Medtronic
7000 Central Ave NE
Minneapolis, MN 55432
www.medtronic.com

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

SynchroMed™ II Implantable Infusion Pumps
Models 8637-20, 8637-40

December 2019

Dear Healthcare Professional,

In October 2019, Medtronic voluntarily recalled a specific subset of SynchroMed™ II Implantable Drug Infusion Pumps, manufactured between May 2018 and April 2019 based on five (5) reports of early permanent motor stall. This voluntary recall was initiated due to the potential for the presence of a foreign particle inside the pump motor assembly which could interfere with motor gear rotation and potentially lead to a permanent motor stall. A customer notification letter provided instructions to inventory managers to return all potentially affected, non-implanted pumps remaining in customer inventory. The source of the foreign particle has been identified as a manufacturing issue and eliminated as of April 2019. This cause of motor stall due to the foreign particle has not been seen prior to these failures. All returned pumps continue to be analyzed, and Medtronic has found no additional occurrences of permanent motor stall due to foreign particle since April 2019.

Medtronic is not recommending prophylactic replacement of potentially affected SynchroMed II pumps, due to the low observed occurrence of motor stall from this issue, the presence of pump alarms, and the risks associated with replacement surgery. We recommend that you re-emphasize to patients and caregivers the signs and symptoms that could occur from a motor stall. Please see additional recommendations below.

Issue Description

As of December 3, 2019, Medtronic has confirmed five (5) reports of early permanent motor stall due to the presence of foreign particles from a manufacturing process, out of 11,299 manufactured pumps potentially affected. Of the five events, two (2) were identified prior to implant; the other three (3) occurred within 5 months of implant. In each case, the pump critical alarm functioned properly. A sixth pump, which was explanted due to infection 4 months after implant, was later found to have a foreign particle within the pumphead assembly, but there was no indication of a motor stall.

This issue presents as a permanent motor stall of the pump. A motor stall triggers the audible pump critical alarm, which is also viewable on the clinician programmer and the A820 myPTM application for patients equipped with the patient programmer. A permanent pump motor stall will result in cessation of drug infusion therapy which may result in return of underlying symptoms and/or withdrawal symptoms, which may be severe. For patients receiving intrathecal baclofen therapy, there exists the risk for Baclofen Withdrawal Syndrome, which can lead to a life-threatening condition. These are the **same symptoms and risks as with a motor stall of any cause.**

Medtronic's conclusion is that the probability of complications due to a surgical procedure and infection is significantly higher than the probability of motor stall in this population. The hazard of motor stall observed with this foreign particle event is 0.04% (0.4/1000). The baseline hazard assessment of permanent motor stall for SynchroMed II pumps is 0.14% (1.4/1000). The projected overall motor stall rate for this pump population is approximately 0.18% (1.8/1000). For context, Medtronic data indicates that a pump implant has associated baseline rates of 2.1% for surgical complications and 7.2% for infection, which could occur with prophylactic pump replacement.

Patient Recommendations

Medtronic is **not** recommending prophylactic replacement of potentially affected SynchroMed II pumps, due to the low observed occurrence of motor stall from this issue, the presence of pump alarms, and the risks associated with replacement surgery. **We recommend that you re-emphasize to patients and caregivers the signs and symptoms that could occur from a motor stall.**

Consider contacting your patients and their caregivers regarding the following:

- Being attentive to all alarms, especially critical alarms
- Steps to take in case of an emergency
- Seek immediate medical attention if they notice signs or symptoms of drug withdrawal or of their underlying condition
- What to do if they receive an alert message in the A820 my PTM application

If a motor stall occurs for any reason, each physician should follow their protocol for troubleshooting motor stalls, based on the individual needs of that patient.

For reference, the Alarms screen on the A810 SynchroMed II application on the clinician tablet programmer may be used to demonstrate the sound of the critical alarm from the patient's pump. In addition, the following link on Medtronic.com demonstrates the sound of the critical alarm tone: https://www.medtronic.com/content/dam/medtronic-com/us-en/patients/treatments-therapies/targeted-drug-delivery/sounds/targeted-drug-delivery-critcal-pump-alarm.wav

Actions
Please review and respond to Medtronic confirming that you have received this notification by completing and returning the enclosed physician confirmation form.

Medtronic has provided, per our records, a list of your patients that have been implanted with a potentially affected pump. Additionally, you can verify whether a SynchroMed II pump is affected by this recall using a serial number lookup tool located at this Medtronic website: http://mdt20-05fp.medtronic.com/.

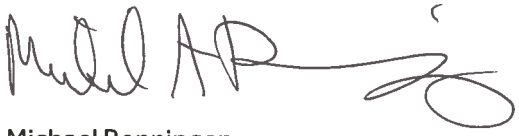
*Note: All affected devices fall within a manufacture date range of May 2018 through April 2019 however **not all serial numbers** within this date range are affected.*

Additional Information
Medtronic is communicating this recall to the appropriate regulatory agencies, including the US Food and Drug Administration (FDA). This information is available on Medtronic's website at www.medtronic.com/tddproductadvisories.

We appreciate your assistance and regret the difficulty this causes you. If you have questions or require assistance, please contact your Medtronic Field Representative or Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays from 7am-6pm CT.

Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA's MedWatch Program (www.fda.gov/medwatch).

Sincerely,



Michael Ronningen
Vice President, Quality & Regulatory Affairs

Enclosure: Physician Confirmation Form, List of potentially affected patients