ACELLFX
Acellular Amniotic Membrane

ALLOGRAFT PACKAGE INSERT

DONATED HUMAN TISSUE

THIS ALLOGRAFT IS SUPPLIED STERILE

This human tissue allograft is processed by CellRight® Technologies and distributed by Théa Pharma. 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)

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.

Tissue has been processed using alcohol as a disinfectant. Tissue is air dried, not chemically dried. Tissue has been sterilized using irradiation to ensure a SAL of 10^{-6} (Sterility Assurance Level).

WARNINGS AND PRECAUTIONS

- Intended for use in one patient, on a single occasion only. Should not be used on patient with evidence of active ocular surface infection.
- 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 physicians.
- 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 End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to transplant.

STORAGE

AIR DRIED TISSUE - Maintain tissue at 15° to 30°C (59° to 86°F). These storage requirements and the expiry date for each graft are provided on the final label that accompanies each graft.

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.

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PREPARATION OF 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.
   a. Recommendation – cut the pouch close to the tissue, and gently separate the layers of the pouch in order to grasp the tissue with forceps.
3. Tissue should be applied dry; rehydration is not required.

ADVERSE OUTCOMES

Adverse outcomes potentially attributable to this tissue must be reported promptly to CellRight® Technologies.

Email: CustomerCare@CellRightTechnologies.com
Phone: 1-210-659-9353

TISSUE TRACKING

Complete the enclosed Allograft Tracking Form and mail to CellRight Technologies. US Federal Regulations (21 CFR 1271.290(b)) requires proper tracking of this tissue. It is the responsibility of the end-user to provide this Information, which enables CellRight Technologies to maintain records for the purpose of tracing the tissue post-transplant.

Processed By:
CellRight® Technologies
1808 Universal City Blvd
Universal City, TX 78148
210-659-9353
Fax: 210-659-9556

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

CellRight Technologies is a Registered Tissue Bank in the following state(s):
Oregon
Delaware

Théa

Distributed by: Thea Pharma

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www.AcellFX.com