Organogenesis
Novachor™
Fresh Chorion Membrane

Organogenesis
Empowering Healing

Allograft Tissue Information and Novachor® Instructions for Use

Contents

This package contains human allograft tissue that is regulated as a Human Cells, Tissues, and Cellular and Tissue Based Products (HCT/Ps) as defined in USFDA 21 CFR Part 1271.

Description

Novachor® is an aseptically processed, hypothermically stored fresh allograft processed by DCI Donor Services (DCIDS) Tissue Bank from donated chorion-derived human tissue. DCIDS Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA.

Intended Use

Novachor® is a fresh allograft wound covering intended for use in the management of acute and chronic wounds. Novachor® 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. Novachor® can be applied from the onset and for the duration of the wound, weekly or at the discretion of the health care practitioner.

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 live human specimens under the CLIA Laboratory Improvement Amendments (CLIA) of 1988 using, when available, FDA approved test kits. The following tests were performed and had 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)
- Syphilis (Serologic Test for Syphilis)
- HTLV I/II Ab
- 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 licensed physician Medical Director. Donor eligibility determination was performed by DCI Donor Services – Tissue Bank, 566 Mainstream Dr., Suite 300, Nashville, Tennessee 37228.

Processing

Technical Quality Assurance standards are rigorously maintained by DCIDS Tissue Bank. Tissue is processed aseptically in a controlled, clean environment. This tissue was processed using some or all of the following agents: Dulbecco's Modified Eagle's Medium (DMEM), vancomycin, gentamicin, and amphotericin B. Although the tissue was rinsed throughout the processing procedure, traces of the agents may remain. The tissue is packaged in a liquid storage solution containing human albumin. Tissue is not released for transplantation unless the final product sterility testing is complete.

Contraindications

- Novachor® is contraindicated for use on clinically infected wounds.

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.
- Return all compromised or flawed packaging to Organogenesis, Inc.
- Once opened, Novachor® must be used immediately or discarded.
- Do not use if expiration date has been exceeded.
- Novachor® must be maintained at a refrigerated temperature of 1ºC-10ºC (34ºF-50ºF) during storage.
- 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, amphotericin B 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 including, but not limited to, 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. promptly.

Tissue Preparation and Use

For topical application to a wound site, carefully follow the tissue preparation and use steps as described below.

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. Using aseptic technique, peel open the outer tray foil lid and drop the inner tray onto the sterile field. Discard the outer tray.
3. Visually inspect the container to ensure it is intact and 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 and remove Novachor® from its packaging and rinse with sterile irrigant. Once opened, allografts must be used immediately or discarded. **Do not return opened allografts to Organogenesis, Inc.**
5. Novachor® is ready for application. Do not allow graft to dry. Keep graft completely submerged in sterile solution until applied.
6. Trim Novachor® as needed so that it is slightly larger than the wound bed.
7. Place either side of Novachor® onto the wound bed.
8. Anchor Novachor® using preferred fixation method. Apply a non-adherent, non-occlusive primary dressing directly over Novachor®.
9. Apply a secondary dressing specific to the wound type. Novachor® 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. 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 use. All fresh allografts must be maintained at refrigerated temperature of 1°C-10°C during storage. Allograft tissue should not be used after the specified expiration date on the product label. 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.

Donor Assessment, Processing, and Release for Distribution by:
DCI Donor Services – Tissue Bank
566 Mainstream Dr., Suite 300
Nashville, TN 37228
(800) 216-0319
tissuebank.dcids.org

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