Medtronic

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URGENT: MEDICAL DEVICE RECALL NOTIFICATION
Retrieval of Specific Serial Numbers of
SynchroMed™ II Implantable Infusion Pumps
Models 8637-20, 8637-40

17 October 2019

Attention: Risk management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Customer,

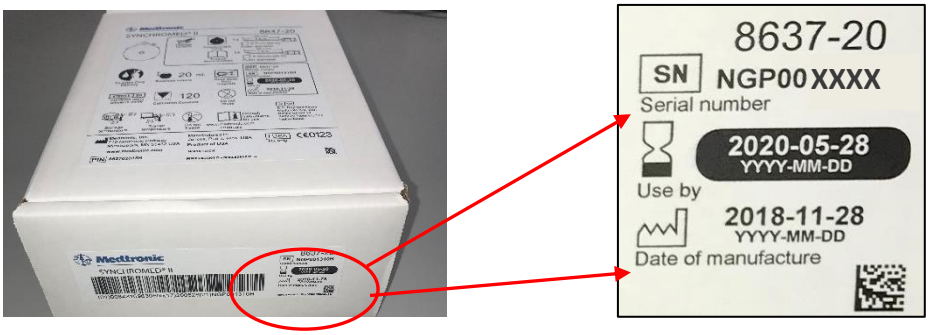
Medtronic is voluntarily retrieving specific SynchroMed™ II Implantable Drug Infusion Pumps, Models 8637-20 and 8637-40, after investigating complaints related to permanent motor stall. This voluntary recall is being conducted due to the potential for the presence of a foreign particle inside the pump 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
- 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.

Medtronic will notify all applicable regulatory agencies about this matter. Please share this notification with others in your organization as appropriate.

Please notify Medtronic of any adverse events or quality problems associated with your use of this product.

We sincerely regret any difficulties this may cause you and your patients. Medtronic remains dedicated to patient safety and will continue to monitor device performance to ensure we meet your needs and those of your patients.

We are committed to patient safety and appreciate your prompt attention to this matter. Please share this notification with others in your organization as appropriate.

Sincerely,

[redacted]
Diana Teo
QRA Lead
SEA Region (Cluster 1)

[redacted]
Chloe Tan
QRA Lead
SEA Region (Cluster 2)