Medtronic
8200 Coral Sea Street NE
Mounds View, MN 55112
medtronic.com

<Medtronic Urgent Medical Device Recall>

Temporary Transvenous Pacing Lead System

Models

Five (5) Pack	Single Pack
6416-100	6416-100S
6416-140	6416-140S
6416-200	6416-200S

June 2016

Dear Health Care Professional,

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 **<Urgent Medical Device 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 02-Jun-2016, Medtronic has received zero (0) reports of adverse patient effects from misuse of the 6416 lead by connecting it to a potentially hazardous voltage. This recall is being taken to prevent this unlikely potential misuse of the 6416 lead.

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 warnings and precautions section.

Customer Actions: Please review your inventory for product affected by this issue as listed on the attached **<Customer Notification Detail Report>** and perform the following:

- Immediately identify and quarantine all unused, affected product in your inventory.
- Return all unused, affected product in your inventory to Medtronic by contacting **<Customer Service at 800-716-6700 and referencing this communication to initiate a return and credit of unused product>.** Your Medtronic sales representative can assist you in the return of affected product as necessary.
- Complete the enclosed **<Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612 to the attention of Customer Focused Quality or scan and email to RS.CFQFCA@medtronic.com>.**

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 applicable regulatory authority of this issue.

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 CRHF Sales Representative.

Sincerely,

Tim Samsel
Vice President, Quality and Regulatory
Medtronic Cardiac Rhythm Heart Failure (CRHF)

Medtronic