جانب تقييم 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

FDA بناء على التقرير الصادر عن وكالة الـFDA والذي يشير إلى وجود خلل في عملية تصنيع الصنف المذكور أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تمييز هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:
- التقرير الصادر عن وكالة الـFDA

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- دائرة البرامج والمشاريع المستشفيات الحكومية المحفوظات
Class 2 Recall
Archer 0.035 inch (0.89mm) Super Stiff Guidewire

Date Posted
March 28, 2013

Recall Number
Z-1019-2013

Product
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 surfactant friction of the guidewire is needed.

Code Information
Model ARCSJ200W Lot Numbers: GFWC1124, GFWC1506, GFWC2138, GFWC2852, GFWC2653, GFWD0353, GFWD0891, GFWD0862, GFWD2048, GFWD2249, GFWD2305, GFWD2051, GFWD2052, GFWE0743, GFWE0744, GFWE0745, GFWE0746, GFWE0374, GFWE0370, GFWE4272, GFWE4273, GFWE4274, GFWE4275, GFWF0143, GFWF0144, GFWF0147, GFWF0148, GFWF0149, GFWG0428, GFWG0429, GFWG0430, GFWG0431, GFWG0432, GFWG0433, GFWG0434, GFWG0435, GFWG0436, GFWG0437, GFWG0338, GFWG0190, GFWG0191, GFWG0192, GFWG0193, GFWG0194, GFWG0195, GFWG0207, GFWG0308, GFWG0309, GFWG0454, GFWG0455, GFWU2456, GFWU2457, GFWU2458, GFWK0192, GFWK0191, GFWL0370, GFWL0371, GFWL0571, GFWL2572, GFWX0224, Model ARCSJ260W Lot Numbers: GFWC1501, GFWC1552, GFWC1503, GFWD0863, GFWD0884, GFWD2356, GFWE0752, GFWE0753, GFWE3771, GFWF00145, GFWF0150, GFWG0425, GFWG0426, GFWG0427, GFWH0344, GFWH0345, GFWH0346, GFWH0347, GFWH0348, GFWH0349, GFWU0202, GFWU0203, GFWU0418, GFWU0419, GFWU0420, GFWU0421, GFWU0422, GFWU0423, GFWU0424, GFWU0425, GFWU0426, GFWU0427, GFWU0428, GFWU0429, GFWU0430, GFWU0431, GFWU0432, GFWU0185, GFWU0186, GFWU0187, GFWU0188, GFWU2449, GFWU2450, GFWU2451, GFWU2452, GFWU2453, GFWU2454.

Recalling Firm/Manufacturer
Medtronic Inc. Cardiac Rhythm Disease Management
8200 Coral Sea St NE
Saint Paul, Minnesota 55112-4391

For Additional Information Contact
Medtronic Customer Service
888-293-7888

Reason for Recall
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.

Action
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 at the attention of Customer Focused Quality. For question contact your local Medtronic representative or Medtronic Customer Service at 1-888-293-7888.

Quantity in Commerce
27,682 devices

Distribution
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, Venezuela, Viet Nam.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesafda/index.cfm
7. ../cfMMV/pmn.cfm

5/7/2013