Overview of Placental Tissue

The placenta is a maternal-fetal organ that develops from the fetus and attaches to the uterus during pregnancy. The placenta is responsible for, among other things, providing the growing fetus with oxygen and nutrients while at the same time removing toxins.[1] Once the baby is born, the placenta detaches from the uterine wall and is expelled from the body.

Placental tissue is harvested after a healthy, concluded birth and then processed into a human tissue allograft.

What's a Placental Allograft?

An allograft is a tissue from a human donor that is transplanted from one body to another. Placental allografts are composed of extracellular matrix (ECM). Placental allografts have been used for many years for various medical conditions.[2]

The extracellular matrix (ECM) is the non-cellular component present within all tissues and organs. It may provide essential physical scaffolding.[3]

FDA Regulation: Tissue allografts are regulated by FDA solely under the authority of section 361, 21 CFR 1271.10(a) of the Public Health Service (PHS) Act — not as drugs, biologics, or medical devices — if they meet the four regulatory criteria described: minimal manipulation, homologous use, being combined only with permitted articles, and not having systemic effect nor depending on the metabolic activity of live cells. These qualifying tissue allografts are exempt from FDA pre-market review, licensure, clearance, and approval from FDA.

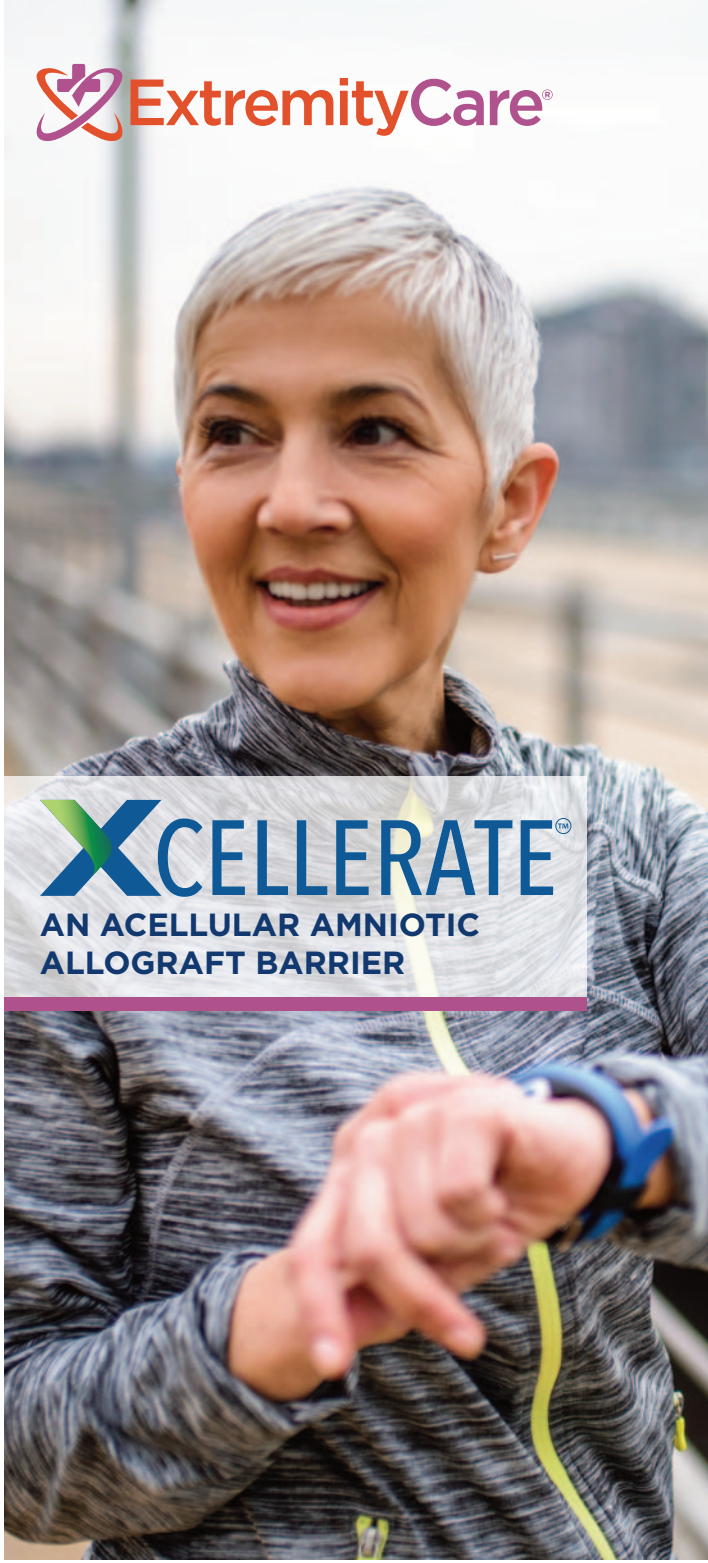
Please consult your doctor to learn more and see if a tissue allograft is right for you. This brochure does not constitute medical advice. None of the statements in this brochure have been evaluated by the FDA.

References:

1. Garnica & WY Chan, The role of the placenta in fetal nutrition and growth, *J Am Coll Nutr.* 1996 Jun;15(3):206-22.
2. McIntyre, et al., The Placenta: Applications in Orthopaedic Sports Medicine, *Am J Sports Med.* 2018;46(1):234-47; see also, Ang, et al., The Role of Placental Membrane Allografts in the Surgical Treatment of Tendinopathies, *Clinics in Podiatric Medicine and Surgery.* 2018;35(3).
3. Frantz C, Stewart KM, & Weaver VM, The extracellular matrix at a glance, *J Cell Sci.* 2010 Dec 15; 123(24): 4195-4200.
4. Barrientos, S., et al. Growth factors and cytokines in wound healing. *Wound Repair and Regeneration.* 16: 585-601, 2008.

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

ExtremityCare®



XCELLERATE™

AN ACELLULAR AMNIOTIC ALLOGRAFT BARRIER

XCELLERATE™ is a Human Cell & 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):

- 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).

XCELLERATE™ is an acellular amniotic allograft barrier/membrane that supports an environment for wound healing.

XCELLERATE™ is aseptically processed to preserve extracellular matrix, growth factors and cytokines native to amniotic tissue.[4]

XCELLERATE™ is indicated for use as a surgical barrier and wound cover.

EPITHELIAL STROMAL

XCELLERATE™ has two distinct sides: an epithelial side and a stromal side. The epithelial side is smooth while the stromal side is dull.

In addition, the graft has a 2-3 mm vertical orientation guide slit that when in the upper right corner, the epithelial side is facing upward.

What is an Amniotic Membrane/Amniotic Patch

Amniotic membrane, or amnion, is **the innermost layer of the placenta and consists of a thick basement membrane and an avascular stromal matrix.** Amniotic membrane transplantation has been used as a graft or as a dressing in different surgical subspecialties.

Amnion Patches are **allografts that may be used as an anatomical barrier in numerous clinical applications.** Proprietary process retains nutrient-rich growth factors essential for signaling.

Donated Tissue Screening: All HCT/Ps are required to be collected aseptically and tested prior to processing, and must be determined to be eligible for transplantation. Applicable donor testing and eligible standards include those prescribed by FDA regulations. The processes used have been developed to preserve the tissue characteristics for transplantation.

Tissue Processing and Sterilization: For 361 HCT/Ps, specific minimally manipulative tissue preparation and preservation methods are used to ensure the intrinsic cellular or tissue characteristics are retained. Many tissues remain in a hydrated form (as they are in normal physiology) and without loss of mechanical integrity. ***As with the implantation of any human tissue, there is always the possibility of an allergic reaction or transmission of a communicable disease.***