

Amnio-Patch™

OCULAR SURFACE ALLOGRAFT

DEHYDRATED HUMAN AMNIOTIC MEMBRANE

Amnio-Patch™ is a **dehydrated human amniotic membrane allograft** intended to provide temporary coverage and protection to the ocular surface. Processed under aseptic conditions and terminally sterilised, it maintains the native membrane architecture, enabling room-temperature storage and straightforward clinical deployment. This document presents a comprehensive clinical and regulatory overview for ophthalmologists, ocular surgeons, and regulatory reviewers.



Intended Use and Homologous Function

Amnio-Patch™ is indicated as a **protective covering for the ocular surface** in clinical situations where the epithelium is compromised, disrupted, or requires temporary structural support. It is designed for placement directly on the corneal surface or beneath the eyelids, providing broad coverage appropriate to a variety of ocular surface pathologies including persistent epithelial defects, chemical or thermal injuries, and post-surgical wound protection.

This intended use is defined as **homologous** – consistent with the natural function of the amniotic membrane in its native anatomical environment. In vivo, the amniotic membrane serves as a protective, structural tissue layer with well-established roles in supporting epithelial repair, modulating inflammation, and providing a basement membrane scaffold. Amnio-Patch™ replicates this function in the ocular context, applying the inherent structural and biological properties of the native tissue to the corneal and conjunctival surface.

The allograft does not rely on living cells to exert its effect. Its function is primarily **mechanical and structural** – providing a physical barrier, retaining moisture, and supporting the underlying epithelium during the repair phase. This is consistent with the tissue's original relevant characteristics and aligns with the homologous use standard under 21 CFR 1271.

Core Functional Alignment

- **Protective Barrier**
Physical coverage for compromised epithelium
- **Moisture Retention**
Maintains a moist healing environment
- **Structural Scaffold**
Basement membrane support for epithelial repair
- **Homologous Use**
Mirrors native amniotic membrane function

Description and Processing of the Allograft

Amnio-Patch™ is a **single-use, devitalised, dehydrated amniotic membrane allograft** processed entirely under aseptic conditions. Terminal sterilisation is achieved via gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6} , providing a high degree of microbiological safety. The tissue is processed with the express purpose of preserving the **native structural architecture** of the amniotic membrane – including the epithelial basement membrane and stromal collagen framework – without altering its original relevant properties.

Processing Standards

Aseptic Processing

All handling conducted under controlled, aseptic conditions throughout manufacturing

Devitalisation

Cells are devitalised to minimise immunogenic potential while retaining matrix integrity

Gamma Irradiation

Terminal sterilisation to SAL 10^{-6} ensuring microbiological safety

Dehydration

Controlled dehydration preserves native membrane architecture and enables ambient storage

Minimal Manipulation Criteria

Processing methods are strictly limited to those that **preserve structural characteristics** without altering the original relevant biological properties of the amniotic membrane. The tissue is **not combined** with any drugs, biologics, or devices. Any ancillary aids – such as a bandage contact lens or eyelid closure – are employed separately by the clinician to maintain positioning after placement and do not constitute combination with the allograft.

- ☐ The dehydration process preserves native membrane architecture, enabling room-temperature storage and extending shelf life without refrigeration.

Donor Eligibility and Tissue Safety

All tissue used in the manufacture of Amnio-Patch™ is recovered from **healthy, consenting donors** following live birth, in full compliance with applicable regulatory requirements. A comprehensive, **Medical Director-supervised eligibility evaluation** is conducted for every donor, encompassing clinical record review, physical examination findings, and results of required laboratory testing. The programme is designed to meet the highest standards of tissue safety prior to any manufacturing activity.

Medical & Behavioural History

Thorough assessment of donor medical history and behavioural risk factors in line with regulatory guidance

Infectious Disease Testing

Required serology and PCR testing for relevant communicable disease agents as mandated under 21 CFR 1271 Subpart C

Physical Examination

Review of physical examination findings and all available medical records at the time of donation

Regulatory Compliance

Full compliance with **21 CFR 1271 Subpart C** Donor Eligibility and Current Good Tissue Practice (CGTP) requirements

Manufactured exclusively from healthy, consenting donors, the safety profile of Amnio-Patch™ is underpinned by rigorous qualification protocols at every stage of tissue recovery, processing, and release. Compliance with **21 CFR Part 1271 (CGTP)** governs all manufacturing activities, providing a robust regulatory framework for tissue safety and traceability.



Clinical Applications

Amnio Patch™ is intended for single use by qualified medical professionals as a dependable, biocompatible solution for a wide range of ocular surface management needs. It provides a protective, biologically active surface that supports epithelial repair, modulates inflammation, and enhances patient comfort – particularly valuable when epithelial integrity is compromised or when extended therapeutic coverage is required.

The membrane's unique capacity to retain the HC HA/PTX3 complex translates directly into clinically meaningful outcomes: suppression of destructive inflammatory cascades, inhibition of fibrotic remodelling, and acceleration of epithelial regeneration. These mechanisms underpin its broad applicability across both acute and chronic ocular surface disease states.



Stevens-Johnson Syndrome (SJS)

Early and subacute phases – provides protective coverage and modulates acute inflammatory destruction of the conjunctival and corneal epithelium.



Post-operative Reconstruction

Supports ocular and conjunctival surface reconstruction following anterior segment surgical procedures, promoting organised re-epithelialisation.



Chemical Injury

Prophylactic management in chemical injury cases – early application reduces symblepharon formation and preserves limbal stem cell populations.



Mild to Moderate Dry Eye Disease

Delivers sustained biological coverage to the ocular surface, supplementing tear film function and reducing epitheliopathy associated with aqueous-deficient or evaporative dry eye.



Persistent Epithelial Defects (PEDs)

Provides a biologically active substrate that promotes re-epithelialisation in recalcitrant defects unresponsive to conventional therapy.



Corneal Ulcers & Neurotrophic Keratitis

Addresses corneal ulcers associated with severe dry eye and Stage 1 neurotrophic keratitis, supporting healing in the context of impaired corneal innervation and trophic support.



Recurrent Corneal Erosion (RCE)

Stabilises the epithelial-stromal interface and reduces erosion frequency through anti-inflammatory and matrix-remodelling mechanisms.



Band Keratopathy (Post-debridement)

Post-procedural application following chelation and debridement, facilitating surface healing and reducing post-operative pain and inflammation.



Superficial Punctate Keratitis (SPK)

Reduces epithelial staining and symptom burden in SPK through biological modulation of surface inflammation and promotion of epithelial integrity.

Available Sizes and Product Configurations

Amnio-Patch™ is available in a comprehensive range of sizes and configurations to accommodate the full spectrum of ocular surface presentations – from small localised corneal defects to large-area conjunctival and scleral coverage. All units are terminally sterilised to SAL 10⁻⁶, individually packaged, and designated for **single use only**. Two primary configurations are offered: **Amnion-only** (approximately 50 microns) and **Amnion + Chorion** (approximately 100 microns), the latter providing additional structural thickness where clinically required.

Available Sizes

Amnio Patch™ is available in an extensive range of configurations to match the full spectrum of ocular surface presentations – from focal epithelial defects requiring precision coverage to diffuse bilateral pathology necessitating large-format grafting. Two thickness profiles are available: 50 micron (amnion only) and 100 micron (amnion with chorion), providing flexibility in clinical decision-making based on the depth of pathology and the degree of structural support required.

All sizes are terminally sterilised to SAL 10⁻⁶, individually packaged, and designated for single-use application only. The 100 micron with chorion configurations offer enhanced structural rigidity for cases requiring greater mechanical support or deeper tissue interface coverage.

30-50 MICRON – AMNION ONLY

Catalogue Code	Dimensions	Configuration
AOPL/AMD/A10.D	1 cm x 1 cm	Amnion Only
AOPL/AMD/A2.D	2 cm x 2 cm	Amnion Only
AOPL/AMD/A3.D	3 cm x 3 cm	Amnion Only
AOPL/AMD/A4.D	4 cm x 4 cm	Amnion Only
AOPL/AMD/A5.D	5 cm x 5 cm	Amnion Only
AOPL/AMD/A6.D	6 cm x 6 cm	Amnion Only
AOPL/AMD/A7.D	10 cm x 6 cm	Amnion Only
AOPL/AMD/A8.D	8 cm x 6 cm	Amnion Only
AOPL/AMD/A9.D	10 cm x 4 cm	Amnion Only
AOPL/AMD/A19.D	6 cm round	Amnion Only
AOPL/AMD/A20.D	10 cm round	Amnion Only
AOPL/AMD/A23.D	20 x 24 cm	Amnion Only

70-100 MICRON – AMNION WITH CHORION

Catalogue Code	Dimensions	Configuration
AOPL/AMD/A11.D	2 cm x 2 cm	Amnion + Chorion
AOPL/AMD/A12.D	3 cm x 3 cm	Amnion + Chorion
AOPL/AMD/A13.D	4 cm x 4 cm	Amnion + Chorion
AOPL/AMD/A14.D	5 cm x 5 cm	Amnion + Chorion
AOPL/AMD/A15.D	6 cm x 6 cm	Amnion + Chorion
AOPL/AMD/A16.D	10 cm x 6 cm	Amnion + Chorion
AOPL/AMD/A17.D	8 cm x 6 cm	Amnion + Chorion
AOPL/AMD/A18.D	10 cm x 4 cm	Amnion + Chorion
AOPL/AMD/A21.D	6 cm round	Amnion + Chorion
AOPL/AMD/A22.D	10 cm round	Amnion + Chorion

Ordering Note: All Amnio Patch™ sizes are individually packaged, terminally sterilised (SAL 10⁻⁶), and designated for single-use application only. Contact your clinical procurement representative for volume pricing, institutional supply agreements, and product availability confirmation.

www.akritiophthalmic.com

Regulatory Positioning

Amnio-Patch™ is positioned for regulation solely under **Section 361 of the Public Health Service (PHS) Act** and **21 CFR Part 1271**, qualifying as a Human Cells, Tissues, and Cellular and Tissue-Based Product (HCT/P) that does not require pre-market approval or clearance. This regulatory classification is supported by satisfaction of all applicable criteria under 21 CFR 1271.10(a).

The product is **minimally manipulated**: the dehydration and sterilisation processes preserve – rather than alter – the original relevant characteristics of the amniotic membrane. It is intended solely for **homologous use**, replicating the membrane's natural protective and structural function on the ocular surface. It does **not rely on living cells** for its principal function and is **not combined** with any non-permitted drugs, biologics, or devices. Its mechanism of action is entirely **local**, with no systemic effect anticipated or intended.

All manufacturing activities comply with the **Current Good Tissue Practice (CGTP)** requirements of 21 CFR Part 1271, and donor eligibility is established in accordance with **21 CFR 1271 Subpart C**. This regulatory framework provides an established, risk-proportionate pathway for tissue-based products that perform a structural or protective function consistent with their native biological role.



Minimally Manipulated

Dehydration preserves original relevant characteristics



Homologous Use

Mirrors native amniotic membrane protective function



No Reliance on Living Cells

Devitalised; function is structural and mechanical



Not Combined

Not combined with non-permitted drugs, devices, or biologics



Local Action Only

Acts locally; no systemic effect intended or expected



CGTP Compliant

Full compliance with 21 CFR Part 1271 CGTP requirements

Amnio-Patch™ meets all criteria under **21 CFR 1271.10(a)** for regulation solely under Section 361 PHS Act – minimally manipulated, homologous use, no living cells, not combined with non-permitted articles, local action, and full CGTP compliance.

Manufacturer Information

Akriti Ophthalmic Pvt Ltd

Amnio-Patch™ is manufactured by **Akriti Ophthalmic Pvt Ltd**, a dedicated ophthalmic medical device manufacturer operating from a purpose-built facility within the Medical Devices Park, Hyderabad, India. The facility is designed and operated to meet the stringent requirements of **Current Good Tissue Practice (CGTP)** as defined under 21 CFR Part 1271, with all manufacturing activities conducted under the oversight of a qualified Medical Director.

The manufacturing site is located at **M34, M35, M36, Medical Devices Park, Sultanpur Village, Pathancheru Mandal, Hyderabad - 502319, Telangana State, India**. All products are released only after satisfying the complete quality and donor eligibility criteria established in the manufacturer's quality management system.

Regulatory Framework

21 CFR Part 1271 – Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); Section 361 PHS Act

Sterilisation Standard

Terminal gamma irradiation to Sterility Assurance Level (SAL) 10^{-6}

Storage Condition

Room temperature in original sealed packaging; no refrigeration required

Single Use

All units individually packaged; strictly for single use; do not re-sterilise or reuse

Manufactured By :

Akriti Ophthalmic Pvt Ltd

**M34, M35, M36 Medical Devices Park Sultanpur Village,
Pathancheru Mandal, Hyderabad-502319, Telangana State India**

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Amnio-Patch-C™

Cryopreserved Amniotic Membrane for Advanced Ocular Surface Regeneration

Akriti[®]
Simplifying Eye Care



Cornea & Tissue Regeneration **Amnio-Patch-C™** Cryogenic Amniotic Membrane Dressing

Supports ocular surface healing, anti-inflammatory, anti-scarring. Bioactive scaffold.

Key Features: Cryogenic, 50/100 microns, Sterile, Individually Sealed, -20°C Stable.

Clinical Applications: Epithelial Defects, Chemical Burns, Pterygium, Dry Eye.

Quality & Compliance: ISO 13485, CDSCO, International Safety.



Simplifying Eyecare by Innovation

Amnio-Patch-C™ is a cryogenically preserved human amnion membrane allograft engineered to retain the highest level of native biological activity – including viable extracellular matrix components and key regenerative cytokines. Designed for direct ocular surface or sub-tarsal placement, it delivers maximum therapeutic potency, exceptional biocompatibility, and reliable clinical performance across a wide range of corneal and conjunctival surface disorders. This document provides ophthalmic surgeons and procurement specialists with a comprehensive clinical and technical overview of the product.

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Product Highlights

Amnio-Patch-C™ is developed to meet the exacting needs of surgeons who require **fresh-tissue-like biological activity** with the convenience of a ready-to-use cryogenic graft. Every aspect of its design – from donor sourcing and processing to terminal sterilisation – is optimised to deliver consistent, reproducible clinical outcomes. The following highlights define the product's core engineering and regulatory credentials.

Cryogenic Preservation

Maintains native ECM, growth factors, HC-HA/PTX3 complex, and anti-inflammatory proteins – closely mimicking fresh amniotic tissue in biological behaviour.

High Biological Potency

Retains the full spectrum of amnion-derived therapeutic molecules supporting anti-inflammatory activity, anti-scarring modulation, epithelial regeneration, and pain reduction.

Flexible Patch Design

Soft, conforming membrane designed for direct corneal placement, sub-tarsal placement under eyelids, and conjunctival surface reconstruction.

Terminal Sterilisation

Gamma-irradiated to a Sterility Assurance Level of 10^{-6} , ensuring microbiological safety while preserving biological activity throughout shelf life.

CGTP & CGMP Compliant

Aseptically processed and cryopreserved under strict U.S. federal tissue standards, ensuring regulatory traceability and institutional procurement confidence.

Consenting Donor Sourcing

Derived exclusively from healthy, consenting donors screened under a rigorous Medical Director-supervised protocol encompassing infectious disease testing, behavioural risk assessment, and full laboratory data evaluation.

Multiple Patch Sizes

Available in a comprehensive range of diameters and thicknesses to suit diverse ocular surface presentations and surgical approaches.

Product Advantages

The cryogenic preservation methodology employed in Amnio-Patch-C™ confers a decisive biological advantage over dehydrated amniotic membrane products. By maintaining the membrane's native architecture at ultra-low temperatures, the processing protocol safeguards the structural and biochemical integrity of all key therapeutic components. Surgeons choosing Amnio-Patch-C™ benefit from a clinically potent graft that performs closer to fresh amniotic tissue than any dehydrated alternative.

Superior Biological Activity — The Cryogenic Advantage

Cryopreservation preserves the **HC-HA/PTX3 complex**, native collagen matrix, regenerative cytokines, and anti-angiogenic factors. This results in maximum therapeutic potency, surpassing dehydrated membranes in biological performance metrics across all key regenerative pathways.

Enhanced Healing Response

Supports rapid epithelialization, reduces inflammation, and modulates fibrosis – making it the graft of choice for severe or non-healing ocular surface disease where biological potency is the primary clinical requirement.

Natural Adhesive & Cohesive Properties

Adheres smoothly to the ocular surface or remains stable under the eyelids by virtue of its natural cohesive matrix, reducing dependence on supplementary fixation in the majority of cases.

Sterile & Single-Use

Terminally sterilised via gamma irradiation to SAL 10⁻⁶. Single-use packaging eliminates cross-contamination risk and simplifies operating theatre workflow and inventory management.

 **Micro filtration**  **50µm**  **18**  **100%**

Sterility Assurance Level

Terminal sterilisation via gamma irradiation

Standard Thickness

Precision-controlled membrane thickness

Available SKUs

Sizes from 1×1 cm to 10×6 cm

Single-Use

Individually packaged for safety and sterility

Clinical Applications

Amnio-Patch-C™ is intended for single use by qualified medical professionals as a potent, biologically active solution for complex ocular surface management. The graft provides a **protective, regenerative scaffold** that accelerates healing and improves patient comfort across a spectrum of acute and chronic conditions. Its exceptional conformability makes it suitable for a wide range of anatomical placements and disease severities. The following conditions represent primary indications where clinical evidence and surgical experience support its use.

Primary Indications

→ Stevens–Johnson Syndrome (SJS/TEN)

Acute and chronic phase management of severe conjunctival and corneal involvement with aggressive anti-inflammatory and regenerative coverage.

→ Chemical or Thermal Injuries

Acute intervention following alkali or acid burns and thermal trauma; reduces neovascularisation and promotes structured re-epithelialization.

→ Persistent Epithelial Defects (PEDs)

Non-healing defects resistant to conventional therapy benefit from the full biological potency of cryopreserved amnion scaffold.

→ Neurotrophic Keratitis (Stage 1–2)

Supports trophic healing in compromised corneas where standard epitheliotropic treatments have failed to achieve closure.

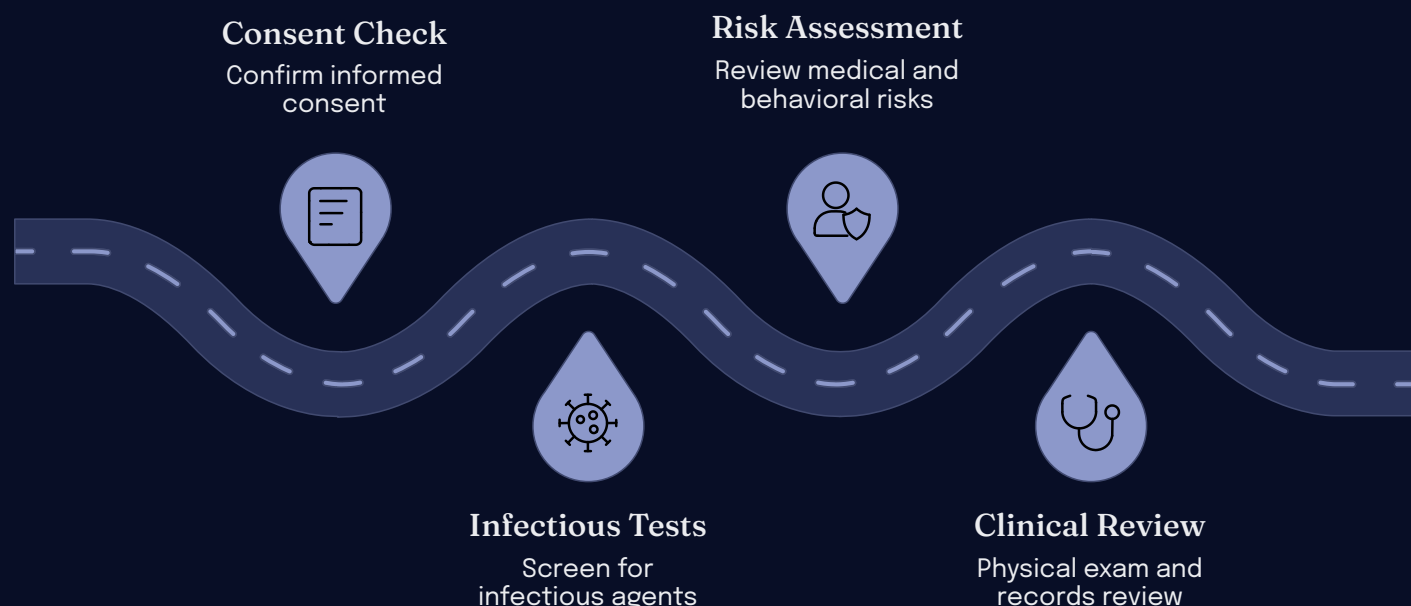
Additional Indications

- **Severe Dry Eye Disease** – sub-tarsal placement for sustained anti-inflammatory and lubricating effect
- **Corneal Ulcers (non-infectious)** – scaffold support for stromal regeneration and epithelial closure
- **Recurrent Corneal Erosion (RCE)** – basement membrane reinforcement to reduce recurrence frequency
- **Limbal Stem Cell Deficiency** – adjunctive use to support LSCT procedures and reduce conjunctivalisation
- **Band Keratopathy (post-debridement)** – post-EDTA chelation surface coverage to accelerate re-epithelialization
- **Post-surgical Reconstruction** – conjunctival and ocular surface reconstruction following pterygium excision, tumour resection, or symblepharon release

- ☐ Amnio-Patch-C™ is particularly valuable in **acute ocular surface emergencies** where immediate, high-potency biological intervention is required to prevent irreversible structural damage.

Donor Screening & Safety Standards

Every Amnio-Patch-C™ unit is derived from human birth tissue obtained from healthy, consenting donors, each undergoing a comprehensive Medical Director-supervised evaluation protocol. The donor screening programme is designed to meet and exceed U.S. federal CGTP and CGMP requirements, ensuring that every allograft released for clinical use carries the highest possible assurance of safety, consistency, and biological quality. No graft is cleared for processing without satisfactory completion of every screening domain.



This stringent, end-to-end protocol ensures **consistent quality, safety, and clinical reliability** across every unit of Amnio-Patch-C™. Infectious disease testing covers all FDA-mandated markers. Medical and behavioural risk assessment captures epidemiological exposures not detectable by serology alone. Physical examination and full medical record review provide contextual verification of donor health status. Laboratory data evaluation confirms haematological and serological profiles prior to final Medical Director sign-off. This multi-layered approach reflects the manufacturer's commitment to patient safety and institutional accountability.



Informed Consent

Full verification of voluntary, informed donor consent obtained prior to tissue collection, in accordance with federal requirements.



Infectious Disease Testing

Comprehensive mandatory serology panel covering all FDA-required communicable disease markers, with zero tolerance for reactive results.



Behavioural Risk Assessment

Structured interview and documentation review to identify epidemiological risk factors not captured by laboratory screening alone.



Laboratory Data Evaluation

Haematological and serological profile review completed prior to final Medical Director release authorisation for processing.

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Application Instructions

Amnio-Patch-C™ is engineered for efficient, surgeon-friendly use. The following step-by-step protocol outlines the recommended procedure for thawing, preparation, and placement. Adherence to aseptic technique throughout is mandatory. The membrane's natural cohesive matrix typically provides sufficient adhesion for most indications; supplementary fixation methods are available where anatomical or clinical factors necessitate additional stability.

01

Thawing

Remove the cryogenic Vial from storage. Allow to thaw at room temperature for the manufacturer-specified duration. Do not accelerate thawing via heat sources.

02

Inspect Packaging

Check for complete seal integrity and accurate labelling prior to opening. Do not use the product if sterility is compromised or the label is illegible.

03

Introduce to Sterile Field

Transfer the Vial to the sterile field using appropriate aseptic technique. Maintain sterile conditions for all subsequent steps.

04

Retrieve the Allograft

Open the inner membrane packaging and remove the amnion membrane carefully using sterile forceps, avoiding excessive tension or tearing.

05

Prepare for Placement

Confirm membrane orientation (stromal side down, epithelial side up). Hydrate briefly in sterile saline if required to optimise conformability.

06

Apply to Ocular Surface or Under Eyelids

For **corneal use**: place directly over the epithelial defect. For **sub-tarsal use**: slide under upper and lower eyelids to achieve full conjunctival surface coverage.

07

Confirm Stability

Natural adhesion is usually sufficient. Suturing or fibrin glue may be used as needed. A bandage contact lens (BCL) may be applied over the graft if additional mechanical stability is desired.

- ❏ **Clinical Note:** Membrane orientation is a critical step. The **stromal side** (rough surface) should be placed against the host tissue to optimise biological integration and epithelial migration over the graft surface.

Available Sizes & Ordering Information

Amnio-Patch-C™ is available in **18 catalogue configurations** across two thickness profiles – 50 Micron and 100 Micron – spanning patch dimensions from 1×1 cm to 10×6 cm. This breadth of sizing ensures appropriate coverage for the full spectrum of ocular surface presentations, from focal persistent epithelial defects to extensive conjunctival reconstruction. All sizes are cryopreserved, terminally sterilised to SAL 10⁻⁶, individually packaged, and supplied as single-use units. Procurement teams should note that each SKU carries a unique catalogue reference for order management and inventory tracking.

50 Micron Variants

Catalogue Ref.	Dimensions	Thickness
AOPL/AMD/A1	1 cm × 1 cm	50 µm
AOPL/AMD/A2	2 cm × 2 cm	50 µm
AOPL/AMD/A3	3 cm × 3 cm	50 µm
AOPL/AMD/A4	4 cm × 4 cm	50 µm
AOPL/AMD/A5	5 cm × 5 cm	50 µm
AOPL/AMD/A6	6 cm × 6 cm	50 µm
AOPL/AMD/A7	10 cm × 6 cm	50 µm
AOPL/AMD/A8	8 cm × 6 cm	50 µm
AOPL/AMD/A9	10 cm × 4 cm	50 µm

100 Micron Variants

Catalogue Ref.	Dimensions	Thickness
AOPL/AMD/A10	1 cm × 1 cm	100 µm
AOPL/AMD/A11	2 cm × 2 cm	100 µm
AOPL/AMD/A12	3 cm × 3 cm	100 µm
AOPL/AMD/A13	4 cm × 4 cm	100 µm
AOPL/AMD/A14	5 cm × 5 cm	100 µm
AOPL/AMD/A15	6 cm × 6 cm	100 µm
AOPL/AMD/A16	10 cm × 6 cm	100 µm
AOPL/AMD/A17	8 cm × 6 cm	100 µm
AOPL/AMD/A18	10 cm × 4 cm	100 µm

Cryopreserved

All SKUs maintained at cryogenic temperatures to preserve maximum biological activity until point of use.

Sterilised

Every unit is processed using validated microfiltration-based sterilisation methods and verified through comprehensive quality and clinical testing, ensuring the highest sterility assurance standards

Individually Packaged

Each graft supplied in a dedicated, labelled pack for safe, traceable single-use deployment.

Single-Use Only

Non-reusable by design; discard after use in accordance with institutional biohazard waste protocols.

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Amnio Disc™

Dehydrated Human Amniotic Membrane Allograft – 361 HCT/P under 21 CFR 1271

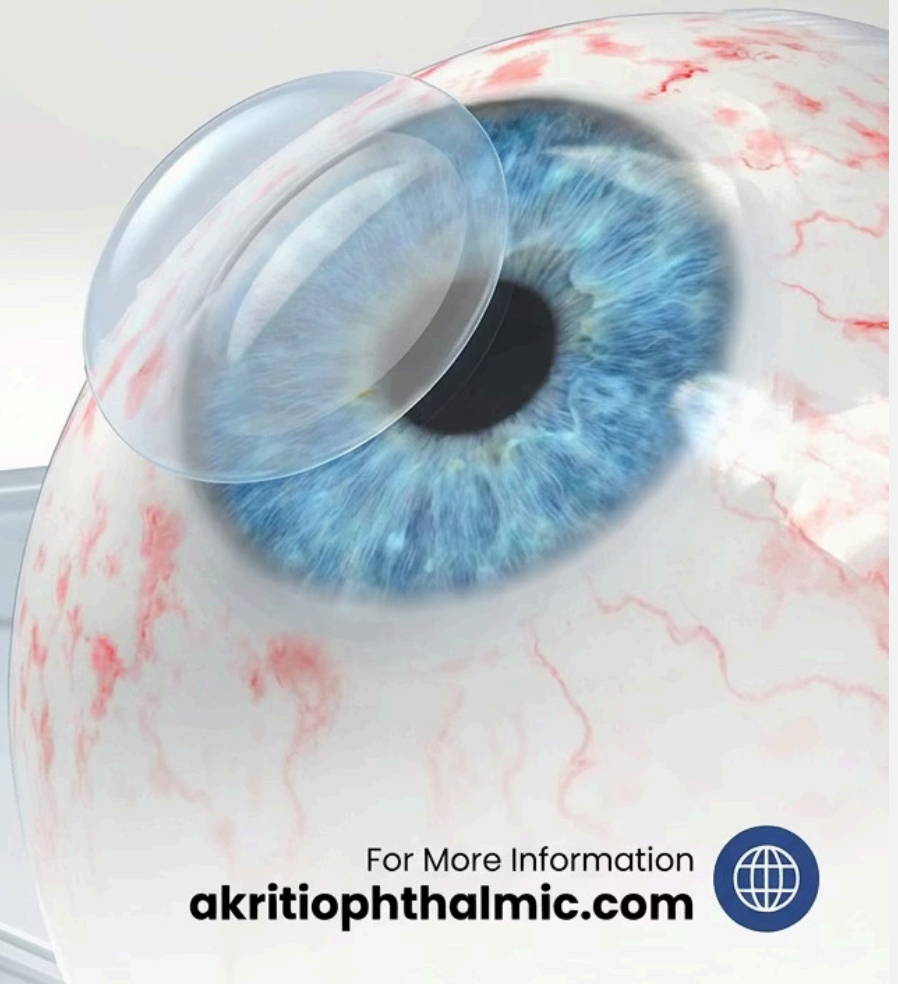
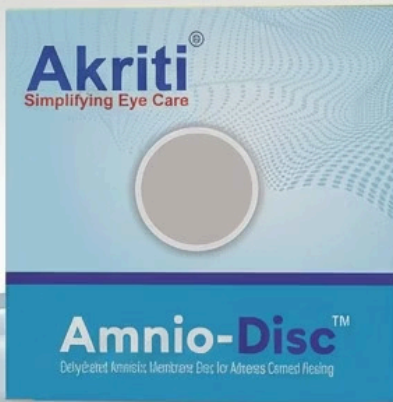
Amnio Disc™ is a dehydrated human amniotic membrane allograft engineered to provide a protective covering and actively support the natural repair environment of the ocular surface. Retaining native membrane architecture through a controlled dehydration process, it offers clinicians a ready-to-use, ambient-storage solution with the structural fidelity of fresh tissue.

Akriti®
Simplifying Eye Care

EXPLORE INNOVATION

Amnio-Disc™

Dehydrated Amniotic Membrane Disc for Advance Corneal Healing



For More Information
akritiophthalmic.com



Intended Use & Homologous Function

Amnio Disc™ is indicated as a protective barrier and covering for the ocular surface in clinical situations where the epithelium is compromised, disrupted, or requires temporary structural support during the healing process. The product is designed for use by qualified ophthalmic surgeons and cornea specialists managing conditions that impair epithelial integrity – including post-surgical surfaces, persistent epithelial defects, chemical injuries, and related presentations.

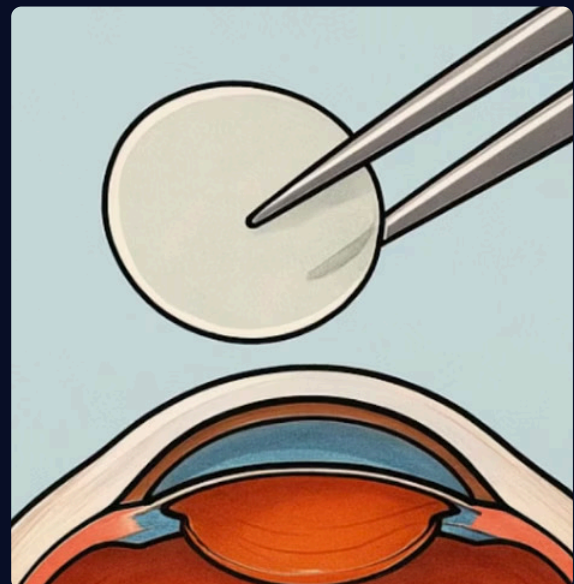
The intended use is strictly homologous to the natural in vivo function of the amniotic membrane. In the human body, the amniotic membrane serves as a protective, multi-layered structural tissue that shields adjacent tissues, maintains a moist microenvironment, and supports cellular repair processes. Amnio Disc™ replicates this function at the ocular surface, providing an analogous mechanical and biological environment that facilitates epithelial recovery without requiring living cells.

Homologous Use Rationale

The amniotic membrane naturally functions as a protective, structural tissue layer in the body. Amnio Disc™ performs the same protective and supportive role at the ocular surface – a directly analogous application consistent with 21 CFR 1271 homologous use criteria.

Target Clinical Presentations

- Compromised or disrupted corneal epithelium
- Post-surgical ocular surface support
- Persistent epithelial defects
- Chemical or thermal ocular injuries
- Temporary coverage during active healing phases



Product Description & Specifications

Amnio Disc™ is a single-use, devitalized, dehydrated amniotic membrane allograft processed under fully aseptic conditions and terminally sterilised using gamma irradiation to a Sterility Assurance Level (SAL) of 10^{-6} . The devitalisation and dehydration process removes cellular components whilst preserving the extracellular matrix architecture, biologically active proteins, and structural integrity that define the membrane's function. Terminal gamma irradiation provides an additional, validated layer of microbial safety assurance for clinical use.

The allograft is supplied in six standardised diameters specifically selected to accommodate the full range of ocular surface presentations encountered in clinical practice – from small focal defects to broader surface coverage needs. Each unit is individually packaged, clearly labelled, and traceable from donor recovery through to clinical application in full compliance with CGTP and CGMP requirements.

Available Diameters

6 mm · 8 mm · 10 mm · 12 mm · 14 mm · 16 mm

Six sizes to accommodate the full spectrum of ocular surface presentations

Sterility Standard

Gamma irradiated to SAL of 10^{-6}

Terminal sterilisation providing validated, reproducible microbial safety assurance

Single-Use Format

Devitalised · Dehydrated · Aseptically processed

No reconstitution required; ready for immediate clinical application

Storage Condition

Ambient room temperature in original sealed packaging

No refrigeration or freezing required – simplifying procurement and inventory

Processing & Preservation – Minimal Manipulation

Processing of Amnio Disc™ is conducted in accordance with the minimal manipulation standard defined under 21 CFR 1271. Each step in the manufacturing workflow is specifically designed to preserve the structural integrity and biological matrix of the amniotic membrane without altering its original, clinically relevant characteristics. The dehydration protocol maintains the native extracellular matrix architecture – including the basement membrane, stromal layer, and retained growth factor and cytokine profile – that underpins the membrane's protective and supportive function.

Critically, the allograft is not combined with any drugs, biologics, or non-permitted devices. It is not modified through the addition of exogenous biological agents or chemical cross-linking. This processing philosophy not only satisfies the regulatory definition of minimal manipulation but also ensures that clinicians are applying a structurally authentic tissue analogue rather than an engineered construct. Independent comparative analyses demonstrate superior structural integrity relative to conventional dehydrated amniotic membrane products on the market.

A bandage contact lens may be applied separately by the clinician following placement of Amnio Disc™ to assist with positioning and retention on the ocular surface. This accessory is applied at the clinician's discretion and remains fully independent of the allograft itself, consistent with the HCT/P regulatory framework.

Native Architecture Preserved

Dehydration protocol maintains basement membrane, stromal structure, and biological matrix without chemical alteration or cross-linking.

No Exogenous Additions

Not combined with drugs, biologics, or non-permitted articles. The allograft matrix is retained in its naturally derived configuration throughout processing.

Superior Structural Integrity

Comparative data demonstrates improved structural integrity versus conventional dehydrated amniotic membrane products available in the ophthalmic market.

Mechanism of Action

Amnio Disc™ functions as a physical and biological covering that replicates the inherent structural role of native amniotic membrane at the ocular surface. Upon application, the dehydrated allograft rapidly conforms to the contours of the ocular surface, providing immediate mechanical protection to the underlying epithelium. The preserved extracellular matrix – including collagen, laminin, fibronectin, and retained signalling proteins – supports the biochemical microenvironment conducive to epithelial cell migration, adhesion, and proliferation.

The allograft does not rely on the presence of living cells to exert its protective effect. Its function is entirely mediated through its structural matrix and retained biological components, making it a consistent, reproducible clinical tool. The mechanism does not involve systemic distribution; all effects are locally acting at the site of application, which is a key determinant of its regulatory classification under Section 361 of the Public Health Service Act.



Ocular Surface Protection

Provides a durable physical barrier that shields the compromised epithelium from external mechanical and environmental insult during the critical healing window.



Moist Environment Maintenance

Supports a sustained moist microenvironment at the ocular surface, a prerequisite for optimal epithelial cell migration and wound closure dynamics.



Epithelial Repair Support

Retained matrix proteins and cytokines provide biologically relevant cues that facilitate natural epithelial repair processes without pharmacological intervention.



Temporary Coverage

Delivers reliable temporary surface coverage during the active healing phase, supplementing the epithelium's natural regenerative capacity until full coverage is restored.

Donor Eligibility & Safety Standards

All tissue used in the manufacture of Amnio Disc™ is recovered from healthy, consenting donors following live birth (caesarean section). Every donation undergoes a comprehensive eligibility evaluation conducted under the supervision of a qualified Medical Director. The screening programme is structured to systematically identify and exclude donors who present risk factors for transmissible disease or tissue quality concerns – ensuring that only tissue meeting the highest safety standards enters the processing workflow.

Screening encompasses a multi-modal assessment that includes a thorough medical and behavioural risk history, physical examination, review of medical records, and a full panel of infectious disease testing for blood-borne and relevant pathogens. This multi-layered approach is designed to provide redundancy across risk identification pathways, recognising that no single screening method is comprehensive in isolation. Processing and donor eligibility determinations comply fully with 21 CFR 1271 Subpart C and all applicable Current Good Tissue Practice (CGTP) requirements.

1

Medical & Behavioural Risk Assessment

Structured history review to identify behavioural or clinical risk factors for communicable disease transmission prior to tissue acceptance.

2

Infectious Disease Testing

Comprehensive blood-borne pathogen screening panel conducted on all donors in accordance with 21 CFR 1271 Subpart C requirements.

3

Physical Examination

Clinical evaluation of the donor to identify physical signs or conditions that may affect tissue eligibility or quality determination.

4

Medical Record Review

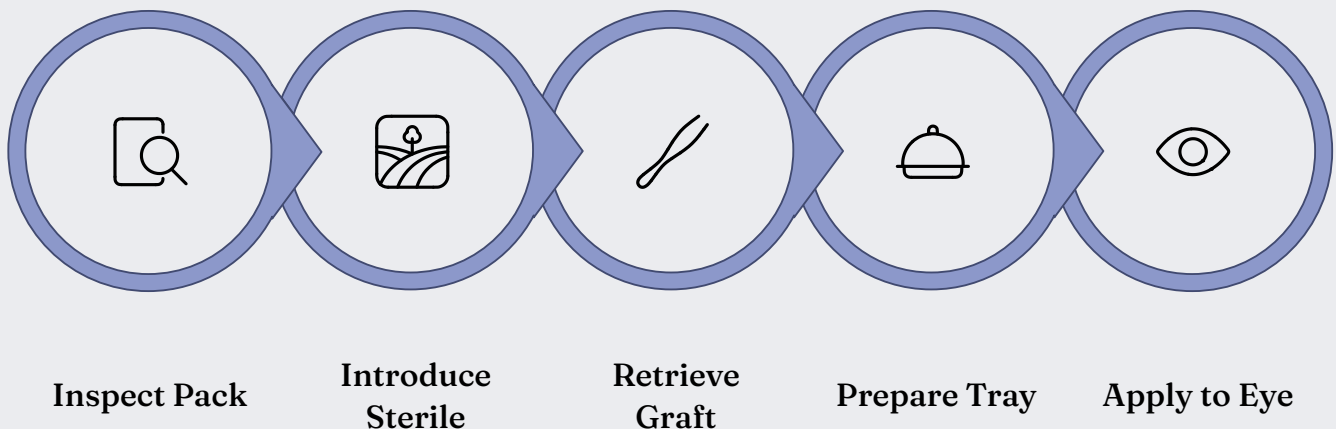
Comprehensive review of available medical and clinical records to supplement direct assessment and ensure completeness of the eligibility determination.

- ☐ All donor eligibility determinations are conducted under Medical Director supervision and comply fully with CGTP and CGMP regulatory requirements as specified under 21 CFR 1271.

Clinical Handling & Application Protocol

Amnio Disc™ is intended exclusively for use by qualified medical professionals with appropriate training in ophthalmic surgical and procedural techniques. The application procedure is designed to be straightforward and efficient, minimising chair time whilst ensuring precise and reliable placement of the allograft onto the ocular surface. No reconstitution, hydration, or special preparation of the allograft itself is required prior to use – the dehydrated format is applied directly to the ocular surface where it conforms rapidly upon contact.

The following standardised application sequence is recommended for consistent, safe clinical use. Clinicians should observe standard aseptic technique throughout and exercise care in handling to preserve the structural integrity of the allograft prior to placement. Following application, a bandage contact lens may be placed by the clinician at their discretion to assist with allograft retention and patient comfort during the initial healing period.



Each step in the application sequence is designed to maintain sterility and ensure accurate positioning of Amnio Disc™ on the target ocular surface. Clinicians are advised to review the full Instructions for Use (IFU) prior to application and to adhere to facility-specific aseptic protocols throughout the procedure.

"Gently position the dehydrated Amnio Disc™ directly onto the ocular surface – the allograft conforms to the surface contour upon application, providing immediate, stable coverage."

Regulatory Classification — Section 361 HCT/P

Amnio Disc™ meets all criteria for regulation solely under Section 361 of the Public Health Service Act (PHS Act) and 21 CFR Part 1271, and therefore does not require premarket approval or clearance as a drug, biologic, or medical device. This classification is based on a rigorous evaluation of the product against the six regulatory criteria established by the FDA for 361 HCT/P classification. Each criterion is independently satisfied, and collectively they establish Amnio Disc™ as an HCT/P regulated exclusively under the tissue framework.

This regulatory pathway reflects the product's authentic tissue-derived nature, the fidelity of its processing to the minimal manipulation standard, and its direct correspondence to the homologous function of native amniotic membrane. Procurement teams should note that this classification simplifies regulatory documentation requirements while maintaining the highest standards of tissue safety and quality under CGTP oversight.



The satisfaction of all six criteria concurrently is what distinguishes Amnio Disc™ as a true 361 HCT/P and positions it clearly within the established FDA regulatory framework for human tissue allografts intended for homologous use in the ocular surface context.

Clinical & Procurement Summary

Amnio Disc™ represents a rigorously processed, regulatory-compliant dehydrated human amniotic membrane allograft specifically designed to meet the demands of contemporary ophthalmic surgical practice. For cornea specialists and ocular surface surgeons, the product offers structural authenticity, reproducible handling characteristics, and a broad size range that accommodates the diverse presentations encountered in clinical settings – from focal epithelial defects to more extensive surface disruption requiring broader coverage.

For clinical procurement teams, the ambient storage profile eliminates the logistical complexities and costs associated with cryopreservation, whilst the 361 HCT/P classification under 21 CFR 1271 provides a well-established, clearly defined regulatory framework that simplifies institutional review and procurement documentation. Full traceability from donor to patient, Medical Director-supervised eligibility determination, and terminal gamma irradiation collectively deliver a safety and quality profile that meets the standards expected for tissue allografts used in sensitive ophthalmic applications.

For Surgeons

- Native membrane architecture preserved
- Six diameters for precise size-matching
- No reconstitution required
- Immediate application from packaging

For Procurement

- Room temperature storage – no cold chain
- 361 HCT/P – simplified regulatory pathway
- Full CGTP and CGMP compliance
- Complete donor-to-patient traceability

Safety Profile

- Terminal gamma irradiation (SAL 10⁻⁶)
- Medical Director-supervised eligibility
- Multi-modal donor screening
- Aseptic processing conditions

Manufacturerd By :

Akriti Ophthalmic Pvt Ltd

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