MiroDry™
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

MiroDry is a dry, open, and porous collagen sheet matrix designed to conform to wound beds. It is derived from highly vascularized porcine liver that has been perfusion decellularized, dried, and packaged. MiroDry is supplied sterile, packaged in a plastic tray with a snap-on lid and Tyvek seal. The plastic tray configuration is sealed in a foil pouch and placed inside a corrugated box. MiroDry is intended for one-time use in a single patient. Prior to clinical use, the device should be hydrated with sterile saline or Lactated Ringer's solution for a minimum of five minutes. MiroDry is a porous sheet scaffold which provides a protective environment for wound management.

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

Table 1: MiroDry Size Offerings

Size (cm)	Total cm^2	Model Number	Quantity
2 x 2	4	6000	1
3 x 3	9	6005	1
4 x 4	16	6010	1
5 x 5	25	6015	1
7 x 5	35	6022	1
10 x 5	50	6025	1

INDICATIONS FOR USE

The MiroDry 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, partial thickness 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 a known sensitivity to porcine material.

This device is not indicated for use in third-degree burns.

WARNINGS

- MiroDry 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 have 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 the device past the expiration date, as the safety and performance have 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.

PRECAUTIONS

- Discard device if mishandling has caused possible damage or contamination, as it may have resulted in breach of sterility or compromised device functionality.
- Soak the device for a minimum of 5 minutes using the tray or a sterile basin and room temperature sterile saline or room temperature sterile Lactated Ringer's solution to allow for desired conformity of the product to the wound site.
- MiroDry should not be used until excessive exudate, bleeding, and acute swelling are controlled, and 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

- MiroDry 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.

The MiroDry is MR safe.

INSTRUCTIONS FOR USING MIRODRY

MiroDry 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) MiroDry device

REQUIRED MATERIALS NOT PROVIDED

- Sterile forceps
- Scalpel or scissors
- Soaking solution: room temperature sterile saline or room temperature sterile Lactated Ringer's solution

Table 2: MiroDry Recommended Soaking Solution Volumes

Size (cm)	Soaking Solution Volume
2 x 2	50 mL
3 x 3	50 mL
4 x 4	175 mL
5 x 5	175 mL
7 x 5	175 mL
10 x 5	175 mL

- 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, peel open the Tyvek seal and remove the plastic snap-on lid.
5. Using aseptic technique, trim or cut the matrix with scissors or a scalpel to obtain the desired size for use and conformity to be in maximum possible contact with healthy, well-vascularized tissue.
6. Add sterile saline or Lactated Ringer's solution into the tray to hydrate the matrix according to Table 2.
7. Place the plastic snap-on lid back on to ensure that the buoyant material remains submerged in the solution. Rehydrate for a minimum of 5 minutes.
8. Maintain the device in the sterile solution and tray until ready for use. The device should be used within 4 hours of hydration.

APPLICATION OF MIRODRY

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. MiroDry 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 desired, secure MiroDry with the physician's preferred fixation method.
3. Use an appropriate non-adherent primary wound dressing over MiroDry 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 MiroDry moist, and keep all layers securely in place.
5. Discard any unused portion of the MiroDry 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 MiroDry may gradually peel. Carefully remove any remaining loose product around the edge as needed. Do not remove any remaining MiroDry 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 MiroDry is free from defects in workmanship and materials prior to the stated expiration date. Liability under this warranty is limited to a refund or replacement of any product found by Reprise Biomedical to be defective in workmanship or materials. Reprise Biomedical shall not be liable for incidental, special, or consequential damage arising from the use of MiroDry. Damage to the product through misuse, alteration, improper storage, or improper handling shall void this limited warranty.

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May be covered by one or more U.S.A. and/or international patents.
See: https://reprisebio.com/pp
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Do Not Use If Package Is Damaged

Sterilized by irradiation


For Single Use Only

MR Safe

Do Not Resterilize

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