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
21 September 2016

Urgent Field Safety Notice - *Second Notice: Additional Lots Affected*

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,

LeMaitre Vascular is announcing an extension of the scope of our recall of HYDRO LeMaitre® Valvulotome devices. An initial notice was sent on August 12, 2016 but, since that time, we have decided to extend the recall to additional lots.

- If you responded to the August 12 mailing, thank you for your cooperation. Please review this notice and reply again to let us know if you have any additional devices at your facility.
- If you have not responded to the August 12 notification, or if you are seeing this recall notice for the first time, please follow the directions in this letter.

Description of the problem:
The 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 serious adverse events have been reported, there is the possibility that a malfunctioning device could damage the vessel upon withdrawal.

- **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.

Lots from Original Recall Notice:

Catalog #	Lot #	Expiration Date (YYYY-MM)
1009-00	ELVH1082V	2021-01
1009-00	ELVH1083V	2021-01
1009-00	ELVH1085V	2021-02
1009-00	ELVH1086V	2021-02
1009-00J	ELVH1078V	2020-10
1009-00J	ELVH1079VA	2020-10

Lots Added to the Recall:

Catalog #	Lot #	Expiration Date (YYYY-MM)
1009-00	ELVH1071VA	2020-07
1009-00	ELVH1080V	2020-10
1009-00	ELVH1094VA	2021-04
1009-00	ELVH1097V	2021-05
1009-00	ELVH1100V	2021-05
1009-00	ELVH1108VA	2021-04

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.**

Actions requested of you:

1. **Please immediately locate and quarantine all affected product from the lots shown in either of the two lists above**. We are requesting that you return those unused devices. LeMaitre Vascular will replace any affected device from above lists with a new device.

2. Please send the enclosed form completed 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 1.5 mm Hydro LeMaitre® Valvulotomes.
   Please do not ship the Hydro LeMaitre® Valvulotome without RGA number, which will ensure a proper tracking of your return shipment.
   Note that the form needs to be returned - even if you have 0 devices in inventory.

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
Senoir Marketing Manager International

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	

❒ If you have already responded to the August 12 mailing, please check here if you already reported or returned material and have no material from the lots that have been added to the recall.

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:_____