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Urgent Field Safety Notice

Medtronic DBS Extension Models 37085 and 37086

Reinforcement of Device Labeling

April 2015

Medtronic reference: FA648

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 cases (occurrence rate of 0.14%¹), 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 root cause investigation of this issue 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 distributed with each device.

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.

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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 9.

Implanting the Neurostimulator

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.

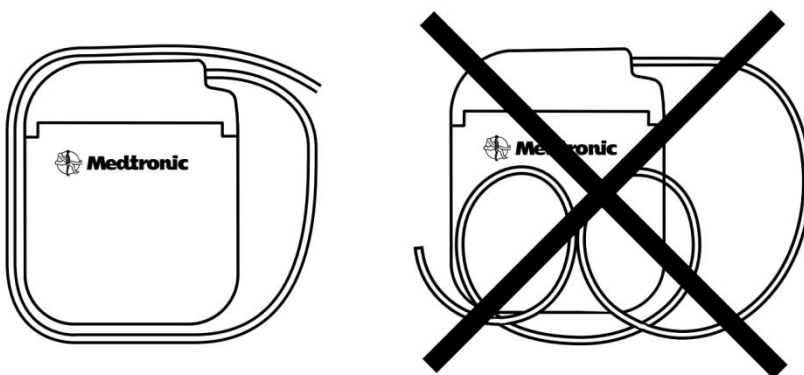


Figure 3. Wrap excess extension around the perimeter of the neurostimulator.

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Additional Information:

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

If you have questions about this information, please contact your Medtronic Field Representative direct or via Telephone No. 353 1 511 1400

Sincerely,

Keith Taverner
Regulatory Affairs Manager UK & Ireland

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%).

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