NeoStim™ Membrane Family

DONATED HUMAN TISSUE

NeoStim Membrane Family is a human allograft tissue that is regulated as a human cells, tissues, and cellular and tissue-based product (HCT/P) as defined by 21 CFR Part 1271. **NeoStim Membrane Family** received written notification by the FDA's Tissue Reference Group confirming NeoStim Membrane Family meets the criteria for regulation solely under Section 361 of the PHS Act as defined in 21 CFR Part 1271.

NeoStim Membrane Family are sterile, single use, dehydrated resorbable allografts derived from donated human placental birth tissue. Allografts are processed using aseptic techniques and terminally sterilized by Electron Beam.

NeoStim Membrane is a single layer amniotic membrane.

NeoStim DL Membrane is a dual layered amniotic membrane.

NeoStim TL Membrane is a triple layer amniotic membrane.

NeoStim Membrane Family is restricted to use by or on order of a licensed healthcare professional.

PRODUCT USE

NeoStim Membrane Family grafts are in sheet form. NeoStim Membrane Family grafts are intended for use as a Human Cell, Tissue, and Cellular and Tissue- Based Product (HCT/P) for repair, reconstruction, replacement and/or supplementation by providing tissue in the form of scaffolding in partial and full-thickness acute and chronic wounds. The NeoStim Membrane Family graft is intended to remain on the recipient and is absorbed into the wound bed. The graft is anchored based on the physician's choice of fixation including but not limited to Steri-Strips, surgical glue, staples, or sutures in surgical procedures when medically necessary. The graft may be used in conjunction with negative pressure wound therapy.

SIZE AND STORAGE

NeoStim Membrane Family is available in a wide range of sizes. NeoStim Membrane Family must be stored in ambient temperature at 15-30°C (59-86°F) prior to patient application. Do not freeze. May be stored up to 5 years. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End- User clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use.

CONTRAINDICATIONS

Allografts including NeoStim Membrane Family should not be used on areas with active infection.

INSTRUCTIONS FOR IMPLANTATION

Wound Bed Preparation

- Prepare the wound bed by using standard methods to ensure it is free of exudate and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- Wait for any bleeding to stop before applying NeoStim Membrane Family grafts.
- Gently cleanse the wound surface with wound cleanser or normal saline; leave the ECM gel intact.

Selection and Preparation of NeoStim Membrane Family grafts

- Measure the wound and select the appropriate size sheet of dry NeoStim Membrane Family grafts. If necessary, the product may be additionally fenestrated or meshed with a scalpel.
- Cut the sheet to a size and shape that will cover the entire wound surface and will extend slightly beyond the wound margins.

Application of NeoStim Membrane Family Allografts

- For ease of handling, apply NeoStim Membrane Family grafts by placing it in a dry state over the wound.
- Position the dry NeoStim Membrane Family grafts to completely contact the entire surface of the wound bed and extend slightly beyond all wound margins. If multiple sheets are necessary to cover the wound, slightly overlap the edges of the sheets.
- As required, securely anchor NeoStim Membrane Family grafts with the physician's choice of fixation including but not limited to Steri-Strips, surgical glue, staples, or sutures in surgical procedures when medically necessary.
- Thoroughly rehydrate NeoStim Membrane Family grafts by applying sterile saline.
- To protect NeoStim Membrane Family grafts from adhering to the secondary dressing, apply an appropriate non-adherent primary wound dressing over NeoStim Membrane Family grafts.
- Apply an appropriate secondary dressing (multi-layer compression bandage system, total contact cast, NPWT, or other appropriate dressing) that will manage the wound exudate, keep the NeoStim Membrane Family grafts moist, and keep all layers securely in place.

Dressing Changes

- To prevent damage to the newly incorporating NeoStim Membrane Family graft, only change the primary dressing as necessary, typically "one to two times" every seven (7) days.
- Change the secondary dressing as appropriate. Take care to avoid dislodging the NeoStim Membrane Family grafts when the secondary dressing is changed.

Wound Assessment and Wound Bed Preparation

- Change all dressings every seven (7) days, or as necessary.

NOTE: If a gel forms on the wound surface, do not attempt to remove it. Successful absorption of NeoStim Membrane Family grafts may form a caramel-colored or off-white gel. Do not remove this gel by debridement. This caramelization contains extracellular matrix (ECM), which continues to replace deficient and missing ECM in the wound.

- As healing occurs, sections of NeoStim Membrane Family grafts may gradually peel. Carefully remove any remaining loose products around the edge as needed.
- Gently cleanse the wound surface with wound cleanser or normal saline; leave the ECM gel intact.
- Carefully reassess the wound and record healing progression such as wound dimensions, wound depth, wound type, and other relevant information.

Reapplication of NeoStim Membrane Allografts and Dressing Changes

- Change secondary dressing as needed (see "Dressing Changes").
- If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared NeoStim Membrane Family grafts over previously absorbed application (see "Application of NeoStim Membrane Family Allograft").
- Reapply NeoStim Membrane Family grafts every seven (7) days or as needed by repeating previous application steps.

DONOR SCREENING AND TESTING

Prior to processing, the donor's medical and social history were screened for conditions and disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures at Surgenex, LLC. All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Each donor is screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of Surgenex, LLC and the donors have been deemed eligible.

Communicable disease testing is performed by an FDA- registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests have been found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)

HIV-1/2 Antibodies (HIV-1/2-Ab)
Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

Hepatitis B Virus (HBV)
HBV Surface Antigen (HBsAg)
HBV Core Antibody (IgG & IgM) (HBcAb) Nucleic Acid Test for HBV DNA (HBV NAT)

Hepatitis C Virus (HCV)
HCV Antibody (HCVAb)
Nucleic Acid Test for HCV RNA (HCV NAT)

Human T Cell Lymphotrophic Virus I/II
HTLV-I/II (Antibody HTLV-I/II-Ab)

Syphilis
Rapid Plasma Reagin (RPR) Screen
T. Pallidum IgG

West Nile Virus (WNV)
Nucleic Acid Test for WNV RNA (WNV NAT)

PROCESSING AND STERILITY

The donors of NeoStim Membrane Family are screened and tested for relevant communicable diseases and disease agents, including COVID-19, in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). NeoStim Membrane Family is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY

DO NOT RE-STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

WARNINGS AND PRECAUTIONS

NeoStim Membrane Family is processed and packaged using aseptic techniques and sterilized. NeoStim Membrane Family must not be transplanted under the following conditions:

- If mishandling caused damage or contamination
- If the allograft is past its expiration date
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible or defaced.
- If the Amniotic Membrane has not been stored according to specifications set forth in this insert

Notify Dynamic Medical Services immediately at (775) 762-8068 if any of these conditions exist or are suspected.

ADVERSE EVENTS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from applications of allografts may include but are not limited to infection, bleeding, swelling, redness, and injury to nerves and other soft tissue. Complications may occur with allograft use, including but not limited to:

- Transmission of disease of unknown etiology
- Transmission of infectious agents including but not limited to HIV, hepatitis, syphilis, or microbial contaminants.
- Graft-versus-host immune rejection or other allergic reactions

Adverse outcomes potentially attributable to NeoStim Membrane Family or other complaints must be promptly reported to Dynamic Medical Services at (775) 762-8068

HCT/P TRACKING

FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained. Joint Commission standard QC.55.310.7 requires that the organization that receives tissue provides a system that fully complies with the completion of tracking tissue usage via Tissue Tracking/Transplant Record (TTR) or provides a web-based program for traceability of the allograft used.

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide the information pertaining to the traceability of the allograft used. Please turn in the TTR card information as directed in the shipment or visit www.surgenex.com/neostimrecords and register the LOT NUMBER located on the product label.

RETURNED GOODS POLICY

Dynamic Medical may accept return of NeoStim Membrane Family allografts for credit or exchange if incorrect product was shipped or product was received in a damaged state. Dynamic Medical reserves the right to reject a return if any of the condition are not met:

- For damaged items and incorrect shipments, Dynamic Medical may replace the product with the appropriate product or issue a credit.
- A Return Material Authorization (RMA) number must be obtained from Dynamic Medical no later than 24 hours from receipt for damaged product or incorrect shipments.
- Original product packaging must be intact and unopened.
- Responsibility for facilitating shipping arrangements must be assumed by the returning facility unless the allograft is damaged or defective. Returning facility must complete, sign, and return the RMA form stating that all required criteria have been met.
- Credit cannot be issued if the RMA form has not been completed by the returning facility and received by Dynamic Medical.

Distributed By:
Dynamic Medical
8905 W. Post Road, Suite 220
Las Vegas, NV 89148
(775) 762-8068

Manufactured By:
Surgenex LLC
15444 N 76 St c110
Scottsdale, AZ 85260
877-880-1862