neox®
CORD RT

Patent Pending
PRODUCT INSERT

DESCRIPTION

NEOX CORD RT is a sterilized, human Umbilical Cord and Amniotic Membrane product classified as a 361 'Human Cells, Tissues, and Cellular and Tissue-based Product' (HCT/P). The tissue is processed from donated human tissue according to current Good Tissue Practices (cGTP) and Good Manufacturing Practices (cGMP) regulations established by the US Food and Drug Administration (FDA). The tissue is stored in saline (0.9% w/v NaCl) and terminally sterilized by gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6}.

INDICATIONS

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

CONTRAINDICATIONS

- **NEOX CORD RT** should not be used on wounds that are actively infected.

PRECAUTIONS

- Do not use **NEOX CORD RT** tissue if the packaging is damaged - contact Amniox Medical immediately if there is any abnormality observed in any area (e.g. labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- Once the outer foil pouch is opened, **NEOX CORD RT** shall either be transplanted or otherwise discarded.
- Do not re-sterilize or autoclave the product before use.

WARNINGS

- 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 tissue 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
Controlled Room Temperature 20°C → 25°C	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

INSTRUCTIONS

1. Open the outer foil pouch and present the clear inner pouch to the sterile field using aseptic techniques.
2. Open the clear inner peel pouch to retrieve the **NEOX CORD RT**.
3. Secure the **NEOX CORD RT** 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, and 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
  — HIV-1 (RNA-NAT)
  — Hepatitis B Surface Antigen (HBsAg)
  — Hepatitis B Core Antibody (HBcAb)
  — Hepatitis B (HBV, DNA-NAT)
  — Hepatitis C Antibody (HCVAb)
  — Hepatitis C Virus (HCV, RNA-NAT)
  — Syphilis (RPR)
  — HTLV I & II Antibody (HTLV I/II Ab)
  — West Nile Virus (WNV, RNA-NAT)

- This tissue has been deemed eligible for transplantation based on acceptable testing and serological 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 (DRI) Card, 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.

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 RT 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, FL 33122 USA
(888) 296-8858

FEI #: 3009809074
Health Canada CTO Registration #10004

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