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. Although this allograft is thoroughly cleaned and rinsed before final packaging, traces of antibiotics/other processing solutions may remain.
- Allografts labeled as "STERILE R" were terminally gamma irradiated within a validated dose range to a Sterility Assurance Level (SAL) of 10-6.
- 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 re-sterilized.
- 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.
- Recipient records must be maintained for the tissue traceability. Please complete and return the 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 JRF Ortho immediately at 877-255-6727.

PRECAUTIONS

- Active, latent or uncontrolled infection at the transplantation site may compromise allograft usefulness.
- While efforts are made to ensure tissue safety, 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 may be used during the recovery and processing of tissue.

SUMMARY OF QUALITY ASSURANCE PROTOCOLS

This allograft was prepared from a donor determined to be eligible by a LifeLink Tissue Bank Medical Director after review of a donor risk assessment interview, relevant medical records, infectious disease testing, physical assessment, 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 or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). A qualified blood sample from the donor has been tested and found to be negative / non-reactive for the minimum following infectious disease tests:

HCVAb	**HIV1 / HIV2 Ab**	Test kits used are FDA approved / licensed where applicable *STS Serologic 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.

LifeLink Tissue Bank follows strict donor screening criteria, recovery and processing methods that are designed to reduce the risk of introduction, transmission, or spread of communicable disease. Tissue processing is performed in a qualified 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 Association for Advancing Tissue and Biologics, 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.

STORAGE AND THAWING OF FROZEN ALLOGRAFTS

Frozen grafts are shipped on dry ice. If the amount is not sufficient to maintain the graft in a frozen state until the procedure, additional dry ice must be added, or the graft must be transferred to a monitored freezer maintained at -20ºC or colder for short-term storage (less than six months) or -40ºC or colder for long-term storage. Unless being thawed for implantation, a graft removed from the freezer should be maintained surrounded by dry ice in a transport package.

To prepare the graft for use, it must be thawed. Thawing time for most grafts is about 15-30 minutes at room temperature. Soft tissue grafts must be thawed until they become soft and pliable.

- Circulator: Open the zip bag provided for shipping purposes only and remove graft. Grasp the outer edges of each peel envelope and pull apart.
- Scrub nurse/tech: Remove the graft from the inner package, place into a sterile basin on the sterile field and completely cover with sterile solution of choice. Antibiotics of a surgeon's preference may be added.
- Implant immediately or refrigerate and use within 24 hours if stored with proper precautions to prevent contamination or discard.

RETURN POLICY

Allograft return may be authorized under certain conditions; a return authorization number must be obtained from JRF Ortho prior to returning any tissue. All return authorization requests are to be completed at www.jrfortho.org/returns.

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

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