

Allograft Tissue Information and Instructions for Use

Contents

This package contains human allograft tissue that is regulated as a Human Cells, Tissue, and Cellular and Tissue Based Product (HCTP) as defined by FDA 21 CFR Part 1271.

Description

NuShield® is a sterile, dehydrated placental allograft 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 CLIA Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA approved test kits. This tissue was tested for and had negative or non-reactive results for the following:

- 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)

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 DCI Donor Services – Tissue Bank, 1714 Hayes Street, Nashville, Tennessee 37203.

Processing

Technical quality assurance standards are rigorously maintained by DCI Donor Services – Tissue Bank (DCIDS). 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 medications and chemicals 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.

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

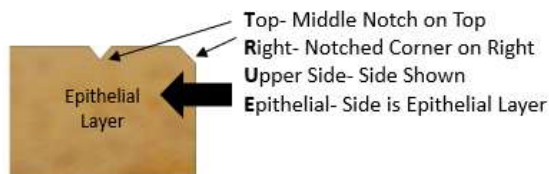
Peel open outer heat-sealed package and drop the inner envelope packing onto the sterile field.

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.

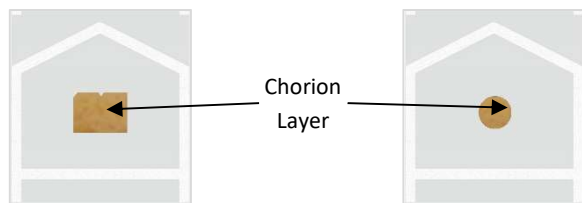
Application

1. The graft may be immediately applied or implanted or may be rehydrated in a sterile solution prior to application or surgical implantation. NuShield is easier to manipulate prior to hydrating.
2. Determine which side of NuShield is the chorion side (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.



3. Place NuShield onto the wound bed or surgical implantation site, being careful to preserve orientation of the product and ensuring that the chorion side is in contact with the wound bed or implant site.
4. Once NuShield is placed, the product may be rehydrated, as necessary, based on the characteristics of the wound or implant site.
5. Anchor NuShield using preferred fixation method.

For topical wound applications:

- apply a non-adherent, non-occlusive primary 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:
DCI Donor Services – Tissue Bank
1714 Hayes Street
Nashville, TN 37203
(P) 800.216.0319
<http://tissuebank.dcmds.org>

Distributed By:
Organogenesis, Inc.
2641 Rocky Ridge Lane
Birmingham, AL 35216
(P) 800.824.9194
(F) 877.402.8598
www.organogenesis.com

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- anti-HIV-1 and anti-HIV-2
- HIV-1/HBV/HCV NAT
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-

HBc)

- Hepatitis C antibody (anti-HCV)
- Syphilis
- HTLV I/II
- WNV NAT

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 DCI Donor Services - Tissue Bank, 1714 Hayes Street, Nashville, TN 37203.

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- Once opened, allografts must be used immediately or discarded.
- Do not use if expiration date has been exceeded.
- Store product at ambient temperature.
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician. Do not use if the tissue has not been stored according to the recommended storage instructions.
- 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.
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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.

Prior to topical application to a wound or surgery, carefully follow the tissue preparation steps as described below. If desired, NuShield may be rehydrated in Lactated Ringers, Normal Saline, or other normal physiologic solution containing antibiotics of the clinician's preference.

1. Visually inspect packaging to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
2. Peel open outer heat-sealed package and drop the inner envelope packing onto the sterile field.
3. Visually inspect the envelope to ensure that it is intact and that its integrity has not been compromised. If the packaging is damaged, the enclosed graft may be contaminated and should not be used.
4. If no damage is detected, open the inner envelope and remove NuShield from its sterile packaging using aseptic techniques, being careful to maintain the sterility of the product. Once opened, NuShield must be used immediately or discarded. **Do not return opened allografts to Organogenesis, Inc.**
5. The graft may be immediately applied or implanted or may be rehydrated in a sterile solution prior to application or surgical implantation. NuShield is easier to manipulate prior to rehydration.
6. Determine which side of NuShield is the chorion side (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.

7. For all sizes, including for the 1.6cm disc that does not have notching, the foil is on the epithelial side, the side without the foil therefore is the chorion side, which should be placed in contact with the wound bed or surgical implantation site.
8. Place NuShield onto the wound bed or surgical implantation site, being careful to preserve orientation of the product and ensuring that the chorion side is in contact onto the wound bed or implant site.
9. Once NuShield is placed, the product may be rehydrated, as necessary, based on the characteristics of the wound or implant site.
10. Anchor NuShield using preferred fixation method.
11. For topical wound applications, apply a non-adherent, non-occlusive primary dressing directly over NuShield which should remain in place for up to one week.
12. For topical wound applications, apply a secondary dressing specific to the wound type. NuShield may be reapplied weekly as needed.

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Nashville, TN 37203
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Website: <http://tissuebank.dcids.org>

Distributed By:

Organogenesis, Inc.
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