NSM Biologics NeoThelium FT Amnion Chorion Membrane

FOR SINGLE PATIENT USE ONLY

Tissue ID Number

Place Sticker Here

PRODUCT DESCRIPTION

NeoThelium FT Amnion Chorion Membrane are resorbable human amnion chorion allografts derived from donated human birth tissue and supplied dry.

NeoThelium FT Amnion Chorion Membrane are processed aseptically and terminally sterilized, it is intended for use in one patient, on a single occasion only. Only qualified health professionals should implant.

NeoThelium FT Amnion Chorion Membrane is intended to provide protective coverage from the surrounding environment for acute and chronic wounds. Acute and chronic wounds may include wounds with or without muscle, tendon, or bone exposure when a protective barrier is medically necessary.

NeoThelium FT Amnion Chorion Membrane may be used in conjunction with standard wound care modalities, including Negative Pressure Wound Therapy (NPWT), at the discretion of the clinician.

"DONATED HUMAN TISSUE": Human tissue for transplantation shall not be offered, distributed, or dispensed for Veterinary Use.

STORAGE CONDITIONS

Specified storage is 15-30°C (59-86°F) until use.

INSTRUCTIONS FOR IMPLANTATION OF ALLOGRAFT

1) Remove carton from storage.
2) Open outer packaging and remove the outer pouch containing the product using aseptic technique. The outer pouch is not sterile and should not be placed directly onto the sterile field.
3) Peel open the outer pouch and remove the inner pouch using aseptic technique. The inner pouch is sterile and may be placed onto the sterile field.
4) Open the inner pouch using aseptic technique and aseptically remove the **NeoThelium FT Amnion Chorion Membrane**. Always use sterile gloves or sterile forceps when handling the allograft.
    - Using sterile scissors, cut open the package.
    - Apply **NeoThelium FT Amnion Chorion Membrane** to the area of interest.
    - **NeoThelium FT Amnion Chorion Membrane** may be re-hydrated in-situ with sterile water or 0.9% Saline.
    - Following wound bed preparation, administer NeoThelium in contact with the entire wound bed. Neothelium conforms well to the internal wound bed and can be used with an overlapping edge to allow for fixation on the intact periwound skin. Overlap edges up to 1cm to on the periwound skin to create a fixation edge with anchoring technique of provider's choice.
5) After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and any applicable local, state and federal laws and regulations.
6) Once container seal has been compromised, the allograft shall either be transplanted, if appropriate, or discarded.

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 Pinnacle Transplant Technologies, LLC (PTT). All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the Association for Advancement of Tissue and Biologics (AATB).

Contraindications for allograft donation include but are not limited to presence of identified infectious disease, neurological degenerative disease, disease of unknown etiology, and exposure to toxic substances. Donor blood sample is taken prior to or at the time of tissue recovery and tested for relevant communicable disease agents in accordance with Federal Regulations.

Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments (CLIA) and 42 CFR Part 493, or that has equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

Names and addresses of testing laboratories, interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at PTT and are available to the end-user upon request, except as prohibited by law. Donor blood samples taken prior to or at the time of recovery were tested and found negative/nonreactive using FDA licensed tests for, at minimum:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis
- HTLV I/II: Human T-Cell Lymphotropic Virus
- WNV: West Nile Virus

Based on screening and testing results, this donated human tissue product has been deemed suitable for transplant by the Medical Director and Quality Assurance.

PROCESSING AND STERILITY

Donor tissue is recovered using safe recovery techniques and sterile equipment to minimize bioburden contamination. Allografts are procured via a network of qualified and trained recovery partners, using a stringent screening and recovery protocol, in a highly controlled processing environment, minimizing risk of disease transmission. All tissues are processed aseptically and sterilized using Gamma irradiation. Do not re-sterilize.

ADVERSE REACTIONS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from application of **NeoThelium FT Amnion Chorion Membrane** 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 unknown infectious agents including but not limited to, HIV, Hepatitis, syphilis and bacteria
- Graft-versus-host immune rejection or other allergic reactions

Any adverse outcomes potentially related to product use must be promptly reported to NSM Biologics, LLC. at 844-464-8252. This product may contain trace amounts of glutaraldehyde; a disinfectant used during processing. Caution should be exercised if the patient is allergic to this agent.

WARNINGS AND PRECAUTIONS

NeoThelium FT Amnion Chorion Membrane must not be transplanted under the following conditions:

- If mishandling has caused possible damage or contamination
- If the allograft is past its expiration date printed on the product carton

- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible or defaced
- If the allograft has not been stored according to specifications set forth in this insert

Notify NSM Biologics, LLC. immediately at 844-464-8252 if any of these conditions exist or are suspected.

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.5.310.7 requires that "the organization that receives tissue provides a system that fully complies with the completion and return of tissue usage information cards requested by source facilities." To comply with these requirements, a Tissue Tracking/Transplant Record (TTR) and pre-printed labels are provided with each product allograft. Record the patient information, the transplant facility name and address, allograft tissue information (using enclosed stickers) and comments regarding tissue use on the TTR. Return the completed TTR to PTT and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification information and reason for discard shall be returned to PTT.

RETURN POLICY

NSM Biologics, LLC. may accept return of **NeoThelium FT Amnion Chorion Membrane** allografts for credit or exchange if incorrect product was shipped or product was received in a damaged state. NSM Biologics, LLC. reserves the right to reject a return if any of the conditions are not met.

1. For damaged items and incorrect shipments, NSM Biologics, LLC. may replace the product with the appropriate product or issue a credit.
2. A Return Material Authorization (RMA) number must be obtained from NSM Biologics no later than 24 hours from receipt for damaged product or incorrect shipments.
3. Original product packaging must be intact and unopened.
4. 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.
5. Credit cannot be issued if the RMA Form has not been completed by the returning facility and received by NSM Biologics, LLC.

If you experience a problem with your product, notify NSM Biologics, LLC. immediately for an RMA number at 844-464-8252 or info@nsmbiologics.com.

LABEL AND PACKAGE SYMBOL DEFINITIONS

	Do not reuse; single patient use only
SN	Serial number (Tissue ID number)
STERILE **R**	Sterile by Gamma Irradiation
	Expiration Date (MM/DD/YYYY)

DISTRIBUTED BY

OrthoEx
7327 E Tierra Buena Lane
Scottsdale, AZ 85260

DISTRIBUTED FOR

NuScience Medical, LLC.
DBA NSM Biologics, LLC.
3729 Easton Nazareth Hwy
Suite LL1
Easton, PA 18045
844-464-8252

PROCESSING AND ELIGIBILITY DETERMINED BY

Pinnacle Transplant Technologies™
Improving today. Advancing tomorrow.

Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd
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Phoenix, AZ 85027
(623) 277-5400

Disclaimer: 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. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. NSM Biologics, LLC. is not liable for any damages, whether direct or indirect, special, incidental or consequential, resulting from improper use of this allograft. These Instructions For Use are specific, and NSM Biologics, LLC. disclaims all responsibility associated with the mishandling, inappropriate storage, misuse, and off-label use of the product included with this insert.