

**KERAMATRIX- dressing, wound, drug not applicable**  
**Molecular Biologicals, LLC**

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**keramatrix®**

Wound Matrix

**Rx Prescription Only**

**Single Use**

<b>STERILE</b>	<b>R</b>
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**C E**  
**0 1 2 3**

**CAUTION**

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician(or properly licensed Healthcare practitioner).

**INDICATIONS FOR USE**

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

**SUGGESTED DIRECTIONS FOR USE**

NOTE: ALWAYS HANDLE USING ASEPTIC TECHNIQUE

<b>WOUND BED PREPARATION &amp; APPLICATION</b>	<b>MATRIX CHANGES AND REAPPLICATIONS</b>
<ol style="list-style-type: none"><li>1. Prepare wound area using standard debridement methods to ensure the wound is free of debris and devitalized tissue. The wound may be surgically debrided to ensure the wound edges contain viable tissue.</li><li>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.</li><li>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.</li><li>4. Place the edge of the sheet in contact with intact tissue and smooth the matrix so that it contacts the underlying wound bed. If</li></ol>	<ol style="list-style-type: none"><li>6. Change keramatrix® sheet 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 a off white light brown color.</li><li>7. Once cleansed with Sterile Saline solution keramatrix may be reapplied. Ensure that there are no bleeding areas and that the wound edges are clean.</li><li>8. 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 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</li></ol>

<p>multiple matrices are used, overlap adjoining sheets to provide coverage of the entire wound. Secure with the preferred method of fixation[steri-strips, sutures, staples, clips}.</p> <p>5. After application use an appropriate, non-adherent, occlusive secondary dressing to maintain a moist environment. Ensure the matrix is well restrained.</p>	<p>wound bed.</p> <p>9. Carefully document healing progression using customary healing parameters. Proceed with reapplication of appropriate non-adherent occlusive secondary dressing and maintain a moist environment.</p> <p>10. If infection, excessive redness, blistering or allergic reaction occurs the matrix material should be removed.</p>
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**CONTRAINDICATIONS**

Any known sensitivity to keratin.

**PRECAUTIONS**

Do not reuse or re-sterilize. Do not use if package is open or unsealed. Use prior to expiration date.

**STORAGE**

Do not use if pouch has been opened or damaged. Should be stored at a clean, dry location at room temperature.

**HOW SUPPLIED**

keramatrix is supplied in a clear pouch with labelled unit cartons.

keramatrix 5cm ×5cm Individual unit	71474-303-05
keramatrix 5cm × 5cm Box of 5 units	71474-303-55
keramatrix 5cm × 5cm Box of 10 units	71474-303-51
keramatrix 10cm × 10cm Individual unit	71474-303-01
keramatrix 10cm × 10cm Box of 5 units	71474-303-50
keramatrix 10cm × 10cm Box of 10 units	71474-303-10

Manufactured for:  
Molecular Biologicals, LLC  
Pasadena, TX 77505 | 1-844-793-9933  
By Keraplast Research Limited  
Gerald St, Lincoln 7674 NZ

**PRINCIPAL DISPLAY PANEL - 5 Matrix Package Box Label**

For Wounds & Burns  
Keramatrix®  
Enriched With Bioactive Keratin  
5x 5 Matrices  
NDC 71474-303-50  
10cm x 10cm (4" x 4")  
LOT EXP1220G3

2020-12-31

CE  
0123  
STERILE R

Rx Only

replicine™

For Topical Use Only

Store in dry conditions between 0°  
and 35°C (32° and 95° F).

Do not use if the packaging has been  
damaged prior to use.

Sterility is guaranteed until the packaging  
is first opened or damaged prior to use.

Do not reuse or resterilize.

See package insert for usage and  
complete Prescribing Information.

MolecularBiologicals.com

MOLECULAR BIOLOGICALS

THE HEALING POWER OF NATURE

Manufactured for:

Molecular Biologicals, LLC  
Pasadena, TX 77505


Manufactured by:

Keraplast Research Limited  
Gerald St.  
Lincoln, 7674  
New Zealand (NZL)

For Wounds & Burns

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 NDC 71474-303-50  
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## KERAMATRIX

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### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:71474-303
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMINO ACIDS, HAIR KERATIN (UNII: G46579QK1M) (AMINO ACIDS, HAIR KERATIN - UNII:G46579QK1M)	AMINO ACIDS, HAIR KERATIN	100 mg

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71474-303-01	1 in 1 POUCH		
1		1 in 1 PACKAGE; Type 0: Not a Combination Product		
2	NHRIC:71474-303-50	5 in 1 BOX		
2		5 in 1 PACKAGE; Type 0: Not a Combination Product		
3	NHRIC:71474-303-10	10 in 1 BOX		

3		10 in 1 PACKAGE; Type 0: Not a Combination Product		
4	NHRIC:71474-303-05	1 in 1 POUCH		
4		1 in 1 PACKAGE; Type 0: Not a Combination Product		
5	NHRIC:71474-303-55	5 in 1 BOX		
5		5 in 1 PACKAGE; Type 0: Not a Combination Product		
6	NHRIC:71474-303-51	10 in 1 BOX		
6		10 in 1 PACKAGE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXEMPT DEVICE	FRO	02/11/2009	

**Labeler** - Molecular Biologicals, LLC (079518915)

Revised: 3/2019

Molecular Biologicals, LLC