Rev 1: September 2018

FSN Ref: CAPA 2022-026 FSCA Ref: CAPA 2022-026

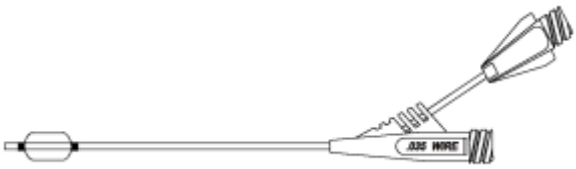
Date: 31:08:2022

Urgent Field Safety Notice
Syntel® Silicone Over-the-Wire Embolectomy Catheter

For Attention of*:Risk Management

Contact details of local representative (name, e-mail, telephone, address etc.)*
Helen Goulding, hgoulding@lemaitre.com, LeMaitre Vascular Limited, Stirling House, Centenary Park, Skylon Central, Hereford HR2 6FJ, United Kingdom, Tel +44 1432 513125

Urgent Field Safety Notice (FSN)
Syntel® Silicone Over-the-Wire Embolectomy Catheter
Risk addressed by FSN

	1. **Information on Affected Devices***
1.	1. Device Type(s)*
	The Syntel® Silicone Over-the-Wire Embolectomy catheter consists of a double-lumen catheter body with a silicone balloon on the distal end and two standard luer connectors on the proximal end. One lumen is used for balloon inflation and the other is used for infusion of fluids, or insertion over a guidewire. The Syntel® Silicone Over-the-Wire Embolectomy catheter is marked every 10cm so that intraluminal length of the inserted portion of the catheter can be identified. Balloon inflation capacity is printed on the proximal end of the catheter. A syringe is included for balloon inflation. Marker bands are located at the proximal end and at the distal end of the balloon to aid in identifying balloon placement under fluoroscopy.
	
1.	2. Commercial name(s)
	Syntel® Silicone Over the Wire Embolectomy Catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
	00607915113414, 00607915110871
1.	4. Primary clinical purpose of device(s)*
	Indication for Use: The Syntel® Silicone Over-the-Wire Embolectomy catheters are indicated for removal of thromboemboli from the peripheral arterial system, for occlusion of the vessel, and for infusion of fluids into a vessel. Contraindications: The Syntel® Silicone Over-the-Wire Embolectomy catheters are contraindicated for endarterectomy procedures or for use in the venous system.
1.	5. Device Model/Catalogue/part number(s)*
	A4E02, A4E08
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	PYT1070, PYT1042
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	The French size next to the OD (outside diameter) symbol on the label does not reflect the 5F catheter extrusion used on all models of the Syntel Silicone Embolectomy Catheter.
2.	2. Hazard giving rise to the FSCA*
	Patients on whom the catheters are used are unlikely to be at risk. All devices are indicated for use with the same guidewire and therefore the compatibility with the accessory device is not challenged. Devices are chosen primarily for the balloon size they can achieve for the vessel size being treated and the labeling for balloon volume is correct. Additionally, balloons are inflated using tactile feedback and inflation is stopped when ideal volume/diameter is felt by the user.
2.	3. Probability of problem arising
	Unlikely
2.	4. Predicted risk to patient/users
	Patients on whom the catheters are used are unlikely to be at risk. All devices are indicated for use with the same guidewire and therefore the compatibility with the accessory device is not challenged. Devices are chosen primarily for the balloon size they can achieve for the vessel size being treated and the labeling for balloon volume is correct. Additionally, balloons are inflated using tactile feedback and inflation is stopped when ideal volume/diameter is felt by the user.
2.	5. Further information to help characterise the problem
	N/A
2.	6. Background on Issue
	The issue was brought to LeMaitre Vascular's attention by a US customer.
2.	7. Other information relevant to FSCA
	N/A

	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 The customer may choose to return the affected devices to LeMaitre or they may keep them. They must complete the form at the end of this letter and return it to LeMaitre, even if they have no devices or choose to keep the devices.	
3.	2. By when should the action be completed?	As soon as possible

3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No This is a low risk situation. It is unlikely that there will be any harm to the patient.	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None The customer may choose to return the device or keep it. Refer to the reply form at the end of this letter.	
3	6. By when should the action be completed?	As soon as possible
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 Choose an item.	

	4. General Information*	
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Choose an item. N/A
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	N/A	
4	6. Anticipated timescale for follow-up FSN	N/A
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 MA 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:	**Reply form**
4.	10. Name/Signature	**Tobias Malcharczik, Director Marketing, EU Authorized Representative** ***tmalcharczik@lemaitre.com***

	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..*

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

CUSTOMER REPLY FORM	DATE OF NOTICE:	

Please complete this reply form and e-mail it to us at recalls-uk@lemaitre.com.
The form must be returned even if you have zero devices in inventory. Email completed form to recalls-uk@lemaitre.com.

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, do you wish to return your affected devices? ☐ Yes ☐ No

1. If you would like to return your devices, complete the table below.
2. **If you are a distributor: you must complete the distributor section on the next page**.

If you have checked your inventory and have no recalled devices, you may simply email ***recalls-uk@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

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.

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.