1.0 Device Identification and General Information

i) Device trade names: XenoSure® Biologic Patch

ii) Manufacturer's name and address:

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

iii) SRN: US-MF-000016778

iv) Basic UDI-DI: 08406631XenoSureKA

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

Manufacture Item Code	Description	GTIN-14 (UDI)
0.6BV8	Xenosure Biologic Vascular Prosthesis Shaped MM 6X80	840663106745
0.8BV8	Xenosure Biologic Vascular Prosthesis Shaped MM 8X80	840663106127
1.5BV10	Xenosure Biologic Vascular Prosthesis Shaped MM 15X100	840663106103
10BV16	Xenosure Biologic Vascular Prosthesis Rectangular MM 100X160	840663106172
12BV25	Xenosure Biologic Vascular Prosthesis Rectangular MM 120X250	840663106776
1BV10	Xenosure Biologic Vascular Prosthesis Shaped MM 10X100	840663106097
1BV14	Xenosure Biologic Vascular Prosthesis Shaped MM 10X140	840663106189
1BV6	Xenosure Biologic Vascular Prosthesis Rectangular MM 10X60	840663106110
2.5BV15	Xenosure Biologic Vascular Prosthesis Rectangular MM 25X150	840663108787
2BV9	Xenosure Biologic Vascular Prosthesis Rectangular MM 20X90	840663106134
4BV4	Xenosure Biologic Vascular Prosthesis Square MM 40X40	840663106141
4BV6	Xenosure Biologic Vascular Prosthesis Rectangular MM 40X60	840663106158
5BV10	Xenosure Biologic Vascular Prosthesis Rectangular MM 50X100	840663108794
6BV8	Xenosure Biologic Vascular Prosthesis Rectangular MM 60X80	840663106707
8BV14	Xenosure Biologic Vascular Prosthesis Rectangular MM 80X140	840663106165

vi) Medical device nomenclature description:

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

vii) Class of device:

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

viii) 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

ix) 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

x) 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 during vascular reconstruction or vessel patching during surgical procedures as a surgical patch material during carotid endarterectomy, mycotic aneurysmal repair

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 peripheral arteries such as femoral, iliac, renal & tibial patching, profundaplasty
- Aneurysm such as mycotic aneurysmal repair

- Target Population: Adults of any gender, age or ethnicity who have carotid stenosis, aneurysm, weakened or damaged peripheral 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 Complications:

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:

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) **Adverse effects**

Improper functioning of an implanted XenoSure Biologic Patch 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 Biologic Patch.

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 Biologic Patch 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 is necessary to reduce 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. It is

recommended that no more than 30 grams of XenoSure Biological Patch Material which is equivalent to two 12x25 XenoSure patches be implanted into one patient. The benefits of use of the XenoSure 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.

iv) 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 2017 through 30 September 2022. The section below provides a summary of each FSCA / recall associated with a CAPA.

CAPA #	Date Initiated	Reason why CAPA was initiated	Products Affected
2018-045	10/16/2018	The device had the wrong date of manufacture. Two pieces of one lot were distributed to one customer in New Zealand.	LOT XBU3781 (REF 0.8P8)
2019-009	2/5/2019	XenoSure lots have wrong labels on them	Lots XBU3188 and XBU3375
2020-005	6/9/2020	Deviation indicated that these devices did not have temperature sensors on them.	Lot XBU4976, 5 pcs sent to Canada
2021-021	8/9/2021	No product recalled. Advisory notice sent to ensure that users are aware of the indications changes.	XenoSure BV
CAPA 2022-001-ES & CAPA 2022-001-GB	3/2/2022	Withdraw and exchange Xenosure devices without a CE mark due to a change in regulatory status.	REF 0.6BV8, 0.8BV8, 1.5BV10, 10BV16, 1BV10, 1BV14, 1BV6, 2BV9, 4BV4, 4BV6, 5BV10, 6BV8, 8BV14

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[45] Liesker, 2022 [35] Zagzoog, 2022 [36]
	Aneurysm such as mycotic aneurysmal repair	Abdominal aortic aneurysm	Not defined; 10BV16	2	7 patients	Anibueze, 2017[52] Holowachuk, 2020[44]
	Weakened or damaged peripheral arteries such as femoral, iliac, renal & tibial patching, profundaplasty,	Femoral artery disease (occlusion, venous obstruction, atherosclerotic lesion, or critical limb threatening ischemia)	Not defined	4	84 patients	Garcia-Dominguez, 2021[43] Karathanos, 2015[54] Piao, 2021[47] Vakhitov, 2021[48]
		Arteriovenous fistula (non-maturation, infection, or stenosis)	Not defined; 2.5BV15; 2BV9	2	177 patients	Fisher, 2018[53] Parker, 2021[46]
		Infected fields (native vessel, prosthetic graft, or hemodialysis graft)	10BV16	2	33 patients	Alonso, 2021[41] Belkorissat, 2020[42]
		TOTAL	**Not defined; 1.5BV10; 10BV16; 2.5BV15; 2BV9**	**13**	**1,087 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%).
(See section 5.1.1 of the CER)

Weakened or damaged peripheral arteries: Use of the XenoSure Biologic Patch was associated with freedom from mortality had a pooled rate (93.36%) 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 95.4% 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 5.2.1 of the CER).

Aneurysm: There were no adverse events reported in the case series pertaining to aneurysmal disease or infected fields. (See section 5.3.2 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, infection, 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., amputation, thrombosis, and complications requiring reoperation), there was in general greater heterogeneity in the pathology of patients being treated for weakened or damaged peripheral arteries than was observed in the state of the art literature. (See Table 5-7 in the CER for justification). The amputation rate was also assessed using a Kaplan-Meier estimate and notably, both the primary and secondary patency rates from this article were also below benchmark acceptance criteria indicating that the patient population may be more at risk in this study than that in the state of the art literature. 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. In addition, a high rate of reoperation was observed in the study for which XenoSure was being used to accelerate arteriovenous fistula maturation, as opposed to correcting stenosis of an existing arteriovenous fistula. The benchmarks for complications requiring reoperation were established solely on patients undergoing endarterectomy for femoral artery disease. Therefore, the rate of this safety outcome may vary dependent upon patient population. There was 1 patient included in a retrospective study on the treatment of infected fields that experienced a pseudoaneurysm. This safety outcome will be reviewed via LeMaitre's risk management process.

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, weakened or damaged peripheral arteries, or aneurysm.

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). The purpose of these clinical trials is to collect safety and effectiveness data to support either cardiac repair indication or peripheral 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 peripheral 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.

For aneurysm indication conclusions were prepared based on the clinical practice guidelines set forth by the European Society for Vascular Surgery (ESVS) 2019 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms.

Further details can be found in the CER sections 3.2.2.1, 3.3.2.1, 3.4.2.1, respectively.

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:

Intended users include vascular surgeons, LeMaitre Vascular, Inc. assumes that any surgeon performing the above operations has received adequate training and is thoroughly familiar with the pertinent scientific literature.

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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and Carotid Endarterectomy with Patch Closure: Comparison of Methods. *Journal of stroke and cerebrovascular diseases : the official journal of National Stroke Association.* 2019;28(3):741-750.

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9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
A	04March2022	Initial release	☒ Yes Validation language: English ☐ No (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)
B	17 March 2023	Made updates to the indications and patient population. Other housekeeping updates throughout	☒ Yes ☐ Validation language:English No

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: 12/1/2022

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. Intended purpose: 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 indicated for the treatment of narrowing arteries, bulging arteries, weakened or damaged peripheral arteries
        ii. Patients of any gender, age or ethnicity who have narrowing arteries, bulging arteries, weakened or damaged peripheral 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 non-pyrogenic 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 complications	Severity	Occurrence	RPN
Calcification (Restenosis)	8	2	16
Complete or partal blockage of a blood vessel (Vessel Occlusion)	8	2	16
the action of dilating a vessel or opening (Dilatation)	8	3	24
Calcification	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 affect both humans and animals (Transmissible Spongiform Encephalopathies (TSE))	10	1	10
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 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.

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.