RestoreFlow® Allografts

CARDIOVASCULAR ALLOGRAFT

Package Insert

I. DESCRIPTION

This 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

This allograft is intended for implantation into humans. 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 cardiovascular 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.

IV. 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) may be present. Trace amounts of Amphotericin B (Vascular only including aortoilial artery) may be present. Trace amounts of Anidulafungin (heart valves only including patches) 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

Potential adverse outcomes include bleeding, infection, graft stenosis, graft occlusion, loss of graft integrity, graft fibrosis, aneurysm formation of graft, allergic reaction, need of re-intervention related to graft, thromboembolism, graft rejections and death. Adverse outcomes attributed to tissue must be promptly reported to LeMaitre Vascular, Inc.

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. If tissue implantation is delayed, tissue shall remain in sterile isotonic solution and basin placed on wet ice (0-10°C) until used. Tissue packaging is labeled with a unique identification number using the ISBT 128 labeling system.

VII. STORAGE

This tissue allograft is shipped to hospital /institution in a cryogenic vapor shipper which maintains cryopreserved tissue at ultra-low temperatures 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. If tissue is to be stored at institution, remove tissue from cryogenic shipper and immediately place into storage freezer. Storage must be in vapor phase and/or stored at -125C and colder.

VIII. 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. Implantation form shall be submitted to LeMaitre Vascular.

The following information is tissue specific,
refer to attached label

Affix Label Here

Anatomical Notes of Graft:

Affix Label Here

Quality Review: _____ Date: _____

LeMaitre Vascular Inc. 912 Northwest Highway Fox River Grove, IL 60021 847-462-2191