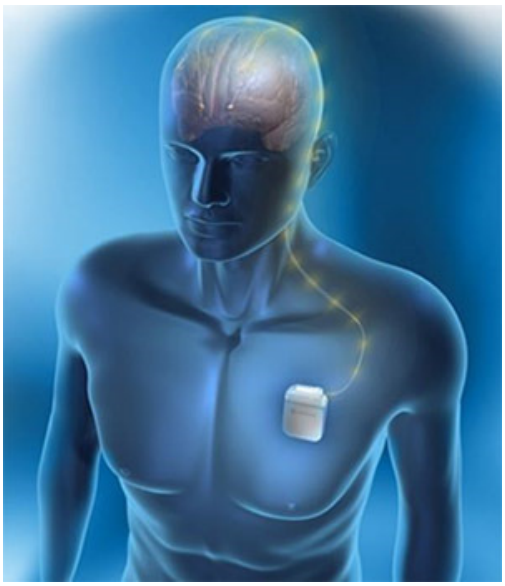
Australian Government
Department of Health
Therapeutic Goods Administration

Medtronic deep brain stimulation devices - multiple models

Hazard alert - risk of loss of coordination in patients' movements

14 June 2016

Consumers and health professionals are advised that Medtronic Australasia, in consultation with the TGA, is issuing a hazard alert for five models of its deep brain stimulation devices regarding the potential for patients to experience a loss of coordination in their movements. Medtronic Australasia is also issuing a recall for product correction to update the Instructions for Use of affected models to advise of this risk.



A deep brain stimulation device

Deep brain stimulation devices are implantable, programmable medical devices that deliver electrical stimulation to the patient's brain. Deep brain stimulation devices are used to treat the symptoms associated with movement disorders, epilepsy and Parkinson's disease, as well as other conditions.

A case report (http://thejns.org/doi/abs/10.3171/2015.5.JNS15589) published in the Journal of Neurosurgery described one Australian patient who lost coordination in the water and became unable to swim during deep brain stimulation therapy, despite being an experienced swimmer. When deep brain stimulation therapy was turned off his coordination in the water improved and he was able to swim again. The patient had experienced positive results from deep brain stimulation therapy in the management of Parkinson's disease symptoms, and did not show evidence of the specific motor coordination symptoms already identified in the existing IFU.

Potentially affected model numbers are:

- Activa PC 37601 (ARTG# 160118)
- Activa SC 37603 (ARTG# 188034)
- Activa RC 37612 (ARTG# 160117)

- Kinetra 7428 (ARTG# 134476)
- Soletra 7426 (ARTG# 134475).

Information for consumers

If you or someone you provide care for has an implanted deep brain stimulator you should be alert to this issue.

Once deep brain stimulation therapy is initiated, patients should be closely supervised while participating in any potentially hazardous activities requiring coordination, such as swimming, until any effects of their therapy become clear. Similarly, such patients should be closely supervised after programming changes until any effects of their therapy on coordination become clear.

Medtronic Australasia has written to health professionals who have implanted deep brain stimulation models affected by the hazard alert, or are managing patients who have these devices, providing further information.

Information for health professionals

If you are treating a patient who has a deep brain stimulation device implanted, alert them to this issue.

If a patient has any questions or concerns about this issue, refer them to their managing surgeon or neurologist.

Information for surgeons and pain specialists

Be alert to the potential for loss of coordination in patients undertaking deep brain stimulation therapy that may result in, for example, the inability to swim.

Patients should be alerted that participating in any activities requiring coordination that they were previously able to perform may place them in an unsafe situation. These activities should be performed under supervision after deep brain stimulation therapy is initiated and after programming changes until any effects of the therapy on coordination are understood.

If you have any questions or concerns regarding this issue, contact Medtronic Australasia customer service on 1800 668 670.

Reporting problems

Consumers and health professionals are encouraged to report problems with medical devices (//www.tga.gov.au/reporting-problems#device). Your report will contribute to the TGA's monitoring of these products. For more information see the TGA Incident Reporting and Investigation Scheme (IRIS) (//www.tga.gov.au/medical-device-incident-reporting-investigation-scheme-iris).

The TGA cannot give advice about an individual's medical condition. You are strongly encouraged to talk with a health professional if you are concerned about a possible adverse event associated with a medical device.

Category: Alert/Advisory, Medical devices safety
Tags: implantable devices, neurostimulation devices
URL: https://www.tga.gov.au/node/727782 (//www.tga.gov.au/alert/medtronic-deep-brain-stimulation-devices-multiple-models)