NEXT BIOSCIENCES

AmnioMatrix Cryopreserved
Amniotic Membrane for Ophthalmology
Packaging Insert

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Read this leaflet carefully before application of AmnioMatrix Cryopreserved

IMPORTANT: REMOVE AND DISCARD THE WHITE NITROCELLULOSE MEMBRANE BACKING BEFORE USE

AmnioMatrix is the trademark name for cryopreserved (frozen) human amniotic membrane from Next Biosciences for use in ophthalmic surgery. **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 in contact with the ocular surface, the amniotic membrane promotes enhanced wound repair and wound healing by eliminating the need to harvest the patient's own tissue.

The 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 for the ocular surface against the external environment.

AmnioMatrix is used in a surgical setting and is attached to the ocular surface with sutures or fibrin 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

CONTRA-INDICATIONS:

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

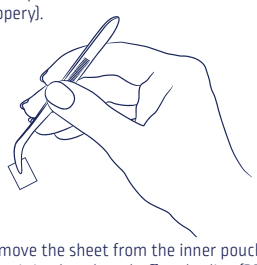
- Areas with an active or latent infection; particularly contra-indicated in the management of persistent epithelial defects with infectious corneal ulcers.
- Do not use on patients with a history of drug reactions to Penicillin, Streptomycin, Amphotericin B or Neomycin.

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 cold storage and leave unopened at room temperature for approximately 5 to 10 minutes.
2. Open the outer foil pouch by tearing across from the tear notch.
3. Apply slight pressure on the sides of the pouch as to widen the mouth of the foil pouch.
4. The inner polyethylene pouch can now either be tilted out of the foil pouch onto a sterile field by turning the foil pouch upside down or it can be fished from the foil pouch with sterile forceps.
5. Place the inner pouch on the sterile field.
6. Use sterile scissors to cut open the inner pouch with enough space to remove the AmnioMatrix sheet.

7. The amnion is placed in a polyethylene pouch on nitrocellulose membrane with the stromal side of the amnion against the nitrocellulose membrane. Thus, the epithelial side is away from the nitrocellulose membrane.
8. Use blunt forceps to grab the AmnioMatrix sheet (please note that the membrane is very slippery).



9. Remove the sheet from the inner pouch and rinse it in phosphate buffered saline (PBS) for approximately 5 minutes for the total removal of the glycerol cryoprotectant.
10. If the orientation of the membrane becomes questionable after loosening from the nitrocellulose membrane, a Weck-Cell tip (cellulose sponge tip) can be used to determine the stromal side.
11. The Weck-Cell bud will only adhere to the stromal side.
12. The stromal side of cryopreserved amniotic membrane should be placed onto the ocular surface for the maximum healing effect.

PROCESSING AND PACKAGING:

AmnioMatrix is processed in sterile conditions in our clean room facility, decontaminated by antibiotic incubation and cryopreserved. Dulbecco's Modified Eagle Medium and Glycerol are used as storage media for protection against freeze injury. The cryopreservation of the membrane ensures retention of its biological properties. No other preservatives or antibiotics are added during cryopreservation storage. The membranes are cryopreserved at – 80°C which kills off all the cuboidal epithelial cells on the membrane surface. It is these cuboidal epithelial cells that can cause graft rejection when transplanted onto the recipient.

AMNIOMATRIX PRODUCT SPECIFICATIONS

Catalogue #	Product Size	Storage Location
CAM2020	20 x 20 mm	Unopened in original packaging
CAM4040	40 x 40 mm	Unopened in original packaging
CAM6060	60 x 60 mm	Unopened in original packaging

Storage Temperature	Cryopreserved AmnioMatrix can be stored in a home freezer at -20°C for up to 3 months.
Expiry Date	Within 2 years from the date of production if stored at -80 °C.
	Within 3 months from receipt of product if stored at -20 °C in a home freezer (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 were 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 anaerobic, aerobic or fungal organisms. The final product is only released after the microbiological test results yielded no growth of micro-organisms (aerobic, anaerobic, or fungal).

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 eliminated.
- It is imperative that the graft is stored properly until transplantation.
- This product is intended for single and prescription patient use only.
- If opened and thawed, this product cannot be re-frozen or re-sterilized

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 Biosciences 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.

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Nothing is inevitable. Anything is possible.

STERILE A