

Medical Device Safety Notification

Reported Events Related to DBS Tunneling Procedure

Deep Brain Stimulation Therapy

Dear Healthcare Professional:

The purpose of this letter is to notify you of information that will be added in the future to Medtronic's Deep Brain Stimulation (DBS) labeling, in connection with the tunneling procedure related to DBS Extensions Models 7483 and 37086. These labeling updates result from Medtronic's ongoing monitoring of reported events and published literature. The labeling updates further clarify potential risks which have been reported with the DBS implant procedure. Medtronic is sharing this information to help you with the DBS implant procedure, patient selection, informed consent, and post-implant follow up for patients treated with DBS Therapy.

Background:

Medtronic's post marketing surveillance for DBS therapy has identified the following serious events or injuries associated with tunneling that are not presented in the current DBS labeling. The following events are associated with the DBS implant and tunneling the extension from the lead to the INS:

- Cases of spinal accessory nerve injury
- Severe bleeding or vascular injury
- An extension inadvertently implanted through the ribs and later found to be close to the heart requiring revision
- Tunneling too superficially resulting in an extension that exited and then re-entered the neck which wasn't discovered until the surgical drape was removed

These events occurred in an estimated 0.008% of tunneling procedures. Note: The specific model of tunneling tool associated with the patient injuries was not reported in many of these events.

Recommendations:

During the DBS implant, use caution while tunneling the extension from the lead to the INS to avoid tunneling too deeply or superficially because serious injury may occur. Complications or effects related to the tunneling procedure may include injury to nerve tissue (such as the spinal accessory nerve), vascular injury that may result in prolonged hospitalization, and tunneling through unintended anatomy (such as in between the ribs and entering the thoracic cavity).

Action in Response to this Letter:

Acknowledge receipt of this letter by completing the attached reply form and returning it to Medtronic using the contact details on the reply form. Maintain a copy of the completed reply form for your records.

Additional information:

Medtronic is communicating this information to the appropriate regulatory agencies globally, including the US Food and Drug Administration. 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 Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST.

Please report any malfunction or adverse event to Medtronic Neuromodulation Technical Services and to FDA's MedWatch Program (www.fda.gov/medwatch).

Sincerely,



Michael Crader
Vice President Quality
Medtronic Neuromodulation