CARDIOGRAFT-MC® PULMONARY ARTERY PATCH

DESCRIPTION

This device, the decellularized pulmonary artery patch allograft, was processed from donated human tissue, resulting from the gift of an individual or his/her family. The device is comprised of pulmonary artery tissue that was cryopreserved. Subsequently, it was thawed, diluted of cryoprotectant solution and decellularized using MatrACELL™ Technology, which is a proprietary detergent and recombinant endonuclease process. The tissue is preserved with glycerol and stored between -40°C and -100°C.

INDICATIONS FOR USE

LifeNet Health's decellularized pulmonary artery patch allograft is indicated for repair of the right ventricular outflow tract.

CONTRAINDICATIONS

LifeNet Health's decellularized pulmonary artery patch allograft is subjected to an antibiotic regimen consisting of Anidulafungin, Ciprofloxacin, Gentamicin, Lincomycin, Mefoxitin, Meropenem, Polymixin B Sulfate, and/or Vancomycin. Additionally, other potential processing reagent residuals are dimethylsulfoxide (DMSO), N-lauroyl sarcosinate (detergent), Benzonase® (endonuclease) and glycerin/glycerol (preservative). Trace amounts of these processing reagents may remain associated with the allograft, and caution should be exercised if the patient has a known sensitivity to or is allergic to any of these processing reagents.

CAUTIONS

- Federal law restricts this device to use by a licensed clinician only.
- Human tissue may transmit infectious agents.
- LifeNet Health makes no claims concerning the biologic or biomechanical properties of the device.
- This device is for single patient use only.
- Do not use this device if the package integrity has been compromised.
- Once the packaging has been opened, it must be implanted during the current operative session or discarded.
- Each device must be thawed and diluted individually.
- Do not re-freeze the device.
- Do not sterilize the device.
- Dropping or jarring the device may compromise the integrity and/or functionality of the device.
- The clinical benefit of the decellularization procedure has not been established in clinical studies.

DEVICE STORAGE REQUIREMENTS

- The Tissue Dispensing Service and/or end-user clinician or facility is responsible for storing this device under appropriate conditions prior to implantation.
- Store in its original cardboard box.
- Transfer device **immediately** from dry ice to an appropriate freezer.
- Store between -40°C and -100°C for the shelf life of the device.

TRACEABILITY

It is the responsibility of the end-user to maintain recipient records for the purpose of tracking tissue post-implantation. As a courtesy to the end-user clinician or facility, LifeNet Health has enclosed a Graft Implant Tracking Card to assist with the postimplantation tracking. Please refer to the enclosed card for additional instructions.

TISSUE RETURNS

Please contact Client Services at 1-888-847-7831 for information regarding LifeNet Health's Tissue Return Policy.

DONOR SCREENING AND TESTING

All donors have been screened and tissue recovered, processed, stored, and distributed according to the current Standards for Tissue Banking set forth by the American Association of Tissue Banks and current federal regulations as promulgated in 21 CFR 1270, 1271 and 820.

This human tissue has been determined to be suitable for transplantation by LifeNet Health. A physician medical director has evaluated the following donor variables to determine suitability: infectious disease test results, current medical history, behavioral risk assessment interview, physical assessment, relevant medical records, including previous medical history, laboratory test results, and autopsy or coroner reports (if performed).

All donors are tested for infectious diseases and found to be negative or non-reactive. LifeNet Health uses FDA-licensed tests. Testing is performed by laboratories that are registered with the FDA and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or equivalent. Testing includes, but is not limited to, the following:

- **HBcAb:** Hepatitis B Core Antibody
- **HBsAg:** Hepatitis B Surface Antigen
- **HCV NAT:** Hepatitis C Virus
- **HCVAb:** Hepatitis C Antibody
- **HIV NAT:** Human Immunodeficiency Virus
- **HIV 1/2 AB:** Human Immunodeficiency Virus Types 1/2 Antibody
- **HTLV I/II:** Human T-Lymphotropic Virus Types I/II Antibody*
- **RPR/STS or Equivalent:** Syphilis

**Not required for donors recovered after March 31, 2010.*

DEVICE TESTING

Every lot of decellularized pulmonary artery patch graft with MatrACELL Technology is assessed to ensure >99% reduction in tissue DNA content and determined to be culture negative via USP <71> microbiological testing.

ADVERSE OUTCOMES

Any adverse event or outcome must be reported promptly. Please call Client Services at 1-888-847-7831 and have the device identification number available.

Potential adverse events or outcomes include but are not limited to infection, rejection of tissue, fibrocalcification, stenosis, hemorrhage, thromboembolism, loss of graft structural integrity, graft rupture, aneurysm, re-operation and death.

LIFENET HEALTH'S COMMITMENT TO QUALITY

We work hard to provide our customers with the highest quality allograft tissue through a rigorous quality assurance program. If you have any questions or comments, we would like to hear from you. Please contact Client Services at 1-888-847-7831. We are available 24 hours a day to assist you. LifeNet Health is a full service, not-for-profit tissue bank, an accredited member of AATB, and an ISO 13485:2003 certified company.

IMPORTANT – PLEASE READ

THESE INSTRUCTIONS ARE DIFFERENT THAN THOSE FOR A TRADITIONAL CRYOPRESERVED ALLOGRAFT. PLEASE READ INSTRUCTIONS CAREFULLY PRIOR TO EXECUTING THE THAWING AND DILUTION PROCEDURE.

THAWING and DILUTION INSTRUCTIONS

This process helps minimize damage to the device by controlling the melting of ice crystals and considerably diluting the preservation agent, glycerin/glycerol. This device has been processed with great care to preserve tissue integrity. Your care in carrying out each step of this thaw and dilution protocol is equally important. **Failure to follow these instructions could result in device failure.** Please coordinate the timing of this procedure with the surgeon.

PREPARATION FOR USE

Preparation Notes:

Use aseptic technique at all times.
Thaw and dilute each device individually.

Sterile Supplies Needed By Hospital:

One Thermometer
One large (5000 ml +) basin
Two 1000 ml basins
One clamp
One pair of scissors
Thawing solution - 1000 ml of warm (37° - 42°C)
0.9%/normal saline
Rinse solution - 5000 ml of warm (37° - 42°C)
0.9%/normal saline

Non-Sterile Team Member

1) Instruct the Sterile Team Member to place the sterile thermometer in the first 1000 ml basin.
2) Pour 1000 ml warmed, 37-42°C, normal saline into the first 1000 ml basin.

CAUTION: Ensure the solution temperature does not exceed 42°C for all solutions as this may damage the device!

CardioGRAFT-MC Graft Preparation

3) Using insulated gloves, retrieve boxed device from freezer. Immediately transport the device to the operating room.
4) Open box lid and carefully inspect pouches for integrity without applying pressure on the device. Do not use this device if package integrity has been compromised.
5) Aseptically open the outer pouch and present inner pouch to the Sterile Team Member.
6) Proceed as quickly as possible with step 14 below to facilitate rapid thawing of the device.

Sterile Team Member – Thaw

7) Double glove.
8) Ensure solution temperature in first 1000 ml basin is 37-42°C.
9) Aseptically remove inner pouch from outer pouch with clamp, holding package firmly by its sealed edge.
10) Slowly lower inner pouch into 37 - 42°C normal saline in the first 1000 ml basin, keep clamp attached.
11) **CAUTION: Do not squeeze the device.**
12) Allow device to thaw for approximately 5 minutes.
13) While device is thawing, add 1000 ml of 37-42°C normal saline to the second 1000 ml basin and add 4000 ml of 37 - 42°C normal saline to the 5000 ml basin.
14) Once the device is aseptically thawed, dry the outside of the inner pouch thoroughly.
15) Open inner pouch with scissors at the square end.

Sterile Team Member – Rinse (Dilution)

Note: Device has been placed into a slip sheet for your convenience.

16) Remove slip sheet and device slowly from inner pouch.
17) By hand, carefully remove device from slip sheet and transfer into the second 1000 ml basin.
18) Gently, hand stir solution surrounding device for a minimum of one (1) minute.
WARNING: Stirring the solution is essential for removing the glycerol from the device prior to implantation. Failure to do so could result in device failure.
19) Confirm solution temperature in 5000 ml basin is 37-42°C.
20) By hand, gently transfer device to 5000 ml basin and allow to soak for a minimum of 15 minutes prior to implantation.
21) Remove outer gloves.
22) The device is now ready for implantation. Keep the device completely immersed until needed.

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www.LifeNetHealth.org