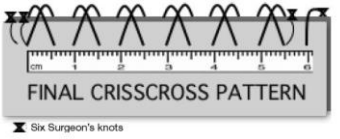
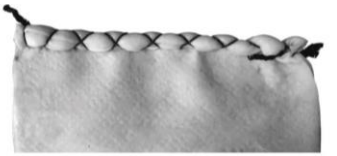


Figure 5: Side View of Example Quilted Matrix



5. Open the quilted matrix so that it is a single layer and observe the crisscross pattern (see Figures 6 & 7). Position the matrix with the suture ridge anterior (visible to the surgeon) with the suture ridge running perpendicular to the incision upon implant (see Figure 8). Complete the standard surgical procedure.

Figure 6: Top View Example of Crisscross Pattern in Quilted Matrix

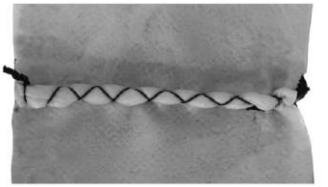


Figure 7: Top View Diagram of Two Quilted Matrices

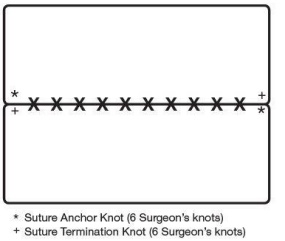
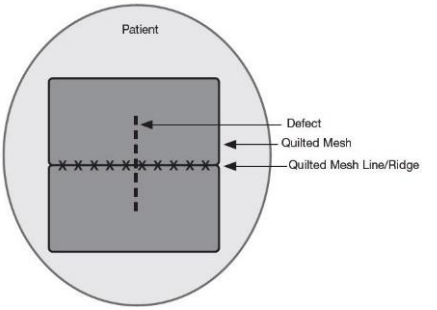


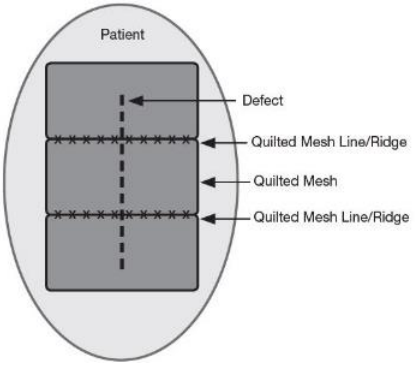
Figure 8: Placement Diagram for Two Quilted Matrices



6. When quilting together multiple matrices (maximum size is 20 cm x 30 cm), ensure each matrix is quilted such that the quilted line will be oriented perpendicular to the defect line (see Figure 9).
7. Once quilting is complete, open the quilted matrix so that it is a single layer. Position the matrix with the suture ridges anterior (visible to the surgeon) with the suture ridge running perpendicular to the incision upon implant (see Figure 9).

8. Complete the standard surgical procedure.

Figure 9: Placement Diagram for Three Quilted Matrices



SYMBOLS GLOSSARY

SYMBOL	TITLE
REF	Catalog number
	Use-by-date (YYYY-MM)
	Manufacturer
	Consult Instructions for Use
STERILE R	Sterilized by irradiation
	Temperature limit
	Do not use if package is damaged
2 STERILIZE	Do not re-sterilize
LOT	Lot number
	Do not re-use
RX ONLY	Prescription use only
MR	MR safe

LIMITED WARRANTY

Reprise Biomedical, Inc. warrants that MiroFlex is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to refund or replacement of any product, which has been found by Reprise Biomedical to be defective in workmanship or materials. Reprise Biomedical shall not be liable for an incidental, special, or consequential damage arising from the use of MiroFlex. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

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