BioStem LIFE SCIENCES

VENDAJE™ family of allografts.

Processed by BioStem Life Sciences, Inc.

**Vendaje, Vendaje Optic: Amnion Membrane single layer only. Vendaje AC: Amnion, and Chorion membrane, dual layer.**

**Membrane For single patient use only**

## DESCRIPTION AND STORAGE CONDITIONS

**Read this entire package insert carefully prior to use.**
**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 donated human tissue.**
Vendaje family are aseptic placental tissue membrane allografts. The Vendaje family of membranes is preserved using a proprietary, minimally manipulated system that retains the extracellular matrix and 3D collagen structure of its scaffold. This allograft provides natural collagen scaffold to support replacement by endogenous tissue. This allograft implant 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.** BioStem Life Sciences assumes no responsibility for the clinical use of this allograft tissue, the administering licensed professional solely determines the route and method of use.

## Donor Screening and Testing

The donated human placental tissue was recovered by a regulated procurement agency, after informed consent, and screening for healthy mothers scheduled for elective Caesarian deliveries. The donor consents to the collection of this tissue, provided that its collection does not cause any harm to their infants. The donor blood was tested for relevant communicable diseases in a laboratory certified under the Clinical Laboratory Improvement Amendments of the 1988 (CLIA) or equivalent and registered with the FDA for donor testing. The following test criteria were met for this donor:

| **Required Donor Testing** All results must be reported negative or non-reactive to allow release | |
|---|---|
| Blood Test | |
| HIV-1/ HIV-2 Antibody | |
| Hepatitis C Virus Antibody | |
| Hepatitis B Surface Antigen/ HBV NAT | |
| CMV with negative/nonreactive IgM antibody required | |
| Hepatitis B Core Antibody (total) | **NOTE:** Screening for exposure to other viruses or parasites may have been completed. A negative / non-reactive result is not required, all results are evaluated by Medical Director: Cytomegalovirus CMV-AB (IgG&IgM) Epstein Barr EBV Ab (IgG-IgM) Toxoplasma gondii Toxoplasma Ab (IgG-igM) Trypansoma Cruzi T.Cruzi Ab (IgG-IgM), Lyme. |
| 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 taken and grown out for evaluation. Donor tissue with cultures testing positive for the following microorganisms are deferred: • *Clostridium* • *Streptococcus pyogenes* (group. A strep.) • *Enterococcus* • Fungi (mold or yeast phase) | |

As a screening tool in addition to blood analysis, the donor completed a social and medical questionnaire. A licensed physician has reviewed the results of testing and determined the donor has met all eligibility requirements. The physician utilized available relevant information which may have included, but was not limited to: donor interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology and other records if available and pertinent. Recipient records must be maintained for tracing tissue post-transplant per JCAHO and FDA requirements.

## Warranty

This biologic allograft processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a specific purpose are applicable. No implied warranties exist as to defects in biologics, which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, all warranties are disclaimed, whether expressed or implied by operation of law or otherwise including all implied warranties of merchantability or fitness for a particular purpose.

## Processing

Donor tissue is recovered using the safest techniques and sterile equipment to minimize any bio-burden contamination. The donor tissue is procured via a network of qualified and trained recovery partners, using the most stringent screening and recovery protocols in a controlled environment, minimizing and limiting the risks of disease transmission at every step of the process. This allograft implant was aseptically processed in a controlled environment from a single donor and terminally sterilized by electron beam. Microbial testing was performed, where appropriate, and results met documented acceptance criteria. The allograft implant was released for transplantation based on the donor eligibility determination and review of processing records.

This product is **STERILE**, only the inner packaging and implant contents are **STERILE**. The product is meticulously processed in an aseptic environment, every precaution was taken and exercised to insure the absence of any bio-burden.

## CONTRAINDICATIONS

The presence of severe vascular compromise, active or latent infection, or uncontrolled infection at the wound site may compromise the usefulness of the tissue

## Storage and Shipping

Store optimally in a clean environment **at room temperature or colder.**

## PACKAGING & LABELING

Dry Placental Membrane is aseptically packaged and sealed in an inner poly/foil peel pouch. The inner pouch containing the allograft is sealed inside an outer poly/foil pouch. The double peel pouched allograft is terminally sterilized by electron beam, labeled, and sealed in a dust cover containing this IFU, patient labels and a tissue tracking card.

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, not legible or is missing; or
- If the expiration date shown on the package label has passed.

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

## HCT/P tracking

Per 21 CFR 1271.290, tracking from the donor to the consignee or final disposition must be maintained. Joint Commission standard QC.5.310.7or equivalent regulations requires 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. Record the patient information, the transplant facility name and address, the allograft tissue information (using stickers) and comments regarding tissue use on the TTR. Return the completed TTR to Biostem Life Sciences 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, Inc.

## Warnings

Same and similar potential medical/surgical, conditions or complications that apply to any surgical procedure may occur during or following implantation, application of this allograft. The physician or surgeon is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist.

**DO NOT USE WITH ANY OTHER PRODUCTS**

## Precautions

Prior to use, the surgeon must become familiar with the implant and the surgical procedure.

The implant should be used with considerable caution in surgical sites where an active infection is present, in necrotic sites or in sites with poor perfusion.

The implant should NOT be used under high tension or pressure. We do **NOT** recommend use in the spinal canal, disc, or epidural space.

Appropriate placement of the allograft is critical for successful outcomes.

## Instructions for use

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

## General Instructions:

1. For use on a single visit/surgery/episode for a single patient, it cannot be shared or reused after opening.
2. Do not use past expiration date specified on the product label.
    a. Do not use if the implant or packaging is damaged.
    b. Do not use if there are discrepancies in label information.
    c. Photograph and document, all packages with flaws in the sterile barrier, or lacking allograft or wrong size or wrong labeling.
    d. To prevent contamination of the implant, use sterile technique for preparation and implantation.
    e. Do not re-sterilize or freeze.
    f. Use standard practices for handling and disposal of human tissue
    g. Promptly report all complaints and patient adverse events to BioStem Life Sciences.
    h. Take photographs if possible to document any concerns.
3. Outer **Packaging is not sterile**, if used in a surgical environment, only put the innermost envelope onto the surgical field.
4. Physician experience and knowledge are key to proper application and usage.
5. If unsure as to appropriate application, do not use until fully informed as to protocol and technique from an experienced user.
6. Fill out the Tissue Tracking Record (even if the allograft is discarded) and return to BioStem Life Sciences. This information is kept confidential and used only for implant tracking.
7. Follow your patient and inform BioStem Life Sciences of any adverse events, concerns, or questions immediately.

**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 info@biostemlife.com.

*Disclaimer:* It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplant in appropriate storage containers and temperatures. Recipient records must be maintained for tracing tissue post-transplantation. BioStem Life Sciences, Inc., will not be liable for any damages, whether direct or indirect, special, incidental, or consequential, resulting from improper use of this allograft. The instructions for use are specific, and BioStem Life Sciences waives all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the allograft tissue included with this insert.

Questions or concerns contact:

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FDA registration 30133239405
Trademarks are on file
BioStem Life Sciences, Inc., Pompano Beach, Florida Manufacturer/Processor

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|---|---|
|  | Read attached information on product use |
|  | To be used with prescription only |
|  | One time use on one recipient |
|   | Serial number and lot number in bar code |
|  | Manufacturing date and expiry date on product label |