Allograft Instructions for Use and Information

Contents

This package contains Human Cellular and Tissue Based Product (HCT/P) as defined in US FDA 21 CFR Part 1271.

Description

The allograft is a sterile, dehydrated amniotic, dehydrated amniotic and chorionic membrane (non-meshed or meshed) processed by DCIDS Tissue Bank from donated human tissue. DCIDS Tissue Bank is a full service not-for-profit tissue bank accredited by AATB and registered with FDA.

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:

- 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

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 policies and procedures.

These test results, as well as, a donor risk assessment questionnaire, donor 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.

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services Tissue Bank. Tissue is processed aseptically in a controlled, ultra-clean environment. Final product is terminally sterilized using a validated gamma irradiation process. These terminally sterilized tissues are labeled as sterile on the product label.

Contraindications

- Active or latent infection in or around the surgical implantation site.
- Sensitivity or allergies to any of the processing agents or antibiotics listed under the Warnings & Precautions section of this document.
- Use in immune compromised patients.

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 packaging has been compromised.
- Do not use if expiration date has been exceeded.
- Use of this tissue is limited to specific health professionals(e.g. physicians, dentist, and/or podiatrists).
- Do not use if tissue has not been stored according to the recommended storage instructions.
- This tissue was processed using some or all the following agents: DMEM, CHAPS Detergent – (3-((3-cholamido-propyl) dimethylammonio)-1-propanesulfonate), Gentamicin, and Vancomycin. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. Use of antibiotics should be discussed with the patient to discern patient status regarding antibiotic sensitivity
- Prior to clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product.

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.
- **Adverse outcomes potentially attributed to the tissue must be reported to Medline Industries, LP. immediately.**

Tissue Preparation/Rehydration

Dehydrated Amnion or Amniotic and Chorionic Membrane

Prior to use, carefully follow the tissue preparation steps as described below.

Non-Sterile Team Member

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 pass the inner envelope packing onto the sterile field.

Sterile Team Member

1. 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.
2. If no damage is detected, open the inner envelope and remove the graft. The graft may be immediately implanted, then rehydrated with sterile solution after implantation.
3. Once opened, allografts must be used immediately or discarded.

HCT/P Tracking

DCI Donor Services Tissue Bank 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, DCI Donor Services Tissue Bank provides an Allograft Tracing Record 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 Allograft Tracing Record. Return the completed form to DCI Donor Services Tissue Bank and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the *Allograft Tracking Record* completed with the allograft identification information and reason for discard needs to be returned to DCI Donor Services Tissue Bank.

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 (15°C to 30°C) prior to use. DO NOT FREEZE.

Return Policy

Please contact Medline Industries, LP at 1-800-MEDLINE. Promptly report any unanticipated or adverse events.

Disclaimer

DCI Donor Services – 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 Medline Industries, LP. immediately.

Donor Assessment, Tissue Processed, Release for Distribution, and Distributed by:

DCI Donor Services Tissue Bank
an extraordinary commitment to science, health and hope

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