Instructions for Use

BioAortic / BioMitral™

Porcine BioProsthesis

Model NR(A/M)

CONTENT
1 Device

CE 0482

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PRODUCT DESCRIPTION

The BioIntegral Surgical No-React® BioMitral®/BioAortic® 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 cytocompatable, while retaining all the positive physical attributes of glutaraldehyde-treated tissues.

The valve is supplied with an integral disposable holder, attached to the bioprosthesis by three blue monofilament sutures.

There is no MRI risk associated with the BioAortic or BioMitral devices.

MODELS AND SIZES

The No-React® BioMitral® (model NRM) is available in sizes (27mm, 29mm, 31mm, 33mm).

The No-React® Bioaortic® (model NRA) is available in sizes (21mm, 23mm, 25mm, 27mm).

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°C. Refrigeration is not required and freezing may damage the device. Room temperature storage is satisfactory (up to 25°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, coloured 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

The BioIntegral Surgical No-React® BioMitral®/ BioAortic® is intended as a replacement for damaged or diseased valves in the presence of infection or in patients with a high risk of infection.

CONTRAINDICATIONS
None known.

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.

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.

STERILIZATION OF ACCESSORIES
See Accessory IFU for more information.

DIRECTIONS FOR USE
HANDLING
No instrument or object should come into contact at any time with the valve cusps as they could be damaged. The shrink seal on the container should be opened and the screw cap lid removed from the jar. Upon opening, verify that there is no evidence of leakage around the edge of the lid. The device can be removed from its container with the aid of the valve handle screwed into the valve holder or by grasping the implantation flange or identification tag with a pair of atraumatic forceps.

The identification tag should be inspected to verify the serial number matches the jar label, and removed prior to implantation.

When removing the holder, make certain that all blue monofilament sutures have been removed from the device. When necessary, the device may be handled with sterile gloved hands, taking care not to touch the cusps and to remove glove powder residue with sterile physiological saline prior to handling the valve.

DEVICE IMPLANTATION

NRM: MITRAL REPLACEMENT

The NRM valve can be used for mitral replacement. In this case the valve holder is on the INFLOW side.

The Mitral annulus should be sized using an appropriate circular sizer which has an outside diameter equivalent to the stated diameter of the Device. When so sized, and with the implantation flange on the atrial side of the mitral annulus, the ventricular portion of the valve will lie within the mitral annulus.

We consider proper orientation of the mitral valve in the annulus to be that which assures the strut is not in the overflow tract of the left ventricle. To facilitate this, one sinus of the valve should face the left ventricular outflow (aortic valve). The center of the sinus (between the commissures) should be placed in the center of the anterior leaflet of the mitral valve so that the two related struts straddle the left ventricular outflow tract.

The mitral valve holder is designed to reduce the risk of suture entrapment around the post as the valve is being lowered into position. Prior to placement of the annular sutures through the implantation flange, the stent posts should be manually deflected inward. The suture that encircles the tips of the posts and exits at the base of the valve holder should be grasped with a clamp at the knot and tractioned up onto the groove in the holder.

The deformable portion of the valve handle should be bent in order to provide the optimal angle for valve insertion. It is suggested that the annular sutures be placed into three groups maintaining traction on all sutures as the valve is slid into the ventricle assuring that the posts all lie within the ventricular cavity. The valve handle is then removed and three sutures at the base of each post are tied, securing the valve in that position. The valve holder is removed by making one single cut adjacent to each of the three knots and slowly separating the holder/handle assembly from the valve, noting the detachment of the suture. It is important that only one single cut be made next to each of the three knots.

In the event the holder prevents lying of the first three annular sutures, the holder must be removed prior to tying but in the same described manner prior to securing the valve in place.

NRA: AORTIC REPLACEMENT
The NRA valve can be used for aortic replacement. In this case the valve holder is on the OUTFLOW side.

The Aortic annulus should be sized using an appropriate circular sizer which has an outside diameter equivalent to the stated diameter of the device. For aortic implantation, the valve can be implanted in either the infraannular or the supraannular position.

The deformable portion of the valve handle should be bent in order to provide the optimal angle for valve insertion.

The disposable aortic valve holder is on the outflow of the valve and is removed in the same fashion as described under NRM: MITRAL REPLACEMENT above.

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.

No special disposal conditions or techniques are required.

INDIVIDUALIZAATION OF TREATMENT: ANTICOAGULATION / ANTIBIOTICS
12 weeks of anticoagulant and/or antiplatelet therapy is always strongly recommended.

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 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 have included: perivalvular leakage, endocarditis, calcification, thrombosis, thromboembolism, primary tissue failure, hemorrhage, unacceptable hemodynamics, congestive heart failure, and hemolysis. As with any major cardiac operation, there are serious potential risks, including the possibility of inflammatory response, bleeding, infection, stroke, or death, which each surgeon must consider alongside the benefits on an individual basis.

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 at 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, 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 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