# INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE

THIS TISSUE HAS BEEN DETERMINED TO BE SUITABLE FOR TRANSPLANTATION

- Read this entire package insert carefully prior to use.
- For single patient use only, on a single visit.
- Restricted to sale by or on the order of a physician.
- Only qualified licensed professionals should transport/transplant this tissue.
- Not intended for veterinary use.

## Description

**VENDAJE AC** is a processed, dehydrated, and sterilized human amniotic membrane allograft supplied in a single use package in a variety of sizes. **VENDAJE AC** is preserved using a proprietary system that minimally manipulates the tissue. **VENDAJE AC** is a dual-layer amnion/chorion membrane allograft that provides a protective barrier or covering. This allograft is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of human tissue. This allograft is processed aseptically and has been terminally sterilized by electron beam irradiation, to a sterility assurance level (SAL) of $10^{-6}$. Variations in color, opacity, and thickness are normal due to the nature of human tissue.

## Intended Use

**VENDAJE AC** provides a protective barrier from the surrounding environment for acute and chronic wounds including partial and full thickness wounds, diabetic ulcers, venous ulcers, pressure sores/ulcers, chronic vascular ulcers, tunneled/undermined wounds, non-pressure ulcers, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds. **VENDAJE AC** dosage is per square centimeter, depending on the size of the wound. Following standard wound preparation, **VENDAJE AC** is applied directly to the wound. **VENDAJE AC** adheres to the wound bed without fixation. **VENDAJE AC** is fully resorbable and does not have to be removed from the wound bed. **VENDAJE AC** should be placed and oriented to overlap the wound edges to ensure adequate coverage. **VENDAJE AC** may be used over exposed bone, muscle, or tendon.

## Storage

**VENDAJE AC** allografts should be stored in a clean, dry environment at a controlled ambient temperature 15-30°C (59-86°F). It is the responsibility of the Tissue Dispensing Service, Tissue Dispensing Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions until ready for use and to track expiration dates accordingly.

## General Information

**It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties.**

- The outer peel pouch is NOT STERILE, only the inner pouch and allograft are STERILE.
- Do not sterilize or autoclave the product before use.
- Do not use the allograft if the pouch integrity has been compromised.
- BioStem Life Sciences assumes no responsibility for the clinical use of this allograft.
- The administering licensed professional determines route and method of use for this allograft.
- For use on a single visit/surgery/episode for a single patient; it cannot be shared or reused after opening.
- Do not use past expiration date specified on the product label.

## Contraindications

The following contraindications should be considered:

- **VENDAJE AC** should not be used on: (1) areas with active or latent infection; and/or (2) into a patient with a disorder that would create an unacceptable risk of postoperative complications.
- **VENDAJE AC** is not intended for veterinary use.

## Warnings

Same and similar potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation or application of this allograft. The licensed medical professional performing medical or surgical application or implantation of the allograft is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. While proprietary processing and validated methods are employed by BioStem Life Sciences to eliminate potential deleterious components of the allograft, the possibility of transmission of RCDADs, rejection, or immunologic response exists.

## Donor Screening and Testing

The donated human birth tissue was recovered by a regulated procurement agency that has obtained both informed consent and healthy screening results from the donor. The donor's blood was tested for Relevant Communicable Disease Agents and Diseases (RCDADs) in a laboratory certified under the Clinical Laboratory Improvement Amendments of the 1988 (CLIA), or equivalent, and registered with the U.S. Food and Drug Administration (FDA) for donor testing. The following communicable disease tests listed below were found to be **nonreactive or negative** for this donor:

- HIV-1/HIV-2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen/ HBV NAT
- Hepatitis B Core Antibody (total)
- Syphilis
- Human T-Cell Lymphotropic Virus 1 Antibody
- Human T-Cell Lymphotropic Virus 2 Antibody
- HIV-1/HCV NAT-TMA
- West Nile Virus (WNV)

At the time of procurement, cultures of the tissue are tested for microbial growth. Donor tissue with cultures testing positive for the following microorganisms are deferred:

- Clostridium
- Streptococcus pyogenes (group A strep)

Screening for exposure to other viruses or parasites may have been completed. A negative/non-reactive result may not be required. As an additional screening tool, the donor completed a social and medical questionnaire. Available relevant information for donor screening may have included, but not limited to; donor interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology, and other records if available and pertinent. The Medical Director of BioStem Life Sciences has reviewed all results and determined the donor eligible for transplantation.

## Recovery

Donor tissue is recovered using current Good Tissue Practices (cGTP) and aseptic technique that is designed to minimize contamination. The donor tissue is procured via a network of qualified and trained recovery partners, using stringent screening and recovery protocols in a controlled environment, minimizing, and limiting the risks of potential contamination at every step of the process.

## Processing

This allograft was aseptically processed in a controlled environment from a single donor and terminally sterilized by electron beam irradiation. This allograft was released for transplantation based on the donor eligibility, independent third-party testing, and review and release of processing records.

## Packaging & Handling

**VENDAJE AC** is aseptically packaged and sealed in a poly/foil peel pouch. The inner pouch containing the allograft is sealed inside an outer poly/foil pouch and terminally sterilized. The sterilized allograft is packaged and sealed accompanied by this IFU, patient labels and a tissue tracking record.

This allograft must NOT be used under any of the following circumstances:

- If the package seal is damaged or not intact.
- If the package label or identifying bar code is severely damaged, illegible or is missing.
- If the expiration date shown on the package label has passed.
- If there are discrepancies in label information.

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

## VENDAJE AC Preparation

Use standard clinical practices for handling and disposal of human tissue. The following recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care. Prior to application, carefully follow the **VENDAJE AC** allograft preparation steps below using aseptic technique:

### Wound Bed Preparation

1. Ensure the wound is free from clinical signs of infection.
2. Prepare wound bed as needed.

### Allograft Preparation

1. **VENDAJE AC** allografts are packaged in a double peel-pouch packaging configuration. The outer peel pouch is NOT sterile. The inner pouch, which contains the allograft, is sterile.
2. Carefully open the peelable corner of the outer pouch and present the inner pouch onto the sterile field.
3. Using a sterile instrument or gloves, remove the inner pouch containing the tissue.
4. Carefully peel or cut open, using sterile scissors, the inner pouch and remove **VENDAJE AC** using sterile forceps.
5. **VENDAJE AC** can be applied wet or dry.
6. **VENDAJE AC** can be hydrated while on the wound site with sterile saline solution. Simply apply several drops of sterile solution to **VENDAJE AC**.
7. Once retrieved, **VENDAJE AC** can be applied directly to the tissue surgical site without concern for orientation of the allograft.

**PLEASE USE CAUTION WHEN REMOVING VENDAJE AC FROM THE INTERNAL POUCH. VENDAJE AC IS THIN AND EXTREMELY LIGHTWIEGHT.**

## VENDAJE AC Application

Absorbable, non-absorbable suture material, and/or tissue adhesives can be used to fixate **VENDAJE AC** to the wound site, if desired.

### Primary Dressing

- **VENDAJE AC** should be covered with a non-adherent contact layer.
- **VENDAJE AC** should NOT be disturbed, if possible, for several days or before the next application, if needed.
- If an infection occurs at the graft site, treat infection per institution's protocol.

### Secondary Dressing

- **VENDAJE AC** requires a moist wound environment. Use appropriate moisture management dressings for the wound type and treatment ideology.

### Support Therapies

- **VENDAJE AC** is compatible with offloading/compression/negative pressure therapies.
- **VENDAJE AC** can be used in conjunction with hyperbaric oxygen therapy.

### Re-Application of VENDAJE AC

- It is recommended that **VENDAJE AC** grafts are applied weekly until wound epithelialization is achieved. However, clinician discretion should be used based on patient and wound condition/progress. It is clinically acceptable to apply **VENDAJE AC** on a biweekly basis if desired.

## HCT/P and Recipient Tracking

Per 21 CFR 1271.290, tracking from the donor to the consignee or final disposition must be maintained. Joint Commission standard QC.5.310.7 or equivalent regulations require that "the organization that receives tissue provide a system that fully complies with the completion and return of tissue usage information cards requested by source facilities." To comply with these requirements, a Tissue Tracking/Transplant Record (TTR) and pre-printed labels are provided with every allograft. The authorized medical professional must complete the enclosed Tissue Tracking Card, including but not limited to; recording the patient information, the transplant facility name and address, the allograft tissue information (using provided labels) and comments regarding tissue use on the TTR. Mail the completed TTR to BioStem Life Sciences (postage-paid) and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification must be returned to BioStem Life Sciences. Please use the remaining peel-off, allograft-tracking labels for patient and hospital records.

Recipient records must be maintained for tracing tissue post-transplant per the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), FDA and the American Association of Tissue Banks® (AATB) requirements.

## Customer Returns and Concerns

BioStem Life Sciences does not accept any returns. If product is unusable, please document the reason why, take photographs of any damage, defects, or deficiencies, and forward this information to quality@biostemlife.com.

*Note*: BioStem Life Sciences makes no claims concerning the properties of allograft tissue.

## Adverse Reactions

An Adverse Reaction is defined by the FDA as any noxious or unintended response for which there is a reasonable possibility that the HCT/P caused the reaction. This includes, but is not limited to, the transmission of communicable diseases or infectious agents such as viruses, bacteria or fungi, or allergic reaction. Adverse Reactions should be reported immediately to BioStem Life Sciences customer service department at (954) 380-8342 or quality@biostemlife.com.

**PRODUCT INFORMATION DISCLOSURE**

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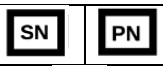
|   | Serial number and part number in bar code |
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