MiroDerm®
Biologic Wound Matrix

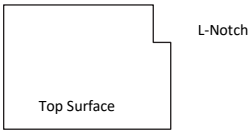
MiroDerm® FENESTRATED AND FENESTRATED PLUS INSTRUCTIONS FOR USE

CAUTION - Rx ONLY
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

DEVICE DESCRIPTION

MiroDerm Biologic Wound Matrix is a non-crosslinked acellular wound matrix that is derived from the highly vascularized porcine liver and is available in two forms: Fenestrated and Fenestrated Plus. The fenestrations on the mesh offer a left-to-right stretch which increases the surface area available to contact the wound. The Fenestrated Plus version provides wider gaps when stretched than the Fenestrated version. Placing MiroDerm in maximum possible contact with healthy, well-vascularized tissue will assist in initiating cell ingrowth and tissue remodeling. The top surface is identified and facing the user when the L-notch is located in the upper right corner; see Figure 1.

Figure 1: MiroDerm Orientation



MiroDerm is processed and stored in a phosphate buffered aqueous solution, is packaged in an inner sterile pouch and outer non-sterile pouch and is intended for single use only. MiroDerm is available in a variety of sizes (see Table 1) that may be trimmed to meet the individual patient's needs. The device is packaged individually, and the exterior package has a heat indicator to identify if the product has been exposed to unacceptable temperature excursions.

Table 1: MiroDerm Size Offerings

Size (dimensions)	Model Number
Fenestrated	
8 cm x 15 cm	BLM-200-02-0815
7 cm x 10 cm	BLM-200-02-0710
8 cm x 8 cm	BLM-200-02-0808
5 cm x 5 cm	BLM-200-02-0505
3 cm x 7 cm	BLM-200-02-0307
4 cm x 4 cm	BLM-200-02-0404
3 cm x 3 cm	BLM-200-02-0303
2 cm x 3 cm	BLM-200-02-0203
2 cm x 2 cm	BLM-200-02-0202
Fenestrated Plus	
8 cm x 15 cm	BLM-200-03-0815
8 cm x 8 cm	BLM-200-03-0808
5 cm x 5 cm	BLM-200-03-0505
3 cm x 3 cm	BLM-200-03-0303

INDICATIONS

MiroDerm (Fenestrated and Fenestrated Plus) is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Tunneled, undermined wounds
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Draining wounds
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)

CONTRAINDICATIONS

- This device is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.
- This device is not indicated for use in third-degree burns.

WARNINGS

- MiroDerm Biologic Wound 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 re-sterilize as the safety and performance has not been evaluated for this scenario. This is a single use device.
- Do not use a device past the expiration date as the safety and performance has not been evaluated for this scenario.
- 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, which may lead to illness or serious injury.
- 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 for 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.
- MiroDerm should be hydrated and moist when the package is opened. If MiroDerm is dry, do not use as a dry device may impact ease of handling or not conform to the site properly, both impacting desired performance.
- Soak the device 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..
- MiroDerm should not be used until excessive exudate, bleeding, acute swelling, and infections are controlled as it may not conform to the site properly and not perform as desired.

POTENTIAL ADVERSE EVENTS

- Allergic reaction
- Excessive redness, pain, swelling, or blistering
- Fever
- Infection
- Chronic inflammation
- Non-healing wound

STORAGE

- MiroDerm (Fenestrated and Fenestrated Plus) 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), month (2 digits), and day (2 digits).

STERILIZATION

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

MR SAFETY INFORMATION

The MiroDerm Biologic Wound Matrix is MR safe.

INSTRUCTIONS FOR USING MIRODERM

The MiroDerm Biologic Wound 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) MiroDerm Biologic Wound Matrix device in a phosphate buffered 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 MiroDerm Biologic Wound Matrix
- Wound dressings: 1) a non-adherent primary wound dressing and 2) a secondary wound dressing (multi-layer compression bandage system, total contact cast, or other appropriate dressing)

PRODUCT PREPARATION INSTRUCTIONS

1. Inspect package and reject product if package is previously damaged or opened.
2. Peel open outer foil package and aseptically deliver inner, sterile package to sterile field.
3. Open the inner pouch and aseptically remove MiroDerm.
4. MiroDerm has a top and bottom surface. To identify the top surface, orient the MiroDerm so that the small L-notch is in the upper right corner (Figure 1). The top surface is then facing the user.
5. Cut MiroDerm to the desired size. If necessary, the product may be additionally fenestrated or meshed with a scalpel using institutional protocol.
6. Soak MiroDerm for a minimum of 2 minutes using a sterile basin and room temperature saline or room temperature sterile Lactated Ringer's solution to cover the matrix and prevent it from drying out.

APPLICATION OF MIRODERM

Prepare the wound using standard methods ensuring that the wound is free of debris and devitalized tissue. An initial debridement of the wound may be necessary to ensure the wound edges contain viable tissue.

1. MiroDerm should be placed into the wound bed so that the top surface is facing out and in contact with the primary dressing (see Figure 1 for identifying the top surface).
2. MiroDerm should be placed in maximum possible contact with healthy, well-vascularized tissue to facilitate the initiation of cellular infiltration and tissue remodeling. Position MiroDerm to extend slightly beyond all wound margins.
3. Secure MiroDerm as desired with physician's preferred fixation method.

4. Use an appropriate non-adherent primary wound dressing over MiroDerm to prevent it from adhering to the dressing and to protect the integrity of the applied product and not disrupt the wound site.
5. Apply an appropriate secondary dressing that will manage the wound exudate, keep MiroDerm moist, and keep all layers securely in place.
6. Discard any unused portion of MiroDerm product and package in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
7. As healing occurs, sections of MiroDerm may gradually peel. Carefully remove any remaining loose product around the edge as needed. Do not remove any remaining MiroDerm that has integrated.
8. If the wound is free of infection and necrosis but not fully epithelialized, follow standard clinical protocol for additional application or therapy.

SYMBOLS GLOSSARY

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

LIMITED WARRANTY

Reprise Biomedical, Inc. warrants that MiroDerm 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 MiroDerm. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

No employee, agent, or distributor of Reprise Biomedical has any authority to alter or amend this limited warranty in any respect. Any purported alteration or amendment shall not be enforceable against Reprise Biomedical.

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PATENTS AND TRADEMARKS

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