AmnioTek™
Processed Amniotic Membrane
Allograft Transplant for the Ocular Surface
SAFE - VIABLE - STERILE

AmnioTek™-C9
Processed Amniotic Membrane
Allograft Transplant for the Ocular Surface
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AmnioTek™-C9D
Processed Amniotic Membrane
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AmnioTek™-VET
Processed Amniotic Membrane
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AmnioTek™-G
Processed Amniotic Membrane
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AmnioTek™2
Processed Amniotic Membrane
Allograft Transplant for the Ocular Surface
SAFE - VIABLE - STERILE

AmnioTek™-C
Processed Amniotic Membrane
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AmnioTek®-Vision
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AmnioTek™, AmnioTek™-Vision, AmnioTek™-C, AmnioTek™-C9, AmnioTek™-C9D , AmnioTek™2, AmnioTek™-G & AmnioTek™-VET (hereby refered to "AM") is processed, dehydrated, sterilized human amniotic membrane allografts.

It is the innermost layer of the foetal embrane of the placenta. It is avascular and has an epithelial layer with a sub-adjacent avascular stromal layer. The amniotic membrane is one of the thickest membranes in the human body. The basement membrane is a thin layer composed of reticular fibers and closely resembles that of the conjunctiva.

The structural integrity, transparency and elasticity of the amniotic basement membrane make it currently the most widely accepted tissue replacement for ocular surface reconstruction. It is processed and sterilized in compliance with all the quality management systems to ensure efficacy and safety.

SURGICAL TECHNIQUES

Corneal surface reconstruction
AmnioTek™-C/Vision is used in patients requiring corneal surface reconstruction, it is a circular disk of 12mm which completely covers the cornea. One single piece of AmnioTek™-C/Vision 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 AmnioTek™-C/Vision sticks to the corneal surface by itself through capillary action. A BCL (Bandage Contact Lens) is applied over the graft. Also, fibrin glue tissue sealant can be used for better adherence.

Conjunctival surface reconstruction
A fibrin glue tissue sealant is recommended to anchor AmnioTek™ to the conjunctiva; also 9-0 or 10-0 vicryl sutures can be used due to rapid healing ability of the conjunctiva. The essence of the surgical technique in each of the indications is adequate dissection and removal of pathological sub conjunctival tissue.

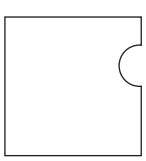
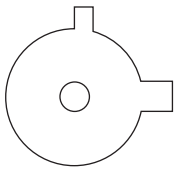
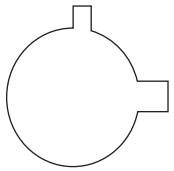
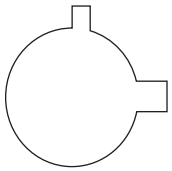
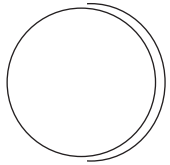
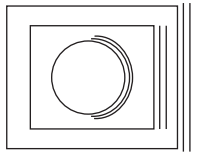
Ocular surface reconstruction
Extensive ocular surface damage seen in severe grades of injury, warrants sequential surface reconstruction. It is important to ensure that all fibrotic tissue is meticulously dissected.

AM is placed on the ocular surface and it is first anchored to the inner surface of the averted lower lid close to the lid margin using multiple interrupted ABSORBABLE sutures. The needles are passed from amniotic membrane through inferior fornix via the full thickness of eyelid and exit through the eyelid skin. A continuous encircling 10-0 nylon suture is used to anchor the membrane at the limbus or the peripheral 360° cornea. Also fibrin glue tissue sealant can be used for additional anchorage.

Glaucoma Surgery
AMT is used to cover the Glaucoma Drainage Device tube for prevention of possible conjunctival tube erosion using 8-0 vicryl sutures. Also can be used as a adjunct tissue with sclera or pericardium grafts or sole use of AMT for bleb revisions and covering for leaking blebs. Fibrin glue can also be used as an adjunct sealant.

Postoperative management
A broad-spectrum topical antibiotic is used for one to two weeks initially, until the epithelium heals. Topical steroids are used for six to eight weeks in tapering doses to reduce surface inflammation. Systemic immunosuppression is not required.

Discard all damaged, mishandled or potentially contaminated tissue.
DO NOT RE-STERILIZE

PRODUCTS	Amniotek™	Amniotek-Vision™	Amniotek-C™	Amniotek-C9™	Amniotek-C9D™	Amniotek-2™	AmnioTek-V™ (AmnioTek-VET™)	Amniotek-G™
INDICATION FOR USE	**Conjunctival Surface**: Pterygium Surgery , Chemical Burns, Conjunctival Chalasis, Leaking Bleb **Corneal Surface Reconstruction**: Non -Healing PED Neurotrophic Ulcers, Keratitis Sicca, Over -Lay 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	All Sizes Available Triple thickness 150 - 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. It can be placed in any orientation, as both sides are epithelial surfaces. 	Triple-layered graft. Both sides are stromal surfaces. 
PRINCIPLE OF SURGERY	Inlay or Graft Technique | Overlay or Patch Technique | Filling-in or Layered Technique							AmnioTek™-G is specifically prepared to cover the three available GDD (glaucoma drainage devices) tube.
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 I DO NOT RE-STERILIZE							

Processed by : BiogenTek Lifescience pvt ltd. 517, Industrial Area,
Phase IX, SAS Nagar 160062 (India)
Regd. Off : 3354, Sector 21D, Chandigarh 160022

LOT Lot number

Do not use if packaging is damaged

Consult instructions for Use

Double sterile barrier system

UDI Unique Device Identifier

Do not resterilize

Prescription Only

STERILE R Sterilized using gamma

Do not reuse

Caution

REF Product Code

Use by date

Keep Dry