

keramatrix® Wound Dressing



STERILE R



Rx Only

Description – keramatrix® is a matrix wound dressing to assist wound healing. It is presented sterile in peel-open packages for single use.

INDICATIONS FOR USE

Acute surgical wounds, donor sites/grafts, podiatric wounds, wound dehiscence, diabetic ulcers, traumatic wounds, first and second degree burns, chronic vascular ulcers, venous ulcers, pressure ulcers, partial and full thickness wounds.

DIRECTIONS FOR USE

(Note: always handle using aseptic technique.)

Wound Bed Preparation and Application	Dressing Changes and Reapplications
<ol style="list-style-type: none">1. Prepare wound area using standard debridement methods to ensure the wound wound may be surgically debrided to ensure the wound edges contain viable tissue.2. Cut the dry keramatrix® sheet into a piece slightly larger than the outline of the wound area. If the wound is larger than a single sheet then multiple sheets may be used, overlapping edges as necessary.3. For a wound with a low-level of exudate hydrate the matrix by soaking it in sterile saline solution for 2 minutes prior to application.4. Place the edge of the sheet in contact with intact tissue and smooth the dressing so that it contacts the underlying wound bed. If multiple sheets are used, overlap adjoining sheets to provide coverage of the entire wound. Secure with Physicians preferred method of fixation (steri-strips, sutures, staples, clips).5. After application use an appropriate, non- adherent, occlusive secondary dressing to maintain a moist environment. Ensure the dressing is well restrained.	<ol style="list-style-type: none">1. Change keramatrix® dressing as necessary every 4 to 5 days or as determined by the healthcare provider. Do not remove existing Gel or Matrix areas. The Matrix will caramelize into a Gel and have an off white light brown color.2. Once cleansed with Sterile Saline solution keramatrix® may be reapplied. Ensure that there are no bleeding areas and that the wound edges are clean.3. For a wound with a medium to high level of exudate, place the edge of the sheet in contact with intact tissue and smooth the dressing so that it contacts the underlying wound bed. Small openings can be cut into the sheet prior to application to allow adequate drainage and ensure tissue matrix contact with the wound bed.4. Carefully document healing progression using customary healing parameters. Proceed with reapplication of appropriate non-adherent occlusive secondary dressing and maintain a moist environment.5. If infection, excessive redness, blistering or allergic reaction occurs the Matrix material should be removed.

CONTRAINDICATIONS

keramatrix® should not be used in patients with known sensitivity to keratin or any of the excipients.

HOW SUPPLIED

keramatrix® is supplied in clear pouch with labelled unit cartons

keramatrix® 5cm x 5cm Individual unit	NDC 71474-303-05
keramatrix® 5cm x 5cm [BOX of 5] units	NDC 71474-303-55
keramatrix® 5cm x 5cm [BOX of 10] units	NDC 71474-303-51
keramatrix® 10cm x 10cm Individual unit	NDC 71474-303-01
keramatrix® 10cm x 10cm [BOX of 5] units	NDC 71474-303-50
keramatrix® 10cm x 10cm [BOX of 10] units	NDC 71474-303-10

STORAGE / PRECAUTIONS

keramatrix® should be stored in dry, clean location between 0° and 35°C (32° and 95°F). Sterility is guaranteed unless the packaging has been opened or damaged prior to use. Do not use if the packaging has been opened, unsealed or damaged. Do not re-use or re-sterilise. Use prior to expiration date.

CAUTION: RX ONLY. Federal law restricts this device to sale by or on the order of a physician.

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The product incorporates patented and/or patent pending technologies owned by Keraplast Technologies LLC.

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