NEXT BIOSCIENCES

AmnioRederm
Placental products for Wound Care
Packaging Insert

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Read this leaflet carefully before application of **AmnioRederm**

IMPORTANT: REMOVE & DISCARD WHITE NYLON MESH BACKING BEFORE USE

AmnioRederm is a denuded, photochemically cross-linked and dehydrated human placental membrane for use in wound healing. AmnioRederm acts as a specialised wound recovery adjunctive, designed to naturally stimulate the recovery of soft tissue wounds.

AmnioRederm, is made from a human amnion-chorion membrane complex, which is a collagen rich structure. It contains natural growth factors and cytokines that are integral to the development of a healthy fetus.

AmnioRederm has been shown to contain significant quantities of bioactive compounds and growth factors associated with the stimulation of wound healing. Further, the structure of the placental membrane itself acts as a natural cellular scaffold, allowing for cellular adhesion and mobility. The placental membranes used to produce **AmnioRederm** are collected from donated placental tissue. The placental tissue is processed in sterile conditions in our clean room facility. It is cleansed and denuded of epithelial cells, photochemically cross-linked, dehydrated, packaged in a clean sterile setting, and sterilized according to strict, quality-controlled protocols without causing adverse effects to the biomechanical properties of the scaffold. **AmnioRederm** can be stored in a clean, dry setting at room temperature.

No special storage is needed for this product.

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:

- Non-healing diabetic ulcers
- Non-healing venous leg ulcers
- Pressure injuries
- Partial thickness burns (scald, flame, and electrical burns)

CONTRA-INDICATIONS:

*AmnioRederm should **NOT** be implanted into:*

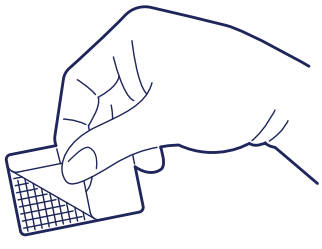
- Areas with an active or latent infection
- Do not use on patients with a history of drug reactions to Amphotericin B, Penicillin, Streptomycin, Neomycin
- This product is intended for single patient use.

USAGE INSTRUCTIONS:

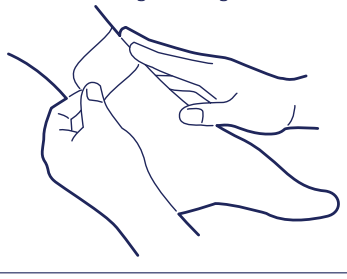
AmnioRederm is intended to be used as an adjunctive to the normal standard of care for small to medium wound healing applications.

AmnioRederm is specifically designed to enhance the recovery of soft tissue wounds, especially chronic non-healing wounds such as diabetic and venous ulcers.

1. Remove AmnioRederm from both the inner and outer pouch.
2. Carefully separate the clear AmnioRederm membrane from the white supporting polyester mesh.



3. Place the AmnioRederm on the cleaned/debrided wound area, pressing gently to contour the membrane around the shape of the wound.
4. Ensure that the AmnioRederm extends to the wound edges to promote epithelialisation.
5. If necessary, secure the AmnioRederm membrane in place with steri-strips and cover with a moisture retentive, non-adhesive dressing followed by an external bandage dressing.



PROCESSING AND PACKING:

The placental 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.

AMNIOREDERM PRODUCT SPECIFICATIONS:

Product Code	Product Size	Storage Location	Storage Temperature
DHAMX2030	20x30 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)
DHAMX4060	40x60 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 AmnioRederm product label)

SOURCE OF PLACENTAL MEMBRANES AND DISEASE TESTING:

The placental membrane, from which **AmnioRederm** 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 **AmnioRederm**. 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 **AmnioRederm**. The final product is only released after the microbiological testing results yields no growth of micro-organisms.

ADVERSE REACTIONS:

Any adverse reactions occurring due to the use of **AmnioRederm**, must be reported to the Next Biosciences representative as soon as possible. An Adverse Event Form will be provided to the healthcare practitioner, 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.
- This product is intended for single and prescription patient use only.
- It is imperative that the graft is stored properly until transplantation.
- If opened, this product cannot be 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 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 all uses to which the user shall apply the allograft.

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Nothing is inevitable. Anything is possible.

STERILE A