

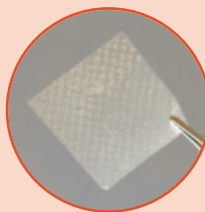
RESTORIGIN™

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Tissue Characteristics

- Dual-layer amniotic membrane.
- Intended for homologous use only. Acts as a sheet scaffold and wound cover, that is a natural bandage shielding wounds from its external environment.
- Minimally processed and packaged. The physical properties of the tissue are maintained relating to its utility to serve as a scaffold or barrier
- Dehydrated, packaged, and terminally sterilized with a 5-year shelf life. Stored at ambient temperature.

Configurations

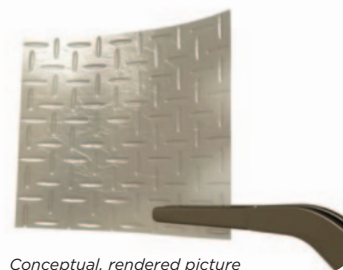


Square sizes:
2x2cm, 4x4cm

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

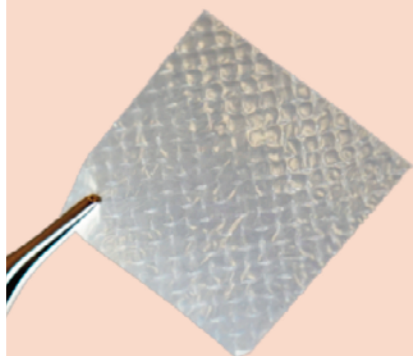
Applications

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



*Conceptual, rendered picture
of Restorigin™*

Tissue Processing - Amniotic Membrane Barrier



- The amniotic membrane for Restorigin™ 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 sheet scaffold and 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}

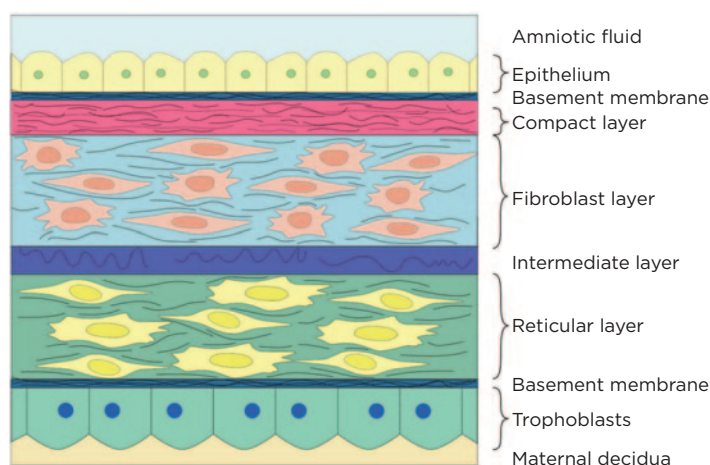
RESTORIGIN™

Ordering Information

SKU	Product Description	Size	Units	UPC
RGN-AM-0202	Restorigin™ Amnion Patch, Thin	2x2cm	4	382567000830
RGN-AM-0203	Restorigin™ Amnion Patch, Thin	2x3cm	6	382567000847
RGN-AM-0204	Restorigin™ Amnion Patch, Thin	2x4cm	8	382567000854
RGN-AM-0404	Restorigin™ Amnion Patch, Thin	4x4cm	16	382567000861
RGN-AM-0406	Restorigin™ Amnion Patch, Thin	4x6cm	24	382567000878
RGN-AM-0408	Restorigin™ Amnion Patch, Thin	4x8cm	32	382567000885

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



AMNIOTIC MEMBRANE DIAGRAM⁴

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, Firouzesh, 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>

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 Restorigin™ 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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