Instructions for Use

BioPulmonic™

Valved Pulmonic Biological Conduit

Model NRPC

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PRODUCT DESCRIPTION

The *BioIntegral Surgical No-React® Valved Pulmonic Conduit Model NRPC* is a porcine valve covered with a porcine pericardial sleeve of 10 cm in length.

MODELS AND SIZES

The BioIntegral No-React® BioPulmonic Conduit prosthesis, model NRPC is available in sizes: 15 mm, 17mm, 19 mm, 21 mm, 23 mm, 25mm, and 27mm.

PACKAGING AND STORAGE

PACKAGING

The device is sterilized in 4% formaldehyde via a validated process. After removing formaldehyde and glutaraldehyde residuals through a proprietary process, the device is packaged in a 2% benzyl alcohol solution. The valved conduit and the storage solution are sterile as long as the container has not been damaged and the shrink seal is intact. The outside of the container is not sterile and should not be placed in the sterile field.

STORAGE

It is recommended that the conduit 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 tissue. The *BioIntegral Surgical No-React® BioPulmonic Conduit* package is supplied with a freeze indicator, which should be inspected upon receipt of the xenograft. If the device is exposed to freeze/thaw conditions, coloured ink will change the color of the indicator paper or bulb.

Do not use the conduit if the indicator has been activated (color on). If it is necessary to store the xenograft under refrigeration, include the freeze indicator with the xenograft package and inspect upon removal for assurance that the xenograft was not exposed to freezing conditions.

INDICATIONS

The BioIntegral Surgical No-React®-treated BioPulmonic Conduit prosthesis is intended as a replacement for diseased or damaged pulmonic valve or artery. This prosthesis can be an alternative to a pulmonic homograft or other xenografts for a replacement of their pulmonic valve or the total right ventricular outflow, and have no good existing alternatives. This prosthesis is also indicated for the Ross procedure when the patient's native pulmonic valve is transplanted into the aortic position.

CONTRAINDICATIONS

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

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 gloved hands.

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.

Do not use the *BioIntegral Surgical **No-React**® BioPulmonic Conduit Model NRPC* when, in the opinion of the surgeon, it is not an appropriate device for the patient.

WARNINGS AND PRECAUTIONS
THIS DEVICE IS FOR SINGLE USE ONLY. DO NOT RESTERILIZE THE VALVE BY ANY METHOD.

If device resterilization or reuse is attempted, the risk of contamination, tissue degeneration or destruction, valve dysfunction, physical deformity, cross-linking destruction, residual sterilant toxicity and other unforeseen risks is high and the user must obtain a new, ready device instead.

DO NOT USE IF:
- The device has been frozen or is suspected of being frozen.
- There has been damage to, or evidence of leakage from the container, or the shrink seal is not intact.
- The storage solution does not completely cover the bioprostheses, or the device has dried.

DO NOT USE **ANY hemostatic agents (e.g., surgical glue or adhesives) especially if they contain glutaraldehyde or formaldehyde, at <u>any</u> concentration. They could interfere with proper healing.**

NOTE: Any conduit, biological or synthetic, must be sutured with non-absorbable suture material. In this case, because we are dealing with No-React treated tissue, which causes no foreign body reaction, blood oozing is impermissible, if such oozing or leaking of blood is present at the time of anastomosis, BioIntegral Surgical suggests to stop the oozing with fine 7-0 interrupted sutures. Do not use of surgical glues or adhesives.

All hemostasis of anastomoses should be done with non-absorbable suture material (6.0 or 7.0 prolene). If a pledget must be used, it should be biologic.

ANITIBIOTICS: the valve should not be exposed to antibiotics prior to implant.

DO NOT EXPOSE TO ANY SOLUTION except for the storage solution or sterile saline.

RINSING IS NOT REQUIRED and could increase the risk of device contamination.

The device is MRI safe, regardless of Tesla rating. The device is only manufactured with biological tissue and polyester sutures. No metallic or magnetic materials are used and therefore it will not pose any risk to the patient while being scanned.

Do not allow the valve tissue to dry. Maintain tissue moisture with periodic irrigation or immersion in saline solution to avoid drying, which can cause irreparable damage to the tissue.

No catheter or pacemaker leads must ever be left across the device. Cardiac catheterization across a device may be accomplished using soft tip catheters that will not damage the tissue. No instruments or objects should come in contact at any time with the valvular tissue.

Do not subject the stentless valved porcine conduit to propylene oxide, steam or gamma irradiation sterilization once it has been removed or while it is in its container.

If the sterility of the product is in question, it should not be used for human implantation.

No special disposal conditions or techniques are required.

DIRECTIONS FOR USE

HANDLING

Inspect the valve container for leakage upon removal from the package. If any is noted, do not implant the valve. The shrink seal on the container should be broken and the screw cap lid removed from the jar and discarded. The valve conduit can be removed from its container by grasping the identification tag with a pair of atraumatic forceps to the sterile field.

Rinsing is not required, but if you wish to rinse, remove any powder residue from gloved hands prior to handling the valve with physiologic saline rinses. Use 500 ml saline solution in one basin and agitate the valve in it for at least 2 minutes. The identification tag should be inspected and removed from the valve just prior to implantation.

PULMONIC ROOPT REPLACEMENT

SIZING THE PULMONIC ANNULUS

The BioIntegral Surgical No-React®-treated BioPulmonic Conduit can be used to replace the pulmonic valve when the latter was transplanted in the aortic position (Ross procedure).

After removal of the pulmonic valve, the subvalvular orifice is generally larger than the diameter of the pulmonary artery.

SURGICAL TECHNIQUE
The annulus made of pericardial tissue should be sutured with multiple interrupted mattress sutures. A combination of multiple suture techniques might be necessary especially for the posterior portion of the muscular part of the right ventricular outflow annulus, however,

IF A "BYPASS" IMPLANT TECHNIQUE IS USED:
If the device is used "as a bypass" (rather than in situ), make a 45° cut on both ends oblique to the heart and pulmonary artery, respectively. This is to allow better resistance to possible fibrin deposits on the anastomosis. In a distal anastomosis, all the suturing must be mattress and exteriorized and no suturing of the posterior wall of the anastomosis should be done from the inner side of the pulmonary artery.

Optimal suture technique is a interrupted mattress sutures using a 6-0 monofilament. The maximum distance between bites is no greater than 2 mm, and no oozing or bleeding is permissible. Post-anastomosis, all bleeding must be stopped by fine 7-0 monofilament sutures, or the surgeon raises the risk of adhesions, imaging halos and/or stenosis, or false aneurysm. If there is any size mismatch, it can be corrected using pericardial patches to bridge any gaps.

Blood management critical before sternal closure
All excess blood must be removed before sternal closure. This includes blood or oozing at the anastomosis sites (see above), as well as any blood on the device or in the chest cavity. Rinse the chest 2-3 times with warm sterile saline and make sure fluids leaving the chest drain are eventually clear.

POST-OPERATIVE TREATMJENT STEPS: ANTICOAGULATION / ANTIBIOTICS
6 week minimum, or 12 weeks of anticoagulant therapy is urged to allow full healing and proper device integration into the body. If there is the presence of any endocarditis 6 weeks of IV antibiotics are additionally recommended. For any patient undergoing dental procedures, oral antibiotics are recommended 24 hours before and 48 hours after those procedures.

The patient's temperature should be checked daily for 3 weeks post-op, and instructed to contact the physician if there is any unexplained fever above 38.5 degrees Celsius. In such cases, it is recommended the physician take blood cultures and simultaneously begin a course of IV antibiotics.

The use of anticoagulant drugs may be contraindicated for some patients. The decision as to whether anticoagulant or antiplatelet therapy is appropriate for the patient must, ultimately, rest with the physician.

COMPLICATIONS

Reported post-operative complications with porcine bioprostheses may include: endocarditis, calcification, thrombosis, thromboembolism, primary tissue failure, hemorrhage, unacceptable hemodynamics, congestive heart failure, stenosis, regurgitation, fever of unknown origin and/or elevated C-reactive protein (CRP) levels, any of which might require re-operation or intervention, and can be totally independent of the device. As with any major cardiac operation, there are risks, including the possibility of death, that each patient and surgeon must consider alongside the benefits on an individual basis when choosing a valvular prosthesis.

While the conduit is intended for long-term use, somatic outgrowth may be inevitable in young, growing patients, as the strong and biocompatible tissue that comprises this No-React® treated device will not dilate or stretch over time. Like all pulmonic conduits in growing patients, all recipients should be monitored closely and regularly by their physician.

SHARING YOUR CLINICAL EXPERIENCE

BioIntegral Surgical, Inc. is very interested in learning of any clinical experiences involving the BioIntegral No-React® BioPulmonic Valve Conduit. It is particularly interested in receiving any explanted valves for analysis. If possible, it would be ideal to receive an explant within 72 hours in a leak proof specimen jar containing refrigerated saline. In not, an appropriate preservation solution such as 10% Formalin may be used to return the valve. Information regarding the patients history (e.g. patient records, test reports) and the reason for explantation would be sent with the product to BioIntegral Surgical, Inc., 1-200 Britannia Road East, Mississauga, ON L4Z 1S6 Canada. In addition, it would be of assistance if the name of an appropriate contact be provided should additional information be required.

PRODUCT INFORMATION DISCLOSURE

BioIntegral Surgical has exercised reasonable care in the manufacture of this device. BioIntegral Surgical 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. Handling and storage of this device by the user as well as factors related to the patient, his diagnosis, treatment, surgical procedures and other matters beyond BioIntegral's control may directly affect this device and the results obtained from its use. BioIntegral Surgical 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.

GLOSSARY OF SYMBOLS

Symbol	Description
	Manufacturer
	Date of Manufacture
	Medical Device
	Do Not Re-use
	Sterile Using Aseptic Processing Techniques
	Consult Instructions for Use
	Caution
	Do Not Use If Package Is Damaged
	Contains Biological Material of Animal Origin
	Contains/Presence of Benzyl Alcohol
	Temperature Limit

PATIENT IMPLANT CARD SYMBOLS

Symbol	Description
	Patient Name
	Hospital
	Date of Implantation
	Medical Device
	Manufacturer
	Website
	Serial Number
	Lot Number
	Unique Device Identifier