



## URGENT: LeMaitre Embolectomy Catheter Recall Notice

October 27, 2015

Risk Management  
 <Customer Name>  
 <Address 1>  
 <Address 2>  
 <City>, <state> <zip>

Dear Valued Customer,

This is to inform you of a product safety notice and voluntary recall involving LeMaitre Vascular, Inc. **Single Lumen Embolectomy Catheters:**

### Affected lots:

Catalog Number	LOT Number	Expiration Date	Quantity Received
<Item Number>	<Lot Number>	<Exp Date>	<SKU_QTY>

Our records indicate that you have received the quantities of catheters from the affected LOTs as listed above. **LeMaitre Vascular, Inc. is requesting that all unused product (s) from the affected LOTs be quarantined and returned to LeMaitre Vascular, Inc. for replacement free of charge.**

This safety notice has been initiated due to the possibility that some products may have a compromised sterile barrier due to a packaging tube defect. While the likelihood of a defect is low (0.02%), the loss of product sterility could lead to cross-contamination and infection.

### Actions requested of you:

- Identify all catheters with the affected LOT and model numbers in your inventory.
- Please quarantine all unused catheters from the affected LOTs and record your action in the attached form.
- Please send the form via mail, email or fax to our Customer Service who will then

**United States**  
 LeMaitre Vascular, Inc.  
 63 Second Avenue  
 Burlington, MA 01803

Tel: 781 221-2266  
 Fax: 781 221-2223

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

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

**Japan**  
 LeMaitre Vascular GK  
 1F Kubodera Twin Tower Bldg.  
 2-9-4 Kudan-minami, Chiyoda-ku  
 Tokyo 102-0074

Tel: +81-(0)3-5215-5681  
 Fax: +81-(0)3-5215-5682

[www.lemaitre.com](http://www.lemaitre.com)  
 NASDAQ: LMAT



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issue an RMA-number (Return Merchandise Authorization number) for the return shipment and replacement of the products.

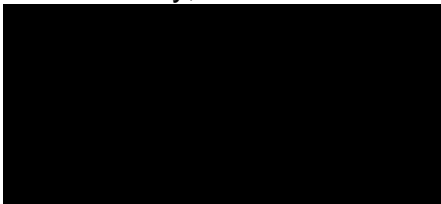
- This notice needs to be passed on to all those who need to be aware within your organization and to any organization to which the potentially affected devices have been transferred.

**LeMaitre Vascular will replace any returned catheters from the affected LOTs (see the list above) for no charge.**

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

We sincerely apologize for the inconvenience this recall may have caused you. If you have any questions concerning this safety notice, please contact me at 781-221-2266 ext. 183.

Sincerely,



Slava Kozin  
Quality Assurance Engineer  
LeMaitre Vascular, Inc.  
781-221-2266 Ext. 183

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Please complete the form below and mail, fax, or e-mail this part of the notice back to us.

Our fax number is 781-221-2223

Our e-mail address is [CSUS@LEMAITRE.COM](mailto:CSUS@LEMAITRE.COM).

If there are no more affected catheters in your inventory, and all have been used, please write zero (0) as the quantity in the box below so that we know that this notice has been received and that action has been taken.

Catalog Number	Description	Lot Number	Quantity of Catheters received	Quantity quarantined and to be returned
<Item Number>	<Description>	<Lot Number>	<SKU_QTY2>	

Hospital Name: \_\_\_\_\_

Contact Information (First Name, Last Name): \_\_\_\_\_

Phone number: \_\_\_\_\_

E-mail: \_\_\_\_\_

LeMaitre Vascular Inc. Customer Service will contact you with further instructions upon receipt of this form.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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