Instructions for Use

Injectable BioPulmonic™

Off-Pump Injectable Porcine Pulmonic BioProsthesis

Model NRIP

CONTENT
1 Device

CE 0482

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PRODUCT DESCRIPTION

The BioIntegral Surgical No-React® Injectable BioPulmonic™ is a glutaraldehyde cross-linked porcine bioprosthesis that has been detoxified with a unique process. In contrast to conventional glutaraldehyde treatment, No-React® detoxified tissue does not leach detectable glutaraldehyde molecules. The No-React® process makes tissue more cytocompatible, while retaining all the positive physical attributes of glutaraldehyde-treated tissues.

The valve structure consists of a porcine pulmonic valve mounted inside a self-expandable nitinol stent which is covered by No-React® treated porcine pericardium (Figure 1). The device is designed to facilitate minimally invasive implantation.

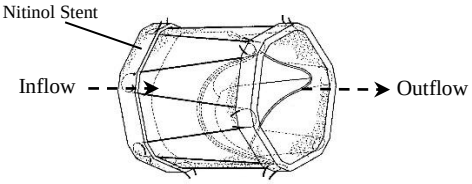

Figure 1: Model NRIP

There is no MRI risk associated with the No-React® Injectable BioPulmonic.

MODELS AND SIZES

The device is available in sizes: 15, 17, 19, 21, 23, 25, 27, 29 and 31 mm.

Size of Trocar and its respective valve size

Trocar Size:	***Valve compatible size(s)***
11mm	15mm
13mm	17mm and 19mm
15mm	21mm – 31mm

PACKAGING AND STORAGE

PACKAGING

The device is supplied STERILE in a 2% Benzyl alcohol solution. The valve 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
The device must be stored in its package at a temperature between 5 and 25 degrees Celsius. Refrigeration is not required, and freezing may damage the device. Room temperature storage is satisfactory (up to 25 Degrees C), provided the device is not exposed to sunlight. The device package is supplied with a freeze indicator that should be inspected prior to use of the device. If the device is exposed to freeze/thaw conditions, colored ink will spread throughout the indicator. Do not use the device if the indicator has been activated. If it is necessary to store the device under refrigeration, include the freeze indicator with the device package and inspect upon removal for assurance that the device was not exposed to freezing conditions.

INDICATIONS
Severe Pulmonic Regurgitation (PR) especially when leading to severe right heart failure complicated by left heart failure along with arrhythmia which can be followed by sudden death. To correct complications that arise from post-operative repair of Tetralogy of Fallot (TOF).

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 manufacturer strongly suggests the user 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 the glass container and jar, and/or the jar cap shrink seal is not intact.
- The storage solution does not completely cover the bioprostheses, or the device has dried.

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.

No instrument or object should come into contact at any time with the valve cusps as they could be damaged.

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 should not damage the tissue.

No special disposal conditions or techniques are required.

STERILIZATION OF ACCESSORIES
See Accessory IFU for more information.

DIRECTIONS FOR USE
SIZING THE PULMONIC ANNULUS
The device is designed to have a larger annular diameter than the actual valve or pulmonary artery. The expandable stent allows the valve to distend and accommodate up to one size larger than the designated diameter. Over-sizing by one valve size according to 2D echocardiography is recommended. The diameter of the pulmonary artery 1 cm below the bifurcation should be designated as the size of the pulmonary artery for the purposes of sizing the valve.

DEVICE IMPPLANTATION
Please consult the Surgical Manual for complete device implantation instructions.

MINIMALLY INVASIVE SURGICAL TECHNIQUE
Post median-sternotomy, make an incision with purse-string sutures over the right ventricle. Follow the instructions outlined below to prepare the device for implantation using the supplied reusable (autoclavable) BioIntegral Surgical Injector.

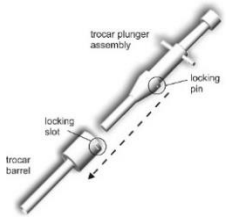

Figure 2: The BioIntegral Surgical Injector

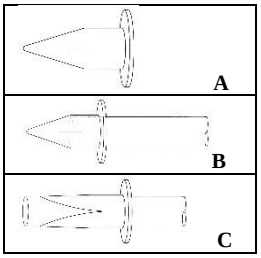

Figure 3: Introducer Tip

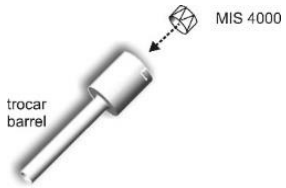

Figure 4: Loading the NRIP into the trocar barrel.

Figure 5: Locking the Trocar Barrel.

LOADING THE INJECTOR

The delivery mechanism for the device consists of three parts: the trocar barrel (Figure 2), the trocar plunger assembly (Figure 2), and the introducer tip (Figure 3). Load the valve into the funnel portion of the trocar barrel as shown in Figure 4 (outflow side facing into the taper; inflow side facing the loading side) and gently advance the valve into the straight portion of the barrel. Insert the trocar plunger into the tapered end of the trocar barrel and gently advance forward, but do not push the valve all the way through the trocar barrel. Rotate the funnel as shown in Figure 5 to lock the pins into the slots. Using the trocar plunger, bring the valve to the edge of the trocar barrel, but not too far, so the stent is not protruding from the barrel tip. Place the supplied introducer tip (Figure 3A) securely on the end of the barrel (Figure 3B).

USING THE INJECTOR

Hold the trocar with the fingers below the side rods and the thumb over the plunger. Using a small rotation without pressure, place the introducer tip and trocar barrel through the incision made in the right ventricle and into the pulmonary artery. Once the pulmonic artery is dilated and the trocar barrel is in the proper position, retract the introducer tip while keeping the device within the ventricle. The introducer tip contains 3 leaflets that will separate once the plunger reaches the ventricle and the tip is pulled back along the trocar barrel (Figure 3C). Place the left index finger on the pulmonic bifurcation and depress partially. Next, slowly depress the plunger and fully eject the valve (Figure 6), ensuring that the outflow of the valve is 1–1.5 cm below the bifurcation to prevent occlusion of the pulmonary arteries and/or migration of the valve. After the device has been fully expelled from the trocar barrel, withdraw the trocar. The assistant should tighten the purse strings to prevent bleeding.

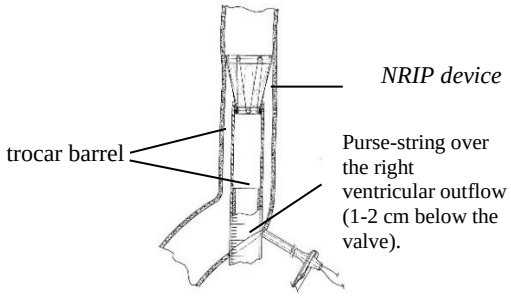

Figure 6: NRIP being released into position.

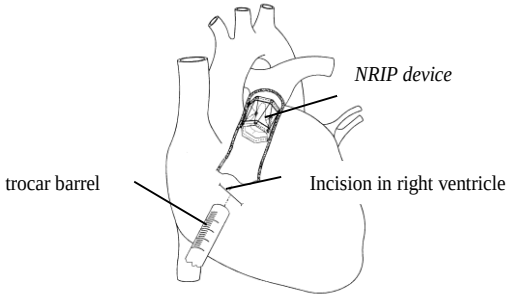

Figure 7: Implantation of the NRIP.

FIXATION

Fixation must be accomplished distally using running sutures or interrupted sutures with pledgets. The inflow end should only be fixed using pledgets, as the cusps come so close to the wall of the device (see Figure 8). Also, after each suture, the echo must be checked to confirm that no cusps have been retracted or snared by the sutures. In certain cases where the base of the patient's pulmonary valve is heavily dilated, and the artery has a conical shape, there may be a space between the inflow end of the valve and the pulmonic artery after injection of the valve, as observed by palpation. In this situation, removal of this space is important, and it is highly recommended to conduct a pulmonic plasty with two or three pledgeted sutures at the base of the valve.

CAUTION: Unlike other implanted tissues, No-React tissues should not cause scarring and thus, should not activate the patient's foreign body response in the event of careless suturing. Always ensure that bleeding or oozing has stopped entirely upon completion.

Figure 8: External pledgeted fixation at the Inflow side of the valve.

INDIVIDUALIZATION OF TREATMENT: ANTICOAGULATION / ANTIBIOTICS

12 weeks of anticoagulant and/or antiplatelet therapy is always strongly recommended.

If there is the presence of 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 the patient should be instructed to contact the physician if there is any unexplained fever above 38.5 degrees Centigrade. 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 postoperative complications with bioprostheses in general have included: perivalvular leakage, endocarditis, calcification, thrombosis, thromboembolism, primary tissue failure, hemorrhage, unacceptable hemodynamics, congestive heart failure, and hemolysis. General risks of cardiovascular operations include: air embolus, CPB, arrhythmia, stroke and death. Each physician must consider all the risks and benefits to the patient on an individual basis when choosing a valvular prosthesis.

RETURN OF EXPLANTED BIOPROSTHESES

BioIntegral Surgical is very interested in learning of any clinical experiences involving our devices. We are particularly interested in receiving for analysis any explants for any reason. It is ideal to receive an explant within 72 hours in a leak proof specimen jar containing refrigerated saline. If not, an appropriate preservative solution such as 10% Formalin may be used to return the device. Information regarding the patient's history (e.g. patient records, test reports) and the reason for explantation should be sent with the product to the company address.

In addition, it would be of assistance if the name of an appropriate contact be provided should additional information be required.

An analysis will be conducted at BioIntegral Surgical 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 our product.

PRODUCT INFORMATION DISCLOSURE

BioIntegral Surgical has exercised reasonable care in the manufacturing, 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 or fitness. Handling and storage of this device by the user as well as factors related to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BioIntegral Surgical's control may directly affect this device and the results obtained from its use. BioIntegral Surgical neither assumes nor authorizes other persons to assume for it any other 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