Certificate Number US21/819944301
The management system of

LeMaitre Vascular Inc.

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

Facility identification number : F005365

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

MDSAP (ISO 13485:2016)

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

Digitally signed by Captari Alexandru
Date: 2022.06.27 19:16:50 EEST
Reason: MoldSign Signature
Location: Moldova

For the following activities and devices

See second page for the scope.

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

Authorised by L Henderson
Business Manager

L. Henderson

SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN,UK
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SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

The management system of

LeMaitre Vascular Inc.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

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

Servicing of Surgical Systems for Peripheral Vein Removal.

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

Additional facilities

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

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

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

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

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

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

Product Service

EC Certificate

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

No. G1 060725 0020 Rev. 00

Manufacturer:

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

Product Category(ies):

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

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

Report No.: 72164019-4

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

Date, 2021-05-25

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV®

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

LeMaitre®
2022 EMEA Product Overview

Updated: March 2022

LeMaitre®

TufTex® Embolectomy Catheter

6-year Shelf Life

Balloon Diameter	Balloon Volume	Diameter	Length	Model #
TufTex® Embolectomy Catheter *(Sterile)*				
4.5 mm	0.05 ml	2F	40 cm	1601-24
4.5 mm	0.05 ml	2F	60 cm	1601-26
4.5 mm	0.05 ml	2F	80 cm	1601-28
8.0 mm	0.20 ml	3F	40 cm	1601-34
8.0 mm	0.20 ml	3F	80 cm	1601-38
10.5 mm	0.75 ml	4F	40 cm	1601-44
10.5 mm	0.75 ml	4F	80 cm	1601-48
13.0 mm	1.50 ml	5F	80 cm	1601-58
13.5 mm	1.60 ml	6F	80 cm	1601-68
14.0 mm	1.75 ml	7F	80 cm	1601-78

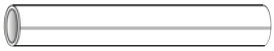
TUFTEX EMBOLECTOMY CATHETER

LifeSpan® ePTFE Vascular Grafts

7-year Shelf Life

Regular Wall *(Sterile)*

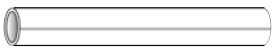
Straight



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



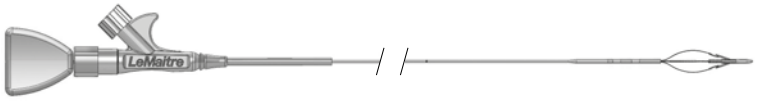
Diameter	Length	Model #
5 mm	20 cm	T05020
6 mm	20 cm	T06020
6 mm	50 cm	T06050
7 mm	50 cm	T07050
8 mm	50 cm	T08050
6 mm	80 cm	T06080
7 mm	80 cm	T07080
8 mm	80 cm	T08080
10 mm	80 cm	T10080

LeMaitre® Valvulotome

5-year Shelf Life

	Diameter	Length	Model #
LeMaitre® Valvulotome *(Sterile)* includes a Retrograde LeMills Valvulotome			
98 cm Valvulotome Kit	1.5 mm	98 cm	1009-00

LEMAITRE VALVULOTOME



LeMaitre® Valvulotome

LEMAITRE VALVULOTOME – THE NEXT GENERATION VALVULOTOME

The LeMaitre Valvulotome represents the new state of the art for valvulotomy. It features a hydrophilic coating of the outer catheter for less traumatic insertion and easier advancement with a blade range of 1.5 to 6 mm. The new depth markings along the catheter support easier valve and tributary location and aid for more controlled positioning in the vein. The modified progressing green safety stripes enable a more controlled ablation of the last distal valve. A further ergonomic design provides a better overall handling of the device.

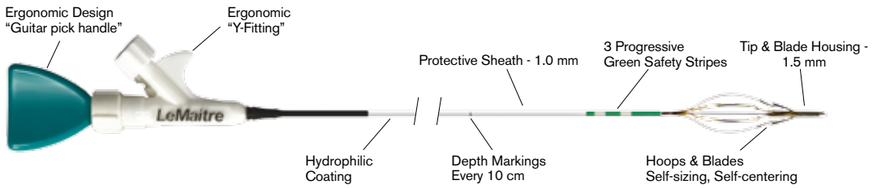
TECHNICAL DATA

Blade Housing Outer Diameter	Outer Diameter of Protective Sheath	Working Length	Overall Length	Maximum Hoop Diameter	Maximum Blade Diameter
1.5 mm	**1.0 mm**	**98 cm**	**110 cm**	**9.5 mm**	**6.0 mm**

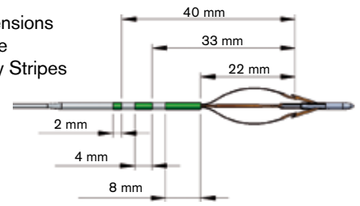
- **Hydrophylic coating**
- **3 Progressive safety stripes**
- **Blade range 1.5 to 6 mm (One size fits all)**
- **Unique self-sizing, self-centering hoops/blades**
- **Depth markers each 10 cm**
- **Irrigation port for saline injection**
- **Kit incl. 1 disposable retrograde LeMills Valvulotome**

ORDERING INFORMATION

	Working Length	Overall Length	Pack size	Model # REF
LeMaitre Valvulotome - 1.5 mm	98 cm	110 cm	1 unit per pack	1009-00



Details/Dimensions
3 Progressive
Green Safety Stripes



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®

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LeMaitre® Valvulotome

Smooth Sailing in Small Vessels

LeMaitre®

LeMaitre® Valvulotome

SMALLER 1.5 MM DIAMETER WITH HYDROPHILIC COATING

The new smaller 1.5 mm diameter and hydrophilic coating allow for easier insertion and enhanced trackability through the vein in a more atraumatic fashion. The wider blade range of 1.5 mm – 6.0 mm diameter provides valve cutting in smaller diameter veins while retaining its ability to cut valves in larger diameter vessels. This innovative device uses unique self-sizing, self-centering hoops for well positioned, clean valve cutting, decreased wound necrosis, and faster patient recovery.

Expanded Indication

The LeMaitre Valvulotome is now intended to cut venous valves during vascular procedures such as:

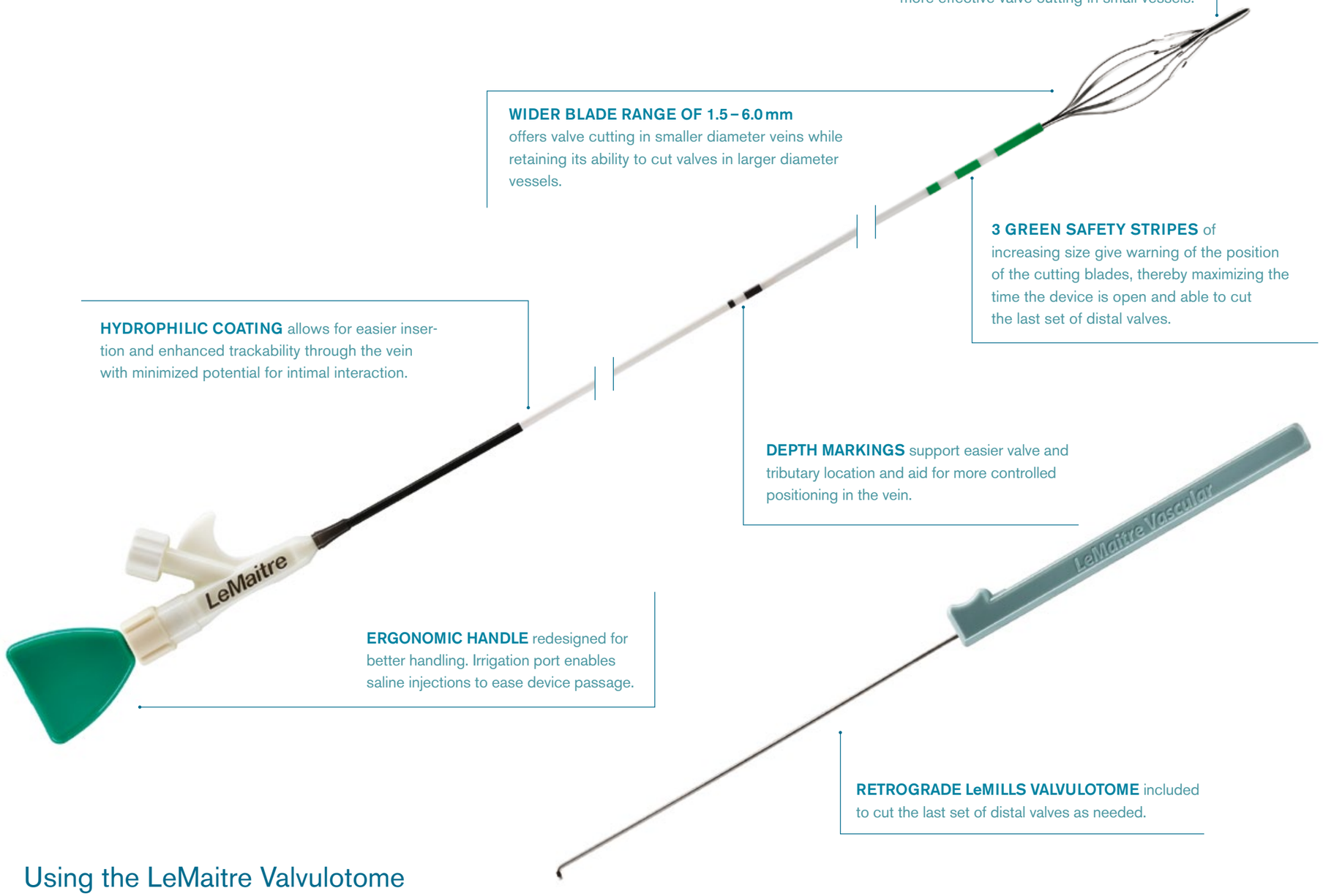
- **In-Situ Peripheral Bypass**
- **Non-reversed Translocated Peripheral Bypass**
- **Coronary Artery Bypass**
- **Arteriovenous Fistula (AVF) Creation (e.g. Proximal Radial Artery (PRA) Procedure)**

1.5 MM LEMAITRE VALVULOTOME VS 1.8 MM EXPANDABLE

- **Blades Remain Open 17% Longer**
- **Hydrophilic Coating Decreases Friction Forces by 50%***
- **Green Safety Stripes Allow Device to Stay Open in Vessel 4.8 cm Longer**

* Data on file at LeMaitre Vascular

LeMaitre®



SMALLER 1.5 mm DIAMETER offers more effective valve cutting in small vessels.

WIDER BLADE RANGE OF 1.5 – 6.0 mm offers valve cutting in smaller diameter veins while retaining its ability to cut valves in larger diameter vessels.

3 GREEN SAFETY STRIPES of increasing size give warning of the position of the cutting blades, thereby maximizing the time the device is open and able to cut the last set of distal valves.

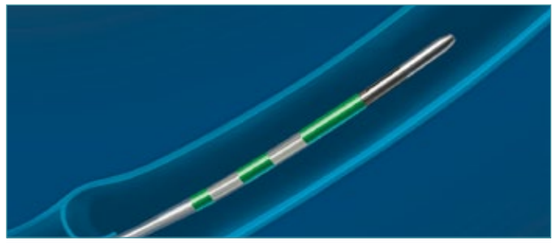
HYDROPHILIC COATING allows for easier insertion and enhanced trackability through the vein with minimized potential for intimal interaction.

DEPTH MARKINGS support easier valve and tributary location and aid for more controlled positioning in the vein.

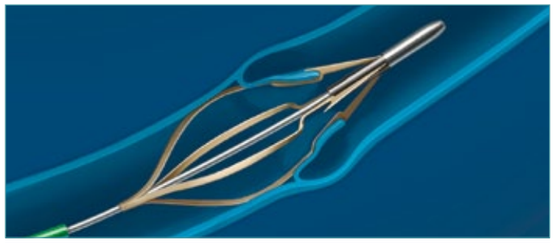
ERGONOMIC HANDLE redesigned for better handling. Irrigation port enables saline injections to ease device passage.

RETROGRADE LeMILLS VALVULOTOME included to cut the last set of distal valves as needed.

Using the LeMaitre Valvulotome



STEP 1 Advance the valvulotome in the closed position 2 – 3 cm distal to the proximal anastomosis. The blades must be above the first set of competent valves.



STEP 2 Open the valvulotome and slowly withdraw the instrument through the saphenous vein. The self-sizing, self-centering hoops automatically adjust to vein diameter for optimal valve cutting.

STEP 3 Three green safety stripes of increasing size give warning of the position of the cutting blades. Close blades of Valvulotome when the third and final green safety stripe appears outside of saphenous vein before withdrawing the instrument.