LeMaitre®
VASCULAR

DuraSure™ Biologic Patch

DuraSure™ Biologic Patch
Instructions for use - English

DuraSure™ Biologic Patch

(Model Numbers e1P1IN, e4P4N, e2P9N, e1P3IN, e2P2IN, e6P8N, e3P3IN, e8P14N, e4P5IN, e10P16N)

Processed Bovine Pericardial Patch

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STERILE A ℞ Rx only

Storage

The DuraSure™ 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. FREEZING MAY SERIOUSLY DAMAGE THE DURASURE™ AND RENDER IT UNFIT FOR USE.

Device Description

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

The DuraSure™ comes in the following sizes:

Model	Size (cm)	Size (in)	Model	Size (cm)	Size (in)
e1P1IN	2.5x2.5	1x1	e6P8N	6x8	2.4x3.1
e4P4N	4x4	1.6x1.6	e3P3IN	7.6x7.6	3x3
e2P9N	2x9	0.8x3.5	e8P14N	8x14	3.1x5.5
e1P3IN	2.5x7.6	1x3	e4P5IN	10x13	4x5
e2P2IN	5.1x5.1	2x2	e10P16N	10x16	3.9x6.3

Indications For Use

The DuraSure™ is intended for use as a surgical patch material to close dura mater during neurosurgery.

Contraindications

None Known.

Potential Complications

- Infection
- Surgical site dehiscence
- Calcification
- Fibrosis
- Adhesion
- Cerebrospinal Fluid Leak
- Hydrocephalus
- Hemorrhage
- Patch rupture
- Dilatation
- Neurotoxicological Effects
- 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 DuraSure™ Biologic Patch must exercise utmost care to avoid damage to the DuraSure™ 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 DuraSure™ 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).
- RINSE the device according to the "RINSE PROCEDURE" section of this booklet before using. The DuraSure™ 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 DuraSure™ Biologic Patch with traumatic instruments. This may damage the device.
- DO NOT use any DuraSure™ Biologic Patch that has been damaged. Device integrity may be compromised.
- DO NOT attempt to repair the DuraSure™ Biologic Patch. Should damage to the DuraSure™ Biologic Patch occur before implantation, replace the DuraSure™ Biologic Patch.
- DO NOT resterilize. Unused sections should be considered non-sterile and discarded.
- DO NOT expose the DuraSure™ 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 DuraSure™ is designed to repair the body's natural organs. Improper functioning of an implanted DuraSure™ 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 DuraSure™.

1. Glutaraldehyde-treated tissue may be subject to late attack by the immune system with subsequent tissue deterioration. The benefits of use of the DuraSure™ must be weighed against the possible risk of late tissue deterioration.
2. 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 DuraSure™ Biologic Patch must be weighed against the possible risk of toxicological effects.
3. 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.

How Supplied

One DuraSure™ 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 DuraSure™ model as appropriate for the type of procedure being performed. The DuraSure™ can be cut to a size appropriate for a given repair. DuraSure™ is for SINGLE USE ONLY.

Patch Preparation

Surgical gloves must be thoroughly washed to remove all powder residues before handling the DuraSure™.

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

DO NOT USE THE DURASURE™ 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 DuraSure™ by grasping its corners with sterile, atraumatic forceps.

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

Model	Size (cm)	Size (in)	Rinse Procedure
e1P1IN	2.5x2.5	1x1	500ml for 2 minutes minimum
e4P4N	4x4	1.6x1.6	
e2P9N	2x9	0.8x3.5	
e1P3IN	2.5x7.6	1x3	
e2P2IN	5.1x5.1	2x2	1000ml for 3 minutes minimum
e6P8N	6x8	2.4x3.1	
e3P3IN	7.6x7.6	3x3	
e8P14N	8x14	3.1x5.5	
e4P5IN	10x13	4x5	
e10P16N	10x16	3.9x6.3	

Implantation

Cut and/or trim the DuraSure™ to the desired shape. Any excess DuraSure™ material should be treated as biological waste and discarded according to hospital procedure. During implantation, irrigate the DuraSure™ tissue frequently with sterile physiologic saline to prevent drying. Visually examine both sides of the DuraSure™ Biologic Patch. If one side appears smoother, implant the smoother surface so that it faces the cerebrospinal fluid.

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

At this time, the long term durability of fixed bovine pericardial tissue is unknown. Long term incidence rates of host reactions (calcification, infection, rejection, and adhesion) during use for dural repair have not been investigated. The clinical advantages in using this material along with its known characteristics must be weighed against its current undetermined long term durability.

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 & shipping of explanted DuraSure:

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 DuraSure 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 pledgets should be minimal if necessary. Proteolytic digestion should not be used in any circumstances.
3. DuraSure 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
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. 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. 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.

Symbol Legend

		Distributed By:	REF	LOT
English	Symbol Legend	Distributed By	Catalog Number	Batch Code

Use-by Date	Date of Manufacture	Non-pyrogenic	Do not re-use.

0°C/32°F		STERILE A
Lower limit of temperature	Keep away from sunlight	Sterilized using aseptic techniques.

Rx only	120 mmHg ≤0.1 mL x cm^{-2} x min^{-1}
Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician	Water permeability

	STORED IN 0.2% GLUTARALDEHYDE	MR
Do Not Use if the Product Sterilization Barrier or its Packaging is Compromised	Stored in 0.2% Glutar-aldehyde	MR Safe

		elfu.LeMaitre.com	MD
Do Not Resterilize	Wall Thickness	Consult instructions for use	Medical Device

LeMaitre®
VASCULAR

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