

Medical Device Safety Notification
Reported Events Related to Loss of Coordination
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 Activa® PC, Activa® SC, and Activa® RC Devices. This information is also applicable to patients previously implanted with Kinetra® and Soletra® Devices. These labeling updates result from Medtronic's ongoing surveillance of reported events and published literature. The labeling updates further clarify potential risks which have been reported with DBS Therapy. Medtronic is sharing this information to help you with management of your current and future patients treated with DBS Therapy.

Background:

Medtronic has become aware of a reported event of inability to swim following DBS implantation and initiation of DBS therapy for Parkinson's disease in a patient who was an experienced swimmer. The patient had experienced an excellent result from DBS therapy in the management of Parkinson's disease symptoms, and did not show evidence of the specific motor coordination symptoms identified in DBS labeling. A video showing the patient's inability to swim can be found via the publication of this event in Bangash et al¹.

Medtronic's current labeling for DBS Therapy for Movement Disorders contains the following potential adverse event:

Motor coordination and balance disorders: akinesia, "freezing," bradykinesia, dyskinesia, paresis, asthenia, muscle spasms/rigidity, tremor, loss of balance/coordination, gait disorder, dizziness, involuntary movements, chorea, dystonia

Note that this issue was identified in a patient being treated for Parkinson's disease (a movement disorder), but may apply to any approved DBS therapy indication.

Recommendation:

Be aware that loss of coordination may be a side effect of DBS therapy, and may result in, for example, the inability to swim. Patients should be made aware that participating in any activities requiring coordination that they were previously able to perform may place them in an unsafe situation; therefore these activities should be performed under supervision after DBS therapy is first turned on and after programming changes until any effects of their DBS therapy on coordination are understood.

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

¹ Bangash OK, Thorburn M, Garcia-Vega J, et al. Drowning hazard with deep brain stimulation: case report. J Neurosurg. 2015:1-4.