Tissue ID Number:

Place Sticker Here

STERILE HUMAN ALLOGRAFT: INSTRUCTIONS FOR USE

DESCRIPTION

OsteoAMP is an allograft derived from DONATED HUMAN TISSUES. The tissue was prepared from a donor determined to be suitable for transplant by the Pinnacle Transplant Technologies Medical Director based on the results of screening and testing. Recovery was performed using sterile surgical procedures and Pinnacle Transplant Technologies' controlled tissue processing environment is designed to ensure tissue allograft bio-implant quality and safety. PTT utilizes a proprietary series of disinfection and sonication soaks validated to significantly reduce bioburden prior to terminal sterilization via gamma irradiation. This allograft was prepared from tissues which may have been treated with 70% isopropyl alcohol, Triton-X 100, hydrogen peroxide, hydrochloric acid, phosphate buffered saline and acetic acid and may contain trace residuals of these agents.

STORAGE

This product should be stored at 11-30°C (51.8-86°F) until expiration date shown on allograft label. The user facility and clinician is responsible for maintaining allograft tissue in appropriate storage conditions prior to transplant.

INSTRUCTIONS FOR PREPARING ALLOGRAFT FOR ADMINISTRATION

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. 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.

TREATMENT WITH GAMMA IRRADIATION

Donor tissue is recovered using the safest recovery techniques and sterile equipment to minimize any bioburden contamination. All PTT tissues are procured via a network of qualified and trained recovery partners, one of the most stringent screening and recovery protocols, validated tissue cleaning and sterilization processes, and a highly controlled processing environment, thus countering the risks of disease transmission at every step. Subsequently, all allografts are terminally sterilized using Gamma irradiation with a dose ≥15.8 kGy to ensure patient safety. The effects of low dose irradiation on the biological properties of human allograft tissues are not fully understood at this time.

INDICATIONS AND USAGE

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.

- Intended for use in one patient, on a single occasion only
- Only qualified health care professionals (e.g. physicians, dentists, podiatrists, etc.) should transplant donated human tissue
- Tissue may not be sterilized or re-sterilized
- Human tissue for transplantation shall not be offered, distributed or dispensed for Veterinary Use.
- PTT assumes no responsibility for the clinical use of this allograft tissue
- Tissues may transmit infectious disease agents. Any adverse outcomes that may be attributable to the implantation of this allograft tissue must be reported to Bioventus as soon as possible.

DONOR SCREENING AND TESTING

PTT only accepts donors from federally designated Organ Procurement Organizations (OPOs) or qualified tissue recovery partners. As these organizations are focused primarily on organ donation and tissue recovery, PTT is responsible for donor screening, tissue processing, and distribution services for our partners. Each partner is routinely audited to guarantee that their recovery practices meet current FDA regulations, AATB standards and PTT's own stringent guidelines. Prior to release for transplantation, each donor is subjected to a thorough eligibility evaluation including review of the donors medical and social history, hospital records, infectious disease screening, autopsy report (if performed), and physical assessment. * Testing includes, but is not limited to, the following:

- HBsAg: Hepatitis B Surface Antigen
- HBcAb: Hepatitis B Core Antibody
- HCVAb: Hepatitis C Antibody
- HIV 1/2/Ab: Human Immunodeficiency Virus Types 1/2 and O Antibody
- HCV NAT: Hepatitis C Virus
- HIV NAT: Human Immunodeficiency Virus
- HBV NAT: Hepatitis B Virus
- RPR/STS or Equivalent: Syphilis

*HTLV I/II testing may have been performed, if testing was performed results were found to be negative/nonreactive.

All required communicable disease tests are negative/nonreactive. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens in accordance with Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Names and addresses of testing laboratories and a listing of the documents reviewed as part of the relevant medical records are kept on file at Pinnacle Transplant Technologies and are available to the End-User

upon request, except such information that may infringe upon the confidentiality of the donor information.

Based on all the screening and testing results this donated human tissue product has been determined to be suitable for transplant by the Medical Director and Quality Assurance.

PRECAUTIONS

Because of potential violations of sterility, this allograft must not be transplanted under the following conditions:

- The container in which the product is stored is damaged compromising packaging integrity
- The tissue's outer packaging is damaged or missing
- The expiration date has been exceeded
- The allograft is not labeled, or the label's information is damaged, defaced or illegible
- The allograft has not been stored according to acceptable storage conditions outlined in this Package Insert
- If any of the allograft or package elements appear to be missing, damaged or tampered with
- If the product label or identifying barcode is severely damaged, illegible or missing
- If any of the aforementioned conditions exist or are suspected, please notify Bioventus immediately for resolution.

CONTRAINDICATIONS, SIDE-EFFECTS AND HAZARDS

No absolute contraindications are known to exist. Trace amounts of Triton X-100, isopropyl alcohol, hydrogen peroxide, hydrochloric acid, phosphate buffered saline and acetic acid may be present and caution should be exercised if the patient is allergic to any of these agents. A relative contraindication would include the presence of infection in the host bed where the allograft is implanted. Limitations of allografts include slow and/or incomplete incorporation and/or resorption which may be due to the difference in histocompatibility factors between the donor and recipient. Bacterial infection at the site of implantation may occur. This complication may not be apparent for long periods of time (6-24 months) after transplantation. Transmissions of infectious disease may occur despite rigorous donor selection and testing.

COMPLICATIONS AND POSSIBLE ADVERSE EVENTS

Inherent uncertainties exist 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 disease 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.

HTC/P TRACKING

Per 21CFR1271.290(e), documentation about the tissue disposition to enable tracking from the donor to the consignee or final disposition must be maintained. Once tissue is used (implanted) on patient, it is a critical that the organization that receives tissue return the tissue usage information card(s) requested by source facilities. To comply with these requirements, a Tissue Transplant Record (TTR) and preprinted labels with every graft is provided. Record the patient information, the transplantation facility name and address, the allograft tissue identification information (using stickers) and comments regarding tissue on the TTR. Return the completed form to Pinnacle Transplant Technologies and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, TTR completed with the allograft identification information and reason for discard needs to be returned to Pinnacle.

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. 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 Authorization Number (RA#) 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.

PROCESSING AND DONOR ELIGIBILITY DETERMINED BY:
Pinnacle Transplant Technologies
1125 W. Pinnacle Peak Rd Building #2, Suite 116
Phoenix, AZ 85027
(623) 277-5400

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

MARKETED BY:
Bioventus LLC
4271 Emperor Blvd., Suite 100
Durham, NC 27703
(800) 836-4080

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant and that Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Advanced Biologics LLC and PTT will not be liable for any damages, whether direct or indirect, special, incidental or consequential resulting from improper use of this allograft. The instructions for use are specific, and PTT waives all responsibility associated with mishandling, inappropriately storing and/or not taking proper precautions with the allograft tissue included with this insert.