PLACENTAL MEMBRANE ALLOGRAFT
TISSUE PACKAGE INSERT

STERILE R Sterilized using electron beam irradiation

Read Before Using

- **This Allograft Unit is Derived from Donated Human Tissue.**
- **This Allograft is Intended for Use in One Patient, on a Single Occasion Only.**
- **Caution: Federal (USA) law restricts this tissue to sale by or on the order of a physician or hospital.**
- **Human tissue for transplantation shall not be offered, distributed or dispensed for veterinary use.**
- **This Allograft may not be Re-Sterilized.**
- **All tissue has been recovered, processed, stored and distributed according to the Standards for Tissue Banking of the American Association of Tissue Banks (AATB), the US FDA regulations and the Health Canada CTO Regulations and associated Standards (when applicable).**

Description
This graft was prepared from tissue procured from donated human placental membrane, determined to be eligible based on the result of donor screening and testing, using aseptic surgical techniques. This graft was processed by Xtant Medical and may contain traces of the processing reagents PBS (phosphate buffered saline) and sterile water. Tissue is terminally sterilized via electron beam irradiation.

Indications and Usage
Human placental membrane allografts are intended to serve as a barrier and provide protective coverage from the surrounding environment when topically applied to chronic and acute wounds. A US flag on the packaging of the graft indicates the graft is only approved for distribution and use in the United States of America.

Donor Eligibility
Donor eligibility (screening and testing) is performed in accordance with US FDA regulations, AATB Standards, and Health Canada CTO regulations. Donor screening includes assessment of the medical and social history as well as physician assessment of the donor to assure that no conditions exist that may make the tissue unacceptable for transplantation.
Donor eligibility determination is conducted by a licensed Medical Director who reviews and approves each donor for processing. Pertinent records may be made available upon written request.

Donor Serological Testing
Communicable disease testing was performed by a laboratory registered with the 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. The testing was conducted using FDA licensed, approved, or cleared donor screening tests where applicable. The records of this testing are maintained at Xtant Medical. The following required testing was performed and found to be negative or non-reactive;

- HBsAg (Hepatitis B Surface Antigen)
- HBcAb (Hepatitis B Core Total Antibody)
- HBV-NAT (Hepatitis B Nucleic Acid Test)
- HCV (Hepatitis C Antibody)
- HIV 1/2-Ab (Antibody to Human Immunodeficiency Virus Types 1 and 2)
- Syphilis
- HIV-1 NAT (HIV-1 Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test)
- WNV NAT

Additional tests including, but not limited to, Human T-Cell Lymphotropic Virus Type I and II (HTLV I & II) may have been performed at the time of donor screening and were found to be acceptable for transplantation. A list of additional communicable disease test(s) performed will be provided upon request.

Warnings/Contraindications
The allograft should not be used if the expiration date has been surpassed, the container in which the product is stored is damaged, the container is not labeled, or the product has not been stored at the recommended temperature. Caution should be exercised if the patient is allergic to any of the chemicals listed in processing and testing. The presence of infection at the transplantation site is a contraindication for the use of this allograft. Xtant Medical makes no claims concerning the biologic or biomechanical properties of this allograft tissue.

Side Effects and Hazards
Despite the extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of an infectious disease through the use of this graft is still possible. Bacterial infection at the graft site may occur.

Any Transmission of disease that is suspected to be caused by the graft or any other adverse outcome potentially attributed to this graft must be reported to Xtant Medical.

Tissue Tracking
This graft is packaged in sterile, single-patient-use containers and the unique graft serial number, expiration date, product code, size, and additional information are listed on the package label.

The Hospital must maintain records so that possible infections or other adverse reactions associated with this graft can be linked back to the original source. It is the responsibility of the user surgeon to complete recipient records for the purpose of tracking tissue post-transplant. Complete the enclosed Transplant Utilization Record in detail and return as indicated. If the graft is not used for any reason after opening, complete the enclosed Transplant Utilization Record in detail, noting the method of disposal, and return as indicated. Copies of this information should be retained by the transplant facility.

Storage
It is the responsibility of the Tissue Dispensing Service and/or end-user clinician or facility to maintain this product in room temperature (15°C to 30°C) storage conditions prior to transplantation.

General Instructions for Use
Always use aseptic technique when handling the graft. Once a package seal has been opened, the tissue shall be either transplanted, if appropriate, or otherwise discarded. Discard all unused portions of the graft.

Opening Instructions:

1. Peel open the outer pouch using aseptic technique.
2. Introduce the sterile contents onto the sterile field.
3. Remove tissue from the sterile package and place directly onto the wound or into a basin at the discretion of the practitioner. Normal saline, water for irrigation, Lactated Ringers or an antibiotic solution of the physician's preference may be utilized.

Returns
If for any reason tissue must be returned, a return authorization is required from Xtant Medical prior to shipping.

Donor eligibility determination, processed, and provided for distribution by:

Xtant Medical
664 Cruise Lane
Belgrade, MT 59714
888-886-9354