

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

Retrieval of Specific Serial Numbers of SynchroMed™ II Implantable Infusion Pumps Models 8637-20, 8637-40

October 2019

Dear Customer,

Medtronic is voluntarily retrieving specific SynchroMed™ II Implantable Drug Infusion Pumps, Models 8637-20 and 8637-40, after investigating complaints related to permanent motor stall. This voluntary recall is being conducted due to the potential for the presence of a foreign particle inside the pump motor assembly which could interfere with motor gear rotation and lead to a permanent motor stall. The source of the foreign particle has been identified and eliminated.

Issue Description

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. For patients receiving intrathecal baclofen therapy, there exists the risk for Baclofen Withdrawal Syndrome, which can lead to a life-threatening condition. As of 30-SEP-2019, Medtronic has confirmed five (5) reports of early permanent motor stall due to the presence of foreign particles from a manufacturing process. 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 alarm functioned properly.

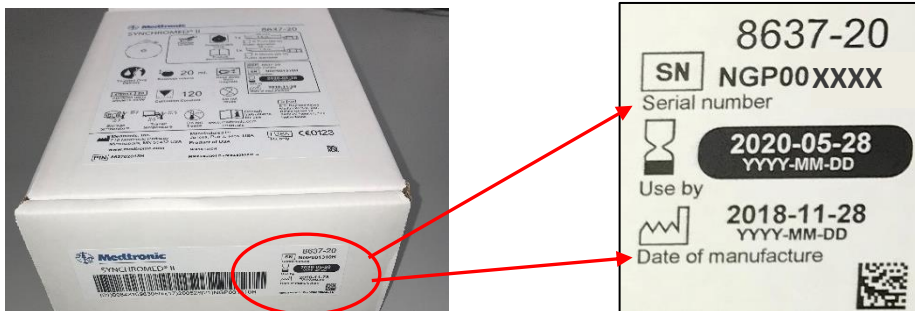
Medtronic is **not** recommending prophylactic replacement of potentially affected SynchroMed II pumps, due to the low observed occurrence of motor stall from this issue, the presence of pump alarms, and the risks associated with replacement surgery.

Product Scope

Refer to the enclosed *Customer Confirmation Form* for a listing of all device serial numbers potentially affected by this recall that, according to our records, are in your inventory. Additionally, you can verify whether your unused inventory is affected by this recall using a serial number lookup tool located at this Medtronic website: <http://mdt20-05fp.medtronic.com/>

Pump Identification

The SynchroMed II pumps that are affected and in scope of this recall can be identified by the serial number and date of manufacture on the box label, as shown below.



Note: All affected devices fall within a manufacture date range of 04-MAY-2018 through 05-APRIL-2019 (2018-05-04 to 2019-04-05), however not all serial numbers within this date range are affected.

Actions

Using the enclosed Customer Confirmation Form and/or serial number lookup website:

- Identify, locate, and segregate from use any affected unused product. Document the product information using the Customer Confirmation Form
- Call Medtronic Customer Service, referencing "FA20-05", for return authorization and credit information (1-888-638-7627)
- Return affected product per instructions located on the Customer Confirmation Form
- Return a copy of the completed Customer Confirmation Form to Medtronic **even if you do not have any unused inventory**
- Share this notification as appropriate with those in your organization who require this information.

Additional Information

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

We appreciate your assistance and regret the inconvenience 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,

A handwritten signature in black ink, appearing to read "Michael Ronningen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael Ronningen
Vice President, Quality & Regulatory Affairs

Enclosure: Customer Confirmation Form