Procedure for the Preparation of 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, Polymyxin B, and/or Gentamicin), 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" or "STERILE R" 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 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 or resterilized.
- 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 Spinal Elements immediately toll free at 877.Spinal5.
- 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 occur.

HANDLING AND RECONSTITUTION

Freeze dried allografts should be stored at ambient temperature (11°C-25°C; 52°F-77°F).

Freeze-dried allografts must be thoroughly rehydrated (reconstituted) prior to use. It is recommended that *the allograft* be rehydrated prior to use by soaking in 0.9% saline solution for approximately fifteen (15) minutes using aseptic/sterile technique. Rehydration can also be achieved by mixing the allograft with the patient's blood.

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 place 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.

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. 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. If an autopsy is performed, a LifeLink Medical Director 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).

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 (**Serological Test for Syphilis)	
HBcAb	**HIV1 / HCV / HBV NAT**	

Additional tests, including but not limited to HTLV I/II Ab may have been performed and were found to be acceptable. Refer to the allograft label for additional information regarding processing/preservation (e.g., freeze-dried, demineralized, 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 CLIA certified and accredited 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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LifeLink Tissue Bank is a not-for-profit organization dedicated to serve those patients in need of transplant therapy.