

SPINE SAFETY CAUTIONARY NOTICE:

**Information for Healthcare Professionals:
Medtronic Model 8637 SynchroMed II Implantable Infusion Pump:
Class 1 Recall**

SOURCE: FDA MedWatch

Date Recall Initiated: July 5, 2011

Product: SynchroMed II Implantable Infusion Pump, models 8637-20 and 8637-40, distributed between May 2004 and July 8, 2011.

Medtronic has a [Device Identification web page](#)^{1,2} where customers can enter the serial number for any SynchroMed II infusion pump to determine if their pump is being recalled.

Use: The SynchroMed II Implantable Programmable Drug Pump is part of the SynchroMed II Infusion system designed to contain and administer prescribed drugs to a specific site. The SynchroMed II Pump is supplied in 20 ml and 40 ml reservoir sizes. In the United States, the SynchroMed II Pump is indicated when patient therapy requires the chronic infusion of the drugs or fluids. This infusion pump is indicated to deliver morphine sulfate, ziconotide and baclofen for the treatment of chronic pain, severe chronic pain and severe spasticity, respectively. It is also indicated for delivery of floxuridine and methotrexate for the treatment of primary or metastatic cancer.

Recalling Firm:

Medtronic, Inc – Neuromodulation
7000 Central Ave NE
Minneapolis, Minnesota 55432-3568

Reason for Recall: There is a potential for reduced battery performance in the SynchroMed II infusion Pump. Medtronic's analysis of the problem indicates it is related to the formation of a film within the pump battery. This problem can lead to the sudden loss of therapy and the return of underlying symptoms and/or therapy withdrawal symptoms. For example, patients receiving intrathecal baclofen therapy for severe spasticity are at risk for baclofen withdrawal syndrome, which can lead to a life-threatening condition if not treated quickly and effectively.

Medtronic encourages patients to carry their patient identification cards with them at all times and to contact their physicians immediately if they experience a return of symptoms or hear a device alarm.


SynchroMed II infusion pumps were recalled for the same battery issue in July 2009.

Public Contact: Patients with questions related to this issue are encouraged to talk with their physicians or contact Medtronic Patient Services at 1-800-510-6735, Monday – Friday, 8 a.m. to 5 p.m. CDT.

Health care providers with questions should contact their Medtronic field representative, or contact Medtronic Neuromodulation Technical Services at 1-800-707-0933.

FDA District: Minneapolis

FDA Comments:

Medtronic began notifying physicians with an [Urgent Medical Device Correction letter](#)³⁴ beginning July 05, 2011. The letter describes the issue, the potential severity of the issue, provides the statistical analysis of the event occurring, and provides patient management recommendations. A news release was issued on July 8, 2011.

Medtronic is not retrieving any implanted SynchroMed II pumps from the field. Medtronic does not recommend prophylactic replacement of SynchroMed II pumps because of the estimated low occurrence rates, the presence of pump alarms, and the risks associated with replacement surgery.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the [FDA's Safety Information and MedWatch Adverse Event Reporting Program](#)⁵ either online, by regular mail or by FAX.

- [Medtronic News Release](#)⁶⁷
- [Medtronic Patient Product Advisory](#)⁸⁹

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS website at <http://www.spine.org/Pages/PracticePolicy/ClinicalCare/SpineSafetyAlerts/Default.aspx>. This information is provided as a service for information and education only.