Medtronic

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Urgent Field Safety Notice

SynchroMed® II Implantable Drug Infusion Pump Design Change

Models 8637-20 and 8637-40

Device Retrieval

December 2017

Medtronic reference: FA794

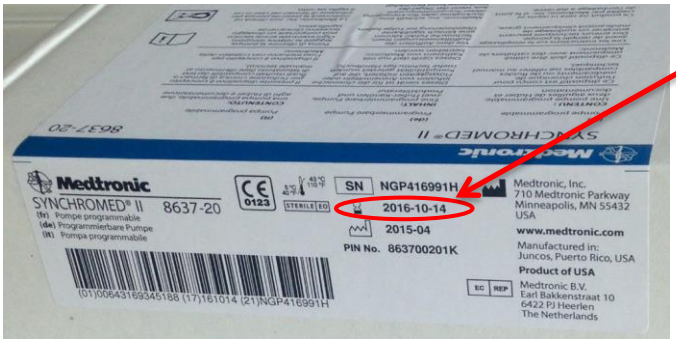
Dear customer,

The purpose of this letter is to advise you that Medtronic is voluntarily retrieving the prior configuration of SynchroMed® II implantable drug infusion pumps, as a new configuration is available with an enhanced motor design. Therefore, we are retrieving all unused pumps that were manufactured prior to the implementation of this design change. With this communication, there is no new information regarding the safety or performance of the pump. No action is required for pumps that have been implanted.

Issue Description
Medtronic has received approval for a design change to the SynchroMed II implantable drug infusion pump. This design change of the motor decreases the potential for intermittent or permanent motor stall which can cause loss of therapy. All SynchroMed II pumps are now being manufactured and distributed with this change.

Actions
Based on our records, you may have unused inventory of the SynchroMed II pump manufactured prior to the design change mentioned above.

1. Review your inventory, segregate any affected product. In Europe, Middle East, Africa, Latin America and India any pump with a Use By Date ***on or before*** 2018-12-31 was manufactured ***prior to*** design change. An image of the Shelf Box Side Label of the SynchroMed II is shown below.



2. Return all unused, affected product in your inventory to Medtronic. Your Medtronic Representative will assist you in the return and replacement of this product as necessary.

3. Pass this notice to all those who need to be aware within your organization or to any organization where the potentially affected products have been transferred.

Additional Information
Information regarding motor stalls was previously communicated in a November 2012 safety notification titled *Use of Unapproved Drugs with the SynchroMed Implantable Infusion Pump* and can be found at medtronic.com/advisories.

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

Medtronic is committed to patient safety and we appreciate your patience and understanding as we work through this transition. If you have any questions related to the retrieval of SynchroMed II pumps manufactured prior to the design change, please contact your Medtronic Representative Directly or via Tel. No 01 51111400. We appreciate your assistance with this matter and apologise for any disruption or inconvenience.

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland