



رقم المحفوظات: ٢٨/٢٥  
رقم الصادر: ١٣/١٤٥٧٣  
بيروت، في: ٢٧ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Medtronic Archer 0.035 inch (0.89mm) Super Stiff Guidewire

الجهاز المعني بالمتابعة:

- Medtronic Archer 0.035 inch (0.89mm) Super Stiff Guidewire, Models ARCSJ200W, ARCSJ260W, and ARCDJ260W.
- Trade Mark: Medtronic Inc.
- Local Representative: Intermedic/ Prime Medical/ Meditec

بناء على التقرير الصادر عن وكالة ال FDA

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

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

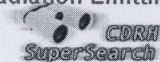
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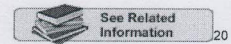


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**Class 2 Recall**  
**Archer 0.035 inch (0.89mm) Super**  
**Stiff Guidewire**



<b>Date Posted</b>	March 28, 2013
<b>Recall Number</b>	Z-1019-2013
<b>Product</b>	Medtronic Archer 0.035 inch (0.89mm) Super Stiff Guidewire, Models ARCSJ200W, ARCSJ260W, and ARCDJ260W. Sterile using ethylene oxide. Product Usage: The Medtronic Archer 0.035 inch (0.89mm) Super Stiff Guidewires are intended to facilitate catheter placement and exchange during diagnostic or interventional procedures in the aorta, where increased support, distal flexibility, and low surface friction of the guidewire is needed.
<b>Code Information</b>	Model ARCSJ200W Lot Numbers: GFWC1124, GFWC1506, GFWC2138, GFWC2652, GFWC2653, GFWD0353, GFWD0881, GFWD0882, GFWD2048, GFWD2049, GFWD2050, GFWD2051, GFWD2052, GFWE0743, GFWE0744, GFWE0745, GFWE0746, GFWE0747, GFWE3710, GFWE4272, GFWE4273, GFWE4274, GFWE4275, GFWF0143, GFWF0144, GFWF0147, GFWF0148, GFWF0149, GFWG0428, GFWG0429, GFWG0430, GFWG0431, GFWG0432, GFWG0433, GFWG0434, GFWH0333, GFWH0334, GFWH0335, GFWH0336, GFWH0337, GFWH0338, GFWI0190, GFWI0191, GFWI0192, GFWI0193, GFWI0194, GFWI0195, GFWJ0027, GFWJ0028, GFWJ0029, GFWJ2454, GFWJ2455, GFWJ2456, GFWJ2457, GFWJ2458, GFWK1910, GFWK1911, GFWL0370, GFWL2571, GFWL2572, GFXA0224. Model ARCSJ260W Lot Numbers: GFWC1501, GFWC1502, GFWC1503, GFWD0883, GFWD0884, GFWD3256, GFWE0752, GFWE0753, GFWE3711, GFWF0145, GFWF0150, GFWG0425, GFWG0426, GFWG0427, GFWH0344, GFWH0345, GFWI0201, GFWI0202, GFWI0203, GFWJ0418, GFWJ0419, GFWJ0420, GFWJ2461, GFWJ2462, GFWJ2464, GFWJ2465, GFWL0368, GFWL0369, GFWL0415, GFWL0416, GFXA0219, GFXA0220, GFXA0221, GFXA0222. Model ARCDJ260W Lot Numbers: GFWC1507, GFWC1508, GFWD0885, GFWE0750, GFWE0751, GFWF0142, GFWF0146, GFWG0423, GFWG0424, GFWH0331, GFWH0332, GFWI0186, GFWI0187, GFWI0188, GFWJ2449, GFWJ2450, GFWJ2451, GFWJ2452, GFWK1844.
<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>	Medtronic Customer Service 888-283-7868
<b>Reason for Recall</b>	Medtronic has identified an issue involving specific lot numbers of the Medtronic Archer 0.035 inch (0.89mm) Super Stiff Guidewire, Models ARCSJ200W, ARCSJ260W, and ARCDJ260W, where a change in the manufacturing process has been identified as the cause for potential kinking and breaking at the proximal weld end of the outer spring coil during in-vivo use.
<b>Action</b>	Medtronic sent an Urgent Medical Device Recall letter dated March 2013 to all affected customers. The letter identifies the affected product, problem and actions to be taken. Customers were instructed to immediately quarantine all affected products and returned to Medtronic. Customers were requested to complete the attached Customer Confirmation Certificate and fax it to Medtronic to the attention of Customer Focused Quality. For question contact your local Medtronic representative or Medtronic Customer Service at 1-888-283-7868.
<b>Quantity in Commerce</b>	27,682 devices
<b>Distribution</b>	Worldwide Distribution - USA (nationwide) including Puerto Rico and the countries of: Argentina, Armenia, Australia, Austria, Belgium, Bolivia, Canada, Chile, China, Colombia, Croatia, Czech Republic, Ecuador, El Salvador, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, India, Indonesia, Iran, Israel, Italy, Jordan, Korea, Kuwait, Latvia, Lebanon, Libya, Malaysia, Montenegro, Morocco, Netherlands, New Zealand, Norway, Oman, Philippines, Poland, Portugal, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, Venezuela, Viet Nam.

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