Neox® RT

U.S. Patent No. 9,682,160; 9,931,423; Patent Pending

Product Insert

Description

Neox RT is a sterile, ultra-thick human amniotic membrane product derived from umbilical cord. **Neox RT** is aseptically processed, devascularized and cell devitalized. **Neox RT** is manufactured, using the SteriTek® preservation process, from donated human birth tissue according to Current Good Tissue Practice (CGTP) and Current Good Manufacturing Practice (CGMP) regulations established by the U.S. Food and Drug Administration (FDA). **Neox RT** is stored in saline (0.9% w/v NaCl) and terminally sterilized via gamma irradiation with a Sterility Assurance Level (SAL) of 10^{-6}. **Neox RT** is for single use only in one patient by a qualified medical professional.

Product Use

- **Neox RT** can be used as a wound covering to create a protective environment for wound healing to occur.

Contraindications

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

Precautions

- Do not use **Neox RT** if the packaging is damaged – Contact BioTissue immediately if there is any abnormality observed (e.g., labeling, packaging, shipping, missing information, etc.). Refer to the Customer Feedback section for reporting.
- Once the outer foil pouch is opened, **Neox 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 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, remove the product from the shipper and store accordingly until use.

Location & Temperature	Use After Receipt
Controlled Room Temperature 20°C → 25°C (68°F → 77°F)	Within the expiration date printed on product packaging (shelf-life is 2 years from date of manufacture)

Instructions

1. Open the outer foil peel pouch and present the clear inner pouch to the sterile field using aseptic techniques.
2. Open the clear inner peel pouch to retrieve **Neox RT**.
3. Secure **Neox RT** onto the wound bed.

Place UDI Label Here
For Canadian Shipments Only

See Reverse

Neox® RT

Donor Eligibility and Summary of Records

- This tissue was procured from a donor determined to be eligible based on the results of donor screening and testing. Donor eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, has been performed and documented by BioTissue Holdings 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 Virus (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 screening, serological and microbial test results.
- A Certificate of Compliance regarding the manufacturing, storage, shipping and tracking controls for BioTissue 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 BioTissue. 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 BioTissue at (888) 709-2140.
Outside of the United States: Report feedback to your local tissue provider.

Adverse Events

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 RT to BioTissue.**

For Adverse Events, notify via:
Website: www.biotissue.com/complaints
Phone: (888) 709-2140
Fax: (305) 675-3262
Email: Customerfeedback@biotissue.com

Scan Code

BioTissue®

Manufactured by BioTissue Holdings Inc.
8305 NW 27th Street, Suite 101, Doral, FL 33122 USA
biotissue.com | (P) 888-709-2140 | (F) 770-874-5563

FEI #: 3009809074
Health Canada CTO Registration #: 100041

AX-PI-0010, Rev. 04