Medtronic

Urgent Field Safety Notice

SynchroMed® II Implantable Infusion Pump

Models 8637-20,8637-40

Recall

October 2019

Medtronic reference: FA889

Dear Healthcare Professional,

This letter is to inform you that 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 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.

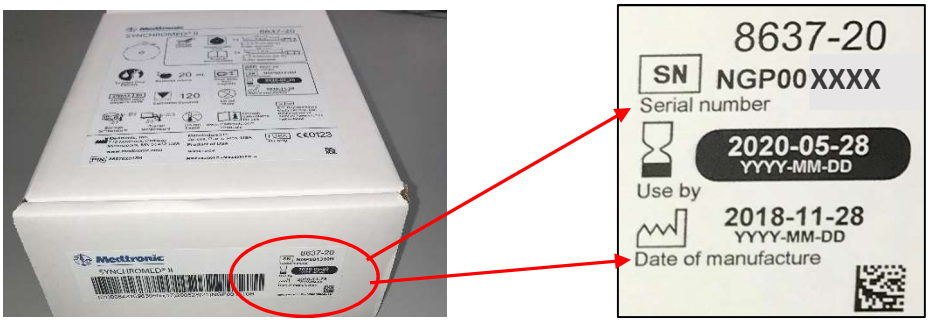
Medtronic is **not** recommending prophylactic replacement of potentially affected SynchroMed II pumps, due to the low observed occurrence of motor stall from this issue, the presence of pump alarms, and the risks associated with replacement surgery.

Product Scope

Refer to Appendix A 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 Appendix, A and/or serial number lookup website:

- Identify and quarantine all unused affected product in your inventory.
- Return all unused affected product in your inventory to Medtronic. Your Medtronic Representative can assist you in the return and replacement of this product as necessary

This notice needs to be forwarded to all those who need to be aware within your organization and to any organization where the affected product may have been transferred. This information will also be available on Medtronic's website at www.medtronic.com/tddproductadvisories.

The Competent Authority of your country has been notified of this action.

We appreciate your assistance and regret the inconvenience this causes you. If you have questions or require assistance, please contact your Medtronic Field Representative.

Sincerely,

Enclosure: Appendix A

Appendix A. Serial number list

Product/Model number	**Serial number**