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This package contains DONATED HUMAN TISSUE allograft as defined in USFDA 21 CFR Part 1271.

Description

OSTEOAMP and OSTEOAMP SELECT are acellular allografts produced from donated human bone tissue and supplied in multiple formats: Freeze-dried OSTEOAMP Granules, Freeze-dried OSTEOAMP Putty, and OSTEOAMP SELECT Flowable - a ready for use allograft in a flowable format that does not require preparation or rehydration.

Donor Screening for Tissue Procurement:

Donor risk assessment is performed at the time of donation according to U.S. Public Health Service guidelines, including discussions with healthcare professionals and/or family members, to identify circumstances which may lead to the exclusion of the deceased from the donor population. All tissue is recovered under appropriate conditions from carefully screened donors. A 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 using, when available, FDA-licensed test kits. DCI Donor Services, Inc. (DCIDS) only releases tissue for transplantation that has negative or non-reactive results for: HIV-1 & HIV-2 antibodies, Hepatitis B surface antigen, Hepatitis C antibody, Hepatitis B core total antibody, HIV-1/HCV/HBV/ NAT by TMA, and Syphilis. Additional test, including, but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. 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. In some instances, postmortem autopsies and/or biopsies are performed as a screen for nonspecific infectious or malignant conditions. Tissue is carefully examined at the time of recovery, and again during processing to ensure that it is suitable for a variety of transplantation applications. Serology test results, medical history, physical assessment, available relevant medical records including previous medical history, laboratory test results, existing autopsy or coroner reports, as well as information from other sources or records which may pertain to donor eligibility, along with tissue procurement test results, have been evaluated by DCIDS Medical Director. The results are sufficient to indicate that the donor eligibility criteria current at the time of tissue recovery have been met. Donor risk assessment, tissue-related information, and tissue processing details shall be made available to the end-user upon request, except such information that may infringe upon the confidentiality of donor information.

Processing

Technical Quality Assurance standards are rigorously maintained by DCIDS. Processing is performed in a controlled, 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 and OSTEOAMP SELECT are packaged in a dual pouch configuration. The inner pouch and its contents are sterile and standard aseptic/sterile technique should be used to open the package and transfer contents into the sterile field.

Indications

OSTEOAMP and OSTEOAMP SELECT may be used in situations where an autograft is appropriate. OSTEOAMP and OSTEOAMP SELECT should be restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects.

Contraindications

- Do not use if active or latent infection in or around the surgical implantation site
- Do not use if patient has sensitivity or allergies to any of the processing agents listed under the **Warnings and Precautions** section of this document
- Do not use in immune compromised patients
- Do not use as a standalone implant 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.
- Do not use product that has damaged, compromised, or missing packaging.
- 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.
- The tissue is intended for use by qualified healthcare specialists.
- Human tissue for transplantation shall not be offered distributed or dispensed for Veterinary use.
- This tissue was processed using some or all of the following agents: Bacitracin, Polymyxin B Sulfate, Gentamycin, Brij® 35, Nonoxynol-9, NP-40, Alcohol, Hydrogen Peroxide, Acetic Acid, Hydrochloric Acid, and/or Mono/DiBasic 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. Antibiotic susceptibility must be discussed with the patient to discern patient status regarding antibiotic sensitivity.

Complications and Possible Adverse Effects

Report any adverse outcomes to Bioventus immediately.

- 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

Tissue Preparation – OSTEOAMP SELECT Flowable

Prior to surgery, carefully follow the tissue preparation steps as described below for the OSTEOAMP SELECT Flowable, ready for use allograft:

1. Open carton and remove pouch.
2. Using a sterile technique, remove product from sterile package and place on sterile field.
3. Remove syringe from the pouch and remove the threaded male cap, taking care to leave the open bore cap securely connected to the syringe.
4. **DO NOT ATTEMPT TO REHYDRATE.** This will change the cohesiveness and flowability properties of the allograft.
5. Push the plunger to express the allograft material through the open bore cap. Initial resistance may occur, but continue to push on the plunger until the material begins to flow.
6. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

- Once the bore cap has been removed, the tissue shall be transplanted or otherwise discarded.

Tissue Preparation/Rehydration – OSTEOAMP Granules and Putty

Prior to surgery, carefully follow the tissue preparation steps as described below. It is recommended to rehydrate allografts in bone marrow aspirate, blood, sterile saline (0.9%), Lactated Ringer's, or other sterile isotonic solution to achieve desired handling properties.

- Open carton and remove pouch.
- Using a sterile technique, remove product from sterile package and place on sterile field.
- If allograft is packaged in a vial:
 - Open jar/vial and add desired amount of reconstitution solution until desired handling properties are achieved. A sterile basin (or equivalent) containing desired solution of choice may also be used. Ensure allograft is completely submerged in the solution.
 - Proceed to step 5.
- If allograft is prepackaged in a graduated syringe:
 - Separate Primary syringe from holding card.
 - Remove luer cap.
 - Connect Primary syringe with a Secondary syringe containing volume of estimated solution:

Granules		
Description	Size (cc)	Estimated Hydration (cc)
OSTEOAMP Granules <2mm & 2-4mm	5	~3
OSTEOAMP Granules <2mm & 2-4mm	10	~8
OSTEOAMP Granules <2mm & 2-4mm	15	~10

Putty		
Description	Size (cc)	Estimated Hydration (cc)
OSTEOAMP Putty	5	~3
OSTEOAMP Putty	10	~6
OSTEOAMP Putty	15	~8

- Invert coupled units with the Primary syringe luer end in a vertical down position.
 - 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.
 - Uncouple Secondary syringe from Primary syringe.
 - Remove clear end cap from Primary syringe to dispense hydrated allograft into a sterile basin.
 - Proceed to step 5.
- Addition of antibiotics of choice is optional.
 - Reconstitution times may vary with the type, size and intended use of the allograft.
 - 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.
 - Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

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 Tracing Record* 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 tracing record. 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, the *Allograft Tracing Record* is to be 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, including expiration date, prior to transplant. All allografts must be maintained at ambient temperature. Reconstituted, freeze-dried allograft may be stored at ambient temperature, or refrigerated, per the timeframes above prior to use. Optimal storage conditions (11°C-30°C, 51.8°F -86°F). DO NOT FREEZE or expose to extreme heat(125°F or greater).

Return Policy

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

- Packaging must be intact, unmarked, and unopened.
- Graft must have been maintained according to the specified storage conditions.
- Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare facility.
- Returning facility must complete, sign and return a Bioventus Return Authorization Form (FRM-000240) stating that all of the required criteria have been met. Call the Bioventus customer service department at 800-637-4391 or email at csurgical@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: No claims can be 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.

Donor Eligibility and Tissue Processing by:

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

Marketed By:



4721 Emperor Blvd. Suite 100. Durham, NC 27703
1.800.637.4391 • www.BioventusSurgical.com

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