LeMaitre® VASCULAR

XenoSure® *Plus* Biologic Patch

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Instructions for use - English

XenoSure® *Plus* Biologic Patch

(Model Numbers e0.8P8T, e1P6T, e1P14T, e2P9T, e6P8T, e10P16T)
Processed Bovine Pericardial Patch
Instructions for Use - English

STERILE A 

Storage

The XenoSure® *Plus* should be stored above 0°C (32°F). Avoid locations where extreme temperature fluctuations may occur; for example, near steam or hot water pipes, air conditioning ducts, or in direct sunlight. REFRIGERATION IS NOT REQUIRED. FREEZING WILL SERIOUSLY DAMAGE THE XENOSURE PLUS AND RENDER IT UNFIT FOR USE.

Device Description

The XenoSure *Plus* 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 *Plus* is liquid chemical sterilized and packaged in a plastic jar containing sterile glutaraldehyde storage solution. The XenoSure *Plus* is designed to repair the body's natural organs.

The XenoSure *Plus* comes in the following sizes:

Model	Size (cm)
e0.8P8T	0.8x8
e1P6T	1x6
e1P14T	1x14
e2P9T	2x9
e6P8T	6x8
e10P16T	10x16

Indications For Use

The XenoSure *Plus* is intended for use as a surgical patch material for cardiac and vascular reconstruction and repair, soft tissue deficiency repair and reinforcing the suture line during general surgical procedures.

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

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 *Plus* Biologic Patch must exercise utmost care to avoid damage to the XenoSure *Plus* 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 *Plus* 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.
- DO NOT expose the device to temperatures below 0°C (32°F). FREEZING WILL SERIOUSLY DAMAGE THE XENOSURE *PLUS* BIOLOGIC PATCH AND RENDER IT UNFIT FOR USE. DO NOT STORE UNDER REFRIGERATION.
- RINSE the device according to the "RINSE PROCEDURE" section of this booklet before using. The XenoSure *Plus* 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 *Plus* Biologic Patch with traumatic instruments. This may damage the device.
- DO NOT use any XenoSure *Plus* Biologic Patch that has been damaged. Device integrity may be compromised.
- DO NOT attempt to repair the XenoSure *Plus* Biologic Patch. Should damage to the XenoSure *Plus* Biologic Patch occur before implantation, replace the XenoSure *Plus* Biologic Patch.
- DO NOT resterilize. Unused sections should be considered non-sterile and discarded.
- DO NOT expose the XenoSure *Plus* 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 *Plus* is designed to repair the body's natural organs. Improper functioning of an implanted XenoSure *Plus* 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 *Plus*.

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 *Plus* 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 reduces the residual glutaraldehyde on the patch to an acceptable level and therefore significantly reduces 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 *Plus* 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 *Plus* 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 *Plus* model as appropriate for the type of procedure being performed. The XenoSure *Plus* can be cut to a size appropriate for a given repair. XenoSure *Plus* is for SINGLE USE ONLY.

Patch Preparation

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

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

DO NOT USE THE XENOSURE *PLUS* 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 *Plus* by grasping its corners with sterile, atraumatic forceps.

Once removed from the container, submerge the XenoSure *Plus* in the sterile saline. Using the same forceps, gently agitate the XenoSure *Plus* in the basin. Allow the XenoSure *Plus* 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® *Plus* 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® *Plus* bovine pericardial patch material have not been tested. Use antibiotics only as indicated by the antibiotics manufacturer.

Model	Size (cm)	Rinse Procedure
e0.8P8T	0.8x8	500ml for 2 minutes minimum
e1P6T	1x6	
e1P14T	1x14	
e2P9T	2x9	
e6P8T	6x8	1000ml for 3 minutes minimum
e10P16T	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^2)
If the patch has an area less than or equal to 37.5m^2, the patch requires a rinse time of 2 minutes in 500ml of saline.
If the patch has an area greater than 37.5cm^2 and less than or equal to 300cm^2, 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 *Plus* to the desired shape. Any excess XenoSure *Plus* material should be treated as biological waste and discarded according to hospital procedure. During implantation, irrigate the XenoSure *Plus* tissue frequently with sterile physiologic saline to prevent drying. Visually examine both sides of the XenoSure® *Plus* 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.

Clinical Experience
Bovine pericardial patches have been successfully used in intracardiac repair procedures for the past 20 years with excellent clinical results. Published data on such use may be found in medical literature.
At this time, the long term durability of fixed bovine pericardial tissue is unknown. The clinical advantages in using this material along with its known characteristics must be weighed against its current undetermined long term durability.

Limited Product Warranty; Limitation of Remedies
LeMaitre Vascular, Inc. warrants that reasonable care has been used in the manufacture of this device. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERMS INCLUDE 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. LeMaitre Vascular makes no representation regarding the

suitability for any particular treatment in which this device is used, which determination is the sole responsibility of the purchaser. 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.

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.

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

Symbol Legend

		Distributed By:	REF	LOT			STERILE A	Rx only		120 mmHg	STORED IN 0.2% GLUTARALDEHYDE
English	Symbol Legend	Distributed By	Catalog Number	Batch Code	Use-by Date	Date of Manufacture	Sterilized using aseptic techniques.	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician	Wall Thickness	Water permeability	Stored in 0.2% Glutaraldehyde

	0°C/32°F				STERILIZE		Open Here	eifu.LeMaitre.com
English	Lower limit of temperature	Keep away from sunlight	Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised	Do not re-use.	Do Not Resterilize	Non-pyrogenic	Open Here	Consult instructions for use

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R3652-00 Rev. A 11/18