Dermacyte® AC Matrix Amniotic Membrane Allograft

General Information and Instructions for Use

Product Description

Dermacyte AC Matrix Amniotic Membrane Allograft is a sterile, lyophilized, gamma irradiated, full thickness allograft which includes amnion and chorion. This allograft was derived from donated human placental tissue that was acquired and processed under aseptic conditions in accordance with the American Association of Tissue Banks (AATB) standards as well as FDA regulations. Dermacyte AC Matrix Amniotic Membrane Allograft is a human cellular and tissue-based product (HCT/P) as defined by US FDA 21 CFR Part 1271 and is intended for use as a protective covering or barrier for internal and external tissue defects.

Antibiotic solutions Amphotericin B, Gentamicin and Vancomycin are used during tissue processing. Although thoroughly cleaned and rinsed before final packaging, traces of antibiotics/other processing solutions may remain on the allograft. Dermacyte AC Matrix Amniotic Membrane Allograft has a 5-year shelf life.

This allograft may only be used by a physician or other qualified healthcare professional and is intended for single patient use, on a single occasion only. This allograft may not be re-sterilized.

Check the package integrity. If there is any doubt, do not open the allograft package. After the package is opened, return or exchange may not be possible.

- It is recommended that materials used to prepare a graft for surgery be documented in the recipient's medical record. Material identification should include lot numbers where appropriate to assist in an Infection Control investigation should an adverse event believed to be allograft related occur.
- Recipient records must be maintained for tissue traceability. Please return a completed allograft usage record to Merakris following allograft use. Peel tabs are provided on the allograft label for use on this record and your internal tracking records.
- If you encounter any problems with this allograft, have any questions, or there is a patient complication possibly related to this allograft, please contact Merakris Therapeutics immediately at (919) 921-8105 or GLOBAL.SAFETY@MERAKRIS.COM.

Summary of Quality Assurance Protocols

LifeLink Tissue Bank is accredited by the American Association of Tissue Banks, registered with the FDA and Health Canada (CTO Certificate# 100144), licensed by the states of Florida, California, Maryland, and New York, and registered with the states of Delaware and Oregon. LifeLink Tissue Bank adheres to the criteria for donor screening, acquisition, processing, and distribution of allografts required by these organizations and all applicable regulations set forth by the U.S. Food and Drug Administration. Birth tissue is acquired and processed under aseptic conditions. Birth Tissue donors undergo careful screening which includes infectious disease testing, and a pre-processing microbiologic culture is collected and evaluated.

This allograft was prepared from a donor determined to be eligible by a LifeLink Tissue Bank medical director based on review of medical and social history, relevant medical records, infectious disease test results, and physical examination. 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).

The following minimum infectious disease tests were performed on a qualified sample from the donor with acceptable test results:

▪ **HIV1 / HIV2 Ab** ▪ **HBsAg** ▪ **HBcAb**	▪ **HCVAb** ▪ **Syphilis** ▪ **HIV1 / HCV / HBV NAT**	▪ **WNV NAT** ▪ **HTLV I/II Ab**
Test kits used for serological assays are approved/licensed by the FDA, where applicable.		

Additional tests, including but not limited to CMV Ab may have been performed and found to be acceptable. Refer to the graft label for additional information (e.g., processing/preservation details).

LifeLink Tissue Bank follows strict donor screening criteria, acquisition and processing methods. These safeguards are designed to prevent the introduction, transmission, or spread of relevant communicable diseases from allografts. LifeLink has a comprehensive Quality Assurance program that monitors the standards and procedures designed to limit risks associated with using allograft tissue. LifeLink's Microbiology Laboratory is CLIA certified and accredited by the College of American Pathologists.

Precautions

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

Recommended Procedure for Storage and Handling

Dermacyte AC Matrix Amniotic Membrane Allograft should be stored at ambient temperature (11°C-25°C; 52°F-77°F). 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. The allograft is packaged with a sterile backing material (for packaging purposes only) into two peel pouches.

- Peel open the outer pouch to reveal the inner pouch. The inner pouch is sterile and may be placed onto the sterile field.
- Aseptically peel open the inner pouch to expose the allograft.
- Ensure the backing material is not attached then place the allograft at the desired location.
- The allograft should be secured based on the physician's choice of fixation.
- The allograft may be rehydrated with sterile solution of choice.

Once opened, the allograft should be used immediately or discarded.

Return Policy and Criteria

Merakris Therapeutics, Inc., does not accept the return of Dermacyte AC Matrix Amniotic Membrane unless it was damaged, or the return is initiated within 30 days. Contact Merakris Therapeutics, Inc., for a Returned Material Authorization (RMA) number prior to return.

Manufactured and Marketed By:

Merakris Therapeutics

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