As a best practice, 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. Tabs are provided on the package label with barcodes containing the 10-digit number that is the unique identifier for the allograft.

Indications and Usage

Human musculoskeletal allograft may be used in a number or orthopedic, reconstructive, and dental applications. Allograft bone can be used in bone grafting procedures in combination with autologous bone or other forms of allograft bone, or it can be used by itself as a bone graft.

Contraindications / Precautions

The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the container is not labeled, or the product has not been stored at the recommended temperature. Caution should be exercised if the patient is allergic to any of the antibiotics or chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for use of this allograft. Xtant Medical makes no claims concerning the biologic or biomechanical properties of this allograft tissue.

Recommended Procedure for Handling and Reconstitution of Freeze-dried Allografts

Freeze-dried allografts should be stored at ambient temperature (11°C-25°C; 52°F-77°F). DO NOT FREEZE. Rehydration time varies with the type of allograft. Freeze-dried weight bearing bone allografts that are to be sawed, drilled, or shaped should be rehydrated to ensure that the tissue will not be brittle. If the allograft is to be rehydrated longer than two hours, it should be refrigerated until use. Smaller non-weight bearing bone allografts generally do not require rehydration. Soft tissue allografts should be rehydrated until they become soft and pliable.

Step 1: The circulator grasps the outer edges of each peel envelope and pulls them apart.

Step 2: The scrub nurse/tech removes the allograft from the inner package and places it into a sterile basin on the sterile field. If rehydration is desired, 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 if stored with proper precautions to prevent contamination or discarded.

Recommended Procedure for Handling and Storing Frozen Allografts

Frozen Tissue – Store at a temperature of -40°C or colder.

Note: Short term storage of up to 6 months is acceptable if tissue is maintained at temperatures between -20°C and -39°C (storage time may not exceed the original expiration date documented on the tissue label). If the tissue is not implanted by the end of the 6 months, it must be discarded.

Frozen Grafts:

Frozen grafts are shipped on dry ice and must be maintained at the recommended temperature until ready for use. Before use, the allograft must be thawed using aseptic practices and utilized as soon as possible following thawing. The allograft must not be refrozen after thawing.

Recommended Procedure for Thawing Frozen Allografts

To prepare the allograft for use, it must be thawed. Thawing time for most allografts is about 15-20 minutes at room temperature. Soft tissue allografts must be thawed until they become soft and pliable.

Step 1: The circulator opens the zip lock bag, provided for shipping purposes only, and removes the packaged allograft.

Step 2: The circulator grasps the outer edges of each peel envelope and pulls them apart.

Step 3: The scrub nurse/tech removes the allograft from the inner package and places it into a sterile basin on the sterile field. Completely cover the allograft with sterile solution of choice. Antibiotics of a surgeon's preference may be added to the solution.

Once thawed, the allograft should be implanted immediately or refrigerated and used within 24 hours (from start of thawing) if stored with proper precautions to prevent contamination or discarded.

Summary of Quality Assurance Protocols

LifeLink Tissue Bank adheres to the criteria for donor screening, recovery, processing, and distribution of allografts required by these organizations and all applicable 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 findings (if one was performed).

Communicable disease testing was performed by a laboratory registered with FDA to perform donor testing and certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493). A qualified sample from the donor has been tested for infectious disease 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 and 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 certification. The Microbiology Laboratory has achieved national accreditation by the College of American Pathologists.

Return Authorization

If for any reason tissue must be returned, a return authorization number and form must be obtained from Xtant Medical prior to shipping.

Distributed by :

XTANT MEDICAL

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664 Cruiser Lane, Belgrade, MT 59714
888-886-9354
www.Xtantmedical.com

Donor Eligibility Determined and Tissue Processed by :

LifeLink® Tissue Bank

LifeLink Tissue Bank
9661 Delaney Creek Blvd, Tampa, FL 33619
813-886-8111 / 800-683-2400
www.lifelinktb.org

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XTANT MEDICAL

Procedure for the Preparation of Allografts for Clinical Use

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

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

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. After the package is opened, return or exchange of the allograft may not be possible.

- Antibiotic solutions (Bacitracin and Polymyxin B) and alcohol are used during soft tissue graft processing. The same solutions along with hydrogen peroxide are used during bone graft 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 "Sterile R" were irradiated within a validated dose range.
- Serologies were performed by a CLIA-certified, FDA-registered laboratory.
- Allografts (excluding cryopreserved) were processed using Allowash® Technology as a further measure to ensure patient safety.
- It is the responsibility of the Tissue Dispensing Service and/or end user clinician to maintain this allograft in the appropriate storage conditions prior to transplant.
- This tissue may only be used by a licensed clinician.
- This allograft is intended for single patient use, on a single occasion only. This allograft may not be reprocessed, including but not limited to resterilization.
- 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 Xtant Medical immediately at 888-886-9354.