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 Vladimir
Date: 2021.12.23 16:46:21 EET
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
t +44 (0)151 3506666 www.sgs.com
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®

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

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

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

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

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

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

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

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LeMaitre®

2021 EMEA Product Overview

Updated: August 2021

www.lemaitre.com

LeMaitre®

LeMaitre®

2021 EMEA Product Overview

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

Tel: +49 (0) 6196 65923-0

Fax: +49 (0) 6196 527072

Email: infogmbh@lemaitre.com

Online

www.lemaitre.com

Customer Service

Customer Service is available Monday through Friday, 8.30 am to 5.30 pm CET.

Terms and Conditions

Prices are subject to change without notice.

All applicable taxes will be charged.

Payment terms are Net 30 Days.

Delivery Conditions

FCA (Incoterm 2010), Sulzbach Germany

Shelf Life

The recommended shelf life is printed on the product's package, varying by product line. Shelf life data is also available on page 31. Clinical use after expiration date is NOT recommended. Single-use products cannot be resterilized.

Customer Service Contacts

Austria: Tel. +43 1 272 99 15, csat@lemaitre.com
Belgium: Tel. +49 6196 65923-0, csbe@lemaitre.com
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Finland: Tel. +35 800 917763, csfi@lemaitre.com
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United Kingdom: Tel. **+44 1432 513125**, csuk@lemaitre.com

www.lemaitre.com

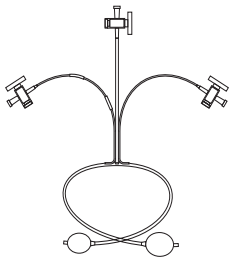
LeMaitre®

Pruitt F3®
Carotid Shunt

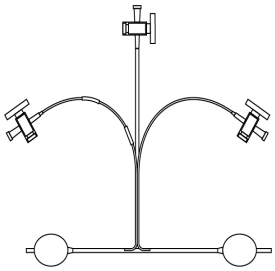
5-year Shelf Life Latex
2-year Shelf Life Polyurethane

	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



TufTex®
Embolectomy Catheter

6-year Shelf Life

TufTex® Embolectomy Catheter *(Sterile)*

Balloon Diameter	Balloon Volume	Diameter	Length	Model #
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

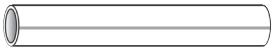
TUFTEX EMBOLECTOMY CATHETER

LifeSpan®
ePTFE Vascular Grafts

7-year Shelf Life

Regular Wall *(Sterile)*

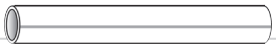
Straight



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



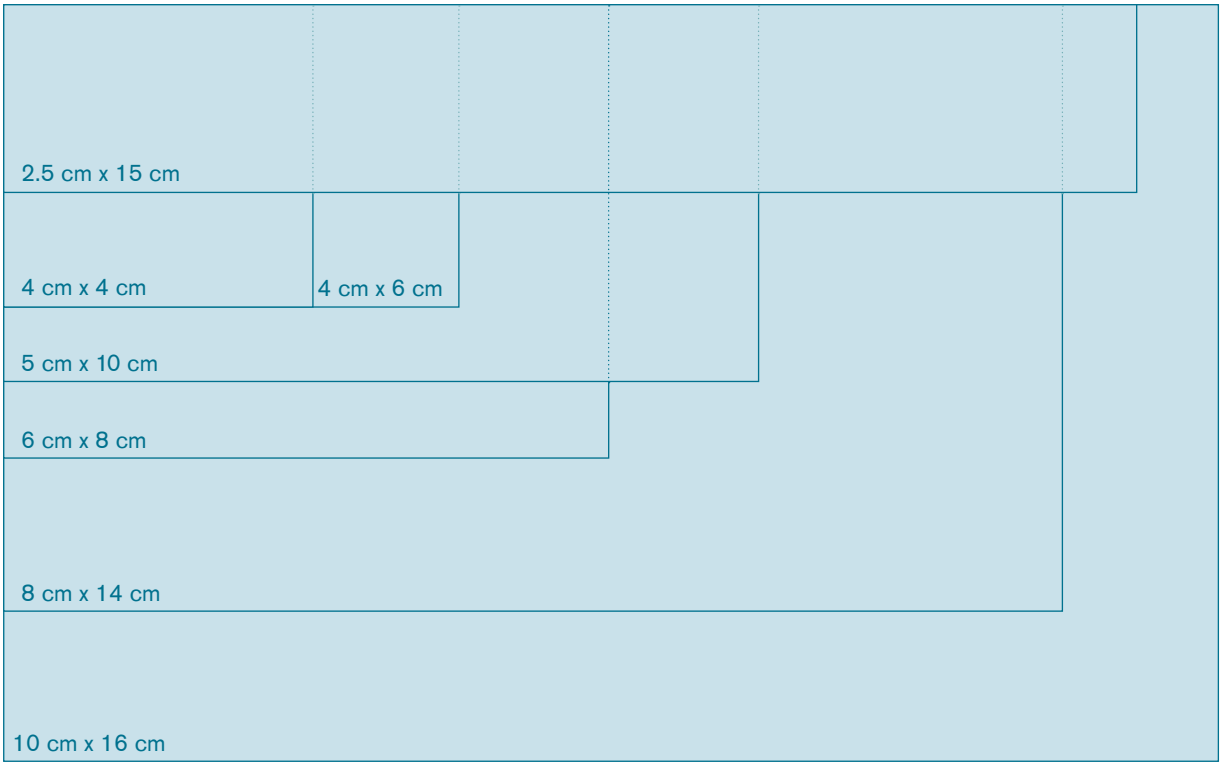
Diameter	Length	Model #
5 mm	20 cm	T05020
6 mm	20 cm	T06020
6 mm	50 cm	T06050
7 mm	50 cm	T07050
8 mm	50 cm	T08050
6 mm	80 cm	T06080
7 mm	80 cm	T07080
8 mm	80 cm	T08080
10 mm	80 cm	T10080

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
Biologic Surgical Patch	12 cm	25 cm	12BV25*

*Model e12**BV**25 is made to order.



Model # 12BV25, 12cm x 25cm (Not Pictured)

XenoSure®
Biologic Patch

EXCEPTIONALLY STRONG, UNIFORM AND EASY TO SUTURE

The XenoSure Biologic Patch is a high-quality bovine pericardium patch used for vascular and cardiovascular repair and reconstructions, suture line reinforcement or soft tissue deficiency repair. Using the same tissue technology developed for heartvalves, the XenoSure patch is exceptionally strong, uniform, easy to handle and suture. The patch material is sourced from the USA or Australia/New Zealand (countries according to OIE-World Organisation for Animal Health classification: "negligible BSE risk").

ORDERING INFORMATION

XenoSure® Biologic Patch (Bovine Pericardium)

Dimension	Model # REF	Rinse Procedure**
6 mm x 80 mm	0.6BV8	500 ml for 2 minutes
8 mm x 80 mm	0.8BV8	
10 mm x 60 mm	1BV6	
10 mm x 100 mm	1BV10	
10 mm x 140 mm	1BV14	
15 mm x 100 mm	1.5BV10	
20 mm x 90 mm	2BV9	
25 mm x 150 mm	2.5BV15	
40 mm x 40 mm	4BV4	
40 mm x 60 mm	4BV6	
50 mm x 100 mm	5BV10	1000 ml for 3 minutes
60 mm x 80 mm	6BV8	
80 mm x 140 mm	8BV14	
100 mm x 160 mm	10BV16	
120 mm x 250 mm	12BV25	

Nominal thickness specification range: 0.6BV8, 0.8BV8, 1BV6, 2BV9 0.45 + 0.15/-0.10 mm, all other larger patches 0.55 ± 0.20 mm

TYPICAL APPLICATIONS:

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

- Reconstruction of large vessels
- Pericardial and ASD / VSD closure
- Cardiac repair procedures
- Heart valve reconstructions
- Soft tissue deficiency

- Dura closure during neuro-surgical procedures*

BENEFITS:

- Biocompatible
- Exceptional tensile and suture retention strength***
- Does not require special sutures
- Uniform collagen thickness results in easier suturing

HANDLING:

- Similar to autologous tissue
- Excellent handling characteristics
- Easily trimmed to desired shape or size

* since June 2014 - please consult Instruction For Use (IFU) of the actual product.
** please consult the actual Instruction For Use (IFU) on our website.
*** data on file at LeMaitre Vascular

eifu.LeMaitre.com

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
Your Peripheral Vision™

CE 0088

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www.lemaitre.com

XenoSure®
Biologic Patch

Exceptionally Strong, Uniform and Easy to Suture

- Vascular & Cardiac Repair
- Suture Line Reinforcement
- Soft Tissue Deficiency Repair
- **NEW** – Dura Repair

LeMaitre® VASCULAR

Your Peripheral Vision™

XenoSure®
Biologic Patch

EXCEPTIONALLY STRONG, UNIFORM AND EASY TO SUTURE

The XenoSure® Biologic Patch is a high-quality bovine pericardium patch used for vascular and cardiovascular reconstructions, suture line reinforcement, soft tissue deficiency repair or dura repair. Using the same tissue technology developed for heartvalves, the XenoSure patch is exceptionally strong, uniform, easy to handle and suture. The patch material is sourced from the USA or Australia/New Zealand (countries according to OIE-World Organisation for Animal Health classification: “negligible BSE risk”).

ANTIBIOTICS IN RINSE SOLUTION*

At the surgeon’s discretion the rinse solution may contain bacitracin (500 U/mL) or cephalexin (10 mg/mL), as testing has shown that the XenoSure® bovine pericardial patch material is not adversely affected by treatment with those antibiotics. The effects of other antibiotics or the long term effects of these antibiotics on the XenoSure® bovine pericardial patch material have not been tested. Use antibiotics only as indicated by the antibiotics manufacturer.

XenoSure Rinse Procedure*

0.6BV8, 0.8BV8, 1BV6, 1BV10, 1.5BV10, 2BV9, 1BV14, 2.5BV15, 4BV4, 4BV6 or any custom made size less or equal to 37.5 cm²

- **2 minutes in 500 ml saline****

1. Fill basin with 500 ml sterile saline
2. Remove patch with atraumatic forceps
3. Gently agitate patch in saline for 2 min.
4. Leave in saline until required by surgeon

5BV10, 6BV8, 8BV14, 10BV16, 12BV25 or any custom made size greater than 37.5 cm²

- **3 minute rinses in 1000 ml saline****

1. Fill basin with 1000 ml sterile saline
2. Remove patch with atraumatic forceps
3. Gently agitate patch in saline for 3 min.
4. Leave in saline until required by surgeon

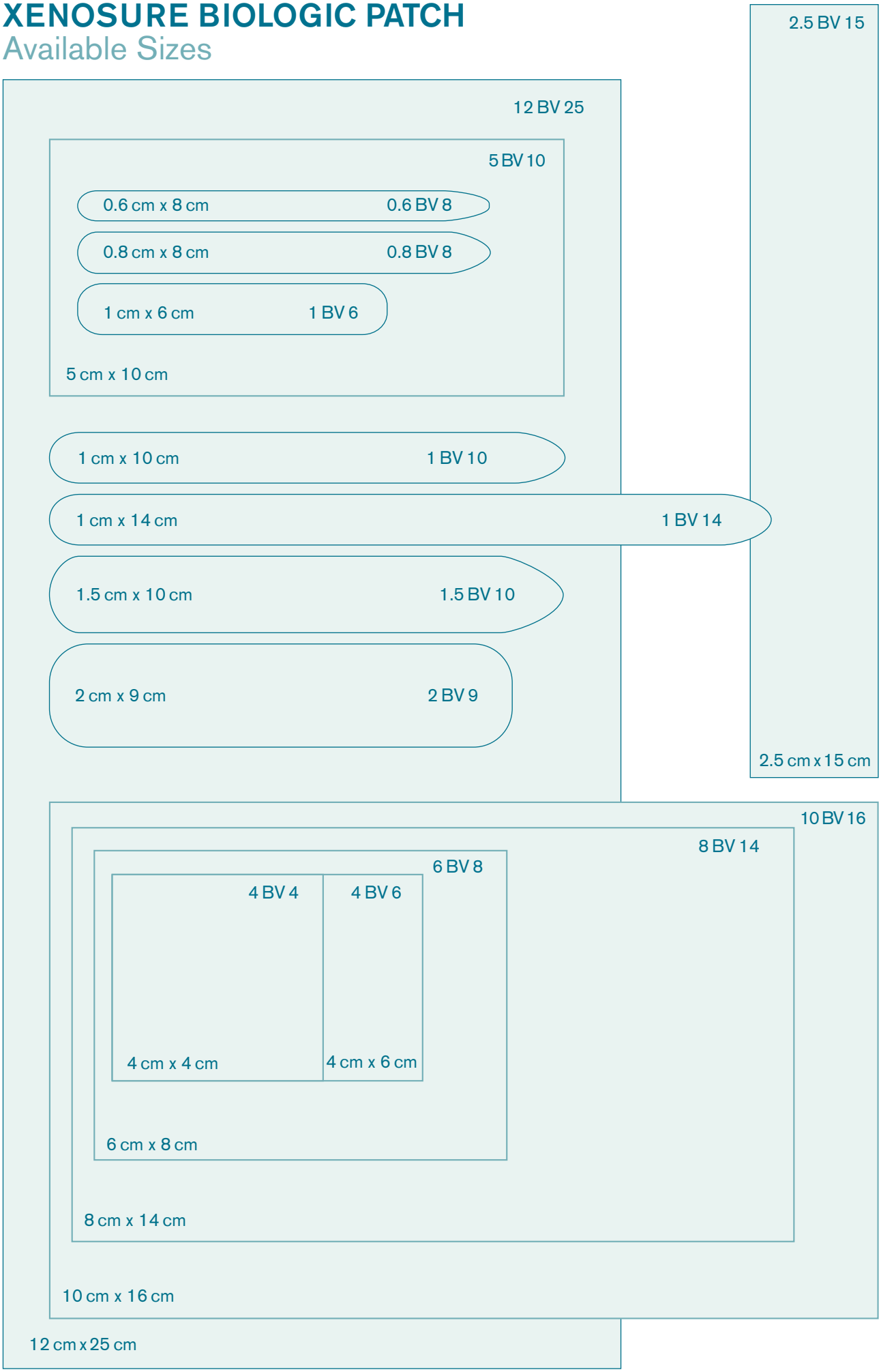
* please consult the actual Instruction For Use (IFU) on our website. eifu.LeMaitre.com

** sterile physiological saline solution (e.g. 0.9% NaCl)

LeMaitre® VASCULAR

Your Peripheral Vision™

XENOSURE BIOLOGIC PATCH
Available Sizes

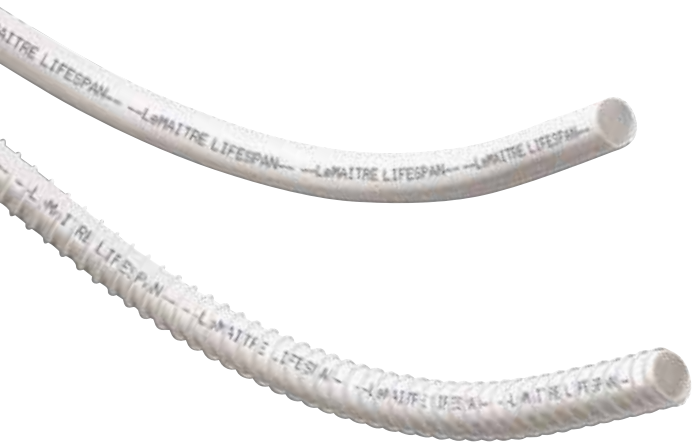


LifeSpan®
ePTFE Vascular Graft

- For Peripheral Reconstructions and Vascular Access
- Proven Performance[1]
- Excellent Handling
- Superb Suture Retention

LeMaitre® VASCULAR

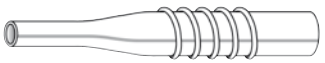
Your Peripheral Vision™



- PERIPHERAL AND VASCULAR ACCESS
- PROVEN PERFORMANCE[1]
- 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 Access[2]. 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

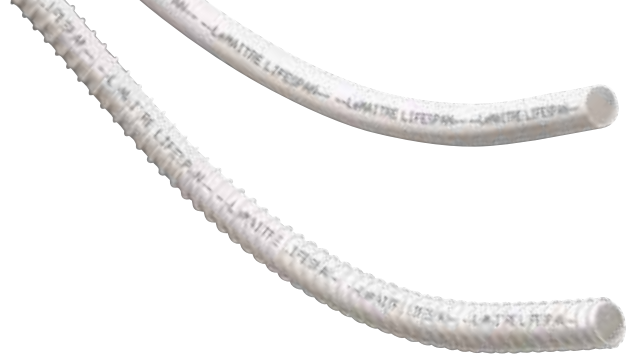
* products not for sale in the U.S.

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 PERFORMANCE[1]

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 PERFORMANCE[1]**
- **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** - **e**xpanded **P**oly**T**etra**F**luro**E**thylene
External Spiral Support:	**PTFE** - **P**oly**T**etra**F**luro**E**thylene
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 Strength[3]:	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

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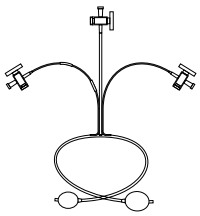
www.lemaitre.com

Pruitt F3™
Carotid Shunt

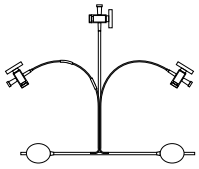
ORDERING INFORMATION

Pruitt F3 Outlying Carotid Shunt



		Model #
8F Pruitt F3 Shunt with T-Port Length 31 cm	1 Pack	2013-10
9F Pruitt F3 Shunt with T-Port Length 31 cm	1 Pack	2012-10
10F Pruitt F3 Shunt with T-Port Length 31 cm	1 Pack	2011-10

Pruitt F3 Inlying Carotid Shunt



		Model #
9F Pruitt F3 Shunt with T-Port Length 15 cm	1 Pack	2012-12
10F Pruitt F3 Shunt with T-Port Length 15 cm	1 Pack	2011-12

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.

The Pruitt F3 Benefits

- ATRAUMATIC DUAL BALLOON OCCLUSION for internal and common carotid arteries.
- INCREASED FLOW RATE over the original Pruitt-Inahara Shunt.
- Designed with a MORE FLEXIBLE material that is also more RESISTANT TO KINKING.
- COLOR-CODED COMMON CAROTID ARTERY INFLATION LUMEN and depth markings highlight the inflation path leading from the blue stopcock to the blue balloon.
- T-PORT for infusion and flushing, monitoring blood flow and blood pressure, patency, and safely removing embolic particles. Smaller inner diameter lowers likelihood of particles entering the shunt.
- SAFETY SHEATH is tinted yellow to enhance visibility. If the internal common carotid over-inflates, the extra pressure is diverted to the safety balloon, preventing arterial damage.
- DEPTH MARKINGS (1 cm) indicate insertion length of the shunt in the carotid arteries.

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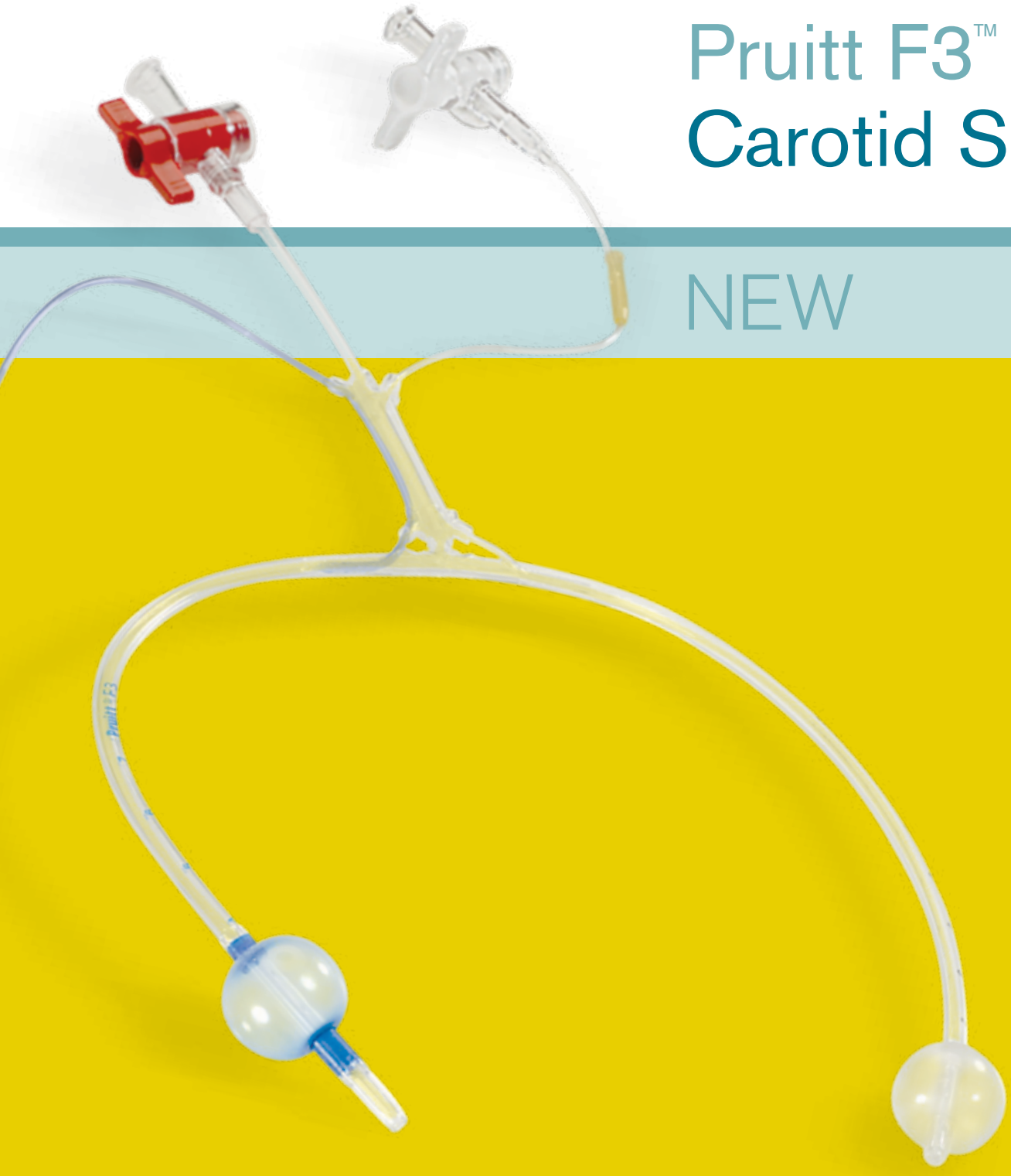
Pruitt F3™
Carotid Shunt

NEW



LeMaitre® VASCULAR

Your Peripheral Vision™

Pruitt F3™
Carotid Shunt

THE NEXT GENERATION BALLOON SHUNT

The Pruitt F3 Carotid Shunt is made with a flexible material that is also more resistant to kinking,* is color-coded for easy identification, and has 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. Balloons hold artery open for better visualization of plaque end points.

* Data on file at LeMaitre Vascular, Inc.

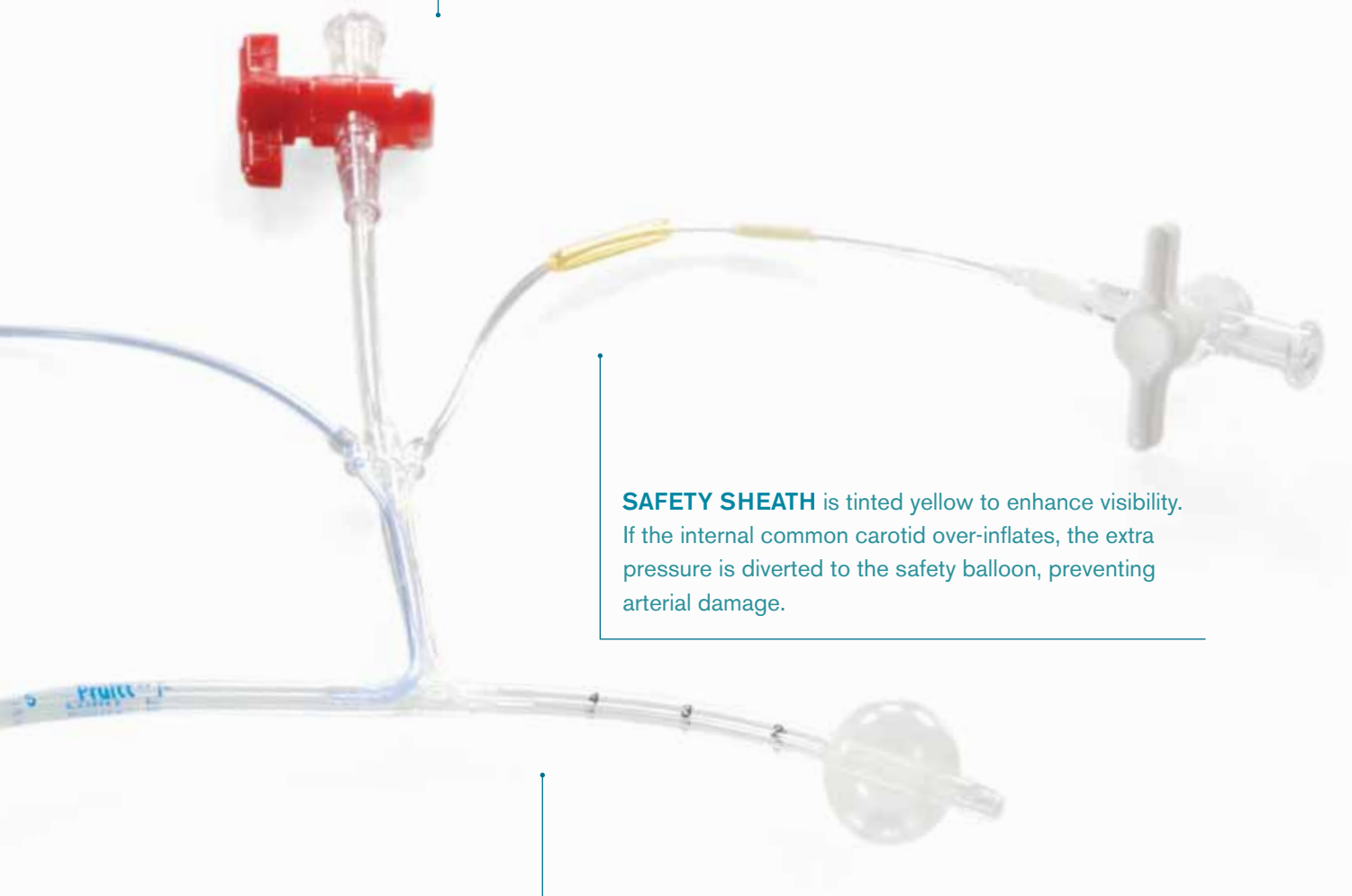
The Pruitt F3 is designed with a more **FLEXIBLE** material that is also more **RESISTANT TO KINKING.**

COLOR-CODED COMMON CAROTID ARTERY INFLATION LUMEN and depth markings highlight the inflation path leading from the blue stopcock to the blue balloon.

LeMaitre® VASCULAR

Your Peripheral Vision™

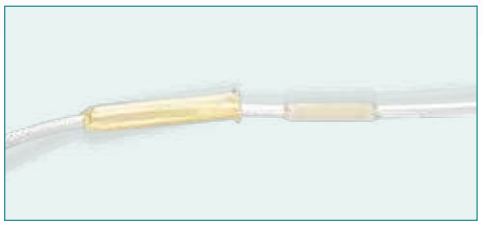
T-PORT for infusion and flushing, monitoring blood flow, blood pressure, patency, and safely removing embolic particles. Smaller inner diameter lowers likelihood of particles entering the shunt.



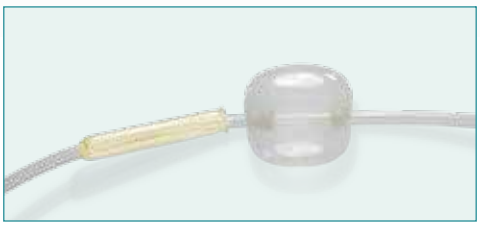
SAFETY SHEATH is tinted yellow to enhance visibility. If the internal common carotid over-inflates, the extra pressure is diverted to the safety balloon, preventing arterial damage.

DEPTH MARKINGS indicate insertion length of the shunt in the carotid arteries.

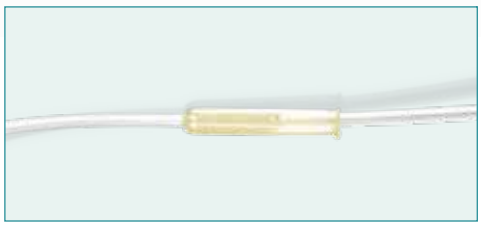
SAFETY BALLOON: PREVENT OVER-INFLATION



STEP 1 Special safety balloon with moveable plastic sheath minimizes risk of Internal Carotid Balloon (ICB) over-inflation. Slide plastic sheath off safety balloon and inflate ICB.



STEP 2 If ICB over-inflates, the extra pressure is diverted to the safety balloon, preventing arterial damage.



STEP 3 After ICB is inflated, slide the plastic sheath over safety balloon to prevent deflation of ICB.