

DX100™ ALLOGRAFT TISSUE INFORMATION & PREPARATION INSTRUCTIONS

Contents

This package contains a human tissue allograft [Human Cellular and Tissue Based Product (HCT/P)] for transplantation regulated by US Food and Drug Administration under 21 CFR Part 1271. In addition to this product insert, the following items should be included in the product package:



1 Outer Box



1 Peel-Pouch
(containing graft)



1 Allograft
Tracking Record



1 Set of
Supplemental
Labels for Patient
Documentation

CAUTION U.S. Federal law restricts this tissue to use by or on the order of a licensed physician.

Product Description

DX100™ placental connective tissue matrix products are sterile, human tissue allografts, intended for homologous use to supplement or replace damaged or inadequate connective tissue.

Storage & Handling



DX100™ ambient version can be stored at ambient temperature (50-86°F / 10-30°C) until ready for use.



DX100™ cryo version must be kept frozen (-20°C or colder for short term storage up to 6 months, or -40°C or colder for long term storage up to 5 years) until ready for use, either in its cryo-cooled shipping container, or in a freezer.



The tissue product is for single patient, one time use only. Once opened, the tissue must be used immediately or disposed of appropriately.



Product has a 5 yr shelf life. Please refer to product ID label for expiry date.



Product must be recorded (see HCT/P Tracking section).

DX100™ is sequentially packaged in a vial, a peel-pouch and an outer box. The tissue in its vial packaging is terminally sterilized via irradiation, and may be placed directly onto the sterile field.

Recommended Instructions For Use

NOTE These recommendations are designed only to serve as general guidelines. They are not intended to supersede any institutional protocols or professional clinical judgment concerning patient care.

PREPARATION & APPLICATION



1. Remove product package from cold storage 15 min prior to use to thaw. (Cryo version only).



5. Shake the vial to mix completely.



2. Open product package & remove the peel-pack containing the vial.



6. Open vial and draw into syringe using 18G needle (or similar). Change to 21-23G to inject.



3. Using aseptic technique, peel open pouch and present vial onto sterile field.



7. Provide maximum coverage using numerous small injections, approx every half cm.



4. If mixing is desired, remove cap and add saline or other fluid, and replace cap. For larger volumes, mix in the syringe if necessary.



8. Inject slowly to allow graft to settle into the tissues.

HCT/P Tracking

IMPORTANT NOTICE TO END-USER Recipient records must be maintained for the purpose of tracking tissue post-transplant per The Joint Commission and FDA requirements. Supplemental labels, which indicate the tissue ID number, are contained in this package to aid in the tracking process. The allograft ID number must be recorded in the operative record. The Allograft Tracking Record must be completed and returned to Skye Biologics, Inc.

Recovery

Tissue recovery is performed using aseptic technique. At the time of recovery, medical records are collected and reviewed as part of determining donor eligibility.

Donor Screening

The **DONATED HUMAN TISSUE** has been determined to be suitable for transplantation by a licensed physician, the Medical Director of the Tissue Bank.

The donor has been deemed free from risk factors for and clinical evidence of infection due to relevant communicable diseases and other exclusionary disease conditions through review of donor records, including medical/behavior risk assessment, medical records, and a recent physical examination.

Additionally, testing of a qualified blood sample indicates that the donor is nonreactive or negative for the following communicable disease markers:

HUMAN IMMUNODEFICIENCY VIRUS (HIV)

- HIV-1/2 Antibodies
- Nucleic Acid Test for HIV-1 RNA

HEPATITIS B VIRUS (HBV)

- HBV Surface Antigen
- HBV Core Antibody (Total)
- Nucleic Acid Test for HBV DNA

HEPATITIS C VIRUS (HCV)

- HCV Antibody
- Nucleic Acid Test for HCV RNA

HUMAN T CELL LYMPHOTROPIC VIRUS I/II

- HTLV-I/II Antibody

SYPHILIS

- Rapid Plasma Reagin Screen*, or
- Treponemal Specific Test

* Tissues from a donor whose blood specimen is unsuitable for the non-treponemal screening assay, such as RPR test, or with a reactive result from the non-treponemal screening assay, are cleared for transplantation use only when the result from the treponemal-specific (confirmatory) assay is nonreactive.

The following non-required screening test for exposure to other viruses listed below may have been performed on the donor. A nonreactive or negative result is not required for this test; however, all donors are evaluated on a case-by-case basis by the Medical Director.

CYTOMEGALOVIRUS

- CMV Antibody (Total)

All laboratories performing these tests are registered with FDA and certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR part 493, or equivalent requirements. Test kits used are approved and cleared (for screening blood specimens collected from living donors) by the FDA. A copy of the medical records can be obtained upon request.

Processing

The HCT/Ps are processed in a controlled environment using methods designed to prevent contamination of the tissues. Tissues are exposed to antibiotics at an initial processing step and subsequently subjected to multiple rinse steps using sterile saline.

Final products are sized and packaged according to approved specifications and procedures and are terminally sterilized by E-Beam irradiation technology in accordance with ANSI/AAMI /ISO11137.

Precautions

- In order to reduce the risk of complications, the tissue should not be implanted in the presence of active infection.
- Although the tissue has been rinsed multiple times with sterile saline during processing, antibiotic residuals such as amphotericin, penicillin, streptomycin and neomycin may remain in the tissue.

Adverse Reactions

No adverse clinical reactions to this tissue product have been reported. Adverse reactions or outcomes that potentially involve the use of this tissue product must be reported immediately to Skye Biologics, Inc.

NOTE Skye Biologics, Inc. and Human Regenerative Technologies, LLC (HRT) make no claims concerning the biological properties of tissue allograft. All tissues have been collected, processed, stored, and distributed in compliance with FDA regulations governing HCT/Ps. Although every effort has been made to ensure the allograft's safety, current technologies may not preclude the transmission of disease.

WARNINGS



Do not re-sterilize. Dispose of all open and unused portions of the product.



Each allograft is intended for single patient use, on a single occasion only.



Use is limited to specific qualified health professionals (e.g. physicians).



Once the expiration date on the label has been reached, the allograft must be disposed of.



Do not use if the package integrity has been violated, opened or damaged, or if mishandling has caused possible damage or contamination. Do not use if seal is broken or compromised.



After use, handle and dispose of all unused product and packaging in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DONOR SUITABILITY DETERMINED & TISSUES PROCESSED BY
Human Regenerative Technologies, LLC

DISTRIBUTED BY Skye Biologics, Inc.

FDA FEI: 3005340932 (FDA Establishment Identifier)

STATE OF CALIFORNIA TB License: CNC 81043 (Tissue Bank)