



DEHYDRATED AMNIOTIC MEMBRANE

AMNIOKERA™ (AM) is processed, dehydrated, sterilized human amniotic membrane allograft.

As a basement membrane, it is the innermost layer of the fetal membrane of the placenta. It is avascular and has an epithelial layer with a sub-adjacent avascular stromal layer. It is composed of reticular fibres that closely resemble those of the conjunctiva. It is one of the thickest membranes in the human body.

The structural integrity, transparency and elasticity of amniotic membrane makes it the most widely accepted tissue replacement for ocular surface reconstruction. It is processed and sterilized in compliance with all appropriate quality management systems to ensure efficacy and safety, and has been declared safe for transplantation.

SURGICAL TECHNIQUES

Corneal surface reconstruction

For patients requiring corneal surface reconstruction, the AMNIOKERA 9 / 9D / 12 / 12V are circular disks that cover the cornea. A single piece of AM can be applied as an inlay graft in dry form on the corneal surface after debridement of cellular debris or exudates from the base of the defect. The dry AM adheres to the corneal surface on its own through capillary action. A bandage contact lens (BCL) is applied over the graft. Fibrin glue tissue sealant can also be used to improve adherence.

Conjunctival surface reconstruction

For conjunctival reconstruction, where the objective is adequate dissection and removal of pathological sub-conjunctival tissue, fibrin glue is recommended to anchor AM to the conjunctiva. For sutures, 9-0 or 10-0 vicryl can be used due to the conjunctiva's rapid healing ability.

Ocular surface reconstruction

In the event of extensive ocular surface damage or from more severe injury, sequential surface reconstruction is often necessary.

In such cases, it is important to ensure that all fibrin tissue is meticulously dissected. AM is then placed

ocular surface and is anchored to the inner surface of the everted lower lid, close to the lid margin, using multiple interrupted ABSORBABLE sutures. Needles are passed from amniotic membrane through inferior fornix via the full thickness of the lid, exiting through the eyelid skin. A continuous encircling 10-0 nylon suture is used to anchor the membrane at the limbus or peripheral 360° cornea. Fibrin glue can be used for additional anchorage.

Glaucoma surgery

For glaucoma surgery, AM is used to cover the glaucoma drainage device tube, using 8-0 vicryl sutures, in order to prevent possible conjunctival tube erosion. AM can also be used as an adjunct tissue in cases of sclera, pericardium grafts, or for bleb revisions and to cover leaking blebs. Fibrin glue can be used as an adjunct sealant.

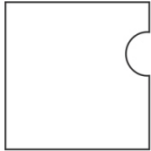
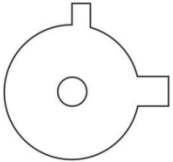
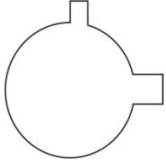
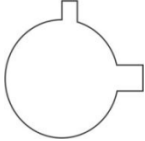
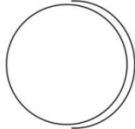


Postoperative management

Following surgery, a broad-spectrum topical antibiotic is recommended for 1-2 weeks until the epithelium heals. Topical steroids are then applied for 6-8 weeks in tapering doses to reduce surface inflammation. Systemic immuno-suppression is not required.

To ensure safety, discard all damaged, mishandled, or potentially contaminated tissue

DO NOT RE-STERILIZE

	Lot number		Product Code
	Sterilized using gamma		Unique Device Identifier
	Do not use if packaging is damaged		Use by date
	Do not reuse		Do not resterilize
	Consult instructions for Use		Keep Dry
	Caution		Prescription Only
	Double sterile barrier system		

PRODUCTS	AMNIOKERA™ 3X3 (Amniotek™)	AMNIOKERA™ 12V (Amniotek™-Vision)	AMNIOKERA™ 12 (Amniotek™-C)	AMNIOKERA™ 9 (Amniotek™-C)	AMNIOKERA™ 9D (Amniotek™-C2)	AMNIOKERA™ 3x3D (Amniotek™-2)	AMNIOKERA™ -G (Amniotek™-G)
INDICATIONS	Conjunctival surface: pterygium surgery, chemical burns, conjunctival chalasis, leaking bleb, corneal surface reconstruction: non-healing PED neurotrophic ulcers, keratitis sicca, overlay post PRK						Glaucoma Shunt Tube Covering
DIMENSIONS	3x3cm 50-micron tissue	12 mm in diameter with 2 mm pin-hole 50-micron tissue	12 mm in diameter 50-micron tissue	9 mm in diameter 50-micron tissue	9 mm in diameter double thickness 100-micron tissue	3x3cm double thickness 100 - micron tissue	2x2cm triple thickness 150 - micron tissue
ORIENTATION	If the membrane's cut edge is facing right and away from the surgeon, the stromal side is facing down and the epithelial side is facing up. 	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea. 	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea. 	If the larger projection is distanced clockwise from the smaller one, the epithelial side is facing the cornea. 	Double-layered graft. It can be placed in any orientation, as both sides are epithelial surfaces. 	Double-layered graft. It can be placed in any orientation, as both sides are stromal surfaces. 	Triple-layered graft. Both sides are stromal surfaces. 
PRINCIPLES OF SURGERY	Inlay or graft technique Overlay or patch technique Filling-in or layered technique						AMNIOKERA is specifically prepared to cover GDD (glaucoma drainage devices) tubes.
SHELF LIFE	3 years						
STORAGE CONDITION	Store in a clean, dry environment at room temperature.						
ADVERSE EFFECTS	The incidence of post-AM transplant microbial infections is very low with dry amniotic membrane.						
CONTRA-INDICATIONS	Areas with active or latent infection AM is suitable for transplantation only from an unopened, undamaged package AM is intended for SINGLE-USE ONLY DO NOT RE-STERILIZE						