

NEW XenoSure® Biologic Pledgets

The Bovine Pericardial Alternative
to Synthetic Pledgets

- General, Vascular & Cardiac Surgery
- Surgical Pledget Material
- Secure and Support Sutures
- Aid in Suture Buttressing



LeMaitre®
VASCULAR

Your Peripheral Vision™

XenoSure® Biologic Pledgets

THE BOVINE PERICARDIAL ALTERNATIVE TO SYNTHETIC PLEDGETS


The XenoSure® Biologic Pledgets are made from high-quality bovine pericardium and are intended for use as a surgical pledget material to secure and support sutures and to aid in suture buttressing during general, vascular and cardiac surgery.

The XenoSure® Biologic Pledget tissue is treated with a glutaraldehyde process which crosslinks the collagen fibers and minimizes antigenicity. The XenoSure® Biologic Pledgets are liquid chemical sterilized, packaged in a plastic jar and stored in a sterile phosphate buffered saline solution containing 0.2% glutaraldehyde. The bovine pledget material is sourced from the USA or Australia/New Zealand (countries according to OIE-World Organisation for Animal Health classification: "negligible BSE risk").



XenoSure Pledgets Rinse Procedure*

- **2 minutes in 500 ml saline****
1. Fill basin with 500 ml sterile saline
 2. Open the jar and remove the cap. The central post of the floating basket rises slowly after opening the jar (it takes approx. 10-15 sec for the basket to rise completely).
 3. Remove the pledgets with the floating basket from the jar and transfer them into the basin
 4. Gently agitate the pledgets in saline for 2 min.
 5. Leave in saline until required by the surgeon

* please consult Instruction For Use (IFU) of the actual product for further details 

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** sterile physiological saline solution (e.g. 0.9% NaCl)

XENOSURE BIOLOGIC PLEDGETS

Available Sizes

PL0307R



3 mm x 7 mm

PL0506R



5 mm x 6 mm

PL0510R



5 mm x 10 mm

ANTIBIOTICS IN RINSE SOLUTION*

At the surgeon's discretion the rinse solution may contain bacitracin (500 U/mL) or cephalixin (10 mg/mL), as testing has shown that the XenoSure[®] bovine pericardial pledget 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[®] bovine pericardial pledget material have not been tested. Use antibiotics only as indicated by the antibiotics manufacturer.



Open the jar and remove the cap in the non-sterile field (the outside and the cap of the jar are non-sterile).



Wait until the central post of the floating basket rises completely (it takes approx. 10-15 sec for the basket to rise completely).



Present the jar with the lifted floating basket to the sterile operator (content of the jar, basket and pledgets are sterile).



Transfer the pledgets in the basket into a basin with 500 ml sterile physiological saline solution and gently agitate the pledgets for min. 2 minutes.

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TECHNICAL DATA

Material:	Bovine Pericardium
Source:	USA or Australia/New Zealand (lowest BSE risk category "negligible BSE risk")
Nominal Thickness:	0.55 mm +/- 0.20 mm
Suture Retention	630 gr. +/- 165 gr. (mean std. def.)***
Storage Container	Plastic jar (177ml / 6oz) with floating basket (to transfer pledgets into rinse solution)
Storage Solution	Stored in a sterile phosphate buffered saline solution containing 0.2% glutaraldehyde. Rinsing in saline solution prior to use is required.
Storage Conditions:	Store in locations above 0°C (32°F), refrigeration is not required. Avoid locations where extreme temperature fluctuations may occur; for example near steam or hot water pipes, air conditioning ducts or in direct sunlight
Shelf Life:	max. 6 years
<ul style="list-style-type: none"> • Do not expose the XenoSure Biologic Patch to temperatures below 0°C (32°F). Freezing will seriously damage the product. • Packaging includes 1 freeze indicator (< 0°C). 	

Size	Picture 1:1	Shape	Quality	Number of pledgets per jar	Model # [REF]	Rinse procedure*
3 x 7 mm		rectangular	soft	10	PL0307R	Minimum: 500ml/2min.
5 x 6 mm		rectangular	soft	10	PL0506R	
5 x 10 mm		rectangular	soft	10	PL0510R	

All XenoSure Biologic Pledgets have a thickness of 0.55 mm +/- 0.20 mm

* please consult Instruction For Use (IFU) of the actual product for further details

** sterile physiological saline solution (e.g. 0.9% NaCl)

*** data on file



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