

ACApatch™

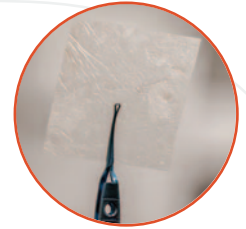
STERILE AMNION CHORION AMNION PLACENTAL MEMBRANE ALLOGRAFT

Tissue Characteristics

- ACApatch™ is a dehydrated tissue product stored at ambient temperature with a 5-year shelf life.
- ACApatch™ retains the placental membrane's natural structure and relevant characteristics including amnion, chorion and spongy layers.
- ACApatch™ acts as a wound cover, that is a natural bandage shielding wounds from its external environment.

Placental Membrane as a Barrier

The placental membrane adheres closely to its underlying surface as a cover protecting wounds and may help prevent formation of dead space on wound.^{1,2}



Configurations

Square sizes:

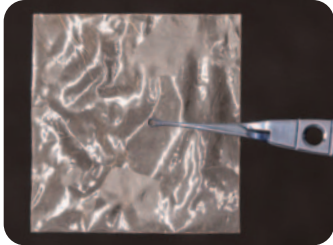
1.5x1.5cm, 2x2cm,
4x4cm, 5x5cm

Rectangular sizes:

2x3cm, 2x4cm,
4x6cm, 4x8cm

Disc Sizes:

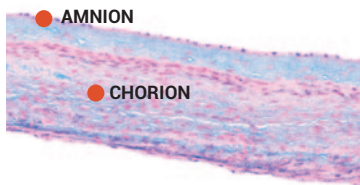
12mm, 16mm



Applications

ACApatch™ serves as a barrier and provides protective coverage from the surrounding environment to acute and chronic wounds.

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



Placental membrane of ACApatch™
where amnion and chorion are shown.

Manufacturing

- The placental membrane for ACApatch™ is sourced from healthy deliveries of placental tissue with maternal consent.
- ACApatch™ contains the amnion and chorion in a full thickness composition which is then combined with another layer of amniotic membrane.
- Through minimally manipulated methods ACApatch™ retains the placental membrane's original properties.
- ACApatch™ is dehydrated, packaged, and terminally sterilized with a 5-year shelf life.





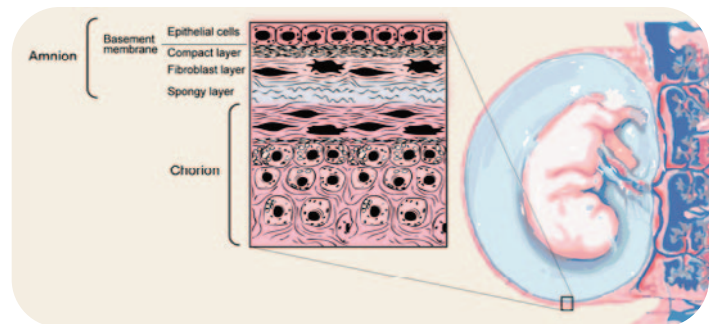
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Ordering Information

SKU	Product Description	Size	Units	UPC
ACP-312	ACApatch™ Amnion Chorion Amnion Membrane	12mm Disc	1	382567002261
ACP-316	ACApatch™ Amnion Chorion Amnion Membrane	16mm Disc	2	382567002278
ACP-01515	ACApatch™ Amnion Chorion Amnion Membrane	1.5x1.5cm	3	382567002254
ACP-022	ACApatch™ Amnion Chorion Amnion Membrane	2x2cm	4	382567000496
ACP-023	ACApatch™ Amnion Chorion Amnion Membrane	2x3cm	6	382567000410
ACP-024	ACApatch™ Amnion Chorion Amnion Membrane	2x4cm	8	382567000502
ACP-044	ACApatch™ Amnion Chorion Amnion Membrane	4x4cm	16	382567000519
ACP-046	ACApatch™ Amnion Chorion Amnion Membrane	4x6cm	24	382567000526
ACP-055	ACApatch™ Amnion Chorion Amnion Membrane	5x5cm	25	382567000540
ACP-048	ACApatch™ Amnion Chorion Amnion Membrane	4x8cm	32	382567000533

Human Amniotic Membrane Background

- The placental membrane is comprised of various layers primarily:
 - the amnion, which is the thin inner most layer surrounding the fetus;³
 - thick basement membrane;
 - an avascular stroma (further comprised of compact, fibroblast, and spongy layers);² and
 - the chorion, which is the outer most layer facing away from the fetus.
- 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



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.

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 ACApatch™ 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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