

## Dual Layer Amniotic Membrane

Amnion is the placental tissue that surrounds and protects the fetus during development in utero. The properties of amnion that benefit the fetus also make it an effective material for protecting a wide variety of wounds, while at the same time creating an environment conducive to the regeneration of healthy tissue. Repurposing this versatile tissue to improve outcomes in wound management is supported by studies in published literature which describes its successful and safe clinical use.

Amnion consists primarily of fibrillar and membranous collagens, elastin, and a mix of growth factors and cytokines that provide the properties unique to placental tissues.

## The Benefits of Amnion

The scientific and peer reviewed literature describe a number of benefits from the clinical use of amnion tissues<sup>1</sup>, including:

- ❑ Safe, natural covering that improves normal wound healing outcomes
- ❑ Reduced inflammation
- ❑ Reduced fibrosis and scarring at the surgical site
- ❑ Decreases pain
- ❑ Provides a substrate for stem cells

## Uses of Amnion

Specifically, amnion has been used to achieve the following outcomes<sup>1</sup>:

- ❑ Inhibit fibrogenesis (scarring) when applied topically to dermal and subcutaneous wounds
- ❑ Prevent adhesions tethered to implanted hardware
- ❑ Reduce the occurrence of dural & nerve root adhesions
- ❑ Prevent adhesions in tendon grafts and repair

Amnion has been used successfully in many clinical applications:

- ❑ Spine/neurologic surgeries
- ❑ Trauma
- ❑ Orthopedics
- ❑ Cranio maxillofacial surgery
- ❑ Sports medicine
- ❑ Podiatric surgery

*1: Though well documented in the clinical literature, these benefits of amnion have not been studied using Axograft™ products.*



## Advantages of Axograft™ Amniotic Membrane

- ☒ Stores dry at room temperature
- ☒ Suitable for immediate use off the shelf
- ☒ Hydrates rapidly in wound environment
- ☒ Readily adheres to the wound surface
- ☒ Terminally sterilized with gamma radiation to SAL 10<sup>-6</sup> in accordance with ISO 11137
- ☒ Not chemically cross-linked
- ☒ Three year shelf life
- ☒ Axograft™ Amniotic Membrane (Dual Layer) version processed with surface layer dimpling for ease of graft placement / handling
- ☒ Axograft™ Amniotic Membrane (Dual Layer) version can be placed with either side in contact with wound surface

## Tissue Safety

- ☒ Collection of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments
- ☒ Placentas are all from planned C-sections which helps to minimize the potential for contamination during recovery
- ☒ Placental donors go through a rigorous pre-screening qualification
- ☒ Placental donors are tested to confirm they are free from disease
- ☒ Processed in accordance with the safety guidelines provided by the U.S. Food and Drug Administration (FDA) - Human Cellular and Tissue-based Products (HCT/P) (21 CFR Part 1271)
- ☒ Processed in accordance with the standards from the American Association of Tissue Banks (AATB)



## Select IFUs

- ☒ Maintain allograft in a clean, dry environment at room temperature (15°C/59°F to 30°C/86°F)
- ☒ No refrigeration is necessary
- ☒ Apply dry with forceps
- ☒ Axograft™ Amniotic Membrane (Dual Layer) construction removes the requirement to apply with one side towards the wound (stromal layer) and a different side (epithelial layer) out
- ☒ If not initially placed properly during surgery, the Axograft™ Amniotic Membrane (Dual Layer) graft can either be manipulated in place or removed; when placed in water or saline, the graft will unfold and can be repositioned

Part #	Description
X090-0025-AMN22CMCC	2 x 2cm Amniotic Membrane, Axograft
X090-0025-AMN44CMCC	4 x 4cm Amniotic Membrane, Axograft
X090-0025-AMN46CMCC	4 x 6cm Amniotic Membrane, Axograft
X090-0025-AMN48CMCC	4 x 8cm Amniotic Membrane, Axograft

INDICATIONS: See Package Insert for a more complete listing of indications, contraindications, warnings, precautions, and other important information.

LIMITED WARRANTY and DISCLAIMER: X-spine products have a limited warranty against defects and workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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Patents Pending.

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