



رقم المحفوظات: ٢٧١٢٥

رقم الصادر: ١٣/١/٢٨٧١١

بيروت، في:

٢ - ايار - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

AlboGraft Knitted with Collagen

الجهاز المعني بالمتابعة:

- AlboGraft Knitted with Collagen
- Trade Mark: LeMaitre Vascular, Inc.
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض،
نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

بيلغ:

دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات

مدير عام الصحة
د. وليد عمار



[Home](#) [Medical Devices](#) [Medical Device Safety](#) [Medical Device Recalls](#)

Medical Devices

LeMaitre Vascular, Inc., Albograft Vascular Graft

Recall Class: Class I

Date Recall Initiated: June 17, 2013

Product: Albograft Vascular Graft

Models: AMC1408, AMC1506, AMC1608, AMC1809, AMC1810, AMC2010, AMC4007, AMC4008, AMC6006, AMC6007, AMC6008, ATC1526, ATC1530, ATC3016, ATC3018, ATC3024, ATC3026, **Batch** 56890A

Within the U.S., this device was only distributed in Pennsylvania.

This device was manufactured in April 2011, and distributed from April 2011, through June 2013.

Use: The Albograft Vascular Graft is made of synthetic material. It is designed to replace or repair a damaged artery with an abnormal enlargement (aneurysm) or a blockage (occlusion) caused by a disease.

Recalling Firm:

Lemaitre Vascular, Inc.
63 Second Avenue
Burlington, Massachusetts 01803

Reason for Recall: This product was recalled due to blood leaking from the surface of the graft after implantation. This product may cause serious adverse health consequences, including death.

Public Contact: Customers with questions can contact LeMaitre Vascular at 781-221-2266, ext. 183.

FDA District: New England District Office

FDA Comments:

On June 19 2013, the firm sent an Urgent Field Safety Notice dated June 19, 2013, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to identify and return the affected devices to LeMaitre Vascular. They in turn will replace the devices.

LeMaitre Vascular visited the U.S. customer on June 18, 2013, and removed the devices.

Customers who have questions about this recall can call the firm at 781-425-1670, ext. 108.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program¹ either online, by regular mail or by FAX.

Page Last Updated: 07/24/2013

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993