

Certificate of Approval

This is to certify that the Management System of:

LeMaitre Vascular, Inc.

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

has been approved by LRQA to the following standards:

ISO 13485:2016



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

Current issue date: 15 January 2019

Expiry date: 31 December 2021

Certificate identity number: 10166853

Certificate approval No: UQA 4000085

Original approval(s):

ISO 13485 – 14 June 2005

Product number: ISO 13485 – 0011617

The scope of this approval is applicable to:

Design and Manufacture of Angioscopes and Accessories/Adaptors, Embolectomy Catheters, Irrigation Catheters, Cholangiogram Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Vascular Patches, Biologic Patches, Non-Occlusive Modeling Catheters, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast Injectors, Tape Measuring Rulers and Calipers, Valvulotomes, Surgical Systems for Peripheral Vein Removal and Vein Strippers for Cardiovascular, Gastroenterology, Urology, Neurosurgery, General and Plastic Surgery Applications.



001

Certificate Schedule

Certificate identity number: 10166853

Location	Activities
63 Second Avenue, Burlington, MA, 01803, United States	ISO 13485:2016 Design and Manufacture of Angioscopes and Accessories/Adaptors, Embolectomy Catheters, Irrigation Catheters, Cholangiogram Catheters, Occlusion Catheters, Synthetic Vascular Grafts, Synthetic Vascular Patches, Surgical Clips, Surgical Clip Removers, Carotid Shunts, Endarterectomy Devices, Contrast Injectors, Valvulotomes, and Surgical Systems for Peripheral Vein Removal Cardiovascular, Gastroenterology, Urology, Neurosurgery, General and Plastic Surgery Applications.
53 Second Avenue, Burlington, MA, 01803, United States	ISO 13485:2016 Design and Manufacture of Synthetic Vascular Grafts, Tape Measuring Rulers and Calipers. Packaging of Medical Devices. Product Testing.
2 Fourth Avenue, Burlington, MA, 01803, United States	ISO 13485:2016 Product Packaging, Storage and Distribution.
43 Second Avenue, Burlington, MA, 01803, United States	ISO 13485:2016 Design and Manufacture of Biologic Patches. Sales Services and Administration.



001

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 February 2021 until 11 February 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 23 October 2023

Issue 1. Certified since 11 February 2021

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



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

HC SGS 13485 2016 0118 M2

Page 1 of 2



LeMaitre Vascular Inc.

ISO 13485:2016
EN ISO 13485:2016



Issue 1

Detailed scope

Design, manufacture and distribution of sterile carotid shunts, sterile surgical clips and removers, sterile vascular patches and sterile synthetic vascular grafts.

Additional facilities

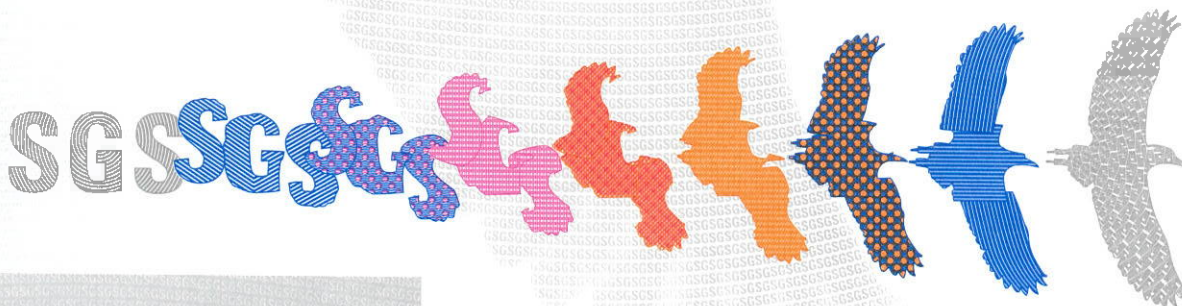
53 Second Avenue, Burlington, MA, 01803, United States

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

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



0005





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 0003 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; Cholangiogram Catheter; Over the Wire Valvulotome; Valvulotome; Contrast Injector; Endarterectomy Devices; Dissectors; Retrieval Device; Dissection/ Transection Device; Universal Clip Remover; Disposable Angioscope; Carotid Shunts.

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. See also notes overleaf.

Report No.:

72147220

Valid from:

2020-02-18

Valid until:

2021-12-31

Date,

2020-02-18

Christoph Dicks
Head of Certification/Notified Body



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 0003 Rev. 00

Facility(ies):

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

LeMaitre Vascular Inc
53 Second Ave, Burlington MA 01803, USA

LeMaitre Vascular Inc
43 Second Ave, Burlington MA 01803, USA

LeMaitre Vascular Inc
2 Fourth Ave, Burlington MA 01803, USA

-/-



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 11 February 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 11 February 2021

Certification is based on reports numbered VV/MC 616691

Authorised by

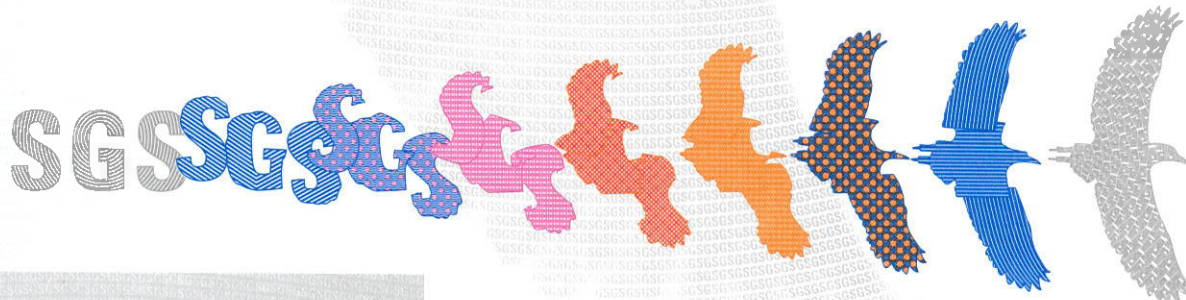
Global Medical Devices Certification Manager

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

LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

Page 1 of 2



This document is issued by the Company subject to its General Conditions of Certification Services, unless otherwise agreed, accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document may be verified at <https://www.sgs.com/en/certified-clients-and-products/certified-client-directory>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

LeMaitre Vascular Inc.

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

Sterile LifeSpan®ePTFE Vascular Graft

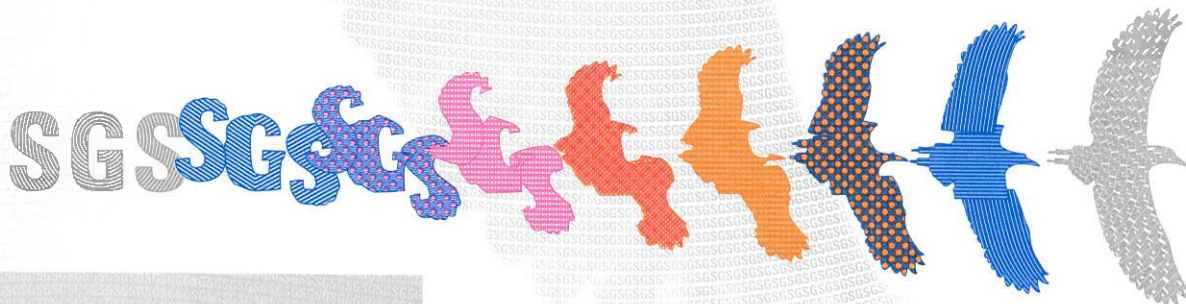
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

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 Certificate – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

LeMaitre Vascular, Inc.

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

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

Current Certificate: 13 June 2019

Expiry Date: 30 September 2019

Certificate Identity Number: 10079095

LRQA Notified Body Number: 0088

Original Approval: 25 July 2005

Approval Certificate Number: MDD – 00007399

EC Certificate – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE IDENTITY No.10079095 SCHEDULE

In accordance with the requirements of the Medical Devices Directive
93/42/EEC and the Medical Devices Regulations 2002, UK Statutory
Instrument 2002 No. 618

LeMaitre Vascular, Inc.

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

<p><u>Class I Sterile Products</u> Vascutape® Glow N' Tell Tape Vascutape® LeMaitre Stent Guide</p>	
<p><u>Class IIa Products</u> LeMaitre® Single Lumen Emblectomy Catheter LeMaitre® Over the Wire Emblectomy Catheter Novasil® Silicone Single Lumen Emblectomy Pruitt® Irrigation Occlusion Catheter Pruitt® Occlusion Catheter Pruitt® Aortic Occlusion Catheter Distal Perfusion Catheter Reddick® Cholangiogram Catheter Reddick® Scoop Tip Cholangiogram Over the Wire Expandable LeMaitre® Valvulotome InvisiGrip® Vein Stripper LeverEdge® Contrast Injector MollRing Cutter® Martin Dissector Periscope® Dissector EndoHelix™ AnastoClip® Universal Clip Remover (single use/sterile) MultiTASC Dissection/Transection Device LeMills Valvulotome HYDRO LeMaitre Valvulotome Disposable Angioscope EZE-SIT Valvulotome</p>	<p><u>Class IIb Products</u> LifeSpan® Vascular Grafts</p>

EC Certificate – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE IDENTITY No.10079095 SCHEDULE

In accordance with the requirements of the Medical Devices Directive
93/42/EEC and the Medical Devices Regulations 2002, UK Statutory
Instrument 2002 No. 618

Class III Products

AnastoClip AC Closure System
Flexcel® Carotid Shunt
AnastoClip GC Closure System
Pruitt® F3™ Carotid Shunt
Pruitt-Inahara® Outlying Carotid Shunt without
T-PORT
Inahara-Pruitt® Inlying Carotid Shunt without
T-PORT
Pruitt-Inahara® Outlying Carotid Shunt with
T-PORT
Inahara-Pruitt® Inlying Carotid Shunt with T-PORT
AlboGraft™ Vascular Graft
AlboSure™ Vascular Patch
LeMaitre Aortic Occlusion Catheter
XenoSure® Biologic Patch

EC Design Examination Certificate

0088/4000085/00245
0088/4000085/00244
0088/4000085/00306
0089/4000085/00318

0088/4000085/00323

0088/4000085/00323

0088/4000085/00323

0088/4000085/00323

0088/4000085/00329

0088/4000085/00357

0088/4000085/00373

0088/4000085/00375

Schedule Issue: 25

Date of Schedule Issue: 13 June 2019

Certificate Identity Number: 10079095

LRQA Notified Body Number: 0088



David Derrick - Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

AlboSure® Polyester Vascular Patch

EXCEPTIONALLY SOFT AND EASY TO SUTURE

With high quality materials, a unique manufacturing technique and advanced sealant technology, the AlboSure Polyester Vascular Patch offers an exceptional combination of softness and suturability. The ultra thin non-velour design offers excellent conformability and ease of handling.



APPLICATIONS

Repairing and grafting of peripheral vascular vessels, like:

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

ORDERING INFORMATION

AlboSure Polyester Vascular Patch

	Dimension	Model # REF
Tapered Sizes 	6 mm x 75 mm	AP06075T
	8 mm x 75 mm	AP08075T
	10 mm x 75 mm	AP10075T
Rectangular Sizes 	20 mm x 90 mm	AP20090R
	10 mm x 100 mm	AP10100R
	10 mm x 150 mm	AP10150R

Overview of available sizes in 1:1 see inside

ALBOSURE SPECIFICATIONS

Patch Structure	Knitted Polyester Non-Velour
Patch Thickness	0.4 mm
Impregnation	Collagen Impregnation Highly Purified Type I Collagen (Bovine)
Waterpermeability	Maximum 1 ml/cm ² /min @ 120 mmHg ⁽¹⁾
Sterilization	Ethyleneoxide (EtO) Sterilization Process

⁽¹⁾ measured at 120 mmHg pressure according to ISO 7198-2: 1998



Your Peripheral Vision™

AlboSure and LeMaitre are registered trademarks and Your Peripheral Vision is a trademark of LeMaitre Vascular, Inc.
©2014 LeMaitre Vascular, Inc. All rights reserved. M0269E Rev. D 09/14



LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts. · Germany
T +49 (0)6196 659230
F +49 (0)6196 527072

LeMaitre Vascular SAS
79 avenue de Villiers
75017 Paris · France
T +33 (0)3 44 26 00 41
F +33 (0)3 44 26 07 31

LeMaitre Vascular S.r.l.
Via Leone Tolstoj 86
20098 San Giuliano Milanese (MI)
Italy
T +39 02 988 48 51
F +39 02 984 97 059

LeMaitre Vascular Spain S.L.
Calle Basauri 17
28023 Madrid · Spain
T +34 902 500 037
F +34 91 184 98 71

LeMaitre Vascular Switzerland GmbH
Neuhofstrasse 5A
CH-6340 Baar · Switzerland
T 0800 561 761
F +41 415 608 236

LeMaitre Vascular AS
Dronning Eufemias gt. 16
NO-0191 Oslo · Norway
T +49 (0)6196 659230
F +47 21 54 74 67

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803 · USA
T +1 781 221 2266
F +1 781 221 2223

LeMaitre Vascular GK · Japan
T +81 (0)3 5215 5681
F +81 (0)3 5215 5682

LeMaitre Vascular ULC · Canada
T +1 905 673 2266 0
F +1 905 673 2223

LeMaitre Vascular PTY LTD · Australia
T +61 (0) 3 9330 4775
F +61 (0) 3 9330 4772

**LeMaitre Medical Technology
(Shanghai) Co., Ltd · China**
T +86 15601732626
F +86 21 61357100

www.lemaitre.com



AlboSure[®] Polyester Vascular Patch

NEW Exceptionally Soft
and Easy to Suture



Your Peripheral Vision™

AlboSure[®] Polyester Vascular Patch

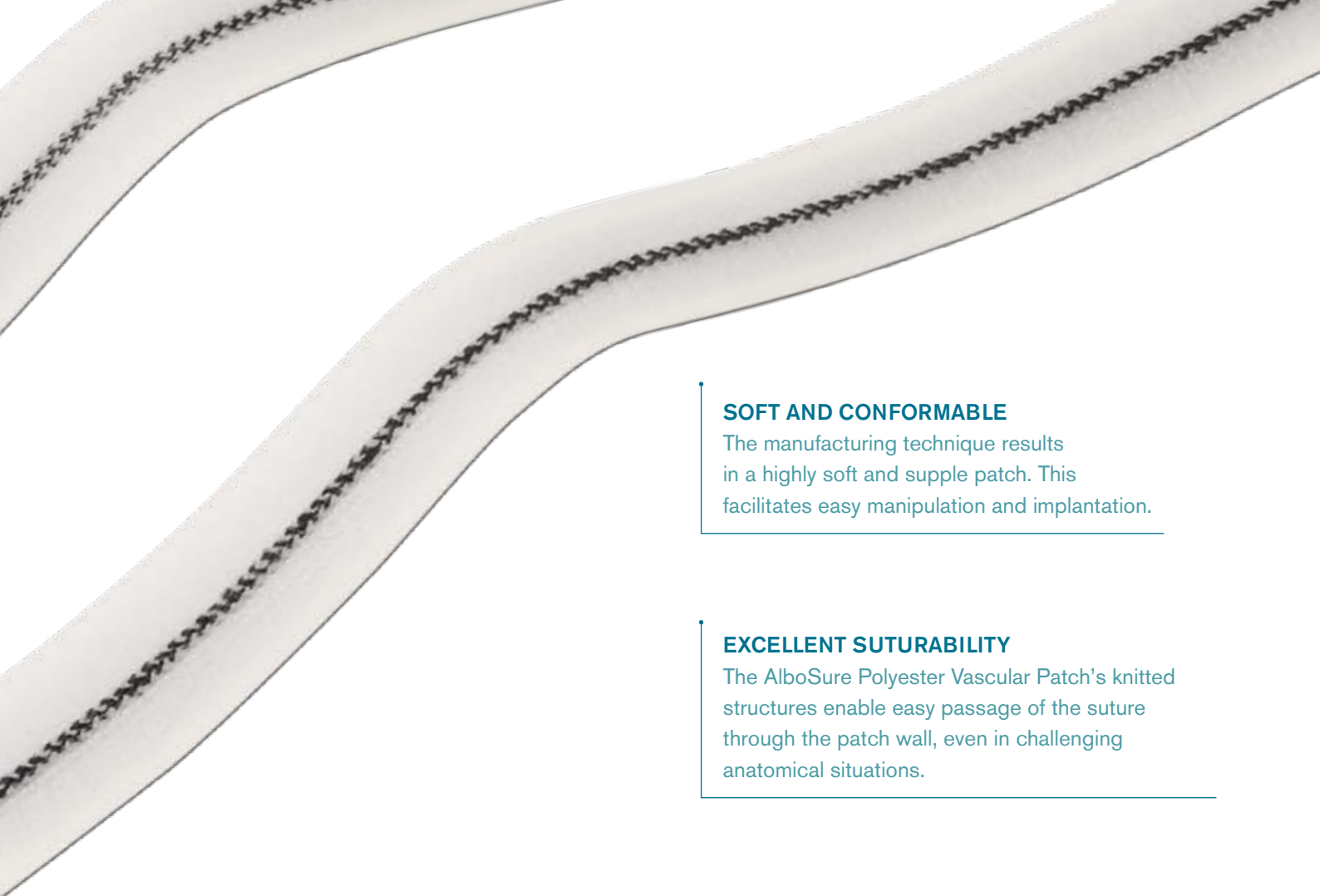
EXCEPTIONALLY SOFT AND EASY TO SUTURE

With high quality materials, a unique manufacturing technique and advanced sealant technology, the AlboSure Polyester Vascular Patch offers an exceptional combination of softness and suturability. The ultra thin non-velour design offers excellent conformability and ease of handling.



BENEFITS

- Ultra thin 0.4 mm design
- Excellent conformability
- Pre-trimmed tapered end carotid sizes
- Advanced collagen sealing technology
- Non-velour design for exceptional handling



SOFT AND CONFORMABLE

The manufacturing technique results in a highly soft and supple patch. This facilitates easy manipulation and implantation.

EXCELLENT SUTURABILITY

The AlboSure Polyester Vascular Patch's knitted structures enable easy passage of the suture through the patch wall, even in challenging anatomical situations.

EXCEPTIONAL SEALING

Advanced sealant technology allows for deep penetration of bovine skin collagen into polyester filaments of the patch structure. This allows for exceptional sealing which is demonstrated in a water permeability of maximum 1 ml/cm²/min⁽¹⁾.

Available Sizes in 1:1

ALBOSURE POLYESTER VASCULAR PATCH

Tapered

6mm x 75mm — AP06075T

8mm x 75mm — AP08075T

10mm x 75mm — AP10075T

Rectangular

20mm x 90mm — AP20090R

10mm x 100mm — AP10100R

10mm x 150mm — AP10150R

LeMaitre[®] Embolectomy Catheters

- Single Lumen
- Over-the-Wire
- Latex-Free

NEW 5F *Plus* Over-the-Wire Catheter
featuring two Radiopaque Bands



Your Peripheral Vision™

LeMaitre[®] Embolectomy Catheters

A COMPLETE RANGE OF QUALITY CATHETERS:

LeMaitre offers an expanded line of premium quality balloon catheters for rapid removal of emboli and thrombi. Available in Single Lumen, Over-the-Wire, and Latex-Free models, LeMaitre Catheters are:

Radiopaque.

For easy visibility of instrument under fluoroscopy

Pliable.

Eases introduction into difficult anatomy

Extended Shelflife.

3 Years - Over-the-Wire Catheters with Latex Balloons

4 Years - Single Lumen Catheters with Latex Balloons

5 Years - NovaSil Latex-Free Catheters

OVER-THE-WIRE

Guidance.

Compatible with standard guidewire to direct catheter to proper position

Dye Enhancement.

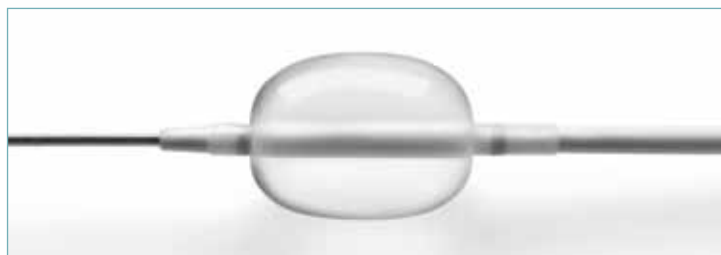
Add contrast media to facilitate emboli/thrombi imaging and improve fluoroscopy control

Irrigation.

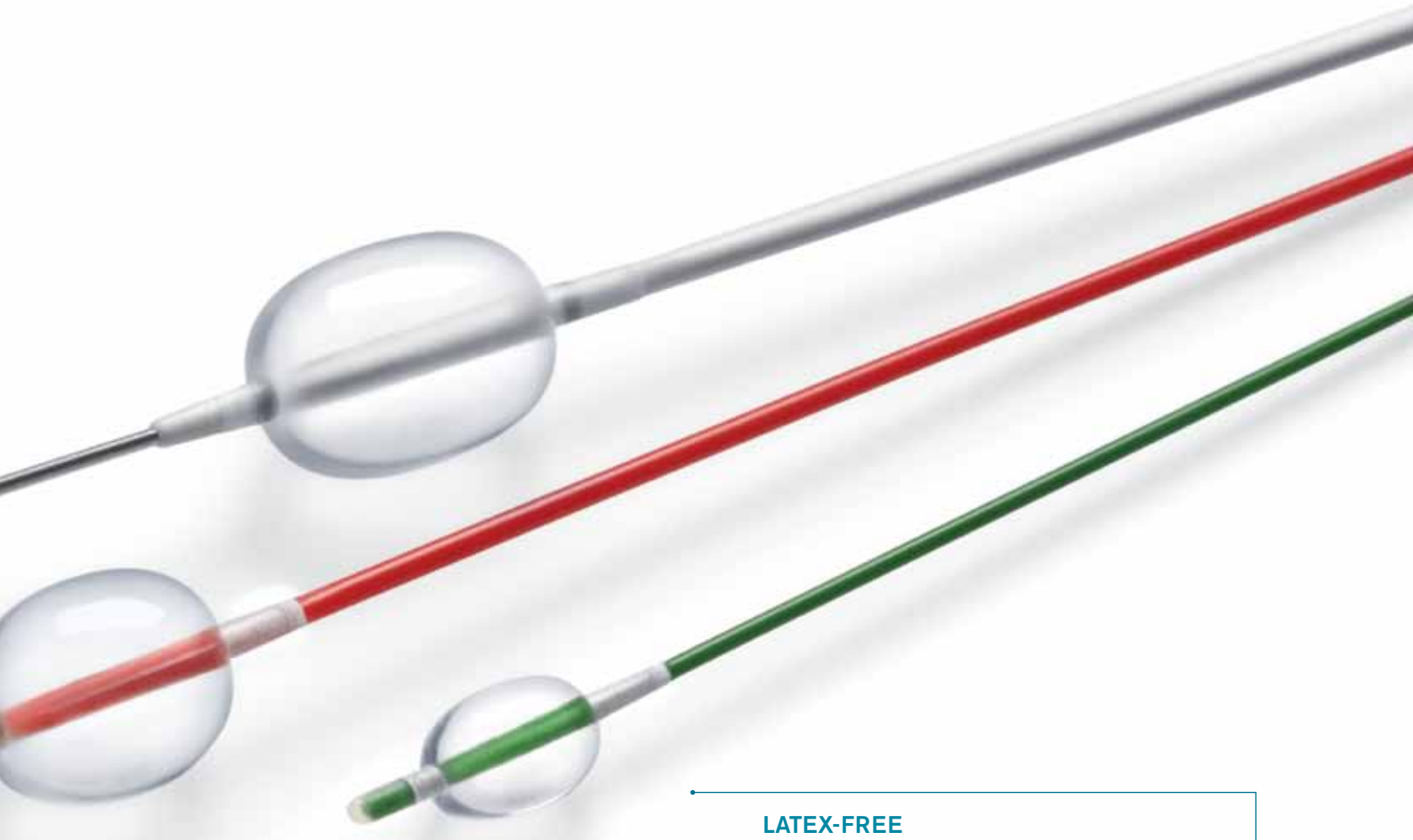
Lubricates with fewer passes and less intimal trauma during catheter withdrawal



5F PLUS: NEWEST ADDITION TO CATHETER LINE



- Two radiopaque bands at proximal and distal ends of balloon for enhanced visibility under fluoroscopy
- Compatible with .035" guidewire and 6F introducer



SINGLE LUMEN

Stability.

Balloons are highly rupture-resistant

Concentricity.

Balloons are well-centered

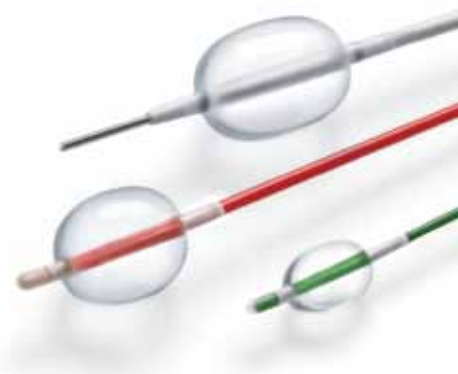
Progressive Inflation.

Balloons inflate at consistent rate as volume increases

LATEX-FREE

The NovaSil line of premium catheters provide a latex-free option for latex sensitivity.

LeMaitre® Embolectomy Catheters



ORDERING INFORMATION

Balloon Diameter	Balloon Volume	Diameter	Color	Length	Guidewire	Model #
Over-the-Wire Embolectomy Catheter						
Compatible with standard guidewires, stopcock and syringe included. Facilitates dye enhancement and irrigation. 3 year shelflife.						
6 mm	0.20 ml	3F	Green	40 cm	.018"	1651-34
6 mm	0.20 ml	3F	Green	80 cm	.018"	1651-38
10 mm	0.75 ml	4F	Red	40 cm	.025"	1651-44
10 mm	0.75 ml	4F	Red	80 cm	.025"	1651-48
12 mm	1.50 ml	5.5F	White	40 cm	.035"	1651-84
12 mm	1.50 ml	5.5F	White	80 cm	.035"	1651-88
13 mm	1.60 ml	6F	Blue	40 cm	.035"	1651-64
13 mm	1.60 ml	6F	Blue	80 cm	.035"	1651-68
14 mm	1.75 ml	7F	Yellow	80 cm	.038"	1651-78

Single Lumen Embolectomy Catheter

Balloon is highly rupture-resistant, well-centered and provides a progressive inflation. 4 year shelflife.

4.5 mm	0.05 ml	2F	Purple	40 cm		1601-24
4.5 mm	0.05 ml	2F	Purple	60 cm		1601-26
4.5 mm	0.05 ml	2F	Purple	80 cm		1601-28
8.0 mm	0.20 ml	3F	Green	40 cm		1601-34
8.0 mm	0.20 ml	3F	Green	80 cm		1601-38
10.5 mm	0.75 ml	4F	Red	40 cm		1601-44
10.5 mm	0.75 ml	4F	Red	80 cm		1601-48
13.0 mm	1.50 ml	5F	White	80 cm		1601-58
13.5 mm	1.60 ml	6F	Blue	80 cm		1601-68
14.0 mm	1.75 ml	7F	Yellow	80 cm		1601-78

NovaSil® Latex-Free Single Lumen Embolectomy Catheter

Provides a latex-free option for latex sensitivity. 5 year shelflife.

4 mm	0.05 ml	2F	Purple	40 cm		1801-24
4 mm	0.05 ml	2F	Purple	60 cm		1801-26
6 mm	0.20 ml	3F	Green	40 cm		1801-34
6 mm	0.20 ml	3F	Green	80 cm		1801-38
9 mm	0.60 ml	4F	Red	40 cm		1801-44
9 mm	0.60 ml	4F	Red	80 cm		1801-48
11 mm	1.00 ml	5F	White	80 cm		1801-58
13 mm	1.60 ml	6F	Blue	80 cm		1801-68
14 mm	1.75 ml	7F	Yellow	80 cm		1801-78

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

LeMaitre Vascular GmbH

Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany

T +49 (0)6196 659230

F +49 (0)6196 527072

LeMaitre Vascular SAS

79 avenue de Villiers
75017 Paris
France

T +33 (0)3 44 26 00 41

F +33 (0)3 44 26 07 31

LeMaitre Vascular S.r.l.

Via Leone Tolstoj 86
20098 San Giuliano Milanese (MI)
Italy

T +39 02 988 48 51

F +39 02 984 97 059

LeMaitre Vascular, Inc.

63 Second Avenue
Burlington, MA 01803
USA

T +1 781 221 2266

F +1 781 221 2223

LeMaitre Vascular GK

1F Kubodera Twin Tower Bldg.
2-9-4 Kudan-minami, Chiyoda-ku
Tokyo 102-0074
Japan

T +81 (0)3 5215 5681

F +81 (0)3 5215 5682



Your Peripheral Vision™

LifeSpan[®] ePTFE Vascular Graft

- For Peripheral Reconstructions and Vascular Access
- Proven Performance¹
- Excellent Handling
- Superb Suture Retention









Your Peripheral Vision™



- PERIPHERAL AND VASCULAR ACCESS
- PROVEN PERFORMANCE¹
- CLINICALLY USED FOR MORE THAN 15 YEARS
- SUPERB SUTURE RETENTION
- HIGH BURST STRENGTH
- COLOUR CODED PACKAGING FOR EASE OF SELECTION

LifeSpan® ePTFE Vascular Grafts for Vascular Access for Haemodialysis










The LifeSpan ePTFE Vascular Graft selection offers various sizes for the creation of Vascular Access for haemodialysis when other access is not available. It has been recommended that regular / standard wall grafts should be the grafts of choice for the creation of Vascular Access². Center spiral models are designed for vascular access procedures requiring enhanced resistance to kinking and compression in the middle section of the grafts (e.g. narrow loop grafts). Stepped and Quick Tapered grafts are designed to reduce the risk of steal syndrome and high cardiac output. The packaging is colour coded for ease of reference.

	Inner Diameter (ID)	Length (L)	Wall Thickness R = Regular Wall/ Standard Wall T = Thin Wall	Description	Colour Code Packaging	Model # REF
 Regular Wall, straight	5 mm	10 cm	R			R05010*
	6 mm	10 cm	R			R06010
	7 mm	10 cm	R			R07010
	8 mm	10 cm	R			R08010
	5 mm	20 cm	R			R05020*
	6 mm	20 cm	R			R06020
	7 mm	20 cm	R			R07020
	8 mm	20 cm	R			R08020
	6 mm	30 cm	R			R06030
	5 mm	50 cm	R			R05050*
	6 mm	50 cm	R			R06050
	7 mm	50 cm	R			R07050
	8 mm	50 cm	R			R08050
 Regular Wall, straight, Center Spiral Support	6 mm	40 cm	R	10 cm Center Spiral		R06040CS
	6 mm	50 cm	R	5 cm Center Spiral		R06050CS5
	6 mm	50 cm	R	10 cm Center Spiral		R06050CS
	7 mm	50 cm	R	10 cm Center Spiral		R07050CS
	8 mm	50 cm	R	10 cm Center Spiral		R08050CS
 Regular Wall, stepped	4-7 mm	50 cm	R			RS47050
 Regular Wall, stepped, Center Spiral Support	4-7 mm	50 cm	R	5 cm Center Spiral		RS4750CS5
	4-7 mm	50 cm	R	10 cm Center Spiral		RS47050CS
 Regular Wall, Quick Taper	4-7 mm	40 cm	R			QT47040
	4-7 mm	50 cm	R			QT47050
 Regular Wall, Quick Taper, Center Spiral Support	4-7 mm	45 cm	R	5 cm Center Spiral		QT4745CS5
	4-7 mm	45 cm	R	10 cm Center Spiral		QT47045CS

* products not for sale in the U.S.

LifeSpan® ePTFE Vascular Grafts for Peripheral Vascular Procedures

The LifeSpan ePTFE Vascular Graft selection also offers various sizes for peripheral reconstructions. Regular/standard wall and thin wall grafts can be used for peripheral vascular reconstructions. Models with full or partial external spiral support are designed for extra-anatomic surgical reconstructions and for reconstructions requiring enhanced resistance to kinking and compression (e.g. axillo-femoral bypass, femoro-femoral bypass, femoro-popliteal or distal bypass). The external spiral support can be removed, facilitating an easy creation of the anastomosis to the vessel. The packaging is colour coded for ease of reference in the operating room.

	Inner Diameter (ID)	Length (L)	Wall Thickness R = Regular Wall/ Standard Wall T = Thin Wall	Description	Colour Code Packaging	Model # [REF]
 Regular Wall, straight	5 mm	10 cm	R			R05010*
	6 mm	10 cm	R			R06010
	7 mm	10 cm	R			R07010
	8 mm	10 cm	R			R08010
	5 mm	20 cm	R			R05020*
	6 mm	20 cm	R			R06020
	7 mm	20 cm	R			R07020
	8 mm	20 cm	R			R08020
	6 mm	30 cm	R			R06030
	5 mm	50 cm	R			R05050*
	6 mm	50 cm	R			R06050
	7 mm	50 cm	R			R07050
	8 mm	50 cm	R			R08050
	5 mm	80 cm	R			R05080*
	6 mm	80 cm	R			R06080
	7 mm	80 cm	R			R07080
	8 mm	80 cm	R			R08080
	10 mm	80 cm	R			R10080
 Thin Wall, straight	5 mm	20 cm	T			T05020*
	6 mm	20 cm	T			T06020
	7 mm	20 cm	T			T07020
	8 mm	20 cm	T			T08020
	5 mm	50 cm	T			T05050*
	6 mm	50 cm	T			T06050
	7 mm	50 cm	T			T07050
	8 mm	50 cm	T			T08050
	5 mm	80 cm	T			T05080*
	6 mm	80 cm	T			T06080
	7 mm	80 cm	T			T07080
	8 mm	80 cm	T			T08080
	10 mm	80 cm	T			T10080
 Regular Wall, straight, Full External Spiral Support	6 mm	50 cm	R	50 cm Spiral Support Length		R06050C50
	7 mm	50 cm	R	50 cm Spiral Support Length		R07050C50
	8 mm	50 cm	R	50 cm Spiral Support Length		R08050C50
	6 mm	80 cm	R	80 cm Spiral Support Length		R06080C80
	7 mm	80 cm	R	80 cm Spiral Support Length		R07080C80
	8 mm	80 cm	R	80 cm Spiral Support Length		R08080C80
	10 mm	80 cm	R	80 cm Spiral Support Length		R10080C80
 Thin Wall, straight, External Spiral Support 50/30	6 mm	50 cm	T	30 cm Spiral Support Length		T06050C30
	7 mm	50 cm	T	30 cm Spiral Support Length		T07050C30
	8 mm	50 cm	T	30 cm Spiral Support Length		T08050C30
 Thin Wall, straight, External Spiral Support 80/50	6 mm	80 cm	T	50 cm Spiral Support Length		T06080C50
	7 mm	80 cm	T	50 cm Spiral Support Length		T07080C50
	8 mm	80 cm	T	50 cm Spiral Support Length		T08080C50
 Thin Wall, straight, Full External Spiral Support	6 mm	50 cm	T	50 cm Spiral Support Length		T06050C50
	7 mm	50 cm	T	50 cm Spiral Support Length		T07050C50
	8 mm	50 cm	T	50 cm Spiral Support Length		T08050C50
	6 mm	80 cm	T	80 cm Spiral Support Length		T06080C80
	7 mm	80 cm	T	80 cm Spiral Support Length		T07080C80
	8 mm	80 cm	T	80 cm Spiral Support Length		T08080C80
	10 mm	80 cm	T	80 cm Spiral Support Length		T10080C80
 Thin Wall, Gradual Taper, External Spiral Support	7-4 mm	80 cm	T	70 cm Spiral Support Length		GT74080C70*
 Regular Wall, Gradual Taper	7-4 mm	70 cm	R			GR74070*
 Thin Wall, Gradual Taper	7-4 mm	70 cm	T			GT74070*

* products not for sale in the U.S.



LifeSpan® ePTFE Vascular Graft

EXCELLENT HANDLING AND PROVEN PERFORMANCE¹

LifeSpan ePTFE Vascular Grafts have been indicated for peripheral vascular reconstructions and Vascular Access for haemodialysis and are used in clinical practice for more than 15 years.

The soft ePTFE material with superb suture retention, high burst strength and excellent handling makes the product an ideal selection as a implant when ePTFE shall be the graft of choice.

A variety of shapes, lengths and diameters provides a good set of options for the surgeon to find the correct implant of choice. The colour coded packaging makes the selection easy in the operating room.

- PERIPHERAL AND VASCULAR ACCESS
- PROVEN PERFORMANCE¹
- CLINICALLY USED FOR MORE THAN 15 YEARS
- SUPERB SUTURE RETENTION
- HIGH BURST STRENGTH
- COLOUR CODED PACKAGING FOR EASE OF SELECTION

TECHNICAL DATA:

Material	
Vascular Graft:	ePTFE - expanded PolyTetraFluoroEthylene
External Spiral Support:	PTFE - PolyTetraFluoroEthylene
Wall Thickness (6 mm graft - nominal)	
Regular/Standard Wall:	0,63 mm
Thin Wall:	0,4 mm
Internodal Distance (nominal):	20 +/- 10 µm
Suture Retention Strength:	min. 300 grams
Average (+/- SD) Min. Burst Strength³:	218 +/- 31 psi

1) Cinat ME, Hopkins J, Wilson SE.
A prospective evaluation of PTFE graft patency and surveillance techniques in hemodialysis access. Ann Vasc Surg 1999;13:191-198.
2) Lenz BJ, Veldenz HC, Dennis JW, et al.
A three-year follow-up on standard versus thin wall ePTFE grafts for hemodialysis. J Vasc Surg 1998;28:464-470
3) Data on file

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany

T +49 (0)6196 659230
F +49 (0)6196 527072

LeMaitre Vascular SAS
79 avenue de Villiers
75017 Paris
France

T +33 (0)3 44 26 00 41
F +33 (0)3 44 26 07 31

LeMaitre Vascular S.r.l.
Via Leone Tolstoj 86
20098 San Giuliano Milanese (MI)
Italy
T +39 02 988 48 51
F +39 02 984 97 059

LeMaitre Vascular Spain S.L.
Calle Basauri 17
28023 Madrid
Spain
T +34 902 500 037
F +34 91 184 98 71

LeMaitre Vascular Switzerland GmbH
Grabenstrasse 25
CH-6340 Baar
Switzerland
T 0800 561 761
F +41 415 608 236

LeMaitre Vascular AS
Dronning Eufemias gt. 16
NO-0191 Oslo
Norway
T +49 (0)6196 659230
F +47 21 54 74 67

LeMaitre Vascular GK
1F Kubodera Twin Tower Bldg.
2-9-4 Kudan-minami, Chiyoda-ku
Tokyo 102-0074
Japan
T +81 (0)3 5215 5681
F +81 (0)3 5215 5682

LeMaitre Vascular ULC
5915 Airport Road, Suite 608
Mississauga, Ontario
Canada L4V 1T1
T +1 905 673 2266 0
F +1 905 673 2223

LeMaitre Vascular PTY LTD
214/189 South Centre Road
Tullamarine, VIC 3043
Australia
T +61 (0) 3 9330 4775
F +61 (0) 3 9330 4772

LeMaitre Vascular, Inc.
63 Second Avenue
Burlington, MA 01803
USA
T +1 781 221 2266
F +1 781 221 2223

www.lemaitre.com



Your Peripheral Vision™