



Allograft Tissue Information and Preparation Package Insert

Contents

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

Description

MEDLINE UNITE[®] bone products consist of cancellous bone and may be used in a variety of orthopedic, neurosurgical, and reconstructive procedures. MEDLINE UNITE[®] demineralized allograft products consist of cortical bone matrix and is supplied as a DBM Gel Paste, DBM Fiber Putty, or DBM Loose Fibers.

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

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 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. DCIDS processes allografts that have been through a validated Terminal Sterilization process in which tissue is subjected to a terminal gamma irradiation process. These Terminally 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 completion 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.
- 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, and 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 Medline Industries, LP. immediately.**

Return Policy

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

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 (15°C to 30°C) prior to reconstitution. **DO NOT FREEZE**. Freeze-dried allografts are provided in an inner tyvek pouch with an outer foil pouch.

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.

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 refrigerator for the rehydration process. Once rehydrated, allografts must be used immediately or discarded. Rehydrated allografts may not be returned to DCIDS.

Demineralized Bone Matrix (DBM) Gel Paste, Fiber Putty

All DBM Gel Paste and Fiber Putty allografts must be maintained at ambient temperature (15°C to 30°C) prior to use.

1. Demineralized Bone Matrix is provided ready for implantation and does not require thawing or rehydration.
2. Using sterile technique, peel open the outer pouch and transfer the inner pouch containing the syringe into the sterile field.
3. Remove syringe of DBM from the inner peel pouch.
4. DBM handles best when extruded and molded into desired shape and pressed into defect.
5. Irrigation resistant once molded and pressed into the defect.
6. For best results, the DBM must fill the defect and contact as much viable bone as possible.
7. Once the packaging has been opened, allografts must be used immediately, if appropriate or discarded.

Demineralized Cortical Bone Fibers Preparation

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 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
2.5cc	2.25-2.5mL
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.
6. Once rehydrated, allografts must be used immediately or discarded. Rehydrated allografts may not be returned to DCIDS.

Donor Assessment, Tissue Processing, and Release for Distribution by:

DCI Donor Services Tissue Bank

566 Mainstream Dr.
Suite 300
Nashville, TN 37228
Ph: (800) 216-0319
Fax: 615 234 5270
Internet: tissuebank.dcid.org

Distributed by:

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US Patent 11.927, 393

US Patent D977, 672