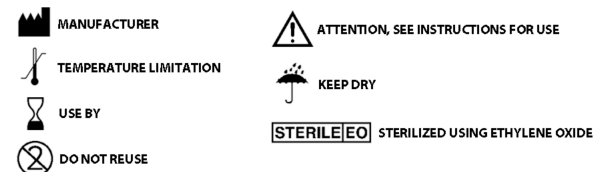




FP0100-01A



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



INTENDED USE:

OASIS[®] Ultra Tri-Layer 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-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)

OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer 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[®] ULTRA TRI-LAYER MATRIX

NOTE: Always handle OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix.
- C. Cleanse the wound thoroughly with sterile saline.

II. Selection and Preparation of OASIS[®] Ultra Tri-Layer Matrix

- A. Measure the wound and select the appropriate size sheet of dry OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix

- A. For ease of handling, apply OASIS[®] Ultra Tri-Layer Matrix by placing it in a dry state over the wound.
- B. Position the dry OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix by applying sterile saline.
- E. To protect OASIS[®] Ultra Tri-Layer Matrix from adhering to the secondary dressing, apply an appropriate non-adherent primary wound dressing over the OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix moist, and keep all layers securely in place.

IV. Dressing Changes

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

V. Wound Assessment and Wound Bed Preparation for Reapplication of OASIS[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix may gradually peel. Carefully remove any remaining loose product 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[®] Ultra Tri-Layer 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[®] Ultra Tri-Layer Matrix over previously absorbed application, (See Steps II and III)
- C. Reapply as needed if OASIS[®] Ultra Tri-Layer Matrix is no longer visible, typically every 7 days.

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