VENDAJE™ OPTIC

INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE

THIS VENDAJE™ OPTIC TISSUE HAS BEEN DETERMINED TO BE SUITABLE FOR TRANSPLANTATION

Distributed By:
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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™ OPTIC is a processed, dehydrated, sterilized human amniotic membrane allograft.

VENDAJE™ OPTIC is preserved using a proprietary system that minimally manipulates the tissue. VENDAJE™ OPTIC is a non-viable amniotic membrane allograft that provides a protective barrier or covering. 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.

Allografts are human tissue products and appearance may vary between donors. Variations in color (tan to light brown), opacity, and thickness are normal due to the nature of human tissue.

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 Caesarean deliveries. The donor consents to the collection of this tissue, provided that its collection does not cause any harm to her infant(s). 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 U.S. Food and Drug Administration (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:

- HIV-1/HIV-2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen/ HBV NAT
- CMV with negative/nonreactive IgM antibody
- 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 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)

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 the Medical Director of BioStem Life Sciences:

- 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

As a screening tool in addition to blood analysis, the donor completed a social and medical questionnaire. The Medical Director (or licensed physician designee) of BioStem Life Sciences has reviewed the results of testing and determined the donor has met all eligibility requirements. Available relevant information for donor screening 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 the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), FDA and the American Association of Tissue Banks (AATB) requirements.

Processing

Donor tissue is recovered using current Good Tissue Practice (cGTP) techniques and sterile equipment that are designed to minimize bio-burden 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 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**.

Storage

VENDAJE™ OPTIC allografts should be stored in a clean, dry environment at ambient conditions. The allografts have a 3 year shelf life. Check the label for the expiration date. Do not use allograft after expiration date.

Packaging & Handling

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.

VENDAJE™ OPTIC is supplied in an easy to use dual peel pouch. Use sterile smooth forceps or gloves to remove the inner pouch containing the tissue. The clear inner pouch may be introduced to the sterile field. Using sterile scissors, cut below the sealed line of the inner pouch and remove VENDAJE™ OPTIC using smooth sterile forceps. Once retrieved from the sterile, clear inner pouch, VENDAJE™ OPTIC can be applied directly to the site without concern for orientation of the allograft.

The tissue is ready for transplantation immediately (or promptly) after removing it from the sterile package without the need for rehydration.

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.5.310.7 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. 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.

Contraindications

VENDAJE™ OPTIC 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.

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 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 exists with use of VENDAJE™ OPTIC allografts.
Proprietary processing and validated sterilization methods are employed to eliminate potential deleterious components of the allograft. However, as with all biological implants, the possibility of rejection or immunologic response exists.

Any adverse reactions, including the suspected transmission of disease attributable to this allograft, should be immediately reported to BioStem Life Sciences.

DO NOT USE WITH ANY OTHER PRODUCTS

Precautions

VENDAJE™ OPTIC is intended for single-patient use only. Discard all unused material according to standard practices for handling and disposal of human tissue.

Do not use the VENDAJE™ OPTIC allograft if the packaging is damaged. Contact BioStem Life Sciences immediately if any abnormality is observed. Discard all damaged, mishandled or potentially contaminated tissue.

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.

Do not sterilize or autoclave the product before use.

DO NOT FREEZE

Outer Packaging is not sterile. If used in a surgical environment, only put the innermost envelope onto the surgical field. Once the inner foil pouch is opened, VENDAJE™ OPTIC should be transplanted promptly or otherwise discarded.

General Instructions

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

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.
3. Do not use if the implant or packaging is damaged.
4. Do not use if there are discrepancies in label information.
5. Photograph and document all packages with flaws in the sterile barrier or lacking allograft or wrong size or wrong labeling.
6. To prevent contamination of the implant, use sterile technique for preparation and implantation.
7. DO NOT RE-STERILIZE OR FREEZE.
8. Use standard clinical practices for handling and disposal of human tissue. Prior to application, carefully follow the VENDAJE™ OPTIC allograft preparation steps below using aseptic technique:
   a) VENDAJE™ OPTIC 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 (unless the pouches are damaged or compromised).
   b) Carefully open the peelable corner of the outer pouch and present the inner pouch onto the sterile field. Ensure the inner pouch does not come in contact with any portions of non-sterile surface of the outer pouch
   c) Use sterile smooth forceps or gloves to remove the inner pouch containing the tissue.
   d) The clear inner pouch may be introduced to the sterile field.
   e) Using sterile scissors, cut below the sealed line of the inner pouch and remove VENDAJE™ OPTIC using smooth sterile forceps.
   f) Once retrieved from the sterile, clear inner pouch, VENDAJE™ OPTIC can be applied directly to the tissue surgical site without concern for orientation of the allograft.
   g) The tissue is ready for transplantation immediately (or promptly) after removing it from the sterile package without the need for rehydration.
9. Promptly report all complaints and patient adverse events to BioStem Life Sciences.
10. Take photographs if possible, to document any concerns.
11. 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.
12. 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
AATB Accredited Member #00327
Trademarks are on file
BioStem Life Sciences, Inc., Pompano Beach, Florida
Manufacturer/Processor

	Read attached information on product use
	One time use on one recipient
	Serial number and lot number in bar code
	Manufacturing date and expiry date on product label