AmnioShield® AC Amniotic Tissue Barrier

Product Instructions and Information Guide for AmnioShield AC

In accordance with FDA Article 21 CFR Part 1271, this package contains donated human cells, tissues, and cellular and tissue-based products (HCT/Ps).

Contents and Description
AmnioShield is a dehydrated, allograft tissue matrix derived from donated human amnion and chorion membrane. Available in multiple sizes to suit varying applications, each unit is visually inspected and carefully tested for quality assurance before distribution. If you received an open or broken package, do not use it, and immediately contact SURGENEX, LLC customer service. AmnioShield is intended to be used on a single patient, on a single occasion, only. Once the AmnioShield pouch has been opened and/or the graft is properly re-hydrated, it must be used immediately or promptly discarded.

Contraindications
AmnioShield should not be used on (1) areas with active or latent infection and/or (2) a patient with a disorder that would create an unacceptable risk to their health while using this product. AmnioShield has not been tested in combination with other products.

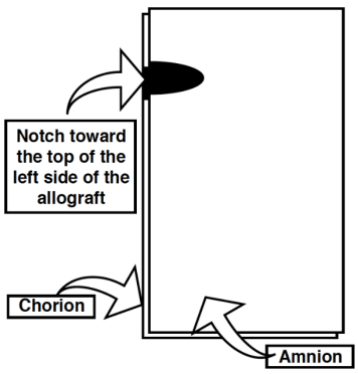
Instructions for Use
The following are recommendations provided as a guide and are not intended to supersede the professional and clinical judgment of the treating physician, concerning patient care.

NOTICE: Federal law requires this HCT/P to be distributed and used by, or on the order of, a licensed physician. Any violations shall be subject to Federal law. This HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent.

Storage Requirements
It is the responsibility of the clinician to store AmnioShield under appropriate storage conditions, in its original packaging, until ready for use. AmnioShield can be maintained at room temperature until the expiration date, indicated on the product label. Do not freeze this allograft product.

Preparation Instructions
The enclosed allograft product is supplied sterile. Open the outer Tyvek pouch by pulling open at the chevron seal and introduce the inner, foil pouch into a pre-arranged sterile field, if applicable.

To identify the chorion and amnion side of the membrane a small notch has been placed in the membrane. With the notch toward the top of the left hand side this will assure the amnion layer is facing up and the chorion layer is down. See the diagram to the right



Open the foil pouch, in the same manner, by pulling open at the chevron seal. For best results and easiest method of handling, grasp the allograft with forceps and remove from the pouch. Place the graft on the area of intended application and re-hydrate *in-situ* with sterile water or 0.9% Saline. Secure the allograft in place using a secondary dressing.

Precautions
Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions. Although SURGENEX, LLC has taken great measures to ensure the safety of our allograft products, current technologies cannot

preclude the transmission of certain diseases known or unknown. Therefore, SURGENEX, LLC can make no claims concerning the biological properties and safety of allograft tissue.

Application and use of any allograft tissue may potentially have negative outcomes. Occurrence of complications at the affected site may transpire post-treatment, without early warning signs. These include, but are not limited to: 1) transmission of communicable diseases; 2) transmission of infectious disease agents; and 3) immune rejection of, and/or allergic reaction to the HCT/P. Any adverse outcomes potentially attributable to the HCT/P must be reported promptly to SURGENEX, LLC.

Sodium Chloride is used in the processing of this allograft. Trace amounts of Sodium Chloride may remain on this allograft.

DO NOT re-sterilize this product. This product has been terminally sterilized via Electron Beam to achieve a Sterility Assurance Level (SAL) of 10^{-6}. An irradiation label is placed on the corner of the foil pouch as an indicator that the product has been irradiated per our validated protocol. A RED indicator signifies that the product is sterile.

SURGENEX, LLC and its affiliates furnish this AmnioShield allograft product without any expressed or implied warranties. All statements or descriptions are informational only and are not to be implied as a warranty of the allograft product. SURGENEX, LLC and its affiliates make no guarantee regarding the biological characteristics of this product. The end-user shall be held responsible for determining the appropriate application and usage of this product.

HCT/P Tracking

The Joint Commission and FDA requires patient records to be properly maintained by storing the allograft ID number (LOT NUMBER) for purposes of tracking the allograft from the donor to the recipient. Please go to our website, www.surgenex.com/amnioshieldrecords and register by using the LOT NUMBER located on the product label.

Donor Selection and Eligibility Determination

This HCT/P was prepared from donor tissue that was determined to be eligible based on the results of donor screening and testing. Donor results from the pre-screening lab tests for applicable communicable disease agents are reviewed and found to be negative for the following:

- HIV-1&2 Plus 0 Antibody
- HIV Type 1 – Nucleic Acid Test (NAT)
- HTLV-1&2 Antibody
- Syphilis – Rapid Plasma Regain (RPR)
- West Nile Virus – Nucleic Acid Test (NAT)
- Hepatitis B Core Antibody
- Hepatitis B Surface Antigen
- Hepatitis B Virus – Nucleic Acid Test (NAT)
- Hepatitis C Antibody
- Hepatitis C Virus – Nucleic Acid Test (NAT)

All communicable disease testing is performed by a laboratory registered with the FDA to perform donor testing and certified to perform such testing on human specimens, in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).

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