

Why Opticyte Matrix?

Protecting the ocular surface, Opticyte® Amniotic Membrane Tissue (AMT) is designed to preserve the native amnion with a basement membrane similar to the conjunctiva.¹

Opticyte Amniotic Membrane Tissue is derived from human amnion that has been gently processed and sterilized using a terminal sterilization procedure validated to ISO 11137 standards.

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.^{2,3} Opticyte is indicated for homologous use as a covering or protective barrier in wound/eye care.

Dry eye

Keratitis

Non-healing corneal wounds

Corneal and stromal ulcerations

Pterygium excisions

Conjunctiva surface reconstruction⁴

Current theory suggests that amniotic membrane augments support for epithelial cells, limbal stem cells, and corneal transient amplifying cells.⁵



PROCEDURE

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

- Absorbable sutures
- Biologic tissue adhesive
- Bandaged Contact Lens (BCL)⁶

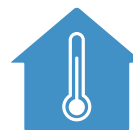


SAFETY & QUALITY

Opticyte is manufactured and processed according to the standards promulgated by the U.S. Food and Drug Administration (FDA) in 21CFR1271.



Minimally processed to preserve the biological characteristics of amniotic tissue



Shelf-stable at room temperature for 5 years



Reimbursement assistance and support



Natural barrier for various corneal defects

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

Opticyte
Amniotic Ocular **Matrix**

CLINICAL

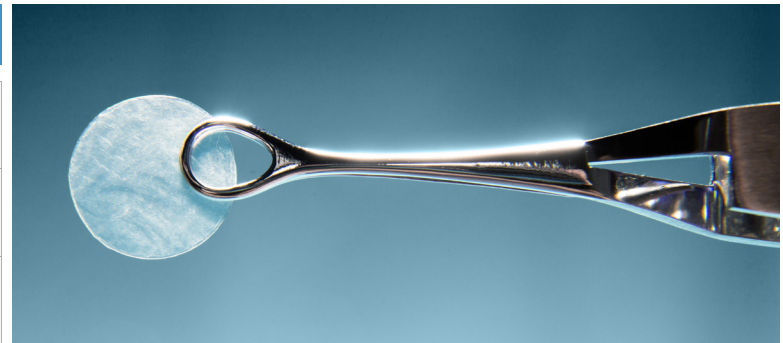
ITEM NUMBER:	MATRIX SIZE
AM-OP1008	8 mm
AM-OP1010	10 mm
AM-OP1012	12 mm
AM-OP1014	14 mm
AM-OP1016	16 mm

SURGICAL

ITEM NUMBER:	MATRIX SIZE
AM-OPS1011	1x1 cm ²
AM-OPS1012	1x2 cm ²
AM-OPS1022	2x2 cm ²
AM-OPS1023	2x3 cm ²
AM-OPS1044	4x4 cm ²

OPTICYTE GRAFT PLACEMENT INSTRUMENTS

OPI-FCPS-01	Tissue Forceps Stainless Steel
OPI-SPEC-01	Speculum
OPI-STRY	Instrument Sterilization Caddy



QUALITY COMPLIANCE & DONOR SCREENING

Opticyte is manufactured and processed according to the standards promulgated by the U.S. Food and Drug Administration (FDA) in 21CFR1271. Donors must provide consent for tissue donation and are screened and tested for communicable diseases using FDA-approved methods, including, but not limited to:

- HIV-1 Antibody
- HIV-1 NAT (Nucleic Acid Test)
- HIV-2 Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Antibody to Core Antigen
- Hepatitis B NAT (Nucleic Acid Test)
- Syphilis Detection Test
- HCV Antibody
- HCV NAT (Nucleic Acid Test)
- WNV NAT (Nucleic Acid Test)

Regulatory Factors

Opticyte Amniotic Ocular Matrix is classified and qualifies as a human tissue allograft (HCT/P) as outlined in 21CFR1271 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. Mamede, A.C., et al. (2012). "Amniotic membrane: from structure and functions to clinical applications." *Cell and Tissue Research*, 349(2), 447-458.
3. Niknejad, H., et al. (2008). "Properties of the amniotic membrane for potential use in tissue engineering." *European Cells & Materials*, 15, 88-99.
4. 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.
5. "Amniotic Membrane Transplantation" EyeWiki, American Academy of Ophthalmology, December 19, 2017, http://eyewiki.aao.org/Amniotic_Membrane_Transplant#Procedure
6. Tseng SCG et al. Amniotic membrane suturing techniques. 2007. Springer Berlin Heidelberg.