Date: 2023-07-13

Field Safety Notice (FSN)
CHEVALIER Valvulotome

For Attention of: Risk Management

Contact details of local representative (name, e-mail, telephone, address etc.)
Authorized Representative: Hélène Plas - PRRC LeMaitre Vascular GmbH Otto-Volger-Strasse 5a/b Sulzback/Taunus 65843-Germany hplas@lemaitre.com +33 (0)6 75 22 32 16

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CHEVALIER Valvulotome

1. Information on Affected Devices

1.1 Device Type(s)

The Chevalier Valvulotome is a device used to disrupt the valves of veins which are to be used as grafts in the in situ or non-reversed bypass procedure. The Chevalier Valvulotome consists of a 700 mm stainless steel shaft with two tips.
-The cutting tip is shaped like an inverted tulip with four teeth at its base. This tip is designed to cut the vein valve cusps.
-The other tip is atraumatic and used to test the patency and the course of the vein before the valvulotomy.
-The device is supplied sterile.

1.2 Commercial name(s)

Chevalier Valvulotome

1.3 Unique Device Identifier(s) (UDI-DI)

Catalog # 40025: 00840663110469
Catalog # 40030: 00840663110476
Catalog # 40035: 00840663110483

1.4 Primary clinical purpose of device(s)

The device is used to disrupt the valves of veins which are to be used as grafts in the in situ or non-reversed bypass procedure.

1.5 Device Model/Catalogue/part number(s)

40025, 40030, 40035

1.6 Software version

Not applicable

1.7 Affected serial or lot number range

Only lots beginning with CHV are being recalled. Lots with CL lot prefixes are not being recalled.

REF (Catalog #)	LOT
40025	CHV1003
40025	CHV1006
40025	CHV1022
40030	CHV1002
40030	CHV1004
40035	CHV1001
40035	CHV1005

1.8 Associated devices

Not applicable

2. Reason for Field Safety Corrective Action (FSCA)

2.1 Description of the product problem

There are burrs on the cutting tip that can cause damage to the veins.

2.2 Hazard giving rise to the FSCA

The risk is to the patient. The burrs could cut the vein and the surgeon would have to take time to repair the vein.

2.	3. Probability of problem arising
	We have had one complaint for this issue (or any issue) of a total of 225 devices distributed. However, the devices were distributed recently (so many may not have been used). Also, we know that the burr problem appears frequently with these lots.
2.	4. Predicted risk to patient/users
	Extended operation time, damage to the vein
2.	5. Further information to help characterise the problem
	None
2.	6. Background on Issue
	We became aware of this problem when we received a complaint from a customer.
2.	7. Other information relevant to FSCA
	The devices were distributed between April 4, 2023 to July 7, 2023.

3. Type of Action to mitigate the risk

3. 1. Action To Be Taken by the User

☐ Identify Device ☒ Quarantine Device ☒ Return Device ☐ Destroy Device

☐ On-site device modification / inspection

☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

Please quarantine the affected devices. Then, return the faxback/reply form (at the end of this FSN) to LeMaitre Vascular as soon as possible. Then, LeMaitre will give you instructions on how to return the devices.

3.	2. By when should the action be completed?	As soon as you receive this FSN.

3. 3. Particular considerations for: N/A

Is follow-up of patients or review of patients' previous results recommended? No

No patient level follow up will be required.

3.	4. Is customer Reply Required? (Please complete the form at the end of this notice.)	Yes

3. 5. Action Being Taken by the Manufacturer

☒ Product Removal
☐ Software upgrade
☐ Other
☐ On-site device modification/inspection
☐ IFU or labelling change
☐ None

3.	6. By when should the action be completed?	As soon as the FSN is received by the customer

3.	7. Is the FSN required to be communicated to the patient /lay user?	No
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	No Not appended to this FSN	

4. General Information		
4.	1. FSN Type	New
4.	2. For updated FSN, reference number and date of previous FSN	Not applicable
4.	3. For Updated FSN, key new information as follows:	
	Not applicable	
4.	4. Further advice or information already expected in follow-up FSN?	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Not applicable	
4.	6. Anticipated timescale for follow-up FSN	Not applicable
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	LeMaitre Vascular, Inc.
	b. Address	63 Second Avenue Burlington, MA 01803 USA
	c. Website address	www.lemaitre.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	9. List of attachments/appendices:	Customer Reply Form
	10. Name Signature for Authorized Representative	***Helene PLAS, Director Regulatory & Quality Affairs EMEA*** Authorized Representative, PRRC

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

Customer Reply Form
July 13, 2023 Chevalier Valvulotomes with CHV lots

This form must be returned to recalls-emea@lemaitre.com even if you have zero devices in inventory.

Account #*	Customer Name*	Address
<<Customer #>>	<<Customer Name>>	<<Address 1>> <<City>>, <<Zip>>

**If you are not the customer listed here, please list your facility information.*

Contact Name	Contact Email	Contact Phone
Signature and Date:		

I have read and understood the recall instructions provided in this letter.
Yes ☐ No ☐

Any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

_____

_____

Do you have any recalled devices at your facility? ☐ Yes ☐ No If Yes, please complete the table below.

If you have checked your inventory and have no recalled devices, you may simply email ***recalls-emea@lemaitre.com*** and indicate that "I have checked our inventory at <<Account #, Hospital Name>> and we have none of the recalled devices."

REF (catalog) #	LOT #	QUANTITY ON HAND

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT:

Please scan the completed form and email it to ***recalls-emea@lemaitre.com.***

If you have transferred devices to another facility, please send them a copy of this recall letter.
If possible: list the facility information, including contact information. Also, please add a note if you received the devices from another facility.
Thank you for your cooperation.