Allograft Tissue Information and Preparation

Contents

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

Donor Screening

An appropriate blood sample from the donor is tested for relevant communicable disease tests 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 using, when available, FDA-licensed test kits. DCIDS only releases tissue for transplantation that has 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 may or may not be performed. If HTLV I/II was performed, the results are non-reactive.

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, donor risk assessment questionnaire, physical assessment/examination and other available relevant donor records have been evaluated by DCIDS and deemed eligible for transplant by a licensed physician Medical Director.

Processing

Technical Quality Assurance standards are rigorously maintained by DCI Donor Services. Processing is performed in a controlled, ultra-clean environment. All tissue is recovered and processed using aseptic techniques. Products are terminally sterilized via gamma irradiation validated for SAL 10^{-6}. These Terminally Sterilized tissues are labeled as STERILE R on the product label.

HCT/P Tracking

DCIDS 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. To comply with these requirements, an Allograft Tracing Record (ATR) and preprinted labels are included 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 ATR. Return the completed form to DCIDS per the printed instructions on the ATR and retain a copy in the patient medical record. If the tissue has been discarded and not subsequently implanted for any reason, the ATR must be completed with the reason for discard identified.

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

Warnings and Precautions

The following precautions must be taken with this allograft:

- Single patient, single use only
- Do not sterilize or re-sterilize
- Do not use if packaging has been compromised. Return all allografts with compromised packaging to Spinal Elements.
- Do not use if the expiration date has been exceeded.
- Use of this tissue is limited to specific health professionals (e.g. physicians, dentists and/or podiatrists).
- Do not use if the tissue has not been stored in accordance with the storage instructions specified in this insert.
- This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamicin, Brij®, Nonoxynol-9, NP-40, Alcohol, Hydrogen Peroxide. In addition, demineralized cortical bone may also be processed using Hydrochloric Acid and/or Mono/DiBasic Phosphate Buffer. Although the tissue was rinsed with sterile water or sterile saline throughout the processing steps, traces amounts may remain. Antibiotic acceptability should be discussed with the patient to discern patient status regarding antibiotic sensitivity.

Inherent uncertainty exists in donor screening and laboratory testing which may not detect known or unknown pathogens.

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 the implanted HCT/P; or
- Loss of function and/or integrity of the implanted HCT/P due to resorption, fragmentation, and/or disintegration.

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 and validated processing methods. **Adverse outcomes potentially attributed to the tissue must be reported to DCI Donor Services or Spinal Elements immediately.**

Return Policy

Spinal Elements is committed to customer satisfaction and will gladly handle your return.

Please note the following items are non-returnable:
- Refrigerated Items
- Items specified as "Non-Returnable" on Packing Slips/Invoices
- If your merchandise was damaged in shipment: PLEASE KEEP THE ORIGINAL SHIPPING CARTON AND IMMEDIATELY CALL CUSTOMER SERVICE AT (760) 607-0121. All packages returned Freight Collect or COD will not be accepted.

Note: DCIDS and Spinal Elements 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 the U.S. Food and Drug Administration.

Tissue Preparation

Prior to surgery, carefully follow the appropriate preparation methods specified below. The appropriate preparation method is dependent on the tissue type and packaging method described below. See product label for method in which tissue is supplied. It is recommended that all freeze-dried allografts be rehydrated 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. It is the responsibility of the distributor and/or end-user to maintain tissue at the appropriate storage conditions described below.

Freeze-Dried Allografts

All freeze-dried allografts must be maintained at ambient temperature (1°C to 37°C) prior to reconstitution. **DO NOT FREEZE**. Freeze-dried allografts are provided in an inner tyvek pouch with an outer foil pouch.

The decision to rehydrate freeze-dried bone should be based upon the surgeon's preference. Inadequate rehydration may result in graft breakage or fracture. The bone tissue may be placed into a refrigerator for the rehydration process. Once rehydrated, allografts must be used immediately or discarded. Rehydrated allografts may not be returned to DCIDS.

Note: Freeze Dried Allografts must be rehydrated according to the instructions listed below. Failure to rehydrate accordingly may impact the graft strength and could potentially result in graft failure.

Nevos Fiber Strips XT in Hydration Pouch

1. Using sterile technique, peel open the foil pouch and transfer the inner pouch into the sterile field.
2. Open the inner pouch and remove the hydration pouch.
3. To evacuate excess air from the hydration pouch, attach an empty syringe to the luer lock port and draw out the excess air.
4. Using the luer lock port, hydrate the graft for 5 – 10 minutes using surgeon's fluid of choice with enough fluid to completely cover the allograft. A maximum of 20 mL fluid may go into the hydration pouch.
5. Gently invert and rotate the pouch to ensure complete hydration of the Fiber Strip.
6. The product maintains maximal cohesion when hydrated with blood, BMA, or PRP.

Disclaimer

DCIDS and Spinal Elements 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 attributed to the tissue must be reported to DCI Donor Services or Spinal Elements immediately.**

Donor Assessment, Tissue Processing, and Release for Distribution by:
DCI Donor Services – Tissue Bank
566 Mainstream Dr., Suite 300
Nashville, TN 37228
800.216.0319
615.327.2381 Fax
Tissuebank.dcids.org

Available Through:
Spinal Elements
3115 Melrose Drive, Suite 200
Carlsbad, CA 92010 USA
(760) 607-0121
www.spinalelements.com