Procedure for Preparation of PUREBONE Allograft for Clinical Use

Please make sure these instructions accompany the enclosed allograft to the Operating Room

The enclosed DONATED HUMAN TISSUE allograft has been recovered and processed under aseptic conditions in accordance with American Association of Tissue Banks (AATB) standards as well as state and federal regulations (FDA and the states of Florida, California, Maryland, and New York).

Check to make sure that the allograft is the one needed for the procedure. Check the package integrity. If there is any doubt, do not open the allograft package.

- Antibiotic solutions (Bacitracin and Polymyxin B), alcohol, and/or Hydrogen Peroxide are used during processing. In addition, demineralized tissue is also processed with hydrochloric acid and sodium phosphate solution. Although this allograft is thoroughly cleaned and rinsed before final packaging, traces of antibiotics/other processing solutions may remain. In addition, allografts labeled "GAMMA IRRADIATED" were irradiated within a validated dose range.
- It is the responsibility of the Tissue Dispensing Service and/or the end user clinician to maintain this allograft in the appropriate storage conditions, as listed below, prior to transplant.
- PUREBONE may only be used by a licensed Clinician.
- PUREBONE allograft is intended for single patient use, on a single occasion only. PUREBONE allograft may not be reprocessed.
- Latex gloves are used during both the recovery and processing of tissue.
- Recipient records must be maintained for the purpose of tracking. Please complete and return the allograft implant record following use. Peel-off tabs on the allograft label have been provided for use on the allograft implant record and your internal tracking records.
- If you encounter any problems with this allograft, have any questions, or if there is a patient complication possibly related to this allograft, please contact Bioventus Surgical Customer Service immediately at 800-637-4391.
- As a best practice, it is highly recommended that all materials used by the hospital to prepare a graft for surgery should be documented in the tissue recipient's medical record. The identification of the materials should include lot numbers where appropriate to assist in an Infection Control investigation should an adverse event believed to be related to the allograft tissue occur.

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 Surgical Return Authorization Form stating that all of the required criteria have been met.

Call the Bioventus Surgical 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 Bioventus Surgical Return Authorization Form has not been completed by the returning facility and received by Bioventus.

STORAGE, HANDLING AND RECONSTITUTION

Freeze-dried allografts should be stored at ambient temperature (11°C-25°C; 52°F-77°F). Rehydration time varies with the type of allograft. If the allograft is to be rehydrated longer than two hours prior to implantation, it should be refrigerated until use. 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.

Step 1: The circulator opens the package to remove the pouch and then grasps the outer edges of each pouch and pulls them apart.

Step 2: Using sterile technique, the scrub nurse/tech removes the allograft from the inner package. If the allograft is packaged in a jar/vial, open the lid and add desired amount of reconstitution solution until desired handling properties are achieved. A sterile basin may also be used. Completely cover the allograft with sterile solution of choice. Antibiotics of a surgeon's preference may be added to the solution.

Once removed from the packaging, the allograft should be implanted immediately or refrigerated and used within 24 hours only if stored with proper precautions to prevent contamination or discarded in the appropriate manner.

SUMMARY OF RECORDS

LifeLink Tissue Bank is accredited by the American Association of Tissue Banks, registered with the FDA and Health Canada (CTO Certificate# 100144) and licensed by the States of Florida, California, Maryland, and New York, and registered with the states of Delaware and Oregon. LifeLink Tissue Bank adheres to the criteria for donor screening, recovery, processing, and distribution of allograft required by these organizations and all regulations set forth by the U.S. Food and Drug Administration. All tissue is recovered and processed under aseptic conditions from carefully screened donors. Musculoskeletal tissue is processed using Allowash® Technology. Comprehensive serologic testing is performed on each donor. In addition, numerous microbiologic cultures are performed and evaluated at tissue recovery and allograft packaging. If an autopsy is performed, the Medical Director or physician designee shall review the autopsy findings before the release of tissue for clinical use.

This tissue has been determined to be suitable for transplantation by a LifeLink Tissue Bank medical director after review of medical and social history, relevant hospital records, infectious disease testing, physical exam, and autopsy report (if one was performed).

A qualified sample from the donor has been tested for infectious disease by a CLIA-certified, FDA-registered laboratory and found to be negative for the minimum following blood tests:

HIV1 / HIV2 Ab	**HCVAb**	Test kits used for serological assays are approved/licensed by the FDA, where applicable
HBsAg	***STS**	
HBcAb	**HIV1 / HCV / HBV NAT**	
*STS Serologic Test for Syphilis		

Refer to the allograft label for a list of serology testing performed, test results and additional information regarding processing/preservation (e.g., frozen, freeze dried, irradiated).

LifeLink Tissue Bank has strict donor screening criteria, recovery and processing methods. These safeguards are designed to prevent the introduction, transmission, or spread of communicable diseases from allografts. While efforts are made to ensure the safety of the tissue, current technologies may not preclude the transmission of infectious agents. LifeLink has a comprehensive Quality Assurance Program that monitors the standards & procedures recognized to be most effective in limiting risks associated with using allograft tissue.

LifeLink's Microbiology Laboratory is inspected regularly to maintain appropriate state licensing and CLIA accreditation. The Microbiology Laboratory has achieved national accreditation by the College of American Pathologists.

LifeLink Tissue Bank makes no claims concerning the biological or biomechanical properties of the provided product. LifeLink Tissue Bank disclaims all liability and responsibility for any misuse of product provided for clinical application.

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