Allograft Tissue Information and Preparation Package Insert

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

These test results, donor risk assessment questionnaire, physical examination/examination and other available relevant donor records have been evaluated by DCIDS and deemed suitable 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. No aseptic tissue is released for transplantation unless the final culture results support no bacterial growth. DCIDS also processes allografts that have been through a validated Terminal Sterilization process in which tissue is subjected to a gamma irradiation process. These Terminaly Sterilized tissues are labeled as sterile on the product label.

HCT/P Tracking

DCIDS is required by FDA 21 CFR 1271 to maintain a method for documenting the disposition of each tissue in order to enable tracking from the donor to the consignee or final disposition. To comply with this requirement, DCIDS provides an Allograft Implant Tracing Record with every graft to be completed post-implantation and returned to DCIDS. In addition to completing the tracing record please record the allograft ID number on the recipient's operative record. Joint Commission standards require the organization that receives tissue provides a system that fully complies with the collection and return of tissue usage information cards requested by source facilities. If you do not have access to the Allograft Implant Tracing Record, please contact DCI Donor Services

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 DCIDS.
- 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® 35, Nonoxynol-9, NP-40, Alcohol, Hydrogen Peroxide, Glycerol and/or Cefazolin. 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 immediately.

Return Policy

DCIDS is committed to maintaining the integrity of the allografts in which tissue donation occurs. In order to conserve this scarce human resource, DCIDS will continue to accept returned allografts for credit (less a handling fee) with specific criteria so as not to compromise the viability of a graft for future use. Allografts may be returned under the following circumstances:

- Graft must have been maintained in accordance with specified storage requirements.
- Responsible for facilitating shipping arrangements must be assumed by the returning healthcare facility.
- The returning facility must complete, sign and return a DCIDS Tissue Return Declaration Form attesting that allografts being returned have been stored in accordance with the required storage conditions outlined in this insert. Call the DCIDS Distribution office at 800-216-0319 for a Return Authorization Number (RA#) prior to shipment return. Credit cannot be issued if the Tissue Return Declaration Form has not been completed by the returning facility and received by DCIDS.

Note: DCIDS makes 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 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. 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 prior to reconstitution. **DO NOT FREEZE.** Freeze-dried allografts are provided in three different packaging configurations: sealed under vacuum in glass containers, inner tyvek pouch in an outer foil pouch, and plastic jar in a plastic tray.

**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.

**Bottle Packaging**

1. Remove the clear plastic, tamper resistant seal or aluminum tear ring. Once this seal has been broken, the tissue shall be either transplanted or discarded.

2. Utilizing a sterile technique, twist open and remove the screw cap, or remove the protective disk from the bottle.

3. Prepare the top surface of the stopper with alcohol or Betadine and allow to dry.

4. Using a sterile syringe and needle, inject a sufficient quantity of the normal physiologic solution to cover the allograft.

5. At the time of surgery, aseptically complete vacuum release from bottle and remove sterile stopper.

6. Transfer the contents to a sterile container on sterile back table.

**Jar & Tray Packaging**

1. Using sterile technique, peel open the foil cover from the tray and transfer the allograft to the sterile field

2. The graft can be hydrated either by adding the rehydrating solution directly into the jar or transferring the contents to a sterile jar containing the rehydrating solution

**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 rehydrating fluid.

The decision to rehydrate freeze-dried bone should be based upon the surgeon’s preference. It is recommended that allografts be rehydrated a minimum of 30 minutes. Cortical bone and allografts that require shaping and/or drilling may require additional time for rehydration. Inadequate rehydration may result in graft breakage or fracture. The bone tissue may be placed into a water bath and left to rehydrate for 30 minutes or until rehydrated. Once rehydrated, allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. Rehydrated allografts may not be returned to DCIDS.

**Frozen Allografts**

Frozen tissue must be maintained at -40ºC or colder. All frozen allografts have been sealed in a clear plastic pouch, a seal pouch for aseptic delivery to the operative field and an outer, clear plastic pouch.

**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 transected or discarded.

2. Utilizing sterile technique, open the peel pouch and pass the inner plastic pouch onto the field.

3. With sterile scissors, open the inner sterile plastic pouch and place contents into a sterile field, followed by rinsing and drying of the allograft. Alternatively, the allograft can be placed into a water bath and left to rehydrate for 30 minutes or until rehydrated. Once rehydrated, allografts must be used immediately (within 24 hours if refrigerated at 4°C) or discarded. Thawed allografts may not be returned to DCIDS.

**Cryoprotected Frozen Skin Allografts**

Cryoprotected Frozen Skin Allografts shall be maintained at a temperature of -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.

**Thawing Procedures:**

1. Set up a large basin of warm tap water (25-40ºC) on a back table in close proximity to the frozen allografts. Frozen skin shall be stored in an insulated box of dry ice until ready for use. Remove the packaged allograft from frozen storage and place directly into the basin of warm water without opening the package. Gently agitate until thawed. When the water temperature drops below 25ºC, replace it with warm water as above. Several allografts may be thawed at the same time.

2. 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.

3. Utilizing sterile technique, open the peel pouch and pass the inner plastic pouch onto the field.

4. With sterile scissors, open the inner sterile plastic pouch and place contents into a sterile field with warm balanced salt solution, e.g., Normal Saline or Lactated Ringers. Gently agitate the allografts to facilitate rinsing.

5. Transfer the allografts to a second sterile field of balanced salt solution and maintain the field there until used. If the surgeon has specified antibiotics, they can be pre-mixed in the balanced salt solution.

6. 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 to DCIDS.

**Allograft Tissue Information Package Insert**

For more information please contact:

DCI Donor Services – Tissue Bank
1714 Hayes Street
Nashville, TN 37203
800.216.0319
615.327.2381 Fax

CTO Registration #100214 (Canada)

New Mexico Donor Services
Sierra Donor Services
Tennessee Donor Services

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