

# Miro3D<sup>®</sup> Fibers

## Wound Matrix

### **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**

Miro3D Fibers is a three-dimensional wound matrix derived from the highly vascularized porcine liver. It is perfusion decellularized and processed in a phosphate buffered aqueous solution, then dried. The resulting dry, porous material is milled to create Miro3D Fibers. Miro3D Fibers is supplied sterile, packaged in a plastic tray with lid, sealed in a foil pouch, and placed inside a corrugated retail box. Miro3D Fibers is intended for one-time use in a single patient. The device may be applied wet or dry. The dressing is a porous scaffold which provides a protective environment for wound management.

Miro3D Fibers is available in four sizes listed in Table 1. Each device is packaged individually.

**Table 1: Miro3D Fibers Size Offerings**

<b>Total Volume (mg)</b>	<b>Model Number</b>	<b>Quantity</b>
100	4000	1
250	4005	1
500	4010	1
700	4015	1

### **INDICATIONS FOR USE**

The Miro3D Fibers wound matrix is intended 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, and 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**

- Miro3D Fibers is supplied sterile for single use only. Reuse of a single-use device creates a potential risk of patient or 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. This is a single-use device. Reuse of this device creates a potential risk of patient infections.
- 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.
- 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.
- Miro3D Fibers has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Miro3D Fibers in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

## **PRECAUTIONS**

- Discard device if mishandling has caused possible damage or contamination as it may have resulted in breach of sterility or compromised device functionality.
- Miro3D Fibers should not be used until excessive exudate, bleeding, and acute swelling are controlled and active infections have been cleared, 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**

- Miro3D Fibers 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.

## **INSTRUCTIONS FOR USING MIRO3D FIBERS**

Miro3D Fibers 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) Miro3D Fibers device**

**REQUIRED MATERIALS NOT PROVIDED**

Miro3D Fibers may require the components listed below for preparation and deployment:

- Sterile forceps for handling the product
  - Note: The product may be applied directly to the wound without forceps.
- Soaking solution: room temperature sterile saline or room temperature sterile lactated Ringer's solution
- Wound dressings: 1) a non-adherent primary wound dressing and 2) a secondary wound dressing

**PRODUCT PREPARATION INSTRUCTIONS**

1. Open the carton and remove the foil pouch.
2. Inspect the foil pouch and do not use if damaged or if the seals are compromised.
3. Peel open the foil pouch and place the plastic tray into the sterile field using aseptic technique.
4. Once in the sterile field, remove the plastic lid.
5. The product can be applied dry or hydrated.
6. If applying hydrated, add sterile saline or lactated Ringer's solution into the tray to hydrate the matrix. Add the fluid volume necessary to create a desired consistency of the Miro3D Fibers. Maintain the device in the sterile soaking solution until ready for use.
7. If hydrated prior to deployment, the device should be used within 4 hours.

**APPLICATION OF MIRO3D FIBERS**

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. Using aseptic technique, manually or with forceps, place the product directly in contact with the wound surface. Miro3D Fibers should be placed in maximum possible contact with healthy, well-vascularized tissue as a scaffold which provides a protective environment for the wound.
2. If choosing to apply the product dry, it may be hydrated in situ with sterile saline or lactated Ringer's solution.
3. Use an appropriate non-adherent primary wound dressing over Miro3D Fibers to prevent it from adhering to the dressing and to protect the integrity of the applied product and not disrupt the wound site.
4. Apply an appropriate secondary dressing that will manage the wound exudate, keep Miro3D Fibers moist, and keep all layers securely in place.
5. Discard any unused portion of the Miro3D Fibers product and the package in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
6. As healing occurs, sections of Miro3D Fibers may not integrate. Carefully remove any remaining loose product as needed. Do not remove any remaining Miro3D Fibers that has integrated.
7. If the wound is free of infection and necrosis but not fully epithelialized, follow standard clinical protocol for additional application or therapy.

## LIMITED WARRANTY

Reprise Biomedical, Inc. warrants that Miro3D Fibers 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 Miro3D Fibers. 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

May be covered by one or more U.S. patents.

Miro3D is a registered trademark of Reprise Biomedical, Inc.



**Do Not Use If Package Is Damaged**



**Sterilized by irradiation**



**For Single Use Only**



**Do Not Resterilize**



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