Opticyte®
Amniotic Ocular Matrix

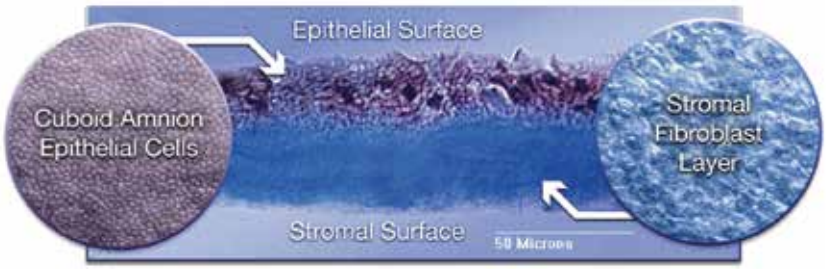
More than just a membrane, Opticyte Ocular Matrix is designed to preserve the native amnion with a basement membrane similar to the conjunctiva.[1]

Opticyte Ocular Matrix is derived from human amnion that has been gently processed and sterilized using an ISO 11137 validated terminal sterilization with a low dose of irradiation.

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. Indication is for homologous use for covering and protecting:

- Corneal and stromal ulcerations
- Pterygium excisions
- Conjunctiva surface reconstruction[2]

For this reason, current theory suggests that amniotic membrane augments support for epithelial cells, limbal stem cells, and corneal transient amplifying cells.[3]



Processed Amnion Histology and Microscopy. Source data on file

PROCEDURE

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

- Absorbable sutures
- Biologic tissue adhesive
- Contact lenses[4]

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

Phone: 919.921.8105
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Email: support@merakris.com

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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^2
AM-OPS1012	1x2 cm^2
AM-OPS1014	1x4 cm^2
AM-OPS1023	2x3 cm^2

Opticyte Graft Placement Instruments

OPI-FCPS-01	Tissue Foreceps 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:

- Hepatitis B Surface Antigen (HBsAG)
- Hepatitis B core Antibody (HBcAb)
- Hepatitis C Antibody (HCV)
- HIV 1/2 Plus O Antibody
- Syphilis Serotolotical Detection Test
- HTLV 1-2 Antibody
- HCV NAT (Nucleic Acid Test)
- HBV NAT (Nucleic Acid Test)
- WNV NAT (Nucleic Acid Test)

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 the FDA.

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 Opthalmol. 1998;116:431-441.
3. "Amniotic Membrane Transplantation" EyeWiki, American Academy of Ophthalmology, December 19, 2017, http://eyewiki.aao.org/Amniotic_Membrane_Transplant#Procedure
4. Tseng SCG et al. Amniotic membrane suturing techniques. 2007. Springer Berlin Heidelberg.

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