

Urgent Field Safety Notice

Medtronic DBS Pocket Adaptor Models 64001 and 64002 Reinforcement of Device Labeling

23 June 2016

Medtronic reference: FA724

Dear Healthcare Professional,

This letter communicates recent results from returned product analysis of Medtronic Neuromodulation Deep Brain Stimulation (DBS) system pocket adaptors with reports of high impedances, and reinforces device labeling specific to the handling of pocket adaptors and system integrity checking during implant procedures. This applies to pocket adaptor Models 64001 and 64002 which can be used with the following implantable Neurostimulators: Activa[®] PC (Model 37601) and Activa[®] RC (Model 37612).

Background:

Medtronic has identified sixteen (16) DBS pocket adaptors that were returned for high impedance measurements and where subsequent Medtronic analysis identified conductor wire fractures in close proximity to the location where the adaptor wire exits the neurostimulator connector block. Approximately 20,000 DBS pocket adaptors have been sold worldwide since product launch in 2009, for a 0,08% reported rate of occurrence.

Of the sixteen (16) returned devices, two (2) were returned after the issue was identified intraoperatively, and 14 were returned after the issue was identified post-implant (requiring revision surgery). Medtronic's root cause investigation of this issue is in process.

The design of the pocket adaptor conductor body is similar to that of DBS Extensions, Models 37085 and 37086. Medtronic issued an Urgent Field Safety Notice (FA648) for these extension models in April 2015, reinforcing device labeling specific to the handling of extensions and system integrity checking during implant procedures due to the fracture rate seen in extensions at that time.

Recommendation:

Current labeling for the handling of the system during implant is described within the implant manuals. To minimize the potential for a conductor wire fracture, please follow the instructions defined within the *DBS Pocket Adaptor Implant Manual* as shown below, to ensure that the adaptor wire is not bent sharply or kinked at the time of implant. The full implant manual can be found in product packaging.

Cautions:

- Do not bend, kink, or stretch the extension or adaptor, which may damage the component.

Implanting the pocket adaptor with the neurostimulator

1. Place the pocket adaptor behind the neurostimulator. Coil the adaptor wire and the excess extension wire behind the adaptor, ensuring there are no sharp bends in any of the wires (Figure 10).

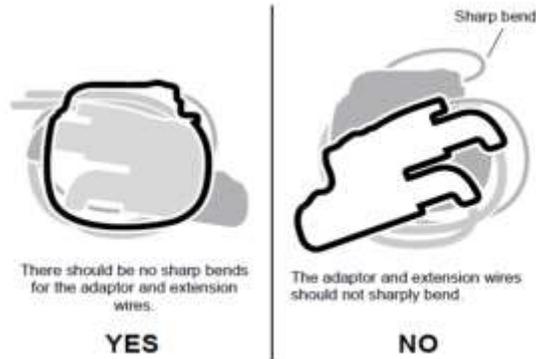


Figure 10. Ensure there are no sharp bends in any of the wires.

In addition, complete a system integrity check for proper electrode impedances prior to pocket closure, as described in the *Activa® PC Model 37601 Implant manual* shown below. The full implant manual can be accessed online at www.medtronic.com/manuals.

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.

The Competent Authority of your country has been notified of this action.

We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner. If you have questions, please contact your Medtronic representative at Medtronic Saudi Arabia LLC.