REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٥ / ٢٧
رقم الصادر : ١٢/١/٢٨٦٠٦
بيروت، في : ٣٠ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Pediatric filter, Affinity Pediatric Arterial Filter

الجهاز المعني بالمتابعة:

- Pediatric filter, Affinity Pediatric Arterial Filter
- Trade Mark: Medtronic Inc Cardiac Rhythm Disease Management Div
- Local Representative: Tamer Frères

بناء على التقرير الصادر عن وكالة ال FDA ،
الذي يشير الى وجود خلل في عملية تصنيع الجهاز المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التقرير الصادر عن وكالة ال FDA

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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Medical & Radiation Emitting Device Recalls

Class 2 Recall
Affinity Pediatric Arterial Filter,

Date Posted	August 14, 2013
Recall Number	Z-1966-2013
Product	Medtronic Affinity Pediatric Arterial Filter, model number S4014, sterilized using ethylene oxide. The Affinity Pediatric Arterial Filters are single-use, sterile, nonpyrogenic devices designed to filter microemboli greater than the specified micron size from the circuit for periods up to 6 hours during cardiopulmonary bypass surgery. These devices are available both in an uncoated and a Carmeda coated option. The Carmeda coating is a BioActive surface that is non-leaching and provides a thromboresistant blood contact surface.
Code Information	Lot Numbers: 12635577 and 12637041
Recalling Firm/ Manufacturer	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
For Additional Information Contact	Technical Services 877-526-7890
Reason for Recall	Medtronic is recalling 148 Affinity Pediatric Arterial Filters from 2 manufacturing lots because a limited quantity of filters may have a small breach in the filter media that may allow unwanted particulate or gaseous emboli to pass through the filter and the outlet of the device, which could result in serious injury to a pediatric patient including neurological damage, or potential patient death.
Action	Customer communication was initiated verbally on June 14, 2013, to the 4 affected customers to quarantine any un-used units. An Urgent Medical Device Recall letter, dated June 26, 2013. was mailed to customers on June 28, 2013. The Urgent Medical Device letter referenced that the letter is in follow-up to the previous phone call. It identified the affected product, stated the issue with the 2 affected lot numbers and health risks, and asked that the affected devices be quarantined for return to Medtronic. If you have any questions please contact your Medtronic Sales representative or Lifeline Techical Services at 1-877-526-7890. 1-763-526-7890.
Quantity in Commerce	148 devices
Distribution	Worldwide Distribution - US Distribution only to MS and IL, and the countries of Argentina and Singapore.

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