Medtronic

March 2014

Urgent Field Safety Notice

SynchroMed® II Implantable Drug Infusion Pump Overinfusion

Medtronic reference: FA596

Dear Healthcare Professional,

This letter provides important new information regarding overinfusion associated with the SynchroMed® II Implantable Pump. Overinfusion can result in a life-threatening overdose and can also result in drug withdrawal due to premature emptying of the pump. Due to the low reported rate of occurrence of this issue and the inability to predict which pumps may be at risk, Medtronic is not recommending prophylactic replacement of pumps.

This communication is based on information available to date and was developed in collaboration with clinical experts. Medtronic continues to investigate this issue and we are committed to providing updates as more information becomes available.

Explanation of the Issue:

Medtronic detected an upward shift in reports of occurrence for overinfusion. Overinfusion is defined as an infusion rate exceeding the programmed infusion rate by more than 14.5% as described in the labeling (see enclosed *flow rate accuracy* section from the SynchroMed II Implant Manual). When overinfusion occurs, it will result in a volume discrepancy at pump refill, where the volume withdrawn from the pump is less than the volume expected. The cause(s) for pump malfunction leading to overinfusion remains under investigation and has not been linked to any specific pump lot, drug used, or geographical area. Based on reports, the onset of overinfusion has occurred as early as five months after implant and throughout the service life of the pump. Reports received indicate that once a pump has started to overinfuse, infusion rates can continue to increase, in some cases abruptly.

Scope and Severity:

Based on current data from Medtronic's prospective, long-term multi-center registry study (ISPR), the occurrence rate for overinfusion is less than 0.16%[1].

As of November 18, 2013, 76 pumps have been confirmed for overinfusion through returned product analysis since the introduction of the device in 2003:

- 44 were explanted for reasons consistent with overinfusion.
  - 14 reports of life-threatening overdose
  - 27 reports of non-life threatening overdose and/or withdrawal
  - 3 reports of volume discrepancy without overinfusion symptoms
- 32 were explanted for reasons other than overinfusion. However, routine testing of returned pumps found these pumps to be overinfusing.

Adverse events associated with overinfusion will vary depending on the drug being infused, but may include confusion or altered mental state, sleepiness, nausea, respiratory depression and