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Your reference

Our reference  
TM

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Date  
28 June 2013

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## Urgent Field Safety Notice

**Device: AlboGraft® Polyester Vascular Graft**

**Action: Return the device to manufacturer via Authorised Representative**

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Dear Sir or Madam

### Description of the affected devices:

Device Name: AlboGraft® Polyester Vascular Graft

Intended Use: The AlboGraft Polyester Vascular Graft is intended to replace sections of damaged or malfunctioning arteries.

Product in your possession:

Model Numbers, Serial Numbers and LOT Number affected:

Model Number	Serial Number (SN)	LOT Number
AMC1608	30008223	56890

### Description of the problem:

LeMaitre Vascular has received reports that AlboGraft Polyester Vascular Grafts did show blood blushing/extravasateing from the surface of the grafts after implantation.

LeMaitre Vascular does not currently have sufficient information to finally determine the root causes of these events. LeMaitre Vascular is therefore issuing this Field Safety Notice to withdraw the affected product from the field while investigating the final root cause of this issue.

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**Actions requested of you if your responsible LeMaitre Representative has not already withdrawn or you have not already returned the product in your possession:**

- identify and quarantine the device with the model numbers and serial numbers (SN) in conjunction with the LOT number 56890
- return the identified device to LeMaitre Vascular

**Transmission of this Field Safety Notice:**

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

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

Please maintain awareness on this notice and resulting action for an appropriate period of 3 months or at least until the action has been finalized to ensure effectiveness of the corrective action.

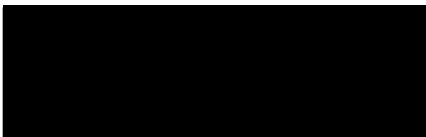
**Contact person :**

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The undersign confirms that this notice has been notified to the Federal Institute for Drugs and Medical Devices in Germany (BfArM).

LeMaitre Vascular GmbH



i.A. Tobias Malcharczik  
International Marketing Manager