LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

CardioGRAFT-MC® Pulmonary Artery Patch

INSTRUCTIONS FOR USE

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 or Denarase (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.

WARNINGS AND PRECAUTIONS
- 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.

TISSUE 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 tissues recovered, processed, stored, tested, and distributed in accordance with current U.S. federal regulations as promulgated in 21 CFR 1270 and 1271, current Standards for Tissue Banking set forth by the American Association of Tissue Banks (AATB) and international laws and regulations as required.

This allograft was deemed suitable for implantation by LifeNet Health. A physician medical director evaluated the following donor variables to determine donor suitability: infectious disease test results, current donor 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 relevant infectious diseases. Testing is performed by laboratories that are registered with the U. S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and 42 CFR 493. Test methods that are FDA-licensed, approved, or cleared for donor screening are used as available. The following test criteria were met for the donor of this allograft.

Required Infectious Disease Testing	
Test	Acceptance Criteria
HBcAb: Hepatitis B Total Core Antibody	Negative/Non-Reactive
HBsAg: Hepatitis B Surface Antigen	Negative/Non-Reactive
HCV NAT: Hepatitis C Virus Nucleic Acid Test	Negative/Non-Reactive
HCVAb: Hepatitis C Antibody	Negative/Non-Reactive
HBV NAT: Hepatitis B Virus Nucleic Acid Test*	Negative/Non-Reactive
HIV-1 NAT: Human Immunodeficiency Virus Type 1 Nucleic Acid Test	Negative/Non-Reactive
HIV 1/2 Ab: Human Immunodeficiency Virus Types 1/2 Antibody	Negative/Non-Reactive
RPR/STS or Equivalent: Syphilis	Confirmatory Negative/Non-Reactive
HTLV I/II Ab: Human T-Lymphotropic Virus Types I/II Antibody**	Negative/Non-Reactive

* Not required for donors recovered prior to December 16, 2016. Performed as required by international laws and regulations.
**Not required for donors recovered after March 31, 2010. Performed as required by International laws and regulations.

DEVICE TESTING
Every pulmonary artery patch graft decellularized using Matracell technology is determined to be culture negative via USP <71> microbiological testing prior to release for implantation. LifeNet Health's decellularized pulmonary artery patch grafts have been validated for the removal of greater than 99% of the donor's DNA.

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 13485:2016 certified company.

WARRANTY STATEMENT
Due to the inherent variability of allograft tissue, biological and biomechanical properties cannot be guaranteed by LifeNet Health.

Manufactured by: LifeNet Health, 1864 Concert Drive, Virginia Beach, Virginia, 23453 USA
Source Establishment: LifeNet Health CTO #100038

For patent information, please visit: www.lifenethealth.org/patents

LifeNet Health®
Saving Lives. Restoring Health. Giving Hope.

CardioGRAFT-MC® Pulmonary Artery Patch

INSTRUCTIONS FOR USE

IT IS IMPORTANT TO READ AND UNDERSTAND THE FOLLOWING INSTRUCTIONS PRIOR TO CLINICAL USE. IMPROPER PREPARATION TECHNIQUE MAY ADVERSELY AFFECT PROPERTIES AND/OR PERFORMANCE.

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

THAW 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 FROM 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

STEP 1:
Instruct the Sterile Team Member to place the sterile thermometer in the first 1000 ml basin.
STEP 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

STEP 3:
Using insulated gloves, retrieve boxed device from freezer. Immediately transport the device to the operating room.
STEP 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.
STEP 5:
Aseptically open the outer pouch and present inner pouch to the Sterile Team Member.
STEP 6:
Proceed as quickly as possible with step 14 below to facilitate rapid thawing of the device.

STERILE TEAM MEMBER

STEP 7:
Double glove.
STEP 8:
Ensure solution temperature in first 1000 ml basin is 37-42°C.
STEP 9:
Aseptically remove inner pouch from outer pouch with clamp, holding package firmly by its sealed edge.
STEP 10:
Slowly lower inner pouch into 37- 42°C normal saline in the first 1000 ml basin, keep clamp attached.

CAUTION: DO NOT SQUEEZE THE DEVICE

STEP 11:
Allow device to thaw for approximately 5 minutes.
STEP 12:
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.
STEP 13:
Once the device is aseptically thawed, dry the outside of the inner pouch thoroughly.
STEP 14:
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.
STEP 15:
Remove slip sheet and device slowly from inner pouch.
STEP 16:
By hand, carefully remove device from slip sheet and transfer into the second 1000 ml basin.
STEP 17:
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.

STEP 18:
Confirm solution temperature in 5000 ml basin is 37-42°C.
STEP 19:
By hand, gently transfer device to 5000 ml basin and allow to soak for a minimum of 15 minutes prior to implantation.
STEP 20:
Remove outer gloves.
STEP 21:
The device is now ready for implantation. Keep the device completely immersed until needed.