Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: July 1, 2013

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Medtronic, Inc. Recall [Medical Device]

SUGGESTED ACTION: **Class I Recall; 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; Information provided in case of consumer inquiry.**

From the information provided by FDA, the recalled products were distributed in the State of Indiana. 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.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

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

FDA Classifies Notifications

Contact
Consumer:
1-800-707-0933

Media:
Donna Marquard
Public Relations
763-526-6248

Jeff Warren
Investor Relations
763-505-2696

FOR IMMEDIATE RELEASE - June 26, 2013 - MINNEAPOLIS – 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 recommendations regarding the SynchroMed Implantable Infusion System priming bolus function. The FDA has classified this notification as a Class I recall.

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 found that any time the priming bolus is used with a SynchroMed pump, drug mixes with the sterile water or cerebrospinal fluid already in the catheter. This mixing results in the unintended delivery of drug prior to the end of the programmed bolus, as well as dilution of some of the drug remaining in the catheter at the end of the bolus. This can contribute to an increased risk of adverse events involving drug overdose or underdose following an initial

system implant or revision. The effects of a drug overdose or underdose will vary depending on the drug being infused but may include, for example, a reduced level of consciousness or a return of underlying symptoms.

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 priming bolus, monitoring patients post implant, and educating patients and caregivers. Medtronic continues to investigate factors related to this issue to determine appropriate product updates.

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 with alarms designed to alert the patient in the event of a motor stall.

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 post implant. Because of the estimated low occurrence rate, the alarm safety feature and the risks associated with replacement surgery, Medtronic is not recommending removal of the devices unless a patient's pump shows signs of a malfunction. Medtronic is in the process of developing design updates to mitigate this issue.

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 implantable pump. As a result, the company has initiated a voluntary removal of unused products manufactured before the catheter design change. To reduce the risk for occlusion, Medtronic strongly recommends that customers discontinue the use of all SC Catheter models 8709SC, 8731SC, 8596SC, 8578 manufactured prior to the design change. These products are identified by a 'use by' date prior to August 25, 2014. The FDA has classified this notification as a Class I recall.

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 previously classified as a Class I recall. The revised reference card reflects new product labeling approved by the FDA to help healthcare professionals reduce the potential for a pocket fill during the SynchroMed pump refill procedure. 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 into the pump.

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[1] or http://professional.medtronic.com/itbadvisories[2].

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[3].

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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