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

Studies in published literature support the efficacy of repurposing this versatile tissue to improve outcomes in wound management and surgical repair. The studies also endorse its safe clinical use.

**Clinical Applications**

- Wound care/burns 12-18
- Spine/neurologic surgeries 23-29
- Podiatric surgery 11
- Ophthalmic procedures 8-10, 33-34, 37-40
- Cranio Maxillofacial surgery 23
- Urology 7
- Ob Gyn 6, 42, 43
- Trauma 6, 23-29
- Dental
- Bariatric surgeries 2
- Sports medicine 19-21
- Cosmetic 11

**Outcomes**

- Prevents adhesions tethered to implant hardware 27, 29
- Prevents adhesions in tendon grafts and repair 18, 20-22
- Inhibits fibrogenesis (scarring) when applied topically to dermal and subcutaneous wounds 12-18, 32-36
- Reduces occurrence of dural and nerve root adhesions 2, 22, 32-36
Benefits and Advantages

Amnion, the inner most layer of the placental tissue, surrounds and protects the fetus during development in utero. Its properties that benefit the fetus also makes it an effective tissue for protecting a wide variety of wounds, while at the same time creating an environment conductive to the regeneration of healthy tissue.

Research has demonstrated the healing power of Amnion

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Benefits

- Non-Immunogenic
- Safe, natural covering that improves normal wound healing outcomes
- Provides a substrate for stem cells
- Anti-adhesive
- Anti-microbial
- Reduces pain
- Reduces inflammation
- Reduces fibrosis and scarring

Advantages

- Single layer
- Stromal or epithelial side can be used
- Can be applied dry, hydrates rapidly in wound environment
- Can be applied wet, hydrate using normal saline, blood or similar solution prior
- Not chemically cross-linked
- Readily adheres to the tissue or wound surface
- Ambient temperature storage
- Can be sutured to prevent migration
- 3 year shelf life from date of packaging
- Proprietary validated viral inactivation process
Safety

Recovery and Processing

• Donor tissue is collected in an aseptic manner by registered tissue procurement organizations.

• Placentas from planned C-sections minimize the potential for contamination during recovery.

• Placental donors go through a rigorous pre-screening qualification in accordance with the U.S. Food and Drug Administration (FDA).

• Placentas are processed in accordance with the safety guidelines provided by the FDA.

• Placentas are sterilized by gamma irradiation to SAL 10-6 in accordance with ISO 11137.

• Amnion is regulated as a human cellular and tissue based products (HCTP) (21 CFR Part 1271) and in accordance with the standards set forth by the American Association of Tissue Banks (AATB).
References

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