neox®
CORD 1K
Patent Pending

## PRODUCT INSERT

### DESCRIPTION
**NEOX® CORD 1K** is a cryopreserved human amniotic membrane product classified as a 361 'Human Cells, Tissues, and Cellular and Tissue-based Product' (HCT/P). **NEOX CORD 1K** is aseptically processed from tissue obtained from donated human tissue (placentas) according to current Good Tissue Practices (cGTP) and Good Manufacturing Practices (cGMP) regulations established by the US Food & Drug Administration (FDA).

### INDICATION
- **NEOX CORD 1K** can be used as a wound covering for dermal ulcers or defects.
- **NEOX CORD 1K** is for single use only in one patient by a licensed physician (DPM, MD, or DO) or a qualified medical professional with relevant clinical experience such as a nurse or PA.

### CONTRAINDICATIONS
- **NEOX CORD 1K** should not be used on wounds that are actively infected.

### PRECAUTIONS
- Do not use **NEOX CORD 1K** if the packaging is damaged - contact Amniox Medical, Inc. immediately if there is any abnormality observed (e.g. labeling, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- **NEOX CORD 1K** exposed to controlled room temperature (20°C to 25°C, 68°F to 77°F) for up to 6 hours may be returned to cold temperature storage in accordance with the Storage section as long as the packaging remains unopened and intact.
- Once the outer foil pouch is opened, **NEOX CORD 1K** shall either be transplanted or otherwise discarded.
- Do not sterilize or autoclave the product before use.

### WARNINGS
- Do not use on patients with a history of drug reactions to Amphotericin B, Glycerol, DMEM, and/or Lactated Ringer's (LR).
- As with the use of any human tissue, the possibility of infectious agent transmission cannot be completely eliminated although all screening and microbial testing results for this donor were satisfactory for transplantation.
- It is imperative that the graft is stored properly until use. For proper storage instructions, refer to the Storage section.

### STORAGE
It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

*Upon receipt, ensure the validated time on the shipper has not expired. Remove the product and store accordingly until use:*

| LOCATION & TEMPERATURE | USE AFTER RECEIPT |
|---|---|
| -80°C → 4°C<br>(-112°F → 39.2°F)<br>Example: ultra-low temperature freezer, standard freezer, or standard refrigerator | Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture) |

### INSTRUCTIONS
1. If frozen, allow **NEOX CORD 1K** to sit at controlled room temperature (20°C to 25°C) in its original unopened packaging for at least 5 minutes.
2. Open the outer foil peel pouch and present the clear inner pouch to the sterile field using aseptic techniques.
3. Open the clear inner peel pouch to retrieve the **NEOX CORD 1K**.
4. The product may be rinsed in sterile saline or water prior to application without affecting the biological activity or potency of **NEOX CORD 1K**.
5. Secure the **NEOX CORD 1K** on the wound bed to act as a covering.

Place UDI Label Here
For Canadian Shipments Only

*See Reverse*

## DONOR ELIGIBILITY AND SUMMARY OF RECORDS

- This tissue was procured from a donor determined to be eligible based on the results of testing. HCT/P donor eligibility and placenta suitability, which is based on the results of donor testing at delivery for infectious, malignant, neurological & auto-immune diseases and for other exposures or social habits, has been determined and documented by TissueTech, Inc.
- A blood specimen, drawn within ± 7 days of donation, has undergone serological testing by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR Part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). The donor has been tested for the following infectious diseases and results were non-reactive:

| | |
|---|---|
| — HIV-1 & HIV-2 Antibody | — Hepatitis C Antibody (HCVAb) |
| — HIV-1 (RNA-NAT) | — Hepatitis C Virus (HCV, RNA-NAT) |
| — Hepatitis B Surface Antigen (HBsAg) | — Syphilis (RPR) |
| — Hepatitis B Core Antibody (HBcAb) | — HTLV I & II Antibody (HTLV I/II Ab) |
| — Hepatitis B (HBV, DNA-NAT) | — West Nile Virus (WNV, RNA-NAT) |

- Microbial testing has also been performed on the final product to ensure no growth of aerobic, anaerobic, or fungal cultures.
- The cell activity in the tissue has been inactivated using our CryoTek® cryopreservation process to reduce the possibility of graft rejection, while retaining the natural biologic properties.
- **NEOX CORD 1K** is stored in a stored in a solution of 1:1, v/v Lactated Ringer's /Glycerol containing 1.25 µg/ml Amphotericin B or 1:1, DMEM/ Glycerol containing 1.25 µg/ml Amphotericin B.
- This tissue has been deemed eligible for transplantation based on acceptable testing, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for Amniox Medical products is available upon request.

## RECIPIENT RECORDS

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User Clinician to maintain records for the purpose of tracing tissue post-transplantation. The transplanting entity should document the disposition (transplanted or discarded) on the Donor and Recipient Information Card (DRI), attach one of the provided product tracking labels to the DRI and mail to Amniox Medical. Attach the remaining labels in patient and hospital records.

## CUSTOMER FEEDBACK

**Within the United States**: Report any customer feedback, including complaint, error or accident notification promptly to Amniox Medical at (888) 709-2140.
**Outside of the United States**: Report feedback to your local tissue provider.

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## ADVERSE EVENT

The FDA requires that information be supplied to the product manufacturer for mandatory reporting of adverse events. Possible significant adverse events include microbial infection and transmission of viral disease. **The doctor is responsible for immediately reporting any adverse event potentially attributable to the use of NEOX CORD 1K to Amniox Medical.**

### For Adverse Events, complete the following section. Notify via:

**Phone**: (888) 709-2140
**Fax**: (305) 675-3262
**Email**: Customerfeedback@amnioxmedical.com

Serial Number: _____

Expiration Date: ___ / ___ / ___

Doctor Name: _____

Facility Name: _____

Transplant Date: ___ / ___ / ___

Diagnosis/Procedure: _____

Site of Use: _____

Point of Contact's Name: _____

Point of Contact's Phone Number: ____ / ____ / _____

Date Adverse Event was Reported: _____

Type of Adverse Event:

☐ Microbial Infection ☐ Transmission of Viral Disease ☐ Other

Describe the Adverse Event: _____

_____

_____

amniox® MEDICAL

Manufactured for Amniox Medical, Inc. by TissueTech, Inc.
8305 NW 27th St, Suite 101, Doral, Florida 33122 USA
(888) 296-8858

Health Canada CTO Registration #: 100041

FEI #: 3009809074
AX-PI-0003, REV 05