Medtronic News

FDA Classifies Medtronic's Worldwide Voluntary Field Action on Guidewires as Class I Recall

Thomson Reuters ONE via COMTEX) --MINNEAPOLIS -- Nov. 15, 2013 -- Medtronic, Inc. (NYSE: MDT) announced today that the U.S. Food and Drug Administration (FDA) has classified the company's recently initiated voluntary field action related to certain guidewires as a Class I recall.

Based on an internal investigation following a limited number of complaints, including one patient injury, Medtronic began notifying hospitals and distributors worldwide the week of Oct. 21 that some models of its guidewires from recent lots have the potential for the coating on their surface to delaminate and detach. The notification requested that all potentially affected units be quarantined immediately and returned to the company as soon as possible for credit and replacement.

Medtronic has also taken the necessary steps to prevent future shipments of the recalled products and notified regulatory agencies around the world as appropriate.

The FDA defines a Class I recall as a situation in which there is a reasonable probability that use of, or exposure to, a violative product will cause serious adverse health consequences or death.

The guidewires covered by this recall are designed to facilitate percutaneous coronary interventions or the placement of left ventricular leads for cardiac rhythm devices. They include specific lots from the following eight product lines that were manufactured after mid-April 2013:

- Cougar nitinol workhorse guidewire

- Cougar steerable guidewire

- Zinger stainless steel workhorse guidewire

- Zinger steerable guidewire

- Thunder extra-support guidewire

- Thunder steerable guidewire

- ProVia crossing guidewire

- Attain Hybrid guide wire

Additional information about the recall, including the lot numbers of affected product, is accessible through the Medtronic website -- specifically, http://www.medtronic.com/for-healthcare-professionals/index.htm.

Observations and consequences of the coating issue related to these guidewires should be reported to Medtronic in the United States by calling +1-877-526-7890 on weekdays from 8am to 5pm U.S. Central Time.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or

- Call FDA at +1-800-FDA-1088

ABOUT MEDTRONIC

Medtronic, Inc. (www.medtronic.com), headquartered in Minneapolis, is the global leader in medical technology -- alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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