

Rev 1: September 2018

FSN Ref: Manufacturer's ref number

FSCA Ref: CAPA 2020-034

Date: 07MAY 2021

Urgent Field Safety Notice
LeMaitre Aortic Occlusion Catheter

For Attention of*:Risk Management

Contact details of local representative (name, e-mail, telephone, address etc.)*
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LeMaitre Vascular GmbH, Tobias Malcharczik, tmalcharczik@lemaitre.com, +49 (0)6196 659230, Otto-Volger-Strasse 5a/b, 65843 Sulzbach/Taunus, Germany
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Urgent Field Safety Notice (FSN)
LeMaitre Aortic Occlusion Catheter
Risk addressed by FSN

1. Information on Affected Devices*																																																																												
1	1. Device Type(s)*																																																																											
.	Aortic Occlusion Catheter																																																																											
1	2. Commercial name(s)																																																																											
.	LeMaitre Aortic Occlusion Catheter																																																																											
1	3. Unique Device Identifier(s) (UDI-DI)																																																																											
.	00840663101634 (2107-80), 00840663101658 (2107-81)																																																																											
1	4. Primary clinical purpose of device(s)*																																																																											
.	The LeMaitre Aortic Occlusion Catheter is indicated for temporary vessel occlusion.																																																																											
1	5. Device Model/Catalogue/part number(s)*																																																																											
.	2107-80, 2107-81																																																																											
1	6. Software version																																																																											
.	Not applicable																																																																											
1	7. Affected serial or lot number range																																																																											
.	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 15%;">REF #</th> <th style="width: 15%;">LOT #</th> <th style="width: 15%;">REF #</th> <th style="width: 15%;">LOT #</th> </tr> </thead> <tbody> <tr><td>2107-80</td><td>OLC1037</td><td>2107-81</td><td>OLC1038</td></tr> <tr><td>2107-80</td><td>OLC1041</td><td>2107-81</td><td>OLC1039</td></tr> <tr><td>2107-80</td><td>OLC1043</td><td>2107-81</td><td>OLC1040</td></tr> <tr><td>2107-80</td><td>OLC1045</td><td>2107-81</td><td>OLC1042</td></tr> <tr><td>2107-80</td><td>OLC1053</td><td>2107-81</td><td>OLC1046</td></tr> <tr><td>2107-80</td><td>OLC1056</td><td>2107-81</td><td>OLC1047</td></tr> <tr><td>2107-80</td><td>OLC1057</td><td>2107-81</td><td>OLC1048</td></tr> <tr><td>2107-80</td><td>OLC1060</td><td>2107-81</td><td>OLC1049</td></tr> <tr><td>2107-80</td><td>OLC1061</td><td>2107-81</td><td>OLC1050</td></tr> <tr><td>2107-80</td><td>OLC1062</td><td>2107-81</td><td>OLC1054</td></tr> <tr><td>2107-80</td><td>OLC1067</td><td>2107-81</td><td>OLC1055</td></tr> <tr><td>2107-80</td><td>OLC1068</td><td>2107-81</td><td>OLC1058</td></tr> <tr><td>2107-80</td><td>OLC1071</td><td>2107-81</td><td>OLC1059</td></tr> <tr><td>2107-80</td><td>OLC1072</td><td>2107-81</td><td>OLC1066</td></tr> <tr><td>2107-80</td><td>OLC1075</td><td>2107-81</td><td>OLC1070</td></tr> <tr><td>2107-80</td><td>OLC1079</td><td>2107-81</td><td>OLC1073</td></tr> <tr><td></td><td></td><td>2107-81</td><td>OLC1074</td></tr> </tbody> </table>				REF #	LOT #	REF #	LOT #	2107-80	OLC1037	2107-81	OLC1038	2107-80	OLC1041	2107-81	OLC1039	2107-80	OLC1043	2107-81	OLC1040	2107-80	OLC1045	2107-81	OLC1042	2107-80	OLC1053	2107-81	OLC1046	2107-80	OLC1056	2107-81	OLC1047	2107-80	OLC1057	2107-81	OLC1048	2107-80	OLC1060	2107-81	OLC1049	2107-80	OLC1061	2107-81	OLC1050	2107-80	OLC1062	2107-81	OLC1054	2107-80	OLC1067	2107-81	OLC1055	2107-80	OLC1068	2107-81	OLC1058	2107-80	OLC1071	2107-81	OLC1059	2107-80	OLC1072	2107-81	OLC1066	2107-80	OLC1075	2107-81	OLC1070	2107-80	OLC1079	2107-81	OLC1073			2107-81	OLC1074
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1	8. Associated devices																																																																											
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2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	LeMaitre Vascular's notified body is requiring the removal of these devices from the EU market because advance notice of a 2014 design change to remove marker bands was not provided to the notified body and the product's technical file was not updated at the time of the marker band removal. The notified body believes that the device without marker bands introduces a risk of malfunction resulting in harm to patients. The current

	accompanying Instructions For Use call out the optional use of fluoroscopy during the procedure.
2	2. Hazard giving rise to the FSCA*
.	A surgeon may experience visibility issues when using the device with fluoroscopy. There have been no complaints related to visibility for the history of use/sales of this device (2014 to present).
2	3. Probability of problem arising
.	There is low probability of a problem arising. Since placement of the device on the market in 2014, there have been zero (0) complaints related to visibility. The catheter is extruded out of a nylon resin that is partially loaded with barium sulfate.
2	4. Predicted risk to patient/users
.	There is no predicted risk to patients or users.
2	5. Further information to help characterise the problem
.	N/A
2	6. Background on Issue
.	LeMaitre conducted a change to the design of this device when it was originally released to the market in 2014: Two marker bands installed under the balloon were removed from the design. This change was implemented before full market release in 2014 and was not reported to the notified body as a significant change. During a recent audit by the notified body, this change was determined to be significant under MDD rules and therefore incorrectly implemented without prior approval of the notified body.
2	7. Other information relevant to FSCA
.	This design change is not, and has not been, the underlying cause of any complaint or any adverse event reported to LeMaitre.

3. Type of Action to mitigate the risk*		
3.	1. Action To Be Taken by the User* <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 type="checkbox"/> Other <input type="checkbox"/> None	
3.	2. By when should the action be completed?	As soon as possible after receiving the letter
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No N/A	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3.	5. Action Being Taken by the Manufacturer		
	<div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> Product Removal <input type="checkbox"/> Software upgrade <input checked="" type="checkbox"/> Other </div> <div> <input type="checkbox"/> On-site device modification/inspection <input checked="" type="checkbox"/> IFU or labelling change <input type="checkbox"/> None </div> </div> <p>Preparing devices with marker bands for the EU, UK markets</p>		
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?		
	N/A		

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? *	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 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:	None
4.	10. Name/Signature	Tobias Malcharczik, Director, Marketing EMEA tmalcharczik@lemaitre.com

Transmission of this Field Safety Notice	
	<p>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>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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:	May 7, 2021
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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.

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 :

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	
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.
