Esano™ AC
Amnion-Chorion Membrane Allograft

Contents and Description:
In accordance with Section 361 of the Public Health Service Act and Article 21 CFR Part 1271, this package contains donated human cells, tissues, and cellular and tissue-based products (HCT/Ps). Derived from donated human amniotic membrane, Esano AC is a sterile, single use, dehydrated allograft. When used in acute and chronic wounds including partial and full thickness wounds, diabetic ulcers, venous ulcers, pressure sores/ulcers, chronic vascular ulcers, tunneled/undermined wounds, non-pressure ulcers, surgical wounds (e.g., donor site/grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, wound dehiscence), trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears), and draining wounds, Esano AC acts as a protective barrier from the surrounding environment.

Instructions for Use:
The usage of Esano AC, measured in square centimeters, is determined by the size of the wound., Esano AC is applied directly to the wound, following standard wound preparation. Esano AC is fully resorbable, does not have to be removed from the wound bed, and adheres to the wound bed without fixation. Esano AC comes in a variety of sizes in single use packages. Esano AC should be placed and oriented to overlap the wound edges to ensure adequate coverage and may be used over exposed bone, muscle, or tendon. Once the primary package has been opened, it must be used immediately or promptly discarded.

Federal law requires this HCT/P to be distributed and used by, or on the order of, a licensed health care provider. Any violations shall be subject to Federal law.

Preparation and Application Instructions:
Esano AC is supplied sterile; always handle Esano AC with asceptic techniques. Open the outer pouch by pulling open at the seal and introduce the inner pouch into a pre-arranged sterile field. Following wound bed preparation, open the inner pouch in the same manner, by pulling open at the seal. For best results and easiest method of handling, grasp the Esano AC allograft with sterile forceps and remove from the pouch. Place the Esano AC allograft on the area of intended application, completely covering the wound. The Esano AC allograft may be applied dry and be rehydrated by wound fluid absorption or, at the health care provider's discretion, the Esano AC allograft may be re-hydrated with sterile water or sterile isotonic solution (0.9% Saline).

These preparation and application instructions are designed to serve as guidance for the health care provider and are not intended to supersede institutional protocols or the professional clinical judgment of the health care provider. The professional and clinical judgment of the health care provider, concerning patient care, should always be exercised when using Esano AC.

Quality Assurance:
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 AlexiGen BioTech™ customer service at **1.877.787.7499** or via email at **info@AlexiGen.com**.

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 I/II	HIV/HCV/HBV/NAT	HBc Ab	HBs Ag
RPR	HCV Ab	WNV NAT	HTLV I/II

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).

Current testing cannot provide absolute assurance that the tissue will not transmit infectious disease to the recipient.

Contraindications:
The enclosed allograft should not be used on (1) areas with active or latent infection, (2) a patient with a disorder that would create an unacceptable risk to their health while using this product and/or (3) a patient with a known hyper-sensitivity to Esano AC. This allograft has not been tested in combination with other products.

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

Warnings and Precautions:
Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions. If a patient has an adverse reaction related to the use of Esano AC, immediately discontinue its use. Although AlexiGen BioTech 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, AlexiGen BioTech can make no claims concerning the biological properties and safety of allograft tissue including, but not limited to, Esano AC.
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 Esano AC. Any adverse outcomes potentially attributable to Esano AC must be reported promptly to AlexiGen BioTech by calling 1.877.787.7499 or via email at info@AlexiGen.com.

DO NOT re-sterilize this product. This product has been terminally sterilized via Electron Beam irradiation.

ALEXIGEN BIOTECH, LLC AND ITS AFFILIATES FURNISH ESANO AC "AS IS" WITHOUT ANY EXPRESS OR IMPLIED WARRANTIES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT OF THIRD-PARTY PROPRIETARY RIGHTS UNLESS DISCLAIMING SUCH WARRANTIES IS PROHIBITED BY LAW. All statements or descriptions are informational only and are not to be a warranty or implied as a warranty of the Esano AC allograft product. ALEXIGEN BIOTECH, LLC AND ITS AFFILIATES MAKE NO GUARANTY REGARDING THE BIOLOGICAL CHARACTERISTICS OF THIS ESANO AC PRODUCT. The health care provider shall be held responsible for determining the appropriate application and usage of this product. In all instances, the health care provider must ensure the Esano AC product is used homologously as a barrier or cover that provides protective coverage from the surrounding environment for acute and chronic wounds.

HCT/P Tracking:

The Joint Commission and FDA requires a system of record keeping that enables the tracking of HCT/Ps from donor to consignee and vice versa. It is the responsibility of the health care provider/clinic to properly maintain patient records by storing the allograft ID number (LOT NUMBER) to the patient who received Esano AC for purposes of tracking the allograft from the donor to the recipient. While it is the responsibility of the practitioner to maintain sufficient records to permit prompt identification of the recipient, AlexiGen BioTech offers three options for the health care provider/clinic to share this information to track and register the use of the Esano AC allograft on the recipient patient as follows:

(1) Access the provider portal you have established with AlexiGen BioTech and register the LOT NUMBER located on the product label with the patient information on whom the product was used.

(2) Contact AlexiGen BioTech customer service at **1.877.787.7499** and register the LOT NUMBER located on the product label with the patient information on whom the product was used.

(3) Email AlexiGen BioTech customer service at **info@AlexiGen.com** and register the LOT NUMBER located on the product label with the patient information on whom the product was used.

NOTE: A fully executed Business Associate Agreement ("BAA") must be in place between AlexiGen BioTech and the health care provider/clinic before sharing identified patient information with AlexiGen BioTech by any of the means set forth above. In the event a BAA is not in place and in force, then the health care provider/clinic must deidentify the patient information and provide the deidentified patient information to AlexiGen BioTech with the LOT NUMBER located on the product label, and the health care provider/clinic must maintain a permanent tracking record that connects the LOT NUMBER on the product label to both the deidentified patient provided to AlexiGen BioTech and identified patient information maintained in the health care provider/clinic's permanent records to ensure full traceability from donor to recipient.

Product Distributed by:

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Processing and Donor Eligibility Determined by:

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