LeMaitre® VASCULAR

Your Peripheral Vision™

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

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www.lemaitre.com

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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

Your reference:

Our reference

Telephone
+49-6196-65923-0

E-Mail
tmalcharczik@lemaitre.com

Date
2 November 2015

Urgent Field Safety Notice

Device: LeMaitre® Single Lumen Embolectomy Catheter

Action: Return of the affected catheters to manufacturer via EU-Authorised Representative

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Dear Valued Customer,

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

Description of the affected devices:

Device Name: LeMaitre Single Lumen Embolectomy Catheter
Intended Use: The LeMaitre Embolectomy Catheter is indicated for the removal of arterial emboli and thrombi.

Affected LOT number(s):

Catalog Number	LOT Number	Expiration Date	Quantity Recieved
1601-XX	XXX XXXX	XX.XX.XXX	XX

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

Description of the problem:

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 (pinhole at the sealed lower end). While the liklihood of a defect is low (0.01%), the loss of product sterility could lead to cross-contamination and infection.

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Actions requested of you:

1. Please identify all catheters of the affected LOT(s) and model numbers in your inventory.

2. Please quarantine all unused catheters from the affected LOTs and record the number of quarantined to be returned catheters in the attached form.

3. Please send the completed form via regular mail, email or fax to our Customer Service who will than issue a RGA-Number (Return Goods Authorisation number) for the return shipment of the catheters. Please do not ship the catheters without RGA number, which will ensure a proper tracking of your return shipment.

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

Transmission of this Field Safety Notice:
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.

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

Please maintain awareness of this notice and resulting action for an appropriate period of 3 months or at least until the action has been finalized to ensure effectiveness of the corrective action.

Contact person :
Tobias Malcharczik
LeMaitre Vascular GmbH
Otto-Volger-Str. 5 a/b
65843 Sulzbach/Ts.
Germany

Tel: +49 (0)6196-659 23-15
Fax: +49 (0)6196-5614343
tmalcharczik@lemaitre.com

The undersign confirms that this notice has been notified to the Federal Institute for Drugs and Medical Devices in Germany (BfArM).

We sincerely apologize for the inconvenience this recall may have caused you.

Sincerely,

LeMaitre Vascular GmbH

Tobias Malcharczik
Senior Marketing Manager International

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

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

Service-Fax: +49 (0)6196-527072
Telephone: +49 (0)6196-65923-0
Email: csde@lemaitre.com

If there are no more affected unused catheters of the below LOTs in your inventory, and all have been used, please write zero (0) as the "quantity quarantined and to be returned" 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
1601-XX	LeMaitre Single Lumen Embolectomy Catheter	XXXXX	XX	

LeMaitre / Hospital Account number:

Hospital Name: _____

Contact Information (First Name, Last Name): _____

Phone number: _____

Contact E-mail: _____

LeMaitre Vascular Customer Service will contact you with an RGA-Number (Return Goods Authorisation number) for the return shipment of the products upon receipt of this form.

Signature: _____ Date: _____