



BioDRestore™
Elemental Tissue Matrix



BioDRestore™ Elemental Tissue Matrix is a morselized, flowable amniotic tissue allograft

INTEGRA®
LIMIT UNCERTAINTY



Advantages of Amniotic Tissue

Why Amniotic Tissue

Human amniotic tissue has been used to treat a variety of wounds for more than 100 years.¹ Research has shown that amniotic tissue can promote angiogenesis and new tissue formation, reduce scar tissue formation, modulate inflammation and may have antimicrobial effects.²⁻¹⁴

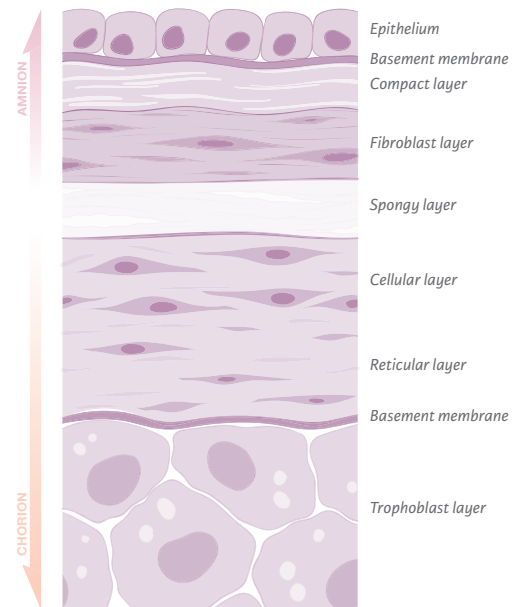
Amniotic tissue is composed of:

- Collagen, proteoglycans, elastin, and fibronectin that provide structural cues to promote reconstruction of damaged tissue
- Key inflammatory modulators such as IL-1RA, IL-4, IL-10 and IL-13, as well as other growth factors that promote tissue repair

Immune-Privileged

Placental tissues are “immune privileged” and therefore rarely cause an immune response in the human body.¹⁵

Structure of the placental membranes



Integra maintains full control over BioDRestore from birth site to processing, and finally, the doctor's office, with a complete chain of custody



Vertical Integration

We maintain full control of the tissue from delivery to the wound. Unlike other companies that use other agencies for some or all of the recovery, tissue processing, and distribution, Integra has its own employees in the delivery room to receive the placental tissue and begin its processing.



Standards of Excellence

Every mother must go through a thorough screening process to receive the required approval from our medical director in order to become a donor. Integra only accepts placental tissues from scheduled cesarean sections. Integra's affiliate has been a registered tissue bank with the FDA since 2006 and is accredited by the American Association of Tissue Banks.



Time to Preservation

The proximity of the tissue recovery sites to the processing facilities allows Integra to start processing the tissue within 4 hours of the baby being born in order to preserve the native tissue characteristics of the placenta.

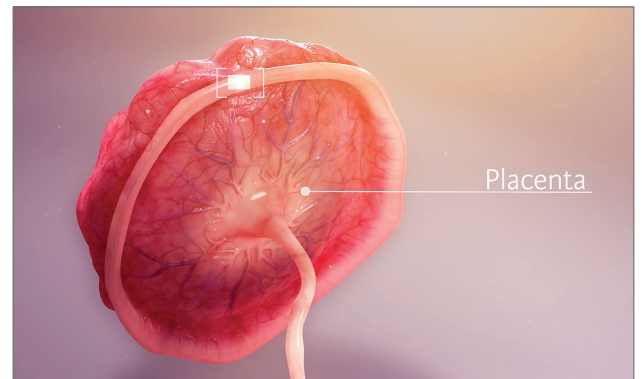
Science Behind BioDRestore

CryoPrime® processing preserves the growth factors, cytokines, and ECM found in native amniotic tissue

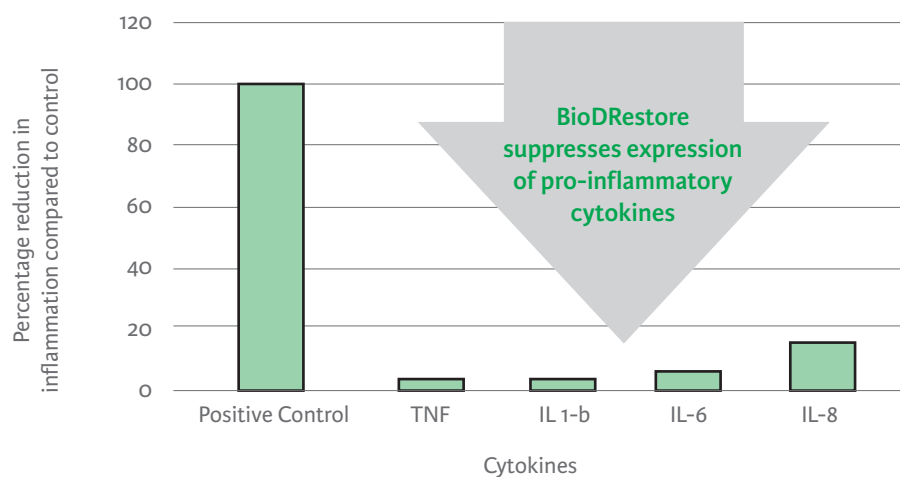
BioDRestore Retains Key Proteins of Unprocessed Human Amniotic Membranes

Anti-Inflammatory / Immunomodulatory Cytokines		
	BioDRestore	Native-Human Amnion
IL-1RA	+	+
IL-4	+	+
IL-10	+	+
IL-13s	+	+
sIL1-RIs	+	+
sIL1-RIIs	+	+
TNF-RIs	+	+
TNF-RIIs	+	+

Anti-Catabolic Factors		
	BioDRestore	Native-Human Amnion
TIMP-1	+	+
TIMP-2	+	+
TIMP-4	+	+



In Vitro Inflammatory Response Assay Shows That the Components of BioDRestore Suppress Cytokines That Normally Lead to an Inflammatory Process



BioDRestore retains potent anti-inflammatory properties as shown in an *in vitro* inflammatory response assay. With BioDRestore, concentrations of *pro-inflammatory mediators* are reduced by more than 95% for TNF-alpha, IL-1beta, and IL-6, and by 80% for IL-8; see figure above.

Preclinical results are not necessarily predictive of clinical outcomes.



Ordering Information

Product ID	Size	Volume
AM-010025	Small (S)	.25 mL
AM-010050	Medium (M)	.5 mL
AM-010125	Large (L)	1 mL
AM-010200	Extra Large (XL)	2 mL
AM-010300	Extra Extra Large (XXL)	3 mL



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References: 1. Davis JW. Skin transplantation. Johns Hopkins Med J 1910;15:307-96. 2. Hao Y, Ma DH, Hwang DG, et al. Identification of antiangiogenic and anti-inflammatory proteins in human amniotic membrane. Cornea 2000;19(3):348-52. 3. Fetterolf DE, Snyder RJ. Scientific and clinical support for the use of dehydrated amniotic membrane in wound management. Wounds 2012(10):299-307. 4. Solomon A. Suppression of interleukin 1alpha and interleukin 1beta in human limbal epithelial cells cultured on the amniotic membrane stromal matrix. Br J Ophthalmol 2001;85(4):444-9. 5. Kim JS, Kim JC, Na BK, et al. Amniotic membrane patching promotes healing and inhibits proteinase activity on wound healing following acute corneal alkali burn. Exp Eye Res 2000;70(3):329-37. 6. Tseng SCG, Li D-Q, Ma X. Suppression of transforming growth factor-beta isoforms, TGF-beta receptor type II, and myofibroblast differentiation in cultured human corneal and limbal fibroblasts by amniotic membrane matrix. J Cell Physiol 1999;179(3):325-35. 7. Lee S-B, Li D-Q, Tan DT, et al. Suppression of TGF-beta signaling in both normal conjunctival fibroblasts and pterygial body fibroblasts by amniotic membrane. Curr Eye Res 2000;20(4):325-34. 8. Adzick NS, Longaker MT. Scarless fetal healing: Therapeutic implications. Ann Surg 1992;215(1):3-7. 9. Cuttle L, Nataatmadja M, Fraser JF, et al. Collagen in the scarless fetal skin wound: Detection with Picrosirius-polarization. Wound Repair Regen 2005;13(2):198-204. 10. Aagaard-Tillery KM, Silver R, Dalton J. Immunology of normal pregnancy. Semin Fetal Neonatal Med 2006;11(5):279-95. 11. Chen EH, Tofe AJ. A literature review of the safety and biocompatibility of amnion tissue. J Impl Adv Clin Dent 2010;2(3):67-75. 12. Bailo M, Soncini M, Vertua E, et al. Engraftment potential of human amnion and chorion cells derived from term placenta. Transplantation 2004;78(10):1439-48. 13. Liu J, Sheha H, Fu Y, et al. Update on amniotic membrane transplantation. Expert Rev Ophthalmol 2010;5(5):645-61. 14. Werner S, Grose R. Regulation of wound healing by growth factors and cytokines. Physiol Rev 2003;83(3):835-70. 15. Kubo M, Sonoda Y, Muramatsu R, et al. Immunogenicity of human amniotic membrane in experimental xenotransplantation. Invest Ophthalmol Vis Sci 2001;42(7):1539-46.

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indication, contraindications, hazards, warnings, precautions, and instructions for use.

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