



Allograft Tissue Information and Product Preparation Insert

Contents

This package contains Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) as defined by US FDA 21 CFR Part 1271.

Product Description

NuCel is an allograft derived from human amnion and amniotic fluid, aseptically processed by Wuxi AppTec, 4751 League Island Blvd, Philadelphia, PA 19112 from donated amniotic-derived human tissue. Wuxi AppTec is an FDA registered and AATB Accredited tissue bank. NuCel is cryopreserved with 10% Dimethyl Sulfoxide (DMSO) and comes frozen in a vial with a screw cap.

CAUTION: Federal Law (USA) restricts this product 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 human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA-licensed test kits. Organogenesis Inc. only releases tissue for transplantation that has negative or non-reactive results for the following:

- 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)
- WNV
- Syphilis
- HTLV I/II

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 licensed physician Medical Director. Donor eligibility was determined by Organogenesis Inc. The results are used by Organogenesis, Inc. to determine that the donor was suitable at the time of tissue recovery, all donor eligibility criteria have been met, and the tissues are acceptable for transplantation.

Processing

Technical quality assurance standards are rigorously maintained by Wuxi AppTec. Tissue is processed aseptically in a controlled, clean environment. The tissue is processed using all of the following agents: 10% Dimethyl Sulfoxide (DMSO), 25% albumin and Plasma-Lyte™. Tissue is not released for transplantation unless the final product sterility testing is complete.

Contraindications

- Nucel is contraindicated for use in the presence of active infection.
- Nucel is contraindicated for use in patients with a known sensitivity or allergies to 10% Dimethyl Sulfoxide (DMSO), 25% albumin, and Plasma-Lyte™.

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 microbiological culturing 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.
- Do not use if any seal is broken or compromised

- Does not use if product arrives thawed.
- Return all compromised or flawed packaging to Organogenesis Inc.
- Once opened, allografts must be used immediately or discarded.
- Do not use if expiration date has been exceeded.
- Store product at $-80^{\circ}\text{C} \pm 10^{\circ}$
- Recommended storage conditions and the maintenance of the tissue for transplantation are the responsibility of the hospital or clinician. Do not use if tissue has not been stored according to the recommended storage instructions.
- The healthcare professional is responsible for informing the patient of 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 unknown infectious agents such as viruses, bacteria and fungi;
- immune rejection of implanted HCT/P's; or
- Loss of function and/or integrity of implanted HCT/P's due to resorption, fragmentation, and/or disintegration

Report any adverse outcomes to Organogenesis Inc. immediately.



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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 judgment concerning patient care.

1. Maintain the product at $-80^{\circ}\text{C} \pm 10^{\circ}$ until immediately prior to use.
2. Remove the product from $-80^{\circ}\text{C} \pm 10^{\circ}$ storage and open the carton to remove the peel pack. Remove the NuCel vial from packaging using standard aseptic techniques. **Do not return opened allografts to Organogenesis, Inc.**
3. Allow NuCel to completely thaw at room temperature or by immersing the vial in warmed saline to 105°F for 1-3 minutes.
4. Using aseptic techniques, dilute NuCel by carefully emptying the contents of the vial into a medicine cup or small basin with an amount of blood or sterile saline as listed below:

Small	0.5cc
Medium	1.0cc
Large	2.0cc
Extra-Large	2.5cc
5. Diluted solution may now be added to the conductive matrix of choice.

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. and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the 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. It is the responsibility of the end user to document and maintain the HCT/P's in its original packaging and at $-80^{\circ}\text{C} \pm 10^{\circ}$ until ready for use. After use, handle and dispose of all unused products and packaging in accordance with accepted medical practice and applicable local, state, and Federal laws and regulations.

Return Policy

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

Disclaimer

Organogenesis, Inc. makes 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.

Plasma-Lyte™ is a trademark of Baxter International Inc.

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