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 any evidence of container damage or the label is damaged, not readable, or missing.

- This tissue may only be used by a qualified 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.
- Recipient records must be maintained for the purpose of tissue traceability. Please complete and return the allograft utilization record following use as indicated. Peel tabs are provided on the allograft package 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 Britecyte immediately at 240-244-0035.

Precautions

- This allograft has been determined to be suitable for transplant. However, while efforts are made to ensure tissue safety, current technologies may not preclude the transmission of infectious agents.
- Immune and non-immune mediated responses to the components of the graft may occur.
- Do not use if there is an active infection at the procedure site.
- Do not use if a patient has an allergy or sensitivity to any of the listed processing agents.

Recommended Storage and Thawing

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

- 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.
- When 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. Once the package is opened, use within 4 hours. If not used within 4 hours, product must be discarded. 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 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 using aseptic practices:

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 an 18-gauge needle or cannula. The use of a smaller bore 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. Volume and implantation technique are at the discretion of the clinician.
9. 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. Do not use if the expiration date has passed.

Summary of Quality Assurance Protocols

Lipoderma is manufactured in partnership with BioBridge Global (BBG) Advanced Therapies, a subsidiary of BBG. BBG Advanced Therapies is registered with the FDA and licensed or registered in multiple states. All testing is performed at a CLIA certified laboratory. Licenses and registrations may be found on the BBG website.

This allograft was prepared from a donor determined to be eligible 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	**HIV I/II**	Test kits used are FDA approved / licensed where applicable.
HBsAg	**RPR or 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.

BBG follows strict donor screening criteria, recovery, and processing methods that 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. BBG Advanced Therapies 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.

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