Medtronic News

Medtronic Issues Medical Device Notifications Regarding the SynchroMed® Implantable Infusion System

Thomson Reuters ONE via COMTEX) --FDA Classifies Notifications

MINNEAPOLIS - June 26, 2013 - In June 2013, Medtronic, Inc. (NYSE: MDT) initiated four medical device notifications to customers worldwide about the SynchroMed® Implantable Infusion System. These notifications provide clinicians with information to help identify and manage issues that impact the safe and reliable delivery of therapy using the SynchroMed Implantable Infusion System.

The United States Food and Drug Administration (FDA) has classified three of these notifications as Class I recalls.The fourth notification is an update to a 2011 action related to pump refill which was previously classified by the FDA as a Class I recall.

Patients are encouraged to maintain regular follow-up appointments with their physicians; however, if they experience a change or return of symptoms or hear a device alarm, they should contact their physician immediately. No action is required of physicians beyond the recommendations provided in the notifications.

Medtronic's intrathecal drug delivery systems are used to treat chronic, intractable pain and severe spasticity of cerebral or spinal origin. These notifications do not involve Medtronic external insulin pumps for diabetes.

Specifically, the Neuromodulation business of Medtronic has initiated the following field corrective actions:

SynchroMed Implantable Infusion Pump Priming Bolus Medtronic has issued an Urgent Medical Device Correction notification which provides physicians with important safety information and patient management recommend
The priming bolus function is used to quickly move drug from the SynchroMed pump reservoir to the catheter tip to initiate intrathecal drug delivery therapy while a patient remains under medical supervision. Medtronic has f
Medtronic recommends healthcare professionals continue using the priming bolus procedure to ensure therapy is initiated while a patient is under medical supervision. Recommendations are being provided for performing a p
SynchroMed Implantable Infusion Pump Shorting
Medtronic has issued an Urgent Medical Device Correction notification to inform physicians about the potential for an electrical short within the SynchroMed pump. The FDA has classified this notification as a Class I recall.
An electrical short could lead to pump motor stall and a subsequent loss of or reduction in therapy, which can result in the return of underlying symptoms and/or withdrawal symptoms. The SynchroMed II pump is equipped wi
Medtronic encourages patients to contact their physicians immediately if they experience a return of symptoms or hear a device alarm. The cumulative failure rate due to this issue is less than one percent at seven years pos
SC Intrathecal Catheter Product Removal
Medtronic has redesigned its Sutureless Connector (SC) Catheter to reduce the potential for occlusion, which is the blockage or cessation of drug flow due to misalignment at the point where the catheter connects to an impla
SynchroMed Implantable Infusion Pump Refill Procedure Safety Update
Medtronic is distributing a revised Clinician Refill Reference Card with information about the pump refill procedure for the SynchroMed Implantable Infusion System. This is a continuation of a 2011 notification that was previou

Medtronic continues to focus on improving the quality and reliability of its implantable drug infusion system. The SynchroMed Implantable Infusion System continues to demonstrate strong overall reliability, and Medtronic remains confident in its ability to deliver safe and effective therapy. Patients and caregivers should be aware of the signs and symptoms associated with intrathecal drug therapy complications and contact their physicians immediately if they hear a device alarm or experience symptoms of a drug overdose or underdose. Patients with questions should contact their physicians.

Additional information is available for healthcare professionals through Medtronic's website at http://professional.medtronic.com/iddadvisories or http://professional.medtronic.com/itbadvisories.

The FDA defines a Class I recall as 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. Any malfunctions or adverse events related to a device should be reported to Medtronic Neuromodulation Technical Services at, 1-800-707-0933, Monday-Friday, 8 a.m. to 5 p.m. CDT, and the FDA's MedWatch Program at http://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.

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Source: Medtronic, Inc. via Thomson Reuters ONE

HUG#1712275
