

ACTIVATE™

PLACENTAL- DERIVED ALLOGRAFT

NIVISION™
BIOMEDICAL TECHNOLOGIES

Exclusively Distributed by

WVC
Innovative Wound Consultants

ACTIVATE™

Activate™ Placental-Derived Allograft is comprised of the amniotic and chorionic membranes, and includes the intermediate (spongy) layer of the placenta. This product is designed as an innovative solution to serve as a barrier or wound cover across a spectrum of clinical needs. Leveraging the structural and biochemical properties of placental tissue, including extracellular matrix proteins, growth factors, and anti-inflammatory cytokines, Activate™ offers a comprehensive biologic approach for a variety of acute or chronic wound applications.

PLACENTAL TISSUE

Placental tissue, previously considered biologic waste following delivery, is a pristine, newly formed extracellular matrix (ECM) replete with growth factors and cytokines produced to protect and support fetal development. Therefore, this tissue represents an untainted extracellular matrix....essentially a neomatrix.

BENEFITS

Research and clinical studies going back over a century have exhibited the beneficial effects of utilizing human placental tissue to manage various types of wounds due to injury, disease, or surgical intervention. These studies have indicated several beneficial properties of the placental tissue including; serving as a protective wound barrier or cover, anti-microbial effects and anti-inflammatory effects, among others (3,4).

DESCRIPTIONS OF LAYERS

Broadly, placental tissue includes an internal or fetus facing amnion and an external or maternal facing chorion. The physical and biochemical properties of the two primary membranes are subtly different owing to the position they occupy in the placenta. The amnion is a thinner yet more compact layer of extracellular matrix while the chorion is a slightly thicker but less compact matrix. Both layers are constituted of collagen fibers (predominantly Types I, III, IV and V), along with other ECM proteins (including laminin, fibronectin, proteoglycans and hyaluronic acid) plus numerous growth factors and cytokines (3).

PROPERTIES

ACTIVATE™

ALL-NATURAL BIOLOGIC WOUND COVERING

The placental membrane is a newly formed extracellular matrix produced during pregnancy. In this role, the membranes play a critical role in cushioning and forming a protective barrier around the developing fetus. Further, the placental membrane acts as a filter for water, soluble materials and bioactive molecules present in the amniotic fluid (5).

ANTI-INFLAMMATORY

Placental membrane products have been shown to be immune privileged due to a significant decrease in Major Histocompatibility Complex (6) and Human Leukocyte Antigens (HLA) (7,8).

CELL SIGNALING AND BIOLOGIC FACTORS

The placental membrane extracellular matrix also functions as a binding site for a number of cell signaling cytokines and growth factors including bFGF, EGF, HA, TGF-beta, IL-1, 6 & 10, PDGF, MMPs and TIMPs (9,10,11,12).

WOUND ECM SCAFFOLD

The extracellular matrix of the placental membranes also acts as a substrate for host cell attachment and proliferation (1).

SAFETY

Donated tissues for Activate™ products are collected from fully consented mothers undergoing full term c-sections. Each donor is screened according to the strict standards required by the U.S. Food and Drug Administration and the American Association of Tissue Banks. Further, Activate™ Placental-Derived Allograft products undergo a validated terminal sterilization process to help ensure these products are safe. All donated tissue is obtained in partnership with FDA regulated and accredited recovery organizations. Additional details of screening procedures can be found in the product package insert or Instructions for Use.

MATERNAL SCREENING INCLUDES:

- o Human Immunodeficiency Virus (HIV)
- o Hepatitis B Virus (HBV)
- o Hepatitis C Virus (HCV)
- o Syphilis
- o West Nile Virus (WNV NAT)



PRODUCT SUMMARY

Activate™ Placental-Derived Allograft products are minimally manipulated and dehydrated and are derived from human amniotic and chorionic membrane. Activate™ allograft tissues retain the structural and functional characteristics of the starting placental membranes. The final products are packaged in different sizes and verified to be terminally sterilized to a 10^{-6} SAL.



INSTRUCTIONS FOR USE

Activate™ Placental-Derived Allograft (361 HCT/Ps) are intended as a natural biologic wound covering or skin substitute for cutaneous wounds. Use of Activate™ Placental-Derived Allograft by qualified health care professionals is for application in a physician office, outpatient, or inpatient setting.



ORDERING INFORMATION

Activate™ tissue is available in the following sizes for a variety of choices depending on the patient and circumstance: Product HCPCS Level II code Q4301, Activate™ Matrix, per square centimeter.

PRODUCT SKU:

ACT-27222

ACT-27224

ACT-27244

ACT-27248

PRODUCT SIZE:

2 X 2

2 X 4

4 X 4

4 X 8

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