

Allograft Tissue Information and Affinity[®] Instructions for Use

Contents

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

Description

Affinity is a human placental allograft tissue composed of fresh, unaltered amniotic membrane, derived from donated human birth tissue, that retains its native extracellular matrix (ECM) scaffolding, proteins, and viable cells. Affinity is aseptically processed and is hypothermally stored in a preservation storage agent. Affinity is provided in a sheet configuration available in multiple sizes (i.e., 1.5cm x 1.5cm and 2.5cm x 2.5cm).

Affinity is 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

Affinity is a human placental allograft tissue intended for use as a protective barrier in the management of acute and chronic wounds. Affinity 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. Affinity can be applied from the onset and for the duration of the wound, with subsequent application at the discretion of the health care practitioner. Affinity will naturally be broken down and resorbed into the wound and is not intended to be removed.

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. 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. Affinity 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 medications and chemicals 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

- Affinity 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.
- Do not use if any seal is broken or compromised.
- Return all compromised or flawed packaging to Organogenesis Inc.
- Once opened, allografts must be used immediately or discarded.
- Do not use if Affinity expiration date has been exceeded, as indicated by the product label.
- Affinity must be maintained at 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 such as viruses, bacteria and fungi; or
- Immune rejection of implanted HCT/P.

Report any adverse outcomes to Organogenesis Inc.

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

Distributed By:

Organogenesis Inc.

150 Dan Road

Canton, MA 02021

Ph: 1-888-432-5232

Organogenesis.com