LeMaitre® VASCULAR
Your Peripheral Vision™

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

Tel: +49-(0)6196-659230
Fax: +49-(0)6196-527072

NASDAQ: LMAT
www.lemaitre.com

Australia · LeMaitre Vascular PTY LTD
Tel: +61-(0)3 9330 4775 · Fax: +61-(0)3 9330 4772
Canada · LeMaitre Vascular ULC
Tel: +1-905 673-2266 · Fax: +1-905 673-2223
France · LeMaitre Vascular SAS
Tel: +33-(0)344 260041 · Fax: +33-(0)344 260731
Italy · LeMaitre Vascular S.r.l.
Tel: +39-02 9884851 · Fax: +39-02 98497059
Japan · LeMaitre Vascular GK
Tel: +81-(0)3-5215-5681 · Fax: +81-(0)3-5215-5682
Norway · LeMaitre Vascular AS
Tel: +49-(0)6196-659230 · Fax: +47-21 547467
Spain · LeMaitre Vascular Spain S.L.
Tel: +34-(0)91 5030040 · Fax: +34-(0)91 1849871
Sweden · LeMaitre Vascular GmbH Norden Filial
Tel: +46-35 105620 · Fax: +46-35 105625
Switzerland · LeMaitre Vascular Switzerland GmbH
Tel: 0800 561761 · Fax: +41-(0)415 608236
United States · LeMaitre Vascular, Inc.
Tel: +1-781 221-2266 · Fax: +1-781 221-2223

<<Customer Name>>
Attn: Risk Management
<<Address 1>>
<<Address 2>>
<<City>> <<State>> <<Zip>>
<<Country

Urgent Field Safety Notice

Commercial Name: LeMaitre Aortic Occlusion Catheter
FSCA-identifier: CAPA 2019-047
Type of action: Return of a medical device to the supplier

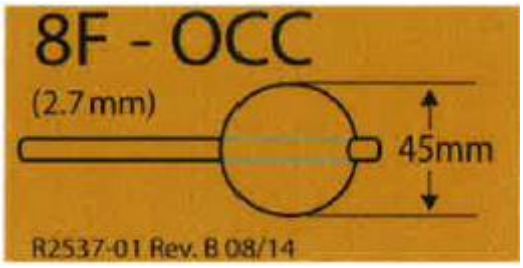
Date: July 26, 2019

Attention: Risk Management

Details on affected devices:

Catalog #	***Lot #***
2107-80	*OLC1051*

Description of the problem:
The end sticker shows a balloon diameter of 45 mm but the main product label correctly shows a product balloon diameter of 28 mm. The devices are model 2107-80 and therefore have an inflated balloon diameter of 28 mm as stated on the main label. The 'end sticker' is therefore conflicting with the main product label.



Diameter should be 28 mm, not 45 mm

Advise on action to be taken by the user:

- *Quarantine any catalog # 2107-80 devices from lot OLC1051.*
- *Complete the enclosed customer reply form and return it to LeMaitre Vascular GmbH by scanning it and emailing it to* recalls-emea@lemaitre.com
  ***NOTE: The customer reply form must be returned even if you have no devices at your facility**.*

LeMaitre Vascular GmbH will contact you with information on how to return the product and they will send you replacement devices.

Transmission of this Field Safety Notice: (if appropriate)
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:
For further information about this recall, contact Tobias Malcharczik at ***tmalcharczik@lemaitre.com****.*

We sincerely apologize for the inconvenience that this incident may have caused you. If you have any questions concerning this safety notice, please contact me at tmalcharczik@lemaitre.com

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Sincerely,

Tobias Malcharczik,
Director, Marketing International

Please complete this reply form and e-mail it to us at recalls-emea@lemaitre.com

The form must be returned even if you have zero devices in inventory.

Account Number*	**Customer Name***
Customer #	**customer**

**If you are not the customer listed here, please include your facility information here. Also, please add a note if you received the devices from another facility.*

Contact Name (First and Last Name)	
Contact Email	
Contact Phone	
Signature	
Date	

Please record how many devices you have at your location:

Catalog Number	Lot Number	Quantity of Devices At Your Location	Qty Confirmed Used
2107-80	OLC1051		

If you have any of these devices, LeMaitre Vascular GmbH will contact you with return instructions upon receipt of this completed form.

Thank you for your cooperation