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, amniotic fluid, processed by DCI Donor Services Tissue Bank from donated human tissue. DCI Donor Services Tissue Bank is a full-service not-for-profit tissue bank accredited by AATB and registered with FDA.

Donor Screening for Tissue Procurement

After authorization for donation is obtained (represented by the mother of the newborn children), DCIDS's Amniotic Fluid is procured from scheduled Caesarean procedures of full-term healthy births. 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 nonreactive 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 West Nile Virus, 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, 1714 Hayes Street, Nashville, Tennessee 37203. Although extensive efforts have been made to ensure the safety of the allograft, there is no assurance that the product is free from all infectious diseases or microbial contamination.

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services – Tissue Bank. Tissue is processed aseptically in a controlled, ultra clean environment. This tissue was processed using some or all of the following agents: DMEM and alcohol. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. Final product is terminally sterilized using a validated gamma irradiation process.

Contraindications

- Active or latent infection in or around the surgical implantation site.
- Sensitivity or allergies to any of the processing agents listed under the processing 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 freeze.
- Return all compromised or flawed packaging to CoreLink, LLC.
- Do not use if expiration date has been exceeded.
- The maintenance of the tissue for transplantation, including recommended storage conditions, is the responsibility of the hospital or clinician. Do not use if tissue has not been stored according to the recommended storage instructions.

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 attributable to the tissue must be reported immediately to CoreLink, LLC.

Liquid Fluid Tissue Preparation

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

3. 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.
4. If no damage is detected, open the inner pouch and remove the vial. Vial is supplied with a flip top for opening. Using aseptic technique, draw fluid out of vial using a needle.
5. Once opened, allografts must be used immediately or discarded. Do not return opened, unused allografts to CoreLink, LLC.

HCT/P Tracking

DCIDS 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, DCIDS Tissue Bank provides a Tissue Utilization 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 Tissue Utilization Record. Return the completed form to DCIDS Tissue Bank and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the Tissue Utilization Record completed with the allograft identification information and reason for discard needs to be returned to DCIDS 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 prior to use. DO NOT FREEZE.

Return Policy

CoreLink, LLC is committed to customer satisfaction. In the event that an allograft needs to be returned to CoreLink,

- Please call Returns (888) 349-7808 to receive a return authorization (RGA) number. Returns will not be accepted without this number.
- All returns under an RGA require an attestation that materials have been properly stored and handled while in the returning party's possession.
- Products must be in salable condition; Product that has been opened, used, written on or otherwise tampered with is not considered to be in salable condition. Product must be in its original purchase form.
- If your merchandise was damaged in shipment: PLEASE KEEP THE ORIGINAL SHIPPING CARTON AND IMMEDIATELY CALL CUSTOMER SERVICE AT (888) 349-7808.

Disclaimer

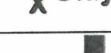
CoreLink, LLC and DCI Donor Services – Tissue Bank make no claims concerning the biologic or biomechanical properties of allograft tissue. All tissue has been collected, processed, stored and distributed according to nationally recognized standards and in compliance with applicable U.S. Food and Drug Administration requirements. Although efforts have been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease.

Donor Assessment and Tissue Processed by:
DCI Donor Services- Tissue Bank
1714 Hayes Street
Nashville, TN 37203
(800) 216-0319
Website: http://tissuebank.dcids.org

Distributed By:
CoreLink, LLC
2072 Fenton Logistics Park
St.Louis, MO 63026
(888) 349-7808
CoreLinkSurgical.com

CAUTION: Federal Law (USA) restricts this material for use by a licensed physician only.

SYMBOLS GLOSSARY

Symbol	Description
	Prescription Required- Federal Law restricts this device to sale by or on the order of a licensed practitioner.
	Manufacturer- Indicates the medical device manufacturer as defined in EU Directives 90/385/EEC, 93/42/EEC, and 98/79/EC.
	Use-by-Date- Indicates the date after which the medical device is not to be used.
	Lot Number- Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Reference Number- Indicates manufacture's catalog number so that the medical device can be identified.
	Sterilized via Irradiation- Indicates a medical device has been sterilized using irradiation.
	Do not re-use- Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Consult instructions for use- Indicates the need for the user to consult the instructions for use.
	Caution- Indications the need for the user to consult the instructions for use important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.