

KEROXX- dressing, wound, drug gel
Molecular Biologicals, LLC

Keroxx®

Flowable Wound Matrix

Rx Prescription Only

Single Use

Topical use Only

STERILE	R
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CAUTION

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

DESCRIPTION

Keroxx® is an advanced wound care device comprised of a flowable wound matrix.

The flowable wound matrix provides a scaffold for cellular migration, proliferation and capillary growth.

It is supplied in single use kits containing one 3cc syringe with flowable wound matrix and one flexible injector.

INDICATIONS FOR USE

Chronic wounds, surgical wounds, Donor sites/grafts, Diabetic ulcers, chronic ulcers of mixed vascular etiologies, venous stasis ulcers, Pressure ulcers (stages I-IV), partial & full thickness wounds, donor sites/grafts.

DIRECTIONS FOR USE

(NOTE: ALWAYS HANDLE USING ASEPTIC TECHNIQUE)

WOUND BED PREPARATION & APPLICATION	DRESSING CHANGES & REAPPLICATIONS
<ol style="list-style-type: none">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. A small influx of blood may be permitted into the wound.2. Remove the tip cap from the 3cc syringe	<ol style="list-style-type: none">5. After application, use an appropriate non-adherent occlusive dressing. Change dressing as necessary.6. Frequency of dressing changes typically occur every 2-5 days, or as determined by the healthcare provider.7. Once wound is cleansed using proper technique Keroxx® Flowable Wound

<p>syringe.</p> <ol style="list-style-type: none"> 3. Attach the flexible injector tip securely to the syringe. 4. Slowly dispense Keroxx® Flowable Wound Matrix into the wound area. Avoid pressing tip directly against the wound bed to ensure proper flow of Keroxx® from the flexible injector. For easily visible wound areas a thin 1-3mm film covering is adequate. 	<p>Matrix may be reapplied.</p> <ol style="list-style-type: none"> 8. Proceed with reapplication of appropriate non-adherent occlusive secondary dressing. 9. If clinical signs of infection, excessive redness, blistering or suspected allergic reaction occurs the Keroxx should not be reapplied and proper notification and documentation should be done.
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CONTRADICTIONS

Keroxx® should not be used in patients with known sensitivity to keratin. The device is not indicated for third degree burns.

ACTIVE INGREDIENT: Keratin

PRECAUTIONS

Do not reuse or re-sterilize. Do not use if package is open or tip cap is missing or not fully attached to syringe, or if package is unsealed. Use prior to expiration date.

STORAGE

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

HOW SUPPLIED

Keroxx® is supplied sterile, in single use kits containing one 3cc syringe with flowable wound matrix, one flexible injector.

Keroxx®
3cc syringe/unit
NDC 71474-304-03

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

Keroxx® is a registered trademark of Molecular Biologicals, LLC.
The product incorporates patented and /or patent pending technologies owned by Molecular Biologicals, LLC.

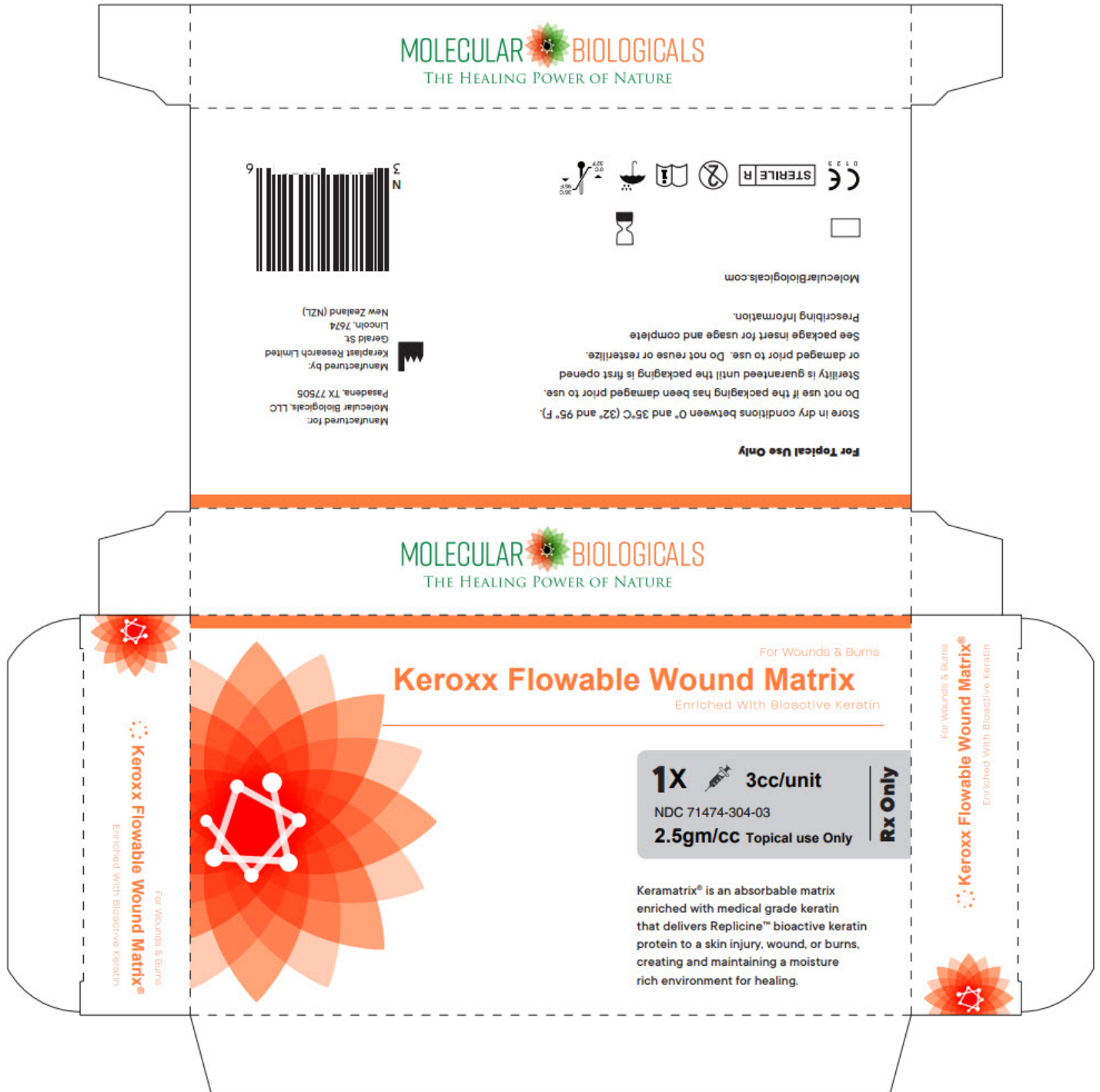
Issue Date 01Jan17
DWG005/9

PRINCIPAL DISPLAY PANEL - 3 cc Syringe Box

For Wounds & Burns
Keroxx Flowable Wound Matrix
Enriched With Bioactive Keratin

1X 3cc/unit
NDC 71474-304-03
2.5gm/cc Topical use Only
Rx Only

Keramatrix® is an absorbable matrix enriched with medical grade keratin that delivers Replicine™ bioactive keratin protein to a skin injury, wound, or burns, creating and maintaining a moisture rich environment for healing.



KEROXX

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Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:71474-304
Route of Administration	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 in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71474-304-03	1 in 1 BOX		
1		7.5 g in 1 SYRINGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
EXEMPT DEVICE	FRO	02/11/2017	

Labeler - Molecular Biologicals, LLC (079518915)

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Molecular Biologicals, LLC