

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. 1,2,3 Additionally, the amniotic membrane has been described as immunologically privileged, meaning it has immunosuppressive properties and presents a low risk of rejection. ^{4,5} In fact, the tissues that comprise the PalinGen XPlus Membrane possess an array of unique properites:

- 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. 6-11 They have been used successfully in pre-clinical studies of tendinosis, and fascitis. 12,13

Neurosurgery – Placental tissues promote healing and lower pain associated with inflammation by enveloping damaged or exposed nervous tissue.14

Spinal Surgery – When integrated into spinal surgeries, placental tissues inhibit scarring, fibrosis, and risk of nerve entrapment.¹⁵

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



- 1. Larsen, B., Davis, B., and Charles, D. (1984). Critical assessment of antibacterial properties of human amniotic fluid. Gynecologic and obstetric investigation 18, 100-104.
- investigation 18, 100-104.

 2. Jackson, N.D., and Rosenblatt, P.L. (1994). Use of Interceed Absorbable Adhesion Barrier for vaginoplasty. Obstetrics and gynecology 84, 1048-1050.

 3. Diaz-Prado, S., Rendal-Vazquez, M.E., Muinos-Lopez, E., Hermida-Gomez, T., Rodriguez-Cabarcos, M., Fuentes-Boquete, I., de Toro, F.J., and Blanco, F.J. (2010). Potential use of the human aminotic membrane as a scaffold in human articular cartilage repair. Cell and tissue banking 11, 183-195.

 4. Akle, C.A., Adinolfi, M., Welsh, K.I., Leibowitz, S., and McColl, I. (1981).
- Immunogenicity of human amnivolunteers. Lancet 2, 1003-1005. amniotic epithelial cells after transplantation
- 5. Yi, T., and Song, S.U. (2012). Immunomodulatory properties of mesenchymal stem cells and their therapeutic applications. Archives of pharmacal research 35, $\,$
- 6. Manuelpillai, U., Moodley, Y., Borlongan, C.V., and Parolini, O. (2011). Amniotic membrane and amniotic cells: potential therapeutic to tissue inflammation and fibrosis? Placenta 32 Suppl 4, S320-325
- 7. Longo, U.G., Loppini, M., Berton, A., La Verde, L., Khan, W.S., and Denaro, V. (2012). Stem cells from umbilical cord and placenta for musculoskeletal tissue engineering. Current stem cell research & therapy 7, 272-281.

- engineering. Current stem cell research & therapy 7, 272-281.

 8. Ozgenel, G.Y., Saml, B., and Ozcan, M. (2001). Effects of human amniotic fluid on peritendinous adhesion formation and tendon healing after flexor tendon surgery in rabbits. The Journal of hand surgery 26, 332-339.

 9. Goncalves, A.I., Rodrigues, M.T., Lee, S.J., Atala, A., Yoo, J.J., Reis, R.L., and Gomes, M.E. (2013). Understanding the role of growth factors in modulating stem cell tenogenesis. PloS one 8, e83734.

 10. Rodrigues, M.T., Lee, S.J., Gomes, M.E., Reis, R.L., Atala, A., and Yoo, J.J. (2012). Bilayered constructs aimed at osteochondral strategies: the influence of medium supplements in the osteogenic and chondrogenic differentiation of amniotic fluid-derived stem cells. Acta biomaterialia 8, 2795-2806.

- aminotic fluid-derived stem cells. Acta biomaterialia 8, 2795-2806.

 11. Barboni, B., Mangano, C., Valbonetti, L., Marruchella, G., Berardinelli, P., Martelli, A., Muttini, A., Mauro, A., Bedini, R., Turriani, M., et al. (2013). Synthetic bone substitute engineered with ammiotic epithelial cells enhances bone regeneration after maxillary sinus augmentation. PloS one 8, e63256.

 12. Coban, I., Satoglu, I.S., Gultekin, A., Tuna, B., Tatari, H., and Fidan, M. (2009). Effects of human ammiotic fluid and membrane in the treatment of Achilles tendon ruptures in locally corticosteroid-induced Achilles tendinosis: an experimental study on rats. Foot and ankle surgery: official journal of the European Society of Foot and Ankle Surgeons 15, 22-27.

 13. Zelen, C.M., Poka, A., and Andrews, J. (2013). Prospective, randomized, blinded, comparative study of injectable micronized dehydrated ammiotic/chorionic membrane allograft for plantar fasciitis—a feasibility study. Foot & ankle international. / American Orthopaedic Foot and Ankle Society [and] Swiss Foot and Ankle Society 4, 1332-1339.

 14. Ozgenel, G.Y., and Filiz, G. (2004). Combined application of human amniotic
- 14. Ozgenel, G.Y., and Filiz, G. (2004). Combined application of human amniotic membrane wrapping and hyaluronic acid injection in epineurectomized rat sciatic nerve. Journal of reconstructive microsurgery 20, 153-157.
- 15. Brown, E.G., Saadai, P., Pivetti, C.D., Beattie, M.S., Bresnahan, J.C., Wang, A., and Farmer, D.L. (2014). In utero repair of myelomeningocele with autologous amniotic membrane in the fetal lamb model. Journal of pediatric surgery 49, 133-137: discussion 137-138.
- 133-13/; discussion 13/-138.
 146. Bolat, E., Kocamaz, E., Kulahcilar, Z., Yilmaz, A., Topcu, A., Ozdemir, M., and Coskun, M.E. (2013). Investigation of efficacy of mitomycin-C, sodium hyaluronate and human amniotic fluid in preventing epidural fibrosis and adhesion using a rat laminectomy model. Asian spine journal 7, 253-259.
 17. Koob, T.J., Lim, J.J., Massee, M., Zabek, N., and Denoziere, G. (2014).
- Properties of dehydrated human amnion/chorion composite grafts: Implications for wound repair and soft tissue regeneration. Journal of biomedical materials research. Part B, Applied biomaterials.
- Tescarut, Fart D, Applied Diomaterials.

 18. Arai, N., Tsuno, H., Okabe, M., Yoshida, T., Koike, C., Noguchi, M., and Nikaido, T. (2012). Clinical application of a hyperdry amniotic membrane on surgical defects of the oral mucosa. Journal of oral and maxillofacial surgery: official journal of the American Association of Oral and Maxillofacial Surgeons 70, 2221-2228.
- 19, Eair N. G., Randolph, M.A., and Redmond, R.W. (2014). The clinical applications of human amnion in plastic surgery. Journal of plastic, reconstructive & aesthetic surgery: JPRAS 67, 662-675.
- 20. Szekeres-Bartho, J. (2002). Immunological relationship between the mother and the fetus. International reviews of immunology 21, 471-495.

General Surgery – Placental tissues ican 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 availabe in a range of sizes for a variety of surgical uses.

1 1	VN4 020101	D.F.C. VM. I. H.1.1
1x1cm	XM-020101	PalinGen XMembrane xsmall 1x1cm
1x2cm	XM-020102	PalinGen X Membrane small 1x2cm
2x2cm	XM-020202	PalinGen X Membrane medium 2x2cm
2x3cm	XM-020203	PalinGen XMembrane 2x3
2x4cm	XM-020204	PalinGen XMembrane 2x4
2x6cm	XM-020206	PalinGen XMembrane 2x6
4x4cm	XM-020404	PalinGen XMembrane large 4x4cm
4x6cm	XM-020406	PalinGen XMembrane xlarge 4x6cm
4x8cm	XM-020408	PalinGen XMembrane xxlarge 4x8cm
custom	XM-020410	PalinGen XMembrane custom 4+x8+cm
8x8	XM-020808	PalinGen Xmembrane special 8x8cm
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1x1cm	XH-040101	PalinGen XMembrane xsmall 1x1cm
1x2cm	XH-040102	PalinGen X Membrane small 1x2cm
1x2cm 2x2cm	XH-040102 XH-040202	PalinGen X Membrane small 1x2cm PalinGen X Membrane medium 2x2cm
1x2cm	XH-040102	PalinGen X Membrane small 1x2cm
1x2cm 2x2cm	XH-040102 XH-040202	PalinGen X Membrane small 1x2cm PalinGen X Membrane medium 2x2cm
1x2cm 2x2cm 2x3cm	XH-040102 XH-040202 XH-040203	PalinGen X Membrane small 1x2cm PalinGen X Membrane medium 2x2cm PalinGen XMembrane 2x3
1x2cm 2x2cm 2x3cm 2x4cm	XH-040102 XH-040202 XH-040203 XH-040204	PalinGen X Membrane small 1x2cm PalinGen X Membrane medium 2x2cm PalinGen XMembrane 2x3 PalinGen XMembrane 2x4
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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.