Allograft Information and Instructions for Use

Ensure the allograft is the one needed for the procedure. Check the package integrity. If there is any doubt, do not open the package.

This allograft was derived from donated human tissue that was recovered and processed under aseptic conditions. This allograft is regulated as an HCT/P (human cells, tissues, and cellular and tissue-based products) as defined by US FDA 21 CFR Part 1271 and is intended for homologous use only.

- Some or all of the following were used during allograft processing: Antibiotic solutions (Bacitracin and Polymyxin B, or Gentamicin), surfactants, alcohol, and hydrogen peroxide. 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.
- Allografts labeled STERILE R were gamma irradiated within a validated dose range.
- This allograft may only be used by a licensed clinician (e.g., physician) and is intended for single patient use on a single occasion only. This allograft may not be reprocessed or re-sterilized.
- Recipient records must be maintained for tissue traceability. Please return a completed allograft utilization record following use. Peel tabs are provided on the allograft label for use on the utilization 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.

PRECAUTIONS

- Active, latent or uncontrolled infection at the transplantation site may compromise allograft usefulness.
- While efforts are made to ensure the safety of the allograft, current technologies may not preclude the transmission of infectious agents.
- Caution should be exercised on patients with known sensitivity to the antibiotics used during tissue processing.
- Latex gloves are used during the acquisition and processing of tissue.

STORAGE AND RECONSTITUTION

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

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.

- Circulator: Grasp the outer edges of each peel envelope and pull apart.
- Scrub nurse/tech: Remove 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.

Implant immediately or refrigerate and use within 24 hours if stored with proper precautions to prevent contamination or discard.

SUMMARY OF QUALITY ASSURANCE PROTOCOLS

This allograft was prepared from a donor determined to be eligible by a LifeLink Tissue Bank Medical Director based on review of a donor risk assessment interview, relevant medical records, infectious disease testing, physical assessment, and autopsy findings (if 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 in accordance with the 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). A qualified blood sample from the donor was found to be negative / non-reactive for the minimum following infectious disease tests:

HCVAb	**HIV1 / HIV2 Ab**	Test kits are FDA approved / licensed where applicable. *Serological Test for Syphilis
HBsAg	***STS**	
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 (e.g., processing/preservation details).

LifeLink Tissue Bank follows strict donor screening criteria, recovery and processing methods which are designed to prevent the introduction, transmission, or spread of communicable disease. Tissue processing is performed in a classified cleanroom environment and numerous microbiologic cultures are collected and evaluated. LifeLink has a comprehensive quality program that monitors standards recognized to be effective in limiting risks associated with using allograft tissue.

LifeLink Tissue Bank is accredited by the American Association of Tissue Banks, registered with the FDA and Health Canada (CTO Certificate# 100144), and licensed or registered in multiple states. The LifeLink Microbiology Laboratory is CLIA certified and accredited by the College of American Pathologists. Licenses and registrations may be found on the LifeLink Tissue Bank website.

Spinal Elements and LifeLink Tissue Bank makes no claims concerning the biological or biomechanical properties of the provided product. Spinal Elements and 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.

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