Medtronic News

FDA Classifies Labeling Corrections Related to Occurrence of Pocket Fills During a SynchroMed(R) Implantable Infusion Pump Refill as a Class I Recal

MINNEAPOLIS, Feb 16, 2011 (BUSINESS WIRE) --

Medtronic, Inc. (NYSE: MDT) announced today that the U.S. Food and Drug Administration (FDA) has classified the corrections being made to product labeling in response to the occurrence of Pocket Fills during a drug refill of a SynchroMed II or SynchroMed EL Implantable Infusion Pump as a Class I recall. A Class I recall is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. This Class I recall is not related to Medtronic external insulin pumps for diabetes.

A pocket fill is the inadvertent injection during a refill procedure of all or some of the prescribed drug into the patient's subcutaneous tissue, which includes the pump pocket (area under the skin where the pump is placed), instead of the pump. Pocket fills may occur because the physician relies heavily on tactile feedback to determine if the needle is correctly positioned in the pump reservoir during drug refill. After an in-depth review of the causes of pocket fills, Medtronic determined that pump labeling could be updated to provide additional information to clinicians on using visual and tactile assessments to attain and maintain the appropriate location of the needle throughout the refill procedure.

A pocket fill can cause life threatening injuries or death due to overdose or underdose of the drug. From May 1996 through September 2010, eight deaths and 270 events requiring medical intervention (serious or life-threatening injury) have been reported related to the occurrence of pocket fills. The reported rate of occurrence per refill opportunity is as high as 1 per 10,000 refills (0.01%).

On January 14, 2011, Medtronic sent an *"Urgent: Medical Device Correction"* letter* to healthcare professionals reminding them of the potential for pocket fills to occur during the SynchroMed II or SynchroMed EL infusion pump refill procedure. Healthcare professionals were reminded that during the pump refill procedure, it is essential that the needle be inserted through the refill septum until it has reached the needle stop in the reservoir. The communication included other recommendations for avoiding pocket fills, such as steps that can be taken to assess needle position throughout the procedure and for managing patients.

The SynchroMed pump manuals and refill kit manuals currently include warnings related to the potential for improper injection. Medtronic is currently updating the labeling for the SynchroMed II and EL pumps and associated refill kits with the information and patient management recommendations from the January 2011 communication.

Medtronic is not retrieving the product from the field or recommending the removal of the product in association with its communication to physicians. Medtronic has communicated with the FDA about this issue. No new action is required of patients or physicians beyond what was included in the January 2011 Dear Healthcare Professional Letter titled, "Important Clinical Information about Pocket Fills."

Patients with questions are encouraged to talk with their physician or contact Medtronic Patient Services at 1-800-510-6735, Monday - Friday, 8 a.m. to 5 p.m. CDT. Physicians with medical questions related to this issue or Medtronic therapies should contact Medtronic at 1-800-328-0810, Monday - Friday, 8 a.m. to 5 p.m. CDT.

Also, any adverse reactions experienced with the use of this product, and/or quality problems should be reported to 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 20857, or on the MedWatch website at http://www.fda.gov/Safety/MedWatch/default.htm.

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.

*The letter can be found at www.medtronic.com/pocketfill/.

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