Lipoderma™

Allograft Information and Instructions for Use

Please ensure these instructions accompany the allograft to the implantation site.

Lipoderma™ is a cryopreserved adipose tissue allograft derived from donated human tissue that was recovered and processed under aseptic conditions. Lipoderma allograft is intended for homologous use only.

Check the allograft package integrity. Do not use if there is evidence of container damage.

- This tissue may only be used by a licensed clinician.
- Tissue was processed using the following: Gentamicin, Vancomycin, Amphotericin B, Dulbecco's Modified Eagle's Medium (DMEM) with phenol red. Although tissue is thoroughly rinsed before final packaging, traces of antibiotics/other processing solutions may remain. Allograft is packaged with 0.5M trehalose with 2.5% human serum albumin.

ADVERSE REACTIONS

Donor screening methods are limited; therefore, certain diseases may not be detected. The following complications of tissue transplantation may occur:

- Transmission of diseases of unknown etiology
- Transmission of known infectious agents including, but not limited to, viruses, bacteria, and fungi
- Immune and non-immune mediated responses to the components of the graft

Recipient records must be maintained for the purpose of 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.

As a best practice, all materials used to prepare a graft for use should be documented in the tissue recipient's medical record including lot numbers where appropriate to assist in an Infection Control investigation should an adverse event occur.

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 Britecyte immediately at 240-244-0035.

Recommended Storage and Thawing

Lipoderma is preserved frozen and must be maintained at a temperature of -40°C or colder excluding the alternate storage conditions listed below:

- Temporary frozen storage between -20°C to -40°C is limited to six months total and has no impact to the expiration date reflected on the package label providing that the allograft is otherwise stored at -40°C or colder for the remaining time.
- Refrigerated storage between 0°C to 10°C is acceptable for a maximum of 12 months from refrigeration start date. Once placed at refrigerated temperatures, Lipoderma may NOT be refrozen, and the allograft must be used within twelve (12) months or discarded. If refrigerated storage is used, the facility must ensure a process is in place to ensure the allograft is used within 12 months or discarded.

If stored frozen, the allograft must be thawed before use using aseptic practices. Once thawed and the package is opened, use within 4 hours if not refrigerated or within 24 hours if stored refrigerated with proper precautions to prevent contamination or discard. The allograft MUST NOT be refrozen after thawing.

It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or end user clinician to maintain this allograft in the appropriate storage conditions prior to implant.

Instructions for Use

The allograft is packaged in a sterile cryogenic vial with a screw cap, which is contained in two chevron-type peel pouches. The inside of the pouches and the vial containing the product have been sterilized.

Follow the steps below:

1. Open each pouch by grasping the chevron end and pulling the layers apart.
2. Retrieve the vial from the innermost pouch. **If using on a sterile field**, take care to not touch the vial and transfer it to the sterile field.
3. Unscrew the cap.
4. Using a syringe with an 18-gauge or larger needle, remove tissue from the vial.
5. Replace the needle on the syringe containing the tissue with a 20-gauge needle. The use of a smaller bore needle may result in clogging.
6. Clean implantation site using 70% isopropanol or equivalent.
7. A skin refrigerant or local anesthetic may be applied at the site just prior to implantation.
8. Implant graft subcutaneously.
9. A cannula may be used to implant the allograft into the affected area using a needle guide if necessary. Grafting of ~0.2 mL in multiple points of the affected area is recommended.
10. Cover the affected area with an appropriate dressing, as necessary.

IMPORTANT**:** Product is intended for single use on a single patient and cannot be re-frozen or sterilized after opening. Any unused product must be discarded.

Summary of Quality Assurance Protocols

Lipoderma is manufactured in partnership with LifeLink Tissue Bank. LifeLink Tissue Bank is accredited by the American Association of Tissue Banks (AATB), 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 (CAP). Licenses and registrations may be found on the LifeLink Tissue Bank website.

This allograft was prepared from a donor determined to be eligible by a LifeLink Tissue Bank medical director based on screening and testing, which includes review of the 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 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 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. *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 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.

Neither Britecyte nor its affiliates expressly or by implication warrant any tissue selected, recovered, processed, or distributed by itself, distributors, representatives, or agents. Lipoderma may not be returned for credit.

Distributed By:

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