MASA valve®

ePTFE Valved Conduit

for Right Ventricular Outflow Tract Reconstruction

Instructions for Use

PECA labs®

Instructions For Use

CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician.

CAUTION:
SINGLE USE ONLY
CAUTION - Investigational device. Limited by Federal law to investigational use.

Authorized by Federal law for Investigational Use in patients under 22 years of age for the correction or reconstruction of Right Ventricular Outflow tract (RVOT) in the following congenital heart malformations and procedures when the patient is not a candidate for a valved conduit which contains biologic tissue, either due to lack of availability or risk of severe adverse event:

- Pulmonary Stenosis
- Tetralogy of Fallot
- Truncus Arteriosus
- Transposition with Ventricular Septal Defect (VSD)
- Pulmonary Atresia

In addition, the conduit is indicated for the replacement of previously implanted, but dysfunctional, pulmonary valves, valved conduits or conduits and for Ross Procedure where the native RVOT is being used to reconstruct the Aorta. The effectiveness of this device for these uses has not been demonstrated.

Device Description

The MASA Valve is a bi-leaflet valved conduit constructed using a expanded polytetrafluorethylene (ePTFE) conduit and valve material attached using polypropylene suture. The device has ink on its outer surface demarcating the area within which the valve is attached to the conduit and the direction of flow allowed by the valve.

Indications for Use

The MASA Valve is a single use device for reconstruction of Right Ventricular Outflow Tract (RVOT) in patients aged less than 22 years with any of the following congenital heart malformations:

- Pulmonary Stenosis
- Tetralogy of Fallot
- Truncus Arteriosus
- Transposition with Ventricular Septal Defect (VSD)
- Pulmonary Atresia

In addition, the conduit is indicated for the replacement of previously implanted, but dysfunctional, pulmonary prosthetic valves or conduits and for Ross procedure where the native RVOT is being used to reconstruct the Aorta.

Contraindications

None known.

Warnings

1. SINGLE USE ONLY
2. DO NOT RESTERILIZE. Exposure of the conduit to irradiation, steam or other chemical sterilants may render the device unfit for use.
3. DO NOT use the device under the following conditions: The device has been dropped, damaged or mishandled in any way such as if the device has been cut in the area between the lines demarcating the valve area (see Figure 1). These lines are present on the outer surface of the MASA Valve using black ink and demarcate that boundaries of the internal valve. Any cuts in this area may damage the valve.
4. The MASA Valve is supplied in a sterile and non-pyrogenic package, the package should not be open or damaged prior to use. MASA Valve is sterilized by ethylene oxide. Each device is intended for single patient use only. DO NOT RESTERILIZE.
5. The MASA Valve has been designed for SINGLE USE ONLY. Reusing this medical device bears the risk of cross-patient contamination as medical devices - particularly those with long and small lumina, joints, and/or crevices between components - are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious contamination.
6. Do not resterilize. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or reserialization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.
7. Do not use after the expiration date printed on the label.
8. Avoid repeated or excessive clamping at the same location on the device. If clamping is necessary, use only atraumatic or appropriate vascular smooth jawed clamps to avoid damage to the device.
9. Exposure to solutions (e.g. alcohol, oil, aqueous solutions, etc.) may result in loss of the device's hydrophobic properties. Loss of the hydrophobic barrier may result in graft wall leakage. Pre-clotting of the device is unnecessary.
10. Avoid excessive manipulation of the device after exposure to blood or body fluids. Do not forcibly inject any solution through the lumen of the graft, or fill the device prior to pulling it through the tunnel as loss of the device's hydrophobic properties may result in graft wall leakage.
11. Do NOT expose MASA Valve to temperatures greater than 500°F (260°C). PTFE decomposes at elevated temperatures producing highly toxic decomposition products.
12. After use, the device may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state and federal laws and regulations.

Precautions

1. Only physicians qualified in cardiac surgery techniques should use this device. The healthcare provider is responsible for all appropriate postoperative care instructions to the patient.
2. The healthcare provider must observe aseptic technique during implantation and postoperatively.
3. When suturing, avoid excessive tension on the suture line, inappropriate suture spacing and bites, and gaps between the graft and host vessel. Failure to follow correct suturing techniques may result in suture hole elongation, suture pull-out, anastomotic bleeding, and/or disruption. Refer to "Suturing" for further instructions.
4. Consider intraoperative and postoperative patient anti-coagulation therapy for each patient as appropriate.

Adverse Events

Prosthetic valves and valved conduits have been associated with serious complications sometimes leading to reoperation and/or death. In addition, complications caused by immunogenic response to the device or to physical, chemical, or biologic changes, may occur at undetermined intervals and may require reoperation and replacement of the device. As the device is indicated for patients less than 18 years, reoperation and replacement of the MASA Valve may be indicated because of the patient's physical growth.

General complications noted with valved conduits implanted at the heart include the following:

- Infection/Endocarditis
- Hemolysis
- Hemorrhage (including anticoagulant-related hemorrhage)
- Immunologic Rejection
- Prosthesis Calcification (intrinsic and extrinsic)
- Prosthesis (conduit) dilation
- Prosthesis nonstructural dysfunction (eg, neointimal thickening and peeling)
- Prosthesis regurgitation
- Prosthesis structural deterioration (perforation, thickening, myxomatous degeneration)
- Prosthesis stenosis
- Prosthesis thrombosis
- Prosthesis occlusion
- Seroma
- Pseudoaneurysm
- Pulmonary hypertension
- Thromboembolism

It is possible that these complications could lead to:

- Reoperation
- Explantation
- Permanent disability
- Death

These complications may present with abnormal heart murmur, shortness of breath, exercise intolerance, dyspnea, orthopnea, anemia, fever, arrhythmia, hemorrhage, low cardiac output, pulmonary edema, myocardial infarction, hemolytic anemia and congestive heart failure.

Patient Counseling

In some conditions, patients may require anticoagulation and/or antiplatelet therapy for an indefinite period. Patients with prosthesis are at risk of bacteremia (eg. undergoing dental procedures) and should be advised about prophylactic antibody therapy. In some cases, patients may need to limit physical activities for some period of time.

Available Models and Sizes

The MASA Valve is sized based on the internal diameter and length of the device. See Table 1 for available product codes and configurations. The inner diameter and length of the MASA Valve are listed on the device packaging. The valve is located in the middle of the conduit and can be identified from the outer surface by two black lines that demarcate the area in which the valve is present. The device also has arrow markers that demarcate the direction of flow allowed by the valve (See Figure 1).

Table 1. Available Product Configurations

Product Code	Inner Diameter (mm)	Total Length (cm)	Radiopaque Ink?
PS010	10	15	No
PS012	12	15	No
PS013	13	20	No
PS014	14	20	No
PS015	15	20	No
PS016	16	20	No

All configurations may not be available in each region.

Packaging

The MASA Valve is provided STERILE and NONPYROGENIC inside two blister cases. The two blister cases are placed within an outer box that has device size, length and unique identifiers along with 4 patient removable patient labels

Storage

The storage life of the deice is recorded on the outer box of the valve. Appropriate inventory control should be so that the prosthesis with an earlier "use by" dates are being preferentially implanted and expiration is avoided. The storage environment should be clean, cool and dry place.

Accessories

None.

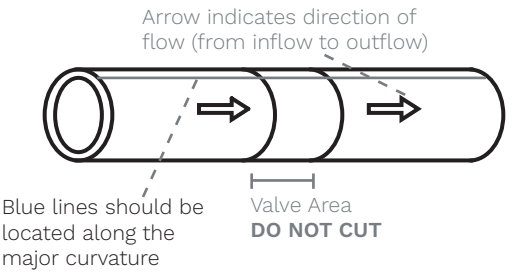
Instructions for Use

The function of a pulmonary valved conduit is sensitive to surgical implantation techniques used. Surgeons performing the implantation must be familiar with the techniques for implanting a pulmonary valved conduit.

The MASA Valve is packaged sterile in a double blister case. Both cases should be examined for any breakages in packaging before use. Any breakage in sterility barriers should be considered as a direct implication for valve sterility being compromised.

The MASA Valve is ready to be used as is outside the package. The device's conduit can be appropriately cut to size however, DO NOT CUT BETWEEN THE TWO BLACK CIRCLES in the middle of the conduit that demarcate the area where the valve is present inside the conduit (see Figure 1 below), as it amy permanently damage the valve. THE BLUE LINES MUST BE LOCATED ALONG THE MAJOR CURVATURE WHEN THE DEVICE IS IMPLANTED.

Figure 1



Surgical Procedure

Cardiac surgical procedures can be complex and subject to Variability, only a qualified cardiac surgeon should be implanting this deivce. The MASA Valve may be used for several indications. The choice of surgical technique must be left to the discretion of the individual surgeon, observing the warnings and instructions for use described herein.

Surgical Precautions: The conduit should be handled carefully and gently. Examine the conduit, and note the direction of the arrow. The arrow denotes the direction of flow. The two circular markers between the arrows denote the area within which the valve is present. If the valve is cut or damaged due to any reason, it should not be used for human implantation. Figure 1 represents these markers that are present on the outer surface of the MASA Valve.

MRI Safety Information

Non-clinical testing has indicated that MASA Valve is MR Safe

MR

Patient Follow-Up

The health care provider is responsible for instructing the patient as to proper postoperative care, including limiting movement of the affected area during the convalescent period. The anti-coagulation in the post-operative period is entirely based on the recommendation from the healthcare providers as well. The device follow-up is most commonly based on the recommendation of the surgeon and the cardiologist involved in the follow-up. Echocardiography, CT Scan or MRI Scans may be recommended in the follow-up period to verify the proper functionality of the device.

Explant of Device

Only a qualified cardiac surgeon should be allowed to remove the device. The graft must be carefully dissected out making sure all the placed sutures at the site of the anastomosis have been excised. All decisions for technique and timing of graft excision eventually must be entirely based on the recommendation from the qualified cardiac surgeon and the healthcare provider.

Return of Explanted Devices

PECA Labs is interested in obtaining recovered MASA Valves. Specific pathological studies of the explanted devices will be conducted under the direction of the consulting pathologist. A written summary of findings will be returned to the physician following up with the patient.

To obtain a return kit, contact PECA Labs directly. If a kit is not available, place the explanted device in a container of 10% buffered formalin immediately after excision. For further instructions on returning of an explanted device, contact PECA Labs.

Patient Information

Patients may require anticoagulation and/or antiplatelet therapy for an indefinite period based on each patient's condition.

Registration Information

A Patient Registration Form is included with each device. After implantation please complete all requested information. The serial number is located on the package. Return the original form to the PECA Labs address indicated on the form and provide the temporary identification card to the patient prior to discharge

Patient Record Card

PECA Labs will provide an implanted device identification card to the patient. The card contains the name and telephone number of the patient's physician as well as information that medical personnel would require in an emergency.

Adverse Event Reporting

Any serious incident that occurs in relation to the device should be reported to PECA Labs and, as applicable, regulatory authorities (for example, the competent authority of the Member State in which the user and/or patient is established for the European Union or to the FDA for all US patients).

Summary of Safety & Clinical Performance

The current Summary of Safety and Clinical Performance is available at the following website:

www.pecalabs.com/MASAValveSafety

Warranty

PECA Labs warrants to the first purchaser of this product that this product will be free from defects in materials and workmanship for a period of one year from the date of first purchase and liability under this limited product warranty will be limited to repair or replacement of the defective product, in PECA Labs' sole discretion or refunding your net price paid. Wear and tear from normal use or defects resulting from misuse of this product are not covered by this limited warranty.

TO THE EXTENT ALLOWABLE BY APPLICABLE LAW, THIS LIMITED PRODUCT WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT WILL PECA LABS BE LIABLE TO YOU FOR ANY INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM YOUR HANDLING OR USE OF THIS PRODUCT.

Some countries do not allow an exclusion of implied warranties, incidental or consequential damages. You may be entitled to additional remedies under the laws of your country.

An issue or revision date and a revision number for these instructions are included for the user's information on the last page of this booklet. In the event 36 months have elapsed between this date and product use, the user should contact PECA Labs to see if additional product information is available.

REF	Catalogue Number
LOT	Lot Number
	Use By
D:	Internal Diameter
L:	Length
	Contents
	Consult Instructions For Use
	Single Use
2 Sterilize	Do Not Resterilize
	Non-Pyrogenic
	Manufacturer
	Lift Here
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package Is Damaged
LATEX	Not Made With Natural Rubber Latex
MR	MR Safe
	Date of Manufacture
	Keep Dry
	Keep Away From Heat
Rx Only	Federal (U.S.A) Law Restrics This Device To Sale By Or On The Order Of A Physician
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LA012 RevIDE1 01/22