

Rev 1: September 2018

FSN Ref: CAPA 2022-028

FSCA Ref: CAPA 2022-028

Date: xx October 2022

Urgent Field Safety Notice
TufTex Embolectomy Catheter®

For Attention of*: Risk Management

Contact details of local representative (name, e-mail, telephone, address etc.)*

LeMaitre Vascular GmbH [REDACTED]
Otto-Volger-Strasse 5a/b Sulzbach/Taunus 65843 - GERMANY

Urgent Field Safety Notice (FSN)
TufTex Embolectomy Catheter®

1. Information on Affected Devices*	
1.	1. Device Type(s)* <i>This is a single lumen embolectomy catheter with a latex balloon. It is supplied sterile.</i>
1.	2. Commercial name(s) <i>TufTex Embolectomy Catheter</i>
1.	3. Unique Device Identifier(s) (UDI-DI) <i>00840663100491 (1601-48)</i>
1.	4. Primary clinical purpose of device(s)* <i>The TufTex Embolectomy Catheter is indicated for the removal of arterial emboli and thrombi.</i>
1.	5. Device Model/Catalogue/part number(s)* <i>1601-48</i>
1.	6. Software version <i>Not applicable</i>
1.	7. Affected serial or lot number range <i>XSL0097, XSL0098 et XSL0099</i>
1.	8. Associated devices <i>Not applicable</i>

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem* <i>Lots tied by trainees (for balloon ligature tying) are required to be tensile tested as part of the operator training process. Internal investigation found that three lots tied by two trainees (Lot #'s: XSL0097, XSL0098, and XSL0099) were released without performing the pull test.</i>
2.	2. Hazard giving rise to the FSCA* <i>The proximal ligature could slip distal (toward the tip of the catheter) and block the inflation hole. That blockage would result in the balloon not deflating. The surgeon would need to deflate the balloon with a pin or another method. However, in extreme cases, if they pull too hard on the catheter, the tip could break off because the extrusion has yielded. Typically, a broken tip would be removed by the surgeon but there is a remote possibility that it could be lost in the blood vessel.</i>
2.	3. Probability of problem arising <i>There is a reasonable probability of a product failure since these lots were not tested. One of the trainees who tied these devices had two lots fail recently.</i>
2.	4. Predicted risk to patient/users <i>There is no risk to the user. To the patient, there is some risk described above.</i>
2.	5. Further information to help characterise the problem <i>Not applicable</i>
2.	6. Background on Issue <i>Lots tied by trainees (for balloon ligature tying) are required to be pull tested as part of the operator training process. Internal investigation found that three lots tied by two trainees (Lot #'s: XSL0097, XSL0098, and XSL0099) were released without performing the pull test.</i>
2.	7. Other information relevant to FSCA <i>Not applicable</i>

3. Type of Action to mitigate the risk*					
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p><i>Complete the form at the end of this FSN and send it to the address shown.</i></p>				
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 40%;">2. By when should the action be completed?</td> <td style="text-align: center;">Oct. 14, 2022</td> </tr> </table>	2. By when should the action be completed?	Oct. 14, 2022		
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3.	<p>3. Particular considerations for: <i>Non applicable</i></p> <p>Is follow-up of patients or review of patients' previous results recommended? No</p> <p><i>No patient-level follow-up is required because this is a single use device. It is not an implantable.</i></p>				
3.	<table border="1" style="width: 100%;"> <tr> <td style="width: 70%;">4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)</td> <td style="text-align: center;">Yes</td> </tr> </table>	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes		
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3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input checked="" type="checkbox"/> Other <input type="checkbox"/> None </p> <p><i>Improvement of the internal lot release procedure</i></p>				
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No					

4. General Information*	
4.	1. FSN Type* <i>New</i>
4.	2. For updated FSN, reference number and date of previous FSN <i>Not applicable</i>
4.	3. For Updated FSN, key new information as follows: <i>Not applicable</i>
4.	4. Further advice or information already expected in follow-up FSN? * <i>No</i>
4	5. If follow-up FSN expected, what is the further advice expected to relate to: <i>Not applicable</i>
4	6. Anticipated timescale for follow-up FSN <i>Not applicable</i>
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 Ave. 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: <i>Reply form at end of this letter</i>
4.	10. Name/Signature ██████████ Director Regulatory & Quality Affairs EMEA ██████████

Transmission of this Field Safety Notice	
	<p style="color: red;">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)</p> <p style="color: red;">Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p style="color: red;">Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p style="color: red;">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..*</p>

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.

CUSTOMER REPLY FORM	DATE OF NOTICE: xx October, 2022
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Please complete this reply form and e-mail it to us at recalls-emea@lemaitre.com.
The form must be returned even if you have zero devices in inventory. Email completed form to recalls-emea@lemaitre.com as soon as possible.

Account #	Customer Name	Address
<<Customer #>>	<<CustomerName>>	<<Address 1>> <<City>>, <<State>> <<Zip>>

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

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

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 to indicate that "I have checked our inventory at <<Account #, Hospital Name>> and we have none of the recalled devices." **NOTE: Distributors must complete the entire form.**

REF #	LOT #	QUANTITY ON HAND

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT :

Distributors:

- I have checked my stock and have quarantined inventory consisting of _____ units.
- I identified and notified all of my customers that are affected by this recall.
- Where applicable, I have notified the country's medical device regulatory agency about this recall.
- I did not notify the regulatory agency. The rationale is listed below.

Rationale:

Name/Title	
Telephone	
Email address	

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.
