

**Pruitt F3® Carotid Shunts**

**The Next Generation Balloon Shunt**

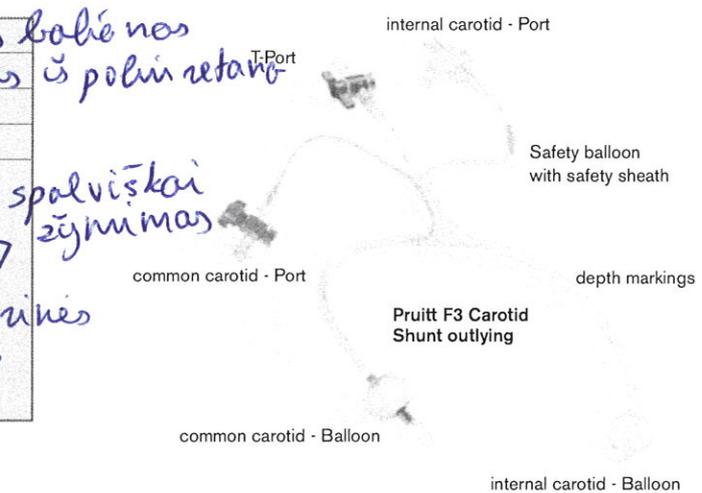
The Pruitt F3 Carotid Shunt is made of a flexible polyurethane material that is also more resistant to kinking\*. The inflation lumen and the common carotid balloon are color-coded (blue) for easy identification. The Pruitt F3 Carotid Shunt has a 10% increased flow over the original Pruitt-Inahara Carotid Shunt\*.

**Atraumatic Dual Balloon Occlusion: No Clamping**

Dual-balloon design for fast, easy insertion and atraumatic no-clamp occlusion of internal and common carotid arteries. Smaller incision, less dissection and shorter arteriotomy. The balloons hold the artery open for better visualization of plaque end points.

**TECHNICAL DATA**

<b>Balloon Material:</b>	Latex <i>lateksinis balonas</i>
<b>Shunt Material:</b>	Polyurethane <i>šuntas iš poliuretano</i>
<b>Length:</b>	15 cm or 31 cm
<b>Shelf Life:</b>	5 years
<ul style="list-style-type: none"> <li>• T-port with stopcock (red)</li> <li>• Color coded stopcocks</li> <li>• Color coded common carotid balloon (blue)</li> <li>• Color coded inflation lumen (blue, clear)</li> <li>• <u>Centimeter depth markings</u> <i>centimetrinės žymės</i></li> <li>• Safety sheath</li> <li>• Safety balloon</li> </ul>	



*ilgis*

*Kedės*

**Pruitt F3 Outlying Carotid Shunts**

Length

Pack size

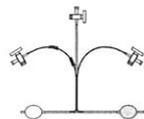
Model # [REF]

- 8F Pruitt F3 Shunt with T-Port
- lygin* 9F Pruitt F3 Shunt with T-Port
- 10F Pruitt F3 Shunt with T-Port

- 31 cm
- 31 cm
- 31 cm

- 1 unit per pack
- 1 unit per pack
- 1 unit per pack

- 2013-10
- 2012-10 *30 pcc.*
- 2011-10



**Pruitt F3 Inlying Carotid Shunts**

Length

Pack size

Model # [REF]

- 9F Pruitt F3 Shunt with T-Port
- 10F Pruitt F3 Shunt with T-Port

- 15 cm
- 15 cm

- 1 unit per pack
- 1 unit per pack

- 2012-12
- 2011-12

\* Data on file at LeMaitre Vascular, Inc.

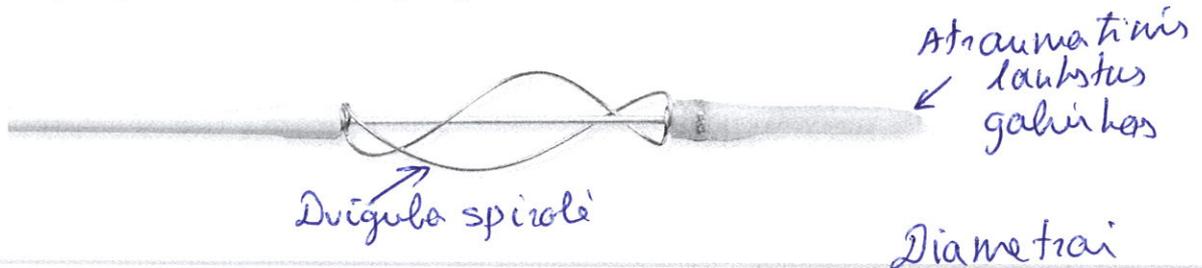
31.poz.

# Fogarty tromblektomijos kateteris dirbtinėms kraujagyslėms

## Fogarty® Graft Thrombectomy Catheters

Designed for removing organised thrombus and adherent thrombotic material from synthetic bypass grafts, specifically, AV fistulas for dialysis access and grafts for iliofemoral bypass

- For extracting thrombus too resistant for an elastomeric balloon
- Provides a larger diameter range than the Fogarty® adherent clot catheter
- The pulling force can be varied by adjusting the diameter



### Fogarty® graft thrombectomy catheters

Dydis

1 unit per tube pack

Color	Model number	Usable length (cm)	Catheter size (F)	Membrane/spiral diameter max. extended (mm)	Membrane/spiral diameter max. retracted (mm)
Spalva Kodas		Ilgis			
○	160245F 31.1	50	5	5.0	16
●	160246F 31.2	50	6	6.0	18

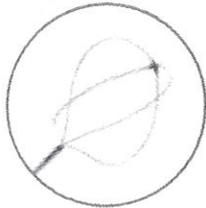
Ranke vėl su užraktu funkcija





# Kobot Stone extractor

## Nitinol Stone Retrieval Tipless Basket



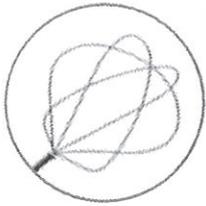
### KOBOT TIPLESS

- 4 wire basket



### ⇒ KOBOT™ CRITERIUM HANDLE

Available with assisted closing System

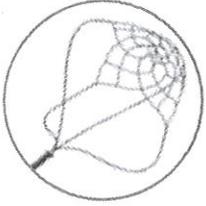


### KOBOT SIX

- 6 wire basket

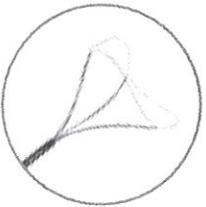
*Be golinko (Tipless)*

*44*



### KOBOT FILTER

- 4/16 wire filter

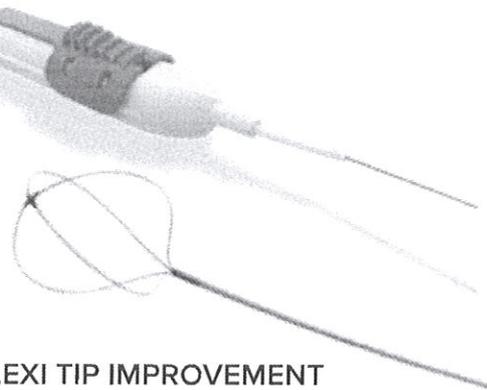


### KOBOT MITT

- 3 wire

### ⇒ FLEXI TIP IMPROVEMENT

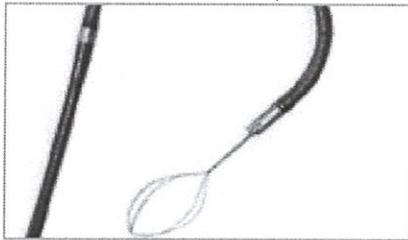
For a better scope deflection



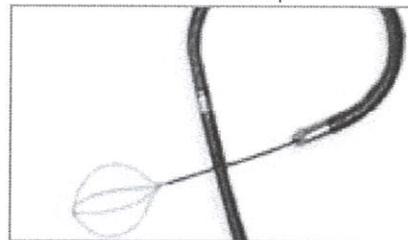
All supplied with Tuohy Borst Connector



Without Flexi-Tip



With Flexi-Tip



*Koden*      *Dyelis*      *Jlejis*

Ref.	Size Fr	Wire	Working Length (cm)	Basket Ø (mm)	Basket Length (mm)	Basket description
ROSZ1930ST	1.9	4	120	12	17.5	Kobot TIPLESS
ROSZ1940ST	1.9	4	120	12	17.5	Kobot TIPLESS with assisted Closing system
ROKT1800ST	1.8	4/16	120	14	18	Kobot FILTER
<b>ROKS1700ST</b>	<b>1.7</b>	6	<b>120</b>	11	15	<u>Kobot SIX</u>
ROKM1900ST	1.9	3	120	10	10	Kobot MITT

*44.*



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



KONFIDENZ



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 0013 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\\_0013\\_Rev.00](http://www.tuvsud.com/ps-cert?q=cert:G1_060725_0013_Rev.00)

**Report No.:**

72164019 - 72164084

**Valid from:**

2021-05-21

**Valid until:**

2024-05-26

KOPIJA TIKRA

Direktorin

**Date,**

2021-05-21

C

Head of Certification/Notified Body

## EC Sertifikatas

Kokybės Užtikrinimo Sistema

Direktyva 93/42/EEC Medicinos prietaisams, Priedas II išskyrus 4 skirsnį  
(Priemonės, priskirtos klasėms IIa, IIb ir III)

KONFIDENCIALU

Nr. G1 060725 0013 Rev. 00

**Gamintojas:** LeMaitre Vascular, Inc.  
63 Second Avenue  
Burlington MA 01803  
JAV

**Produktai:** Vieno liumeno embolektominiai kateteriai; silikoniniai vieno liumeno embolektominiai kateteriai; irigaciniai okliuziniai kateteriai; okliuziniai kateteriai; aortos okliuziniai kateteriai; distalinės perfuzijos kateteriai; ant vielos maunami valvulotomai; valvulotomai; kontrasto injektoriai; priemonės endarterektomijai; disektoriai; ištraukimo priemonės; vienkartiniai angioskopai; biologiniai lopinėliai; sintetiniai kraujagyslių protezai.

TUV SUD Product Service GmbH sertifikavimo įstaiga pareiškia, kad aukščiau minėtas gamintojas įdiegė atitinkamų prietaisų / prietaisų kategorijų projektavimo, gamybos ir galutinio tikrinimo kokybės užtikrinimo sistemą pagal MDD II priedą. Ši kokybės užtikrinimo sistema atitinka šios direktyvos reikalavimus ir yra periodiškai prižiūrima. Prekiaujant III klasės prietaisais, būtinas papildomas II priedo 4 dalies sertifikatas. Turi būti laikomasi visų taikomų TUV SUD Group testavimo ir sertifikavimo reglamento reikalavimų. Dėl sertifikato galiojimo žiūrėti: [www.tuvsud.com/ps-cert?q=cert:G10607250013REV.00](http://www.tuvsud.com/ps-cert?q=cert:G10607250013REV.00)

Pranešimo Nr.: 72164019 - 72164084

Išgaliojimo data: 2021-05-21

Galioja iki: 2024-05-26

Išdavimo data: 2021-05-21

/Parašas/  
Christoph Dicks

Vertimas tikras





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 conjunction 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:

Addendum Date  
N/A

Reason for Addendum  
N/A

Authorised by

Global Medical Devices Head of Notified Body

## SGS Belgium NV, Notified Body 1639

SGS House Noordertaan 87 2030 Antwerp Belgium  
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5009 - Certificate CE1639 Annex II section 4 ECDE Rev. 2

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## CE Declaration of conformity

We, ROCAMED France, ZI de Signes, Allée de Stockholm, 83870 Signes FRANCE, declare under our full responsibility that the medical devices:

Medical Devices for Urological and Endoscopy.  
Single-use, Sterile, Implantable or Not-Implantable Medical devices.  
**Family ROS**

fulfil the dispositions of the Council Medical Device European directive 93/42/EEC of 14 June 1993 and to its transposition into the applicable Part V Book II of the French Public Health Code.

The conformity of these products is based on:

- The technical file (CE marking file) established in accordance with point 3 of Annex VII of the Medical Device Directive 93/42/EEC.
- The CE Conformity Certificate number n°29628 rev.9 following annex V point 3 of the Medical Device Directive 93/42/EEC (Approval of the Production Quality Assurance System related to securing and maintaining sterile conditions), delivered by the G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15, France, registered number 0459.

This statement applies to all devices listed in Annex 1 of this document.

Monaco, May 18<sup>th</sup>, 2021

**ROCAMED**  
Stockholm  
SIGNES  
80 706 00021  
- Fax : 04 94 98 60 55

Tahiana Rasolotomana  
*Regulatory Affairs Specialist*

**Annex 1 – Family ROS Product List**

Reference	Designation of the product	Class.
ROKM1900ST	Kobot Mitt Stone Extractor – Ø 10mm ; 1.9Fr ; 120cm	Is
ROKS1700ST	Kobot Six Stone Extractor – Ø 11mm ; 1.7Fr ; 120cm	Is
ROKT1800ST	Kobot Filter Stone Extractor – Ø 14mm ; 1.8Fr ; 120cm	Is
ROSZ1930ST	Kobot Tipless Stone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm	Is
ROSZ1940ST	Kobot Tipless Stone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm with assisted Closing system	Is
ROSZ1300ST	Kobot Tipless Stone Extractor – Ø 12mm ; 1.3Fr ; 120cm	Is
ROSZ1900ST	Kobot Tipless Stone Extractor – Ø 16mm : 1.9Fr ; 120cm	Is
ROSZ2200ST	Kobot Tipless Stone Extractor – Ø 16mm ; 2.2Fr ; 120cm	Is
ROSH2500ST	RocaStone Extractor – Ø 11,5mm Helical ; 2.5Fr ; 120cm	Is
ROSH2590ST	RocaStone Extractor – Ø 11,5mm Helical ; 2.5Fr ; 90cm	Is
ROSH4000ST	RocaStone Extractor – Ø 16mm Helical ; 4Fr ; 120cm	Is
ROSS2500ST	RocaStone Extractor – Ø 13,5mm Straight ; 2.5Fr ; 120cm	Is
ROSS2590ST	RocaStone Extractor – Ø 13,5mm Straight ; 2.5Fr ; 90cm	Is
ROSS4000ST	RocaStone Extractor – Ø 16mm Straight ; 4Fr ; 120cm	Is
ROSZ1910ST	Tipless RocaStone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm	Is
ROSZ1920ST	Tipless RocaStone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm	Is
ROSZ3000ST	RocaStone Tipless Stone Extractor – Ø 16mm straight; 3Fr ; 120cm	Is
ROSZ3030ST	RocaStone Tipless Stone Extractor – Ø 12mm straight; 3Fr ; 90cm	Is
ROMA0000ST	Assisted arm for flexible ureteroscopy	Is
ROXE03807ST	X-Filter – Stone Management Device - 7 cm tip Proximal Stone	Is
ROXE03812ST	X-Filter – Stone Management Device - 12cm tip length Mid Distal Stone	Is
ROXE363609ST	X-Filter™ – Anti-migration device - 9cm / 3,6Fr Ø12mm 3,6Fr 150cm	Is

**ROCAMED**  
Allée de Stockholm  
83870 SIGNES  
Siret n° 440 880 706 00021  
Tel. : 04 94 90 54 00 - Fax : 04 94 98 60 55

## Declaration of Conformity Statement

I, Erica Tartaglione, Head of Regulatory and Quality Affairs Rocamed,

declares that:

- the Medical Devices indicated within Annex 1 and belonging to the **ROS Family** was certified under the medical Device Directive 93/42/EEC before May 26th, 2021.
- the CE Certificates n° 29628 is valid until May 26<sup>th</sup>, 2024, but will be valid until December 2028 because we asked the certification under MDR (extension of Period of Grace, Legislative amendments implemented in February 2023).

The declaration of conformity signed after May 26th, 2021 (on January 19<sup>th</sup>, 2023) remains valid until the CE certificate is valid.

Monaco, February 16<sup>th</sup>, 2024

**ROCAMED France**

Allée de Stockholm

83870 SIGNES

Siret n° 440 880 706 00021

Tél. : 04 94 90 54 00 - Fax : 04 94 98 60 55

Erica Tartaglione  
Head of Regulatory and Quality Affairs  
Rocamed

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### Rocamed SAM

S.S.E.E. 4618 Z1 5522 – R.C.I. 13 S 05920  
N° individuel d'identification FR62000100056

Le Copori – 9, avenue Albert II – MC 98000 MONACO  
Tel. +377 97 98 42 43 – Fax +377 92 05 61 50  
e-mail: [info@rocamed.com](mailto:info@rocamed.com)

### Rocamed France

SIRET : 44088070600021 N° TVA : FR85440880706  
Code NAF : 3250A RCS Toulon 440 880 706

Parc d'activités de Signes - Allée de Stockholm - 83870 Signes  
Tel. : 04 94 90 54 00 Fax : 04 94 98 60 55  
Adresse postale : BP 719 83030 Toulon Cedex 9

## Annex 1 – Family ROS product list

Reference	Designation of the product	Class.
ROKM1900ST	Kobot Mitt Stone Extractor – Ø 10mm ; 1.9Fr ; 120cm	Is
ROKS1700ST	Kobot Six Stone Extractor – Ø 11mm ; 1.7Fr ; 120cm	Is
ROKT1800ST	Kobot Filter Stone Extractor – Ø 14mm ; 1.8Fr ; 120cm	Is
ROSZ1930ST	Kobot Tipless Stone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm	Is
ROSZ1940ST	Kobot Tipless Stone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm with assisted Closing system	Is
ROSZ1300ST	Kobot Tipless Stone Extractor – Ø 12mm ; 1.3Fr ; 120cm	Is
ROSZ1900ST	Kobot Tipless Stone Extractor – Ø 16mm ; 1.9Fr ; 120cm	Is
ROSZ2200ST	Kobot Tipless Stone Extractor – Ø 16mm ; 2.2Fr ; 120cm	Is
ROSH2500ST	RocaStone Extractor – Ø 11,5mm Helical ; 2.5Fr ; 120cm	Is
ROSH2590ST	RocaStone Extractor – Ø 11,5mm Helical ; 2.5Fr ; 90cm	Is
ROSH4000ST	RocaStone Extractor – Ø 16mm Helical ; 4Fr ; 120cm	Is
ROSS2500ST	RocaStone Extractor – Ø 13,5mm Straight ; 2.5Fr ; 120cm	Is
ROSS2590ST	RocaStone Extractor – Ø 13,5mm Straight ; 2.5Fr ; 90cm	Is
ROSS4000ST	RocaStone Extractor – Ø 16mm Straight ; 4Fr ; 120cm	Is
ROSZ1910ST	Tipless RocaStone Extractor – Ø 12mm Mini ; 1.9Fr ; 120cm	Is
ROXE363609ST	X-Filter™ – Anti-migration device - 9cm / 3,6Fr Ø12mm 3,6Fr 150cm	Is

### Rocamed SAM

S.S.E.E. 4618 Z1 5522 – R.C.I. 13 S 05920  
N° individuel d'identification FR62000100056

Le Copori – 9, avenue Albert II – MC 98000 MONACO  
Tel. +377 97 98 42 43 – Fax +377 92 05 61 50  
e-mail: [info@rocamed.com](mailto:info@rocamed.com)

### Rocamed France

SIRET : 44088070600021 N° TVA : FR85440880706  
Code NAF : 3250A RCS Toulon 440 880 706

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Adresse postale : BP 719 83030 Toulon Cedex 9