MICROVASCULAR TISSUES

THIS GRAFT IS DERIVED FROM HUMAN TISSUE WHICH WAS GENEROUSLY DONATED SO THAT OTHERS MAY BENEFIT. EACH UNIT IS INTENDED FOR SINGLE PATIENT, SINGLE USE ONLY.

THE mVASC® MICROVASCULAR TISSUE TREATMENT IS NOT SUITABLE FOR INTRAVENOUS INJECTION.

NO ADDITIONAL STERILIZATION STEPS ARE TO BE PERFORMED BY THE USER.

All tissue has been recovered according to the Food and Drug Administration Regulations (FDA).

DESCRIPTION/ USE:

mVASC® tissue is derived from human microvascular tissue that has been aseptically processed, lyophilized to remove moisture while preserving biologic components and then terminally sterilized (SAL of 10^{-6}). mVASC® contains microvascular tissue fragments (capillaries and venules), extracellular matrix components and non-viable cells, which are naturally present in the microvasculature. Each mVASC® vial, contains at least 500,000 microvascular tissue fragments, to be used topically or reconstituted in water for injection.

mVASC® is restricted to homologous use for the repair, reconstruction, replacement, or supplementation of microvascular tissues.

Each package of mVASC® microvascular tissue is intended for use in one patient, on a single occasion.

CONTRAINDICATIONS

The mVASC® manufacturing process involves exposure to Gentamycin and Clindamycin. The safety of product use for patients with hypersensitivities to these antibiotics is unknown.

The mVASC® manufacturing process involves exposure to collagenase and neutral proteases. The safety of product use for patients with hypersensitivities to these compounds is unknown.

WARNINGS

Processing of the human tissue, laboratory testing and careful donor screening reduces the risks of donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, there is still a potential for the transmission of infectious diseases.

No studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of mVASC® microvascular tissue treatment.

Do not use if expiration date has been exceeded or if there is evidence of defects in the package or label integrity.

PRECAUTIONS

Restricted to use by a licensed health care professional.

The licensed health care professional is responsible for determining the appropriate amount and use of mVASC® microvascular tissue for each application.

Healthcare practitioners are responsible for maintaining recipient records for the purpose of tracking tissue post-implantation. Patient tracking labels are provided for this purpose.

Normal rehydration of mVASC® microvascular tissue is usually accomplished in 2 minutes.

Do not centrifuge.

Do not use if the package seal is broken.

Unused or expired product should be discarded in accordance with local, state and institutional human tissue disposal requirements.

ADVERSE REACTIONS

Donor screening methods are limited, therefore certain diseases may not be detected. The following complications of tissue transplantation may occur:

- Transmission of known infectious agents including but not limited to viruses and fungi.
- Transmission or causation of diseases of unknown etiology and characteristics.

MVT requests that licensed health care professionals report any transmissions of known infectious agents or diseases of unknown etiology potentially associated with the use of mVASC® to MVT Customer Service at +1 858-522-0633.

Adverse reactions associated with mVASC® microvascular tissue or the implant procedure include:

- Seroma
- Infection
- Wound dehiscence
- Disease transmission
- Hypersensitive, allergic or other immune response

REGULATORY CLASSIFICATION

mVASC® microvascular tissue is regulated by the U.S. Food and Drug Administration (FDA) as a human tissue intended for transplantation. mVASC® is obtained, processed and sold in accordance with FDA's requirements for banked human tissue (21 CFR Parts 1270 and 1271).

DONOR SCREENING AND TESTING

Microvascular Tissues, Inc. has determined that the donor of this microvascular tissue is an eligible donor based on the results of donor screening and testing records. Donor screening was performed in accordance with FDA regulations and AATB® standards and includes, but is not limited to: review of relevant medical records, physical examination of the donor, laboratory test results, existing coroner and autopsy results, as well as other information pertaining to risk factors for relevant communicable diseases.

The following list serves as the *Summary of Records* that details the communicable disease testing performed on mVASC® tissue: antibodies to human immunodeficiency virus type 1; antibodies to human immunodeficiency virus type 2; nucleic acid test (NAT) for HIV-1, Hepatitis B surface antigen, Hepatitis B core antibody, Hepatitis C antibody, NAT for HCV, antibodies to HTLV-1, NAT for HBV, antibodies to HTLV-2 and Treponema pallidum (syphilis).

Communicable disease testing was performed by a CLIA certified laboratory:
QualTex Laboratories
6211 IH 10 West
San Antonio, TX 78201

Recovery and Donor Screening was performed by an AATB accredited Tissue Bank:
Gencure
6211 IH 10 West
San Antonio, TX 78201

This testing determined that mVASC® microvascular tissue tested negative or non-reactive for all of these communicable diseases.

Due to limitations in testing technology, donor screening and testing alone cannot totally eliminate the risk that human source material will transmit disease.

HOW SUPPLIED

The mVASC® microvascular tissue is provided sterile, in an amber vial that is secured in a tray with a sealed Tyvek lid and packaged in an outer box.

STERILITY

mVASC® microvascular tissue is sterilized by gamma irradiation to a SAL of 10^{-6}. The product is sterile unless the package has been opened or damaged. DO NOT RESTERILIZE.

DIRECTIONS FOR USE

Flowable Use

Equipment Needed

- 1 ml USP sterile water for injection
- Sterile syringe
- Needle (in simulated use studies mVASC® could be delivered through needles as small as 30 gauge)

Vial Removal from Packaging

(1) mVASC® is packaged in a PETG tray with a peelable Tyvek lid. The inside of the tray and the vial containing the product have been sterilized. The outside of the tray is not sterile.
(2) Grasp the Tyvek lid at the designated corner and pull the lid off the tray, taking care not to touch the vial.
(3) The vial can be removed by presenting the opened tray to a second, sterile-gloved person who will remove the vial using aseptic technique.

Rehydration Steps

Rehydration of mVASC microvascular tissue is usually accomplished in two (2) minutes. When preparing to use mVASC microvascular tissue in the operating room, the following rehydration procedure should begin approximately two (2) minutes prior to use, to allow for adequate rehydration prior to implantation. Use immediately after rehydration.

(4) Draw 1 ml of USP sterile water for injection into the syringe.
(5) Remove the flip-off cap from lid of the amber vial of mVASC® microvascular tissue in the sterile field.
(6) Add 1 ml of USP sterile water for injection into the mVASC® microvascular tissue vial.
(7) Agitate the vial for 2 minutes to ensure rehydration of the mVASC® microvascular tissue.
(8) Check vial to ensure that product is completely hydrated.
(9) Draw the hydrated mVASC® microvascular tissue from the vial into the syringe.
(10) Implant hydrated mVASC®.

Topical Use

Equipment Needed

- Sterile blunt hemostat and round-end forceps

(1) – (3): Follow the same instructions as above for removal of the mVASC® vial from its packaging.

(4) Remove the flip-off cap from lid of the vial of mVASC® microvascular tissue in the sterile field.

(5) Completely remove the metal collar remaining around the vial, fully exposing the rubber stopper. Further remove the rubber stopper from the vial.

(6) Use the sterile blunt hemostat or equivalent instrument to break the dry mVASC® cake into pieces or into powder, as desired.

(7) Gently and evenly disperse mVASC® into the intended site.

(7a) If a non-adherent dressing is used, the mVASC® may alternately be placed on the side of the dressing that will contact the intended site. Carefully position and secure the dressing over the site, ensuring the mVASC® comes into full contact with the desired location.

POST TRANSPLANT TRACKING RECORDS

Enclosed in the mVASC® box is a Tissue Transplant Tracking Record (TTTR). Microvascular Tissues Inc., as well as implanting facilities are required to keep records of tissue transplants. Please use the tracking labels provided and complete the TTTR for the patient. Follow the instructions provided on the TTTR and return to Microvascular Tissues, Inc. at the address shown. Note: if the tissue is not used and discarded, please return the TTTR to Microvascular Tissues, Inc. with the required information and reason for discard.

STORAGE AND HANDLING

Store in a dry place at room temperature and in a manner that protects the integrity of the package and sterile barrier.

PACKAGING AND LABELING

- The mVASC® should be accepted only if the factory packaging and labeling arrive intact.
- Contact Customer Service at Tel: +1 858-522-0633 if package has been opened or altered.
- The expiration date for mVASC® microvascular tissue is provided on the product label. Do not use the product if it exceeds the expiration date. The product is not to be used after the last day of the month indicated.

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed health care professional.

INFORMATION

For more information or a demonstration, contact Microvascular Tissues Inc. at the number shown below.

CUSTOMER SUPPORT

Processed, Marketed and Distributed By:
Microvascular Tissues, Inc.
6199 Cornerstone Court East
Suite 109
San Diego CA 92121 USA
Tel: +1 858-522-0633 (Customer Service)