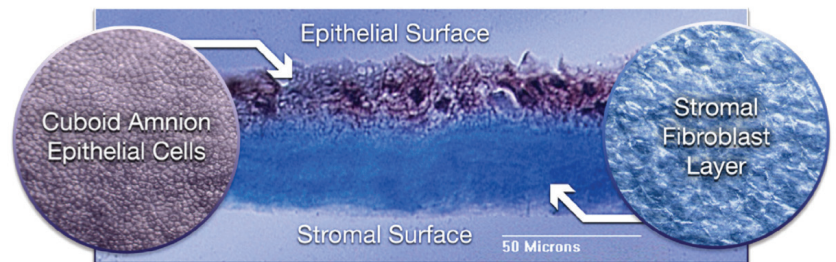


More than just a membrane, Opticyte™ Ocular Matrix is designed to preserve the native amnion with a basement membrane similar to the conjunctiva.¹

Opticyte™ Ocular Matrix is biological tissue derived from human amnion that has been gently processed without crosslinking reagents, and sterilized using a significantly lower dose of irradiation compared to other commercial grafts.

This customized process yields a graft that is optimized for use by ophthalmic professionals as a biological bandage that protects and provides a protein-rich extracellular matrix. Primary indication is for homologous use, covering and protecting:

- Corneal and stromal ulcerations
- Pterygium excisions
- Conjunctiva surface reconstruction²
- Enhancing epithelialization in limbal stem cell deficiency or epithelial defects³



Processed Amnion Histology and Microscopy.

PROCEDURE

Opticyte™ Ocular Matrix can be easily applied to the ocular surface by:

- Absorbable sutures
- Biologic tissue adhesive
- Contact lenses⁴

SAFETY & QUALITY

Opticyte™ Ocular Matrix is processed at an FDA-registered and AATB-accredited institution, providing clinicians a safe and high-quality tissue product for use in ophthalmic procedures.

Opticyte™ Ocular Matrix

Product Offering:

Item Number:	Size
AM-OP1010	10 mm
AM-OP1012	12 mm
AM-OP1014	14 mm
AM-OP1016	16 mm



Quality Compliance & Donor Screening

Opticyte™ tissue is procured and processed in the United States according to standards and/or regulations established by the American Association of Tissue Banks (AATB) and the United States Food & Drug Administration (FDA). Donor ethics and negative FDA-approved serological screening includes:

- Donor consent prior to collections
- HBsAG (Hepatitis B Surface Antigen)
- HBcAb (Hepatitis B core antibody)
- HCV (Hepatitis C antibody)
- HIV 1/II-Ab (HIV Nucleic Acid Test)
- HCV NAT (HCV Nucleic Acid Test)

References

1. Fukuda K et al. Differential distribution of subchains of the basement membrane components type IV collagen and laminin among the amniotic membrane, cornea, and conjunctiva. *Cornea*. 199;18:73-79.
2. Tseng SCG et al. Amniotic membrane transplantation with or without limbal allografts for cornea surface reconstruction in patients with limbal stem cell deficiency. *Arch Ophthalmol*. 1998;116:431-441.
3. "Amniotic Membrane Transplantation" EyeWiki, American Academy of Ophthalmology, December 19, 2017, http://eyewiki.aaao.org/Amniotic_Membrane_Transplant#Procedure.
4. Tseng SCG et al. Amniotic membrane suturing techniques. 2007. Springer Berlin Heidelberg.

Regulatory Factors

Opticyte™ Ocular Matrix is classified and qualifies as a human tissue allograft (HCT/P) as outlined in 21CFR 1271 under Section 361 of the Public Health Service Act. Opticyte™ Ocular Matrix is intended for "Homologous Use" as it is used to cover and protect tissue.

Disclaimer

This product is intended for homologous use and should not be used to prevent, treat, or cure a disease. Any use of this product outside of homologous use area may require an Investigational New Drug or Investigational Device Exemption filing with FDA.