NEXT BIOSCIENCES

AmnioDental

Biological products for oro-facial defect repair
Packaging Insert

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Read this leaflet carefully before application of AmnioDental

IMPORTANT: REMOVE AND DISCARD WHITE NYLON MESH BACKING BEFORE USE

AmnioDental is a human placenta derived amniotic collagenous membrane which is denuded, photochemically cross-linked and dehydrated for use in oro-facial defect repair. **AmnioDental** acts as a specialised wound recovery adjunctive. It is designed to naturally stimulate the recovery of oro-facial soft tissue wounds; to aid in the mechanical repair of minor oro-facial osseous and epithelial-lined defects.

AmnioDental is made from human amniotic membrane, which is a collagen rich structure comprising the innermost layer of the fetal membrane of the placenta. The cellular amniotic membrane contains multiple extracellular matrix proteins, natural growth factors and cytokines that are integral to the development of a healthy fetus. **AmnioDental** has been shown to contain significant quantities of bioactive compounds and growth factors associated with the stimulation of wound healing. Further, the structure of this amniotic membrane itself acts as a natural cellular scaffold, allowing for cellular adhesion and mobility.

The amniotic membranes used to produce **AmnioDental** are collected from donated placental tissue samples. The placental samples are (a) processed in sterile conditions in our clean room facility; (b) cleansed and denuded of the epithelial cellular layer; (c) photochemically cross-linked; (d) dehydrated; (e) packaged in a clean sterile setting and (f) sterilized via gamma-irradiation. Processing steps are subject to strict, quality-controlled protocols without causing adverse effects to the biomechanical properties of the scaffold. **AmnioDental** allografts are human derived products whose appearance may vary between donors. Variations in colour (from light yellow to light brown), opacity and thickness are due to the nature of the human tissue. **AmnioDental** can be stored in a clean dry setting at room temperature. No special storage is needed for this product.

APPLICATIONS:

AmnioDental is intended to be used as an adjunctive to the normal standard of care for small to medium wound healing applications. **AmnioDental** is specifically designed to enhance the recovery of soft tissue wounds, especially chronic non-healing wounds such as ulcers and lesions. **AmnioDental** is also designed to function as a barrier membrane in guided osseous regeneration procedures and for the repair of epithelial perforations.

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 in pain reduction at affected site
- Non-immunogenic and has low antigenicity
- Provision of a natural biological barrier
- Resorption between 5 to 6 weeks when used in situ for guided bone regeneration procedures
- Thickness of ~0.3 microns

INDICATIONS:

- Non-healing oro-nasopharyngeal ulcers
- In-situ barrier for minor guided bone regeneration procedures of the maxilla and mandible
- Oral vestibuloplasty procedures
- Nasal septum perforation repair
- Maxillary antrum Schneiderian Membrane perforation repair
- Facial traumatic wound barrier

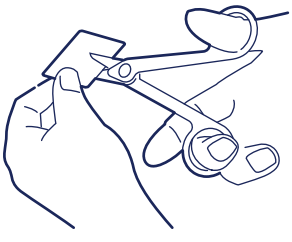
CONTRA-INDICATIONS:

*AmnioDental should **NOT** be used on:*

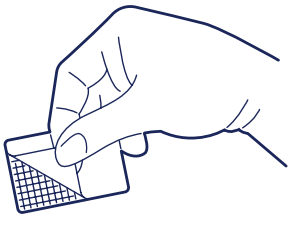
- Areas with an active or latent infection
- Patients with a history of drug reactions to Amphotericin B, Penicillin, Streptomycin, Neomycin
- Patients with a disorder that would create an unacceptable risk of post-operative complications
- Patients if the package and contents appear defective or damaged in any way
- Patients without the direct supervision of a registered health care professional
- Patients who do not completely understand the reaction of the body to any biological implant
- Multiple patients as this product is intended for single patient use only

USAGE INSTRUCTIONS:

1. Remove AmnioDental from both the inner and outer pouch
2. Pre-trim the AmnioDental membrane to the desired shape while still attached to the white supporting nylon mesh
3. Be sure to maintain a dry environment when trimming with sharp, dry non-serrated scissors to prevent hydration before implantation



4. Carefully separate the AmnioDental membrane from the white supporting nylon mesh
5. Place AmnioDental on the clean and prepared recipient bed area and press gently to contour the membrane around the shape of the wound, defect or perforation; use wetted instruments once AmnioDental is wet
6. If necessary, secure the AmnioDental membrane in place with the appropriate resorbable suture



ORIENTATION:

AmnioDental is oriented epithelial side down and laid onto a specifically designed polyester net before being dehydrated for packing

PLACEMENT VARIATIONS AND GUIDELINES:

- AmnioDental may be implanted dry or after flash hydration where the membrane is passed through sterile irrigation before implantation
- Drops of irrigation may be applied to the membrane post implantation
- For sinus perforations AmnioDental should be applied dry to the moist Schneiderian Membrane with an extension of at least 4mm to 5mm relative to the wound tear margin
- AmnioDental may be used with appropriate graft materials in guided bone regenerative procedures
- AmnioDental may be implanted before or after membranes such as titanium mesh or polytetrafluoroethylene (PTFE)
- AmnioDental may (a) be left exposed to the oral environment when primary closure is not obtainable (if adequate fixation has been achieved and the membrane has been adequately tucked under the gingival margins); (b) not in this instance be covered so as to adversely affect cellular migration

PROCESSING AND PACKING:

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 photochemically cross-linked and is oriented epithelial side down onto a specifically designed polyester net before being dehydrated for packing. Once aseptically packaged, the dehydrated membrane is sterilised by gamma irradiation.

AmnioDental can be stored at room temperature for up to 4 years after the date of production.

AmnioDental product specifications

Product Code	Product Size	Storage Location	Storage Temperature
IAMX2030	20x30 mm	Unopened in original packaging	Room Temperature (10°C – 28°C)

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

SOURCE OF AMNIOTIC MEMBRANES AND DISEASE TESTING:

Placental donations are collected during the birthing process in accordance the National Health Act of South Africa.

The amniotic membrane, from which **AmnioDental** 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's 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 **AmnioDental**. 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 AmnioDental. 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 **AmnioDental** must be reported to Next Biosciences 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