BIOVANCE® 3L Ocular

Human Amniotic Membrane Allograft

DESCRIPTION

BIOVANCE® 3L Ocular is a tri-layered, decellularized, dehydrated human amniotic membrane (DDHAM) with a preserved natural epithelial basement membrane and an intact extracellular matrix structure. The epithelial basement membrane and extracellular matrix of this allograft provide a natural scaffold. BIOVANCE 3L Ocular provides a protective cover.

INDICATIONS FOR USE

BIOVANCE 3L Ocular is an allograft intended for use as a biological membrane covering that provides an extracellular matrix. As a barrier membrane, BIOVANCE 3L Ocular is intended to protect the underlying tissue and preserve tissue plane boundaries. Applications include, but are not limited to, corneal and conjunctival related injuries or defects such as corneal epithelial defects, pterygium repair, fornix reconstruction, and other procedures.

REGULATORY STATUS

BIOVANCE 3L Ocular 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 3L Ocular is produced from human amniotic membrane derived from the placentas of normal, healthy, full-term pregnancies. Each donor has been determined by trained, qualified, and responsible personnel to meet the screening and testing requirements of 21 CFR Part 1271 Subpart C: Donor Eligibility. The record of this determination, including Donor Medical History Record, test results, test methods, and the name and address of the testing laboratories are retained on file for each donor by Celularity Inc. The communicable disease testing was performed by a laboratory certified under the CLIA of 1988 (42 USC 263a) and 42 CFR part 493. Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient.

BIOVANCE 3L Ocular 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/piece. BIOVANCE 3L Ocular is non-pyrogenic.

CONTRAINDICATIONS

BIOVANCE 3L Ocular is contraindicated in patients with a known hyper-sensitivity to BIOVANCE 3L Ocular.

WARNINGS

If a patient has an adverse reaction related to the use of BIOVANCE 3L Ocular, immediately discontinue its use. BIOVANCE 3L Ocular 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 3L Ocular must be used prior to the expiration date on the product pouch.
- BIOVANCE 3L Ocular should not be used together with a collagenase product on the wound.

HOW SUPPLIED

BIOVANCE 3L Ocular is supplied in disc and rectangle configurations as a single 10 mm, 12 mm, 15 mm, 15 mm x 20 mm, 25 mm x 25 mm, and 35 mm x 35 mm 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 3L Ocular 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 3L Ocular 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 3L Ocular should not be applied until excessive exudate or bleeding, acute swelling, and infection are controlled.

BIOVANCE 3L Ocular should not be applied for structural support.

Each package of BIOVANCE 3L Ocular is intended for use on a single patient on one occasion.

Discard any unused portions of BIOVANCE 3L Ocular per institutional procedures.

No specific orientation (which side is up or down) of BIOVANCE 3L Ocular is required.

- Always handle BIOVANCE 3L Ocular 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 3L Ocular from its inner peel-pouch.

Instructions for Corneal Surface Abnormalities

1. Apply drop of topical ophthalmic anesthetic.
2. Insert lid speculum or manually hold lids apart.
3. Apply BIOVANCE 3L Ocular dry to the corneal surface with fine smooth platform forceps.
4. Hydrate BIOVANCE 3L Ocular with an artificial tear drop or sterile saline as needed. Smooth the BIOVANCE 3L Ocular so that it conforms to the corneal surface.
5. After application of BIOVANCE 3L Ocular, place a bandage contact lens over the Biovance and cornea.
6. Remove lid speculum.
7. Bandage Contact lens needs to be monitored and removed once the amniotic membrane has been absorbed.

   NOTE: When repairing the cornea and conjunctiva at the same time follow the conjunctival use instructions below.

Instructions for Conjunctival Use (Bulbar or Palpebral)

1. Repair the conjunctival tissue defect using standard surgical methods appropriate for type of repair.
2. BIOVANCE 3L Ocular may be trimmed to the desired shape and size. It is best to cut BIOVANCE 3L Ocular 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. Place BIOVANCE 3L Ocular dry over the surface defect 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 3L Ocular so that it conforms to the repair.
5. BIOVANCE 3L Ocular may be secured with sutures or tissue adhesive. The clinician should determine the need for and method of anchoring BIOVANCE 3L Ocular. When suturing the sheet, ensure that BIOVANCE 3L Ocular is in contact with the affected area.
6. After BIOVANCE 3L Ocular placement, close the overlying tissue or structure utilizing standard surgical techniques.

celularity®

Celularity Inc.
170 Park Avenue
Florham Park, NJ 07932

VERSÉA™ Ophthalmics

Verséa Ophthalmics, LLC
1000 N Florida Ave.
Tampa, FL 33602
ophthalmics@versea.com
www.versea.com/ophthalmics

For product information, contact 1-800-397-0670. For adverse reaction reporting, contact 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 Celularity 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 CELULARITY 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.