

Rev 1: September 2018

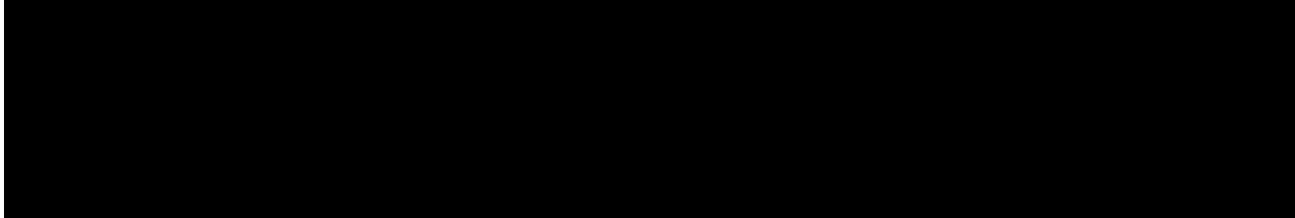
FSN Ref: CAPA 2021-015

FSCA Ref: CAPA 2021-015

Date: 20 Apr 2021

Urgent Field Safety Notice
LeverEdge Contrast Injector

For Attention of*:Risk Management



Urgent Field Safety Notice (FSN)
LeverEdge Contrast Injector
Loose particulate could contaminate sterile field

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	35 cc syringe with ISO 594 female luer lock. The device is intended to be used to perfuse contrast medias into the vessels for angiographic procedures.
1	2. Commercial name(s)
.	LeverEdge Contrast Injector
1	3. Unique Device Identifier(s) (UDI-DI)
.	00840663102549
1	4. Primary clinical purpose of device(s)*
.	The device is intended to be used to perfuse contrast medias into the vessels for angiographic procedures.
1	5. Device Model/Catalogue/part number(s)*
.	4100-00
1	6. Software version
.	Not applicable
1	7. Affected serial or lot number range
.	LC11091, LC11092, LC11093, LC11095, LC11096
1	8. Associated devices
.	None

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The packaging foam has produced particulate.
2	2. Hazard giving rise to the FSCA*
.	Particulate not identified prior to opening the pouches could contaminate the sterile field.
2	3. Probability of problem arising
.	The probability of the product having particulates is very high based on our inspection of lots.
2	4. Predicted risk to patient/users
.	Based on the health hazard analysis, the probability of the patient being exposed to the particulate is unlikely. Our complaints have been from one customer and the product was not used,
2	5. Further information to help characterise the problem
.	N/A
2	6. Background on Issue
.	The manufacturer became aware of the problem when one customer recently submitted three complaints of particulate. The customer's OR team noticed black spots inside the packaging so the surgeon decided not to use these devices. The root cause is that a new lot of packaging foam contained excessive debris. Devices with the new lot of foam were compared to devices with old foam lots. The devices packaged with the old foam lots were acceptable and the new lot produces debris. The lots being recalled were made with the new lot of foam.
2	7. Other information relevant to FSCA
.	N/A

3. Type of Action to mitigate the risk*	
3.	<p>1. Action To Be Taken by the User*</p> <p> <input checked="" type="checkbox"/> Identify Device <input checked="" type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input type="checkbox"/> Destroy Device </p> <p> <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Follow patient management recommendations </p> <p> <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>Quarantine the devices and complete the reply form at the end of the FSN. Send this form to LeMaitre Vascular GmbH and they will provide you with instructions to return the devices.</p>
3.	<p>2. By when should the action be completed?</p> <p style="text-align: center;">As soon as possible</p>
3.	<p>3. Particular considerations for: Choose an item.</p> <p>Is follow-up of patients or review of patients' previous results recommended?</p> <p>No</p> <p>Not applicable</p>
3.	<p>4. Is customer Reply Required? * Yes</p> <p>(If yes, form attached specifying deadline for return)</p>
3.	<p>5. Action Being Taken by the Manufacturer</p> <p> <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection </p> <p> <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change </p> <p> <input type="checkbox"/> Other <input type="checkbox"/> None </p> <p>When the completed form is received, LeMaitre Vascular GmbH will instruct you regarding the return of the recalled devices.</p>
3	<p>6. By when should the action be completed?</p> <p style="text-align: center;">As soon as possible</p>
3.	<p>7. Is the FSN required to be communicated to the patient /lay user? No</p>
3	<p>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?</p> <p>Choose an item. Choose an item.</p>

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? * Choose an item. Not applicable
4	5. If follow-up FSN expected, what is the further advice expected to relate to: Not applicable
4	6. Anticipated timescale for follow-up FSN Non-responders will be contacted after approximately 2 weeks.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)
	a. Company Name
	b. Address
	c. Website address
4.	8. The Competent (Regulatory) Authority communication to customers. *
4.	9. List of attachments/appendices:
4.	10. Name/Signature

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:	April 20, 2021
----------------------------	-----------------	----------------

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.
