

Germany

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NASDAQ: LMAT

www.lemaitre.com

Hospital Name/Distributor
Contact Person
Address



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Date
15 June 2010

Urgent Field Safety Notice

Device: The UnBalloon Non-Occlusive Modeling Catheter

Action: Return the device to manufacturer via Authorised Representative

Dear Contact Person,

Description of the affected devices:

Device Name: The UnBalloon Non-Occlusive Modeling Catheter

Intended Use: The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self expanding endoprotheses in large diameter vessels.

Model Number: 4300-02, 4300-03

Lot Number:
UMC1002 to UMC1019

Description of the problem:

LeMaitre Vascular has received reports that The Unballoon device could not be fully re-sheathed after usage.

LeMaitre Vascular does not currently have sufficient information to 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 we investigate the root cause of this issue.

Actions requested of you if your responsible LeMaitre Representatives has not already withdrawn the products in your possession:

- identify and quarantine all devices with lot numbers noted above
- return all identified devices to LeMaitre Vascular

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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 finalised 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

