Medtronic SynchroMed II and SynchroMed EL Implantable Infusion Pump and Refill Kits: Class 1 Recall

U.S. Food & Drug Administration

AUDIENCE: Hospital Risk Manager

ISSUE: Pocket fills (the unintended injection of drugs or fluids into the patient's subcutaneous tissue at the pump pocket site instead of the pump) may result in patient harm, serious injury, and/or death due to drug overdose or underdose. Products Affected:

- SynchroMed II (Model No: 8637)
- SynchroMed EL (Model No: 8626 and 8627)
- Refill Kits (Model No: 8551, 8555, 8561, 8562, 8564, 8565, and 8566)

BACKGROUND: The SynchroMed II Programmable Pump and the SynchroMed EL Infusion System are used in patients undergoing therapy that requires the constant delivery of drugs or fluids into a patient's body. The Medtronic refill kit is used in refilling Medtronic implantable infusion pumps, with the exception of Medtronic MiniMed Infusion Pumps.

RECOMMENDATION: Medtronic reminded healthcare professionals to check needle placement within the pump septum during the drug refill procedure. According to Medtronic, it is essential that the needle be inserted through the refill septum until it has reached the needle stop in the pump reservoir. At every refill, patients and caregivers should be reminded about the signs and symptoms of drug overdose, underdose, and withdrawal.

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

[02/16/2011 - Medical Device Recall [3] - FDA]

SOURCE [4]

Source URL (retrieved on *10/20/2014 - 9:19am*):
http://www.mdtmag.com/news/2011/02/medtronic-synchromed-ii-and-synchromed-el-implantable-infusion-pump-and-refill-kits-class-1-recall?qt-video_of_the_day=0&qt-recent_content=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm243634.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm243686.htm