Contents/ How Supplied

This package contains one Dehydrated Human Cellular and Tissue based Products (HCT/P) as defined by US FDA 21 CFR Part 1271.

CAUTION

Law restricts this product to sale by or on the order of a licensed physician.

The Donated Human Tissue has been determined eligible for transplantation by a licensed Medical Director according to the criteria listed in the Donor Selection section below

Product Description

AMsurgtek® is an amniotic allograft membrane provided in prescribed multiple geometric configurations. AMsurgtek® membrane is dehydrated during processing and should be visibly dry when the package is opened.

- AMsurgtek® membrane is sterile and packaged for single patient, one-time use only
- Once opened, AMsurgtek® membrane must be used immediately or discarded

Donor Selection

The Medical Director of Biogentek® has determined that the donor of the tissue contained in this product is eligible to donate tissue for transplantation based on meeting the following criteria

1. The results of donor screening indicated that the donor was free from risk factors and clinical evidence of infection due to relevant communicable disease agents and diseases
2. The results of donor testing for the following relevant communicable disease agents are negative or nonreactive antibodies to the human immunodeficiency virus type1 and type 2 (anti-HIV-1 and anti-HIV-2

- HIV-1/Hepatitis B/Hepatitis C by Transcription Mediated Amplification
- Hepatitis B surface antigen (HBSAg)
- Hepatitis B total core antibody
- Antibodies to the Hepatitis C virus (anti-HCV)
- Syphilis using vDRL tests

All infectious disease tests were performed by NABL & CAP Accredited laboratories to perform laboratory testing.

Additionally, a donor's medical history and behavior risk assessment, incorporating India , Public Health Service guidelines are obtained prior to donation. Discussions with physicians and/or the donor's mother are conducted to identify circumstances that may lead to the exclusion of the donor or donated tissue. The blood sample test results, donor medical history, behavior risk assessment, physical assessment, and information from other sources or records, which may pertain to donor suitability, have been evaluated by a Medical Director. 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. The names and addresses of the testing laboratories, the interpretation of all required infectious disease tests, a listing of the documents reviewed as part of the relevant medical records and all pertinent donor medical information can be quickly retrieved upon request for any allograft tissue by Biogentek® Lifescience.

Recovery

Tissue recovery is aseptically performed. At the time of recovery medical records are collected and reviewed as part of donor eligibility.

Processing

AMsurgtek® membrane is processed by Biogentek® using proprietary Drytek™ process in a controlled environment using methods designed to prevent contamination and cross-contamination of the products. Technical quality assurance standards are rigorously maintained.

Tissue Distribution

AMsurgtek® membrane is distributed by Biogentek® Lifescience.

Tissue Storage

It is the responsibility of the Tissue Dispensing Service and/or end user to maintain AMsurgtek® membrane in its original packaging and at room temperature until ready for use.

HCT/P Tracking

Important notice to end user: Recipient records must be maintained for the purpose of tracing tissue post-transplant per The joint Commission on Accreditation of Healthcare Organizations. Patient labels, which include Lot No., are contained in this package to aid in the tracking process.

General Usage

AMsurgtek® membrane is intended for use as a wound cover. This product is intended for use as a protective barrier covering during the repair of soft tissue wounds at the direction of a physician.

Precautions

1. In order to reduce the risk of complications, Drytek™ membrane should not be used in the presence of active infection
2. Although donor tissue is evaluated and processed following strict Indian FDA guidelines,the donor screening methods are limited and may not detect all diseases. As with any allograft complications at the graft site may occur post-operatively that are not readily apparent

These include, but are not limited to:

- Transmission of communicable diseases, including those of unknown etiology
- Transmission of infectious agents such as viruses, bacteria and fungi
- Immune rejection of, or allergic reaction to, implanted HCT/P

Adverse Reactions

An Adverse Reaction is defined by the FDA as any noxious or unintended response for which there is a reasonable possibility that the HCT/P caused the reaction. This includes, but is not limited to, the transmission of communicable diseases or

infectious agents such as viruses, bacteria or fungi, or allergic reaction. Adverse reactions should be reported immediately to Biogentek® LifeSciences Customer Service Department at Recommended Instructions for Use of AMsurgtek® Membrane These recommendations are designed only to serve as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

Preparation Instructions

1. Open carton or box containing AMsurgtek® membrane and remove the foil pouch
2. Peel open the outer foil pouch and remove the graft using aseptic techniques

- Care must be taken in transferring/ removing the graft from the package as it is lightweight and may be easily displaced.
- The AMsurgtek® graft is translucent and may look off-white or yellowish
- Remove the allograft from the pouch and place it at the desired location for transplant
- Anchor the allograft using the physician's choice of fixation if needed

Return Policy

All return orders of AMsurgtek® membrane require a Return Authorization (RA) number before product may be returned for credit. Please contact the Biogentek® LifeSciences Customer Service Team for more information. All products being returned must be in original unopened packaging and in feasible condition.

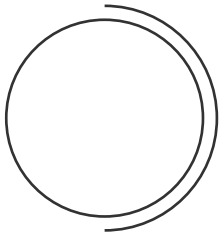
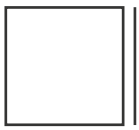
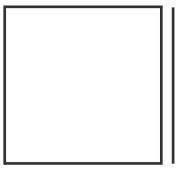
Note: Biogentek® Lifescience makes no claims concerning the biological properties of allograft tissue. All tissue has been collected, processed, stored, and distributed in compliance with the local FDA regulations governing HCT/Ps. Although every effort has been made to ensure the safety of allograft material, current technologies may not preclude the transmission of disease.

Product information disclosure biogentek has exercised reasonable care in the selection of materials and the manufacture of these products. Biogentek® excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Biogentek shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of this product. Biogentek® neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products.

Rx ONLY Use is limited to specific health professionals (e.g. physicians). After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

- Do not re-sterilize QTY1
- Consult the Package Insert
- Store at room temperature.

AMsurgtek® Product Range

INDICATIONS	All chronic and dry ulcers, Diabetic Foot, Bed Sores Debridement, amputations, dehiscence, flaps, decubitus ulcers trauma, pilonidal cysts, port sites and burns, port sites and burns, Donor Sites in plastic surgery			
DIMENSIONS	50 mm disc (100 microns)	30x30 mm (100 microns)	40x40 mm (100 microns)	60x40 mm (100 microns)
DESIGN				
SHELF LIFE	3 Years			
STORAGE	Store in clean, dry environment at room temperature			

Caution | Do not reuse | Do not resterilize | Keep Dry | LOT Lot number | Use by date | Prescription Only

Do not use if packaging is damaged | STERILE R Sterilized using gamma | Consult instructions for Use www.biogenteklifescience.com/docs | Store in room temperature

ISO 13485 | ISO 9001:2008 | ISO 14001:2004 | OHSAS 18001:2007

BIOGENTEK LIFESCIENCE PVT LTD

Donor Procurement, Eligibility Determined and Processed & distributed by:
BIOGENTEK LIFESCIENCE PRIVATE LIMITED
Corporate Identification Number (CIN) is U33110CH2022PTC044499
517, Phase-9, Industrial Area, Sec. 66, Mohali - 160062 (INDIA). | www.biogenteklifescience.com

FOR MORE INFORMATION OR TO PLACE AN ORDER, PLEASE CONTACT US AT **contact@biogenteklifescience.com**