



Your Peripheral Vision™

Germany

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
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Switzerland - LeMaitre Vascular Switzerland GmbH
Tel: 0800 561761 - Fax: +41-(0)415 608236
United Kingdom - LeMaitre Vascular Limited
Tel: +44-(0)870 2406640 - Fax: +44-(0)870 2406641
United States - LeMaitre Vascular, Inc.
Tel: +1-781 221-2266 - Fax: +1-781 221-2223

Name of Person

Hospital 1

Hospital 2

Street 1

Street 2

Your reference: **Account No.**

Our reference

Telephone

+49-6196-65923-0

E-Mail

tmalcharczik@lemaitre.com

Date

9 August 2016

Urgent Field Safety Notice

Device: 1.5 mm Hydro LeMaitre® Valvulotome

Action: Return of the affected 1.5 mm LeMaitre Hydro valvulotomes to the manufacturer via the EU-Authorised Representative

Dear Valued Customer,

This is to inform you of a product safety notice and recall involving the **1.5 mm Hydro LeMaitre® Valvulotome**.

- REF # 1009-00, 1.5 mm HYDRO LeMaitre® Valvulotome, 98 cm
- REF # 1009-00J, 1.5 mm HYDRO LeMaitre® Valvulotome, 98 cm

Description of the affected devices:

Device Name: 1.5 mm Hydro LeMaitre® Valvulotome

Intended Use: The 1.5 mm HYDRO LeMaitre® Valvulotome is a device that cuts venous valves during vascular procedures such as in-situ peripheral bypass, non-reversed translocated bypass, coronary artery bypass, and arterio-venous fistula creation.

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Affected LOT number(s):

Ref #	LOT Number	Expiration Date (YYYY-MM)
1009-00	ELVH1072V	2020-07
1009-00	ELVH1078V	2020-10
1009-00	ELVH1082V	2021-01
1009-00	ELVH1083V	2021-01
1009-00	ELVH1084V	2021-02
1009-00	ELVH1085V	2021-02
1009-00	ELVH1086V	2021-02
1009-00	ELVH1087V	2021-02
1009-00	ELVH1088V	2021-03
1009-00	ELVH1090V	2021-03
1009-00J	ELVH1079VA	2020-10

Our records indicate that you have received some quantity of the 1.5 mm Hydro LeMaitre® Valvulotome from the affected LOTs 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 and recall has been initiated due to reported issues of hoops failing to close when the device was actuated. In some cases this issue has been discovered in-use. While no adverse events have been reported, there is the possibility that a malfunctioning device could damage the vessel upon withdrawal.

Actions requested of you:

1. Please identify all 1.5 mm Hydro LeMaitre® Valvulotomes of the affected LOT(s) and model numbers in your inventory.
2. Please quarantine all unused 1.5 mm Hydro LeMaitre® Valvulotomes 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 then issue a RGA-Number (Return Goods Authorisation number) for the return shipment of the 1.5 mm Hydro LeMaitre® Valvulotome. Please do not ship the Hydro LeMaitre® Valvulotome without RGA number, which will ensure a proper tracking of your return shipment.

LeMaitre Vascular will replace any returned 1.5 mm Hydro LeMaitre® Valvulotomes from the affected LOTs (see the list above) for no charge.



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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 1.5 mm Hydro LeMaitre® Valvulotome 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 Hydro LeMaitre® Valvulotome received	Quantity quarantined and to be returned
Pls insert	1.5 mm Hydro LeMaitre® Valvulotome	Pls insert	individual notification	

LeMaitre / Hospital Account number: **Insert 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: _____