Instructions for Use

NR Patch™

Porcine Pericardial Patch

Model NRPP

CONTENT
1 Device

CE 0482

BioIntegral Surgical, Inc.
1-200 Britannia Road East
Mississauga, ON L4Z 1S6, CANADA
Phone: +1-905-268-0866
Email: info@biointegral-surgical.com
www.BioIntegral-Surgical.com

EMERGO EUROPE
Prinsessegracht 20
2514 AP The Hague
The Netherlands

Consult instruction for use at this website:
www.BioIntegral-Surgical.com/elabel

PRODUCT DESCRIPTION

The BioIntegral Surgical No-React® porcine pericardial patch is a glutaraldehyde cross-linked porcine collagen 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.

There is no MRI risk associated with the No-React® porcine pericardial patch.

MODELS AND SIZES

The pericardial patch device is available in sizes 0.8x8 cm, 1x6 cm, 1x7 cm, 2x7 cm, 2x9 cm, 3x3 cm, 4x4 cm, 4x14 cm, 5x5cm, 6x8 cm, 6x10 cm and 8x14 cm and 9 mm, 11 mm, 13 mm and 15 mm curved diameters.

PACKAGING AND STORAGE

PACKAGING

The device is supplied STERILE in a 2% Benzyl alcohol solution. The patch 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® patch is intended for use as an intracardiac patch to close intercavity defects, enlarge the aortic root, carotid endarterectomy, and for pericardial closure. The device can be made square, rectangular, circular, oval or any shape or size required for a specific operation. It is available in various sizes, but it also may be tailored by the surgeon during surgery to meet the surgeon's needs.

CONTRAINDICATIONS

The device is not recommended for patients having active sternal infection.

WARNINGS AND PRECAUTIONS

THIS DEVICE IS FOR SINGLE USE ONLY. DO NOT RESTERILIZE THE PATCH BY ANY METHOD.

If device resterilization or reuse is attempted, the risk of contamination, tissue degeneration or destruction, 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 container 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 patch 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 patch 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

There are no accessories related to this device.

DIRECTIONS FOR USE

HANDLING

Rinsing is not required; however immersion in sterile saline can assist in preventing dry-out during operation.

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. If the device will be handled directly with gloves, remove glove powder residue with sterile physiological saline prior to handling the device.

Remove the device from its container by grasping with atraumatic forceps or with sterile gloved hands; if the device includes an identification tag, then use that tag as a grasp point.

DEVICE IMPLANTATION

Tailor the device to the appropriate size and configuration using sterile forceps and surgical scissors.

Drainage lines may be placed above or below the implanted patch. The surgical technique used is the responsibility of the implanting surgeon.

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 or inadequate suturing. Always ensure that bleeding or oozing has stopped entirely upon completion.

To date, there is insufficient data on the use of the device in immunosupressed patients. Close follow-up is recommended when using the patch in this patient population.

COMPLICATIONS

Reported post-operative complications with the Porcine Pericardial Patch may include: infection, calcification, bleeding or oozing any of which might require re-operation. Complete heart block and complete right bundle heart block have been reported for procedures involving cardiac repair near the atrioventricular conduction bundles, most notably for repair of atrial septal defects.

As with any major cardiac operation, there are serious potential risks, including the possibility of 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 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, 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 Manufacturer
	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