osteoamp™
Allogeneic Morphogenetic Proteins

Contents
This package contains DONATED HUMAN TISSUE allograft as defined in USFDA 21 CFR Part 1271.3.

Description
OSTEOAMP is an acellular allograft produced from donated human bone tissue and supplied in various formats; granules, sponge, and putty.

Donor Screening for Tissue Procurement:
Tissue was prepared from a donor determined to be eligible based on the results of screening and testing. Donor risk assessment is performed at the time of donation according to U.S. FDA regulations and American Association of Tissue Banks standards, 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. Communicable disease testing was performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and 42 CFR Part 493 or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS) using, when available, FDA-licensed test kits. Community Tissue Services (349 S. Main St., Dayton, OH 45402) 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 tests, including, but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. 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 Community Tissue Services' Medical Director. The results are sufficient to indicate that the donor suitability 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 Community Tissue Services. 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 is packaged in a Tyvek/ClearFoil inner pouch, Foil/ClearFoil outer pouch configuration. This packaging facilitates the introduction of the tissue product onto the sterile field.

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

Contraindications
- Do not use if active or latent infection is present 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.

This tissue is intended for use by qualified healthcare specialists.

Warnings & Precautions
Tissue may transmit infectious agents. 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 product that has damaged, compromised, or missing labels/instructions for use, including barcodes.
- 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.
- Tissue has been processed with Bacitracin and/or Polymyxin B, alcohol, acetic acid, hydrochloric acid, sodium phosphate solution, hydrogen peroxide, as well as chemicals specific to the proprietary bioburden reduction process. 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.
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.

Complications and Possible Adverse Effects
- 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 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, 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.
8. Once the container seal has been compromised, the tissue shall be either transplanted or otherwise discarded.

HCT/P Tracking

Community Tissue Services 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, Community Tissue Services provides an *Allograft Tracking Form* 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 tracking form. Return the completed form to Community Tissue Services and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, the Allograft Tracking Form is to be completed with the allograft identification information and reason for discard needs to be returned to Community Tissue Services .

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. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. All freeze-dried allografts must be maintained at ambient temperature prior to reconstitution. Optimal storage conditions (11°C-30°C; 52°F-86°F). DO NOT FREEZE.

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.

1. Packaging must be intact, unmarked, and unopened.
2. Graft must have been maintained according to the specified storage conditions.
3. Responsibility for facilitating shipping arrangements must be assumed by the returning healthcare facility.
4. 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 cssurgical@bioventusglobal.com for a Return Materials Authorization Number (RMA#) prior to shipment return. Credit cannot be issued if the 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.

Tissue Processed and Distributed by:
Community Tissue Services
2900 College Drive
Kettering, OH 45420
(937) 222-0228

Marketed By:

bioventus®

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

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