FSN Ref: CAPA 2023-028 FSCA Ref: CAPA 2023-028

Date: 11th April 2024

Field Safety Notice (FSN)
Syntel® Silicone Thrombetomy Catheter

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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Syntel® Silicone Thrombectomy Catheter

1. Information on Affected Devices	
1.	1. Device Type(s)
	The Syntel® Silicone Thrombectomy Catheter consists of a catheter body with a balloon on the distal end and an inflation hub on the proximal end.
1.	2. Commercial name(s)
	Syntel® Silicone Thrombectomy Catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
	00840663109838 (Model # A4558) 00840663109814 (Model # A4548)
1.	4. Primary clinical purpose of device(s)
	The Syntel® Silicone Thrombectomy Catheter is indicated for use in vascular grafts and peripheral venous thrombectomy procedures.
1.	5. Device Model/Catalogue/part number(s)
	A4548 A4558
1.	6. Software version
	Not applicable
1.	7. Affected serial or lot number range

Catalogue #	Lot #
A4548	SST1045
A4558	SST1038
A4558	SST1038
A4558	SST1013

1.	8. Associated devices
	None

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	It has been reported that during the use of the Syntel® Silicone Thrombectomy Catheter, the guide tip (not the balloon or catheter) can become damaged and result in tip detaching.
2.	2. Hazard giving rise to the FSCA
	The guide tip (not the balloon or catheter) can become damaged and result in tip detaching.
2.	3. Probability of problem arising
	There is a remote chance of an adverse event.
2.	4. Predicted risk to patient/users
	The remote risk of this issue is that the distal tip of the catheter separates while in use in the patient and requires additional medical intervention to prevent injury.
2.	5. Further information to help characterise the problem
	There have been four complaints.
2.	6. Background on Issue
	We received complaints and conducted an engineering study.
2.	7. Other information relevant to FSCA
	Not applicable

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 Complete the reply form at the end of this letter. This form needs to be returned even if you have no more devices in your inventory.	
3.	2. By when should the action be completed?	**As soon as the FSN is received.**
3.	3. Particular considerations: N/A Is follow-up of patients or review of patients' previous results recommended? No There have been no adverse events associated with this issue.	
3.	4. Is customer Reply Required?	Yes
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Quarantining affected product in our inventory. Notifying customers and subsidiaries. Validating a more robust method of attaching the tip to the catheter.	
3.	6. By when should the action be completed?	We expect to have a response from our 1 EU (Spain) customer within 1 week.
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?	
	Not Applicable	

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:	
	No follow-up FSN is planned	
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 Ave. Burlington, MA 01803 US
	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
4.	10. Name/Signature	***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.

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Customer Reply Form
Syntel® Silicone Thrombetomy Catheter

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

Account #*	Customer Name*	Address
39107	Hospital Marqués de Vadecilla	Avda de Valdecilla, nº 25 Planta -2, entre torres B y C Santander, ES 39008

**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 and we have none of the recalled devices."

REF #	LOT #	QUANTITY ON HAND
A4558	SST1038	
A4558	SST1013	
A4548	SST1045	

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT:

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.