

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

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: 01 January 2019

Expiry Date: 30 June 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 Catheter TRIVEX System Pruitt® Irrigation Occlusion Catheter Pruitt® Occlusion Catheter Pruitt® Aortic Occlusion Catheter Distal Perfusion Catheter Reddick® Cholangiogram Catheter Reddick® Scoop Tip Cholangiogram Catheter Expandable LeMaitre® Valvulotome 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: 24

Date of Schedule Issue: 01 January 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

LeMaitre® Embolectomy Catheters

ORDERING INFORMATION

Balloon Diameter	Balloon Volume	Diameter	Color	Length	Guidewire	Model #
Over-the-Wire Embolectomy Catheter Compatible with standard guidewire sizes. Stopcock and syringe included.						
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	5F	White	40 cm	.028"	1651-54
12 mm	1.50 ml	5F	White	80 cm	.028"	1651-58
12 mm	1.50 ml	5F <i>Plus</i>	White	40 cm	.035"	1651-84
12 mm	1.50 ml	5F <i>Plus</i>	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						
4.5 mm	0.05 ml	2F	Purple	40 cm		1601-24
4.5 mm	0.05 ml	2F	Purple	60 cm		1601-26
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						
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

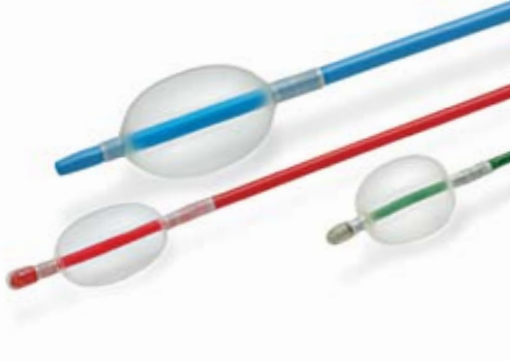
LeMaitre Catheter Rack Catheter rack compatible for all single lumen, over-the-wire, and latex-free catheters.	
Catheter Rack	A3000-00
Wall Mount	A3000-01

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.



Your Peripheral Vision™

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LeMaitre® Embolectomy Catheters

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For More Information:

Contact your local LeMaitre
Vascular Sales Representative.

For Customer Service:

Call 800 628 9470

www.lemaitre.com



Your Peripheral Vision™

5F *Plus* featuring two radiopaque bands for visibility



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

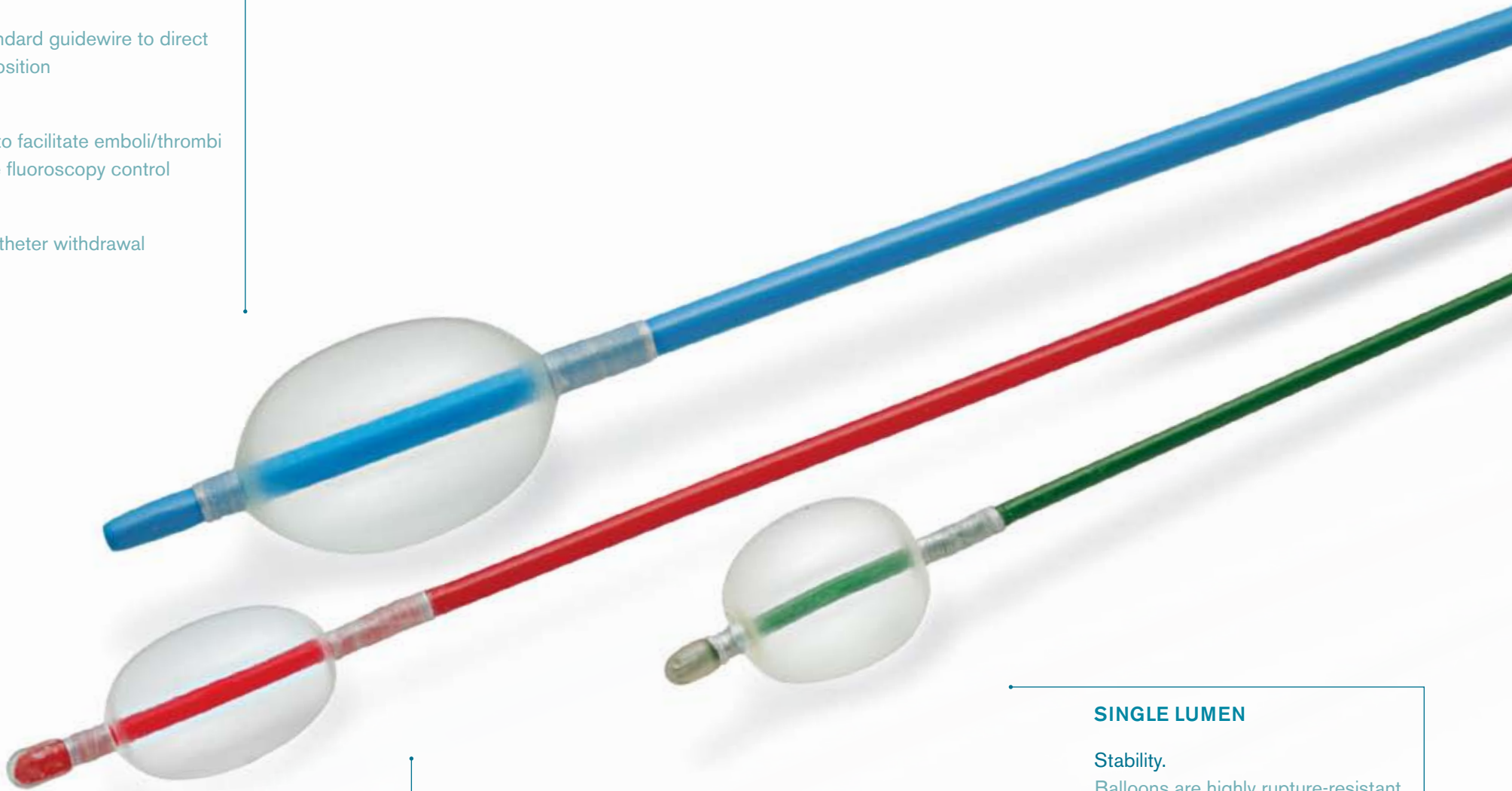
Sterile.
Three-year sterility for latex balloons; five-year for latex-free

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 during catheter withdrawal



SINGLE LUMEN

Stability.
Balloons are highly rupture-resistant

Concentricity.
Balloons are well-centered

Progressive Inflation.
Balloons inflate at consistent rate as volume increases

LeMaitre also offers NovaSil® **LATEX-FREE** Catheters. This line of premium quality silicone balloon catheters provides a latex-free option for latex sensitivity.

5F PLUS



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