BIOVANCE®

Human Amniotic Membrane Allograft

DESCRIPTION

BIOVANCE®is a decellularized, dehydrated human amniotic membrane (DDHAM) with a preserved natural epithelial basement membrane and an intact extracellular matrix structure with its biochemical components. The epithelial basement membrane and extracellular matrix of this allograft provide a natural scaffold that allows cellular attachment or infiltration and growth factor storage. BIOVANCE provides a protective cover and supports the body's wound healing processes.

INDICATIONS FOR USE

BIOVANCE is an allograft intended for use as a biological membrane covering that provides the extracellular matrix while supporting the repair of damaged tissue. As a barrier membrane, BIOVANCE is intended to protect the underlying tissue and preserve tissue plane boundaries with minimized adhesion or fibrotic scarring. Indications include, but are not limited to, surgical covering, wrap or barrier, application to partial- and full-thickness, acute and chronic wounds (such as, traumatic and complex wounds, burns, surgical and Mohs surgery sites; and diabetic, venous, arterial, pressure and other ulcers), including wounds with exposed tendon, muscle, bone or other vital structures.

REGULATORY STATUS

BIOVANCE is minimally manipulated during processing and is regulated by the FDA as a human tissue-based product under Section 361 of the Public Health Service Act when applied for homologous use in the recipient.This product is distributed only to licensed health care practitioners.

QUALITY ASSURANCE

BIOVANCE is produced from human amniotic membrane derived from the placentas of normal, healthy, full-term pregnancies. Each donor is carefully screened. Comprehensive medical and social histories of the donors are obtained and tissues are procured, processed, and tested in accordance with standards established by the AABB and FDA requirements to minimize potential risks of disease transmission to recipients. Infectious disease testing is performed at a CLIA-certified laboratory. Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient.

The following tests are performed on donor samples and the infectious disease markers are interpreted as negative or non-reactive for release of product with the exception of CMV. Maternal blood is tested for CMV Antibody, but amniotic membrane is not discarded due to maternal CMV status.

MATERNAL BLOOD TESTING

- HIV 1/2 Antibodies
- Hepatitis C Antibody
- Antibody Screen
- HIV NAT
- Hepatitis C NAT
- Syphilis Screening Assay
- HTLV I/II Antibodies
- West Nile Virus NAT
- CMV Antibodies
- Hepatitis B Core Antibody
- Hepatitis B Surface Antigen
- Hepatitis B NAT
- Trypanosoma cruzi -(Chagas) Antibody

BIOVANCE is tested post-sterilization to demonstrate the absence of bacterial and fungal pathogens.

Testing for endotoxins is conducted to assure levels are below 20 EU/sheet. BIOVANCE is non-pyrogenic.

CONTRAINDICATIONS

BIOVANCE is contraindicated in patients with a known hypersensitivity to BIOVANCE.

WARNINGS

If a patient has an adverse reaction related to the use of BIOVANCE, immediately discontinue its use. BIOVANCE should not be used on clinically infected wounds.

PRECAUTIONS

- The pouch contents are sterile if the pouch is unopened and undamaged. Do not use if package seal is broken. Discard material if mishandling has caused possible damage or contamination. Do not resterilize.
- BIOVANCE must be used prior to the expiration date on the product pouch.
- BIOVANCE should not be used together with a collagenase product on the wound.

HOW SUPPLIED

BIOVANCE is supplied as a single 1 cm x 2 cm, 2 cm x 2 cm, 2 cm x 3 cm, 2 cm x 4 cm, 3 cm x 3.5 cm, 4 cm x 4 cm, 5 cm x 5 cm and 6 cm x 6 cm dehydrated sterile sheet in a single-patient, single-use, double–peel pouch. The transparent inner peel pouch and single tissue sheet are supplied sterile and may be placed directly into the sterile field. Included in the packaging with the product pouch are this insert, a Tissue Tracking Letter, and a set of 6 patient labels.

Once opened, allograft must be used immediately or discarded.

STORAGE

Store in a clean, dry environment at ambient room temperature.

STERILIZATION

BIOVANCE is an aseptically processed product and is terminally sterilized with E-beam irradiation.

RECIPIENT TRACKING

The FDA requires a system of record keeping that enables the tracking of human tissue-based products from donor to consignee and vice versa. It is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient. Tracking labels are enclosed in the BIOVANCE packaging to facilitate this process and should be affixed to the patient medical records. The enclosed Tracking Letter provides more detailed instructions.

INSTRUCTIONS FOR USE

These recommendations are designed to serve only as general guidelines. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

BIOVANCE should not be applied until excessive exudate or bleeding, acute swelling, and infection are controlled.

BIOVANCE should not be applied for structural support.

Each package of BIOVANCE is intended for use on a single patient on one occasion.

Discard any unused portions of BIOVANCE per institutional procedures.

No specific orientation (which side is up or down) of BIOVANCE is required.

- Always handle BIOVANCE using aseptic techniques.
- The inner pouch is sterile and may be placed in the surgical field; however, the outer pouch is not sterile and should be handled accordingly.
- Sterile atraumatic forceps should be used to remove BIOVANCE from its inner peel-pouch.

Instructions for Wound Care

1. Prepare the wound area using standard methods to ensure the wound is free of debris and necrotic tissue; if necessary, debride the wound to ensure the wound edges and base contain viable tissue prior to placement of BIOVANCE.
2. BIOVANCE can be trimmed to the desired shape and size when dry out of the package. If the wound is larger than a single sheet, multiple sheets of BIOVANCE (overlapping edges) may be used to cover the open wound area.
3. Apply BIOVANCE dry and allow wound fluid absorption to hydrate or add sterile saline or other sterile isotonic solution, as needed to hydrate. Smooth the BIOVANCE so that it conforms to the wound surface.
4. The clinician should determine how to anchor BIOVANCE. When suturing, taping or stapling the sheet, ensure that BIOVANCE overlaps adjacent intact skin.
5. If there is a concern about wound fluid collection beneath BIOVANCE, small slits may be made through the allograft to facilitate drainage.
6. After application of BIOVANCE, use an appropriate, nonadherent, secondary dressing to maintain a moist wound environment and the placement of the tissue.
7. Change the secondary dressing as needed to maintain a moist, clean wound area. Wound type, location, size, depth, amount of exudate, and user preference determine the optimal secondary dressing.
8. Do not forcibly remove sections of BIOVANCE that are adhered to the wound. On inspection, if BIOVANCE is no longer covering the wound, or healing progress has slowed, place an additional piece of BIOVANCE over the wound.
9. Discontinue BIOVANCE treatment upon complete healing of the wound.

Instructions for Surgical Applications

1. Repair the tissue defect using standard surgical methods appropriate for type of repair of tendon, muscle, or other vital structures.
2. BIOVANCE may be trimmed to the desired shape and size. It is best to cut BIOVANCE when it is dry. This may be done while it is still within the inner sterile pouch by cutting through the pouch and the tissue simultaneously.
3. More than one sheet of BIOVANCE may be applied to provide the desired coverage.
4. Place BIOVANCE dry as a surgical covering or wrap to the affected area that requires its barrier function utilizing the clinician's preferred technique. Allow fluid absorption to hydrate or add sterile saline or other sterile isotonic solution, as needed, to hydrate. Smooth the BIOVANCE so that it conforms to the repair.
5. The clinician should determine the need for and method of anchoring BIOVANCE. When suturing or stapling the sheet, ensure that BIOVANCE is in contact with the affected area.
6. After BIOVANCE placement, close the overlying tissue or structure utilizing standard surgical techniques.

Alliqua BIOMEDICAL *Restoring tissue. Rebuilding lives.*

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HLI CELLULAR THERAPEUTICS, LLC

BIOVANCE is processed for Alliqua BioMedical, Inc. by:
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45 Horsehill Road, Suite 107
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For product information or adverse reaction reporting, telephone 1-844-WND-CARE (1-844-963-2273)

The Health Care Practitioner receiving this human tissue shall have sole discretion and responsibility to determine in accordance with applicable law and professional standards if the tissue is usable and suitable for any and all uses to which the Health Care Practitioner shall apply the tissue, and upon delivery of the human tissue by Alliqua Biomedical, Inc. to the Health Care Practitioner and thereafter the Health Care Practitioner accepts and shall have full responsibility and liability with respect to such tissue. ALL HUMAN TISSUE FURNISHED BY ALLIQUA BIOMEDICAL, INC TO THE HEALTH CARE PRACTITIONER IS PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF THIRD PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW.