

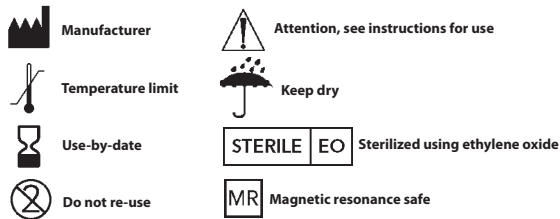


OASIS[®] MICRO

Micronized Wound Matrix

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OASIS[®] MICRO

Micronized Wound Matrix

DESCRIPTION

OASIS MICRO is an advanced wound care product comprised of micronized extracellular matrix (ECM) from small intestinal submucosa (SIS) used to manage wounds. Once applied, it provides a scaffold for cellular invasion and capillary growth, and maintains and supports a healing environment for wound management.

INTENDED USE

OASIS MICRO is intended for the management of wounds including:

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

OASIS MICRO is provided sterile and is intended for one-time use.

Rx ONLY This symbol means the following:

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed health-care practitioner.

CONTRAINDICATIONS

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

PRECAUTIONS

- OASIS MICRO is designed for single use only. Attempts to reprocess, re-sterilize and/or reuse may lead to failure and/or transmission of disease.
- Discard all open and unused portions of OASIS MICRO.
- OASIS MICRO is sterile if the pouch is dry, unopened and undamaged. Do not use if the pouch seal is broken.
- OASIS MICRO must be used prior to the expiration date.
- Discard OASIS MICRO if mishandling has caused possible damage or contamination.
- OASIS MICRO should not be applied until excessive exudate, bleeding, acute swelling and infection are controlled.

POTENTIAL COMPLICATIONS

The following complications are possible. Consider removing any residual product if any of these conditions occur.

- Allergic reaction
- Blistering
- Infection
- Inflammation (Initial application of wound dressings may be associated with transient, mild, localized inflammation.)
- Pain
- Redness
- Swelling

STORAGE

This product should be stored in a clean, dry location at room temperature.

STERILIZATION

The product is sterilized using ethylene oxide.

INSTRUCTIONS FOR USE

NOTE: Always handle OASIS MICRO using aseptic technique.

1. Prepare the wound using standard-of-care methods to ensure that the wound is free of debris and necrotic tissue. If necessary, debride the wound to ensure that the wound edges contain viable tissue.

2. Remove the bottle and dispensing cap from the pouch.

NOTE: All contents within the peel pouch are sterile and may be placed onto a sterile field.

3. Peel the seal from the bottle neck and attach the dispensing cap.

4. Remove the red spout tip from the dispensing cap. If a wider spout is preferred, use scissors to trim the spout, taking care not to trim below the etched line. Alternatively, OASIS MICRO can be dispensed without the cap onto the wound.

5. Squeeze the bottle to dispense the product and lightly cover the wound bed.

NOTE: Gently shaking the bottle may help ease application.

6. If needed, moisten the application area with sterile saline to ensure the product adheres to the wound.

NOTE: Alternatively, a small amount of sterile saline can be mixed with the product in a sterile container to make a paste prior to application.

7. Apply an appropriate non-adherent dressing over the product.

8. Assess the wound to determine moisture conditions and apply appropriate secondary dressing

layers to maintain a moist wound environment.

9. Change the secondary dressing layers as necessary, taking care to avoid dislodging the product and the non-adherent dressing.

10. Approximately every 7 days, change all dressings and reassess the wound.

NOTE: Successful integration of OASIS MICRO may appear as off-white or caramel-colored, similar to slough. This is usable extracellular matrix product and should not be removed.

11. Carefully remove any remaining loose OASIS MICRO around the wound edges. Do not forcibly remove attached OASIS MICRO.

12. Gently cleanse the wound surface with sterile saline, leaving the OASIS MICRO intact.

13. If the wound is free of infection and necrosis but is not fully epithelialized, reapply OASIS MICRO to the unhealed area.

14. Reapply OASIS MICRO every 7 days or as needed by repeating the previous application steps.