1.0 Device Identification and General Information

i) **Document number/Version:** MS-0089 Rev. C

ii) **Device trade names:** XenoSure® Biologic Patch

iii) **Manufacturer's name and address:**

Legal manufacturer name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue, Burlington, MA. 01803, USA

iv) **SRN:** US-MF-000016778

v) **Basic UDI-DI:** 08406631XenoSureKA

vi) **Device Item Codes, Descriptions, Basic UDI, GMDN Code and MDR Classification:**

Catalog Number	Description	GTIN
0.6BV8M	XenoSure Biologic Patch	00840663111367
0.8BV8M	XenoSure Biologic Patch	00840663111374
1BV6M	XenoSure Biologic Patch	00840663111381
1BV10M	XenoSure Biologic Patch	00840663111398
1.5BV10M	XenoSure Biologic Patch	00840663111404
1BV14M	XenoSure Biologic Patch	00840663111411
2BV9M	XenoSure Biologic Patch	00840663111428
2.5BV15M	XenoSure Biologic Patch	00840663111435
4BV4M	XenoSure Biologic Patch	00840663111442
4BV6M	XenoSure Biologic Patch	00840663111459
5BV10M	XenoSure Biologic Patch	00840663111466
6BV8M	XenoSure Biologic Patch	00840663111473
8BV14M	XenoSure Biologic Patch	00840663111480
10BV16M	XenoSure Biologic Patch	00840663111497

vii) **Medical device nomenclature description:**

a. **EMDN:** P07020101/ VASCULAR PATCHES, PERICARDIUM
b. **UMDN:** 25708/ CARDIOVASCULAR PATCH IMPLANTS
c. **GMDN:** 35273/ CARDIOVASCULAR PATCH, ANIMAL DERIVED

viii) **Class of device:**

Manufacture Name	MDR Classification	Rule
Xenosure Biologic Vascular Prosthesis (all models)	III Implantable	18

ix) Year when the first certificate (CE) was issued covering the device:

Device Name	Date of Initial CE Mark	Date of 510(k)	Date of Approval in Canada	Data of Approval in New Zealand
XenoSure Biologic Patch (previously marketed as Peripatch)	2009 (by previous owner Neovasc Inc.)	15 June 2004 (K040835) 16 September Month 2003 (K031948)	1998 (Device License # 134)	March 2015

x) Authorised representative if applicable; name and the SRN:

EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany
SRN:	DE-AR-000013539

xi) NB's name (the NB that will validate the SSCP) and the NB's singleidentification number:

BSI Group the Netherlands B.V.
Identification Number: 2797
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

2.0 Intended use of the device:

i) Intended purpose: The XenoSure Biologic Patch is intended for use as a surgical patch material for vascular reconstruction or vessel patching during surgical procedures.

ii) Indication(s) and target population(s)

Indication: The XenoSure Biologic Patch is indicated for the following conditions:

- Carotid stenosis such as carotid endarterectomy
- Weakened or damaged femoral arteries

Target Population: Adults of any gender, age or ethnicity who have carotid stenosis, or weakened or damaged femoral arteries.

iii) Contraindications and/or limitations

- Contraindicated in patients with known or suspected hypersensitivity to bovine collagen and bovine pericardium;
- Contraindicated for patients with hypersensitivity to glutaraldehyde

3.0 Device Description:

i) Description of the device

XenoSure Biologic Patch are sterile non-pyrogenic flexible collagen-tissue patches cut from a uniform area of chemically-treated bovine pericardium. XenoSure Biologic Patch is intended for use as a surgical patch material for vascular reconstruction and repair, the subject devices are permanent implants (>30 days) in direct contact with vascular tissue, blood.

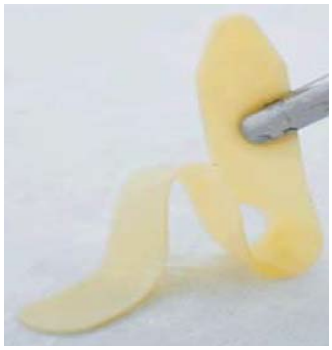
XenoSure Biologic Patch consists of one piece of quadrilateral shaped xenograft patch of bovine pericardial tissue selected for minimal tissue blemishes and even tissue thickness. The bovine pericardial tissue is treated with a glutaraldehyde fixation process which cross- links the collagen fibers and minimizes the antigenicity. Chemicals including EDTA, isopropyl alcohol (IPA), saline, glutaraldehyde, and formaldehyde, are used in the processing of the final product. The glutaraldehyde-fixed tissues are subsequently liquid chemically sterilized and packaged in a plastic jar containing sterile glutaraldehyde storage solution (0.2% glutaraldehyde in phosphate-buffered saline PBS).

The product's biocompatibility allows optimal incorporation with the host tissue, and no special sutures or needles are required to make a secure seal. Cross linked with glutaraldehyde, XenoSure is safe, durable and resistant to tearing.

The design of XenoSure Biologic patch facilitates quick preparation and simple surgical application. The images below show examples of XenoSure Biologic patches with varied design characteristics.

A. XenoSure Model 1x6 cm (rounded edges)

B. XenoSure Model 4x4 cm (square shape)



C. XenoSure Model 0.8x8cm (tapered for easier suturing)

The Xenosure Biological Patch has two sides with different appearance: a fibrinocollagenous or fibrous surface with cilia (small hairs) and a serous side, which has a hairless and glistening surface. The image below illustrates the fibrous and serous sides. Non-clinical acute thrombogenicity tests have demonstrated that the serous side of bovine pericardial tissue is less thrombogenic than the fibrous side and should be placed towards the flow of blood.

Fibrous (top) and serous (bottom) sides of the XenoSure Biologic Patch.[1]

ii) A reference to previous generation(s) or variants if such exist, and a description of the differences:

The product is a mature product currently on the market for a well-established intended use. It has been developed by incremental changes and is based on the Peripatch predecessor device.

There are no novel design features, indications, claims, or target populations for the subject device compared to the predecessor device that impact safety and performance, although minor changes have been made to the device to provide incremental benefits to the user/patients. These include additional source of bovine tissue from within the US and additional patch sizes (i.e., larger size patches).

iii) Description of any accessories which are intended to be used in combination with the device: No accessories are supplied with this device.

iv) Description of any other devices and products which are intended to be used in combination with the device: No other devices or products are intended to be used in combination with this device.

4.0 Risks and Warnings:

i) Residual risks and undesirable effects

- Residual risk evaluation is conducted as part of our FMEAs and risk management procedure. We essentially conclude that the benefits outweigh any residual risks and that the risk has been reduced as far as possible

Potential device related complications:

Adverse Event	Rate	Source from CER
Restenosis	3.5%	Grimsley, 2001
Occlusion	10.5%	Almasi-Sperling, 2020
Dilation	0%	Almasi-Sperling, 2020
Calcification	0.70%	Safety Reporting
Fibrosis	-	Not listed
Bleeding	0%	Sowa, 2021
Patch Rupture	3.5%	Noronen, 2022
Patch delamination	0.0011%	Complaints
Cross-contamination or infection	11.1%	Gowing, 2021
Graft degradation	-	Not listed
Emboli or thrombi in bloodstream	-	Not listed
Sterile barrier compromised	-	Not listed
Transmissible Spongiform Encephalopathies (TSE)	-	Not listed
Allergic reaction	0.17%	Safety reporting
Suture line tearing and bleeding emboli	-	Not listed

Potential procedural and secondary complication:

Adverse Event	Rate	Source from CER
Stroke	0%	Bracale, 2022; Leonore, 2021; Zagzoog, 2022
Myocardial infarction	4-7%	Elsharkawi, 2021
Wound infection	1.8%	Savolainen, 2007
Pneumonia	1.8%	Savolainen, 2007
Amputation	≤7.28%	Karathanos, 2015
Death	≤ 1.1%	Song, 2014

Respiratory failure	0.17%	Safety reporting
Atrial fib	2%	Papakostas
Chylothorax	-	Not listed
Transient delirium	-	Not listed
Visceral ischemia	-	Not listed

ii) **Warnings and precautions**

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.
- DO NOT expose the device to temperatures below 0°C (32°F). FREEZING WILL SERIOUSLY DAMAGETHE XENOSURE 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 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 implant the 12x25cm XenoSure Patch in patients under 25kg (See Adverse Effects).
- 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.

iii) Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

- There were 5 FSCAs / recalls that have been initiated for the subject device from 01 January 2019 – 31 August 2024. The section below provides a summary of each FSCA / recall associated with a CAPA.

FSCA summary

ID	Date	Countries affected	Action Taken	Status (Date Closed)
CAPA2018-045	16 Oct 2018	New Zealand	Advised by AUS/NZ regulatory sponsor – incorrect date of manufacture	12/02/2019
CAPA2019-009	5 Feb 2019	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Israel, Italy, Kosovo, Netherlands, Norway, Romania, Spain, Sweden, Switzerland, UK	Labels for 2 lots were mixed so some customers received products that did not match the label. Recalled lots XBU3375 and XBU3188	03/11/2022
CAPA2020-005	9 Jun 2020	Canada	Recall – product shipped without temperature sensor	08/17/2021
MHRA # 2021/008/009/601/501	23 July 2021	UK	Advisory notice to UK customers, at the request of MHRA, to explain the changes in the IFU (indications for use) and shortened shelf life.	11/12/2021
CAPA 2022-001-ES & CAPA 2022-001-GB	2 March 2022	Spain, UK	Withdraw and exchange XenoSure devices without a CE mark due to a change in regulatory status.	04/28/2022

During the reporting period of 01 January 2019 – 31 August 2024, 8 CAPAs related to safety and performance were opened. Six of the CAPAs were successfully closed and two opened in 2024 remain in process. A summary of CAPAs opened during the reporting period is in the table below.

CAPA #	Problem	Summary of Action Taken	Date closed
2019-009	Packaging issue (mixed inventory)	Have clearly marked storage locations between tables.	03/11/2020
2019-019	Packaging issue (damaged/ leaking)	Provide (and provide a storage place for) table dividers for the times when the table does need to be used for more than one lot.	08/17/2021
2020-005	Packaging issue (temperature indicator is missing)	Have a designated person who prints all of the labels. This person does not label the product but can check line clearance, etc.	018/17/2021
2021-021	Labeling issue	Recalled lots XBU3375 (1BV10) and XBU3188 (1BV6).	11/12/2021
2022-001	Labeling issue	Unrelease lots XBU4976 and XBU4978. Quarantine any devices from these lots and lot XBU4993, which has not been released yet.	04/28/2022
2023-010	Packaging issue (temperature indicator is missing)	Initiate a recall of the 5 devices that were shipped to Canadian customers.	08/25/2023
2024-010	EU distribution center continually receive shipments containing errors	CAPA in process	Open
2024-011	There is a trend of increasing customer complaints for XenoSure Leaking Jars and XenoSure Seal Dislodged with 26 total in 2022, 12 total in 2023, and 19 complaints as of September 2024.	The most likely root cause is the seal is not correctly positioned before the lid is applied to the jar (1). The secondary contributor is the shipping configuration. The plan is to: 1. Create and implement a new fixture to assist with manual assembly or re-seating of the seal during aseptic processing. 2. Update SOP15-004 to clarify proper packaging including adding dunnage to partially filled boxes. If there is a partial box add enough dunnage/paper to prevent movement and completely fill the void. 3. Notify LeMaitre subsidiaries that insufficient dunnage during shipment may impact jar integrity and cause leaking jars and recommend them to update their procedures to require partials with packaging voids to be filled to limit movement of jars and protect product from damage.	Open

A total of 850 complaints were received for XenoSure during the reporting period. The overall complaint rate for the product family is 0.127% for the reporting period. The table and graph below display the complaint rate trends for the subject devices.

Complaints by region/year

Complaints by Region / Year	2019	2020	2021	2022	2023	2024*	Total
Total Complaints	125	99	175	111	146	194	850
Total Sales	119,895	107,430	103,671	118,477	129,340	93,033	671,272
Total Complaint Rate	0.105%	0.092%	0.169%	0.094%	0.113%	0.209%	0.127%
EU	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	58	41	23	28	37	162	349
Sales	51,376	45,883	37,701	50,417	55,847	41,072	282,296
Rate (complaints/sales)	0.113%	0.089%	0.061%	0.056%	0.066%	0.394%	0.124%
ROW	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	67	58	152	83	109	32	501
Sales	67,945	61,547	65,970	68,060	73,493	51,961	388,976
Rate (complaints/sales)	0.099%	0.094%	0.230%	0.122%	0.148%	0.062%	0.129%

**Through August*

5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

i) **Summary of clinical data related to equivalent device, if applicable:** NA

ii) **Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable:** NA

iii) **Summary of clinical data from other sources, if applicable:**

Studies included in the literature evaluation by device and indication

Device	Indication from IFU	Indication from article	Variant	Total Studies	Total Subjects	References
XenoSure Biologic patch	Carotid stenosis such as carotid endarterectomy	Any condition requiring CEA	Not defined; 1.5BV10	3	786 patients	Leonore, 2021 Liesker, 2022 Zagzoog, 2022
	Weakened or damaged femoral arteries	Femoral artery disease (occlusion, venous obstruction, atherosclerotic lesion, or critical limb threatening ischemia)	Not defined	4	84 patients	Garcia-Dominguez, 2021 Karathanos, 2015 Piao, 2021 Vakhitov, 2021
		TOTAL	**Not defined; 1.5BV10; 10BV16; 2.5BV15; 2BV9**	**7**	**870 patients**	

iv) **An overall summary of the clinical performance and safety:**

Performance and Clinical Benefit

Carotid Stenosis:
Use of the XenoSure Biologic Patch was associated with freedom from stroke pooled rate (98.14%) similar to rates observed for synthetic patches and alternative treatments determined by intra-study comparisons as well as meeting the pooled rate acceptance criteria established by the state of the art (97.90%). Freedom from mortality had a pooled rate (99.46%) similar to rates observed for similar devices determined by intra-study comparisons as well as meeting the pooled rate acceptance criteria established by the state of the art (98.85%). The pooled rate of restenosis was lower following use of Xenosure compared to the pooled rate from bovine pericardium state of the art studies and determined by no significant differences in intra-study comparisons compared to alternative patch materials and alternative treatments (See section 5.1.1 of the CER).

Weakened or damaged femoral arteries: Three studies reported postoperative primary patency rates that were consistent with the state of the art literature on similar devices. In addition, XenoSure and eversion techniques following endarterectomy can result in 100% primary patency. Two studies reported restenosis rate as 36.3% and 50%, not meeting the benchmark established for state of the art. Piao et al. reported the lowest primary patency rate (36.3%) following endarterectomy to treat chronic venous obstruction with post-thrombotic trabeculation involving the common femoral vein. This condition may be particularly difficult to treat with lower than usual expectations for primary patency. Consistent with this possibility, intra-study comparisons demonstrated that endovascular treatment alone without endophlebectomy and patch closure was associated with similar primary patency as the combined treatment (p=0.84). The remaining study that reported low rates of primary patency had a small sample size (n=12).

Freedom from mortality had a pooled rate (94.9%) similar to rates observed for similar devices determined by intra-study comparisons as well as meeting the pooled rate acceptance criteria established by the state of the art (78.76%). Xenosure also resulted in clinical improvement of 97.5% compared to a single study in the state of the art literature with a clinical improvement of 80%. Freedom from amputation was higher following use of Xenosure (95.27%) compared to following use of similar devices (92.27%). (See section 5.2 of the CER).

Summary of undesirable side-effects

The device-related safety outcomes or outcomes associated with clinical benefit measures reported in the literature included mortality, amputation, infection, bleeding, complications requiring reoperation, new ischemic lesion and thrombosis. The benchmarks were met for mortality, amputation, complications requiring reoperation and new ischemic lesion. Bleeding was not presented in the state of the art literature and therefore comparison was not possible. While the benchmarks were not met for all outcomes (i.e., infection), there was in general greater heterogeneity in the pathology of patients being treated for weakened or damaged femoral arteries than was observed in the state of the art literature. (See Table 5-6 in the CER for justification). Some studies reported rates of complications requiring reoperation that exceeded the benchmarks for state of the art. It was noted that the underlying disease pathology for subjects treated for peripheral indications with XenoSure was heterogenous, with some patients experiencing more severe symptoms (tissue loss, rest

pain). Therefore, the need for reintervention may not have been the result of the subject device, but instead due to underlying morbidity.

Outcome Measures

The outcome parameters associated with device performance and clinical benefits for the subject device have been compared to the results for the control in the PMCF study and similar devices reported in the literature studies. Similar devices have been used as benchmarks since the generic device group has been on the market for over 10 years and these devices are an established treatment for occlusive and aneurysmal vascular disorders. The frequency of residual risks and side-effects associated with the device safety have been quantified based on the rates of device related adverse events reported in the clinical investigations, literature studies, and PMS data and compared to the rates for similar devices in the state of the art. The outcomes for benefits and performance have been considered against the safety outcomes, considering the state of the art, to confirm the acceptability of the benefit-risk ratio for treatment of patients with carotid stenosis, or weakened or damaged femoral arteries.

Based on this clinical evaluation, which includes both non-clinical and clinical data, there is sufficient data to demonstrate conformity to the applicable requirements and confirm that the subject device is safe and performs as intended and claimed by LeMaitre Vascular, Inc. and is state of the art device for use as a surgical patch material for vascular reconstruction or vessel patching during surgical procedures such as carotid endarterectomy. Review of the post-market data, information materials provided by LeMaitre Vascular, Inc., and the risk management documentation confirms that the risks are appropriately identified and consistent with the state of the art, and that the risks associated with the use of the device are acceptable when weighed against the benefits.

v) **Ongoing or planned post-market clinical follow-up:**

The manufacturer conducts ongoing post-market surveillance (PMS) of the subject device according to the following procedure, SOP-28-001. Post-Market Clinical Follow-up (PMCF) activities are planned for the subject device. A multi-stepped approach will be used to substantiate the performance claims of the device and ensure that the risk/benefit remains positive. First, a thorough literature review will be conducted to capture all relevant and up to date published information regarding the XenoSure device. The second step will involve completion of 2 on-going clinical studies (ClinicalTrials.gov identifier NCT03176225 and NCT03173703). NCT03173703 is focused on cardiac repair. The purpose of these clinical trials is to collect safety and effectiveness data to support either cardiac repair indication or femoral vascular indication of XenoSure biologic patch. These trials are performed to meet the China FDA regulations for this kind of device. The clinical trials will be performed solely inside China under GCP regulation and all applicable China regulations on medical device clinical trial. Once the current studies are complete, LeMaitre Vascular, Inc. will review all data available for the XenoSure Patch to ensure continued positive benefit/risk ratio. The updated information will be used to design further on-going registry studies to begin collecting prospective registry data going forward. These studies will be designed to identify possible systematic misuse or off-label

use of the device, with a view to verifying that the intended purpose is correct. This will be completed through the safety assessment and the clinician survey. Finally, this study will be used to confirm the safety and performance throughout the expected lifetime of the device through the proactive and continuous collection of data.

6.0 Possible diagnostic or therapeutic alternatives:

For carotid stenosis indication conclusions were prepared based on the clinical practice guidelines set forth by the Society for Vascular Surgery Clinical Practice Guidelines for Management of Extracranial Cerebrovascular Disease (2021); A comparison of the Society for Vascular Surgery and the European Society for Vascular Surgery guidelines to identify which asymptomatic carotid patients should be offered a CEA; Management of Atherosclerotic Carotid and Vertebral Artery Disease: 2017 Clinical Practice Guidelines of the European Society for Vascular Surgery (ESVS).

For weakened or damaged femoral arteries indication conclusions were prepared based on the clinical guidelines set forth by the 2017 European Society of Cardiology (ESC) Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS); Society for Vascular Surgery Practice Guidelines for Atherosclerotic Occlusive Disease of the Lower Extremities: Management of Asymptomatic Disease and Claudication (2015); European Society for Vascular Surgery (ESVS) 2020 clinical practice guidelines on the management of vascular graft and endograft infections.

Further details can be found in the CER section 3.

There are a number of treatment alternatives for the clinical applications for which bovine pericardial patches like XenoSure are indicated. For vascular indications, primary suturing or alternative patch materials (e.g. polyester or PTFE) are possible treatment options. A meta-analysis demonstrated that patch closure (type not specified) of the carotid arteriotomy was associated with a statistically significant lower risk of restenosis6. Overall, the data with regards to restenosis support comparable performance for bovine pericardial patches (range 2%[2] - 12%[9]) as those composed of alternative materials (range 0% - 3.8%) [2, 3]. However, restenosis rates may be improved with alternative biologic grafts, like autoarterial remodeling (12% vs 4%) [10]. There is also evidence that bleeding, measured as hemostasis time or suture line bleeding, is significantly reduced with use of bovine pericardial patches[3, 10].

Complications associated with use of bovine pericardial patches also vary by the surgical procedures employed. After CEA, the following, predominately procedural, complications were reported: stroke, bleeding, restenosis, transient ischemic attack, myocardial infarction, neck hematoma. Use of a patch closure method instead of suturing after CEA was associated with reduced risk of stroke. There are low rates of other complications like bleeding, myocardial infarction, and bleeding associated with biologic patches.

In conclusion, bovine pericardial patches are a well-established device for use in multiple indications with a low risk of postoperative complications, and their use results in comparable outcomes when compared with other devices or alternative treatments assessed under the state-of-the-art.

7.0 Suggested profile and training for users:

The XenoSure biologic patch is a surgical tool intended for use by experienced vascular surgeons trained in the procedures for which they are intended.

8.0 Reference to any harmonized standards and CS applied:

Standard Title	Standard Reference: Revision Year
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 2: Requirements for aseptically processed medical devices	EN 556-2:2015
Information supplied by the manufacturer of medical devices	EN 1041:2008
Cardiovascular implants and extracorporeal systems – Vascular prostheses -- Tubular vascular grafts and vascular patches	ISO 7198:2016
Biological evaluation of medical devices – Part 1: Evaluation and testing	ISO 10993-1:2009
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3:2009
Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2006
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	EN ISO 10993-6:2007
Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	ISO 10993-10:2010
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	ISO 10993-11:2018
Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2008
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2006
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2006
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2006
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2009
Aseptic processing of health care products – Part 1: General requirements	ISO 13408-1:2008
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO 14160:2011
Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	ISO 14644-1:2015
Medical devices – Application of risk management to medical devices	EN ISO 14971:2012
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements	EN ISO 15223-1:2016
Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	ISO 22442-1:2015

Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling	ISO 22442-2:2015
Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and TSE agents	ISO 22442-3:2007

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9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the Notified Body
A	04/03/2022	Initial release	☐ Yes Validation language: English (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB) ☒ No, pending initial review
B	25/07/ 2023	Updated the indications and patient population, removal of aneurysm	☒ Yes Validation language:English (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

		and peripheral references from patient section, Other minor updates throughout	☐ No
C	15/11/2024	Periodic update	☐ Yes; Validation language: English (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB) ☒ **No; NB approval not needed. The safety and performance of the device has not changed since the last NB approval.**

10.0 Patient Information

A summary of the safety and clinical performance of the device, intended for patients, is given below.

Summary of safety and clinical performance
Document revision: B
Date issued: 7/25/2023

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document. The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

1. **Device identification and general information**
    a. Device trade name: XenoSure Biologic Patch
    b. Manufacturer; name and address 32 Third Ave.
    c. Basic UDI-DI: 08406631XenoSureKA
    d. Year when the device was first CE-marked: 2009
2. **Intended use of the device**
    a. Used for: The patch is intended to be used as a surgical patch material during vascular repair or vessel patching during surgical procedures.
    b. Indications and intended patient groups:
        i. The Patch are used for the treatment of narrowing arteries, or weakened or damaged femoral arteries
        ii. Patients of any gender, age or ethnicity who have narrowing arteries, weakened or damaged femoral arteries.
    c. Do not use for: not for use in patients with allergies to proteins derived from cows.
3. **Device description**
    a. Device description and material/substances in contact with patient tissues
        i. The patches are sterile not sensitive to heat, flexible collagen-tissue patches cut from a uniform area of chemically-treated proteins derived from cows. The patches are permanent implants in direct contact with vascular tissue and blood.
    b. Information about medicinal substances in the device, if any
        i. NA
    c. Description of how the device is achieving its intended mode of action
        i. Per regulations, the Graft achieves its affect through non-medicinal means. It achieves this goal as a physical barrier device as its mode of action.
    d. Description of accessories, if any
4. **Risks and warnings**

Contact your healthcare professional if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

Device related problems	Severity	Occurrence	RPN
Buildup of excess calcium (Restenosis)	8	2	16
Complete or partial blockage of a blood vessel (Vessel Occlusion)	8	2	16
the action of dilating a vessel or opening (Dilatation)	8	3	24
Buildup of excess calcium	8	2	16
thickening or scarring of the tissue (Fibrosis)	7	2	14
Bleeding	8	2	16
Patch Rupture	8	3	24
Patch separation along a plane parallel to a surface (Patch delamination)	8	2	16
Cross-contamination or Infection	8	3	24
A thrombus is a blood clot that forms in a vein. An embolus is anything that moves through the blood vessels until it reaches a vessel that is too small to let it pass (Emboli or thrombi in bloodstream)	7	2	14
Sterile barrier compromised	8	1	8

Potential procedural and secondary complications	Severity	Occurrence	RPN
Stroke	10	1	10
Heart attack (Myocardial Infarction)	10	1	10
Wound infection	8	1	8
an infection that inflames the air sacs in one or both lungs (Pneumonia)	10	1	10
Amputation	10	1	10
Death	10	1	10
a serious condition that makes it difficult to breathe on your own (Respiratory failure)	10	1	10
an irregular and often very rapid heart rhythm (arrhythmia) that can lead to blood clots in the heart (Atrial fib)	8	1	8
a rare but serious condition in which lymph formed in the digestive system (chyle) accumulates in your chest cavity (Chylothorax)	8	1	8
usually reversible, cause of mental dysfunction (Transient delirium)	8	1	8
occurs when narrowed or blocked arteries restrict blood flow to your small intestine. (Visceral ischemia)	8	1	8
a family of rare progressive neurodegenerative brain disorders that	10	1	10

affect both humans and animals (Transmissible Spongiform Encephalopathies (TSE))			
Allergic reaction	7	1	7
Suture line tearing and bleeding	8	1	8
a blood clot, air bubble, piece of fatty deposit, or other object which has been carried in the bloodstream to lodge in a vessel and cause an embolism (Emboli)	10	1	10

How potential risks have been controlled or managed

- Risk analysis have concluded that the benefits outweigh the risks. That the risks identified have been reduced as far as possible.

Remaining risks and undesirable effects

- The data in this clinical report is adequate to determine if unwanted side effects exist for the subject device. It concludes that the device conforms to the requirement on how acceptable the side effects are. No gaps were identified in the clinical data. However, there was a limited operative performance data for the subject device. A future study will be completed to continue collecting safety and performance data on the device.

Warnings and precautions:

Warnings:

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

Precautions:

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

- FOR SINGLE USE ONLY. Do not reuse, reprocess, or re-sterilize. Reuse, reprocessing, and/or re-sterilization 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.
- DO NOT expose the device to temperatures below 0°C (32°F). FREEZING WILL SERIOUSLY DAMAGETHE XENOSURE 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 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 implant the 12x25cm XenoSure Patch in patients under 25kg (See Adverse Effects).
- 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 re-sterilize. 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.

5. Summary of clinical evaluation and post-market clinical follow-up

a. Clinical background of the device

There are several synthetic and biologic patches, composed of various materials, available for use in vascular repair procedures. Synthetic patches are often multi-layered, and may be impregnated with collagen to reduce bleeding risk or eliminate the need for pre-clotting. Biologic patches are most similar, and synthetic patches are considered in this assessment as patch alternatives.

The safety of the subject device is checked through the risk management files. The risks related to shunting were described above. No adverse event was directly related to the subject device in the clinical data.

b. The clinical evidence for the CE-marking

The device was first approved for CE mark under LeMaitre Vascular Inc. in 2009. Studies were conducted to ensure the grafts were safe and effective. See the IFU for further details. There were no safety-related outcomes reported by the physicians.

c. Safety

A post market study to assess the performance and safety profile of the Shunt. The study includes a literature review, a post market study, and an end-user survey. The planned study aims to 1) confirm the safety of the medical device, 2) identify previously unknown side effects 3) monitor side effects 4) identify and analyze emergent risks, 5) ensure the continued approval of the benefit-risk ratio, and 6) identify possible misuse or off-label use of the device. Study sample size, timing, and endpoints will be determined as part of the clinical research plan.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, please contact your healthcare professional.

7. Suggested training for users

This device is intended to be used by surgeons. Considering how complex this surgery is, it is left to the surgeon to decide proper surgery and graft type as well as the therapy to adopt before, during, and after the operation.