Biovance®·3L

HUMAN AMNIOTIC MEMBRANE ALLOGRAFT

OCULAR

REDIRECT THE CURRENT IN AMNIOTIC MEMBRANE GRAFTS

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.

Important Safety Information

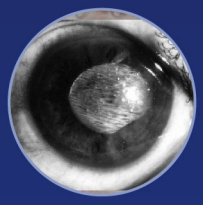
BIOVANCE 3L Ocular is contraindicated in patients with a known hyper-sensitivity to BIOVANCE 3L Ocular. If a patient has an adverse reaction related to the use of BIOVANCE 3L Ocular, immediately discontinue its use. BIOVANCE 3L Ocular should not be used on clinically infected wounds. The pouch contents 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.

VERSÉA™ Ophthalmics

Redirecting The Current In Eye Care

Verséa™ Ophthalmics, Inc. is on a mission to transform and personalize clinical and therapeutic decisions in eye care. The company focuses on delivering an innovative Tear-based Point-of-Care (T-POC) quantitative testing platform and biologic solutions that optimize diagnosis, treatment, and management of various eye care conditions, including ocular surface disease and pterygium surgery.

MEETING THE CLINICAL NEEDS OF OCULAR SURFACE DISEASES



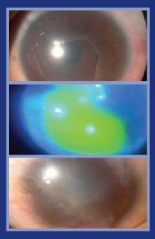
PEDs can result in significant complications, including infection and vision loss[1]

Disruption of the tear film is a hallmark of dry eye disease (DED), which can ultimately give rise to sight-threatening epithelial defects and corneal ulcers. Therefore, a stable preocular tear film is integral in maintaining a healthy ocular surface.[2]

Corneal epithelial defects are some of the most common ocular pathologies that present to eye care professionals. Persistent corneal epithelial defects (PEDs) result from the failure of rapid re-epithelialization and closure within 10-14 days after a corneal injury, even with standard supportive treatment.[3-4] Corneal epithelial defects are focal areas of epithelial loss most frequently caused by mechanical trauma, corneal dryness, neurotrophic keratitis, post surgical changes, or infection.[5]
If left untreated, PEDs can result in significant complications, including infection and vision loss.[1]

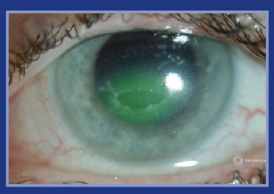
Amniotic membrane acts as a physical barrier, protecting the injured corneal surface from eyelid friction and by preventing water loss through desiccation.

Furthermore, when used as a graft to treat chronic corneal pathologies such as PEDs and limbal stem cell deficiencies, amniotic membrane serves as a substrate for the migration, adhesion, and proliferation of corneal epithelial cells and limbal stem cells.[5]

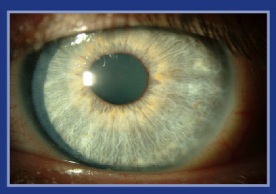


Amniotic membrane graft applications as a cover or barrier may include, but are not limited to, corneal and conjunctival related injuries or defects such as corneal epithelial defects, pterygium repair, fornix reconstruction and other procedures.

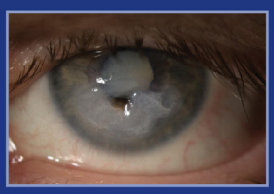
Common diagnoses resulting in or associated with corneal defects include:



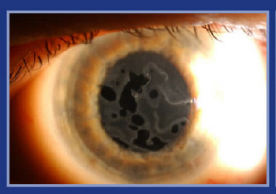
Persistent Epithelial Defect



Superficial Punctate Keratitis



Neurotrophic Keratitis



Anterior basement membrane dystrophy

Pterygium

WHAT IS **BIOVANCE 3L OCULAR?**

Decellularized Dehydrated Human Amniotic Membrane (DDHAM)

Designed for superior handling while optimizing a ringless design

Unique 3-layer amnion basement membrane construction

Does not include DNA, cells, growth factors, antibodies, preservatives, or excipients

Designed for Premium Handleability

Biovance® 3L Ocular is a three-layer decellularized, dehydrated, human amniotic membrane.[6] Cut and assembled as a unique laminated tri-layer design with the stromal side of amniotic membrane on both sides of the scaffold facing out to ensure the correct side interfaces with the ocular surface regardless of the orientation of the scaffold.

Biovance 3L Ocular provides an extracellular matrix while supporting the repair of damaged tissue. The membrane serves as a natural scaffold with an intact basement membrane.

Biovance® 3L Ocular's three layer design **enhances its handling properties,** without the need for a ring.

Processed for Optimized Function as a Barrier and Extracellular Matrix

Placenta procurement & donor eligibility

Amnion separation

Washed, rinsed, & cleaned

Cut & assembled into tri-fold scaffold

Sterilized & packaged

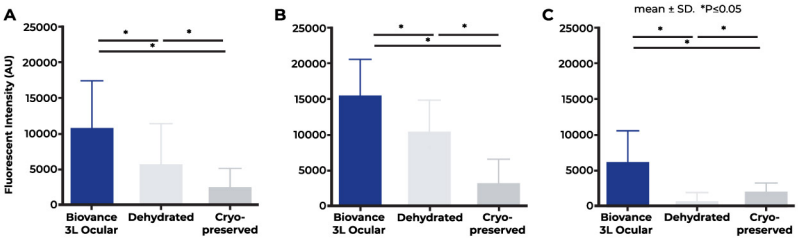
REDIRECT THE CURRENT TO ADVANCED SCIENCE

Biovance 3L Ocular serves as a cell-friendly structure that promotes cell attachment within hours. Cell attachment is a natural stimulus for the orderly release of growth factors and cytokines.

An in vitro test was conducted to measure viability, adhesion, and proliferation of human corneal and conjunctival epithelial cells at days 1, 4, and 7[10-13]

Significantly Greater Cell Viability

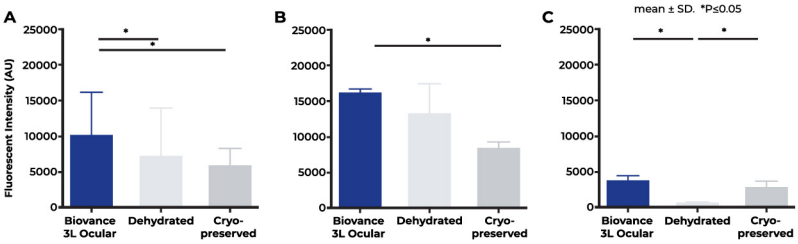
Ocular epithelial cell viability significantly greater than ChAM and DhAM ($p<0.001$)



Human corneal epithelial cells and Human conjunctival epithelial cells (A). Human corneal epithelial cells (B). and Human conjunctival epithelial cells (C). The viability of adhered cells was detected using the alamarBlue assay.

Significantly Greater Cell Adhesion

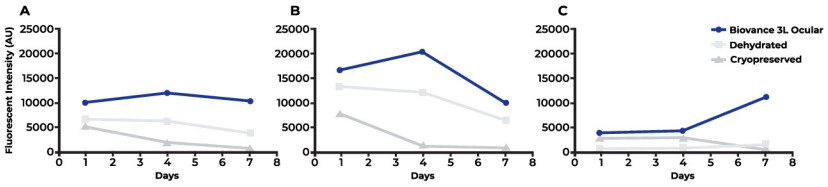
Ocular epithelial cell adhesion significantly greater as compared to ChAM ($p<0.001$) and DhAM ($p<0.011$)



Human corneal epithelial cells and human conjunctival epithelial cells were seeded onto scaffolds and incubated for 24H. Adhesion of human corneal epithelial cells and Human conjunctival epithelial cells (A). Human corneal epithelial cells (B). and Human conjunctival epithelial cells (C).

Significantly Greater Cell Proliferation

Ocular epithelial cell proliferation rate significantly greater than ChAM ($p<0.001$)

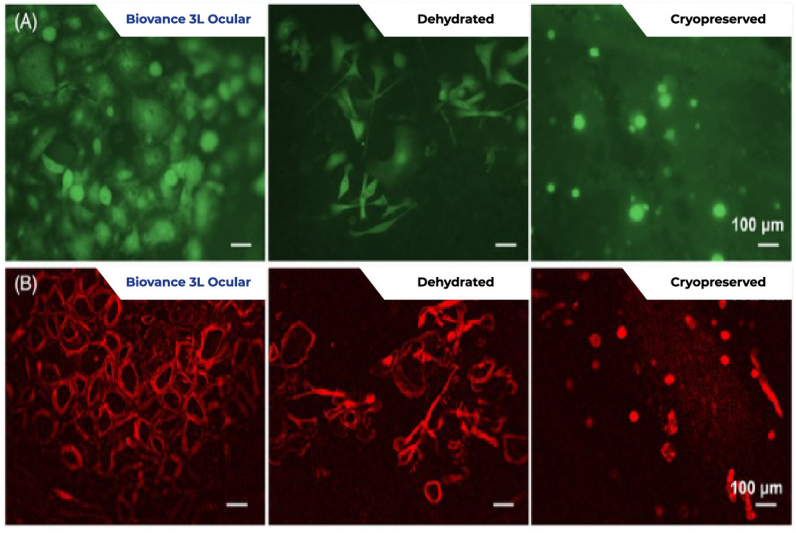


Proliferation of human corneal epithelial cells and human conjunctival epithelial cells (A), human corneal epithelial cells (B), and human conjunctival epithelial cells (c)

Visual Comparison of Amniotic Membrane Grafts at Day 4[10-13]

Ocular epithelial cell viability with Biovance 3L Ocular is significantly greater than ChAM or DhAM at day 4.

Human corneal epitheal cells were seeded on the different scaffolds, cultured, and stained with Calcein AM to visualize viable cells at Day 4 (A). The morphology of Human corneal epithelial cells on scaffolds was monitored by actin staining on Day 4 (B).



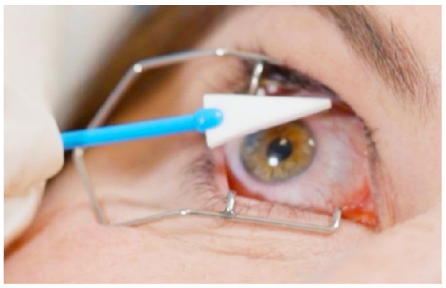
REDIRECT THE CURRENT TO A TRIPLE LAYER COVERING THAT IS FREE OF DONOR DEBRIS

Biovance® 3L Ocular human amniotic membrane allograft is a natural extracellular matrix that acts as a scaffold for restoration of functional tissue and allows for host cell migration.

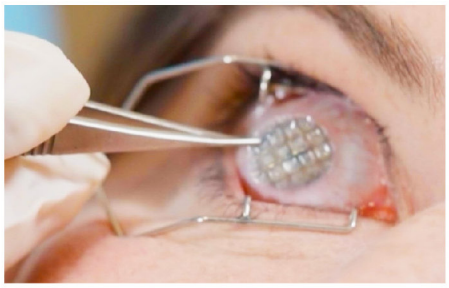
CLINICAL APPLICATION PROCESS

Scan QR code to watch our clinical application process video

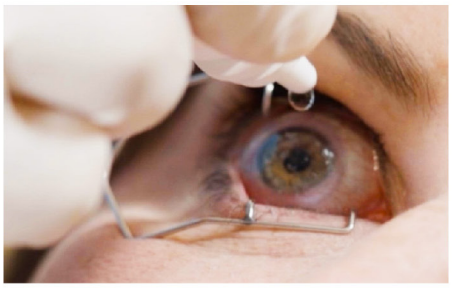
Prepare



Place



Post Application



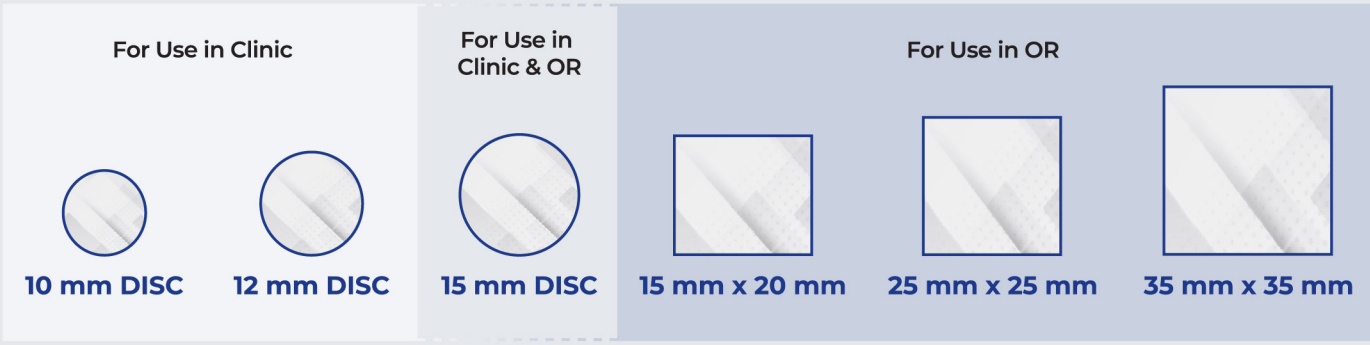
TOP 10 REASONS TO REDIRECT THE CURRENT WITH BIOVANCE 3L OCULAR

1. Unique 3-layer design
2. Easy to handle
3. No upfront preparation
4. Decellularized
5. Protects underlying tissue
6. Ringless design
7. Bidirectional
   Can apply on either side
8. Room temperature storage
9. 10-year shelf life
10. Access support for patients
    e.g. benefits verification

ACCESS SUPPORT FOR BIOVANCE 3L OCULAR

- Verifying coverage and explanation of insurance benefits
- Provide coding and billing assistance
- Facilitating prior authorization/ pre-certification
- Conducting onboarding call and education
- Appeal assistance after insurance denial

6 Convenient Shapes & Sizes
To Support Your Treatment Application Needs



For product information, contact 1-800-397-0670. For adverse reaction reporting, contact l-844-963-2273.
Please refer to the Biovance 3L Ocular package insert for complete product information.

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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.

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References: **1.**Vaidyanathan U. et al; Med Hypothesis Discov Innov Ophthalmol. 2019 Autumn; 8(3): 163–176 **2.**Mead et al; Taiwan J Ophthalmol 2020;10: 13-21 **3.**ht tps://nam10.safelinks.protection.ouTlook.com/?url=https%3A%2F%2F www.ncbi.nlm.nih.gov%2Fp mc%2Farticles%2FPMC6778469%2F%23B4&data=05%7C02%7Cr ahim%40versea.com%7Cd7ec9bfb33c5432c7e9c08dc648e7a15%7C39030a6c273b4eeea6d2a16b6 3d08ea0%7C0%7C0%7C638495810328394158%7CUnknown%7CTW FpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIi LCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C 0%7C%7C%7C&sdata=3xvaztNcOxOyXTrP2Ilo1d1HWtj5YrSEIlo9dCY% 2F6Ps%3D&reserved=0 **4.**https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww. ncbi.nlm.nih.gov%2Fpmc%2Farticles%2FPMC6778469%2F%23 B5&data=05%7C02%7Crahim%40versea.com%7Cd7ec9bfb33c5432c7e9c08dc648e7a15%7C39030a6c273b4eeea6d2a16b63d08ea0%7C0%7C0%7C6384958103z2840 9511%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C%7C&sdata=69ep%2FzXdJmyblyj%2 BLgg7P6mhQplylq9oFyzgj82xkjE%3D&reserved=0 **5.**Thia et al; Surv Ophthalmol. 2023 Nov-Dec;68(6):1093-1114. doi: 10.1016/j.survophthal.2023.06.001. Epub 2023 Jun 8. **6.**Biovance 3L Ocular Package Insert. **7.**Ambrosio R. J Refract Surg 2008; 24:396-407. **8.**Fournie PR, Gordon GM, Dawson DG, et al. Arch Ophthalmol 2010; 128:426-436. **9.**Venkateswaran N, Luna RD, Gupta PK. Ocular surface optimization before cataract surgery. Saudi J Ophthalmol. 2022 Aug 29;36(2):142-148. **10.**Golhait P, Peseyie R. Persistent Epithelial Defect. [Updated 2023 Jul 31]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan **11.**Diaz V. et al; ARVO 2022 Poster; A Comparison Study of the Effects of Ocular Scaffolds on Human Ocular Epithelial Cells; **12.**Rutgers Benchtop Data Report: Biovance 3L Ocular; Data on file. **13.**Mao Y, Protzman NM, John N, et al. An in vitro comparison of human corneal epithelial cell activity and inflammatory response on differently designed ocular amniotic membranes and a clinical case study. J Biomed Mater Res. 2022;1-17. doi:10.1002/jbm.b.35186.

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