Digitally signed by Captari Alexandru
Date: 2023.09.22 12:36:15 EEST
Reason: MoldSign Signature
Location: Moldova

Certificate US21/819944236

The management system of

LeMaitre Vascular Inc.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Design, development, Manufacture, 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.

This certificate is valid from 14 February 2022 until 11 February 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date.
Issue 3. Certified since 11 February 2021

This is a multi-site certification.
Additional site details are listed on subsequent pages.

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

21HC 13485 MS 0721

LeMaitre Vascular Inc.

ISO 13485:2016
EN ISO 13485:2016

Issue 3

Certified activities are performed by the sites on the list.

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

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

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

43 second avenue, Burlington, MA 01803, United States

UKAS MANAGEMENT SYSTEMS
0005

DECLARATION OF CONFORMITY

Application of Council Directive(s):	93/42/EEC, as amended by 2007/47/EC
Standard(s) to which conformity is declared:	ISO 13485: 2016 93/42/EEC Annex II Other applicable Standards in ERC D1719
Notified Body:	SGS Belgium NV (1639) Noorderlaan 87, BE-2030 Antwerpen Belgium
Manufacturer:	**LeMaitre Vascular, Inc.**
Manufacturer Address:	63 Second Avenue Burlington, MA 01803 USA.
Name of Device:	**LifeSpan ePTFE Vascular Grafts**
Intended Use:	The LifeSpan Vascular Grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access.
Device Classification:	IIb, Rule 8
Type No. / Model No. / Ref. No.:	See attached pages
EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform with the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 U.S.A.

Xiang Zhang
VP, Regulatory Affairs

Validity Period: February 19, 2021 to May 24, 2024

List of Applicable LifeSpan Vascular Graft
Product Model Code

GR74070	T05020	R06050	T07080C80
GT74070	T05050	R06050C50	T08010
GT74080C70	T05080	R06050CS	T08020
QT46040	T06010	R06050CS5	T08050
QT47030	T06020	R06080	T08050C30
QT47040	T06050	R06080C80	R07080C80
QT47045CS	T06050C30	R07010	R08010
QT47050	T06050C50	R07020	R08020
QT4745CS5	T06050CS	R07050	R08050
QT47050CS	T06080	R07050C50	R08050C50
R05010	T06080C50	R07050CS	R08050CS
R05020	T06080C80	R07080	R08050CS30
R05050	T06080CS60	R08080C80	R08080
R05050CS5	T07010	R10080	T08050C50
R05080	T07020	R10080C80	T08080
R06010	T07050	RS47050	T08080C50
R06015CS	T07050C30	RS47050CS	T08080C80
R06020	T07050C50	RS47050CS5	T10080
R06030	T07080	T05010	T10080C80
R06040CS	T07080C50		

DECLARATION OF CONFORMITY

Application of Council Directive(s):	93/42/EEC, as amended by 2007/47/EC
Standard(s) to which conformity is declared:	ISO 13485: 2016 93/42/EEC Annex II Other applicable Standards in ERC D1321-00
Notified Body:	SGS Belgium NV (1639) Noorderlaan 87 BE-2030 Antwerpen Belgium
Manufacturer: Manufacturer Address:	**LeMaitre Vascular, Inc.** 63 Second Avenue Burlington, Massachusetts 01803 U.S.A.
Name of Device:	**Pruitt® F3 and F3-S Carotid Shunts**
Intended Use:	The Pruitt F3 and F3-S Carotid Shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.
Device Classification:	Class III, Rule 7, Indent 1
Type No. / Model No. / Ref. No.:	F3 Shunt - 2011-10, 2011-12, 2012-10, 2012-11, 2012-12, 2012-13, 2013-10 F3-S Shunt – 2014-10, 2015-10
EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform with the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 U.S.A.

Xiang Zhang
Vice President, Regulatory Affairs

Validity of the Certificate: May 25, 2021 to May 24, 2024

DECLARATION OF CONFORMITY

Application of Council Directive(s):	93/42/EEC, as amended by 2007/47/EC EU 722/2012
Standard(s) to which conformity is declared:	EN ISO 13485: 2016 MDD Annex II Other applicable Standards in ERC D1752
Notified Body:	TUV SUD Product Service GmbH (0123) Ridlerstraβe 65 80339 Munich Germany
Manufacturer: Manufacturer Address:	**LeMaitre Vascular, Inc.** 63 Second Avenue Burlington, MA 01803 USA.
Name of Device:	**XenoSure Biologic Patch**
Intended Use:	The XenoSure Biologic Patch is intended for use as a surgical patch material for vascular reconstruction or vessel patching during surgical procedures such as carotid endarterectomy.
Indication for Use:	The XenoSure Biologic Patch is indicated for the following conditions: Carotid Stenosis; Aneurysm; Weakened or damaged peripheral arteries.
Device Classification:	III, Rule 17 and Rule 8
Type No. / Model No. / Ref. No.:	See attached page
EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform to the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices. This declaration is issued under the sole responsibility of LeMaitre Vascular, Inc.

Place: LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 U.S.A.

Xiang Zhang
VP, Regulatory Affairs

Validity Period: May 21, 2021 to May 26, 2024

List of Model Numbers

Model Number
1BV6
0.6BV8
0.8BV8
1BV10
2BV9
1BV14
1.5BV10
4BV4
4BV6
6BV8
8BV14
10BV16
2.5BV15
5BV10
12BV25

Responsible	Description of Change	ECO#	Revision	Date
X. Zhang	Initial release of DOC	2147	A	05/01/2014
X. Zhang	Add additional sizes	3315	B	08/22/2016
X. Zhang	Add additional sizes	3651	C	12/6/2017
X. Zhang	Add EU 722/2012	4094	D	02/03/2019
A Gadgil	Update notified body to TUV SUD. Add certificate validity and reference to the product ERC.	CO5255	E	See the last page

EC Certificate Full Quality Assurance System: Certificate US21/819944244

The management system of

LeMaitre Vascular Inc.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 24 May 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 11 February 2021.

Certification is based on reports numbered WW/MC 616691

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LeMaitre Vascular Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 2

Detailed scope

Sterile LifeSpan ePTFE Vascular Graft, Flexcel Carotid Shunt, Pruitt F3 and F3-S Carotid Shunt, AnastoClip AC and GC Closure System includes the Applier and the Clip Remover

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

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

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

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

EC Design Examination Certificate: Certificate US21/819944384

LeMaitre Vascular Inc.

63 Second Avenue
Burlington, MA
USA 01803

Device Identification:
Pruitt F3 and F3-S Carotid Shunt

Intended Purpose of Device:

The Pruitt F3 and F3-S Carotid Shunts are for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II section 4

It is certified that the manufacture's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjuction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 21 May 2021 until 24 May 2024
Issue 1

Certification is based on reports numbered WW/PCI 616726 dated 06 April 2021
Addenda to that report have been issued on the following dates:

Addedum Date	Reason for Addendum
N/A	N/A

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Product Service

Add value.
Inspire trust.

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

To whom it may concern

Munich, 2021-06-08
Order No.: 713218224

Confirmation concerning EC Certificate G1 060725 0020 Rev. 00, G1MS 060725 0017 Rev. 00, G7 060725 0011 Rev. 00, G7AO 060725 0018 Rev. 00 and G7AO 060725 0019 Rev. 00

We confirm that the following certificates:

G1 060725 0020 Rev. 00	(valid until 2024-05-26)
G7 060725 0011 Rev. 00	(valid until 2024-01-12)
G7AO 060725 0018 Rev. 00	(valid until 2024-05-26)
G7AO 060725 0019 Rev. 00	(valid until 2024-05-26)
G1MS 060725 0017 Rev. 00	(valid until 2024-05-26)

issued to the legal medical device manufacturer:

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

cover the Directive 93/42/EEC on Medical Devices with the scope (G1 060725 0020 Rev. 00):

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.

and the following devices:

MD Code	model number	model name
MD 0101_1	1601-24	TufTex Embolectomy Catheter
	1601-26	
	1601-28	
	1601-34	
	1601-38	
	1601-44	
	1601-48	
	1601-58	
	1601-68	
	1601-78	

Product Service

MD Code	model number	model name
MD 0101_1	1651-34	TufTex Over-The-Wire embolectomy catheter
	1651-38	
	1651-44	
	1651-48	
	1651-84	
	1651-88	
	1651-64	
	1651-68	
	1651-78	
	1801-26	Syntel Silicone Embolectomy Catheter- Regular Tip
	1801-34	
	1801-38	
	1801-44	
	1801-48	
	1801-54	
	1801-58	
	1801-68	
	1801-78	
	A4F00	Syntel Silicone Embolectomy Catheter- Spring Tip
	A4F01	
	A4F02	
	A4F03	
	A4F04	
	A4F05	
	A4F06	
	A4F07	
	A4F08	
	A4538	Syntel Silicone Thrombectomy Catheter
	A4545	
	A4548	
	A4554	
	A4558	
	A4568	
	A4518	
	A4E01	Syntel Silicone Over-the-Wire Embolectomy Catheter
	A4E02	
	A4E03	
	A4E04	
	A4E05	
	A4E06	
	A4E07	
	A4E08	
	A4E09	
	A4G02	Latis Silicone Graft Cleaning Catheter
	A4G00	
	A4GW6	Latis Silicone Over-the-Wire Graft Cleaning Catheter
	2102-09	Pruitt irrigation occlusion catheter
	2103-36	Pruitt occlusion catheter
	2103-46	
	2103-56	
	2105-15	Distal perfusion catheter
MD 0106	1009-00	LeMaitre valvulotome
	1009-00J	
	1010-00	
	1050-00	LeMills valvultome
	1050-01	
	1050-02	
	TIVK2030	EZE-SIT valvulotome
	4100-00	LeverEdge contrast injector

Product Service

MD Code	model number	model name
MD 0106	4200-40	Mollring cutter
	4200-41	
	4200-42	
	4200-43	
	4200-44	
	4200-45	
	4200-10	Martin dissector
	4200-00	Periscope dissector
	4200-20	Endohelix
	4500-03	MultiTASC dissector
	4500-04	
	4500-05	
	4500-06	
	4500-07	
	4500-08	
	4500-09	
	4500-10	
MD1104_2	A5000	PeriVu Disposable angioscope
	ANG-080-D10K	

cover the Directive 93/42/EEC on Medical Devices with the scope (G7 060725 0011 Rev. 00):

Catheters for Single Use
Aortic Occlusion Catheter

and the following devices:

LeMaitre Aortic Occlusion Catheter 2107-80
LeMaitre Aortic Occlusion Catheter 2107-81

cover the Directive 93/42/EEC on Medical Devices with the scope (G7AO 060725 0018 Rev. 00):

Vascular Grafts
Synthetic Vascular Graft

and the following devices:

AMC1506 AlboGraft Knitted Collagen Straight Graft 15cmx6mm [LxD]
AMC3006 AlboGraft Knitted Collagen Straight Graft 30cmx6mm [LxD]
AMC4006 AlboGraft Knitted Collagen Straight Graft 40cmx6mm [LxD]
AMC6006 AlboGraft Knitted Collagen Straight Graft 60cmx6mm [LxD]
AMC1006 AlboGraft Knitted Collagen Straight Graft 100cmx6mm [LxD]
AMC4007 AlboGraft Knitted Collagen Straight Graft 40cmx7mm [LxD]
AMC1508 AlboGraft Knitted Collagen Straight Graft 15cmx8mm [LxD]
AMC3008 AlboGraft Knitted Collagen Straight Graft 30cmx8mm [LxD]
AMC4008 AlboGraft Knitted Collagen Straight Graft 40cmx8mm [LxD]
AMC6007 AlboGraft Knitted Collagen Straight Graft 60cmx7mm [LxD]
AMC6008 AlboGraft Knitted Collagen Straight Graft 60cmx8mm [LxD]
AMC1008 AlboGraft Knitted Collagen Straight Graft 100cmx8mm [LxD]
AMC1510 AlboGraft Knitted Collagen Straight Graft 15cmx10mm [LxD]
AMC3010 AlboGraft Knitted Collagen Straight Graft 30cmx10mm [LxD]
AMC4010 AlboGraft Knitted Collagen Straight Graft 40cmx10mm [LxD]
AMC6010 AlboGraft Knitted Collagen Straight Graft 60cmx10mm [LxD]
AMC1010 AlboGraft Knitted Collagen Straight Graft 100cmx10mm [LxD]
AMC1512 AlboGraft Knitted Collagen Straight Graft 15cmx12mm [LxD]
AMC3012 AlboGraft Knitted Collagen Straight Graft 30cmx12mm [LxD]
AMC1514 AlboGraft Knitted Collagen Straight Graft 15cmx14mm [LxD]
AMC3014 AlboGraft Knitted Collagen Straight Graft 30cmx14mm [LxD]
AMC1516 AlboGraft Knitted Collagen Straight Graft 15cmx16mm [LxD]

Product Service

AMC3016 AlboGraft Knitted Collagen Straight Graft 30cmx16mm [LxD]
AMC1518 AlboGraft Knitted Collagen Straight Graft 15cmx18mm [LxD]
AMC3018 AlboGraft Knitted Collagen Straight Graft 30cmx18mm [LxD]
AMC1520 AlboGraft Knitted Collagen Straight Graft 15cmx20mm [LxD]
AMC3020 AlboGraft Knitted Collagen Straight Graft 30cmx20mm [LxD]
AMC1522 AlboGraft Knitted Collagen Straight Graft 15cmx22mm [LxD]
AMC3022 AlboGraft Knitted Collagen Straight Graft 30cmx22mm [LxD]
AMC1524 AlboGraft Knitted Collagen Straight Graft 15cmx24mm [LxD]
AMC4012 AlboGraft Knitted Collagen Straight Graft 40cmx12mm [LxD]
AMC3024 AlboGraft Knitted Collagen Straight Graft 30cmx24mm [LxD]
AMC1207 AlboGraft Knitted Collagen Bifurcated Graft 12mmx7mm [DxD]
AMC1407 AlboGraft Knitted Collagen Bifurcated Graft 14mmx7mm [DxD]
AMC1408 AlboGraft Knitted Collagen Bifurcated Graft 14mmx8mm [DxD]
AMC1608 AlboGraft Knitted Collagen Bifurcated Graft 16mmx8mm [DxD]
AMC1609 AlboGraft Knitted Collagen Bifurcated Graft 16mmx9mm [DxD]
AMC1809 AlboGraft Knitted Collagen Bifurcated Graft 18mmx9mm [DxD]
AMC1810 AlboGraft Knitted Collagen Bifurcated Graft 18mmx10mm [DxD]
AMC2010 AlboGraft Knitted Collagen Bifurcated Graft 20mmx10mm [DxD]
AMC2011 AlboGraft Knitted Collagen Bifurcated Graft 20mmx11mm [DxD]
AMC2211 AlboGraft Knitted Collagen Bifurcated Graft 22mmx11mm [DxD]
AMC2412 AlboGraft Knitted Collagen Bifurcated Graft 24mmx12mm [DxD]
ASC3006AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx6mm[LxD]
ASC4006AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx6mm[LxD]
ASC6006AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx6mm[LxD]
ASC8006AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx6mm[LxD]
ASC3007AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx7mm[LxD]
ASC4007AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx7mm[LxD]
ASC6007AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx7mm[LxD]
ASC8007AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx7mm[LxD]
ASC3008AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx8mm[LxD]
ASC4008AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx8mm[LxD]
ASC6008AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx8mm[LxD]
ASC8008AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx8mm[LxD]
ATC1506 AlboGraft Woven Collagen Straight Graft 15cmx6mm[LxD]
ATC3006 AlboGraft Woven Collagen Straight Graft 30cmx6mm[LxD]
ATC4006 AlboGraft Woven Collagen Straight Graft 40cmx6mm[LxD]
ATC6006 AlboGraft Woven Collagen Straight Graft 60cmx6mm[LxD]
ATC1508 AlboGraft Woven Collagen Straight Graft 15cmx8mm[LxD]
ATC3008 AlboGraft Woven Collagen Straight Graft 30cmx8mm[LxD]
ATC4008 AlboGraft Woven Collagen Straight Graft 40cmx8mm[LxD]
ATC6008 AlboGraft Woven Collagen Straight Graft 60cmx8mm[LxD]
ATC1510 AlboGraft Woven Collagen Straight Graft 15cmx10mm[LxD]
ATC3010 AlboGraft Woven Collagen Straight Graft 30cmx10mm[LxD]
ATC4010 AlboGraft Woven Collagen Straight Graft 40cmx10mm[LxD]
ATC6010 AlboGraft Woven Collagen Straight Graft 60cmx10mm[LxD]
ATC1512 AlboGraft Woven Collagen Straight Graft 15cmx12mm[LxD]
ATC3012 AlboGraft Woven Collagen Straight Graft 30cmx12mm[LxD]
ATC4012 AlboGraft Woven Collagen Straight Graft 40cmx12mm[LxD]
ATC1514 AlboGraft Woven Collagen Straight Graft 15cmx14mm[LxD]
ATC3014 AlboGraft Woven Collagen Straight Graft 30cmx14mm[LxD]
ATC1516 AlboGraft Woven Collagen Straight Graft 15cmx16mm[LxD]
ATC3016 AlboGraft Woven Collagen Straight Graft 30cmx16mm[LxD]
ATC1518 AlboGraft Woven Collagen Straight Graft 15cmx18mm[LxD]
ATC3018 AlboGraft Woven Collagen Straight Graft 30cmx18mm[LxD]
ATC1520 AlboGraft Woven Collagen Straight Graft 15cmx20mm[LxD]
ATC3020 AlboGraft Woven Collagen Straight Graft 30cmx20mm[LxD]
ATC1522 AlboGraft Woven Collagen Straight Graft 15cmx22mm[LxD]
ATC3022 AlboGraft Woven Collagen Straight Graft 30cmx22mm[LxD]
ATC1524 AlboGraft Woven Collagen Straight Graft 15cmx24mm[LxD]
ATC3024 AlboGraft Woven Collagen Straight Graft 30cmx24mm[LxD]
ATC1526 AlboGraft Woven Collagen Straight Graft 15cmx26mm[LxD]
ATC3026 AlboGraft Woven Collagen Straight Graft 30cmx26mm[LxD]
ATC1528 AlboGraft Woven Collagen Straight Graft 15cmx28mm[LxD]
ATC3028 AlboGraft Woven Collagen Straight Graft 30cmx28mm[LxD]
ATC1530 AlboGraft Woven Collagen Straight Graft 15cmx30mm[LxD]

Product Service

ATC3030 AlboGraft Woven Collagen Straight Graft 30cmx30mm[LxD]
ATC1532 AlboGraft Woven Collagen Straight Graft 15cmx32mm[LxD]
ATC3032 AlboGraft Woven Collagen Straight Graft 30cmx32mm[LxD]
ATC1534 AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]
ATC3034 AlboGraft Woven Collagen Straight Graft 30cmx34mm[LxD]
ATC1538 AlboGraft Woven Collagen Straight Graft 15cmx38mm[LxD]
ATC3038 AlboGraft Woven Collagen Straight Graft 30cmx38mm[LxD]
ATC1207 AlboGraft Woven Collagen Bifurcated Graft 12mmx7mm[DxD]
ATC1407 AlboGraft Woven Collagen Bifurcated Graft 14mmx7mm[DxD]
ATC1408 AlboGraft Woven Collagen Bifurcated Graft 14mmx8mm[DxD]
ATC1608 AlboGraft Woven Collagen Bifurcated Graft 16mmx8mm[DxD]
ATC1609 AlboGraft Woven Collagen Bifurcated Graft 16mmx9mm[DxD]
ATC1809 AlboGraft Woven Collagen Bifurcated Graft 18mmx9mm[DxD]
ATC1810 AlboGraft Woven Collagen Bifurcated Graft 18mmx10mm[DxD]
ATC2010 AlboGraft Woven Collagen Bifurcated Graft 20mmx10mm[DxD]
ATC2011 AlboGraft Woven Collagen Bifurcated Graft 20mmx11mm[DxD]
ATC2211 AlboGraft Woven Collagen Bifurcated Graft 22mmx11mm[DxD]
ATC2412 AlboGraft Woven Collagen Bifurcated Graft 24mmx12mm[DxD]
AMC6012 AlboGraft Knitted Collagen Straight Graft 60cmx12mm[LxD]
AMC6014 AlboGraft Knitted Collagen Straight Graft 60cmx14mm[LxD]
AMC6016 AlboGraft Knitted Collagen Straight Graft 60cmx16mm[LxD]
AMC6018 AlboGraft Knitted Collagen Straight Graft 60cmx18mm[LxD]
AMC6020 AlboGraft Knitted Collagen Straight Graft 60cmx20mm[LxD]
AMC6022 AlboGraft Knitted Collagen Straight Graft 60cmx22mm[LxD]
AMC6024 AlboGraft Knitted Collagen Straight Graft 60cmx24mm[LxD]
AMC7008 AlboGraft Knitted Collagen Straight Graft 70cmx8mm[LxD]
AMC7010 AlboGraft Knitted Collagen Straight Graft 70cmx10mm[LxD]
AMC7512 AlboGraft Knitted Collagen Straight Graft 75cmx12mm[LxD]
AMC7514 AlboGraft Knitted Collagen Straight Graft 75cmx14mm[LxD]
AMC7516 AlboGraft Knitted Collagen Straight Graft 75cmx16mm[LxD]
AMC7518 AlboGraft Knitted Collagen Straight Graft 75cmx18mm[LxD]
AMC7520 AlboGraft Knitted Collagen Straight Graft 75cmx20mm[LxD]
AMC7522 AlboGraft Knitted Collagen Straight Graft 75cmx22mm[LxD]
AMC7524 AlboGraft Knitted Collagen Straight Graft 75cmx24mm[LxD]
AMC8008 AlboGraft Knitted Collagen Straight Graft 80cmx8mm[LxD]
AMC8010 AlboGraft Knitted Collagen Straight Graft 80cmx10mm[LxD]
ATC4007 AlboGraft Woven Collagen Straight Graft 40cmx7mm[LxD]
ATC6012 AlboGraft Woven Collagen Straight Graft 60cmx12mm[LxD]
ATC6014 AlboGraft Woven Collagen Straight Graft 60cmx14mm[LxD]
ATC6016 AlboGraft Woven Collagen Straight Graft 60cmx16mm[LxD]
ATC6018 AlboGraft Woven Collagen Straight Graft 60cmx18mm[LxD]
ATC6020 AlboGraft Woven Collagen Straight Graft 60cmx20mm[LxD]
ATC6022 AlboGraft Woven Collagen Straight Graft 60cmx22mm[LxD]
ATC6024 AlboGraft Woven Collagen Straight Graft 60cmx24mm[LxD]
ATC6026 AlboGraft Woven Collagen Straight Graft 60cmx26mm[LxD]
ATC6028 AlboGraft Woven Collagen Straight Graft 60cmx28mm[LxD]
ATC6030 AlboGraft Woven Collagen Straight Graft 60cmx30mm[LxD]
ATC3036 AlboGraft Woven Collagen Straight Graft 30cmx36mm [LXD]
ATC1536 AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]
ATC6007 AlboGraft Woven Collagen Straight Graft 60cmx7mm[LxD]
AMC1206 AlboGraft Knitted Collagen Bifurcated Graft 12mmx6mm[DxD]
AMC1507 AlboGraft Polyester Vascular Graft, knited straight, 15cmx7mm
AMC3007 AlboGraft Polyester Vascular Graft, knited straight, 30cmx7mm[LxD]
AMC7006 AlboGraft Polyester Vascular Graft, knited straight, 70cmx6mm[LxD]
AMC1007 AlboGraft Polyester Vascular Graft, knited straight, 100cmx7mm[LxD]
AMC8006 AlboGraft Polyester Vascular Graft, knited straight, 80cmx6mm[LxD]
ATC1507 AlboGraft Polyester Vascular Graft, woven straight, 15cmx7 mm (LxD)
ATC3007 AlboGraft Polyester Vascular Graft, woven straight, 30cmx7mm (LxD)
ATC6032 AlboGraft Woven Collagen Straight Graft 60cmx32mm [LXD]
ATC6034 AlboGraft Woven Collagen Straight Graft 60cmx34mm [LXD]
ATC6038 AlboGraft Woven Collagen Straight Graft 60cmx38mm [LXD]
ATC1206 AlboGraft Woven Collagen Bifurcated Graft 12mmx6mm[DxD]
AMC4014 AlboGraft Knitted Collagen Straight Graft 40cmx14mm[LxD]
AMC4016 AlboGraft Knitted Collagen Straight Graft 40cmx16mm[LxD]
AMC4018 AlboGraft Knitted Collagen Straight Graft 40cmx18mm[LxD]

Product Service

AMC4020 AlboGraft Knitted Collagen Straight Graft 40cmx20mm[LxD]
AMC4022 AlboGraft Knitted Collagen Straight Graft 40cmx22mm[LxD]
AMC4024 AlboGraft Knitted Collagen Straight Graft 40cmx24mm [LxD]

cover the Directive 93/42/EEC on Medical Devices with the scope (G7AO 060725 0019 Rev. 00):

Patch of Animal Origin
Cardiovascular Patch

and the following devices:

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**

and covers the Directive 93/42/EEC on Medical Devices with the scope (G1MS 060725 0017 Rev. 00):

Radiopaque Tapes

and the following devices:

MD Code	model number	model name
MD 0106	1100-20	VascuTape Radiopaque Tape
	1100-50	
	1100-00	
	1108-20	
	1102-20	
	1102-50	
	1102-00	
	1109-20	

Product Service

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificates are valid.

R. Köhler

MÜNCHEN TÜV SÜD PRODUCT SERVICE

Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

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

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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

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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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

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TÜV®

LeMaitre®
2022 EMEA Product Overview

Updated: March 2022

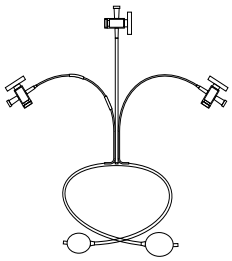
LeMaitre®

Pruitt F3® Carotid Shunt

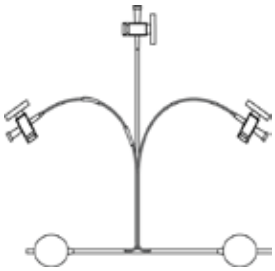
5-year Shelf Life Latex
2-year Shelf Life Polyurethane

	Diameter	Length	Model #
Pruitt F3® Outlying Carotid Shunt *(Sterile)*			
Shunt with T-Port	8F	31 cm	2013-10
Shunt with T-Port	9F	31 cm	2012-10
Shunt with T-Port	10F	31 cm	2011-10
Pruitt F3® Inlying Carotid Shunt *(Sterile)*			
Shunt with T-Port	9F	15 cm	2012-12
Shunt with T-Port	10F	15 cm	2011-12
Pruitt F3®-S Polyurethane Outlying Carotid Shunt *(Sterile)* Safety balloon not available on polyurethane models.			
Shunt with T-Port	8F	31 cm	2015-10
Shunt with T-Port	9F	31 cm	2014-10

OUTLYING CAROTID SHUNT



INLYING CAROTID SHUNT

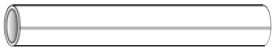


LifeSpan® ePTFE Vascular Grafts

7-year Shelf Life

Regular Wall *(Sterile)*

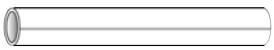
Straight



Diameter	Length	Model #
5 mm	20 cm	R05020
5 mm	50 cm	R05050
6 mm	10 cm	R06010
6 mm	20 cm	R06020
7 mm	20 cm	R07020
8 mm	20 cm	R08020
6 mm	30 cm	R06030
6 mm	50 cm	R06050
7 mm	50 cm	R07050
8 mm	50 cm	R08050
6 mm	80 cm	R06080
7 mm	80 cm	R07080
8 mm	80 cm	R08080

Thin Wall *(Sterile)*

Straight



Diameter	Length	Model #
5 mm	20 cm	T05020
6 mm	20 cm	T06020
6 mm	50 cm	T06050
7 mm	50 cm	T07050
8 mm	50 cm	T08050
6 mm	80 cm	T06080
7 mm	80 cm	T07080
8 mm	80 cm	T08080
10 mm	80 cm	T10080

XenoSure® Biologic Surgical Patch

4-year Shelf Life

	Width	Length	Model #
XenoSure® Biologic Surgical Patch *(Sterile)* (Bovine Pericardium) **Thickness range 0.350 - 0.750 mm**			
Biologic Surgical Patch	4 cm	4 cm	4BV4
Biologic Surgical Patch	4 cm	6 cm	4BV6
Biologic Surgical Patch	6 cm	8 cm	6BV8
Biologic Surgical Patch	5 cm	10 cm	5BV10
Biologic Surgical Patch	8 cm	14 cm	8BV14
Biologic Surgical Patch	2.5 cm	15 cm	2.5BV15
Biologic Surgical Patch	10 cm	16 cm	10BV16