PalinGen XPlus Membrane and HydroMembrane

The Best of Regenerative Medicine: Minimally Manipulated Placental Tissue Allografts

PalinGen XPlus Membrane by Amnio Technology is a human allograft derived from amniotic membrane donated by healthy mothers undergoing elective Caesarian section. PalinGen XPlus HydroMembranes provide greater tensile strength, shape manipulation, and slower resorption in vivo. PalinGen XPlus HydroMembrane is a wet form of PalinGen XPlus Membrane with greater pliability. PalinGen XPlus Membrane and PalinGen XPlus HydroMembrane have powerful anti-adhesion capabilities that make them an ideal protective tissue covering to prevent adhesion formation during healing, as with hernia repair, post-surgical prostate protection, and other organ wrapping.

Placental tissues contain a number of invaluable elements that promote tissue repair such as collagen substrates, growth factors, cytokines, and extracellular matrix. These tissues have anti-bacterial, anti-inflammatory, anti-adhesive, and anti-fibrotic properties. Additionally, the amniotic membrane has been described as immunologically privileged, meaning it has immunsuppressive properties and presents a low risk of rejection. In fact, the tissues that comprise the PalinGen XPlus Membrane possess an array of unique properties:

- Creates an ideal environment for tissue healing
- Stimulates cell renewal and proliferation
- No reported adverse reactions
- Anti-inflammatory
- Wound and organ protection
- Provides building blocks to support cell proliferation
- Anti-adhesive tissue barrier
- Non-immunogenic
- Backed by peer-reviewed clinical research

Human placental tissue allografts have tremendous therapeutic potential across a range of specialties. An increasing number of novel indications are currently in pre-clinical and clinical testing at Amnio Technology and elsewhere.

Orthopedic Surgery – Placental tissues reduce inflammation in soft tissues, tendons, ligaments, and joint capsules and have been shown to contribute to tenogenesis, chondrogenesis, and osteogenesis in degenerating and injured tissues. They have been used successfully in pre-clinical studies of tendinosis, and fascitis.

Neurosurgery – Placental tissues promote healing and lower pain associated with inflammation by enveloping damaged or exposed nervous tissue.

Spinal Surgery – When integrated into spinal surgeries, placental tissues inhibit scarring, fibrosis, and risk of nerve entrapment.

PalinGen Membrane does not require fetal sacrifice; recovery is performed with maternal consent during live birth.

CHORION FREE

General Surgery – Placental tissues can inhibit postsurgical development of scar tissue and adhesions, and provide healing tissues with a comprehensive suite of growth factors known to promote and support tissue growth.16, 17

Dental Surgery – Placental tissues have been shown to promote oral tissue repair in chronic lesions and wounds after dental surgery. Recently, placental tissues have demonstrated potential in resolving gum insufficiency.18

Plastic Surgery – Placental tissues may improve outcomes in cosmetic procedures by promoting postprocedural tissue healing, acting as a tissue barrier and promoting vascular reconstruction.19

To ensure the highest standards of safety and quality, Amnio Technology aseptically harvests placental tissues from carefully selected donor mothers following planned Caesarian delivery. The donated tissue is collected aseptically and tested prior to processing and cleansing. Our PalinGen XPlus Membranes then undergo gamma sterilization. We have developed our procedures based on 21 CFR Part 1271 and the American Association of Tissue Banks (AATB) standards.

Another way that we ensure unparalleled safety and quality in our products is by removing the chorion, the outermost embryonic membrane, before processing. The chorion, a proven source of maternal antigens, has been associated with graft-versus-host disease (GVHD), and severe immunogenic reactions.20

The PalinGen XPlus Membrane and PalinGen XPlus HydroMembranes are available in a range of sizes for a variety of surgical uses.

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PRODUCT NOTES:
- Tissue can be sutured, glued, or just put in place, surgeons preference.
- Antigen expression is mitigated, immunogenicity is minimized.
- Intrinsically; anti fibrotic, anti adhesion, easily resorbed in vivo, anti-inflammatory. By extension reduces risk of post-operative complications.
- Stored at ambient temperature
- Can be cut, trimmed to any size, easy to apply.
- Multiple peer reviewed case series dating back to 1910, have clearly demonstrated the power of this allograft in a multitude of anatomic surgical specialties. There are no reported adverse reactions or side effects.
- All processed tissue tested per U.S. Pharmacopeial Convention (USP) guidelines prior to any lot release
- Suppresses Class II antigen expression and minimizes immunogenicity
- Requires no fetal sacrifice; recovery performed with maternal consent during live Caesarian birth.
- Dry and wet membrane sheets for placement in tissues
- When integrated into surgical therapies may reduce risk of postoperative complications
- Room temperature storage

PalinGen Membrane is regulated by the FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act; PalinGen Membrane is processed and packaged at an FDA-registered, AATB-accredited tissue bank in accordance with cGTP standards. PalinGen® is a registered trademark of Amnio Technology.