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

Description

OsteoAMP is an acellular allograft produced from donated human bone tissue and supplied in various formats; granules, sponge, putty, concentrate, and structural versions.

Donor Screening for Tissue Procurement:

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/HCV NAT by TMA
- Hepatitis B surface Antigen (HBsAg)
- Hepatitis B Core total antibody (anti-HBc)
- Hepatitis C antibody (anti-HCV)
- Syphilis
- HTLV I/II

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, Inc. (DCIDS). Processing is performed in a controlled, ultra clean environment. This aseptic handling of the tissue continues throughout processing. Products are terminally sterilized via gamma irradiation validated for SAL 10^{-6} .

Packaging

OsteoAMP is packaged in a Tyvek/foil pouch configuration. This packaging facilitates the introduction of the tissue product into the sterile field.

Indications

OsteoAMP may be used in situations where an autograft is appropriate, such as spinal fusion procedures. It should be restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects.

Contraindications

- Active or latent infection in or around the surgical implantation site
- Sensitivity or allergies to any of the processing agents listed under the warnings and precautions section of this document
- Use in immune compromised patients
- Use as a standalone in load-bearing applications

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 and terminal sterilization by gamma irradiation.

- **Single patient, single use only.**
- **Do not resterilize.**
- Return all packages with flaws to the supplier.
- Do not use if expiration date has been exceeded
- Recommended storage conditions and the maintenance of the tissue for transplantation are 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.
- This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamycin, Allowash®, Alcohol, and/or Hydrogen Peroxide. Although the tissue was rinsed with sterile water or sterile saline throughout the processing procedure, traces of the medications and chemicals may remain. Antibiotic acceptability must be discussed with the patient to discern patient status regarding antibiotic sensitivity.

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

Report any adverse outcomes to Bioventus immediately.

Tissue Preparation/Rehydration

Prior to surgery, carefully follow the tissue preparation steps as described below. OsteoAMP is freeze-dried allograft.

It is recommended to rehydrate allografts in bone marrow aspirate, blood, sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution.

1. Open carton and remove pouch.
2. Using a sterile technique, remove product from sterile package and place on sterile field.

3. If allograft is packaged in a vial:
 - a. Open jar/vial and remove tissue.
 - b. Place the allograft in a sterile basin (or equivalent) containing desired solution of choice. Ensure allograft is completely submerged in the solution.
 - c. Proceed to step 5.
4. If allograft is prepackaged in a graduated syringe (Primary):
 - a. Separate Primary syringe from holding card.
 - b. Remove red luer cap.
 - c. Connect Primary syringe with a Secondary syringe containing volume of desired solution.
 - d. Invert coupled units with the Primary syringe luer end in a vertical down position.
 - e. Slowly dispense solution from Secondary syringe into Primary syringe ensuring solution migrates up to the specified volume of the Primary syringe. Note: DO NOT overfill past specified volume.
 - f. Uncouple Secondary syringe from Primary syringe.
 - g. Remove clear end cap from Primary syringe to dispense hydrated allograft into a sterile basin.
 - h. Proceed to step 5.
5. Addition of antibiotics of choice is optional.
6. The decision to reconstitute freeze dried allografts prior to transplantation should be based upon the surgeon's preference. Reconstitution times may vary with the type and size and intended use of the allograft.
7. Allograft should be implanted as soon as possible after reconstitution. Tissue should be used within 6 hours of opening container if stored at ambient temperature, or within 36 hours if stored refrigerated with proper precautions to prevent contamination. Reconstitution times may vary with the type and size and intended use of the allograft.
8. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

allografts for credit (less a handling fee). The specific criteria for returning allograft tissue products ensure that the viability of the graft is not compromised and are listed below.

1. Graft must be returned within 30 days of receipt.
2. Packaging must be intact, unmarked, and unopened.
3. Graft must have been maintained according to the specified storage conditions.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare facility.
5. Returning facility must complete, sign and return a Bioventus Tissue Return Authorization Form stating that all of the required criteria have been met. Call the Bioventus customer service department at 800-836-4080 or email at CustomerServiceUSA@bioventusglobal.com for a Return Materials Authorization Number (RMA#) prior to shipment return. Credit cannot be issued if the Tissue Return Authorization Form has not been completed by the returning facility and received by Bioventus.

Disclaimer: Bioventus 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. 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 Bioventus.

Tissue Processed by:

DCI Donor Services, Inc.
1714 Hayes Street
Nashville, TN 37203
(800) 216-0319

Distributed By:

Advanced Biologics LLC
2800 Roosevelt Street
Carlsbad, CA 92008
(800) 272-0267

Marketed By:

Bioventus LLC
4721 Emperor Blvd. Suite 100
Durham, NC 27703
(800) 836-4080

CAUTION: Federal Law (USA) restricts this material to use by a licensed physician

HCT/P Tracking

DCIDS is required by 21 CFR 1271.290(e) to maintain documentation about the disposition of each tissue to enable tracking from the donor to the consignee or final disposition. Joint Commission requires 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 provides an *Allograft Implant Tracing Record (AITR)* 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 AITR. Return the completed form to DCIDS and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, AITR completed with the allograft identification information and reason for discard needs to be returned to DCIDS

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 freeze-dried allografts must be maintained at 11-30°C (51.8-86°F) temperature prior to reconstitution. DO NOT FREEZE.

Return Policy

Bioventus is committed to honoring the altruism of tissue donation. In accordance with this commitment, Bioventus will accept returned