Diamond Health
Medical Care Center

Discover the Innovation in Wound Care:

MEMBRANE WRAP™

AMNIOTIC ALLOGRAFT MEMBRANE

Membrane Wrap is a human tissue allograft derived from the amniotic membrane that provides structural tissue for use as a wound and protectant covering. It is minimally manipulated, preserving the properties that it exhibits in its natural state

BENEFITS

- *Strong Tensile Strength*
- *Efficient and Fast*
- *Safe and Effective*
- *Stable Shelf-Life*

PRODUCT DESCRIPTION

Membrane Wrap is a human tissue allograft derived from the amniotic membrane that provides structural tissue for use as a wound and protectant covering.

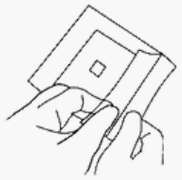
Membrane Wrap is a human tissue allograft [Human Cellular and Tissue Based Product (HCT/P)] for transplantation regulated by the US Food and Drug Administration under 21 CFR Part 1271.

PACKAGE CONTENTS

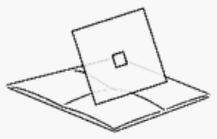
The product package contains the following items:

- One tissue graft, double packaged in sealed pouches
- Instructions for Use insert (this document)
- One set of supplemental Tracking Labels
- One allograft Tissue Tracking Record (TTR) card

PREPARATION & APPLICATION



Open product box and remove the product pouch.



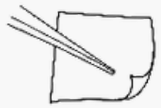
Using aseptic technique, peel open the outer pouch and place the inner pouch into the sterile field.

When ready to use, either tear open the inner pouch at the notch or cut the pouch at the notch to expose the graft.

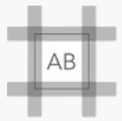
Remove graft using dry, sterile gloves or forceps.

Graft may be cut with scissors before hydration to apply over multiple sites.

If desired, graft may be hydrated prior to application with sterile saline for tight or hard to reach areas.



Use forceps to apply the graft over the intended site.
Achieve full contact.



Ensure the HCT/P is secured in place by the Physician’s choice of fixation.

STORAGE & HANDLING

- Store product at ambient temperature (15-25°C, 59-77°F).
- Handle using aseptic techniques.

WARNINGS

- For single patient use only.
- To be used under the supervision of a qualified healthcare provider.
- Do not use if the product sterile barrier system or its packaging is compromised.
- Cannot be re-sterilized.

PRECAUTIONS

- The graft should not be applied in the presence of a live infection.
- Diamond Health's Sciences makes no claims concerning the biological properties of this allograft tissue.
  All tissues have been collected, processed, stored, and distributed in compliance with US Food and Drug Administration (FDA) regulations governing human cells, tissues, and cellular and tissuebased products (HCT/Ps) to prevent the transmission of communicable diseases listed on page two. Current technologies may not preclude the transmission of communicable diseases.

HCTP RECORD TRACKING

Recipient records must be maintained for the purpose of tracking tissue post-transplant in accordance with The Joint Commission standards and the FDA requirements under 21 CFR Part 1271. Supplemental labels, which indicate the tissue ID number, are contained in this package for tracking processes. The allograft ID number must be recorded in the operative record. The provided Tissue Tracking Record (TTR) must be completed and returned to Diamond Health's Sciences.

PROCESSING

The HCT/Ps are processed in accordance with FDA's Good Tissue Practice regulations in a controlled cleanroom environment, using processes designed to prevent contamination of the tissue, and to prevent the introduction, transmission, or spread of communicable diseases. The tissue products are sterilized using electron-beam irradiation for a Sterility Assurance Level of SAL

DONOR SCREENING, TESTING & ELIGIBILITY

The donated human birth tissue has been determined to be eligible for transplantation by a licensed physician, the Medical Director of Diamond Health's Sciences. In accordance with FDA regulations under 21 CFR Part 1271, the donor has been deemed to be free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases and other exclusionary disease conditions through review of donor records, including a medical/behavior risk assessment, medical records, and a recent physical examination. Additionally, testing of a qualified blood sample indicates that the donor is nonreactive or negative for the following communicable disease markers:

- Antibody to human immunodeficiency virus (HIV) types 1 & 2
- Hepatitis B surface antigen (HBsAg)
- Hepatitis B core (HBc total)
- Antibody to hepatitis C (HCV)
- Syphilis (RPR)
- WNV NAT
- HCV NAT
- HIV NAT
- HBV NAT

ADVERSE REACTIONS

No adverse clinical reactions to this tissue product have been reported. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to our clinic.

HUMAN CELL AND TISSUE PRODUCTS (HCT/PS)

HCT/Ps: 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) is authorized under the communicable disease authority of section 361 of the Public Health Service Act (PHSA) to regulate products that meet specific criteria as "HCT/Ps" that do not require premarket review and approval.

Acellular Tissue: The term “acellular” generally refers to biological tissue material that lacks intact cells, is not divided into cells, or is devoid of cells. This tissue is processed in such a way as to remove cells, while retaining some of the extracellular matrix (ECM). The ECM is the non-cellular component present within all tissues and organs.

HUMAN CELL AND TISSUE PRODUCTS (HCT/PS)

Under FDA regulation, 21 CFR 1271.10(a), an HCT/P must satisfy 4 requirements to qualify as a 361 HCT/P exempt from pre-market approval from FDA.

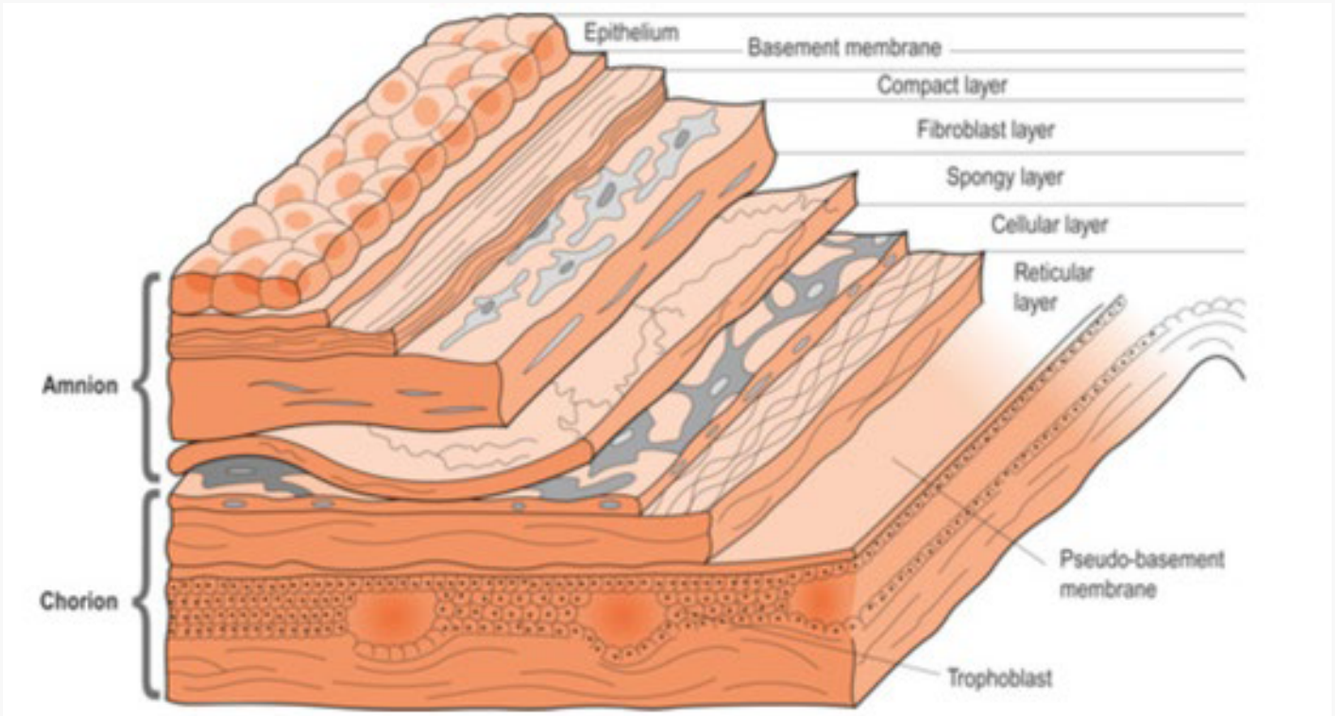
Minimally Manipulated

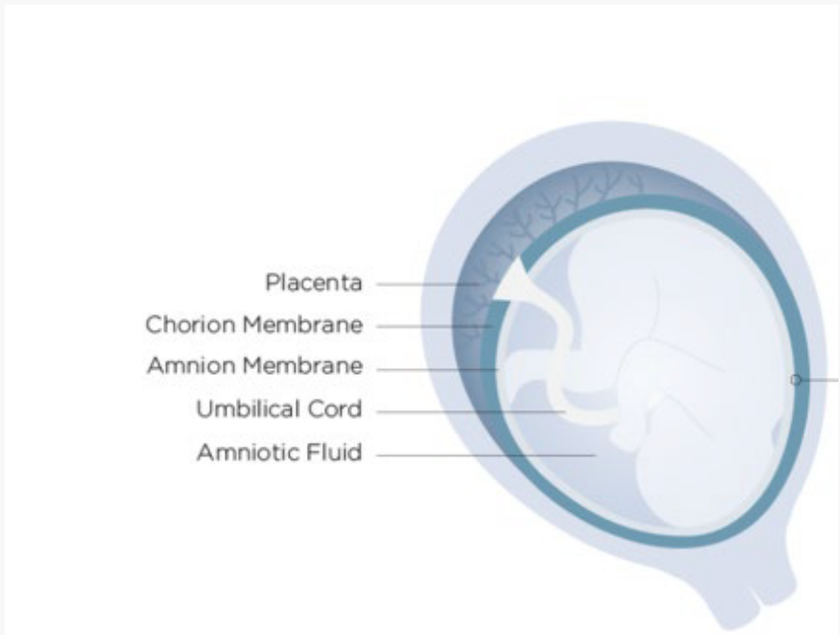
For structural tissue, the processing must not alter the original relevant characteristics of the tissue relating to the tissue’s utility for reconstruction, repair, or replacement. For cells or nonstructural tissues, "minimally manipulated" means "processing that does not alter the relevant biological characteristics of cells or tissues."

Homologous use

The HCT/P must be intended for the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor, as reflected by the labeling , advertising, or other indications of the manufacturer’s objective intent.

OVERVIEW PLACENTAL TISSUE





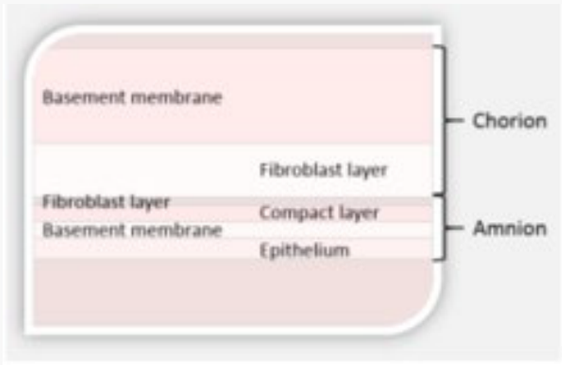
Disclaimer: None of the statements or pictures on this page are intended to make any claims about Diamond Health, but instead describe many of the basic functions and anatomy of native placental tissue. Per FDA Guidance, it is not necessary for the HCT/P in the recipient to perform all of the basic functions it performed in the donor in order to meet the definition of homologous use.

ACELLULAR AMNIOTIC MEMBRANES/BARRIERS

Anecdotal Overview:

- Placental tissue can be a rich source of extracellular matrix, (ECM) proteins and growth factors.
- Placental Membrane Tissue is commonly used in an array of therapeutic wound care applications.
- Amniotic Membranes are mostly aseptically recovered, processed and preserved in a variety of methods designed to preserve ECM and growth factors native to amniotic tissue.
- Amniotic Barriers/Membranes are acellular. They need a host to be activated. After implantation, acellular ECMs may trigger cues (signals for an action) that specific portion of a perceptual field or pattern of stimuli to which a subject has learned to respond

Placental Layers:



Cellular Characteristics of Epithelial Tissue:
cellularity, polarity, attachment, vascularity, and regeneration

Composition:
Amniotic Membranes/Barriers may be composed of Structural Extracellular Matrix (ECM), Growth Factors, Cytokines and other mediators native to placental tissue.

DEFINITIONS

What's a Fibroblast?

A fibroblast is the most common type of cell found in connective tissue. Fibroblasts secrete collagen proteins that are used to maintain a structural framework for many tissues. They also play an important role in healing wounds.

Fibroblasts' most well-known biological role is the production of the rich ECM of connective tissues. Fibroblasts produce and secrete all components of the ECM, including the structural proteins, adhesive proteins, and a space-filling ground substance composed of glycosaminoglycans and proteoglycans.

What is Epithelial Tissue?

Epithelial tissues line the outer surfaces of organs and blood vessels throughout the body, as well as the inner surfaces of cavities in many internal organs. An example is the epidermis, the outermost layer of the skin.

Despite there being many different types of epithelial tissue all epithelial tissue have just five characteristics, these are cellularity, polarity, attachment, vascularity, and regeneration.

THE AMNION STORY

A Simply Remarkable Tissue

- Versatile, powerful tissue that supports the development of the fetus in utero. The properties of amnion that benefit the fetus also make it an ideal material for covering wounds.

- Allogeneic human birth tissues may be used as a protective barrier. Published literature shows that amnion contains important growth factors such as extracellular matrix molecules, hyaluronic acid, fibronectin, laminin, prostaglandins, and cells.

- Amnion is intended for topical application as a covering over wounds. Birth tissues are recovered during planned cesarean sections and processed aseptically to preserve the tissue's inherent properties.

THE AMNION STORY & WOUND HEALING

The Process of Wound Healing

Amniotic Tissue as a Barrier

- Anti-microbial and anti-viral propierties - due ti its mechanical hability to adhere closely to its underlying surface, amniotic membrane prevents infiltration and adhesion of microorganisms to wound.
- Covering propierties - by mechanically adhering to the underlying wound, amniotic membrane prevents formation of dead space and accumulation of serous discharge.

Amniotic Tissue as a Scaffold

- Promotion of epithelization - the epitelium layer serves as a substrate that promotes epithelial cell growth supporting wound closure
- Supporting body's healing process - The epithelium and basement membrane layers serve as a structural scaffold that supports cell attachment and support for the body's wound healing process like cellular proliferation and remodeling.

CASCADE OF TISSUE & WOUND HEALING

CASCADE

1. Hemostasis: Hemostasis is a process to prevent and stop bleeding, meaning to keep blood within a damaged blood vessel. It is the first stage of wound healing.
2. Inflammatory phase: Begins at the time of injury and lasts up to four days. It includes clotting of platelets and constriction of blood vessels to stop blood loss.
3. Proliferative phase: Begins about three days after injury and overlaps with the inflammatory phase. It involves cells called fibroblasts that help to produce new collagen, create new blood vessels, and repair the avascular epithelial tissue.
4. Remodeling phase: Can continue for six months to one year after injury. Collagen continues to increase and the tissue begins to contract with the help of fibroblasts.

The Problem with Chronic Wounds

In a chronic wound, the cascade of wound healing may be stalled in the inflammatory stage. This decreases growth factor production and creates an imbalance in enzymes, favoring degradative versus protective enzymes, which leads to breakdown of the
extracellular matrix.
For Surgical Barriers & Wound Covering: Amniotic membranes may provide growth factors necessary to facilitate tissue growth and healing, and to overcome the stalled cycle of a chronic wound. Membranes may also have antimicrobial and anti-inflammatory
properties

OUR MEMBRANE WRAP ADVANTAGES

It is a dual layer amnion/amnion membrane

- Slower degradation rate, i.e. remains intact longer than a single layer grafts.
- More tensile strength than a single layer amnion or amnion/chorion graft.
- Easy to handle, place and reposition.
- Agnostic with respect to sidedness. Both surfaces are identical.

VIDEO 1

VIDEO 2

Diamond Health
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How to Get Started with Membrane WrapTM?

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