Medtronic Ireland Ltd
Unit GA,
Swords Business Campus,
Balheary Road, Swords
Co. Dublin
Tel. 353 1 511 1400
Fax 353 1 872 2077
vat IE 9513488W

Urgent Field Safety Notice

SynchroMed® II Implantable Drug Infusion Pump

Potential for Audible Alarm to Cease Functioning
Specific Serial numbers of Model 8637-20 and 8637-40

Recall

14 April 2015

Medtronic reference: FA649

Dear Customer/Risk manager,

The purpose of this letter is to notify you that Medtronic is conducting a voluntary removal for a finite subset of Model 8637-20 and 8637-40 SynchroMed® II implantable drug pumps (based on serial number), which were manufactured between 5 December 2014 and 10 February 2015, because the audible alarm could cease to function. Medtronic has received no complaints of audible alarm failure due to this issue and is not aware of any occurrences of patient injury related to this issue. The cause of the issue has been addressed, therefore only products identified by this removal notification are potentially affected.

Medtronic does not recommend prophylactic replacement of potentially affected pumps that have already been implanted. More detailed patient management recommendations are being developed for physicians who have implanted devices from the potentially affected population or manage patients who have received potentially affected devices. These recommendations will be communicated to the impacted physicians in the coming 2 weeks.

Our records indicate that your facility has received one or more SynchroMed II pumps from the potentially affected population of devices. Please review your inventory for these specific serial numbers and perform the following actions.

REQUIRED ACTIONS:

- Immediately quarantine and do not use affected product(s)
- Return all unused affected SynchroMed II pumps to Medtronic. Your Medtronic Sales Representative will assist you with this process.
- Please share this notification with others in your organization as appropriate. If any product within scope of this issue has been sent to another facility, please notify that facility of this issue and facilitate the retrieval of that product.

Credit will be issued when Medtronic receives the product. Replacement product can be ordered, as needed, through your Medtronic Sales Representative.

To ensure timely removal of unused product, your prompt action is appreciated and important to the effectiveness of this product retrieval.

Medtronic has notified the Competent Authority of your country of this action.

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We appreciate your assistance with this matter and apologize for the disruption and inconvenience. Our field team is prepared to help with the removal process and we will strive to facilitate an efficient process. If you have questions, please contact Medtronic Customer Servicer Tel No. 353 1 511 1400.

Sincerely,

Keith Taverner
Regulatory Affairs Manager – UK & Ireland