tidesmedical®

INSTRUCTIONS FOR USE		
Document Title	Document Description	Version No.
IFU-016	**ARTACENT WOUND PRO INSTRUCTIONS FOR USE**	**0**

Description:
This human tissue allograft is supplied and processed by Tides Medical. Artacent Wound Pro is a dehydrated human amniotic membrane allograft. Human amniotic membrane is a thin collagenous membrane derived from the submucosa of the placenta, the organ that connects the developing fetus to the mother's uterus. A human amniotic membrane consists of multiple layers including epithelial cells, a basement membrane, and a stromal matrix, which provides a natural scaffold that allows cellular attachment or infiltration and growth factor storage. Artacent Wound Pro provides a protective cover and supports the body's wound healing processes. This allograft is supplied sterile and not intended to be removed.

Regulatory Classification:
This allograft is a human tissue product for homologous transplantation. It is minimally manipulated and distributed in accordance with Federal Drug Administration (FDA) requirements for Human Cellular and Tissue-based Products (HCT/P) (21 Code of Federal Regulations Part 1271, per Section 361 of the PHS Act), State regulations, and the guidelines of the American Association of Tissue Banks (AATB).

Caution: Federal Law restricts this product from being sold by or on the order of a licensed medical professional, not for veterinary use.

Intended Use**:**

Artacent Wound Pro is intended for use as a biological membrane that provides the extracellular matrix, scaffolding, while supporting the repair of damaged tissue. It may be used in various surgical procedures including acute and chronic wounds:

- Diabetic ulcers
- Pressure ulcers
- Venous ulcers
- Draining wounds
- Partial or full thickness wounds
- Tunneled, undermined wounds
- Surgical wounds (i.e., donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (i.e., abrasions, lacerations, second-degree burns, skin tears)
- Wounds with exposed tendon, muscle, bone or other vital structures.

Preparation of Allograft for Use:
Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or properly discarded. Used allograft containers should be disposed of in accordance with recognized procedures for discarding medical waste material.

Prepare the allograft for use in accordance with the following procedures:

1. Open the 1st peel pouch and the 2nd innermost peel pouch and deliver the allograft material to a sterile field. Note: Only contents inside of the innermost pouch are sterile. The outside of the innermost pouch is not sterile.
2. Carefully deliver the graft to a sterile field for transplantation. PLEASE USE CAUTION WHEN REMOVING ALLOGRAFT FROM POUCH AS THE ALLOGRAFT IS THIN AND LIGHTWEIGHT
3. The excess allograft may folded into the wound or cut to the appropriate size required prior to placement. Do not soak allograft in saline or buffer prior to application on wound bed.
4. The allograft should then be placed onto the surgical site.
5. Anchor graft using preferred method of fixation. Absorbable/non-absorbable suture material and/or tissue adhesives may be used to apply the graft to the surgical site, if necessary.
6. Once applied to the surgical site, the allograft can be hydrated with sterile saline or other sterile solution, if needed.

If for any reason the graft is opened and not used, it should be disposed of properly or returned to Tides Medical by contacting Customer Service and following appropriate return procedures. Document the reason for the non-use of the graft and indicate the disposition of the tissue on the enclosed Transplant Record and return the record to Tides Medical.

Donor Recovery, Screening and Processing:
After authorization for donation is obtained (represented by the mothers of the newborn children), collection of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. Donor eligibility is carefully evaluated as required by the US FDA and in accordance with AATB Standards and applicable federal and state guidelines. Tissue donors are evaluated for high-risk behaviors and relevant communicable diseases. Screening includes a review of the donor medical and social history, a physical assessment, serological screening, and tissue collection microbiology.

Each donor is tested and shown to be negative or nonreactive for the following:

HIV-1&2 Antibody	Syphilis Rapid Plasma Reagin or Treponemal Specific Assay	Hepatitis C Virus Antibody
Hepatitis B Surface Antigen	Hepatitis B Core Antibody (total)	HIV1/HCV/HBV Nucleic Acid Test (NAT)
Human T-Cell Lymphotropic Virus Type I Antibody (not required)	Human T-Cell Lymphotropic Virus Type II Antibody (not required)	West Nile Virus (WNV NAT)

This testing is 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, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS). Test kits used are approved by the FDA.

Tides Medical's Medical Director has determined this donor tissue to be eligible for transplantation. The testing and medical release records are maintained by Tides Medical.

Allograft tissues are processed in a controlled environment using methods designed to prevent contamination and cross contamination. Proprietary physiological buffers and surfactants are used during processing. Allograft tissue may contain traces of these processing agents. Final products are sized and packaged according to approved specifications and procedures and are sterilized using terminal sterilization.

Note: Allograft tissues will naturally vary in color. Occasional dark spots or localized discoloration is a normal occurrence.

Warnings and Contraindications:

Careful donor screening, laboratory testing, tissue processing, and terminal sterilization have been utilized to minimize the risk of transmission of relevant communicable diseases to the patient. As with any processed human donor tissue, this graft cannot be guaranteed to be free of all pathogens.

This allograft is intended for single patient use only. Do NOT reuse or re-sterilize.

Prior to Usage: Examine Allograft Packaging – Do Not Use This Allograft If:

- Any part of the package or product elements appear to be missing, tampered with, or damaged.
- The product label or identifying bar code is severely damaged, illegible, or missing.
- 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.

Contraindications:

Dehydrated amnion allografts should not be implanted into: (1) areas of active or latent infection; and/or (2) into a patient with a disorder that would create an unacceptable risk of post-operative complications. Additional contraindications for the use of this allograft shall be determined by a licensed practitioner.

The use of antimicrobial or cleaning agents that negatively impact the wound healing cascade or resident wound cell viability may impact product performance.

Packaging and Labeling:

Each allograft distributed by Tides Medical is identified by its own unique serial number. The allograft is packaged in a pouch. Each pouch features a peel back seal and is also heat sealed to provide a sterile barrier. The package label includes graft details such as dimensions. Contents of the innermost package are sterile unless the package is opened or damaged.

Recommended Storage and Expiration:

Maintain allograft in a clean, dry environment at ambient temperature (15°C to 30°C). No refrigeration is necessary, protect from freezing.

See package label for expiration dates.

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 and that recipient records must be maintained for the purpose of tracing tissue post-transplantation.

Returns:

If for any reason tissue must be returned, a return authorization is required from Tides Medical prior to shipping. It is the responsibility of the health care institution returning the tissue to adequately package and label the tissue for return shipment.

Recipient Tracking:

The FDA requires that recipient records be maintained for the purpose of tracking the allograft following surgical transplantation. The surgeon or operating staff member must complete the enclosed Allograft Tracking Card, attach a peel-off allograft-tracking label and patient label, and mail it to Tides Medical. Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Adverse Effects and Reporting:

As allografts are composed of proteins such as collagen, the potential for hypersensitivity, allergic reactions or other immune responses may exist. All adverse outcomes potentially attributed to this allograft must be promptly reported to Tides Medical.

Possible complications can occur with any surgical procedure including, but not limited to pain, infection, hematoma, and/or immune rejection of the introduced tissue.

Disease screening methods are limited; therefore, certain diseases may not be detected.

The following complications of tissue transplantation may occur:
Transmission of diseases of unknown etiology;
Transmission of known infectious agents including, but not limited to viruses, bacteria, and fungi.

Any adverse reactions, including the suspected transmission of disease attributable to this allograft should be immediately reported to Tides Medical.

Disposal:

Allograft disposal shall be in accordance with local, state, and federal regulations for human tissue.

Inquiries:
For additional information, to place an order, or to report adverse reactions, contact:
Tides Medical Customer Service at: Phone: 888-494-4441 | Fax: 781-823-0321 | customerservice@tidesmedical.com
Donor eligibility determination and processed by Tides Medical | 1819 W. Pinhook Road, Suite 206 | Lafayette, LA 70508 | (888) 494-4441
FDA Registration FEI: 3010125671