

Risk Management
<<Sell-to Cust. Name>>
<<Address 1>>
<<Address 2>>
<<Post Code>> <<City>>
NL

February 18, 2022

URGENT FIELD SAFETY NOTICE: AlboGraft Polyester Vascular Graft

Dear Sir or Madam,

LeMaitre is withdrawing and exchanging certain AlboGraft devices due to a change in regulatory status.

BACKGROUND: In 2020, Ministerie van Volksgezondheid, Welzijn en Sport granted LeMaitre permission (derogation) to supply AlboGraft devices on the Dutch 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 Ministerie van Volksgezondheid, Welzijn en Sport for allowing us to serve our customers while we worked to gain approval from our new notified body. They have 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.

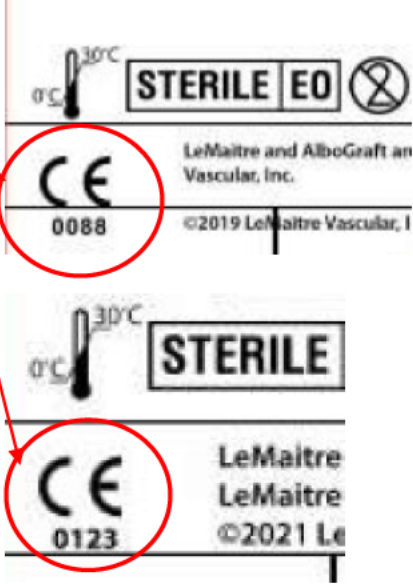
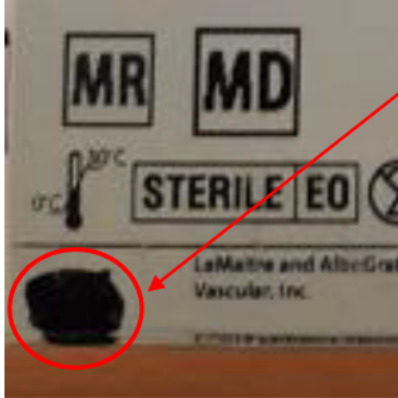
ACTIONS TO BE TAKEN BY THE CUSTOMER:

- 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 recall 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 and those devices do not need to be returned.) 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 it 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.

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

AMC1407	AMC1407	AMC1518	AMC1608	AMC1608	AMC1809	AMC2010	AMC3008
30081123	30093816	30080276B	30078912	30086197	30084156	30089761	30095127
30081989	30093817	30080925A	30078948	30086400	30084166	30089764	30095237
30083622	AMC1408	30080925B	30078949	30086405	30084173	30090505	30098230
30084552	30083811	30081088A	30078956	30086684	30084175	30090564	30098298
30084555	30083854	30084845B	30079002	30086691	30084866	30090848	30098304
30084570	30085861	30087411B	30079550	30086696	30084950	30092490	AMC3010
30084575	AMC1516	30087418A	30079576	30086697	30084952	AMC2211	30092938
30084577	30048878A	30087428A	30082275	30086940	30085009	30081705	30093042
30085144	30048948A	30087428B	30082294	30086942	30085010	30085377	30093044
30085152	30076795B	30087429A	30083874	30086999	30085015	30085786	30096398
30085174	30077750A	30087705B	30083887	30087041	30086147	AMC3006	30096682
30085175	30077750B	AMC1520	30083902	30087044	30086148	30087548B	AMC3014
30086059	30077776A	30054664A	30083922	30087069	30086705	30087623A	30085459
30086666	30077776B	30054665B	30083929	30088735	30086986	30087623B	AMC3016
30086672	30078195A	30054666A	30083936	30088755	30086987	30088352A	30048772A
30086958	30078195B	30054668A	30084890	30088760	30087274	30088412A	AMC3018
30087076	30078199A	30054669B	30084900	30088880	30088511	30091530	30081081
30087079	30080418A	30054670A	30085429	30089189	30088512	30091533	30082016
30087085	30080418B	30054670B	30085954	30089347	30088765	30091943A	30087711
30088473	30085753A	30080755B	30085958	30090572	30088774	30091944B	30087712
30089326	30086127A	30080756A	30085961	30091885	30088997	30091952B	AMC3020
30090861	30086127B	30080756B	30085966	30093634	30088998	30094767A	30086644
30091808	30086129B	30080758A	30086066	AMC1809	30089359	30095248B	AMC3022
30092982	30086429A	30081176A	30086070	30076752	30089674	30095302A	30063893
30093088	30086429B	30081176B	30086077	30076766	30092281	AMC3008	AMC4006
30093089	30086433A	30081179A	30086087	30076967	30094736	30080944	30085562
30093092	30086433B	30081179B	30086091	30081407	AMC2010	30083662	30085565
30093093	30086436B	30087158A	30086092	30082010	30085344	30083684	30085566
30093096	30087970A	AMC1522	30086093	30083601	30086165	30083695	30085567
30093097	AMC1518	30063828B	30086095	30083623	30086381	30083696	30085568
30093098	30076461A	30063831A	30086119	30083626	30086992	30084799	30087389
30093108	30076734B	30063833A	30086133	30084117	30086993	30087646B	30087886
30093813	30076984A	30064516A	30086184	30084123	30088484	30087791	30087892
30093814	30078171B	30064517A	30086196	30084154	30088493	30087792	30087895
		30064517B					30087897

AMC4007	AMC6006	AMC6008	AMC6008	ASC4008	ASC6008	ASC6008	ASC8008
30073772	30088913	30083568	30087951	30078149	30079640	30091505	30094080
30074485	30088941	30083570	30087952	30078150	30079641	30094453	30094081
30074526	30088947	30085047	30087955	30078788	30081756	30094454	30094093
30084837	30090537	30085048	30087957	30079029	30081763	30094455	30094094
30085104	AMC6007	30085056	30087960	30079117	30081765	30094462	30094099
30085108	30075758	30085063	30087966	30079618	30081782	30094463	30094137
30085178	30075768	30085064	30087969	30079623	30081919	30094464	30095007
30087660	30075774	30085065	30087985	30079626	30081920	ASC8006	30095010
30089645	30075776	30085085	30088003	30082966A	30082630	30034132	30095477
AMC4008	30082759	30085100	30088007	30082966B	30082631	30049352	ATC1207
30085632	30082760	30085603	30088309	30083117	30082714	30089834	30083768
30085690	30082829	30085622	30088316	30083150	30082971	30090287	30083775
30089135	30085303	30085623	30088318	30091400B	30082977	30090368	
30089136	30088362	30085648	30088320	ASC6006	30082978	30090371	
30089142	30088363	30085656	30088328	30088095	30082981	30090373	
AMC6006	30088364	30087813	30088329	30088096	30082983	30090392	
30033944	30088365	30087822	30088330	30088097	30082984	30091378	
30036486	30088367	30087828	30088930	30088411	30082988	30091390	
30048791	30088368	30087829	30088936	30088415	30083000	30091391	
30084962	30092110	30087830	30088939	30088416	30083005	ASC8008	
30085209	AMC6008	30087831	30089423	30088422	30083018	30082639	
30086658	30082689	30087835	30092572	30091513	30083019	30082642	
30086659	30082691	30087836	AMC6010	30091518	30083572	30082645	
30087096	30082692	30087914	30082838	30091519	30088108	30082682	
30088300	30082693	30087916	30082840	30091521	30088109	30082790	
30088349	30082707	30087918	30082842	30091524	30088110	30082803	
30088785	30082712	30087919	30085801	30092776	30091261	30082973	
30088786	30082813	30087920	30085812	30092777	30091263	30082989	
30088787	30082814	30087923	30093573	30094785	30091264	30083004	
30088788	30083026	30087926	ASC4006	30094788	30091284	30085241	
30088789	30083029	30087927	30088086A	30094789	30091344	30085242	
30088790	30083038	30087932	30088086B	30094791	30091345	30085255	
30088792	30083167	30087940	30088087A	30094792	30091346	30091822	
30088793	30083564	30087948		30094793	30091348	30091825	
	30083565			30094902			

<p>Labels with either CE0123 or CE0088 are acceptable. No action is required by the customer.</p>	<p>Labels (shown below) with the CE mark blacked out are the devices that we are withdrawing from the market.</p>
	
<p>ACTION: No action is required by the customer. You do not need to send a reply form LeMaitre.</p>	<p>ACTION: <u>If you HAVE any affected devices in your inventory that have no CE mark or a blacked out CE mark</u>, please complete the 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.</p>

Transmission of this Field Safety Notice:

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

Please transfer this notice to other organisations on which this action has an impact.



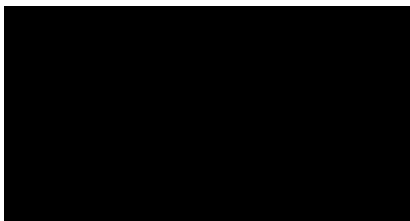
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65843 Sulzbach/Ts.
Germany

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+49 (0)6196 527072 Fax

 www.lemaitre.com

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersigned confirms that this notice has been sent to the appropriate Regulatory Agency.



EU Authorized Representative
LeMaitre Vascular GmbH
Otto-Volger-Str. 5 a/b
65843 Sulzbach, Germany
+49 (0)6196 659 23-0

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>>, NL <<Postal Code>>

**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 facility.

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.