



## The FDA Safety Information and Adverse Event Reporting Program

### Medtronic SynchroMed Implantable Infusion System Devices: Class 1 Recalls - Feed Through Failure, Failure of Priming Bolus, and Catheter Occlusion

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**AUDIENCE:** Patients, Healthcare Professionals, Risk Managers

**ISSUE:** In June 2013, Medtronic, Inc. initiated four medical device notifications to customers worldwide about the SynchroMed Implantable Infusion System. The 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.

#### Medtronic SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps – Failure of Priming Bolus

- *Reason for Recall:* The SynchroMed Implantable Infusion Pumps are being recalled because of the unintended delivery of drugs during the priming bolus procedure. During this procedure, patients may receive the drug unintentionally at a high rate of infusion in the cerebrospinal fluid (CSF) followed by a period of reduced drug delivery after the priming bolus. This can result in a drug overdose or under dose which can lead to serious medical illness such as respiratory depression, coma or death.
- *Products:* SynchroMed II, Model 8637 (20 ml or 40 ml reservoir size) and SynchroMed EL Programmable Pumps, Models 8626, 8626L, 8627, 8627L (10 ml or 18 ml reservoir size).
- Medtronic recommends healthcare professionals continue using the priming bolus procedure to ensure therapy is initiated while a patient is under medical supervision. For Complete list of recommendations please see Class 1 Recall Notice.

#### Medtronic SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps – Feed Through Failure

- *Reason for Recall:* There is a potential for electrical shorting, internal to the SynchroMed infusion pump. An electrical short circuit in a feedthrough may present as a motor stall or low battery reset/alarm and may lead to a loss of or reduction in therapy. This may result in the return of underlying symptoms and/or withdrawal symptoms. Use of this recalled product may result in serious adverse health consequences, including death.
- *Products:* SynchroMed II, Model 8637 (20 ml or 40 ml reservoir size) and SynchroMed EL Programmable Pumps, Models 8626, 8626L, 8627, 8627L (10 ml or 18 ml reservoir size).

#### Medtronic Sutureless Connector Intrathecal Catheter Products – Catheter Occlusion

- *Reason for Recall:* The Sutureless Connector Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion, which is the blockage or stoppage of drug flow due to misalignment at the point where the catheter connects to an implantable pump. Medtronic is removing all unused products that were manufactured with the previous design. Medtronic recommends the previous design of Sutureless Connector Intrathecal Catheter Products no longer be used due to greater potential for misalignment and subsequent occlusion. This product may cause serious adverse health consequences, including drug under dose, loss of symptom relief, drug withdrawal symptoms caused by the lack of drug delivery to the Intrathecal space, and/or death.
- *Products:* Sutureless Connector Intrathecal Catheters, Models 8709SC, 8731SC and Sutureless Revision Kits, Models 8596SC, 8578
- Medtronic does not recommend the use of any affected devices with the old design.

## 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.

**BACKGROUND:** Medtronic's intrathecal drug delivery systems are used to treat chronic, intractable pain and severe spasticity of cerebral or spinal origin.

The SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps (SynchroMed Implantable Infusion Pumps) contain and administer prescribed drugs to a specific site inside the patient's body. Currently, the approved drugs for use with the SynchroMed Infusion Pump are Infumorph, Lioresal, Prialt (Ziconotide), Floxuridine, Methotrexate and Gablofen. The SynchroMed pumps are used to treat primary or metastatic cancer, chronic pain, and severe spasticity. The implantable components of the SynchroMed II infusion system include the pump, catheter, and catheter accessories.

The Sutureless Connector Intrathecal Catheter and Revision Kits are accessories to an implanted infusion system designed to store and deliver parenteral drugs to the Intrathecal space. The implanted infusion system components consist of a Medtronic SynchroMed implantable drug infusion pump and an Intrathecal Catheter. The Sutureless Revision Kit is used when a pump connector for an Intrathecal Catheter is required.

**RECOMMENDATION:** 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. 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 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- Download form6 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Read the Complete MedWatch Safety Alert with Links to Recall Notices:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm359118.htm>