Medtronic of Canada Ltd
99 Hereford Street
Brampton, ON L6Y 0R3
Canada
www.medtronic.ca

URGENT MEDICAL DEVICE RECALL

For a Subset of Medtronic
Dual Chamber Pacemakers

January 2019

Dear Risk Manager,

Medtronic is informing physicians of a voluntary recall and distribution suspension affecting a subset of Medtronic dual chamber pacemakers distributed worldwide between 10 March 2017 and 7 January 2019 under the brand names **Adapta™, Versa™, Sensia™, Relia™, Attesta™ and Sphera™**. Please refer to the enclosed Urgent Medical Device Recall letter for additional information regarding this advisory.

Our records show that one or more of these devices have been distributed to your facility. The enclosed Customer Notification Detail Report summarizes the list of affected dual chamber pacemakers distributed to your facility, but not registered with Medtronic.

Customer Actions for Unused Affected Product Inventory
For unused product with serial numbers listed on the enclosed Customer Notification Detail Report**,** Medtronic requests that you immediately take the following actions:

1. Segregate and remove all unused affected product from your inventory.
2. Return all unused listed product in your inventory to Medtronic. Contact Medtronic Customer Service at rs.canomshospitals@medtronic.com to initiate a product return and credit. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.

Customer Actions for Implanted Product that is not registered with Medtronic
For listed devices that have been distributed to your facility (see enclosed Customer Notification Detail Report) and implanted, but not registered with Medtronic, please contact your Medtronic representative, **or our Patient Registration Department at 1-888-660-4616** if assistance is needed in registering these devices.

Please complete the enclosed Customer Confirmation Certificate and return via email to rs.canfieldactions@medtronic.com or fax it to Medtronic Quality at *905-460-3930*.

This notice needs to be shared with those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Sincerely,

D. Boyce

Dawn Boyce
Supervisor, Post-Market Vigilance (Field Corrective Actions)
Medtronic of Canada Ltd

Enclosures

- Urgent Medical Device Recall Letter
- Customer Notification Detail report
- Customer Confirmation Certificate