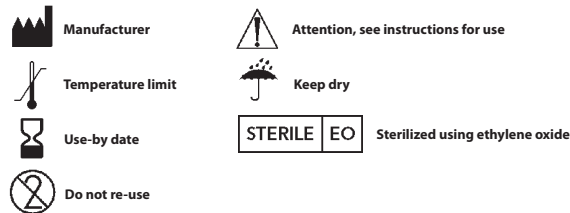




Rev. 05/14

FP0080-01C



Marketed by:

Smith & Nephew, Inc.

Fort Worth, TX 76107

Toll free: 1-800-441-8227

www.smith-nephew.com

COOK®

Manufactured by:

Cook Biotech Incorporated
West Lafayette, IN 47906

sis®
Technology

INTENDED USE:

OASIS® Wound Matrix is indicated for the management of wounds including:

- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Tunneled, undermined wounds
- Diabetic ulcers
- 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)

OASIS® Wound Matrix is supplied sterile in peel-open packages and is intended for one-time use.

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

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.

PRECAUTIONS:

- Do not re-sterilize. Discard all open and unused portions of OASIS® Wound Matrix.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- OASIS® Wound Matrix should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled.

POTENTIAL COMPLICATIONS: The following complications are possible. If any of these conditions occur, the device should be removed.

- Infection
- Chronic inflammation (Initial application of wound dressings may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Excessive redness, pain, swelling, or blistering

STORAGE: This device should be stored in a clean, dry location at room temperature.

STERILIZATION: This device has been sterilized with ethylene oxide.

SUGGESTED INSTRUCTIONS FOR USING OASIS® WOUND MATRIX

NOTE: Always handle OASIS® Wound Matrix using aseptic technique.

I. Wound Bed Preparation

- A. Prepare the wound bed using standard methods to ensure it is free of exudate and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- B. Wait for any bleeding to stop before applying OASIS® Wound Matrix.
- C. Cleanse the wound thoroughly with sterile saline.

II. Selection and Preparation of OASIS® Wound Matrix

- A. Measure the wound and select the appropriate size sheet of dry OASIS® Wound Matrix. If necessary, the product may be additionally fenestrated or meshed with a scalpel.
- B. Cut the sheet to a size and shape that will cover the entire wound surface and will extend slightly beyond the wound margins.

III. Application of OASIS® Wound Matrix

- A. For ease of handling, apply OASIS® Wound Matrix by placing it in a dry state over the wound.
- B. Position the dry OASIS® Wound Matrix to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple sheets are necessary to cover the wound, slightly overlap the edges of the sheets.
- C. As required, securely anchor OASIS® Wound Matrix with physician's preferred fixation method (e.g., STERI-STRIP™, tissue sealant, bolsters, dissolvable clips, sutures, staples, or other appropriate fixation method) based on the type of wound, location of wound, patient's mobility, and patient compliance.
- D. Thoroughly rehydrate OASIS® Wound Matrix by applying sterile saline.
- E. To protect OASIS® Wound Matrix from adhering to the secondary dressing, apply an appropriate non-adherent primary wound dressing over the OASIS® Wound Matrix.
- F. Apply an appropriate secondary dressing (multi-layer compression bandage system, total contact cast, or other appropriate dressing) that will manage the wound exudate, keep the OASIS® Wound Matrix moist, and keep all layers securely in place.

IV. Dressing Changes

- A. To prevent damage to the newly incorporating OASIS® Wound Matrix, only change the primary dressing as necessary, typically every 7 days.
- B. Change the secondary dressing as appropriate. Take care to avoid dislodging the OASIS® Wound Matrix when the secondary dressing is changed.

V. Wound Assessment and Wound Bed Preparation for Reapplication of OASIS® Wound Matrix

- A. Change all dressings every 7 days, or as necessary.

NOTE: If a gel forms on the wound surface, do not attempt to forcibly remove it. Successful absorption of OASIS® Wound Matrix may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

- B. As healing occurs, sections of OASIS® Wound Matrix may gradually peel. Carefully remove any remaining loose products around the edge as needed.
- C. Gently cleanse the wound surface with sterile saline; leave the ECM gel intact.
- D. Carefully reassess the wound and record healing progression such as wound dimensions, wound depth, wound type, and other relevant information.

VI. Reapplication of OASIS® Wound Matrix and Dressing Changes

- A. Change secondary dressings as needed (see step IV).
- B. If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared OASIS® Wound Matrix over previously absorbed application (see steps II and III).
- C. Reapply OASIS® Wound Matrix every 7 days or as needed by repeating previous application steps.

NOTE: If excess exudate collects under the sheet, small openings can be cut in the sheet to allow the exudate to drain.