ExtremityCare®

carePATCH™

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Characteristics

- carePATCH™ is a dehydrated tissue product stored at ambient temperature with a 2 Year Shelf Life.
- carePATCH™ retains amniotic membrane's natural structure and relevant characteristics including epithelium and basement membrane layers.
- carePATCH™ acts as a wound cover, that is a natural bandage shielding wounds from its external environment.

Configurations

These different configurations serve as barriers for different types of wounds.



Figure 1 *Disc sizes 12mm-16mm*

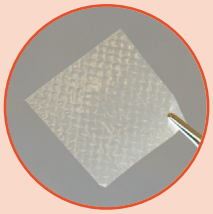


Figure 2 *Patch 1.5x1.5cm -4x8cm*

Amniotic Tissue as a Barrier

- Amniotic membrane adheres closely to its underlying surface as a cover protecting wounds and may help prevent formation of dead space on wound.[2, 3]
- Amniotic membrane's barrier function may help prevent infiltration and adhesion of microorganisms to wounds.[2, 3]

Applications

carePATCH™ is intended only for homologous use as a barrier that protects wounds from the surrounding environment during the wound healing process.[1] This includes non-healing wounds and surgically created wounds.

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





Figure 3 *Amniotic membrane of carePATCH™ where epithelial layer is in purple/blue areas and basement membrane is in pink.*

Manufacturing

- The amniotic membrane for carePATCH™ is sourced from healthy deliveries of placental tissue with maternal consent.
- carePATCH™ is produced using minimally manipulated amniotic membrane in a dual layer composition.
- Through minimally manipulated methods carePATCH™ retains amniotic membrane's original relevant characteristics relating to its utility to serve as a barrier, specifically its physical integrity, tensile strength, and elasticity.
- carePATCH™ retains the amniotic membrane's key structural components related to its utility to serve as a barrier, specifically:
  - Epithelium Layer
  - Basement Membrane
- carePATCH™ is dehydrated, packaged, and terminally sterilized with a 2 year shelf life.

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 carePATCH™ 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).

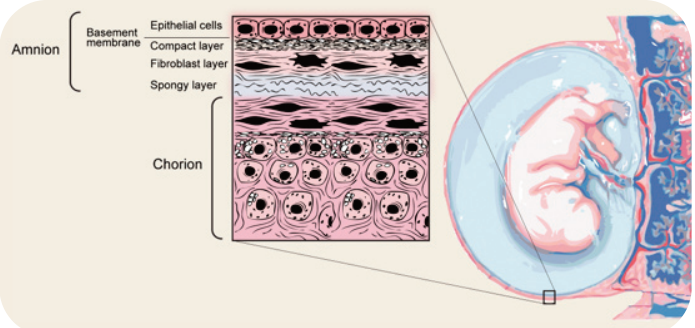
carePATCH™

Ordering Information

SKU	Description	Size	Units	UPC
CPT312S	carePATCH™ Amniotic Membrane	12mm	1	382567000106
CPT316S	carePATCH™ Amniotic Membrane	16mm	2	382567000113
CPT01515S	carePATCH™ Amniotic Membrane	1.5x1.5cm	3	382567002377
CPT022S	carePATCH™ Amniotic Membrane	2x2cm	4	382567000014
CPT023S	carePATCH™ Amniotic Membrane	2x3cm	6	382567000090
CPT024S	carePATCH™ Amniotic Membrane	2x4cm	8	382567000021
CPT044S	carePATCH™ Amniotic Membrane	4x4cm	16	382567000038
CPT046S	carePATCH™ Amniotic Membrane	4x6cm	24	382567000045
CPT055S	carePATCH™ Amniotic Membrane	5x5cm	25	382567000052
CPT048S	carePATCH™ Amniotic Membrane	4x8cm	32	382567000059

Human Amniotic Membrane Background

- Amniotic membrane is the inner most layer surrounding the fetus[4], that is comprised of various layers primarily:
  - epithelial cell layer;
  - thick basement membrane; and
  - an avascular stroma (further comprised of compact, fibroblast, and spongy layers).[3]
- The tissue's tensile strength is attributed to its epithelial cell layer and basement membrane (refer to Figure 1.)
- 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.[3]



[1] Velnar T, Bailey T, Smrkolj V. The wound healing process: an overview of the cellular and molecular mechanisms. *J Int Med Res.* 2009 Sep-Oct;37(5):1528-42. doi: 10.1177/147323000903700531. PMID: 19930861.

[2] 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.

[3] 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.

[4] 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.

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