LeMaitre® VASCULAR

Your Peripheral Vision™

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

Tel: +49-(0)6196-659230
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NASDAQ: LMAT
www.lemaitre.com

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United States · LeMaitre Vascular, Inc.
Tel: +1-781 221-2266 · Fax: +1-781 221-2223

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

Your reference:

Our reference
TM/Marketing

Telephone
+49-6196-65923-0

E-Mail
tmalcharczik@lemaitre.com

Date
13 February 2017

URGENT: MEDICAL DEVICE RECALL
NEW LOTS ADDED FEBRUARY 2017

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

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Dear Valued Customer:

LeMaitre Vascular is announcing an extension of the scope of our recall of HYDRO LeMaitre® Valvulotome devices. **Please read and respond to this letter even if you have replied to earlier letters.**

The additional lots that are being recalled are:

Catalog #	Lot #	Expiration Date
1009-00	ELVH1101V	2021-06
1010-00	ELVH1112V	2021-07
1009-00J	ELVH1113V	2021-07

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 and has led to vessel damage. If the blades are stuck in the open position, the device must be removed in the open state. The removal of the device without sheathing may cause damage to the vein either during use or when the blades pass the opening of the vessel.

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Lots Recalled Earlier:

Catalog #	Lot #	Expiration Date (YYYY-MM)
1009-00	ELVH1071VA	2020-07
1009-00	ELVH1072V	2020-07
1009-00J	ELVH1078V	2020-10
1009-00J	ELVH1079VA	2020-10
1009-00	ELVH1080V	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
1010-00	ELVH1089V	2021-03
1009-00	ELVH1090V	2021-03
1010-00	ELVH1091V	2021-03
1010-00J	ELVH1093V	2021-04
1009-00	ELVH1094VA	2021-04
1009-00	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

Actions to be taken by the customer:

1. **Please immediately locate and quarantine all affected product.** We are requesting that you return those unused devices. LeMaitre Vascular, Inc. will replace any affected device with a new device at no charge to the customer.

2. Complete the enclosed customer reply form, and return it to LeMaitre Vascular GmbH at csde@lemaitre.com or via fax +49 (0)6196-527072. **Please 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.

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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.

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 +49 (0)6196-659230.

Sincerely,

LeMaitre Vascular GmbH

Tobias Malcharczik
Director, Marketing International

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Please complete this reply form and e-mail it to us at csde@lemaitre.com or Fax +49 (0)6196-527072.

The form should be returned even if you have zero devices in inventory.

Customer Number*	Customer Name*
<Account Number>	<Customer Name>

**If you are not the customer listed here, please include your facility information here. Also, please add a note if you received the devices from another facility.*

Contact Name (First and Last Name)	
Contact Email	
Contact Phone	
Signature	
Date	

CHECK ONE BOX BELOW ☑	DISPOSITION
☐	We will return devices for replacement.
☐	We have zero units in inventory.

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.

Thank you for your cooperation.