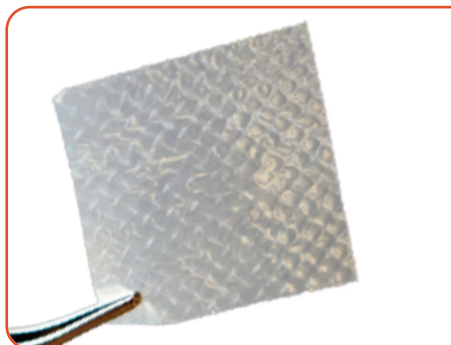


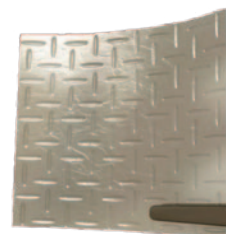
## Tissue Characteristics

- 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.



## Applications

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



Conceptual, rendered  
picture of alloPLY™

## Configurations

### Square sizes:

1.5x1.5cm, 2x2cm,  
4x4cm, 5x5cm

### Rectangular sizes:

2x3cm, 2x4cm,  
4x6cm, 4x8cm

### Disc Sizes:

12mm, 16mm

## Tissue Processing - Amniotic Membrane Barrier

- The amniotic membrane for alloPLY™ 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.<sup>1,2</sup>
- May prevent infiltration and adhesion of microorganisms to wounds.<sup>1,2</sup>





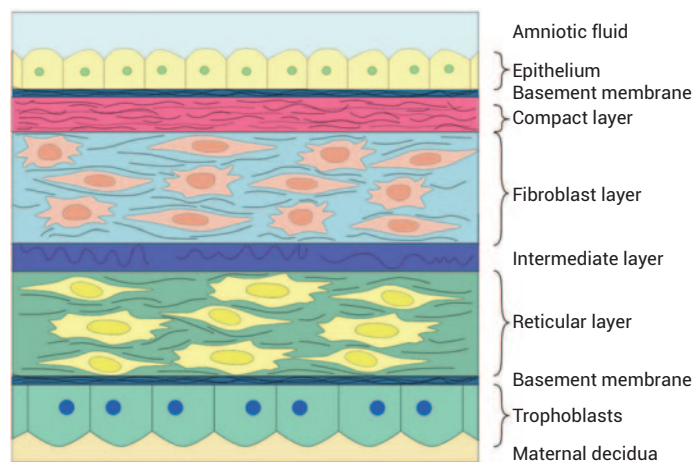
## Dual Layer Amniotic Membrane Allograft

### Ordering Information

SKU	Product Description	Size	Units	UPC
APY312S	alloPLY™ Amniotic Patch	12mm Disc	1	382567002292
APY316S	alloPLY™ Amniotic Patch	16mm Disc	2	382567002308
APY01515S	alloPLY™ Amniotic Patch	1.5x1.5cm	3	382567002285
APY022S	alloPLY™ Amniotic Patch	2x2cm	4	382567000397
APY023S	alloPLY™ Amniotic Patch	2x3cm	6	382567000403
APY024S	alloPLY™ Amniotic Patch	2x4cm	8	382567000427
APY044S	alloPLY™ Amniotic Patch	4x4cm	16	382567000434
APY046S	alloPLY™ Amniotic Patch	4x6cm	24	382567000441
APY055S	alloPLY™ Amniotic Patch	5x5cm	25	382567000465
APY048S	alloPLY™ Amniotic Patch	4x8cm	32	382567000458

### Human Amniotic Membrane Background

- Amniotic membrane is the inner most layer surrounding the fetus<sup>3</sup>, 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.<sup>2</sup>



AMNIOTIC MEMBRANE DIAGRAM<sup>4</sup>

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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 reviewed that alloPLY™ 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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