Vim®
INJECTABLE AMNION

HT0003-01E

COOK® BIOTECH

Manufacturer	**Attention, see instructions for use**
Temperature limit	**Keep dry**
Use-by date	STERILE A **Aseptically processed**
Do not re-use	MR **Magnetic resonance safe**

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ALLOGRAFT PROCESSING

Vim® Injectable Amnion is an aseptically processed tissue that meets the requirements for a Human Cellular and Tissue Based Product (HCT/p) as defined by US FDA 21CFR Part 1271.

The tissue is processed to preserve the biological components and structure of the extracellular matrix (ECM). The amniotic membrane (AM) is characterized by structural proteins such as collagen, glycoproteins, proteoglycans, and growth factors.[1,2] This natural scaffold is crucial to the biochemical and biomechanical processes occurring at a cellular level. Wound healing, guided cell migration, and tissue morphogenesis are a few of the attributes associated with the ECM.

All tissues are obtained from consenting donors and tested for infectious diseases. This product is cryopreserved in 10% Dimethyl Sulfoxide (DMSO) solution and provided in a 20-gauge needle.

INTENDED USE

Vim Injectable Amnion is an allograft sheet intended for homologous use at the direction of a physician where injection delivery may be beneficial, (including but not limited to tunneled or undermined wounds or injuries). The graft is supplied sterile and is intended for one-time use in a single patient.

This DONATED HUMAN TISSUE has been determined eligible for transplantation by a licensed Medical Director.

This product is intended for use by a trained medical professional.

CONTRAINDICATIONS

This Vim Injectable Amnion is not intended for injection into the vascular, respiratory, or central nervous systems.

This Vim Injectable Amnion may contain gentamicin and should not be used in patients with known hypersensitivity to gentamicin or other aminoglycosides.

PRECAUTIONS

This product is designed for single use only. Attempts to reprocess, re-sterilize, and/or re-use may lead to failure and/or transmission of disease.

Do not re-sterilize. Discard all open and unused portions of the graft.

The graft is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.

Discard graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.

Although donor tissue is evaluated and processed following strict FDA guidelines, donor screening methods are limited and may not detect all diseases.

POTENTIAL COMPLICATIONS

Possible adverse reactions with the use of any prosthesis may include, but are not limited to:

- Fever
- Immune or allergic reaction to the implanted product
- Infection of soft tissue and/or bone (osteomyelitis)
- Inflammation
- Pain
- Recurrence of tissue defect
- Transmission of communicable diseases including those of unknown etiology
- Transmission of infectious agents such as viruses, bacteria, and fungi

Complications such as delayed wound infection and the need for re-operation should be reasonably expected in patients who are critically ill or who have severely contaminated wounds. Patients with significant comorbidities are more prone to complications.

Adverse outcomes potentially attributable to the tissue must be promptly reported to Cook Biotech, Inc.

STORAGE

It is the responsibility of the Tissue Dispensing Service and/or end user to maintain Vim Injectable Amnion in its original package at -65°C or colder until ready for use.

Once opened, Vim Injectable Amnion must be used immediately or discarded.

DONOR SCREENING AND TESTING

Prior to donation, the donor's medical and social history is screened for medical conditions or disease processes that would contraindicate the donation of tissues in accordance with current policies and procedures approved by Cook Biotech, Inc.

Donor blood samples taken at the time of recovery were tested by a CLIA licensed facility for:

- Hepatitis B Surface Antigen
- Hepatitis B Core Antibody
- Hepatitis C Antibody
- HBV NAT
- HCV NAT
- HIV-1/2 Antibody
- HIV NAT
- HTLV I/II Antibodies
- Syphilis
- West Nile Virus

The results of all serological testing were negative. This allograft tissue has been determined to be suitable for transplant.

The infectious disease test results, consent, current donor medical history, interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, and information obtained from a source or records which may pertain to donor suitability, have been evaluated by a Medical Director for Cook Biotech, Inc.

The Medical Director is a licensed physician who completes a comprehensive review of every donor record. The results are used to determine that the donor suitability criteria at the time of tissue recovery have been met, and that the tissue is acceptable for transplantation.

INSTRUCTIONS FOR USE

1. Open the secondary product packaging and remove the cryovial from the box.
2. Thaw the product for a minimum of 15 minutes at room temperature.
3. Using aseptic technique, remove the threaded cap from the cryovial.
4. Load a syringe with a minimum of 2 mL of sterile saline or other appropriate solution.
5. Insert syringe into the hub of the needle in the cryovial. Ensure the needle is completely affixed to the syringe.
6. After preparing the site, insert the needle into the patient tissue as required.
7. Apply gentle consistent pressure to eject the Vim Injectable Amnion from the needle to the wound site.

Note: A 3 cc syringe is recommended.

TISSUE TRACKING

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of allograft tracking. Peel off stickers and a Tissue Utilization Record have been included with each package. Please record the requested information on the card and return it to Cook Biotech, Inc. Alternatively the card can be submitted electronically to TUR@CookBiotech.com.

ADVERSE EVENTS

Immediately report all adverse events to Cook Biotech, Inc. customer service at vimfeedback@CookBiotech.com.

REFERENCE

1. Niknejad, et al. Properties of the Amniotic Membrane for Potential Use in Tissue Engineering. *European Cells and Materials* 2008;15:88-99.
2. Francisco et al. Amniotic Membrane as a Potent Source of Stem Cells and a Matrix for Engineering Heart Tissue. *J. Biomedical Science and Engineering* 2013;6:1178-1185.