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Urgent Field Safety Notice

Temporary Transvenous Pacing Lead System
Model 6416-100, 6416-140 and 6416-200
Recall

16 June 2016

Medtronic reference: FA721

Dear Health Care Professional, Risk Manager,

This letter is to inform you that Medtronic has identified a compliance issue with Model 6416 Temporary Transvenous Pacing Lead System. The product is not compliant with Section 8.5.2.3 of IEC 60601-1, and corresponding provisions of FDA 21 CFR 898, which relate to design standards to prevent connecting a patient's lead to a possible hazardous voltage. Medtronic is initiating a voluntary recall for all lots and models of 6416 Temporary Transvenous Pacing Lead Systems that were manufactured after 01-May-2014. According to our records, you have received one or more of the affected temporary leads. This issue does not affect any other Medtronic products.

Through 2-Jun-2016, Medtronic has received **no customers reports and no reports of adverse patient effects related to this issue.**

For patients who have previously received treatment using a Model 6416 lead affected by this recall, no action is necessary as this is an acute use product. Patients who are currently receiving treatment should continue to be managed with your standard patient management protocol and per the product labeling.

Customer Actions: Please review your inventory for product affected by this issue and perform the following actions:

- Immediately 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 of affected product as necessary.

Please share this notification with others in your organization as appropriate. If product within scope of this recall has been forwarded to another facility, please notify the facility of the issue and assist with the return of affected product.

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

We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause. Please be assured that patient safety and product quality remain our primary concern. If you have any questions, please contact your Medtronic Representative directly or via Tel No: +353 1 5111 400

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland