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 a human placental allograft tissue composed of fresh, unaltered chorion membrane, derived from donated human birth tissue, that retains its native extracellular matrix (ECM) scaffolding, proteins, and viable cells. Novachor is aseptically processed and is hypothermically stored in a preservation storage agent. Novachor is provided in a sheet configuration (e.g., 1.5cm x 2.75cm)

Novachor is 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 human placental allograft tissue intended for use as a protective barrier in the management of acute and chronic wounds. Novachor may be applied to a variety of partial- and full-thickness acute and chronic wounds, such as dermal ulcers, and wounds with exposed tendon, muscle, joint capsule, and bone. Novachor can be applied from the onset and for the duration of the wound, with subsequent application at the discretion of the health care practitioner. Novachor will naturally be broken down and resorbed into the wound and is not intended to be removed.

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 found to be negative or non-reactive:

- 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
- 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.

The donor was determined to be eligible by a DCIDS Tissue Bank Medical Director after review of these test results, donor risk assessment questionnaire, physical examination, and other available relevant donor records.

Processing

Technical Quality Assurance standards are rigorously maintained by DCIDS Tissue Bank. Novachor 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 and negative for microbial growth.

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 under strict processing controls, and sterility testing 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 Novachor expiration date has been exceeded, as indicated on the product label.
- Novachor must be maintained at a refrigerated temperature of 1°C-10°C (34°F-50°F) 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; or
- Immune rejection of implanted HCT/P.

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, Novachor may be contaminated and should not be used.
2. Peel open the outer tray foil lid and drop the inner tray onto the sterile field. Discard the outer tray.
3. Visually inspect the inner tray to ensure it is intact and its integrity has not been compromised. If the packaging is damaged, Novachor may be contaminated and should not be used.
4. If no damage is detected, locate Novachor within the inner tray prior to opening the container.
5. Gently peel open the inner tray foil lid and remove Novachor from the container using aseptic technique. Carefully rinse with sterile irrigant while maintaining control of Novachor. Once opened, allografts must be used immediately or discarded. **Do not return opened allografts to Organogenesis Inc.**
6. Novachor is ready for application. Do not allow Novachor to dry. Keep Novachor completely submerged in sterile solution until applied. Novachor can be temporarily placed into a sterile basin and submerged in sterile solution prior to application.
7. Trim Novachor as needed so that it is slightly larger than the wound bed.
8. Place either side of Novachor onto the wound bed. Using two forceps at the corners will help maintain correct orientation.
9. Anchor Novachor using preferred fixation method such as sutures or adhesive strips.
10. Apply a non-adherent, non-occlusive dressing directly over Novachor followed by a secondary dressing specific to the wound type.
11. Novachor can be applied at the onset of the wound, with subsequent application at the discretion of the health care practitioner. Novachor will naturally be broken down and resorbed into the wound and is not intended to be removed.

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 (34°F-50°F) 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, Tissue Processing, and Release for Distribution By:
DCI Donor Services (DCIDS) Tissue Bank
566 Mainstream Dr., Suite 300
Nashville, TN 37228
(800) 216-0319
tissuebank.dcids.org

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