Medtronic News

FDA Classifies Previous Field Action of Medtronic Surgical Device as Class I Recall

MINNEAPOLIS, Oct 29, 2010 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) has classified the company's previous action related to the Octopus(R) Nuvo Tissue Stabilizer as a Class I recall. FDA classifies a recall as Class I when the agency believes that there is a reasonable probability that use of the recalled product will cause serious adverse health consequences or death. On Sept. 14, 2010, Medtronic proactively and voluntarily recalled the device from the market due to the potential that a component of the device could fracture during use. The resulting potential hazards are that fragments of the component could fall into the patient's chest cavity and/or damage the heart tissue. Medtronic has received two reports of device failure occurring during patient use, which required retrieval of device fragments from the surgical wound; neither event resulted in permanent impairment or death.

Healthcare facilities should immediately discontinue use of the device and return all unused Octopus Nuvo Tissue Stabilizer devices to Medtronic. No action is required of patients, as any adverse event related to the disposable device would have occurred at the time of surgery.

All Octopus Nuvo Tissue Stabilizer devices are affected; no other models in the Octopus family of products are affected by this recall.

Five-hundred and seventy-one devices have been distributed to healthcare facilities in the U.S., Europe and Canada. All affected healthcare facilities have been notified, and Medtronic is in the process of working with them to retrieve all remaining devices. The FDA has been apprised of this action.

Physicians and healthcare facilities can direct questions to their Medtronic representative or contact the CardioVascular Lifeline for technical services, Monday through Friday during business hours, at 1-877-526-7890. Any adverse reactions experienced with the use of this product, and/or quality problems also should be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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.

SOURCE: Medtronic, Inc.

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