

DefEYEing Convention

Elevating the management of ocular surface disease and ocular surgery



The **only** decellularized basement membranes (DBMs)¹

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.

Persistent epithelial defects (PEDs)

Etiologies, drivers, and burden

PEDs are corneal epithelial defects that fail to heal within 2 weeks and arise from diverse etiologies²

Category	Etiologies of PEDs
Surgical	Incisional or laser-based ocular surgeries Cataract surgery Pterygium removal surgery Laser-assisted in situ keratomileusis (LASIK) Penetrating or lamellar keratoplasty Neurosurgeries causing damage to the trigeminal ganglion
Injury	Exogenous injury Chemical or thermal burns Ultraviolet light injury Exposure keratopathy Prolonged overuse of contact lenses External agents Viral infection (eg, herpetic keratitis) Drugs (eg, Stevens-Johnson syndrome)
Autoimmune	Sjögren syndrome Ocular cicatricial pemphigoid Ectodermal dysplasia
Allergic	Vernal keratoconjunctivitis Atopic keratoconjunctivitis
Other	Vitamin A deficiency Severe dry eye disease Corneal dystrophies

All PEDs share common pathophysiological drivers²

1. Tear disorder (dry eye)

Inadequate tear film leads to reduced lubrication and excessive friction between the eyelid and the cornea, causing mechanical and inflammatory damage

2. Limbal stem cell deficiency

Disruption of the limbal stem cell niche reduces the regenerative capacity of epithelial cells

3. Inflammation

Elevated proinflammatory mediators (eg, IL-1β, TNF, IL-6, IL-8, matrix metalloproteinases) contribute to extracellular matrix (ECM) degradation and epithelial cell loss

4. Neurotrophic keratopathy

Alterations in corneal nerves lead to impaired sensory and trophic function, resulting in breakdown of the corneal epithelium

IL-1β, interleukin-1β; TNF, tumor necrosis factor; IL-6, interleukin-6; IL-8, interleukin-8.

Serious wounds require intervention beyond ocular surface lubrication and discontinuation of preservative-containing medications²

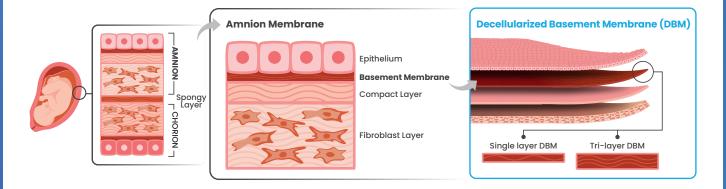
Human AMT-derived allografts

The gold-standard physical barrier for ophthalmic wound repair^{2,3}

The stratified biological organization of AMT makes it appealing as a scaffold for ophthalmic wound repair³

How AMT helps repair ophthalmic wounds

- Acts as a physical barrier, protecting the eye against mechanical trauma from lid closure and preventing surface desiccation by maintaining a hydrated microenvironment²
- Is rich in growth factors and structural proteins that promote corneal healing³
- Serves as a substrate for adhesion, migration, and proliferation of corneal epithelial cells and limbal stem cells when used as a graft to treat corneal pathologies²



Only DBM offers all the benefits of AMTs, without donor cell debris, while preserving ECM functionality and triggering an efficient host cell-mediated response^{1,4}

AMT, amniotic membrane tissue

DBM represents an advance over cryopreserved and conventional dehydrated AMTs:



Removes donor cell debris and proinflammatory chorion to minimize immune responses⁴



Preserves the matrix scaffold and ECM protein production⁴



Adheres efficiently to reduce slippage and allow for glueless, sutureless surgery^{5,6}

BIOVANCE° **3L Ocular and BIOVANCE**° are the only decellularized basement membranes for ophthalmic wound care applications¹

Biovance³L

BIOVANCE® 3L Ocular | BIOVANCE®

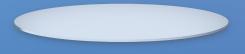
The only decellularized basement membranes (DBMs)1

Tri-layer architecture with a preserved natural epithelial basement membrane and intact ECM structure¹



DBM DBM DBM





BIOVANCE

- Storage at ambient room temperature¹
- No specific orientation (which side is up or down) required, allowing ease of handling
- Does not contain a symblepharon ring, which may be associated with eye pain, headache, and discomfort^{1,7}
- Aseptically processed and terminally sterilized with E-beam irradiation¹
- Tested poststerilization to demonstrate the absence of bacterial and fungal pathogens¹

Three-layer & single-layer designs are available in 6 convenient shapes & sizes¹



Simple and intuitive application process¹

Not actual size.

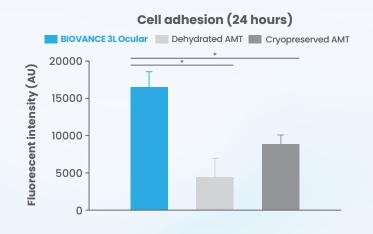


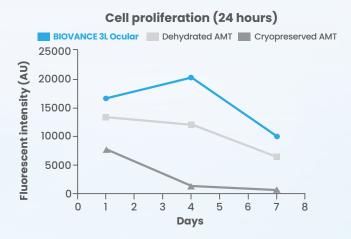
Visit <u>defeye.com</u> to watch our clinical application process video

Stronger adhesion. Greater proliferation. Only with BIOVANCE® 3L Ocular.

Outperforms other AMTs in supporting cell adhesion and proliferation in *in vitro* studies^{4,8}

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.

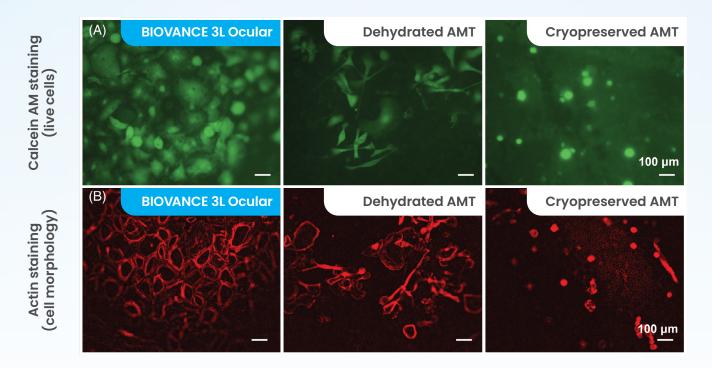




Methods: Human corneal epithelial cells were seeded onto the AMTs and incubated for 24 h. Two-way ANOVA with Tukey post hoc tests analyzed the effects of amniotic membrane on epithelial cell adhesion. ANOVA, analysis of variance; AU, arbitrary units.

*P<0.05

Fluorescence imaging confirms strong epithelial cell viability, adhesion, and proliferation⁴



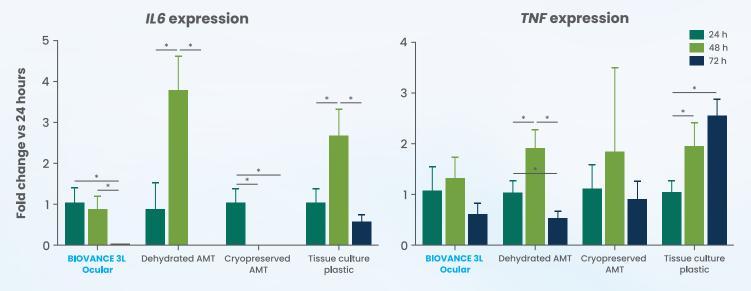
Methods: Human corneal epithelial cells were seeded onto the stromal side of the 3 AMTs, cultured, and stained with Calcein AM to visualize live cells or for actin on Day 4.

Biovance³L

Shown to reduce inflammation and promote wound closure

Reduced inflammatory response over time with BIOVANCE® 3L Ocular4

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.



Methods: Relative mRNA expression across time is normalized to expression at 24 h. One-way ANOVA with Tukey post hoc tests analyzed the effect of time on mRNA expressions. Statistical comparisons are between time points for each amniotic membrane under stimulated conditions (+TNF).

*P<0.05

Significant re-epithelialization with BIOVANCE 3L OCULAR or BIOVANCE® and a pressure patch⁵

100%

- Re-epithelialization of cornea with both BIOVANCE 3L Ocular and BIOVANCE in 24 h
- Dissolution of both BIOVANCE 3L Ocular and BIOVANCE grafts at Week 1

Methods: Retrospective study of 144 patients—80 (55.6%) had a diagnosis of neurotrophic keratitis (NK) and 64 (44.4%) had a diagnosis of persistent superficial punctate keratitis related to dry eye disease (DED).

Incorporate BIOVANCE 3L Ocular into your practice to manage the full spectrum of ocular surface diseases and ocular surgery

BIOVANCE® 3L Ocular in practice

Proven performance across corneal pathologies

Demonstrated efficacy of BIOVANCE 3L Ocular on ocular surface wounds **Anterior basement** Pterygium removal⁶ membrane dystrophy4 **Pre-application** Peri-application Placement of **BIOVANCE 3L Ocular Post-application** Month 2 Week 1

"Unlike other placental-based allografts, [BIOVANCE 3L Ocular] is completely devoid of cells, hormones, cytokines, and growth factors. This leaves a clean scaffold that can be populated with autologous cells and growth factors after application to a surgical site."

Visit <u>defeye.com</u> to watch the pterygium surgical video featuring BIOVANCE 3L Ocular

Biovance³L

DefEYEing convention in ocular surface disease & ocular surgery

BIOVANCE® 3L Ocular is a novel decellularized basement membrane for ophthalmic applications

- Triple-layer design, with no specific orientation required for placement and no symblepharon ring¹
- Ambient room temperature storage, with no upfront preparation required
- Diverse product configurations, with a simple, intuitive application process
- Promotes corneal epithelial cell viability, adhesion, and proliferation in vitro4
- Demonstrated ability to promote ocular surface healing across diverse corneal pathologies^{4,6}

Access support



Verification of coverage and explanation of insurance ben<u>efits</u>



Coding and billing assistance



Facilitation of prior authorization or precertification



Onboarding call and education



Appeal assistance after insurance denial



Brought to you by DefEYE—a leader in ocular surface disease & ocular surgery solutions

DefEYE, Inc. is on a mission to transform and personalize therapeutic approaches in eye care. The company focuses on delivering innovative decellularized biologic solutions that optimize treatment and management of various eye care conditions, including ocular surface diseases, pterygium surgery, and other surgical interventions. **To learn more, visit www.defeye.com**.



For product information, contact 786-723-7178 or email info@defeye.com. For adverse reaction reporting, contact 844-963-2273. Please refer to the BIOVANCE 3L Ocular package insert for complete product information.

Warnings

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Precautions

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References: I. BIOVANCE 3L Ocular. Package insert. 2. Thia ZZ, Ho YT, Shih KC, Tong L New developments in the management of persistent corneal epithelial defects. Surv Ophthalmol. 2023;68(6):1093-1114. 3. Dadkhah Tehrani F, Firouzeh A, Shabani I, Shabani A. A review on modifications of amniotic membrane for biomedical applications. Front Bioeng Biotechnol. 2021;8:606982. 4. 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 B Appl Biomater. 2023;111(3):684-700. 5. Linsey K. Use of an eyelid pressure patch concomitantly with a decellularized dehydrated amniotic membrane for ocular surface disease management. Ophthalmol Ther. 2025;14(3):573-584. 6. Rivera-Morales P, Barnard L, Linderman W, Gill M, Diaz V. Surgical time and postoperative symptoms study in pterygium excision and amniotic membrane graft using Celularity triple layer dehydrated amniotic membrane. Clin Ophthalmol. 2023;17:1967-1974. 7. Pachigolla G, Prasher P, Di Pascuale MA, McCulley JP, McHenry JG, Mootha VV. Evaluation of the role of ProKera in the management of ocular surface and orbital disorders. Eye Contact Lens. 2009;35(4):172-175. 8. Data on file. DefEYE Ophthalmics, Inc.



