NEXT BIOSCIENCES

AmnioMatrix Dehydrated

Amniotic Membrane for Ophthalmology
Packaging Insert

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Read this leaflet carefully before application of **AmnioMatrix Dehydrated**

IMPORTANT: REMOVE AND DISCARD WHITE NYLON MESH BACKING BEFORE USE

AmnioMatrix is the trademark name for dehydrated, photochemically cross-linked amniotic membrane from Next Biosciences. **AmnioMatrix** accelerates the regeneration of damaged tissue and reduces the discomfort and pain associated with the reconstruction of the ocular surface.

The amniotic membrane is the innermost membrane of the placenta, and it contains natural growth factors and cytokines that are integral to the development of a healthy fetus. When applied to the ophthalmic surface, the amniotic membrane promotes enhanced wound repair and wound healing as well as relief from pain. The amniotic membrane allografts are thin, opaque and extremely lightweight. Dehydrated amniotic membrane provides natural healing properties to wounds with minimal inflammation and scarring.

Dehydrated amniotic membrane processing and preservation methods used by Next Biosciences retains the vital cytokines and growth factors, that have therapeutic actions, such as anti-inflammatory, anti-scarring, anti-angiogenesis and pain reduction. It supports epithelial healing and serves as a physical barrier against the external environment. **AmnioMatrix** is used in a surgical setting and can be adhered to the ocular surface with sutures or tissue glue.

CHARACTERISTICS:

- 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
- Helps pain reduction at affected site
- Non-immunogenic and has low antigenicity
- Provision of a natural biological barrier

INDICATIONS FOR THE USE OF AMNIOMATRIX:

Indications of Corneal Surface Reconstruction

- Persistent Epithelial Defects
- Anticipated delayed re-epithelialisation
- Non-healing Stromal Ulcers
- Partial Limbal Stem Cell Deficiency
- Bullous Keratopathy
- 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
- Stevens Johnson Syndrome

CONTRA-INDICATIONS:

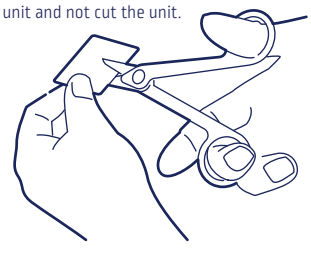
*Amniotic Membrane should **NOT** be implanted into:*

- Areas with an active or latent infection; particularly contra-indicated in the management of persistent epithelial defects with infectious corneal ulcers.
- This product is intended for single and prescription patient use only.
- If opened, this product cannot be re-sterilized.

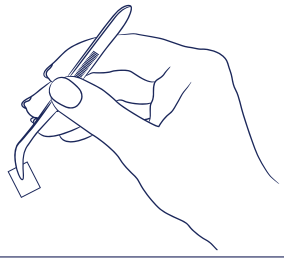
USAGE INSTRUCTIONS:

AmnioMatrix should always be handled using sterile/ aseptic technique.
Opening the pouch and removing the AmnioMatrix sheet:

1. Remove the AmnioMatrix package from the envelope.
2. Open the outer pouch by using normal aseptic technique.
3. The inner polyethylene pouch can now either be tilted out of the pouch onto a sterile field by turning the pouch upside down or it can be fished from the pouch with sterile forceps.
4. Place the inner pouch on the sterile field.
5. Use sterile scissors to cut open the inner pouch with enough space to remove the AmnioMatrix unit and not cut the unit.



6. Use sterile blunt forceps to grab the **AmnioMatrix**



PLEASE TAKE CARE WHEN REMOVING THE AMNIOMATRIX FROM THE INTERNAL POUCH AS IT IS THIN AND EXTREMELY LIGHTWEIGHT.

- The AmnioMatrix can be cut in its dry state and prior to administrating the graft to the wound surface.
- The amnion is oriented with the basement membrane side (epithelial side) of the amnion against the polyester net. Thus, the epithelial side is towards the polyester net carrier.
- The amnion should be gently peeled off the polyester net and placed on the surgical site. (Clinical literature suggests that the epithelium side should be in contact with the wound surface).
- The AmnioMatrix will rehydrate when placed on the ocular surface.

PROCESSING AND PACKAGING:

The amniotic membrane layer is mechanically separated from the placenta under aseptic conditions, before being enzymatically treated to remove epithelial cells from the membrane surface. The membrane is also photochemically cross-linked. The membrane is oriented epithelial side down and laid onto a specifically designed polyester net before being dehydrated for packing. Once aseptically packaged, the dehydrated membrane is sterilised by gamma irradiation.

AMNIOMATRIX PRODUCT SPECIFICATIONS

Catalogue #	Product Size	Storage Location	Storage Temperature
LAMX1515	15x15 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)
LAMX2020	20x20 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)
LAMX3030	30x30 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)
LAMX4040	40x40 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)

Expiry Date	Within 4 years from the date of production (Expiry date will be printed on each AmnioMatrix product label)

We recommend that the size ordered is approximately 1.0 cm larger than the proposed surgical site to be covered with amniotic membrane.

SOURCE OF AMNIOTIC MEMBRANE AND DISEASE TESTING:

The amniotic membrane, from which **AmnioMatrix** is processed, is recovered aseptically from donated placental membranes through elective caesarean section. All donors are screened for infectious, malignant, neurological, and autoimmune diseases to determine whether they are suitable for donation.

The donor blood is tested by an independent certified laboratory at the time of delivery. Only donor tissue of donors that have tested negative for the minimum serological tests are used to produce **AmnioMatrix**. Tests conducted are: HIV PCR Qualitative, HIV I & II ELISA, Hepatitis B surface antigen (HBsAg), Hepatitis B surface antibodies (HBsAb), Hepatitis B core antibody (HBcAb), Hepatitis C Antibody (HCVAb), HTLV I & II antibodies, Syphilis (RPR), Treponema pallidum IgG, Treponema pallidum IgM, CMV IgG, CMV IgM and IgG antibodies.

Microbiological Testing:

Microbiology testing of all tissue is done by an independent certified pathology laboratory. Random samples of each donor placenta are tested for any signs of growth of micro-organisms. The amniotic membrane is processed using a validated method to produce **AmnioMatrix**. The final product is only released after the microbiological testing results yielded no growth of micro-organisms.

ADVERSE REACTIONS:

Any adverse reactions occurring due to the use of **AmnioMatrix** must be reported to the Next Biosciences representative as soon as possible. An Adverse Event Form will be provided to the surgeon to facilitate an in-depth probe into the course of the adverse reaction.

WARNINGS:

- As with the use of any human tissue, although all screening and microbial testing results were satisfactory for this donor, the possibility of infectious agent transmission cannot be completely eliminated.
- This product is intended for single and prescription patient use only.
- It is imperative that the graft is stored properly until transplantation.

WARRANTY:

Next Biosciences supplies this allograft without any express or implied warranties. All statements or descriptions are informational and not given as warranty of the allograft. Next Bioscience makes no guarantee whatsoever to the biological or biomechanical properties of the allograft. The user shall be solely responsible for determining the adequacy and appropriateness of the allograft for any and all uses to which the user shall apply the allograft.

Manufactured by: Next Biosciences (Pty) Ltd

Tel: +27 (0)11 697 2900
Fax: +27 (0)11 697 2901
Web: www.nextbio.co.za
E-Mail: orders@nextbio.co.za
Address: International Business Gateway
Cnr. New Road and 6th Road, Midrand, 1685

Nothing is inevitable. Anything is possible.

STERILE A