NuShield®
Sterilized, Dehydrated Placental Allograft

Organogenesis
Empowering Healing

Allograft Tissue Information and NuShield® Instructions for Use

Contents

This package contains 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.

Description

NuShield® is a sterile, dehydrated placental allograft, consisting of amnion and chorion membranes, processed by DCI Donor Services (DCIDS) Tissue Bank from donated amniotic-derived human tissue.

DCIDS Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA.

Intended Use

NuShield is an allograft intended for use in the management of acute and chronic wounds as well as appropriate surgical applications. NuShield may be applied as a wound covering to a variety of partial- and full-thickness acute and chronic wounds, and wounds with exposed tendon, muscle, joint capsule and bone. NuShield can be applied from the onset and for the duration of the wound, weekly or at the discretion of the health care practitioner.

CAUTION: This product is restricted to sale by or on the order of a physician or properly licensed practitioner.

Donor Screening for Tissue Procurement

An appropriate blood sample from the donor is tested for relevant communicable diseases by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on live human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA approved test kits. The following tests were performed and found to be negative or non-reactive:

- Human Immunodeficiency Virus (HIV) 1 & 2 Antibodies
- HIV/HCV/HBV Nucleic Acid Test (NAT)
- Hepatitis B (HBV) Surface Antigen (HBsAg)
- Hepatitis B (HBV) Core Total Antibodies
- Hepatitis C Virus (HCV) Antibody
- Syphilis
- Human T-Cell Lymphotropic Virus (HTLV) Type 1 & 2 Antibodies
- West Nile Virus (WNV) Nucleic Acid Test (NAT)

Additional tests for other communicable diseases, such as T. Cruzi, Cytomegalovirus and Epstein Barr Virus may have been performed. The results of all additional communicable disease tests have been evaluated by the Medical Director and have been found acceptable according to regulations, standards and DCIDS Tissue Bank policies and procedures.

These test results, donor risk assessment questionnaire, physical examination and other available relevant donor records have been evaluated and deemed eligible for transplant by a Medical Director. Donor eligibility determination was performed by DCIDS Tissue Bank, 1714 Hayes Street, Nashville, Tennessee 37203.

Processing

Technical quality assurance standards are rigorously maintained by DCIDS Tissue Bank. Tissue is processed aseptically in a controlled, clean environment. This tissue is processed using some or all of the following agents: Dulbecco's Modified Eagle's Medium (DMEM), vancomycin and gentamicin. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the agents may remain. Final product is terminally sterilized using a validated gamma irradiation process.

Contraindications

NuShield is contraindicated for:

- use on clinically infected wounds.
- surgical implantation sites with active or latent infection.

Warnings & Precautions

As with all allogeneic materials, it is not possible to provide an absolute guarantee that no infectious disease will be transmitted. However, this risk is greatly reduced by using processing treatments shown to be capable of reducing this risk as well as the use of strict donor screening criteria, laboratory testing, aseptic processing and terminal gamma irradiation of final product.

- **Single patient, single use only.**
- **Do not sterilize or re-sterilize.**

Do not use if:

- the package integrity has been violated, opened, or damaged, or if mishandling has caused possible damage or contamination.
- if any seal is broken or compromised.
- expiration date has been exceeded.
- the tissue has not been stored according to the recommended storage instructions.

- Return all compromised or flawed packaging to Organogenesis Inc.
- Once opened, allografts must be used immediately or discarded.
- Store product at ambient temperature.
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician.
- Caution should be exercised on patients with known sensitivity or allergies to vancomycin, gentamicin, or any of the processing agents listed under the processing section of this document.
- The healthcare professional is responsible for informing the patient of the risks associated with his/her treatment and the possibility of complications or adverse reactions.

Complications and Possible Adverse Effects

Inherent uncertainty exists in medical and social histories and lab testing which may not detect known or unknown pathogens.
Therefore, the following complications may occur with tissue transplantation:

- Transmission of diseases of unknown etiology;

- Transmission of known infectious agents such as viruses, bacteria and fungi;
- Immune rejection of implanted HCT/P; or
- Loss of function and/or integrity of implanted HCT/P due to resorption, fragmentation, and/or disintegration.

Report any adverse outcomes to Organogenesis Inc. immediately.

Tissue Preparation and Use

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

Visually inspect package and inner envelope to ensure that it is intact and that its integrity has not been compromised. Do Not Use if the packaging is damaged.

Peel open outer heat-sealed package and drop the inner envelope packing onto the sterile field using aseptic techniques.

Once opened, NuShield must be used immediately or discarded. Do not return opened allografts to Organogenesis Inc.

Any unused portion of NuShield should be discarded per institutional protocol.

Application

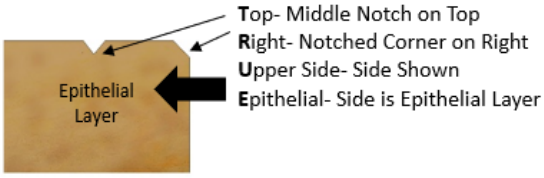
1. For topical application, debride the wound to establish healthy viable wound margins. Hemostasis should be achieved and heavy exudate controlled.

2. Using aseptic techniques, remove NuShield from the package. NuShield can be trimmed prior to hydrating if necessary.

3. NuShield may be applied or implanted in a dry state or hydrated in Lactated Ringers, Normal Saline, or other normal physiologic solution containing antibiotics of the clinician's preference.

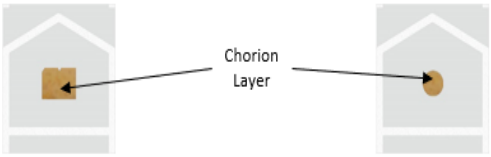
4. NuShield meshed should be rehydrated prior to expanding.

5. Gently, handle NuShield. Determine which side of NuShield is the chorion layer (to be placed in contact with the wound bed or surgical implantation site) using the T.R.U.E. method: when the middle notch is at the top, and the notched corner is to its right, then the upper side is epithelial and the side facing down is chorion.



Product Orientation in Package

NuShield has the chorion visible in the package. The epithelial layer is not visible and is in contact with the white packaging.



6. Apply or implant NuShield onto the site, being careful to preserve orientation of the product and ensuring that the chorion side is in contact with the wound bed or implant side.

7. Anchor NuShield using preferred fixation method.

For topical wound applications:

- apply a non-adherent, non-occlusive dressing directly over NuShield which should remain in place for up to one week.
- apply a secondary dressing specific to the wound type. NuShield may be reapplied weekly as needed.

HCT/P Tracking

Organogenesis Inc. is required by 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission standards require 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, Organogenesis Inc. provides an *Allograft Implant Record (AIR)* and preprinted labels with every graft. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the AIR. Return the completed form to Organogenesis Inc. (see address below) and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, AIR completed with the allograft identification information and reason for discard needs to be returned to Organogenesis Inc.

Storage and Handling

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions prior to transplant. All dehydrated allografts must be maintained at ambient temperature prior to use. DO NOT FREEZE.

Return Policy

Please contact Customer Service at 1-888-432-5232 for information regarding Organogenesis Inc. Tissue Return Policy.

Disclaimer

Organogenesis Inc. and DCIDS Tissue Bank make no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease. Adverse outcomes potentially attributable to the tissue must be reported immediately to Organogenesis Inc.,

Processed by:
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