AmnioMatrix

What is an amniotic membrane graft?

AmnioMatrix is an amniotic membrane graft which brings a new generation of ocular surface tissue therapy to South Africa which can accelerate the regeneration of damaged tissue and reduce the discomfort and pain of the patient, associated with the reconstruction of the ocular surface.

The amniotic membrane is the innermost membrane of the Placelta and it contains natural growth factors and cytokines that are integral to the development of a healthy foetus. When applied to the ophthalmic surface, the amniotic membrane promotes enhanced wound repair and wound healing as well as the relief of pain. The amniotic membrane allografts are thin, opaque and extremely lightweight.

Characteristics [1-6]

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- Provides a structure for cellular migration and proliferation
- Contains collagen types IV, V and VII which promote cellular differentiation and adhesion
- Anti-inflammatory
- Anti-microbial
- Anti-scarring and anti-adhesive
- Help in pain reduction at affected site
- Non-immunogenic and has low antigenicity
- Provision of a natural biological barrier

AmnioMatrix is used in a surgical setting and can be adhered to the ocular surface with sutures or tissue glue. Placelta produces 2 different types of amniotic membrane product -

~~CRYOGENIC AMNIOMATRIX~~CRYOPRESEVED AMNIOMATRIX
DEHYDRATED AMNIOMATRIX

DEHYDRATED AMNIOMATRIX

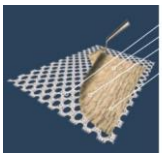
Dehydrated AmnioMatrix is a dry amniotic membrane that has had the epithelial layer of cells removed, therefore no living cells are exposed to the patient. This membrane acts as a scaffold onto which new cells can grow once it has been placed on the wound. Dried amniotic membrane provides natural healing properties to wounds with minimal inflammation and scarring. The amniotic epithelial cells have been removed from surface of the basement membrane.

Dehydrated amniotic membrane processing and preservation methods used by Placelta retain the vital cytokines and growth factors, that have therapeutic actions, such as anti-inflammation, anti-scarring, anti-angiogenesis, pain reduction, it supports epithelial healing and serves as a physical barrier against the external environment.

The dehydrated amnion is processed in accordance with ISO 13485 standards and protocols. It is treated with antibiotics, denuded of cells and then dehydrated in our state-of-the-art clean room facility and finally terminally sterilized by gamma-radiation . The process has been optimized to ensure that there are no adverse effects on the biomechanical properties of the collagen in the membrane.

Packaging

The amnio membrane is spread on a polyester net with the epithelial side orientated onto the net. The membrane is dehydrated, cut to size and packaged aseptically in an inner polyethylene pouch and sealed with an outer peel pouch. Dehydrated denuded human amniotic membrane is terminally sterilised by gamma-irradiation.



Storage

Dehydrated AmnioMatrix can be stored in a clean dry setting at room temperature for up to 5 years. No special storage is needed for this product.

Location	Temperature	Use after Receipt
Unopened	Room Temperature (10°C – 28°C)	Within the expiration date printed on the product label. Usually 5 years from the day of production.

Available sizes

Dehydrated amnio is available in a number of sizes: We recommend that the size ordered is approximately 0.5cm larger than the proposed surgical site, to be covered with amniotic membrane.

Sizes	Catalogue #
1. 1.5 cm x 1.5 cm	LAM1515
2. 2.0 cm x 2.0 cm	LAM2020
3. 3.0 cm x 3.0 cm	LAM3030
4. 4.0 cm x 4.0 cm	LAM4040

Process

CRYOPRESERVED AMNIOMATRIX

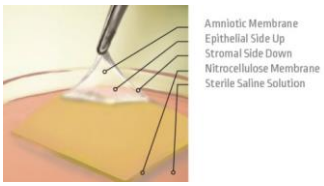
Cryopreserved AmnioMatrix is fresh amniotic membrane that is processed and stored frozen at -80°C. With this method the epithelial layer of cells is retained as well as the important biological factors and cellular mediators.

Cryopreserved AmnioMatrix preserves the native integrity, activity, and function, exhibited by the in-utero tissue for ocular surface wound repair and healing. The processing and preservation methods used by Placelta retains the vital cytokines and growth factors, that have therapeutic actions, such as anti-inflammation, antiscarring, antiangiogenesis, pain reduction, supports epithelial healing and serves as a physical barrier for the ocular surface against the external environment.

Cryopreserved amniotic membrane is processed in asceptic conditions in our state-of-the-art clean room facility, decontaminated by antibiotic incubation and frozen. The freezing of the membrane helps to retain biological properties of the membrane. The membranes are frozen at – 80°C which kills off all the cuboidal epithelial cells on the membrane surface. It is these cuboidal epithelial cells that have the ability to cause graft rejection when transplanted onto the recipient.

Packaging

The membrane is orientated with the basement on a nitrocellulose membrane (epithelial side up). The amniotic membrane is packaged in an inner polyethylene pouch with a 1:1 ratio of Dulbecco's Modified Eagles Medium and Glycerol for protection against freeze damage. The inner pouch is then packed in an outer aluminium foil pouch, sealed and frozen to - 80°C.



Storage

Dehydrated AmnioMatrix can be stored in a clean dry setting at room temperature for up to 5 years. No special storage is needed for this product.

Location	Temperature	Use after Receipt
Unopened Insulated Shipping Container	Frozen(-80°C)	Within the expiration date, printed on the package label
Standard Freezer (home or general use)	Frozen(-20°C)	Within 3 months of placing the product in the freezer or until expiration date printed on outer product packaging, whichever comes first

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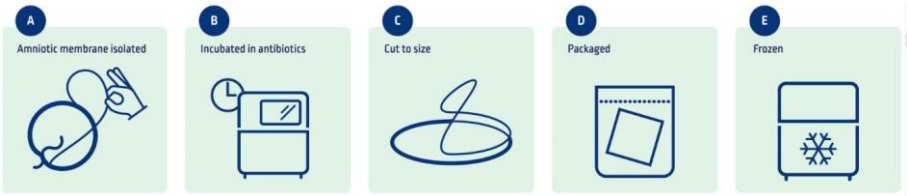
Available sizes

Cryopreserve amnio is available in a number of sizes: We recommend that the size ordered is approximately 0.5cm larger than the proposed surgical site, to be covered with amniotic membrane.

Sizes	Catalogue #
1. 2.0 cm x 2.0 cm	CAM2020
2. 4.0 cm x 4.0 cm	CAM4040
3. 6.0 cm x 6.0 cm	CAM6060
4. 8.0 cm x 8.0 cm	CAM8080

Process



APPLICATION

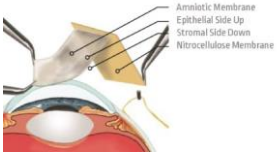
Orientation Guide

AmnioMatrix Dehydrated Amniotic Membrane

Placement of the Dehydrated Amniotic Membrane on the wound site.

AmnioMatrix Cryopreserved Amniotic Membrane

Placing of Cryopreserved Amniotic Membrane on the wound site. Removal of the nitrocellulose membrane should only be done during the placement of the membrane.

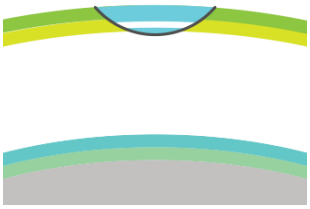


Application Techniques[13]

Epithelium
Bowman layer
Stroma
Descemet membrane
Endothelium
Anterior chamber

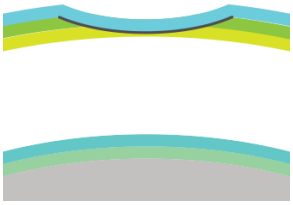
~~Röck T. et al. Amniotic membrane transplantation in reconstructive and regenerative ophthalmology Ann Transplant, 2018; 23: 160-165~~

A. Inlay (Graft)



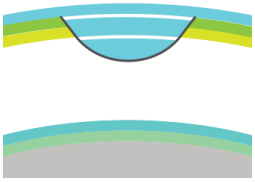
For deeper epithelial defects extruding to the stroma. Epithelium grows over the graft, securing itself to the basement membrane of the graft.

B. Overlay (Patch)



For corneal diseases with nonhealing epithelial defects having no or only shallow stromal defects. Epithelium grows beneath the patch.

C. Sandwich



For deep stromal defects with large nonhealing epithelial defects.

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Videos

Video to illustrate the use of frozen amniotic membrane as a graft in conjunctival surgery.

Video to illustrate Eye Socket Reconstruction Deepening of the Inferior Fornix

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Video to illustrate the use of dehydrated amniotic membrane as a graft in Pterygium surgery

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INDICATIONS

Ophthalmic indications used as a substrate to replace the damaged ocular or subcutaneous tissue or as a biological dressing in:

Indications of Corneal Surface Reconstruction

- Persistent Epithelial Defects
- Anticipated delayed re-epithelialisation
- Non-healing Stromal Ulcers
- Partial Limbal Stem Cell Deficiency
- Bullous Keratopathy Total Limbal Stem Cell Deficiency
- Band Keratopathy
- Mooren's Ulcer

Indications of Conjunctival Surface Reconstruction

- Chemical Burns
- Descemetocoele
- Cicatrizing Conjunctivitis
- Ocular Surface Squamous Neoplasia (OSSN)
- Leaking Blebs
- Filtering Surgery
- Symblepharon Release
- Fornix Reconstruction
- Socket Reconstruction
- Entropion Correction
- Scleral Melt
- Pterygium Surgery

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