SimpliMax

Amniotic Membrane Allograft

ALERCE BIOLOGIX

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). SimpliMax is a dehydrated, dual-layer amnion membrane allograft. The allograft is derived from human placental membrane collected from consenting donor and processed aseptically. It is terminally sterilized to achieve a sterility assurance level (SAL) of 1 x 10-6 utilizing gamma irradiation. SimpliMax is packaged as a sterile product in sealed, single-use pouches.

INSTRUCTIONS FOR USE:

SimpliMax is intended for homologous use only as a barrier or cover that provides protective coverage, from the surrounding environment, for acute and chronic wounds. SimpliMax 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:

SimpliMax is supplied sterile; always handle SimpliMax with aseptic 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 SimpliMax allograft with sterile forceps and remove from the pouch. Place the SimpliMax allograft on the area of intended application, completely covering the wound. The SimpliMax allograft may be applied dry and be rehydrated by wound fluid absorption or, at the health care provider's discretion, the SimpliMax 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 SimpliMax

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 +1.201-800-5929 or via email at accounts@alercebiologix.com.

This HCT/P is manufactured from "DONATED HUMAN TISSUE". All tissue recovered meets stringent specifications during donor screening and laboratory testing to reduce the risk of transmitting infectious disease.

The Medical Director has assessed the results of infectious disease testing, consent documentation, the donor's current medical history interview and behavior risk assessment, physical examination, and relevant medical records, including past medical history, laboratory tests, and other pertinent information regarding donor suitability. Based on this evaluation, it has been determined that the donor meets the criteria for suitability in accordance with the current standards established by the American Association of Tissue Banks and FDA regulations outlined in 21 CFR Part 1271 on Human Cells, Tissues, and Cellular and Tissue-Based Products, where applicable as well as relevant international laws and regulations.

The donor's blood samples are screened negative/non-reactive for the following infectious diseases:

- HIV-1/2 antibody
- Hepatitis B surface antigen
- Hepatitis B core antibody (Total)
- Hepatitis C antibody
- HTLV I/II
- HIV (NAT)
- HBV (NAT)
- HCV (NAT)
- Malaria
- Syphilis
- WNV (NAT)

CONTRAINDICATIONS:

SimpliMax should not be used in patients with known sensitivity to ofloxacin, vancomycin, and amphotericin B.

It 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 of post-operative complications.

STORAGE REQUIREMENTS:

Store in a clean and dry environment at ambient room temperature. Do Not FREEZE

SHELF LIFE:

Refer package label for expiration date.

WARNINGS AND PRECAUTIONS:

1. Do not resterilize, keep away from sunlight, do not use if package is damaged and consult instructions for use, Keep dry, keep out of reach of children. Do not re-use. Contains biological material of human origin.
2. Caution should be used when treating patients with a known sensitivity to ofloxacin, vancomycin, and amphotericin antibiotics. Expert opinion is required before use on babies and pregnant women.
3. The graft is intended for single-patient use only.
4. Strict donor screening and laboratory testing, along with dedicated processing and sterilization methods are employed to reduce the risk of any disease transmission. However, as with all biological implants, an absolute guarantee of tissue safety is not possible. 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/Ps
5. Discard all damaged, mishandled or potentially contaminated tissue.
6. This product has not been tested in combination with other products.
7. SimpliMax shall not be ordered, distributed or dispensed for veterinary use

ALERCE BIOLOGIX, LLC AND ITS AFFILIATES FURNISH SimpliMax “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 SimpliMax allograft product. ALERCE BIOLOGIX, LLC AND ITS AFFILIATES MAKE NO GUARANTEE REGARDING THE BIOLOGICAL CHARACTERISTICS OF THIS SimpliMax 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 SimpliMax product is used homologously as a barrier or cover that provides protective coverage from the surrounding environment for acute and chronic wounds.

RETURNS:

If for any reason tissue must be returned, Contact Alerce Biologix customer care at +1 201-800-5929 or via Email at Orders@alercebiologix.com to schedule all returns.

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 SimpliMax 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 SimpliMax allograft on the recipient patient as follows:

(1) Contact Alerce Biologix customer care at +1 201-800-5929 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.
(3) The health care provider/clinic should use provided peel-o tracking labels on the patient record and enclosed Tissue Utilization Card. The card must be completed and mailed to the distributors.

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.

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PRODUCT DISTRIBUTED BY:

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