Restoring Health | Enhancing Life

FEMORAL VEIN ALLOGRAFT
Package Insert

I. DESCRIPTION
This femoral vein allograft is donated human tissue authorized by law as an anatomical gift. The donor of this tissue has been determined as eligible for transplantation by medical review of all relevant medical records and infectious disease testing as determined by FDA 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products.

II. INDICATIONS FOR USE
Femoral vein allografts are intended for use as vascular replacement when a patient's autologous tissue is not a viable option. Femoral vein allografts may be used for bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, for dialysis access, patients with infected operative fields, or for other vascular procedures. Tissue is intended for use in one patient on a single occasion only. This tissue is intended for use by health care professionals specializing in vascular reconstruction.

III. CONTRAINDICATIONS

Contraindications for the use of this tissue allograft shall be determined by a licensed practitioner. This tissue allograft may contain trace amounts of processing agents listed in the Precautions section of this insert.

VI. WARNINGS
This tissue has been tested and found non-reactive or negative for the following infectious diseases:

anti-HIV-1 and anti-HIV-2
NAT for HIV-1/HBV/HCV
HBsAg *Anti-HBc-total*
Anti-HCV
Syphilis
Aerobes, Anaerobes and Fungus

Any additional testing, refer to Summary of Records

Although this tissue has been tested and screened for infectious diseases, recovered, and processed under aseptic conditions, human allograft tissue may transmit infectious agents.

V. PRECAUTIONS
Trace amounts Amikacin, Vancomycin, Carbapenem (Meropenem, Imipenem or Ertapenem) and Amphotericin B may be present. Tissue may not be sterilized. Tissue has been cryopreserved in 10% DMSO and RPMI supplemented with HEPES and L- glutamine, trace amounts of these products may be present. Caution should be exercised if patient is allergic to any of these agents.

VI. ADVERSE REACTIONS
Adverse outcomes attributed to tissue must be promptly reported to Restore Flow Allografts.

VII. PACKAGING and LABELING
Each tissue allograft is packaged in a triple pouch system, providing double sterile barrier for the tissue. If packaging is damaged, do not use. When tissue has been removed from packaging, tissue must be used for patient, otherwise, tissue must be discarded. Tissue is intended for use in one patient on a single occasion only. If tissue implantation is delayed, tissue shall remain in sterile isotonic solution and basin placed on wet ice (0-10°C) until used. Delayed time shall not exceed 4 hours. Tissue packaging is labeled with a unique identification number using the ISBT 128 labeling system.

VIII. STORAGE
This tissue allograft is shipped to hospital /institution in a cryogenic vapor shipper which maintains cryopreserved tissue at ultralow temperature of -125°C and colder. Tissue shall remain in cryogenic shipper container until just prior to use. If received thawed, do not use. For removing tissue from cryogenic shipper, thawing / opening packaging, and preparing tissue for implantation, refer to each respective procedure in the Tissue Implantation Packet provided with each tissue.

IX. USAGE INSTRUCTIONS
It is the responsibility of the end user to maintain tissue intended for transplantation in appropriate storage conditions prior to transplant and that recipient records (implantation form) is documented and maintained for the purpose of tracing tissue post-transplantation.

The following information is tissue specific,
refer to attached label

Affix Label Here

Anatomical Notes of Graft:

Affix Label Here

Quality Review: _____ Date: _____