RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٤٥
رقم الصادر: ٥٨٥/١/١٣
بيروت، في: ٩ أيار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Markers, Implantable Radiographic, VascuTape Radiopaque Tape, LeMaitre Stent Guide.

الجهاز المعني بالمتابعة:

- Markers, Implantable Radiographic, VascuTape Radiopaque Tape, LeMaitre Stent Guide.
- Trade Mark: LeMaitre Vascular GmbH
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى اشكالية في طريقة التوضيب مما قد يؤثر على عملية التعقيم، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

Class 2 Recall
VascuTape Radiopaque Tape

See Related Information 20

Date Posted	April 04, 2013
Recall Number	Z-1055-2013
Product	Glow 'N Tell 20 cm Tape: 1100-00 (100 strips); 1100-50 (50 strips); 1100-20 (20 strips). Intended to be placed on the skin to assist during imaging procedures.
Code Information	SGL1190, exp 2017-02; SGL1196, exp 2017-09; SGL1197, exp. 2017-09
Recalling Firm/ Manufacturer	LeMaitre Vascular, Inc. 63 2nd Ave Burlington, Massachusetts 01803-4413
For Additional Information Contact	Laurie Churchill 781-221-2266 Ext. 108
Reason for Recall	Devices were not sealed correctly during the manufacturing process, and the sterility of these products have been compromised.
Action	LeMaitre sent an "URGENT:VASCUTAPE RADIOPAQUE TAPE DEVICE FIELD SAFETY NOTICE" dated March 20, 2013 to affected customers. The recall letter contains a form that requests customers to return to LeMaitre Vascular, Inc. as a record of notification and reconciliation. The letter provides instructions on how the customer can inspect the defective tape seals and/or return the affected products for replacement/credit.
Quantity in Commerce	13560
Distribution	Worldwide Distribution-USA (nationwide) and the countries of Canada, EU, and Asia.

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17. ../Medsun/searchReportText.cfm
18. ../cfClia/Search.cfm
19. ../cfTPLC/tplc.cfm
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=%3Ch3%3Erelated%20recalls%20for%20VascuTape%20Radiopaque%20Tape%3C%2Fh3%3E&item1_url=www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?