



ARMSV-7506-1 Rev. B

FASCIA LATA PACKAGE INSERT

DONATED HUMAN TISSUE

THIS ALLOGRAFT IS SUPPLIED STERILE

This human tissue allograft is processed by CellRight Technologies and supplied by ARMS Medical. All tissue was retrieved, processed, stored and distributed for use in accordance with the standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/PS 21 CFR Part 1271), and applicable State regulations. The Donor has been determined to be eligible based on the results of screening and testing. Screening includes a review of medical and social history, available hospital records, infectious disease screening, autopsy report (if performed), and physical exam. The Donor has been tested and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1, Hepatitis C Virus, Hepatitis B Virus Nucleic Acid Test (HIV 1/HCV/HBV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay
- *West Nile Virus Nucleic Acid Test (WNV NAT)

*Birth Tissue Only

Additional tests, including but not limited to HTLV I/II, may have been performed and were found to be acceptable for transplantation. U.S. Food and Drug Administration (FDA) licensed, approved, or cleared donor screening test kits are used when available. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing 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 list of additional communicable disease test(s) performed will be provided upon request.

CellRight Technologies Medical Director has determined this donor tissue to be suitable for transplantation. The testing and medical release records are maintained by CellRight Technologies. The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, and a listing of the documents reviewed as part of the relevant medical records are kept on file at CellRight Technologies and are available upon request.

Allografts are processed using some or all of the following agents: alcohols, surfactants, Vancomycin HCl, Amphotericin B, Primaxin and traces may remain.

Tissue is supplied freeze dried. CellRight provides storage requirements in the package insert and on the final label that accompanies each graft. . . . When applicable, a description of how the tissue is supplied (Freeze Dried, Air Dried, or Frozen; Demineralized or Mineralized) is contained in the upper right hand corner of the final label included with the graft.

WARNINGS AND PRECAUTIONS

- Intended for use in one patient, on a single occasion only.
- Do not use if package integrity has been compromised. Once the user breaks the seal on the inner-most pouch, the tissue grafts must be transplanted or discarded.
- Tissue may not be sterilized or re-sterilized by your facility.

- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrist.
- Although this tissue has been tested and screened for human pathogens, and processed under aseptic conditions, human derived tissue may still transmit infectious agents.
- It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further Distribution or transplant.

STORAGE

FREEZE-DRIED TISSUE - Maintain tissue at ambient temperature (15°C – 30°C).

TISSUE PREPARATION

BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:

1. Any of the package elements appear to be missing, tampered with or damaged.
2. The product label or identifying bar code is severely damaged, illegible or missing.
3. The expiration date shown on the package label has passed.

If any of the above conditions exist or are suspected, this allograft should NOT be used.

PREPARATION OF FREEZE-DRIED / AIR-DRIED ALLOGRAFT TISSUE FOR USE

1. Opening Peel Packages: peel outer package down and aseptically deliver inner peel pouch to the sterile field or sterile team member.
2. Remove tissue from Inner peel pouch.
3. Rehydrate the tissue, when applicable.
 - a. Final determination of allograft reconstitution should be made by the physician prior to use. Rehydrate using a sterile isotonic solution or solution of physicians' choice.
 - b. Recommendation – Fascia Lata soft tissue should be reconstituted for a minimum of 10 minutes.
4. Tissue should be used as soon as possible after reconstitution. If tissue is to be stored for longer than 2 hours after reconstitution, it should be refrigerated at 1°C to 10°C in an aseptic container for no longer than 6 hours.
5. **IMPORTANT!** Peel away and remove all internal packaging materials, if present, from the graft (i.e. gauze or mesh) prior to implantation.



CUSTOMER RETURNS

For further info please reference our return policy at www.armsmedical.com or contact:

ARMS Medical by email or phone.

Email: orders@armsmedical.com

Phone: 1-781-499-2767

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ADVERSE OUTCOMES

Adverse outcomes potentially attributable to this tissue must be reported promptly to ARMS Medical.

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and mail to ARMS Medical. US Federal Regulations (21 CFR 1271.290(b)) and Joint

Commission Standards (TS.03.02.01 , EP 7) require proper tracking of this tissue. It is the responsibility of the end-user to provide this information, which enables ARMS Medical to maintain records for the purpose of tracing the tissue post-transplant.

Processed By:



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210-659-9353
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www.CellRightTechnologies.com

CellRight Technologies holds:

AATB Accreditation No. 00212
US FDA Registration No. 3009234552
Canadian Registration No. 100228
California Tissue Bank ID No. CNC80949
Florida License No. 212
Maryland Tissue Bank No. TB1898
New York State Tissue Bank ID No. 1779
Illinois Registration No. 0319

CellRight is Registered with the State Tissue Bank in:
Oregon and Delaware

Distributed By:



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ARMS Medical holds:

US FDA Registration No. 3013535496