# Instructions for Use

# BioConduit™

# Valved Aortic Biological Conduit

## Model NRAC

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## PRODUCT DESCRIPTION

The *BioIntegral Surgical No-React® Stentless Valved* Aortic *Conduit Model NRAC* is a flexible, unstented, non-rotatable, supra-annular porcine aortic valve covered with a bovine pericardial sleeve which is to be sutured to the aortic root. The sleeve is 15 cm in length.

## MODELS AND SIZES

The *BioIntegral Surgical No-React® Stentless Valved Aortic Conduit* is available for replacement of the aortic valve in sizes 21mm, 23mm, 25mm, 27mm and 29mm.

## 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

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 valvular tissue. The *BioIntegral Surgical No-React® Stentless Valved Aortic 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, colored ink will change the color of the indicator paper or bulb.

Do not use the conduit if the indicator has been activated. 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®** Stentless Valved Aortic Conduit Model NRAC* is intended as a replacement for damaged or diseased aortic heart valve, particularly when the ascending aorta and valve need to be replaced, in cases where the patient cannot be anticoagulated, presenting with endocarditis, or WHEN FABRIC IS CONTRAINDICATED, AND NO HOMOGRAFT IS AVAILABLE.

## CONTRAINDICATIONS

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

If using the device to treat infective endocarditis, do NOT use synthetic materials in conjunction with the BioConduit™. Use only ***No-React***® treated pericardial patches or autologous tissue.

There is no MRI risk associated with the No-React® NRAC device. The NRAC is MRI safe and compatible regardless of Tesla rating.

## 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, 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 would interfere with proper healing and tissue integrity.**

All hemostasis of anastomoses should be done with suture material (5.0 or 6.0). 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.
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.

Do not subject the stentless valved bovine conduit to propylene oxide, steam or gamma irradiation 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 instruments or objects should come in contact at any time with the valvular tissue.

It is extremely important that patients above 65 do not have any dental issues that would lead to bacteremia. These dental issues should ideally be resolved before surgery.

**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 by grasping the implantation flange or identification tag with a pair of traumatic forceps. The identification tag should be inspected to verify the serial number matches the jar label and removed prior to implantation.

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.

No special disposal conditions or techniques are required.

**DEVICE IMPLANTATION**

VALVE SIZING

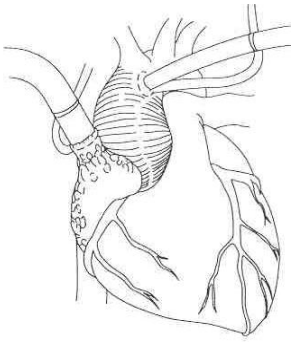
Sizing should be done with any sterile sizers for any heart valve or Hagar dilators. Hagar dilators are preferred. They mimic the proper physiologic radial pressure on the conduit

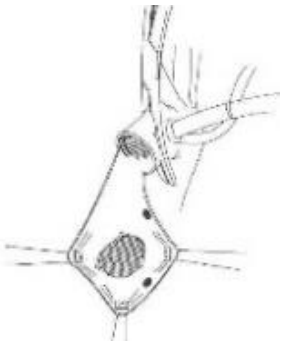
during systole and best approximate working size. The opportunity to oversize is also better judged with gentle dilation.

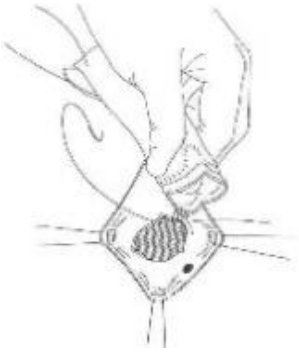
**AORTIC ROOT REPLACEMENT**

*The BioIntegral Surgical* **No-React®** *Stentless Valved Aortic Conduit Model NRAC* is implanted using the Bentall technique.

*The aneurysm is resected, leaving the posterior portion intact*





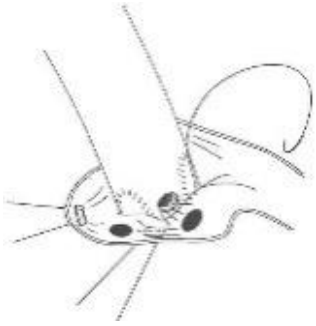


*The* NRAC *is ideally secured with interrupted mattress sutures to maximize EOA and flow.*

**IMPLANTATION**

*Openings are made in the graft adjacent to the left coronary ostium. NOTE: the suture line of the tube of the conduit should face the middle of the non-coronary cusp. Otherwise, the surgeon may find himself perforating the suture line to anastomose the right or left coronary artery*

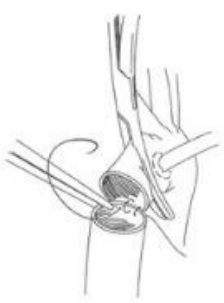
*Anastomoses are made between the graft and the right coronary orifice.*

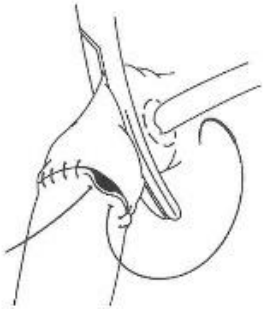


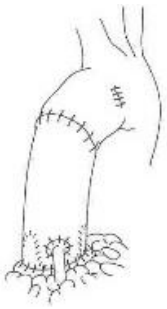
*NOTE: Any aortic conduit, biological or synthetic, must be sutured with non-absorbable suture material. We are dealing with No-React tissue, which causes no foreign body reaction, so blood oozing is completely impermissible. If such oozing or leaking of blood is present, BioIntegral Surgical suggests to stop the oozing with 5-0 interrupted sutures. No use of surgical glues or adhesives are permitted on the device or at the anastomoses sites.*

*If the surgeon permits mild bleeding or oozing, the surgeon cannot rely on the oozing to stop and in rare cases, hematoma can result. Again, this is not a synthetic conduit, and scar formation cannot be expected.*

*The distal anastomosis is completed. Air is aspirated from graft, cannulae removed.*







The surgeon can tailor the outflow of the valve according to the need. The larger pericardial sleeve will permit the surgeon to use this valve as a mini-root or full root replacement.

Make sure bleeding and oozing have been taken care of with careful suturing as per all anastomoses with the device. Do not close the sternum if any oozing is present. Since the conduit is always longer than you need, you can use a few pericardial strips on the aortic level as a long pledget, which will reduce any oozing significantly. In addition, rinse the chest with warm saline to ensure no fibrinolytic factors are present around the device to minimize risk of adhesions.

**REQUIRED POST-OPERATIVE CARE: ANTICOAGULATION / ANTIBIOTICS**

6 weeks minimum, or 12 weeks of anticoagulant therapy is required immediately for ideal patient healing and to minimize fibrin deposits on the device while integration is occurring. If there is the presence of any infection, a maximum exposure to IV antibiotics is recommended (6 weeks, if feasible).

If any hematoma is developed post-operation, it generally means that the blood clotted before it was drained.

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.

## POSSIBLE COMPLICATIONS

Reported postoperative complications with bioprostheses have included: perivalvular leakage, endocarditis, calcification, thrombosis, thromboembolism, hematoma, stenosis, regurgitation, tissue failure, hemorrhage, unacceptable hemodynamics, congestive heart failure, pseudoaneurysm, hemolysis, fever of unknown origin, which is possible from any operation, with or without implant, and/or elevated C-reactive protein (CRP) levels. 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 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 |