Allograft Tissue Information and Preparation Package Insert

Contents

This package contains Donated Human Tissue Allografts as defined in FDA 21 CFR Part 1271.

Donor Selection

Donor risk assessment is obtained at the time of donation according to FDA regulations and AATB standards, including discussions with physicians and/or family members, to identify circumstances which may lead to the exclusion of the deceased from the donor population. An appropriate blood sample from the donor is tested by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and 42 CFR 493 using, when available, FDA-licensed test kits. These test results, donor risk assessment questionnaire, physical assessment and other available relevant medical records have been evaluated by the Processor and deemed eligible for transplant by a licensed physician Medical Director. The donor eligibility criteria current at the time of tissue recovery have been met and this allograft has been determined to be eligible for transplant.

Summary Of Records

Tissues collected at recovery were tested for microbiological contaminants that would preclude the tissue from transplantation. The results were evaluated by the Processor and found to be acceptable per guidelines set forth in the AATB Standards and the Processor's policies and procedures.

This tissue was tested for and had negative/non-reactive results for the following:

HIV-1 & HIV-2 Antibodies
HBsAg (Hepatitis B Surface Antigen)
HCV Ab (Hepatitis C Antibody)
HBcAb (Hepatitis B total core Antibody)
HIV-1/HBV/HCV Nucleic Acid Testing (NAT)
Syphilis
HTLV I/II

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.

Donor eligibility determination was made at: DCI Donor Services Tissue Bank, 1714 Hayes Street, Nashville, TN 37203

Processing

Technical Quality Assurance standards are rigorously maintained by the Processor. Processing is performed in a controlled, ultra clean environment. All tissue is recovered and processed using aseptic techniques. No aseptic tissue is released for transplantation unless the final culture results support no bacterial growth. The Processor also processes allografts that have been through a validated Terminal Sterilization process in which tissue is subjected to gamma irradiation. These Terminally Sterilized tissues will be 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 listed below.
- Use in immune compromised patients

Tissue Preparation

It is the responsibility of the user facility and user clinician to maintain allograft tissue in appropriate storage conditions, dependent on the storage method, prior to transplant. Once the expiration date on the label has been reached, the allograft must be discarded. **Each allograft is intended for single patient use, on a single occasion only**. Do not use if package integrity has been violated. This allograft may not be sterilized or re-sterilized. Use is limited to licensed medical professionals.

Prior to surgery, carefully follow the tissue preparation steps as described below. Use the appropriate preparation methods depending on the packaging and storage method specified below. See the product label for the appropriate storage method in which the tissue is supplied. It is recommended that all freeze-dried and frozen allografts be rehydrated and/or thawed in Lactated Ringers, Normal Saline, or other normal physiologic solution containing antibiotics of the surgeon's preference. Antibiotic acceptability must be discussed with the surgeon to discern patient status regarding antibiotic sensitivity.

NOTE: Record the allograft ID number in the operative record. DCIDS Tissue Bank is required by FDA 21 CFR 1271 to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. To comply with this requirement, an *Allograft Tissue Tracing Record* is provided. Record the patient information, the transplantation facility name and address, the allograft tissue identification information and comments regarding tissue on the Tracing Record. Return the completed form and retain a copy in the patient medical record. If the tissue has been discarded for any reason, the Tracing Record must be completed, and a reason for discard provided. If you do not have access to the *Allograft Tissue Tracing Record*, please contact DCIDS Tissue Bank.

Freeze-Dried Allografts

All freeze-dried allografts must be maintained at ambient temperature prior to reconstitution. **DO NOT FREEZE**. Freeze-dried allografts are provided in foil pouch packaging. This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamicin, Brij® 35, Nonoxynol-9, NP-40, Alcohol and/or Hydrogen Peroxide. Additional agents used in processing demineralized bone products include Hydrochloric acid and Mono/Di Basic Phosphate Buffer. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain.

NOTE: FREEZE DRIED ALLOGRAFTS MUST BE REHYDRATED

IN ACCORDANCE WITH INSTRUCTIONS LISTED BELOW. FAILURE TO REHYDRATE IN ACCORDANCE WITH SPECIFIED REQUIREMENTS MAY IMPACT GRAFT STRENGTH AND MAY POTENTIALLY RESULT IN GRAFT FAILURE.

AlphaGraft DBM Fibers

1. Using sterile technique, peel open the outer pouch and transfer the inner pouch containing the jar into the sterile field.
2. Remove jar of DBM fibers from the inner peel pouch.
3. Add the surgeon's fluid of choice in the following amounts directly into the jar of fibers. Gently mix for 30-60 seconds until completely hydrated.

Size	Volume
1.0cc	0.9-1.0mL
5.0cc	4.5-5.0mL
10.0cc	9.0-10.0mL

4. The product handles best when hydrated with blood, BMA, or PRP.
5. Once hydrated the product can be molded into desired shape and pressed into defects.

Freeze – Dried Foil Pouch Packaging

1. Using sterile technique, peel open the outer pouch and transfer the inner pouch into the sterile field.
2. Open the inner pouch and transfer the graft into a basin containing the hydrating fluid.

Once rehydrated, allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. Rehydrated allografts may not be returned.

Frozen Allografts

Frozen tissue must be maintained at –40ºC or colder. All frozen allografts have been sealed in a clear plastic pouch, a peel pouch for aseptic delivery to the operative field and an outer, clear plastic pouch. This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamicin, Brij® 35, Nonoxynol-9, NP-40, Alcohol, or Hydrogen Peroxide. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medication and chemicals may remain.

Thawing Procedures:

1. Remove the outer clear plastic pouch. This may be accomplished by wiping off excess water and using clean scissors and cutting along any border seam of the outer pouch. Care must be taken to avoid cutting the peel pouch. **Once this outer pouch has been compromised, the allograft shall be transplanted or discarded.**
2. Utilizing a sterile technique, open peel pouch and pass sterile inner plastic pouch onto the field.
3. With sterile scissors, open inner sterile plastic pouch and place contents into a sterile basin with thawing solution. Thaw grafts quickly in warm solution (37-40°C) containing antibiotics of the surgeon's preference.
4. **Allow at least 30 minutes for the graft to fully thaw. Once thawed, all frozen allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. Thawed allografts may not be returned**.

Return Policy

Alphatec is committed to maintaining the integrity of the altruism in which tissue donation occurs. In order to conserve this scarce human resource, Alphatec will accept returned allografts if the product was received damaged or at the end of a consignment contract. The following criteria must be met for returned product to be accepted.

1. Original packaging must be intact and unopened.
2. Allograft must have been maintained in a controlled room temperature environment.
3. Responsibility for shipping arrangements must be assumed by the Alphatec distributor and/or the returning healthcare facility.
4. **The Alphatec distributor and/or healthcare facility must call Alphatec's Order Management Department at 800-922-1356 for Return Material Authorization and detailed instructions regarding the return shipment prior to return**.

Note: No claims are made 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 the U.S. Food and Drug Administration. 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 Alphatec Spine.

Processed by:
DCI Donor Services Tissue Bank
1714 Hayes Street
Nashville, TN 37203

Distributed by:
Alphatec Spine, Inc.
5818 El Camino Real, Carlsbad CA 92008

Spine Approach Technologies

For more information please contact:

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800-922-1356
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