MiroTract®
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

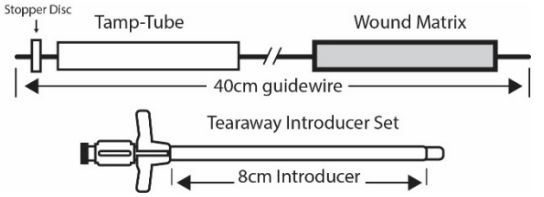
MiroTract wound matrix consists of a compressed segment of dry decellularized porcine liver that is loaded onto a guidewire along with a plastic tamp tube and a stopper disc. For user convenience, the guidewire and tamp tube provide a delivery system for the wound matrix to be placed into a wound bed or tract, such as a crack, crevice, undermining, and tunneling space. If using the guidewire and tamp tube delivery system, after the guidewire position is established, the user slides the tamp tube down the guidewire to the distal end of the wound matrix and then pushes the matrix off the wire and into the wound bed. Once in place, the guidewire and tamp tube are removed and only the wound matrix remains within the wound bed. Alternatively, the wound matrix may be removed from the guidewire and delivered manually into the wound bed.

MiroTract contains a separately packaged optional tearaway introducer set. The introducer set is comprised of a dilator and an 8cm long tearaway sheath. If desired, the tearaway introducer set can aid in delivering the wound matrix to the desired location in the wound bed, however it is not required. Once the introducer set is positioned, the dilator is removed, and the wound matrix is delivered through the in-place sheath. The tearaway sheath is then removed along with the guidewire and tamp tube while the matrix remains in the wound bed.

Once in place, the wound matrix can be hydrated by the natural wound environment, or it can be hydrated with sterile saline or sterile Lactated Ringer's solution in situ. This hydrating process relaxes the wound matrix and allows it to conform to the wound bed. MiroTract is a porous scaffold which provides a protective environment for wound management.

MiroTract is supplied sterile, packaged in a plastic tray which is sealed in a foil pouch, and placed inside a corrugated box. MiroTract is intended for one-time use in a single patient.

Each MiroTract device will contain the wound matrix, tamp tube, and a stopper disc on a guidewire. The stopper disc is for packaging purposes only and should be removed before delivery of the device. An optional tearaway introducer set is packaged separately and included with each MiroTract device.



MiroTract is available in four configurations as listed in the table below. Each device is packaged individually.

MiroTract Wound Matrix

Model Number	Outer Diameter (Dry State)	Wound Matrix Length	Introducer Set	Quantity
5000	3mm	5cm	10F	1
5010	3mm	9cm	10F	1
5020	5mm	5cm	16F	1
5030	5mm	9cm	16F	1

INDICATIONS FOR USE

The MiroTract 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 known sensitivity to porcine material.

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

WARNINGS

- MiroTract 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.

- Do not use the device on persons with a hypersensitivity or allergy to nickel or titanium as the nitinol wire component of the device contains these alloys and may create a potential allergic response.
- 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.
- Avoid hydrating the MiroTract wound matrix before use as it may prematurely relax and expand and inhibit device delivery.
- If using the tearaway introducer for device delivery, take caution to deliver without using excessive force to avoid device damage or additional trauma to the wound bed.
- If using the tearaway introducer set to deliver the MiroTract, take caution to carefully remove the sheath, guidewire, and tamp tube as to not disrupt the intended placement of the wound matrix in situ.
- MiroTract 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.
- If deploying the device into a tunneling space, take caution to pre-measure the depth of the wound bed, using standard clinical practice methods (e.g., long cotton tipped applicators or surgical probe). Note the depth of the wound in relation to the overall length of the guidewire to assist in delivery of the wound matrix to the terminal end of the tunnel space or blinded wound bed to reduce the potential risk of a void space that may lead to non-healing wounds or patient infections.

POTENTIAL ADVERSE EVENTS

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

Potential adverse events only related to wire or introducer set:

- Device dislodgment
- Device fracture or separation
- Inflammation
- Necrosis
- Pain
- Scarring
- Tissue puncture or perforation

STORAGE

- MiroTract 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.

Only the wound matrix component of the MiroTract device is MR Safe.

INSTRUCTIONS FOR USING MIROTRACT

MiroTract 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) MiroTract device and one (1) Tearaway Introducer set.

REQUIRED MATERIALS NOT PROVIDED

MiroTract may require the components listed below for preparation and deployment:

- Sterile forceps for handling the product
- Scissors or scalpel to cut excess MiroTract once in place
- Flushing solution: sterile saline or 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 pouches.
2. Inspect the pouches and do not use if damaged or if the seals are compromised.
3. Peel open the pouches and place the MiroTract tray and introducer set into the sterile field using aseptic technique.
4. Once in the sterile field, remove the plastic lid from the MiroTract tray.
5. Once MiroTract is removed from the tray, remove, and discard the stopper disc on the back of the guidewire. The stopper disc is for packaging purposes only to ensure the tamp tube doesn't prematurely slide off of the guidewire.
6. The product should be applied dry.

APPLICATION OF MIROTRACT

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

tissue. Follow standard clinical and hospital protocol.

If using the tearaway introducer set for deployment, follow steps 1 through 5 below. If not using the tearaway introducer set, follow step 1 then skip to step 6.

1. Measure the initial size of the wound, including depth, using standard clinical practice methods (e.g.; long cotton tipped applicators or surgical probe). Note the depth of the wound in relation to the overall length of the guidewire to assist in delivery of the device to the terminal end of a tunnel space or blinded wound bed.
2. Place the tearaway introducer set in the desired wound location.
3. Once the sheath is in the desired location, remove the dilator.
4. Locate the guidewire and wound matrix system, remove and discard the stopper disc from the distal end of the tamp tube.
5. Insert the guidewire with the wound matrix and tamp tube through the lumen of the sheath.
6. Ensure the stopper disc is removed from the end of the wire. Then, using aseptic technique, navigate the tip of the guidewire to the desired terminal end of wound.
7. Slide the tamp tube to the distal end of the wound matrix and gently push the matrix off the guidewire and into the wound. MiroTract should be placed in maximum possible contact with healthy, well-vascularized tissue as a scaffold to provide a protective environment for the wound.
8. If using the tearaway introducer set, grasp the butterfly hub and separate it. Gently peel the tearaway sheath down, exposing the tamp tube, guidewire, and placed wound matrix. Alternatively, the sheath can be removed without using the tearaway function. Carefully remove the remaining tearaway sheath, tamp tube, and guidewire, leaving the wound matrix in place.
9. Using sterile scissors or scalpel, carefully cut away any excess wound matrix outside of the wound space.
10. Using sterile saline or Lactated Ringer's, flush the wound containing the wound matrix to allow it to hydrate, relax, and conform to the wound bed.
11. Use an appropriate non-adherent primary wound dressing over MiroTract to maintain matrix adherence and protect the wound area.
12. Apply an appropriate secondary dressing that will manage the wound exudate, keep MiroTract moist, and securely in place.
13. Discard the wire, tamp tube, stopper disc, sheath/dilator, and packaging in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.
14. Per standard clinical protocol, the patient should be monitored by trained clinicians to full resolution of the wound using the minimum standard follow-up intervals of every seven to fourteen days with in-person visits for physical examination of the target wound.
15. As healing occurs, sections of MiroTract may not integrate. Carefully remove any remaining loose product as needed. Do not remove any remaining MiroTract that has integrated.
16. 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 MiroTract 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 MiroTract. 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.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE OR ANY OBLIGATION OF REPRISE BIOMEDICAL.

PATENTS AND TRADEMARKS

May be covered by one or more U.S.A. and/or international patents. See: https://reprisebio.com/pp

MiroTract is a trademark of Reprise Biomedical, Inc.

Do Not Use If Package Is Damaged

Sterilized by Irradiation

For Single Use Only

MR Safe Wound Matrix Only

Do Not Resterilize

Reprise Biomedical

17400 Medina Road Suite 100
Plymouth, MN 55447
763-284-6780
Reprisebio.com

42-1004-01 Rev. A