LYOPHILIZED TISSUE ALLOGRAFT PACKAGE INSERT AND TISSUE TRACKING INFORMATION

DESCRIPTION / USE

Cytoplast™ MicroDerm is an acellular dermal matrix sourced from donated human tissue. Cytoplast™ MicroDerm is micro-surfaced, supplied in a range of sizes for surgical use by licensed clinicians, and is intended for homologous use only. Tissue is processed and packaged using aseptic techniques, freeze dried, and terminally sterilized.

DONATED HUMAN TISSUE

In accordance with FDA Article 21 CFR Part 1271, this package contains a product classified as human cells, tissues, and cellular and tissue-based product (HCT/P).

This 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. Screening includes a review of medical and social history, available hospital records, infectious disease testing, autopsy report (if performed), and physical examination of the Donor. 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).

THIS ALLOGRAFT IS SUPPLIED STERILE

This tissue allograft has been sterilized, via Gamma irradiation, to a SAL of 10^{-6} (Sterility Assurance Level). Allografts are processed using some or all of the following agents: physiological buffers, acids, alcohols, hydrogen peroxide, chlorhexidine gluconate, Triton X-100 and traces of these may remain.

WARNINGS AND PRECAUTIONS

- This allograft is intended for use in one patient, on a single occasion only.
- Do not use if the package integrity has been compromised. Once the user breaks the seal on the inner-most pouch, the tissue grafts must be transplanted or discarded.
- The tissue allograft must not be sterilized or re-sterilized by your facility.
- This tissue is intended for use by qualified healthcare specialists such as physicians, dentists, or podiatrists.
- Although this tissue has been tested and screened for relevant communicable diseases and disease agents, and processed under aseptic conditions, human derived tissue allografts may still transmit infectious agents, known or unknown.
- It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant.

STORAGE

Maintain the tissue allograft at ambient room temperature. No refrigeration is necessary.

TISSUE PREPARATION

BEFORE USE – Examine Allograft Packaging – Do Not Use This Allograft If:

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

If any of the above conditions exist or are suspected, this allograft should NOT be used.

PREPARATION OF FREEZE-DRIED TISSUES

Cytoplast™ Microderm rapidly hydrates upon contact with blood or saline solution. If pre-hydration is desired, a hydration time of one minute is recommended.

ADVERSE OUTCOMES

Adverse outcomes potentially attributable to this tissue must be reported promptly to Surgenex®, LLC. Please contact Surgenex®, LLC at 1-877-880-1862.

TISSUE 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, https://osteogenics.com/fda-tissue-tracking and submit tissue tracking information.

Distributed By:

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Source Establishment / Donor Eligibility Determination By:

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