Instructions for use, Shelhigh Porcine Pulmonic Valve Conduit prosthesis Model NR-4000 with "No-React®" treatment*
INSTRUCTIONS FOR USE

Humanitarian Device.
Authorized by federal law for use in the treatment of diseased, damaged, or absent pulmonic artery in small children or infants up to age 4 years, with Transposition of Great Arteries, Truncus Arteriosus, Tetralogy of Fallot with associated cardiac anomalies with Pulmonary Atresia, or replacement of failed conduits in young patients with accelerated conduit failure. **The effectiveness of this device for this use has not been demonstrated.**

PRODUCT DESCRIPTION

The device is a glutaraldehyde fixed porcine pulmonic valve and pulmonary artery, to which segments of bovine pericardial tissue are attached to allow for trimming to fit. For this indication, the valve will be available in sizes 11 – 18 mm. The device has been treated with a proprietary "detoxification" process called "No-React®" for the purpose of reducing or delaying the onset of calcification.

The **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment, is designed to facilitate implantation. The valve area is covered with *No-React*® treated pericardial patch material. This patch material extends beyond the base of the valve to create a biological annulus to facilitate implantation.

MODELS AND SIZES

The **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment, is available in sizes: 11, 12, 13 , 14, 15 16, 17 , and 18 mm.

Indications for use

For use as a replacement for the diseased, damaged, or absent pulmonic artery in small children or infants up to age 4 years, with Transposition of Great Arteries, Truncus Arteriosus, Tetralogy of Fallot with associated cardiac anomalies or with Pulmonary Atresia, or replacement of failed conduits in young patients with accelerated conduit failure.

STORAGE

It is recommended that the prosthesis be stored in its package at a temperature between 5 and 25 degrees Celsius. Refrigeration of this device is not necessary. Care must be exercised to avoid freezing, which may damage the valvular tissue. Each **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment, package is supplied with a freeze indicator that should be inspected upon receipt of the valve. If the prosthesis has been exposed to freeze/thaw conditions, the Freeze Watch ampoule will break and release a blue liquid, staining the indicator paper.

Do not use the valve conduit if the indicator has been activated. It is not necessary to store the valve under refrigeration. Inspect the freeze indicator upon removal for assurance that the valve was not exposed to freezing conditions.

PRECAUTIONS

The valve should not be implanted if there is evidence of damage to, or leakage from, the container as the sterility of the product may have been compromised.

Do not subject any porcine pulmonic valve conduit to ethylene oxide, propylene oxide, steam, or gamma irradiation sterilization either in or out of its container.

Do not expose the prosthesis to solutions other than sterile physiological saline.

No instruments or objects should come in contact at any time with the valve tissue.

Handle the valve by grasping the identification tag with atraumatic forceps, or with sterile gloves.

Extreme care should be taken when cardiac catheterization across a pulmonic valve conduit prosthesis must be accomplished. The use of soft tip catheters that will not damage the porcine leaflets is recommended.

HANDLING AND RINSING PROCEDURES

Rinsing is not required. If you wish to rinse, follow these procedures: All subsequent handling must be with sterile gloved hands. The surgical gloves must be thoroughly washed to remove glove powder prior to touching the valve conduit. Handle the valve by grasping the identification tag with atraumatic forceps or with sterile gloved hands and remove it from the container. Immerse the *valve* in a sterile basin containing 500 ml of sterile physiologic saline.

The valve can stay in the saline solution until ready to be implanted.
The identification tag should be inspected and removed from the valve just prior to implantation.

PULMONIC ROOT REPLACEMENT

Sizing the Pulmonic Annulus

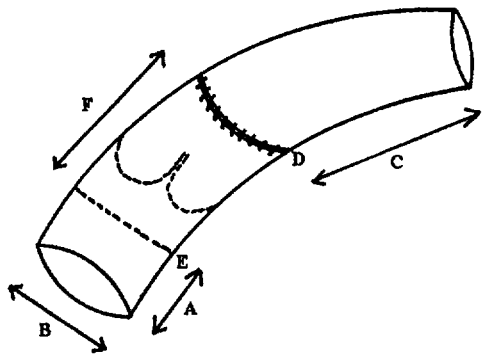
The **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment, was designed to have a larger annular diameter than the actual valve or pulmonary artery. The pericardial annulus (A) is relatively long (3 to 5 cm) and somewhat distendable; it generally can be adapted for one size larger than the designated diameter. This "tube" (B) can be tailored or cut to adapt it over the right ventricle. The distal part of the valve conduit (C) consists of the actual porcine pulmonary artery. It can be shortened if necessary.

Surgical Technique

The annulus made of pericardial tissue can be inserted with a continuous monofilament suture or by using multiple interrupted sutures. A combination of both might be necessary especially for the posterior portion of the muscular part of the right ventricular outflow annulus.

Periodically irrigate the valve conduit with saline to avoid drying of the tissue which could enhance early degradation.

Warning



The **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis** Model NR-4000 with "No-React®" treatment has a natural curve; it is important that the concave part of the curve faces the posterior part of the annulus. The conduit can be shortened when necessary, but it cannot be shortened beyond the first suture line of the pericardial cover (D). On the inflow segment, the pericardial annulus can not be shortened beyond the suture line between the pericardium and the muscular part of the valvular apparatus (E). The valve complex (F) can not be shortened.- (For Truncus Arteriosis a shortened inflow sleeve conduit is available upon request)

The distal part of the pulmonic conduit can be sewn to the patient's pulmonary artery using a continuous monofilament suture. If there is any size mismatch, it can be corrected using a pericardial patch to bridge any gap.

ANTICOAGULATION

Anticoagulation may be necessary for some patients during approximately the first three months following surgery. After this interval such patients may be maintained on antiplatelet drugs.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

The durability of glutaraldehyde-fixed porcine tissue is currently unknown. Reported post-operative complications with porcine bioprostheses have included: endocarditis, calcification, thrombosis, thromboembolism, primary tissue failure, hemorrhage, unacceptable hemodynamics, arrhythmia, and congestive heart failure.

IMPLANTATION DATA CARD

An implantation data card is provided with each **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment. Shelhigh Inc. requests that the information on this implantation card be completed and that the pre-addressed postcard be returned to Shelhigh Inc. Upon receipt of this card, Shelhigh Inc. will prepare a patient identification card which will be sent to the attending physician for subsequent delivery to the patient.

CLINICAL EXPERIENCE

Summary of the clinical experience with the SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis, Model NR-4000 with "No-React®" treatment.
Since November 1997 more than 70 ***SHELHIGH*** **Pulmonic Valve Conduit,** with "No-React®" treatment, were implanted in 8 centers in Europe . Most of the conduits (n = 47) were implanted in infants, when a homograft was not available. No major complications related to the conduit have been reported. One child died of a non-valve related cause. The follow up using 2-D Echo shows good function of the valves; however, long term follow up has not been performed to date.

Shelhigh Inc. is very interested in learning of any clinical experiences involving the **SHELHIGH Porcine Pulmonic Valve Conduit Prosthesis,** Model NR-4000 with "No-React®" treatment, and is particularly interested in receiving for analysis, any valves explanted. If possible, it would be ideal to receive an explant within 72 hours in a leak proof specimen jar containing refrigerated saline. If not, an appropriate preservation solution such as 10% Formalin may be used to return the valve. Information regarding the patient's history (e.g. patient records, test reports) and the reason for explantation

should be sent with the product to Shelhigh Inc. PO. Box 884, Millburn, NJ 07041 USA. In addition, it would be of assistance if the name of an appropriate contact be provided, should additional information be required.

An analysis of the valve will be conducted at Shelhigh Inc. in accordance with the reported clinical experience of the device. Upon completion of this analysis a written report will be submitted to the physician. The information obtained from these reports will enable us to monitor the clinical experience with this product.

PRODUCT INFORMATION DISCLOSURE

Shelhigh Inc. has exercised reasonable care in the manufacture of this device. Shelhigh Inc. excludes all warranties whether expressed or implied by operation of the law or otherwise including but not limited to any implied warranties of merchantability of fitness. Shelhigh Inc. neither assumes, nor authorizes any other person to assume for it any other or additional liability, or responsibility in connection with this device. This device should not be used except on the order of a physician.

Freeze Watch is a registered trademark of PyMaH Corp.
No-React® is a registered Trademark of Shelhigh Inc.

***No clinical data are available which evaluate the long-term impact of the "No-React®" detoxification treatment.**

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Shelhigh Pulmonic Valve Conduit with "*No-React*®" Treatment.

Patient Information (Parents or Guardians)

Humanitarian Device.
Authorized by federal law for use in the treatment of diseased, damaged, or absent pulmonic artery in small children or infants up to age 4 years, with Transposition of Great Arteries, Truncus Arteriosus, Tetralogy of Fallot with associated cardiac anomalies or with Pulmonary Atresia, or replacement of failed conduits in young patients with accelerated conduit failure. **The effectiveness of this device for this use has not been demonstrated.**

Description: The human heart contains two (2) major pumping chambers, the right and left ventricles. The right ventricle pumps oxygen-poor blood to the lungs through the pulmonary valve and pulmonary artery. The left ventricle pumps oxygen-rich blood through the aortic valve and associated aorta.

If your physician has suggested that your child be implanted with the **Shelhigh Pulmonic Valve Conduit** (tube), your child was probably born with a heart defect necessitating the replacement or the bypass of the pulmonic valve and artery. (Please contact your child's pediatrician for more information on his or her heart defect).

The Shelhigh Pulmonic Valve Conduit with "*No-React*®" Treatment is a valve and pulmonary artery taken from a pig and treated chemically to help prevent rejection and to resist degradation. Pig valves have been implanted in humans for the last 30 years with acceptable results, but in children, calcium tends to form on implanted devices made of animal tissue. The device then may fail to operate correctly. For young children, the best choice for replacement of the pulmonary valve and artery is a homograft, which is tissue taken from another child who died of unrelated causes. For obvious reasons, these homografts are not available in sufficient quantities to satisfy the needs of all children requiring such a valve conduit substitute.

Risks and Benefits:

Pig valves have been implanted into the right side of the heart for many years, but they tend to fail as the heart/child outgrows the conduits, and, as noted above, due to calcium deposits. One reason for the calcium deposits is believed to be a reaction to the leaching (or slight leaking) of chemicals used during processing. To overcome these problems, Shelhigh, Inc., has developed a new treatment that prevents the leaching of the chemicals used to treat these valves and arteries. Clinical experience in Europe with these conduits has been, so far, very gratifying.

Potential complications do exist, and they can necessitate valve conduit replacement. Such complications include:

- unacceptable flow conditions of the blood;
- right heart failure (failure of the heart to maintain adequate circulation of the blood);
- thrombosis (clot);
- anticoagulant (blood thinners) complications (i.e., hemorrhage);
- endocarditis (inflammation of the lining membrane of the heart);
- calcification (hardening of the valve);
- arrhythmia (irregular heart contractions);
- severe heart failure leading to death.

No unusual risks are expected as a direct result of the implants of this conduit. However, should an unforeseen adverse reaction manifest itself, appropriate medical care, as determined by your child's physician, will be provided. Expenses arising from any need for medical therapy or surgical intervention will not be provided by Shelhigh, Inc.

Benefits: Your child is expected to benefit from this surgical intervention which is intended to replace a diseased, damaged, malfunctioning, or absent pulmonic valve and/or artery. Potential benefits include improved cardiovascular function and a greater life expectancy. If no other alternatives exist, it may save the life of your child.

Informational source: Inquiries regarding this device, your child's rights, or any other matter should be directed to your child's physician. You should also make sure you follow religiously the instructions of your physician, relating to taking medications as prescribed (e.g. anticoagulation and other drugs) as well as other pertinent instructions.

Warning: Shelhigh, Inc., is stressing the need for the parents to be well informed about the type of heart defect their child was born with, the type of operation, the type of the conduit, the date of the operation, the drug regimen, and any pertinent treatment their child should follow.

Need for Reoperation:

As the child grows, a larger conduit may be necessary. Depending upon the child's age and growth rate, the new conduit may be required in two (2) to four (4) years.

For convenience enclosed is a short form that your doctor should help you fill out and can be used for future reference:

*Note: This form should be available for any eventual clinical visit or hospitalization. Make as many copies as you might need.

Short Information Form

Patient Name: _____ Age: _____

Address: _____

_____

Diagnosis: _____

_____

Date of Implantation: _____

Operation: _____

Conduit Type: _____ Size: _____

Serial Number: _____

Surgeon's Name: _____

Telephone#: _____ Fax#: _____

E-mail address: _____

Institution (Hospital): _____
Hospital address: _____

Drugs Prescribed: _____ Dose: _____
_____ Dose: _____
_____ Dose: _____
_____ Dose: _____
_____ Dose: _____

Comments: _____
_____
_____
_____
_____

*Note: This form should be available for any eventual clinical visit or hospitalization. Make as many copies as you might need.