



DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Tissue Characteristics

- Dual-layer amniotic membrane.
- Intended for homologous use only. Acts as a wound cover, that is a natural bandage shielding wounds from its external environment.
- Proprietary processing of the tissue ensures that the natural structure and relevant characteristics are preserved.
- Dehydrated, packaged, and terminally sterilized with a 2-year shelf life. Stored at ambient temperature.

Configurations



Square sizes: 2x2cm, 4x4cm

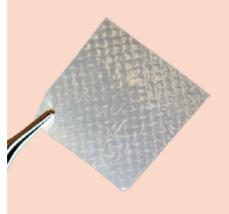
Rectangular sizes: 2x3cm, 2x4cm, 4x6cm, 4x8cm

Applications

- Wound Covering
- Venous Stasis Ulcer Covering
- Diabetic Foot Ulcer Covering
- Burn Covering



Tissue Processing - Amniotic Membrane Barrier



- The amniotic membrane for barrera™ is sourced from healthy deliveries of placental tissue with maternal consent.
- Processed using minimally manipulated amniotic membrane in a dual layer composition to retain the amniotic membrane's original relevant characteristics of the placental extracellular matrix (ECM).
- The amniotic membrane's key structural components, specifically the epithelium layer, as well as the basement layer of the placental tissue, are retained to allow the membrane its utility to serve as a barrier.
- May adhere to the underlying wound surface as a cover protecting wounds and may help prevent formation of dead space on wounds.^{1,2}
- May prevent infiltration and adhesion of microorganisms to wounds.^{1,2}

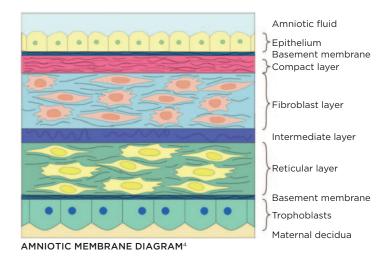


Ordering Information

SKU	Product Description	Size	Units	UPC
BRD-022	barrera™ Dual Layer Amniotic Membrane	2x2cm	4	382567000137
BRD-023	barrera™ Dual Layer Amniotic Membrane	2x3cm	6	382567000144
BRD-024	barrera™ Dual Layer Amniotic Membrane	2x4cm	8	382567000151
BRD-044	barrera™ Dual Layer Amniotic Membrane	4x4cm	16	382567000168
BRD-046	barrera™ Dual Layer Amniotic Membrane	4x6cm	24	382567000175
BRD-048	barrera™ Dual Layer Amniotic Membrane	4x8cm	32	382567000182

Human Amniotic Membrane Background

- Amniotic membrane is the inner most layer surrounding the fetus³, that is comprised of various layers.
- The tissue's tensile strength is attributed to its epithelial cell layer and basement membrane.
- Furthermore, amniotic tissue has been characterized in the literature to comprise a rich proteinaceous components like collagen types I, III, IV, V, and VI, and a host of growth factors.²



Disclaimer: Please consult your doctor to see if tissue allograft is right for you. No medical advice has been offered herein. None of the statements in this brochure have been evaluated by the FDA.

Amniotic tissue allografts are not intended to diagnose, treat, cure or prevent any disease.

The FDA's Tissue Reference Group (TRG) has determined that barrera™ appears to meet all of the criteria for regulation solely under section 361 of the Public Health Service Act and the regulations in 21 CFR part 1271 governing Human Cell, Tissue and Cellular and Tissue-Based Products (HCT/Ps).

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¹ Malhotra C, Jain AK. Human amniotic membrane transplantation: Different modalities of its use in ophthalmology. World J Transplant. 2014 Jun 24;4(2):111-21. doi: 10.5500/wjt.v4.i2.111. PMID: 25032100; PMCID: PMC4094946.

² Gupta A, Kedige SD, Jain K. Amnion and Chorion Membranes: Potential Stem Cell Reservoir with Wide Applications in Periodontics. *Int J Biomater.* 2015;2015:274082. doi: 10.1155/2015/274082. Epub 2015 Dec 6. PMID: 26770199; PMCID: PMC4684856.

³ Mamede AC, Carvalho MJ, Abrantes AM, Laranjo M, Maia CJ, Botelho MF. Amniotic membrane: from structure and functions to clinical applications. *Cell Tissue Res.* 2012 Aug;349(2):447-58. doi: 10.1007/s00441-012-1424-6. Epub 2012 May 18. PMID: 22592624.

⁴ Tehrani, F, Firouzeh, A, Shabani, I, Shabani, A. A Review on Modifications of Amniotic Membrane for Biomedical Applications. *Front. Bioeng. Biotechnol., 13 January 2021 Sec. Regenerative Medicine Volume 8 - 2020* https://doi.org/10.3389/fbioe.2020.606982