Medtronic of Canada Ltd
99 Hereford Street
Brampton, ON L6Y 0R3

April 16, 2015

Urgent Medical Device Safety Notification

Important information regarding extension handling during implant procedure
Medtronic DBS Extensions Models 37085 and 37086

Dear Healthcare Professional,

This letter communicates recent results from returned product analysis of Medtronic Neuromodulation Deep Brain Stimulation (DBS) system extensions with reports of high impedances, and reinforces device labeling specific to the handling of extensions and system integrity checking during implant procedures. This applies to extension Models 37085 and 37086 which can be used with the following implantable Neurostimulators: Activa® PC (Model 37601), Activa® RC (Model 37612), and the Activa® SC (Model 37603).

Background:
Medtronic completed analysis of fourteen (14) extensions returned between October 1st, 2014 and March 2nd, 2015 for complaints of high impedance. Per customer reports, high impedance for thirteen (13) of the extensions was observed at implant and one extension after approximately two months from implant. Medtronic analysis of the returned extensions identified conductor wire fractures in close proximity to the location where the extension exits the connector block, and not within the connector block itself. In all fourteen (14) cases (occurrence rate of 0.14%[i]), it was reported that the extension was successfully replaced, but resulted in a prolonged surgical procedure for thirteen (13) of the cases and a revision surgery for the one extension reported approximately two months from implant. Medtronic's investigation of the root cause is continuing. A damaged extension not detected during the implant procedure could result in loss of stimulation.

Recommendations:
Current labeling for the handling of the system during implant is described within the implant manual.
To minimize the potential for a conductor wire fracture, please follow the instructions defined within the Neurostimulator implant manual related to extension implantation, specifically to ensure that the extension is not bent sharply or kinked. Check electrode impedances for open circuits, prior to pocket closure, which could indicate a potential conductor fracture. An example of the implant manual sections, relevant to these recommendations, is shown below from the *Activa® PC Model 37601 Implant manual*.

Checking system integrity

△ **Caution:** To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Note: The neurostimulator should be in the pocket during system interrogation for integrity to ensure proper readings.

1. To ensure proper connection of each extension to the neurostimulator, use the clinician programmer to program the basic stimulation parameters, check the battery status, and check the electrode impedances to rule out a short or open circuit.
2. If the system integrity test results are not acceptable, refer to "Connecting the extension to the neurostimulator" on page 13.

Implanting the Neurostimulator

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1. Place the neurostimulator into the subcutaneous pocket with the Medtronic logo facing outward, away from muscle tissue, and ensure that the extension is not bent sharply.

   ⚠ **Cautions:**

   - Ensure that the neurostimulator is placed no deeper than 4 cm (1.5 in) below the skin and is parallel to the skin. If the neurostimulator is too deep or is not parallel to the skin, telemetry may be unsuccessful.
   - Do not coil excess extension in front of the neurostimulator. Wrap excess extension around the perimeter (Figure 3) of the neurostimulator to minimize subcutaneous pocket depth, help minimize potential damage during neurostimulator replacement surgery, help minimize potential kinking of the extension, and minimize interference with telemetry. Excess extension should not exceed two wraps around the perimeter of the neurostimulator. Extension lengths requiring more than two wraps can interfere with telemetry.

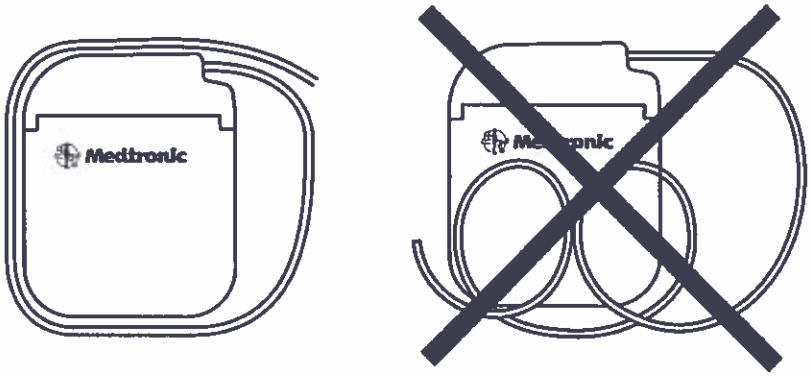

Figure 3. Wrap excess extension around the perimeter of the neurostimulator.

Additional Information:
We appreciate your assistance with this matter and apologize for the inconvenience. Please sign and return the attached Physician Reply Card within ten (10) days.

Health Canada has been notified of this communication.

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health product treatments. Any incident of serious or unexpected adverse incidents involving medical devices manufactured and/or distributed by Medtronic should be reported to Medtronic, or to Health Canada at the following address:

Medtronic of Canada Ltd.
99 Hereford St.
Brampton, Ontario L6Y 0R3
Tel: 1-800-268-5346

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9

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Tel: The Inspectorate Hotline: 1 800 267 9675

The Medical Devices Problem Report Form and Guidelines can be found on the Health Canada web site.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/md-mm_form-eng.php

http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2011-devices-materiaux/index-eng.php

If you have questions, please contact your local Medtronic Representative or Medtronic Neuromodulation Technical Services at 1--877-895-7226 weekdays 8 a.m. – 7 p.m. PST.

Sincerely,

Pam Winsor
Director Health Policy & Stakeholder Engagement
Chief Marketing Officer

Enclosed: *Physician Reply Form*

[i] For the affected extensions from October 1st, 2014 to March 2nd, 2015 there have been 14 confirmed fractures from the 9,711 extensions sold for an occurrence rate of 0.0014 (0.14%).