



**XenoSure® Biologic Patch**  
Instructions for use - English

**Patch Biologique XenoSure®**  
Mode d'emploi – Français

**Parche Biológico XenoSure®**  
Instrucciones de uso - Español

**Penso Biológico XenoSure®**  
Instruções de utilização - Português

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**XenoSure® Biologic Patch**

# XenoSure® Biologic Patch

(Model Numbers 0.6P8, 0.8P8, 1P6, 1P10, 1.5P10, 1P14, 2P9, 4P4, 4P6, 6P8, 8P14, 10P16)

Processed bovine pericardial patch

Instructions for use - English

**STERILE** **A**  **Rx only**

## Storage

The XenoSure® Biologic Patch should be stored at room temperature. Refrigeration is not required.

## Device Description

The XenoSure Biologic Patch consists of one piece of bovine pericardial tissue that has been selected for minimal tissue blemishes. The tissue is treated with a glutaraldehyde process which crosslinks the collagen fibers and minimizes antigenicity. The XenoSure Biologic Patch is liquid chemical sterilized and packaged in a plastic jar containing sterile glutaraldehyde storage solution. The XenoSure Biologic Patch is designed to repair the body's natural organs.

The XenoSure Biologic Patches come in the following sizes:

Model	Size (cm)	Model	Size (cm)
0.6P8	0.6x8	2P9	2x9
0.8P8	0.8x8	4P4	4x4
1P6	1x6	4P6	4x6
1P10	1X10	6P8	6x8
1.5P10	1.5X10	8P14	8x14
1P14	1x14	10P16	10x16

## Indications For Use in Australia

The XenoSure Biologic Patch is intended for use as a surgical patch material for cardiac and vascular reconstruction and repair.

## Indications For Use in Other Countries

The XenoSure Biologic Patch is intended for use as a surgical patch material for cardiac and vascular reconstruction and repair, soft tissue deficiency repair, reinforcing the suture line during general surgical procedures, and to close dura mater during neurosurgery.

The indication of "close dura mater during neurosurgery" is not approved by the French authorities in the French Republic.

## Contraindications

None known.

## Potential Complications

- Restenosis
- Pseudoaneurysm formation
- Infection
- Thrombosis
- Calcification
- Fibrosis
- Vessel occlusion
- Patch rupture
- Dilatation
- Myocardial infarction
- Bleeding
- Cerebrospinal fluid leakage
- Stroke
- Death
- Meningitis

## Warnings

The principal complications that have been reported for bovine pericardial tissue are fibrosis and infection. These complications are observed only in a small minority of patients after implantation of the bovine pericardial tissue.

## Precautions

All persons responsible for the handling and preparation of the XenoSure Biologic Patch must exercise utmost care to avoid damage to the XenoSure Biologic Patch tissue.

- **FOR SINGLE USE ONLY.** Do not reuse, reprocess, or resterilize. Reuse, reprocessing, and/or resterilization of the device and/or failure could cause patient injury, illness or death. Any unused pieces of XenoSure Biologic Patch must be discarded. Note product "Use By" date.
- **INSPECT** sealed sterile package before opening. If seal is broken, contents may not be sterile and may cause infection in the patient. **DO NOT USE.** Do not discard the product. Please contact your distributor for

further instructions.

- RINSE the device according to the "RINSE PROCEDURE" section of this booklet before using. The XenoSure Biologic Patch storage solution contains glutaraldehyde and may cause irritation of skin, eyes, nose and throat. DO NOT BREATHE STORAGE SOLUTION VAPOR. Avoid prolonged skin contact and immediately flush area with water. In case of contact with eyes, seek medical assistance immediately. The liquid chemical storage solution should be disposed according to hospital procedure.
- DO NOT handle the XenoSure Biologic Patch with traumatic instruments. This may damage the device.
- DO NOT use any XenoSure Biologic Patch that has been damaged. Device integrity may be compromised.
- DO NOT attempt to repair the XenoSure Biologic Patch. Should damage to the XenoSure Biologic Patch occur before implantation, replace the XenoSure Biologic Patch.
- DO NOT resterilize. Unused sections should be considered non-sterile and discarded.
- DO NOT expose the XenoSure Biologic Patch to steam, ethylene oxide, chemical or radiation (gamma/electron beam) sterilization. Damage may result!
- DO NOT use cutting suture needles or cutting point armed sutures. This may damage the device.
- DO NOT allow the patch tissue to dry out during handling.
- DO NOT use if the device is beyond the expiration date.

### **Adverse Effects**

The XenoSure Biologic Patch is designed to repair the body's natural organs. Improper functioning of an implanted XenoSure Biologic Patch produces symptoms identical to symptoms that arise from deficiencies in the natural organ. It is the responsibility of the implanting surgeon to inform the patient of the symptoms that indicate improper functioning of the XenoSure Biologic Patch.

1. Complete heart block and right bundle branch block are known complications reported for procedures involving cardiac repair near the A-V conduction bundles.
2. Glutaraldehyde-treated tissue may be subject to late attack by the immune system with subsequent tissue deterioration. The benefits of use of the XenoSure Biologic Patch must be weighed against the possible risk of late tissue deterioration.
3. Residual glutaraldehyde presents a risk of toxicological effects. Completing the appropriate rinsing procedure as listed within the IFU is necessary to reduce the risk of acute toxicological effects. Review of published literature has not resulted in an established safe limit for glutaraldehyde exposure when implanted within the vasculature. The risks increase when implanting large amounts of glutaraldehyde treated tissue (e.g. Multiple large patches) or within patients with less mass. The benefits of use of the XenoSure Biologic Patch must be weighed against the possible risk of toxicological effects.
4. Animal studies with bovine pericardium have reported calcification and histological signs of deterioration as an adverse reaction. Findings include phagocytosis with accompanying chronic inflammatory infiltrate at the interface between bovine pericardium and surrounding host tissue with focal degradation of implant collagen consistent with host vs. graft reaction.
5. Bovine pericardium used for pericardial closure has been associated with epicardial inflammatory reactions and adhesions of the patch to the heart. Pericardial adhesions may increase the difficulty of repeat sternotomy.

### **How Supplied**

One XenoSure Biologic Patch is provided sterile and non-pyrogenic in a sealed container; DO NOT RESTERILIZE. The patch is stored in a sterile phosphate buffered saline solution containing 0.2% glutaraldehyde. Sterility is assured if the package is unopened and has an undamaged seal. Unused sections should be considered non-sterile and discarded.

### **Directions For Use**

Choose the required XenoSure Biologic Patch model as appropriate for the

type of procedure being performed. The XenoSure Biologic Patch can be cut to a size appropriate for a given repair. XenoSure Biologic Patch is for SINGLE USE ONLY.

### Patch Preparation

Surgical gloves must be thoroughly washed to remove all powder residues before handling the XenoSure Biologic Patch.

Examine the information of the jar label to verify selection of the correct XenoSure Biologic Patch size. Carefully inspect the entire container and tamper-evident seal for damage.

DO NOT USE THE XENOSURE BIOLOGIC PATCH IF THE JAR IS DAMAGED OR IF THE SEAL IS BROKEN. Do not discard the product. Please contact your distributor for further instructions.

### Rinse Procedure

The appropriate rinse procedure, per attached table, must be followed in order to reduce patients exposure to residual glutaraldehyde. Rinse multiple patches separately with new sterile saline.

Remove the tamper-evident outer plastic seal and unscrew the jar cap. The contents of the jar are sterile and must be handled aseptically to prevent contamination. The outside of the jar is not sterile and must not enter the sterile field.

From the jar, remove the XenoSure Biologic Patch by grasping its corners with sterile, atraumatic forceps.

Once removed from the container, submerge the XenoSure Biologic Patch in the sterile saline. Using the same forceps, gently agitate the XenoSure Biologic Patch in the basin. Allow the XenoSure Biologic Patch to remain in the rinse basin until required by the surgeon.

At the surgeon's discretion the rinse solution may contain bacitracin (500 U/mL) or cephalexin (10 mg/mL), as testing has shown that the XenoSure<sup>®</sup> bovine pericardial patch material is not adversely affected by treatment with those antibiotics. The effects of other antibiotics or the long term effects of these antibiotics on the XenoSure<sup>®</sup> bovine pericardial patch material have not been tested. Use antibiotics only as indicated by the antibiotics manufacturer.

Model	Size (cm)	Rinse Procedure
0.6P8	0.6x8	500ml for 2 minutes minimum
0.8P8	0.8x8	
1P6	1x6	
1P10	1x10	
1.5P10	1.5x10	
1P14	1x14	
2P9	2x9	
4P4	4x4	
4P6	4x6	
6P8	6x8	1000ml for 3 minutes minimum
8P14	8x14	
10P16	10x16	

### Alternate Patch Size Rinse Procedure

For any patch size not listed in the table, use the following rinse instructions.

Patch length (cm) x Patch width (cm) = Patch area (cm<sup>2</sup>)

If the patch has an area less than or equal to 37.5 cm<sup>2</sup>, the patch requires a rinse time of 2 minutes in 500ml of saline.

If the patch has an area greater than 37.5 cm<sup>2</sup> and less than or equal to 300cm<sup>2</sup>, the patch requires a rinse time of 3 minutes in 1000ml of saline.

*Note: The patch area is based on one side of the patch. This calculation has been formulated intentionally. Please follow the instructions.*

### Implantation

Cut and/or trim the XenoSure Biologic Patch to the desired shape. Any excess XenoSure Biologic Patch material should be treated as biological waste and discarded according to hospital procedure.

During implantation, irrigate the XenoSure Biologic Patch tissue frequently

with sterile physiologic saline to prevent drying. Visually examine both sides of the XenoSure® Biologic Patch. If one side appears smoother, implant the smoother surface so that it faces the blood flow.

### **Surgical Technique**

It is beyond the scope of this Instructions for Use booklet to instruct the surgeon in specific repair procedures. LeMaitre Vascular, Inc. assumes that any surgeon performing the above operations has received adequate training and is thoroughly familiar with the pertinent scientific literature.

### **Safe Handling and Disposal**

If serious medical incidents should arise during use of this medical device, users should notify both LeMaitre Vascular and the Competent Authority of the country where the user is located.

This product contains no sharps, heavy metals or radioisotopes, and is not infectious or pathogenic. No special requirements for disposal are evident. Please consult local regulations to verify proper disposal.

Dispose storage solution according to local and federal regulations. Solution should not be disposed using septic systems. If there are no disposal restrictions, solution may be diluted and disposed in a sanitary sewer system. For more information see: <https://www.osha.gov/Publications/glutaraldehyde.pdf>

### **Packaging and shipping of explanted XenoSure:**

Return of the shipment to LeMaitre Vascular depends on 3 crucial questions:

1. Is the explant obtained from a patient with a known or presumed pathogenic condition at the time of the explant?
2. Is the explant obtained from a patient that has a known treatment history that involves therapeutic radionuclides within the last 6 months?
3. Has the clinician obtained consent from the patient for the sample to be returned to the manufacturer for research purposes?

In the event that the response to question 1 or 2 is affirmative, LeMaitre Vascular does not provide adequate guidance for shipment. **THESE EXPLANTS SHOULD NOT BE RETURNED TO LEMAITRE VASCULAR UNDER ANY CIRCUMSTANCES.** In these cases, the explant should be disposed according to local regulations.

For explants that do not have pathogenic or radiologic hazards, please use the following:

### **Pre-explantation:**

1. If possible, perform a CT or Ultrasound scan of the device to document patency.
2. LeMaitre Vascular can accept clinical information that is patient-anonymized. LeMaitre Vascular requests information including:
  - a. The original diagnosis which resulted in use of the implant.
  - b. The patient's medical history relevant to the implant, including the hospital or clinic at which the device was implanted.
  - c. The patient's implant experience prior to implant removal.
  - d. The hospital or clinic at which the explantation was done, and date of retrieval.

### **Explantation:**

1. Explanted XenoSure patches should be directly transferred to a sealable container filled with a solution of alkaline buffered 2% glutaraldehyde or 4% formaldehyde prior to shipment.
2. Cleaning of explanted patches should be minimal if necessary. Proteolytic digestion should not be used in any circumstances.
3. XenoSure explants should not be decontaminated under any circumstances. **DO NOT** autoclave the sample or use ethylene oxide gas to decontaminate.

### **Packaging:**

1. Explants should be sealed and packed in a manner that minimizes potential for breakage, contamination of the environment or exposure to those handling such packages during transit. Material that is absorbent and is cushioning should be selected for isolating

the sealable container inside the secondary packaging. Primary and secondary packaging must then be packaged inside an outer package.

2. Explants in sealed primary containers should be labeled with an ISO 7000-0659 Biohazard symbol. The same symbol should be attached to the secondary packaging and to the outer packaging. Outer packaging should also be labelled with Name, Address and Telephone Number of Sender, and the statement, "Upon discovery of damage or leakage, the package should be isolated and sender notified".
3. Packages prepared in the above manner may be shipped to:  
LeMaitre Vascular  
Attn: Complaint Lab  
63 Second Avenue  
Burlington, MA 01803

**Limited Product Warranty; Limitation of Remedies**

LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY, OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US\$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

These limitations do not apply to consumers in Australia or to the extent they are precluded by local law in any other jurisdiction.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.









# XenoSure® Biologic Patch

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