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FSN / FSCA Ref: CAPA 2025-007

Date: xx-Apr-2025

Field Safety Notice
TufTex® Over-the-Wire Embolectomy Catheter
Pruitt® Occlusion Catheter
Pruitt® Irrigation Occlusion Catheter

For Attention of: Risk Management

Contact details of local representative / Authorized Representative:
Hélène Plas (PRRC)
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1. Information on Affected Devices

1.1. Device Type(s):	Embolectomy Catheter, Occlusion Catheter.
1.2. Commercial name(s):	TufTex® Over-the-Wire Embolectomy Catheter, Pruitt® Occlusion Catheter, Pruitt® Irrigation Occlusion Catheter
1.3. Unique Device Identifier(s) (UDI-DI):	1651-34: 00840663100651 1651-38: 00840663100668 1651-44: 00840663100675 1651-48: 00840663100682 1651-64: 00840663100712 1651-68: 00840663100729 1651-78: 00840663100736 1651-84: 00840663100743 1651-88: 00840663100750 2103-36: 00840663101559 2103-46: 00840663101566 2103-56: 00840663101573 2102-09: 00840663101535
1.4. Primary clinical purpose of device(s):	TufTex® Over-the-Wire Embolectomy Catheter: indicated for use in the removal of emboli and thrombi during embolectomy and/or thrombectomy. It can also be used for catheter placement over a guidewire, vessel occlusion, fluid infusion and/or aspiration.
	Pruitt® Occlusion Catheter: indicated for the occlusion of vessels both arterial and venous for the control of bleeding.
	Pruitt® Irrigation Occlusion Catheter: indicated to temporarily occlude vessels for the control of bleeding. To access the vessel lumen distal to the point of occlusion.
1.5. Device Model/ Catalogue / part number(s):	TufTex® Over-the-Wire Embolectomy Catheter: 1651-34, 1651-38, 1651-44, 1651-48, 1651-64, 1651-68, 1651-78,1651-84, 1651-88 Pruitt® Occlusion Catheter: 2103-36, 2103-46, 2103-56, Pruitt® Irrigation Occlusion Catheter: 2102-09

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1.6. Affected serial or lot number range:	**See attached Impacted Lots List document.** The potentially impacted lot numbers were determined by reviewing the maximum shelf life of each product line. TufTex® Over-the-Wire Embolectomy Catheter (6 years shelf life) – distributed from April 2019 to April 2025 Pruitt® Occlusion Catheter (7 years shelf life) - distributed from July 2018 to April 2025 Pruitt® Irrigation Occlusion Catheter (5 years shelf life) – distributed from September 2020 to April 2025

2. Reason for Field Safety Corrective Action (FSCA)

2.1. Description of the product problem:	Inadequate Tray Seals were found on samples from these three product lines.
2.2. Hazard giving rise to the FSCA:	The potential hazard is infection if the sterile barrier of the packaged device is broken.
2.3. Probability of problem arising:	No complaints have been received about this issue. Following inspection and testing of finished product samples, the results suggest that only approx. **1%** of the population may have a compromised package.
2.4. Predicted risk to patient / users:	The potential hazard is infection to the patient if the sterile barrier of the packaged device is broken. Only patients undergoing surgery with the use of the TufTex® Over-the-Wire Embolectomy Catheters, Pruitt® Occlusion Catheters, or Pruitt® Irrigation Occlusion Catheters are at risk.
2.5. Further information to help characterize the problem:	None
2.6. Background on Issue:	The inadequate tray seal issue was observed during an unrelated test to TufTex® OTW Catheters. It was then further reviewed and confirmed by Quality and Manufacturing Engineering where some parts (roughly 10% of any given lot) could exhibit voids on the seal area in the location where the tubing connects to the boat tray. The voids were observed visually against backlight and confirmed upon opening of Tyvek lid. Seal integrity testing (dye penetration) of other samples with visually detected voids subsequently confirmed failures in some of the samples, indicating compromised packaging (1%), which can allow microorganisms to enter and contaminate the device, leading to potential infection transmitted by the compromised device.

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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 Quarantine the product. Complete the form at the end of the FSN and return the form to LeMaitre Vascular GmbH.
3.2. By when should the action be completed (by the user)?	As soon as possible.
3.3. Particular considerations for:	Is follow-up of patients or review of patients' previous results recommended? ☐ Yes ☒ No No follow up action is required.
3.4. Is customer Reply Required?	☒ Yes ☐ No
3.5. Action Being Taken by the Manufacturer:	☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None
3.6. By when should the action be completed (by the manufacturer)?	30 October 2025

4. General Information

4.1. FSN Type:	New		
4.2. Further advice or information already expected in follow-up FSN?	☐ Yes	☐ No	☒ Not planned yet

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4.3. Manufacturer information:	(For contact details of local representative refer to page 1 of this FSN) Company Name: LeMaitre Vascular, Inc. Address: 63 Second Ave. Burlington, MA 01803 USA Website address: www.lemaitre.com
4.4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.5. Name / Signature	**Hélène Plas,** **Director, Regulatory & Quality Affairs - EMEA** **Authorized Representative, PRRC**

5. Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations 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.

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Customer Reply Form

Date of Notice: xx-APR-2025

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.

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."

REF #	LOT #	QUANTITY ON HAND

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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.

☐ If the product was distributed outside the US, I have notified that 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

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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.

Thank you for your cooperation!