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FSN / FSCA Ref: CAPA 2025-006

Date: 27-Mar-2025

Field Safety Notice
Flexcel™ Carotid Shunt

For Attention of: Risk Management

Contact details of local representative / Authorized Representative:

[redacted] (PRRC)
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Otto-Volger-Strasse 5a/b
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1. Information on Affected Devices

1.1. Device Type(s):	The Flexcel™ Carotid Shunt is a single lumen blood conduit for use in the carotid artery. The shunt is equipped with depth markings running the length of the device and features atraumatic tips. In addition, the shunt has a removable tether to facilitate the removal of the shunt after the procedure.
1.2. Commercial name(s):	Flexcel™ Carotid Shunt
1.3. Unique Device Identifier(s) (UDI-DI):	2020-25M = 00840663111114 / 2020-21M = 00840663111107 2020-35M = 00840663111138 / 2020-31M = 00840663111121
1.4. Primary clinical purpose of device(s):	Carotid shunts are indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.
1.5. Device Model/ Catalogue / part number(s):	2020-35M (5-pack box) with inside 5 units of 2020-31M (single pouch) 2020-25M (5-pack box) with inside 5 units of 2020-21M (single pouch)
1.6. Affected lot number range:	2020-35M / 2020-31M = FLX0003131 2020-25M / 2020-21M = FLX0003134

2. Reason for Field Safety Corrective Action (FSCA)

2.1. Description of the product problem:	Mixed inner/outer packaging between 2 lots (FLX0003131 and FLX0003134): - Flexcel Carotid Shunt 10F Box (5-pack) is labeled with ref. 2020-25M (Lot FLX0003134), but inside the box the five (5) pouched units are 12F ref. 2020-31M (Lot FLX0003131). - Flexcel Carotid Shunt 12F Box (5-pack) is labeled with ref. 2020-35M (Lot FLX0003131), but inside the box the five (5) pouched units are 10F ref. 2020-21M (Lot FLX0003134). No additional lots are impacted.
2.2. Hazard giving rise to the FSCA:	Size mentioned on the pouch and size mentioned on the box do not match. The product is violative but use of or exposure to the product is not likely to cause any adverse health consequences.

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2.3. Probability of problem arising:	Unlikely. The innermost package (pouch) is labeled correctly and can be easily identified by user.
2.4. Predicted risk to patient / users:	No adverse health consequences. Patients on whom the shunts are used are not at risk of an actual hazard since the innermost package (pouch) is labeled with the correct size and if differing from the box (5-pack) label, the difference in size can be easily identified on the individual shunt pouch label during product receipt / inventory management, picking from an inventory location, surgery preparation or pre-use check.
2.5. Background on Issue:	One (1) complaint has been received for lot FLX0003134.

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 - Please check inventory of 2020-25M / 2020-35M and 2020-21M/2020-31M. - Quarantine the product if affected lots are in your inventory. - Complete the form at the end of the FSN and return the form to LeMaitre Vascular GmbH. - LeMaitre Vascular GmbH will contact the customer with information on how to return the devices, either as full 5-pack boxes (Cat. 2020-25M/2020-35M) or in single pouches (Cat. 2020-21M/2020-31M).
3.2. By when should the action be completed (by the user)?	**30 April 2025**
3.3. Particular considerations for:	Is follow-up of patients or review of patients' previous results recommended? ☐ Yes ☒ No
3.4. Is customer Reply Required?	☒ Yes ☐ No

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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 (by the manufacturer)?	**31 May 2025**

4. General Information

4.1.	FSN Type:	New
4.2.	Further advice or information already expected in follow-up FSN?	☐ Yes ☒ No ☐ Not planned yet
4.3.	Manufacturer information:	(For contact details of local representative refer to page 1 of this FSN) Company Name: LeMaitre Vascular, Inc. Address: 63 Second Ave. Burlington, MA 01803 US Website address: www.lemaitre.com
4.4.	The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.5.	Name / Signature	[redacted], Director, Regulatory & Quality Affairs - EMEA Authorized Representative, PRRC

5. Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. (As appropriate)

Please transfer this notice to other organizations 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

Date of Notice: 27-MAR-2025

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

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.

- If you have checked your inventory and have no recalled devices, you may simply email regulatory-emea@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	
2020-35M (5-pack box)	FLX0003131	Quantity of full 5-pack boxes	
2020-31M (single pouch)	FLX0003131	Quantity of pouches (if partial box)	
2020-25M (5-pack box)	FLX0003134	Quantity of full 5-pack boxes	
2020-21M (single pouch)	FLX0003134	Quantity of pouches (if partial box)	

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. **Thank you for your cooperation!**