LEGACY MEDICAL
CONSULTANTS

Zenith Amniotic™ Membrane

DONATED HUMAN TISSUE

Zenith Amniotic Membrane is a resorbable allograft derived from donated human placental birth tissue. **Zenith Amniotic Membrane** is a sterile, single use, dehydrated allograft processed using aseptic techniques and terminally sterilized by Electron Beam.

Zenith Amniotic Membrane is restricted to use by or on order of a licensed healthcare professional *(physician, dentist, podiatrist, optometrist, nurse practitioner or physician assistant).*

PRODUCT USE

Zenith Amniotic Membrane is intended for use as a protective wound covering in partial- and full-thickness acute and chronic wounds. Acute and chronic wounds include diabetic foot ulcers, venous leg ulcers, pressure injuries, trauma wounds, chronic vascular wounds, surgical wounds, dehisced wounds and tunneling wounds with or without muscle, tendon, or bone exposure when a protective barrier is medically necessary. Zenith Amniotic Membrane can be applied for the duration of the wound, weekly or at the discretion of the health care clinician.

Zenith Amniotic Membrane received written notification by the FDA's Tissue Reference Group confirming Zenith Amniotic Membrane meets the criteria for regulation solely under Section 361 of the PHS Act as defined in 21 CFR Part 1271.

SIZE and STORAGE

Zenith Amniotic Membrane is available in a wide range of sizes. Zenith Amniotic Membrane must be stored in ambient temperature at 15-30°C (59-86°F) prior to patient application. Do not freeze. May be stored up to 5 years. It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use.

CONTRAINDICATIONS

Allografts including Zenith Amniotic Membrane should not be used on areas with active or latent infection.

INSTRUCTIONS FOR IMPLANTATION

ONCE THE ALLOGRAFT SEAL HAS BEEN COMPROMISED, the allograft shall be transplanted or discarded. DO NOT USE THE ALLOGRAFT if the pouch integrity has been compromised.

Step 1: Inspect packaging when removing carton from storage.

Step 2: Utilizing aseptic technique, peel open the outermost pouch (Tyvek peel pouch) from the chevron end and remove the inner foil pouch. The outermost pouch is not sterile. The inner pouch is sterile and may be placed onto the sterile field.

Step 3: Open the inner pouch utilizing aseptic technique, peel open the inner Foil peel pouch from the chevron end. Using sterile gloves or sterile forceps, remove the Zenith Amniotic Membrane from the inner foil and place onto the wound or surgical site prepped for the allograft.

DONOR SCREENING AND TESTING

Prior to processing, the donor's medical and social history were screened for conditions and disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures at Surgenex, LLC. All policies and procedures for donor screening, serologic and microbiologic testing meet current Standards established by the Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB). Each donor is screened and tested for communicable disease risks and other exclusionary medical conditions. The results of the donor screening and testing have been reviewed by the Medical Director (or licensed physician designee) of Surgenex, LLC and the donors have been deemed eligible.

Communicable disease testing is performed by an FDA-registered laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions. Results from the following infectious disease tests have been found to be nonreactive or negative:

Human Immunodeficiency Virus (HIV)
- HIV-1/2 Antibodies (HIV-1/2-Ab)
- Nucleic Acid Test for HIV-1 RNA (HIV-1 NAT)

Hepatitis B Virus (HBV)
- HBV Surface Antigen (HBsAg)
- HBV Core Antibody (IgG & IgM) (HBcAb)
- Nucleic Acid Test for HBV DNA (HBV NAT)

Hepatitis C Virus (HCV)
- HCV Antibody (HCVAb)
- Nucleic Acid Test for HCV RNA (HCV NAT)

Human T Cell Lymphotrophic Virus I/II
- HTLV-I/II (Antibody HTLV-I/II-Ab)

Syphilis
- Rapid Plasma Reagin (RPR) Screen
- T. Pallidum IgG

West Nile Virus (WNV)
- Nucleic Acid Test for WNV RNA (WNV NAT)

PROCESSING AND STERILITY

The donors of Zenith Amniotic Membrane are screened and tested for relevant communicable diseases and disease agents, including COVID-19, in compliance with the FDA regulations, relating to human cells, tissues, and cellular and tissue-based products (21 CFR part 1271). Zenith Amniotic Membrane is processed using aseptic techniques and microbiologically tested. The allograft has been terminally sterilized by electron beam radiation technology in accordance with ANSI/AAMI/ISO 11137. Although all efforts have been made to ensure the safety of the allograft, there is no assurance that this allograft is free from all infectious diseases or microbial contamination.

DO NOT FREEZE the allograft by any method.

FOR USE IN ONE PATIENT, ON A SINGLE OCCASION ONLY

DO NOT RE-STERILIZE the allograft by any method. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

WARNINGS AND PRECAUTIONS

Zenith Amniotic Membrane is processed and packaged using aseptic techniques and sterilized. Zenith Amniotic Membrane must not be transplanted under the following conditions:

- If mishandling caused damage or contamination
- If the allograft is past its expiration date
- If any of the allograft elements, packaging, labels and/or barcodes are missing, damaged, illegible or defaced
- If the Amniotic Membrane has not been stored according to specifications set forth in this insert

Notify Legacy Medical Consultants immediately at (817) 961-1288 if any of these conditions exist or are suspected.

ADVERSE EVENTS

Health professionals should discuss possible adverse reactions prior to product use. General risks and complications arising from applications of allografts may include but are not limited to infection, bleeding, swelling, redness, and injury to nerves and other soft tissue. Complications may occur with allograft use, including but not limited to:

- Transmission of disease of unknown etiology
- Transmission of infectious agents including but not limited to HIV, hepatitis, syphilis, or microbial contaminants.
- Graft-versus-host immune rejection or other allergic reactions

Adverse outcomes potentially attributable to Zenith Amniotic Membrane or other complaints must be promptly reported to Legacy Medical Consultants (817) 961-1288.

HCT/P TRACKING

FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained. Joint Commission standard QC.55.310.7 requires that the organization that receives tissue provides a system that fully complies with the completion of tracking tissue usage via Tissue Tracking/Transplant Record (TTR) or provides a web-based program for traceability of the allograft used.

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide the information pertaining to the traceability of the allograft used. Please turn in the TTR card information as directed in the shipment or visit www.Surgenex.com and register the LOT NUMBER located on the product label.

RETURNED GOODS POLICY

Legacy Medical Consultants, LLC may accept return of Zenith Amniotic Membrane allografts for credit or exchange if incorrect product was shipped or product was received in a damaged state. Legacy Medical Consultants, LLC reserves the right to reject a return if any of the condition are not met:

1. For damaged items and incorrect shipments, Legacy Medical Consultants may replace the product with the appropriate product or issue a credit.
2. A Return Material Authorization (RMA) number must be obtained from Legacy Medical Consultants no later than 24 hours from receipt for damaged product or incorrect shipments.
3. Original product packaging must be intact and unopened.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning facility unless the allograft is damaged or defective. Returning facility must complete, sign, and return the RMA form stating that all required criteria have been met.
5. Credit cannot be issued if the RMA form has not been completed by the returning facility and received by Legacy Medical Consultants. Please contact Legacy Medical immediately at (817) 961-1288 if you experience a problem with our product.

Distributed By: **Legacy Medical Consultants LLC**
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