LeMaitre Vascular GmbH
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FSN / FSCA Ref: CAPA-00101

Date: 27-Aug-2025

Field Safety Notice
Artegraft Collagen Vascular Graft

For Attention of: Risk Management

Contact details of local representative / Authorized Representative:
Hélène Plas (PRRC)
LeMaitre Vascular GmbH
Otto-Volger-Strasse 5a/b
65843 Sulzbach/Taunus
Germany
regulatory-emea@lemaitre.com
[redacted]

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Artegraft Collagen Vascular Graft

1. Information on Affected Devices

1.1. Device Type(s):	The Artegraft is composed of a section of specially selected bovine carotid artery to serve as a substitute conduit for blood where bypass or replacement of occluded or diseased arterial segments is required or to establish a conduit for hemodialysis.
1.2. Commercial name(s):	Artegraft Collagen Vascular Graft
1.3. Unique Device Identifier(s) (UDI-DI):	AG630M = 00316837000015 AG636M = 00316837000022 AG730M = 00316837000060 AG740M = 00316837000084 AG845M = 00316837000138
1.4. Primary clinical purpose of device(s):	The Artegraft is indicated for the following: Hemodialysis, AV fistula salvage and repair, Primary AV Graft, AV Graft Replacement, Lower extremity bypass, Arterial trauma.
1.5. Device Model/ Catalogue / part number(s):	AG630M, AG636M, AG730M, AG740M, AG845M
1.6. Affected serial number range:	Limited to 10 devices: AG630M = 24H361-021, 24H361-022, 24HH359-016 AG636M = 24H380-009 AG730M = 24H380-014, 24H380-004 AG740M = 24H380-003, 24H380-002 AG845M = 24HH350-017, 24HH359-011

2. Reason for Field Safety Corrective Action (FSCA)

2.1. Description of the product problem:	A labeling issue led to non-compliance to MDR 2017/745 (EU), MedDo (CH) and MDR 2002 (UK). 10 devices were distributed with incorrect label without CE and UKCA mark, missing Patient Leaflet and Patient Implant Card (LeMaitre has received CE and UKCA approval on 28 April 2025).
2.2. Hazard giving rise to the FSCA:	No Adverse Health Consequences
2.3. Probability of problem arising:	Patient Leaflet and Patient Implant Card will not be included with the 10 affected products. The physical product and product performance is not impacted.

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2.4. Predicted risk to patient / users:	None, labelling issue only, no risk to patient safety. **If the product has been implanted, graft explantation/patient intervention is NOT required.**
2.5. Further information to help characterize the problem:	Identified devices were wrongly shipped to markets that require a CE and/or UKCA mark.
2.6. Background on Issue:	Three (3) complaints have been received.

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 **If the product has been implanted, graft explantation/patient intervention is NOT required.** If the product has not yet been used: Quarantine the product. 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.
3.2. By when should the action be completed (by the user)?	31 Oct 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)?	30 Nov 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: 206 North Center Drive North Brunswick, NJ 08902 USA 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	**Hélène Plas,** **Director, Regulatory & Quality Affairs - EMEA** **Authorized Representative, PRRC** _____	

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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-Aug-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 ☐ No, Graft was Implanted
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 #	Serial #	QUANTITY ON HAND

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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!**