VIAFLOW™

ALLOGRAFT TISSUE INFORMATION AND 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:

- One (1) Outer Box
- One (1) Peel-Pouch (containing the graft)
- One (1) Allograft Tracking Record
- One (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 physician.

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

HANDLING
VIAFLOW™ 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.

- VIAFLOW™ is for single patient, one time use only.
- Once opened, VIAFLOW™ must be used within one (1) hour.
- Product use must be recorded (see HCT/P TRACKING section).

STORAGE
It is the responsibility of the Tissue Dispensing Service and/or the end user to maintain the graft in its original packaging and at ambient temperature (50-86°F / 10-30°C) until ready to use.

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
1. Open the box package containing VIAFLOW™ and remove the peel-pack.
2. Using aseptic technique, peel open the pouch and present the vial onto the sterile field.

   NOTE: The vial containing product is sterile.

APPLICATION
1. Shake the vial to mix completely.
2. Open the vial and draw into syringe using 18G needle (or similar). Change to 21-23G needle to inject.
3. Provide maximum coverage using numerous small injections, approximately every half centimeter.

NOTE: Once the package is opened, the graft should be used within one (1) hour or disposed of appropriately.

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 Human Regenerative Technologies, LLC (HRT).

RECOVERY
Tissue recovery is performed using aseptic technique. At the time of recovery, medical records are collected and reviewed as part of 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 **negative** or **nonreactive** 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 Lymphotrophic 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 the virus listed below may have been performed on the donor. A negative / nonreactive 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 using E-Beam irradiation technology in accordance with ANSI/AAMI/ISO 11137.

PRECAUTIONS
1. In order to reduce the risk of complications, VIAFLOW™ should not be implanted in the presence of active infection.

2. Although the tissue has been rinsed several 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 product have been reported. Adverse reactions or outcomes that potentially involve the use of VIAFLOW™ must be reported immediately to Human Regenerative Technologies, LLC (HRT).

NOTE: Human Regenerative Technologies, LLC (HRT) makes no claims concerning the biological properties of the 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 safety of the allograft, current technologies may not preclude the transmission of disease.

WARNINGS

Do not re-sterilize. Dispose all open and unused portions of the product.
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.
Store at ambient temperature, and keep away from excessive heat. **DO NOT FREEZE.**
Once the expiration date on the label has been reached, the allograft must be disposed with other medical waste.
Each allograft is intended for single patient use, on a single occasion only.
Use is limited to specific qualified health professionals (e.g. physicians).
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.

Distributed by:
Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
901-867-9971

Donor Suitability Determined by:
Human Regenerative Technologies, LLC

Manufactured by:
Human Regenerative Technologies, LLC
2629 Manhattan Beach Boulevard
Redondo Beach, CA 90278
424-297-0564