Acesso TL

Acesso TL Package Insert – Product Instructions & Information Guide

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

Donor Screening & Testing: The enclosed human tissue allograft was processed, packaged, and labeled by Surgenex. All tissue was recovered, processed, stored and distributed for use in accordance with the Standards of the American Association of Tissue Banks (AATB), FDA requirements for Human Cellular and Tissue Based Products (HCT/Ps 21 CFR Part 1271), and applicable State regulations. Surgenex has determined the Donor to be eligible, based on the results of screening and testing. The Donor has been tested using FDA licensed, approved, or cleared donor screening test kits and was found negative or non-reactive for:

- Human Immunodeficiency Virus Types 1 and 2 Antibody (anti-HIV-1/anti-HIV-2)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis B Core Antibody - Total (anti-HBc)
- Hepatitis C Virus Antibody (anti-HCV)
- Human Immunodeficiency Virus 1, Hepatitis B Virus and Hepatitis C Virus Nucleic Acid Test(s) (HIV 1/HBV NAT/HCV NAT)
- Syphilis Rapid Plasma Reagin or Treponemal Specific Assay

Additional tests, including but not limited to HTLV I/II, CMV or West Nile Virus, may have been performed and were found to be acceptable for transplantation. Communicable disease testing has been performed by a laboratory registered with the FDA to perform donor testing 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).

Product Details: Acesso TL allografts are a dehydrated sheet of amniotic and/or chorionic membrane, which is intended for use as a biological barrier; to provide protective coverage from the surrounding environment for acute and chronic wounds. Acute and chronic wounds may include wounds with or without muscle, tendon, or bone exposure when a protective barrier is medically necessary. This allograft may be affixed when necessary, and is intended to be used on a single patient, on a single occasion, only.

Surgenex and its affiliates furnish this 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 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.

Federal law limits this HCT/P to be used by, or on the order of, a licensed healthcare professional. 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. Human Tissue for transplant shall not be offered, distributed or dispensed for veterinary use.

This product is provided sterile. 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 inner foil pouch as an indicator that the product has been irradiated per our validated protocol. A RED indicator signifies that the product has been sterilized. DO NOT STERILIZE OR RE-STERILIZE THIS PRODUCT BY ANY MEANS. Exposure of the allograft and packaging to irradiation, steam, ethylene oxide, or other chemical sterilant may render the allograft unfit for use.

It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain this tissue allograft in its original packaging, in appropriate storage conditions prior to further distribution or transplant. This allograft may be stored at ambient temperatures between 15-30°C (59-86°F), until the expiration date indicated on the product label.
THIS PRODUCT MUST NOT BE FROZEN.

Contraindications: The enclosed allograft 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.

Caution should be taken when administering this product to immunocompromised individuals, such as patients suffering from HIV or other highly immunocompromised conditions.

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

Precautions: Although Surgenex, LLC has taken great measures to ensure the safety of these allograft products, application and use of any allograft tissue may potentially have negative outcomes. However, this risk is greatly reduced by using processing treatments shown to reduce risk as well as strict donor screening criteria, laboratory testing and terminal irradiation of the final allograft product.

Healthcare professionals should discuss possible complications with the recipient prior to product use. General risks and complications arising from application of allografts may include but are not limited to infection, bleeding, swelling, redness, and potential injury to nerves and other soft tissue.

Precautions (continued): 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.

Adverse outcomes may occur with allograft use, including but 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.

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Preparation and Use: Before use, examine the allograft packaging. If any of the following conditions are observed, do not use the allograft product and notify Surgenex, LLC immediately:

- Any of the package elements appear to be missing, tampered with or damaged.
- The product label or identifying barcode is severely damaged, illegible or missing.
- The expiration date shown on the package label has passed.

Open the cardboard envelope by pulling at the perforated tab and remove the pouch. Note: The inner pouch, its contents, and the inside of the outer pouch are sterile. The outside of the outer pouch is not sterile. Use standard aseptic/sterile technique to open the pouches. Once the outermost Tyvek seal has been compromised, the tissue must be either transplanted, if appropriate, or otherwise discarded.

Starting at the end with the chevron seal, peel open the outer poly/Tyvek pouch. Using aseptic technique, transfer the inner pouch and contents to a sterile field. Starting at the end with the chevron seal, peel open the inner foil package and remove the allograft. For best results and easiest method of handling, grasp the allograft with forceps and remove from the pouch. Note: The inner pouch provides the sterile and moisture barrier for the product. Once the inner pouch has been opened, the implant should be used within an hour of opening.

Place the graft on the area of intended application and re-hydrate in-situ with sterile water or 0.9% Saline. The allograft may be folded into or, applied over the wound when medically necessary. It may be anchored based on the physician's choice of fixation.

HCT/P Tracking: FDA 21 CFR 1271.290, Regulation of Human Cells, Tissue, and Cellular and Tissue-Based Products (HCT/Ps) requires that documentation regarding tissue disposition enabling tracking from donor to the consignee and/or final disposition be maintained.

Joint Commission standard QC.55.310.7 requires that the organization that receives tissue provides a system that fully complies with the completion of tracking tissue usage via Tissue Tracking/Transplant Record (TTR) or provides a web-based program for traceability of the allograft used.

Patient records must be maintained for the purpose of traceability. It is the responsibility of the End-user or the Clinician to provide the information pertaining to the traceability of the allograft used. Please visit www.surgenex.com/acessorecords and register the LOT NUMBER located on the product label.

Returns: Dynamic Medical Services may accept return of Acesso TL allografts for credit or exchange if incorrect product was shipped or product was received in
a damaged state. Dynamic Medical Services reserves the right to reject a return if any of the condition are not met:
1. For damaged items and incorrect shipments, Dynamic Medical Services may replace the product with the appropriate product or issue a credit.
2. A Return Material Authorization (RMA) number must be obtained from Dynamic Medical Services no later than 24 hours from receipt for damaged product or incorrect shipments.
3. Original product packaging must be intact and unopened.
4. Responsibility for facilitating shipping arrangements must be assumed by the returning facility unless the allograft is damaged or defective. Returning facility must complete, sign, and return the RMA form stating that all required criteria have been met.
5. Credit cannot be issued if the RMA form has not been completed by the returning facility and received by Dynamic Medical Services. Please contact Dynamic Medical Services immediately at (775) 762-8068 if you experience a problem with our product.

Surgenex will not be held liable for packages that were lost or damaged while in transit to us. Allograft(s) must be shipped to Surgenex within 24 hours of RMA # being issued.

Surgenex reserves the right to refuse to issue credit if the conditions of the above criteria have not been met; or deems the tissue unacceptable for return. Surgenex may assess a 35% restocking fee on all tissue components returned.

Processing and Donor Eligibility Determination Conducted By:

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