LeMaitre Vascular GmbH
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65843 Sulzbach/Ts.
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+49 (0)6196 659230
+49 (0)6196 527072 Fax
www.lemaitre.com

URGENT FIELD SAFETY NOTICE: AlboGraft Polyester Vascular Graft

February 15 , 2022

Risk Management/Recalls
<<Hospital>>
<<Address>>
<<City>> <<Postal code>> Spain

Dear Sir or Madam,

LeMaitre is withdrawing and exchanging AlboGraft devices without a CE mark due to a change in regulatory status.

BACKGROUND: In 2020, AEMPS granted LeMaitre permission (derogation) to supply AlboGraft devices on the Spain market, without a CE mark. This derogation was requested because our previous notified body had stopped providing CE marking services and our new notified body had not completed their on-boarding review of the technical documentation. We are grateful to AEMPS for allowing us to serve our customers while we worked to gain approval from our new notified body. AEMPS has received a copy of this letter.

LeMaitre has now received the CE mark approval from our new notified body for AlboGraft and we now have adequate capacity to serve all of our European customers with CE marked product. Although there is no safety risk with any of the derogated devices, we are required to withdraw any remaining devices as a condition of the derogation.

ACTIONS TO BE TAKEN BY THE CUSTOMER:

- Please pass this field safety notice to all those who need to be aware of it within the organization and maintain awareness of the issue.
- If you have transferred devices to another facility, please send them a copy of this re-call letter.
- Check the following lists against your inventory. If you have any of these devices, check if they have a CE mark. (Either CE0123 or CE0088 is fine.) If they have no CE mark, quarantine them.
- Please complete the form at the end of this letter with information about your quarantined devices. Return the form to LeMaitre. If we do not hear from you by March 30, 2022, we will assume that you do not have any of these devices.
- If you return a reply form, we will send you instructions for returning your devices with no CE mark. When the devices are received at our facility, we will send you replacement devices.

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The affected AlboGraft SN's are shown in the table below. The REF's are in bold print.

AMC1407	**AMC1608**	**AMC1809**	**ASC4008**	**ATC3006**
30070232	30085314	30088762	30079029	30085951B
30084574	30086064	30088770	30082968A	**ATC3008**
30084584	30086103	30092826	30083113	30084081A
30086057	30086106	**AMC2211**	**ASC8006**	30084224B
30086765	30086112	30085365	30050476	30091148A
30089399	30086681	30085972	30090742	**ATC3028**
30093087	30087045	**AMC3016**	**ASC8008**	30069690
30093963	30089213	30086435	30071019	30078350
AMC1608	30093685	30048772B	30071645	30083459
30056991	**AMC1809**	**AMC3018**	30085260	**ATC3030**
30066712	30064994	30048711B	**ATC1526**	30078398
30072687	30081406	30081149	30080228A	30078412
30078916	30082006	30087687	**ATC1528**	30079701
30079545	30082011	**AMC3020**	30077484A	30079710
30082254	30084116	30053168	30078367B	30080494
30082278	30084119	**AMC6006**	30080562B	30080506
30082280	30084138	30088291	30080572A	30081305
30082293	30084867	30088292	30082492A	**ATC3032**
30082320	30084869	**ASC4006**	**ATC1530**	30078575
30083897	30088517	30088087A	30082473A	30079377
30083918	30088518	30088091B	30083339A	30080526
30083945	30086984	30088092B		**ATC4006**
		30088293A		30082031
				30082382

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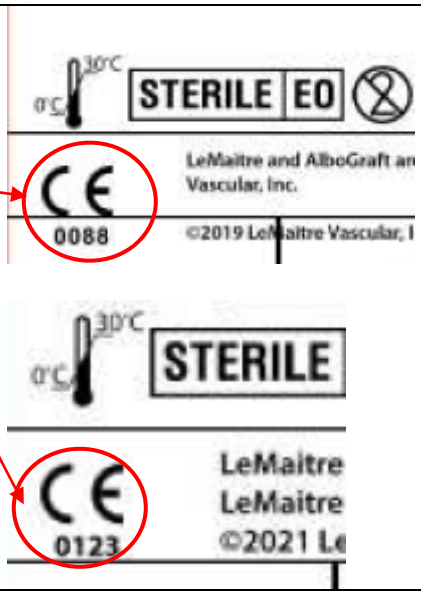
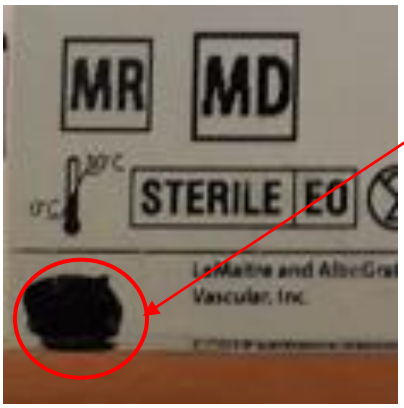
Labels with either CE0123 or CE0088 are acceptable. No action is required by the customer.		Labels with no CE mark and blacked out CE mark. These are the devices that we are withdrawing from the market.
		
ACTION: No action is required by the customer. You do not need to send a reply form LeMaitre.		ACTION: If you HAVE any affected devices in your inventory that have no CE mark or a blacked out CE mark, please complete he attached form, scan it and email it to recalls-emea@lemaitre.com.by March 30, 2022 . We will send you instructions on how to return the devices and, when they are received, we will send you replacement devices..

Thank you very much for your assistance.

Sincerely,

[redacted]

[redacted]
EU Authorized Representative
LeMaitre Vascular GmbH
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If you have affected devices, please scan the completed form and email it to **recalls-emea@lemaitre.com**.

If we do not receive a reply form from you by March 30, 2022, we will assume that you have no devices that need to be returned.

Account #*	Customer Name*	Address
<<Customer #>>	<<CustomerName>>	<<Address 1>> <<City>>, <<State>> <<Zip>>

**If you are not the customer listed here, please list your facility information.*

Contact Name	Contact Email	Contact Phone
Signature and Date:		

List the affected devices you have at your facilty.

REF (catalog) #	LOT #	QUANTITY ON HAND

ADDRESS TO WHICH REPLACEMENT DEVICES SHOULD BE SENT :

Distributors: Please check the boxes below.

☐ 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.