



رقم المحفوظات: ٣٨١٢٥  
رقم الصادر: ١٣/١/١٤١٦٦  
بيروت، في: ٢٤ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Amplatz TorqVue FX Delivery System

الجهاز المعنى بالمتابعة:

- Amplatz TorqVue FX Delivery System
- Trade Mark: St. Jude Medical Inc.
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA ، والذي يشير الى وجود خلل في طريقة عمل الصنف الوارد اعلاه ، مما قد يؤثر على سلامة المريض، 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 عمّار



U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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**Class 1 Recall  
AMPLATZER® TorqVue® FX  
Delivery System**

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<b>Date Posted</b>	February 11, 2013
<b>Recall Number</b>	Z-0763-2013
<b>Product</b>	St. Jude Medical, AGA Medical corporation, AMPLATZER® TorqVue® FX Delivery System. Model #'s: 9-ITVFX06F45/60, 9-ITVFX07F45/60, 9-ITVFX007F45/80, 9-ITVFX08F45/60, 9-ITVFX08F45/80, 9-ITVFX09F45/80, 9-ITVFX10F45/80 9-ITVFX12F45/80, 9-ITVFX13F45/80. Cardiac surgical instrument, used to close atrial septal defects between the right and left atriums.
<b>Code Information</b>	all batches
<b>Recalling Firm/ Manufacturer</b>	St Jude Medical Inc 177 E County Road B Saint Paul, Minnesota 55117-1951
<b>Reason for Recall</b>	The distal end of the core wire of the TorqVue FX Delivery System could potentially fracture when exposed to a combination of certain cardiac anatomies and usage conditions.
<b>Action</b>	St. Jude Medical sent an "URGENT MEDICAL DEVICE RECALL NOTICE" dated January 18, 2013 to all affected customers. The letter identified the product, problem, and actions to be taken by the customers. Customers were advised to discontinue use of the device and remove it from inventory. Customers should contact their SJM sales representative for questions relating to this recall.
<b>Quantity in Commerce</b>	635
<b>Distribution</b>	Nationwide Distribution-including DC and the states of AL, AR, AZ, CA, CO, CT, DE, FL, GA, HI, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, NE, NH, NJ, NV, NY, OH, OK, OR, PA, RI, SC, TX, VA, WA, and WI.

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
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3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. [../cfPMN/pmn.cfm](..cfPMN/pmn.cfm)
8. [../cfRL/rl.cfm](..cfRL/rl.cfm)
9. [../cfMAUDE/TextSearch.cfm](..cfMAUDE/TextSearch.cfm)
10. [../cfRES/res.cfm](..cfRES/res.cfm)
11. [../cfPMA/pma.cfm](..cfPMA/pma.cfm)
12. [../cfPCD/classification.cfm](..cfPCD/classification.cfm)
13. [../cfStandards/search.cfm](..cfStandards/search.cfm)
14. [../cfCFR/CFRSearch.cfm](..cfCFR/CFRSearch.cfm)
15. [../cfPCD\\_RH/classification.cfm](..cfPCD_RH/classification.cfm)
16. [../cfAssem/assembler.cfm](..cfAssem/assembler.cfm)
17. [../Medsun/searchReportText.cfm](..Medsun/searchReportText.cfm)
18. [../cfClia/Search.cfm](..cfClia/Search.cfm)
19. [../cfTPLC/tplc.cfm](..cfTPLC/tplc.cfm)
20. [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page\\_title=medical%20device%](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recall)