

**KERASORB- dressing, wound, drug**  
**Molecular Biologicals, LLC**

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**Kerasorb®**

Foam 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).**

**DESCRIPTION**

Kerasorb® is an advanced bilayer wound care device designed for medium to highly exudative wounds. It is comprised of an absorbent foam with a Keratin (Replicine) wound matrix layer designed for wounds with medium to high exudate. Kerasorb foam wound matrix provides a scaffold for cellular migration, proliferation and capillary growth, while permitting drainage of excess fluids that may accumulate onto the wound bed. It is supplied in single use keratin foam matrix.

**INDICATIONS FOR USE**

Medium to High exudative wounds: 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 with medium to high exudate.

<b>DIRECTIONS FOR USE (NOTE: ALWAYS HANDLE USING ASEPTIC TECHNIQUE)</b>	
<p><b>WOUND BED PREPARATION &amp; APPLICATION</b></p> <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. A small influx of blood may be permitted into the wound.</li><li>2. Using sterile technique remove Kerasorb foam wound matrix from the pouch.</li><li>3. If necessary cut the Kerasorb foam wound matrix into a piece slightly larger than the outline of the wound area (approximately 1.5cm).</li><li>4. Apply Kerasorb® Foam Wound Matrix into</li></ol>	<ol style="list-style-type: none"><li>5. After application use an appropriate occlusive</li></ol> <p><b>MATRIX CHANGES &amp; REAPPLICATIONS</b></p> <ol style="list-style-type: none"><li>6. Change kerasorb foam wound matrix as necessary. Frequency of dressing changes typically occur every 5-7 days, or as determined by the healthcare provider.</li><li>7. Once wound is cleansed using proper technique Kerasorb® Foam Wound Matrix may be reapplied.</li><li>8. Proceed with reapplication of appropriate occlusive secondary dressing.</li><li>9. If clinical signs of infection, excessive</li></ol>

the wound area. Ensure that the keratin matrix layer ("shiny side") makes contact with the wound bed. Secure in place using preferred method by healthcare provider (Steri-strips, sutures, tape). dressing.

redness, blistering or suspected allergic reaction occurs the Matrix material should not be reapplied and proper notification and documentation should be done.

## **CONTRADICTIONS**

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

## **PRECAUTIONS**

Do not reuse or re-sterilize. Do not use if package is open 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**

Kerasorb® is supplied sterile, in single use pouch containing one foam wound matrix.

Kerasorb® 4cm × 4cm/ unit SKU/Model 71474-305-01

Kerasorb® 4cm × 4cm/ [Box of 5] units SKU/Model 71474-305-05

Manufactured for:

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

Kerasorb® 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 - 5 Package Box**

kerasorb

5 x NDC 71474-305-05

10 cm x 10 cm (4" x 4")

MOLECULAR  
BIOLOGICALS

replicine™

LOT

DWG007/5

C E

0 1 2 3

STERILE R

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0°C

32°F

35°C

95°F

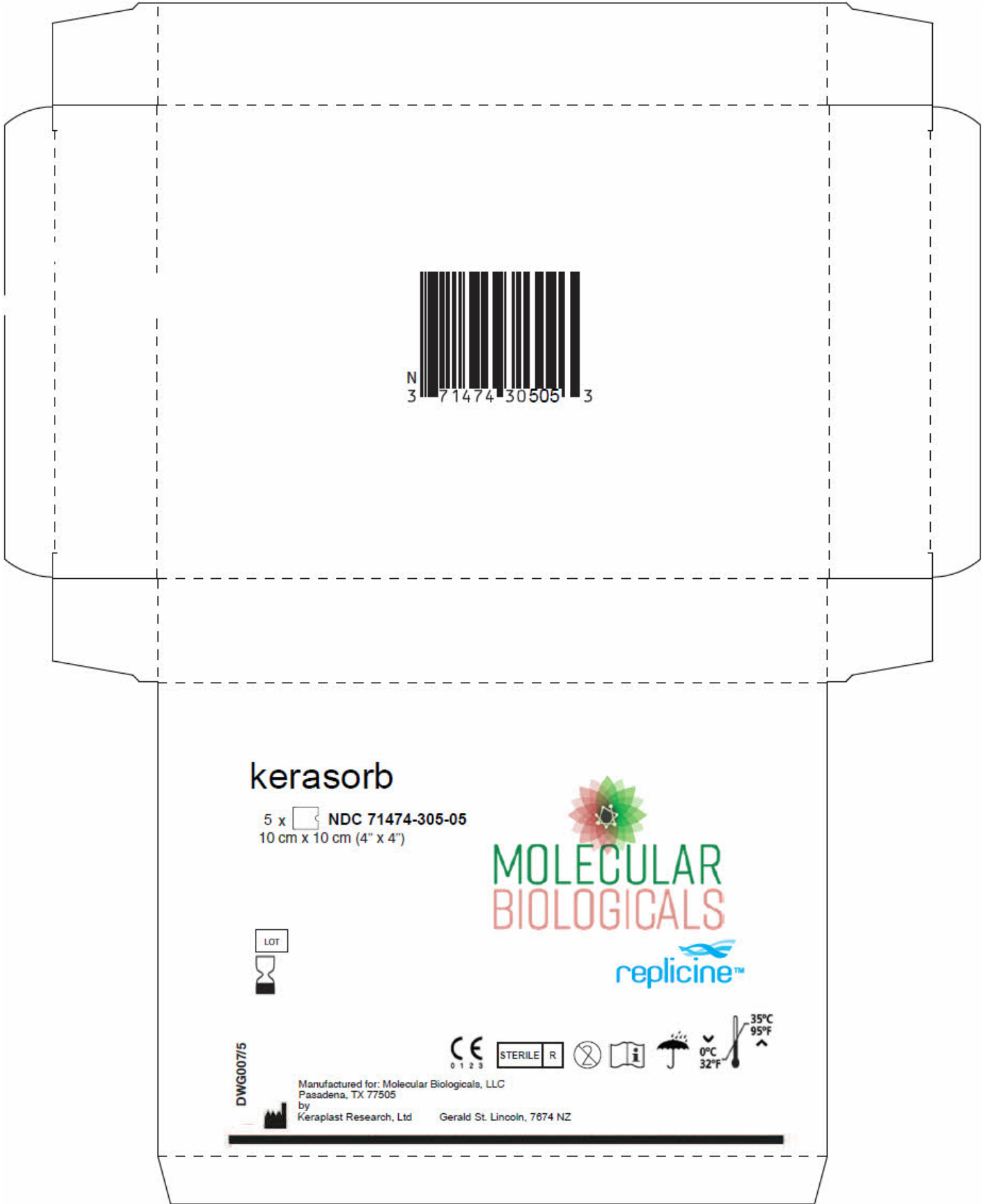
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kerasorb

5 x [box icon] NDC 71474-305-05  
10 cm x 10 cm (4" x 4")



DWG007/5



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**KERASORB**  
dressing, wound, drug

**Product Information**

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRIC:71474-305
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NHRIC:71474-305-01	1 in 1 POUCH		
1		1 in 1 PACKAGE; Type 0: Not a Combination Product		
2	NHRIC:71474-305-05	5 in 1 BOX		
2		5 in 1 PACKAGE; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
EXEMPT DEVICE	FRO	12/11/2018	

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

Revised: 12/2018

Molecular Biologicals, LLC