Environment Protection & Non-Healing Wounds

carePATCH™ is a placental-derived human tissue amniotic membrane that is used in wound protection. The allograft is intended to protect wounds from the surrounding environment during the normal process of healing. Our placental tissues are aseptically processed and dehydrated in a minimally manipulated processing method in order to preserve the native tissue structure and characteristics. carePATCH™ is a natural and homologous approach to address environment protection among patients with full thickness and slow to heal wounds.

carePATCH™ comes in a variety of sizes and shapes that conforms seamlessly over a variety of anatomies with the tensile strength suitable to suture to serve as a barrier that protects surgically created wounds, or simply applied directly as a cover to non-surgical wounds. This barrier is comprised of multiple layers that preserve the amniotic membrane's key structural components and relevant characteristics. The carePATCH™ allografts are stored at room temperature and are available in a variety of sizes for greater off-the-shelf convenience to both the provider and the patient.

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).[2] 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]

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™ may be used for Homologous Use as either a protective barrier to support the wounds surrounding environment during the healing process.

FDA Regulation:
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).

LETTER FDA/TRG 361 ON FILE

Please consult your doctor to learn more and see if a tissue allograft is right for you. This brochure does not constitute medical advice. None of the statements in this brochure have been evaluated by the FDA.

References:

[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] 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.

[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.

Disclaimer: The information provided is for informational purposes only and is not intended to be medical advice. It does not replace the professional training, experience and knowledge of the healthcare provider responsible for patient care, who must base treatment upon the unique characteristics of each patient. Every patient's case is unique, and each patient should follow his or her doctor's specific instructions. For detailed product information please consult each product's Instructions for Use (IFU) prior to use.

For more information, please contact

Extremity Care LLC
555 E North Lane, Ste 5000, Bldg D
Conshohocken, PA 19428
1.888.694.6694
customerservice@extremitycare.com
www.extremitycare.com

carePATCH™ is a trademark of Extremity Care LLC.

L-125, Revision 02

ExtremityCare®

carePATCH™

DUAL LAYER AMNIOTIC MEMBRANE ALLOGRAFT

Protection for Wounds



carePATCH™ & FDA Compliance

Tissue Product (HCT/P)

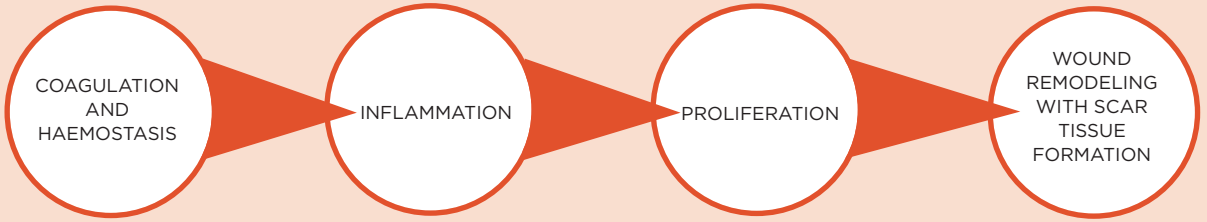
Human cells, tissues, and cellular and tissue- based products (HCT/Ps) are products containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. The U.S. Food and Drug Administration (FDA) regulates an HCT/P solely through its authority in section 361 of the Public Health Service Act to prevent the transmission of communicable diseases — i.e., as a "361 product" rather than as a drug, biologic or medical device — if it meets all the following criteria in 21 CFR 1271.10(a) including:

- The HCT/P is minimally manipulated.
- The product is intended for homologous use only (meaning that the HCT/P performs the same function(s) in the recipient as in the donor).
- The HCT/P does not involve the combination of the cells or tissues with another article — except for water, crystalloids, or a sterilizing, preserving or storage agent.
- The product does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function (which is satisfied if the product is acellular, meaning that it has no living cells).

About carePATCH™

carePATCH™ is a dual layer amniotic membrane for homologous use. Proprietary processing techniques are used to maintain the intrinsic characteristics of the placental tissue. The tissue is minimally manipulated only and is delivered at ambient temperature with a 2-year shelf life. The intended use of carePATCH™ is as a topical wound cover or wound barrier to protect from the environment. It does not need to be rehydrated. Both membrane sides consist of amniotic tissue and no attention to which side of the graft is facing the wound is necessary.

The Process of Wound Healing[3]



Amniotic tissue as a barrier that protects wounds, including surgically created wounds, from the surrounding environment during the wound healing process.

- Amniotic membrane adheres closely to its underlying surface as a cover protecting wounds and may help prevent formation of dead space on wound.[1, 2]
- Amniotic membrane's barrier function may help prevent infiltration and adhesion of microorganisms to wounds.[1, 2]

Natures Protection & Tissue Stewardship

carePATCH™ comes from the placenta of consenting female donors as part of child birth. The tissues are collected by appropriately licensed tissue establishments after maternal consent and using aseptic techniques to prevent contamination. Donor eligibility is carefully evaluated as required by the FDA and in accordance with appropriate standards and applicable state guidelines. Screening includes a review of the donor medical and social history, a physical examination, serological screening, and tissue collection microbiology. Placental allograft has a long history of safe use as a barrier in clinical applications.

Applications

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

The need for wound covering and protection as dictated by your doctor may come in several different forms. Some wounds may be naturally occurring such as venous stasis ulcers or diabetic foot ulcers. Other wounds may be due to trauma such as burns. Finally, wounds are sometimes surgically created for other clinical reasons and wound covering may be indicated in these cases too. In any case, amniotic membrane is an option for use as a wound covering barrier during the wound healing process.