

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

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 reconstruction<sup>2</sup>
- Enhancing epithelialization in limbal stem cell deficiency or epithelial defects<sup>3</sup>



Processed Amnion Histology and Microscopy.

## Procedure

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

- Contact lenses<sup>4</sup>
- Absorbable sutures
- Biologic tissue adhesive

## 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.

For information related to Opticyte insurance benefit verifications, prior authorization assistance, or claims appeal assistance, please contact our **Reimbursement Support Line**.

**Phone:** (919) 921-8105 Ext 119

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# Opticyte<sup>®</sup>

## Amniotic Ocular Matrix

### Clinical

Item Number:	Size
AM-OP1008	8 mm
AM-OP1010	10 mm
AM-OP1012	12 mm
AM-OP1014	14 mm
AM-OP1016	16 mm

### Surgical

Item Number:	Size
AM-OPS1011	1x1 cm <sup>2</sup>
AM-OPS1012	1x2 cm <sup>2</sup>
AM-OPS1014	1x4 cm <sup>2</sup>
AM-OPS1023	2x3 cm <sup>2</sup>

### Opticyte Graft Placement Kit (AM-OPI-KIT)

OPI-FCPS-01 - Tissue Forceps Stainless Steel

OPI-SPEC-01 - Speculum

OPI-STRY - Instrument Sterilization Caddy

### 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 1/11-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*. 1999;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.aaopt.org/Amniotic\\_Membrane\\_Transplant#Procedure](http://eyewiki.aaopt.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.