

Akriti[®] Simplifying Eye Care

Amnio-Patch[™]

Dehydrated Amnio-Patch for Advance Wound Healing Dressing Patch



SURGICAL TECHNIQUES

Instructions for Use for Amnio-patch[™] In Ophthalmology

Amnio-Patch[™] 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-Patch[™] is used in patients requiring corneal surface reconstruction, it is a square size varies from 3 cm X 3 cm, 5 cm X 5 cm, which completely covers the cornea or complete eye. One single piece of Amnio-patch[™] 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-patch[™] 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-patch[™] 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-patch[™] 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-patch[™] 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 immuno-suppression is not required.

Instructions for Use of Amnio-Patch[™] in Wound Healing:

Amnio-Patch[™] is a specialised wound healing patch derived from amniotic membrane, known for its regenerative properties. It serves as a biological scaffold that promotes tissue repair and reduces inflammation. Some key benefits include:

- **Enhanced Healing:** Provides essential growth factors that accelerate wound closure.
- **Anti-Inflammatory Properties:** Reduces inflammation and pain at the wound site.
- **Scar Minimization:** Helps prevent excessive fibrosis and scarring.
- **Antimicrobial Barrier:** Protects against infections while supporting natural healing.
- **Versatile Applications:** Used in chronic wounds, burns, surgical sites, and trauma cases.

Amnio-Patch[™] have been successfully used in diabetic ulcers, venous leg ulcers, and post-surgical wound care. Their ability to retain moisture and support epithelialization makes them a valuable tool in regenerative medicine.

Indication for use in Wound:

- **Chronic Wounds:** Used in diabetic foot ulcers, venous leg ulcers, and pressure sores to accelerate healing.
- **Burns:** Helps in reducing pain and promoting epithelialization in partial-thickness burns.
- **Surgical Wounds:** Applied in post-surgical sites to minimize scarring and enhance tissue repair.
- **Traumatic Wounds:** Effective in treating complex wounds with exposed tendons or bones.
- **Lower Extremity Repair:** Used in fasciitis and tendonitis cases to support tissue regeneration.

Discard all damaged, mishandled or potentially contaminated tissue.

Approvals:



Contact Us:



Akriti Ophthalmic Pvt Ltd

M34,M35, M36

Medical Devices Park

Sultanpur Village, Pathancheru Mandal,
Hyderabad-502319

Telangana State

India

Care : +91 984 919 3447

+91 916 000 3972

Email: sales@akriti.co.in

Web: www.akriti.co.in

Amnio-Patch™

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Amniotic Membrane: A Versatile Solution for Regenerative Medicine

The amniotic membrane is a powerful biological material known for its regenerative, anti-inflammatory, and anti-scarring properties. Its applications span multiple medical disciplines, providing effective solutions for tissue repair and healing.

Key Medical Applications

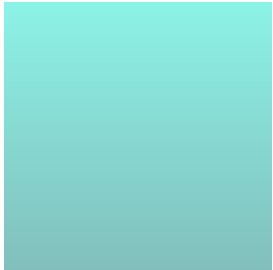

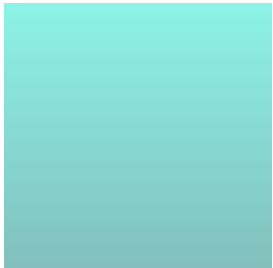
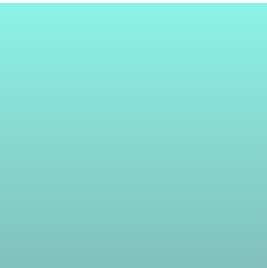
Ophthalmology

- Supports ocular surface reconstruction in conditions such as corneal ulcers, conjunctival defects, and pterygium surgery.
- Promotes epithelial healing and reduces inflammation in cases of severe dry eye disease and chemical burns.

Wound Healing

- Accelerates tissue regeneration in chronic wounds, diabetic ulcers, and pressure sores.
- Provides a protective barrier and reduces fibrosis in burn injuries.

By leveraging the unique biological attributes of the amniotic membrane, healthcare professionals can offer enhanced healing and improved patient outcomes.

SKU	
	AOPL/AMD/A2.D - 2 cm X 2 cm 50 Micron,
	AOPL/AMD/A3.D - 3 cm X 3 cm 50 Micron,
	AOPL/AMD/A4.D - 4 cm X 4 cm 50 Micron,
	AOPL/AMD/A5.D - 5 cm X 5 cm 50 Micron,
	AOPL/AMD/A6.D - 6 cm X 6 cm 50 Micron,
	AOPL/AMD/A7.D - 10 cm X 6 cm 50 Micron,
	AOPL/AMD/A8.D - 8 cm X 6 cm 50 Micron,
	AOPL/AMD/A9.D - 10 cm X 4 cm 50 Micron,
	AOPL/AMD/A10.D - 1 cm X 1 cm 100 Micron,
	AOPL/AMD/A11.D - 2 cm X 2 cm 100 Micron with chorion,
	AOPL/AMD/A12.D - 3 cm X 3 cm 100 Micron with chorion,
	AOPL/AMD/A13.D - 4 cm X 4 cm 100 Micron with chorion,
	AOPL/AMD/A14.D - 5 cm X 5 cm 100 Micron with chorion,
	AOPL/AMD/A15.D - 6 cm X 6 cm 100 Micron with chorion,
	AOPL/AMD/A16.D - 10 cm X 6 cm 100 Micron with chorion,
	AOPL/AMD/A17.D - 8 cm X 6 cm 100 Micron with chorion,
	AOPL/AMD/A18.D - 10 cm X 4 cm 100 Micron with chorion,
	AOPL/AMD/A19.D - 6 mm round 50 Micron,
	AOPL/AMD/A20.D - 10 mm round 50 micron,
	AOPL/AMD/A21.D - 6 mm round 100 Micron with chorion,
	AOPL/AMD/A22.D - 10 mm round 100 Micron with chorion,
	AOPL/AMD/A23.D - 20X24 cm

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-Patch™ : Advanced Amniotic Membrane for Ocular Healing Applications

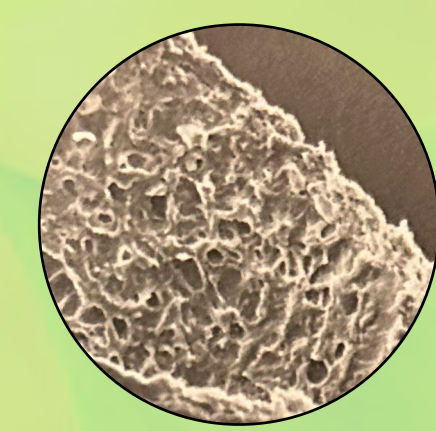
Engineered for precision and therapeutic efficacy, **Amnio-Patch™** harnesses the regenerative power of amniotic tissue to **enhance healing, minimize complications, and optimize surgical outcomes**.

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

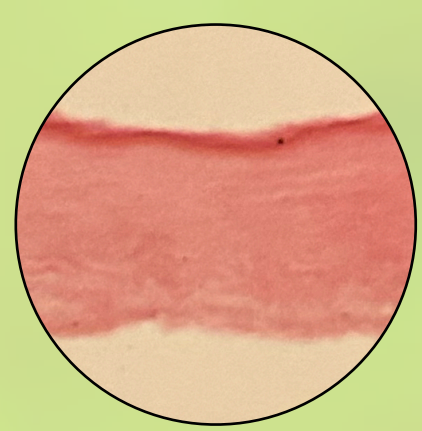
Amnio-Disc™ is designed to empower **surgeons and clinicians with a reliable, advanced solution**, setting a new benchmark in **utility, safety, and clinical effectiveness**.



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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