Certificate Number US21/819944301
The management system of

LeMaitre Vascular Inc.

63 Second Avenue, Burlington, MA, 01803, United States

Facility identification number : F005365

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP (ISO 13485:2016)

Australia:
Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]
Brazil:
RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009
Canada:
Medical Devices Regulations – Part 1 SOR 98/282
Japan:
MHLW Ministerial Ordinance 169 /Article 4 to Article 68 / PMD Act
United States:
21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2021-03-29 until Expiry Date: 2024-03-28
And remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2024-02-25
Issue 1. Certified since 2021-03-29

Authorised by L Henderson
Business Manager

L. Henderson

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SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Digitally signed by Captari Alexandru
Date: 2021.09.04 13:29:47 EEST
Reason: MoldSign Signature
Location: Moldova

The management system of

LeMaitre Vascular Inc.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design, development, Manufacturing, and distribution of Sterile and nonsterile Angioscopes and Accessories/Adaptors, Embolectomy Catheters, Irrigation Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Patches, Biologic Vascular Grafts, Biologic Patches, Biosynthetic Grafts, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast Injectors, Tape Measuring Rulers, Valvulotomes, Surgical Systems for Peripheral Vein Removal for the areas of Peripheral Vascular Surgery, Cardiac Surgery, Neurosurgery, and General Surgery.

Servicing of Surgical Systems for Peripheral Vein Removal.

Distribution of Biologic patches, Endarterectomy Devices, Embolectomy Catheters, Biologic Vascular Grafts.

Additional facilities

53 Second Avenue, Burlington, MA, 01803, United States

43 Second Avenue, Burlington, MA, 01803, United States

2 Fourth Avenue, Burlington, MA, 01803, United States

32 Third Avenue, Burlington, MA, 01803, United States

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 060725 0020 Rev. 00

Manufacturer:

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington MA 01803
USA

Product Category(ies):

Single Lumen Embolectomy Catheter; Silicone Single Lumen Embolectomy Catheter; Irrigation Occlusion Catheter; Occlusion Catheter; Aortic Occlusion Catheter; Distal Perfusion Catheter; Over the Wire Valvulotome; Valvulotome; Contrast Injector; Endarterectomy Devices; Dissectors; Retrieval Device; Dissection/Transection Device; Disposable Angioscope; Biologic Patches; Synthetic Vascular Grafts.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II.
This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 060725 0020 Rev. 00

Report No.: 72164019-4

Valid from: 2021-05-25
Valid until: 2024-05-26

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7AO 060725 0019 Rev. 00

Manufacturer: **LeMaitre Vascular, Inc.**
63 Second Avenue
Burlington MA 01803
USA

Product: **Patch of Animal Origin**
Cardiovascular Patch

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with the directive 93/42/EEC Annex II (4) and Regulation (EU) 722/2012 on medical devices manufactured utilizing tissues of animal origin. The design of the devices conforms to the requirements of the Directive and the Regulation. If a certificate of the European Directorate for the Quality of Medicines (EDQM) has been issued for the respective material of animal origin, the validity of our certificate is associated with the validity of the EDQM certificate. Any changes of the EDQM certificate need to be reported immediately to TÜV SÜD Product Service GmbH by a change notification. For marketing of these devices an additional Annex II without (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:G7AO 060725 0019 Rev. 00

Report no.: 72161580

Valid from: 2021-05-21
Valid until: 2024-05-26

Date, 2021-05-21

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Medizinprodukten
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ZLG-BS-244.10.08

Product Service

EC Certificate

EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7AO 060725 0019 Rev. 00

Model(s): **XenoSure Biologic Patch**

Description	Model
XenoSure Biologic Patch	1BV6
XenoSure Biologic Patch	0.6BV8
XenoSure Biologic Patch	0.8BV8
XenoSure Biologic Patch	1BV10
XenoSure Biologic Patch	2BV9
XenoSure Biologic Patch	1BV14
XenoSure Biologic Patch	1.5BV10
XenoSure Biologic Patch	4BV4
XenoSure Biologic Patch	4BV6
XenoSure Biologic Patch	6BV8
XenoSure Biologic Patch	8BV14
XenoSure Biologic Patch	10BV16
XenoSure Biologic Patch	2.5BV15
XenoSure Biologic Patch	5BV10
XenoSure Biologic Patch	12BV25
XenoSure Biologic Patch	1P6
XenoSure Biologic Patch	0.6P8
XenoSure Biologic Patch	0.8P8
XenoSure Biologic Patch	1P10
XenoSure Biologic Patch	2P9
XenoSure Biologic Patch	1P14
XenoSure Biologic Patch	1.5P10
XenoSure Biologic Patch	4P4
XenoSure Biologic Patch	4P6
XenoSure Biologic Patch	6P8
XenoSure Biologic Patch	8P14
XenoSure Biologic Patch	10P16

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

XenoSure®
Biologic Patch

EXCEPTIONALLY STRONG, UNIFORM AND EASY TO SUTURE

The XenoSure Biologic Patch is a high-quality bovine pericardium patch used for vascular and cardiovascular repair and reconstructions, suture line reinforcement or soft tissue deficiency repair. Using the same tissue technology developed for heartvalves, the XenoSure patch is exceptionally strong, uniform, easy to handle and suture. The patch material is sourced from the USA or Australia/New Zealand (countries according to OIE-World Organisation for Animal Health classification: "negligible BSE risk").

ORDERING INFORMATION

XenoSure® Biologic Patch (Bovine Pericardium)

Dimension	Model # REF	Rinse Procedure**
6 mm x 80 mm	0.6BV8	500 ml for 2 minutes
8 mm x 80 mm	0.8BV8	
10 mm x 60 mm	1BV6	
10 mm x 100 mm	1BV10	
10 mm x 140 mm	1BV14	
15 mm x 100 mm	1.5BV10	
20 mm x 90 mm	2BV9	
25 mm x 150 mm	2.5BV15	
40 mm x 40 mm	4BV4	
40 mm x 60 mm	4BV6	
50 mm x 100 mm	5BV10	1000 ml for 3 minutes
60 mm x 80 mm	6BV8	
80 mm x 140 mm	8BV14	
100 mm x 160 mm	10BV16	
120 mm x 250 mm	12BV25	

Nominal thickness specification range: 0.6BV8, 0.8BV8, 1BV6, 2BV9 0.45 + 0.15/-0.10 mm, all other larger patches 0.55 ± 0.20 mm

TYPICAL APPLICATIONS:

- Carotid endarterectomy
- Femoral, iliac, renal and tibial patching
- Profundaplasty
- Arteriovenous access revisions
- Suture line reinforcement

- Reconstruction of large vessels
- Pericardial and ASD / VSD closure
- Cardiac repair procedures
- Heart valve reconstructions
- Soft tissue deficiency

- Dura closure during neuro-surgical procedures*

BENEFITS:

- Biocompatible
- Exceptional tensile and suture retention strength***
- Does not require special sutures
- Uniform collagen thickness results in easier suturing

HANDLING:

- Similar to autologous tissue
- Excellent handling characteristics
- Easily trimmed to desired shape or size

* since June 2014 - please consult Instruction For Use (IFU) of the actual product.
** please consult the actual Instruction For Use (IFU) on our website.
*** data on file at LeMaitre Vascular

eifu.LeMaitre.com

These specifications are not intended as a warranty. In the interest of product improvement, these specifications may be changed from time to time without notice. Please consult your sales representative for details.

LeMaitre® VASCULAR
Your Peripheral Vision™

CE 0088

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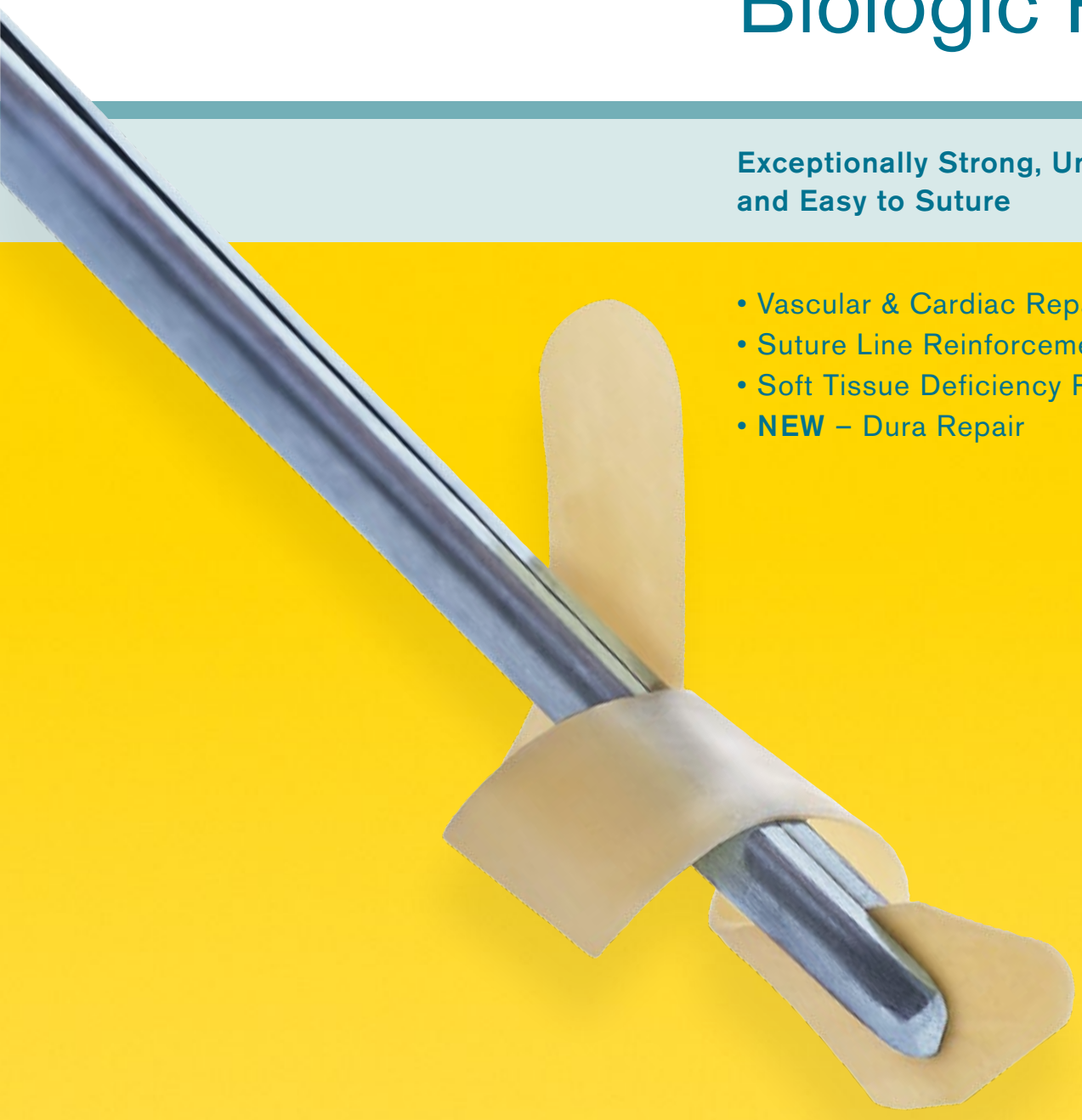
XenoSure®
Biologic Patch

Exceptionally Strong, Uniform and Easy to Suture

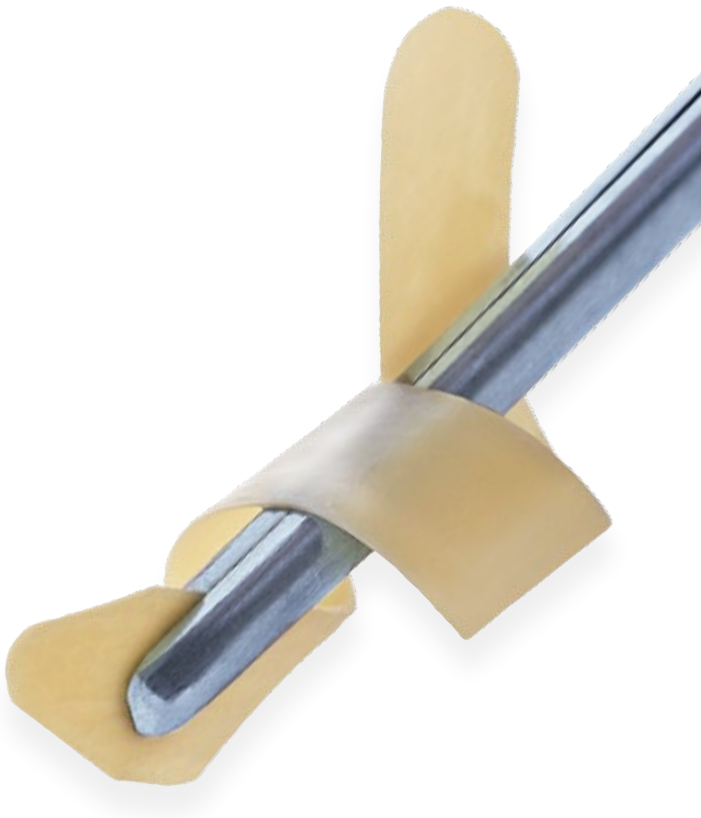


- Vascular & Cardiac Repair
- Suture Line Reinforcement
- Soft Tissue Deficiency Repair
- **NEW** – Dura Repair

LeMaitre® VASCULAR

Your Peripheral Vision™

XenoSure®
Biologic Patch



EXCEPTIONALLY STRONG, UNIFORM AND EASY TO SUTURE

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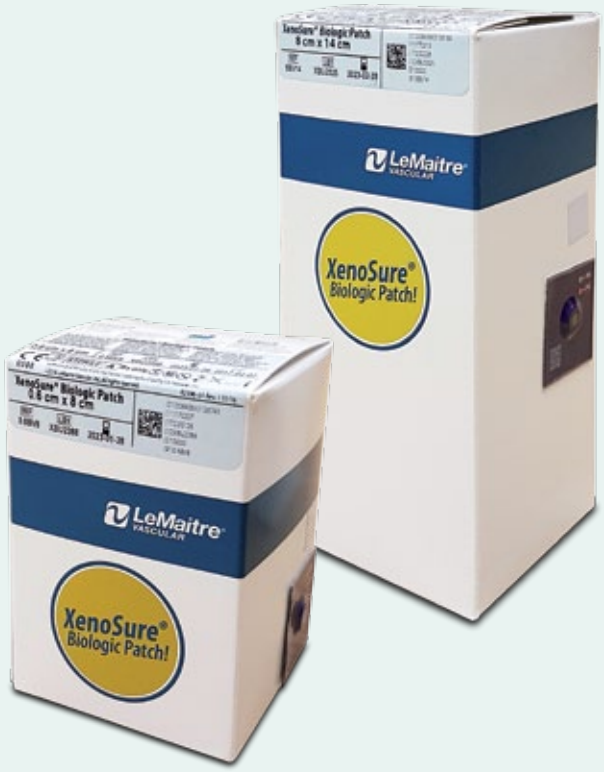

ANTIBIOTICS IN RINSE SOLUTION*

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® 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® bovine pericardial patch material have not been tested. Use antibiotics only as indicated by the antibiotics manufacturer.

XenoSure Rinse Procedure*

0.6BV8, 0.8BV8, 1BV6, 1BV10, 1.5BV10, 2BV9, 1BV14, 2.5BV15, 4BV4, 4BV6 or any custom made size less or equal to 37.5 cm²

- **2 minutes in 500 ml saline****

1. Fill basin with 500 ml sterile saline
2. Remove patch with atraumatic forceps
3. Gently agitate patch in saline for 2 min.
4. Leave in saline until required by surgeon

5BV10, 6BV8, 8BV14, 10BV16, 12BV25 or any custom made size greater than 37.5 cm²

- **3 minute rinses in 1000 ml saline****

1. Fill basin with 1000 ml sterile saline
2. Remove patch with atraumatic forceps
3. Gently agitate patch in saline for 3 min.
4. Leave in saline until required by surgeon

* please consult the actual Instruction For Use (IFU) on our website. eifu.LeMaitre.com

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

LeMaitre® VASCULAR

Your Peripheral Vision™

XENOSURE BIOLOGIC PATCH
Available Sizes