LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

<<Customer Name>>
<<Risk Management Department>>
<<Adresse 1>>
<<Zip>> <<City>>

Date: 24 Mar 2020

Urgent Field Safety Notice
LeMaitre Over the Wire Embolectomy Catheter, 5F Plus

For Attention of:Risk Management/ Recalls Department

Contact details of local representative (name, e-mail, telephone, address etc.)
<<Risk Management Department>> <<Customer Name>> <<Address 1>> <<City>>, <<State>> <<Zip>>

Urgent Field Safety Notice (FSN)
LeMaitre Vascular 5F Plus Embolectomy Catheter
Risk addressed by FSN

	1. **Information on Affected Devices**
1.	1. Device Type(s)
	Embolectomy Catheter
1.	2. Commercial name(s)
	LeMaitre Vascular 5F Plus Embolectomy Catheter
1.	3. Unique Device Identifier(s) (UDI-DI)
	00840663100743 (REF 1651-84), 00840663100750 (REF 1651-88)
1.	4. Primary clinical purpose of device(s)
	The LeMaitre Over the Wire Embolectomy Catheter is 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.
1.	5. Device Model/Catalogue/part number(s)
	1651-84, 1651-88
1.	6. Software version
	Not applicable. This product contains no software.
1.	7. Affected serial or lot number range
	Refer to Appendix 1.
1.	8. Associated devices
	Not applicable. This is a standalone device.

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

	2 Reason for Field Safety Corrective Action (FSCA)
2.	1. Description of the product problem
	The 2020 complaint data displayed an increasing trend in ligature slippage/tip separation.
2.	2. Hazard giving rise to the FSCA
	If the ligature slips, the ligature may cover the deflation hole so the balloon does not deflate. This will require extra time for the surgeon to deflate the balloon. If the surgeon pulls very hard on the catheter (trying to pull it out), the extrusion could stretch to a point where the tip could break off.
2.	3. Probability of problem arising
	Based on our complaint rate in the last year, there is a probability that 1 in 2000 catheters will have this problem.
2.	4. Predicted risk to patient/users
	The surgery time would be prolonged and there is a slight probability that the tip may break off in the patient blood vessel.
2.	5. Further information to help characterise the problem
	Refer to the list of affected lots.
2.	6. Background on Issue
	Through our market surveillance activities, LeMaitre detected an increased trend in reports of catheters failing to deflate during use. The issue occurs if the thread windings around the balloon slip under tension and allow the inflated balloon's proximal ligature to slide over the inflation hole. Under continued tension, the tip of the catheter can begin to stretch, which can lead to tip separation. In these cases, the surgeon may need to intervene by popping the balloon to ensure deflation, and/or retrieve a dislodged catheter tip from the patient's vessel.
2.	7. Other information relevant to FSCA
	Quarantine the product. ***The form must be returned even if you have zero devices in inventory. Email completed form to recalls-emea@lemaitre.com.***

	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 ***RETURN ATTACHED REPLY FORM TO recalls-emea@lemaitre.com***	
3.	2. By when should the action be completed?	*As soon as this letter is received.*

FSN Ref: CAPA 2020-001 FSCA Ref: CAPA 2020-001

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

3.	3. Particular considerations for: Is follow-up of patients or review of patients' previous results recommended? *No* *No patient followup required.*	
3.	4. Is customer Reply Required?	*Yes. Reply within 1 week of receiving notification.*
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?	*June 30, 2020*
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 required.	

	4. General Information	
4.	1. FSN Type	*New*
4.	2. For updated FSN, reference number and date of previous FSN	
4.	**3.** For Updated FSN, key new information as follows:	
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:	
	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 Avenue Burlington, MA 01803***
	c. Website address	**www.lemaitre.com**

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
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:	*Appendix 1 (List of Lots), Reply form*
4.	10. Name/Signature	**xxx**

	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.

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

Appendix 1, Recalled Lots Distributed in Europe

CATALOG # 1651-84

CATALOG #	LOT #	EXPIRATION DATE		CATALOG #	LOT #	EXPIRATION DATE
1651-84	OTW2847	2020-04		1651 - 84	OTW3758	2023-12
1651-84	OTW2897	2020-06		1651 - 84	OTW3805	2024-02
1651-84	OTW3273	2022-01		1651 - 84	OTW3865	2024-04
1651-84	OTW3333	2022-03		1651 - 84	OTW3879	2024-04
1651-84	OTW3379	2022-05		1651 - 84	OTW3892	2024-05
1651-84	OTW3394	2022-06		1651 - 84	OTW3966	2024-08
1651-84	OTW3418	2022-07		1651 - 84	OTW4009	2024-09
1651-84	OTW3530	2023-02		1651 - 84	OTW4010	2024-09
1651-84	OTW3543	2023-03		1651 - 84	OTW4018	2024-10
1651-84	OTW3564	2023-03		1651 - 84	OTW4024	2024-10
1651 - 84	OTW3620	2023-05		1651 - 84	OTW4063	2024-12
1651 - 84	OTW3700	2023-09		1651 - 84	OTW4065	2024-12
1651 - 84	OTW3740	2023-12		1651 - 84	OTW4117	2025-01

CATALOG # 1651-88

CATALOG #	LOT #	EXPIRATION DATE		CATALOG #	LOT #	EXPIRATION DATE
1651-88	OTW2957	2020-10		1651 - 88	OTW3728	2023-11
1651-88	OTW3001	2020-12		1651 - 88	OTW3747	2023-12
1651-88	OTW3190	2021-09		1651 - 88	OTW3769	2024-01
1651-88	OTW3266	2021-12		1651 - 88	OTW3770	2024-01
1651-88	OTW3267	2021-12		1651 - 88	OTW3775	2024-01
1651-88	OTW3395	2022-06		1651 - 88	OTW3776	2024-01
1651-88	OTW3400	2022-07		1651 - 88	OTW3779	2024-01
1651-88	OTW3424	2022-08		1651 - 88	OTW3780	2024-01
1651-88	OTW3531	2023-02		1651 - 88	OTW3810	2024-02
1651-88	OTW3565	2023-03		1651 - 88	OTW3820	2024-02
1651 - 88	OTW3637	2023-07		1651 - 88	OTW3821	2024-02
1651 - 88	OTW3638	2023-07		1651 - 88	OTW3853	2024-04
1651 - 88	OTW3658	2023-07		1651 - 88	OTW3854	2024-04
1651 - 88	OTW3665	2023-07		1651 - 88	OTW3880	2024-04
1651 - 88	OTW3670	2023-08		1651 - 88	OTW3881	2024-04
1651 - 88	OTW3671	2023-08		1651 - 88	OTW3886	2024-05
1651 - 88	OTW3682	2023-08		1651 - 88	OTW3893	2024-05
1651 - 88	OTW3683	2023-08		1651 - 88	OTW3898	2024-05
1651 - 88	OTW3694	2023-09		1651 - 88	OTW3899	2024-05
1651 - 88	OTW3695	2023-09		1651 - 88	OTW3915	2024-06

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

CATALOG #	LOT #	EXPIRATION DATE		CATALOG #	LOT #	EXPIRATION DATE
1651 - 88	OTW3701	2023-10		1651 - 88	OTW3916	2024-06
1651 - 88	OTW3708	2023-10		1651 - 88	OTW3924	2024-07
1651 - 88	OTW3727	2023-11		1651 - 88	OTW3930	2024-07
1651 - 88	OTW3957	2024-08		1651 - 88	OTW4075	2024-12
1651 - 88	OTW3958	2024-08		1651 - 88	OTW4092	2025-01
1651 - 88	OTW3981	2024-09		1651 - 88	OTW4093	2025-01
1651 - 88	OTW3982	2024-09		1651 - 88	OTW4098	2025-01
1651 - 88	OTW4011	2024-09		1651 - 88	OTW4099	2025-01
1651 - 88	OTW4025	2024-10		1651 - 88	OTW4105	2025-01
1651 - 88	OTW4026	2024-10		1651 - 88	OTW4120	2025-02
1651 - 88	OTW4030	2024-10		1651 - 88	OTW4157	2025-03
1651 - 88	OTW4031	2024-10		1651 - 88	OTW4158	2025-03
1651 - 88	OTW4052	2024-11		1651 - 88	OTW4247	2025-07
1651 - 88	OTW4053	2024-11		1651 - 88	OTW4249	2025-02
1651 - 88	OTW4054	2024-11		1651 - 88	OTW4258	2024-12
1651 - 88	OTW4066	2024-12		1651 - 88	OTW4259	2025-02
1651 - 88	OTW4068	2024-12		1651 - 88	OTW4260	2025-02
1651 - 88	OTW4074	2024-12		1651 - 88	OTW4261	2025-02

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

CAPA 2020-001 Recall of 5F Plus Over the Wire Embolectomy Catheters

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.

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.

REF #	LOT #	QUANTITY ON HAND

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT :

LeMaitre VASCULAR
Your Peripheral Vision™

LeMaitre Vascular GmbH
Otto-Volger-Str. 5a/b
65843 Sulzbach/Ts.
Germany
+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

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 have sent evidence of this to the recall coordinator at rlerer@lemaitre.com

☐ 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.