Account number: <Customer #>

URGENT: MEDICAL DEVICE RECALL
Second Notice--Additional Lots Affected

August 29, 2016

Risk Management
<Customer Name>
<Address 1>
<City>, <State> <Zip>

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 2, 2016 but, since that time, we have decided to extend the recall to additional lots.

- If you responded to the August 2 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 2 notification, or if you are seeing this recall notice for the first time, please follow the directions in this letter.

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.

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

NASDAQ: LMAT

Account number: <Customer #>

Lots from Original Recall Notice:

Catalog #	Lot #	Expiration Date (YYYY-MM)
1009-00	ELVH1072V	2020-07
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	ELVH1078V	2020-10
1009-00J	ELVH1079VA	2020-10
1010-00	ELVH1089V	2021-03
1010-00	ELVH1091V	2021-03

Lots Added to the Recall as of August 24, 2016:

Catalog #	Lot #	Expiration Date (YYYY-MM)
1009-00	ELVH1071VA	2020-07
1009-00	ELVH1080V	2020-10
1010-00J	ELVH1093V	2021-04
1009-00	ELVH1094VA	2021-04
1099-00	ELVH1096VA	2021-04
1009-00	ELVH1097V	2021-05
1009-00	ELVH1098V	2021-05
1010-00	ELVH1099V	2021-05
1009-00	ELVH1100V	2021-05
1009-00J	ELVH1104VA	2021-04
1009-00	ELVH1106VA	2021-04
1009-00	ELVH1108VA	2021-04

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Actions to be taken by the customer:

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, Inc, will replace any affected device with a new device.

2. Complete the enclosed customer reply form, and return it to LeMaitre Vascular, Inc. by either:
   - Scanning it and emailing it to CSUS@lemaitre.com or
   - Faxing it to 781-221-2223
   - **Note that the form needs to be returned—even if you have 0 devices in inventory.**

3. Please forward a copy of this letter to other facilities or departments within your institutions to ensure that those locations are aware of this action.

4. If you are a dealer, wholesaler, or distributor/reseller that distributed any product to other facilities, please notify your customers of this communication in accordance with your customary procedures.

After our customer service department receives your completed form:

- They will contact you with an RMA number and instructions on how to return the recalled product at no charge to you. **Please ensure that the RMA number is marked on the shipping box.**
- They will arrange for you to receive replacement product.

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

Sincerely,

Rose Lerer
Senior Quality Engineer

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Please complete this form fax or e-mail this part of the notice back to us. *The form should be returned even if you have zero devices in inventory.*

Our fax number is 781-221-2223. Our e-mail address is CSUS@LEMAITRE.COM.

Account number: <Customer #>

Hospital Name: _____

Contact Information (First Name and Last Name): _____

Phone number: _____

E-mail: _____

CHECK ONE BOX BELOW	DISPOSITION
	We will return devices for replacement.
	We have zero units in inventory.
	If you have already responded to the August 2 mailing, please check here if you already returned material and have no material from the lots that have been added to the recall.

Please record how many devices you have at your location:

CATALOG #	LOT #	QUANTITY ON HAND (Write 0 if there are no devices.)

If a replacement is requested, LeMaitre Vascular Customer Service will contact you with further instructions upon receipt of this request.

Signature: _____ Date:_____

Thank you for your cooperation.

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