Evolution ®

# Esano® ACA

**Amnion-Chorion-Amnion 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). Esano ACA consists of a dehydrated, tri-layer human amnion-chorion-amnion membrane allograft. Esano ACA is available in multiple sizes to suit varying applications.

**Instructions for Use:**
Esano ACA is intended for homologous use only as a barrier or cover that provides protective coverage, from the surrounding environment, for acute and chronic wounds. Esano ACA is intended to be used on a single patient, on a single occasion, only. 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 ACA is supplied sterile; always handle Esano ACA 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 ACA allograft with sterile forceps and remove from the pouch. Place the Esano ACA allograft on the area of intended application, completely covering the wound. The Esano ACA allograft may be applied dry and be rehydrated by wound fluid absorption or, at the health care provider's discretion, the Esano ACA 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 ACA.

**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 Alerce Biologix™ customer service at 1.201.299.5111 or via email at accounts@alercebiologix.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:

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| 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 ACA. This allograft has not been tested in combination with other products.

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

**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 ACA, immediately discontinue its use. Although Evolution Biologyx® has taken great measures to ensure the safety of its allograft products, current technologies cannot preclude the transmission of certain diseases known or unknown. Therefore, Evolution and Alerce Biologix can make no claims concerning the biological properties and safety of allograft tissue including, but not limited to, Esano ACA.

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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 ACA. Any adverse outcomes potentially attributable to Esano ACA must be reported promptly to Alerce Biologix™ customer service at 1.201.299.5111 or via email at accounts@alercebiologix.com..

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

EVOLUTION BIOLOGYX, LLC AND ALERCE BIOLOGIX, LLC AND ITS OR THEIR RESPECTIVE AFFILIATES FURNISH ESANO ACA "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 ACA allograft product. EVOLUTION BIOLOGYX, LLC AND ALERCE BIOLOGIX, LLC AND ITS OR THEIR RESPECTIVE AFFILIATES MAKE NO GUARANTY REGARDING THE BIOLOGICAL CHARACTERISTICS OF THIS ESANO ACA 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 ACA 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 ACA 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, Alerce Biologix offers three options for the health care provider/clinic to share this information to track and register the use of the Esano ACA allograft on the recipient patient as follows:

(1) Contact Alerce Biologix customer care at 1.201.299.5111 and register the LOT NUMBER located on the product label with the patient information on whom the product was used.

(2) Email Alerce Biologix customer care at accounts@alercebiologix.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 Alerce Biologix and the health care provider/clinic before sharing identified patient information with Alerce Biologix 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 Alerce Biologix 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 Alerce Biologix and identified patient information maintained in the health care provider's/clinic's permanent records to ensure full traceability from donor to recipient.

Product Distributed by:

ALERCE BIOLOGIX, LLC
78 JOHN MILLER WAY
KEARNY, NJ 07082
1.201.299.5111
www.alercebiologix.com
accounts@alercebiologix.com

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