Medtronic Model 8637 SynchroMed II Implantable Infusion Pump: Class I Recall - Potential for Reduced Battery Performance

U.S. Food & Drug Administration

ISSUE: Medtronic and FDA notified healthcare professionals of a Class I recall of the SynchroMed II Infusion system. 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.

The recall includes the SynchroMed II Implantable Infusion Pump models 8637-20 and 8637-40, distributed between May 2004 and July 8, 2011.

BACKGROUND: 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. 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.

RECOMMENDATION: 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.

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 [1]
- Download form [2] 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

[09/12/2011 - Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *01/27/2015 - 10:31am*):
http://www.mdtmag.com/news/2011/09/medtronic-model-8637-synchromed-ii-impla

ntable-infusion-pump-class-i-recall-potential-reduced-battery-performance?qt-recent_content=0

Links:
[1] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM172798
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm271492.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm271510.htm