



رقم المحفوظات: ٤٧ / ٢٥  
رقم الصادر: ١٢ / ١ / ٢٨٦.٦  
بيروت، في: ٢٠ 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 اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

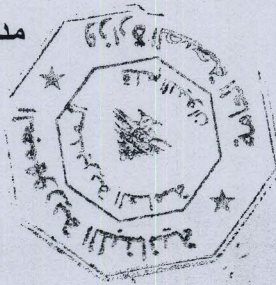
- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة

د. وليد عمار





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## Medical & Radiation Emitting Device Recalls

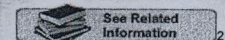


510(k)<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>10</sup> | PMA<sup>11</sup> | Classification<sup>12</sup> | Standards<sup>13</sup> | Inspections<sup>14</sup>  
 CFR Title 21<sup>15</sup> | Radiation-Emitting Products<sup>16</sup> | X-Ray Assembler<sup>17</sup> | Medsun Reports<sup>18</sup> | CLIA<sup>19</sup> | TPLC<sup>20</sup>

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### Class 2 Recall Affinity Pediatric Arterial Filter,



<b>Date Posted</b>	August 14, 2013
<b>Recall Number</b>	Z-1966-2013
<b>Product</b>	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.
<b>Code Information</b>	Lot Numbers: 12635577 and 12637041
<b>Recalling Firm/ Manufacturer</b>	Medtronic Inc. Cardiac Rhythm Disease Management 8200 Coral Sea St NE Saint Paul, Minnesota 55112-4391
<b>For Additional Information Contact</b>	Technical Services 877-526-7890
<b>Reason for Recall</b>	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.
<b>Action</b>	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 Technical Services at 1-877-526-7890. 1-763-526-7890.
<b>Quantity in Commerce</b>	148 devices
<b>Distribution</b>	Worldwide Distribution - US Distribution only to MS and IL, and the countries of Argentina and Singapore.

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