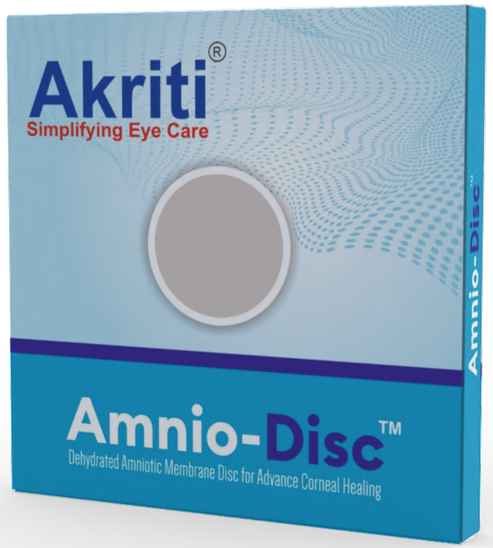
Akriti®

Simplifying Eye Care

Amnio-Disc™

Dehydrated Amniotic Membrane Disc for Advance Corneal Healing



Instructions for Use Amnio-Disc TM

Amnio-Disc™ is processed, 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

Amnio-Disc™ is used in patients requiring corneal surface reconstruction, it is a round size varies from 6cm,
8cm and 10 cm, which covers the cornea. One single piece of Amnio-Disc TM 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. Amnio-Disc™ 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 Amnio-Disc™ 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. Amnio-Disc™ 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

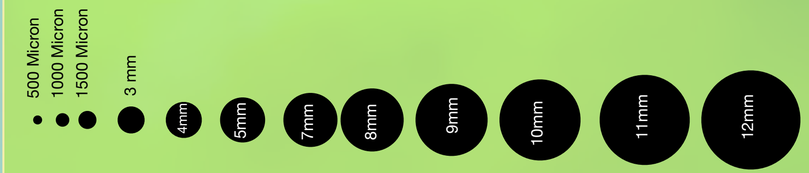
Amnio-Disc™ is used to cover the Glaucoma Drainage Device tube for prevention of possible conjunctival tube erosion using 8-0 vicryl sutures. Also can be used as a adjunct tissue with sclera or pericardium grafts or sole use of AMT for bleb revisions and covering for leaking blebs. Fibri glue can also 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 immuno-suppression is not required.

Discard all damaged, mishandled or potentially contaminated tissue.

Sizes :



Approvals:

ISO 9001 REGISTERED

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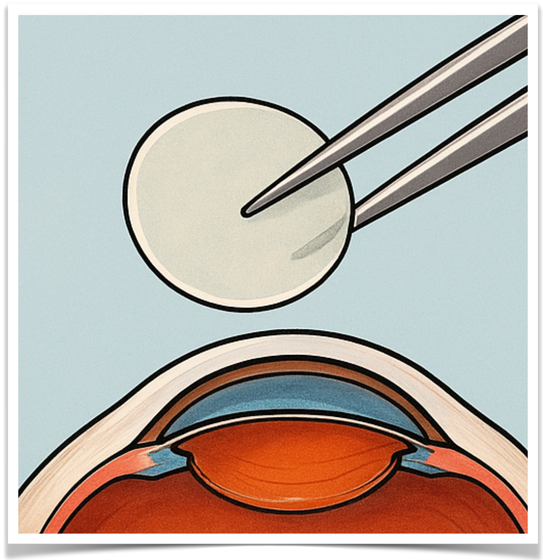
Amnio-Disc™

Dehydrated Amniotic Membrane Disc for Advance Corneal Healing

Amnio-Disc™: Precision-Engineered for Optimal Surgical Application

Designed for advanced ophthalmic and wound care procedures, **Amnio-Disc**™ is a meticulously crafted, single-layer amnion graft, precision-cut into an ellipse or disc shape. This configuration is optimized to **maximize the clinically usable surface area**, ensuring broad coverage while minimizing pre-operative handling. Its streamlined design supports efficient graft placement, enhancing procedural precision and reducing surgical complexity.



Amnio-Disc: Precision-Cut Amniotic Tissue for Ophthalmic Applications

Amnio-Disc™ is a meticulously crafted single-layer amnion, shaped as an ellipse or disc to **maximize clinically usable surface area** while minimizing pre-operative handling. Designed for ophthalmic applications, it offers a versatile solution for promoting tissue repair and optimizing surgical outcomes.

Setting new standards:

- **Acellular & Biocompatible** – Purified to eliminate cellular components, ensuring safe and effective tissue integration.
- **Sterile & Ready-to-Use** – Processed under strict quality control for a **contamination-free surgical experience**.
- **Extended Shelf Life (5 Years)** – Maintains structural integrity and efficacy **without degradation** over time.
- **Room Temperature Storage** – Eliminates the need for specialized refrigeration, enhancing ease of handling and accessibility.
- **Precision-Configured for Consistency** – Each graft is **meticulously cut and shaped** for uniformity, ensuring predictable surgical outcomes.

Amnio-Disc™ : Advanced Amniotic Membrane for Ocular Healing Applications

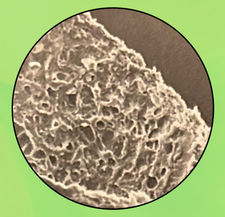
Engineered for precision and therapeutic efficacy, **Amnio-Disc™** harnesses the regenerative power of amniotic tissue to **enhance healing, minimize complications, and optimize surgical outcomes**.

Key Functional Benefits

- **Potent Anti-Inflammatory Action** – Reduces post-surgical inflammation, soothing damaged tissue and promoting recovery.
- **Natural Anti-Microbial Properties** – Helps create a **biologically protective barrier**, minimizing infection risks.
- **Prevents Excessive Scarring** – Regulates fibroblast activity to **ensure smooth tissue regeneration** while preventing abnormal scar formation.
- **Reduces Adhesion Formation** – Supports optimal healing by limiting unwanted tissue adhesions, preserving functionality.
- **Accelerates Healing & Tissue Repair** – Enhances **epithelialization**, fostering faster recovery and improved patient outcomes.
- **Boosts Fibrogenesis & Angiogenesis** – Stimulates **collagen synthesis and vascular growth**, ensuring robust tissue integration and regeneration.

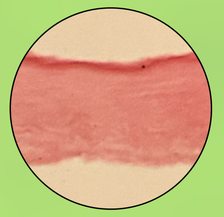
Amnio-Disc™ represents a breakthrough in **biological wound management and ophthalmic care**, empowering clinicians with **a superior, bioactive graft that aligns with natural healing processes**.

Amnio-Disc™ is designed to empower **surgeons and clinicians with a reliable, advanced solution**, setting a new benchmark in **utility, safety, and clinical effectivenes**



Hematoxylin and eosin (H&E) staining of processed tissue shows the decellularization of a two-layered structure still containing preserved ECM.

Scanning Electron Microscopy of Surface morphology & topology.



Coll IV staining indicating preserved basement membrane Structure.

Key features:

ISO 10993 Biocompatibility Testing
Sterilization Validation
Lot to Lot Sterility Testing
Viral Inactivation Validation
Robust In vitro Comparative Characterization including Residual DNA Quantification, Biomechanical (uniaxial, stuture pullout, ball burst), SEM, Histological, Immunohistochemical, SDS Page, cell culture analysis & Degradation Analysis

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