Medtronic Issues Warning on Deep Brain Stimulation Devices? Wire Fracture Risk

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Medtronic warned that it received 16 reports of high impedance measurements associated with its Activa deep brain stimulation (DBS) devices. In a letter to physicians, the company said the high impedance measurements were caused by wire fractures.

Parker Waichman LLP, a national law firm dedicated to protecting the rights of victims injured by defective drugs and medical devices, comments on recent safety updates involving device maker Medtronic?s Deep Brain Stimulation (DBS) devices. According to a June 2016 letter to healthcare professionals, the company identified 16 reports of high impedance with its DBS pocket adaptors. Subsequent analysis showed that the high impedance measurements, which indicate low current, were caused by wire fractures. The safety alert cautioned surgeons against implanting DBS devices with sharply bent or kinked wires. The warning applies to pocket adaptor Models 64001 and 64002, which can be used for implantable Neurostimulators Activa PC (Model 37601) and Activa RC (Model 37612).

According to Medtronic's website, DBS devices are used to treat movement disorders in patients with Parkinson's disease, tremor, and dystonia. DBS therapy provides electrical stimulation to structures located

deep within the brain.

In its June 2015 Urgent Field Safety Notice to healthcare professionals, Medtronic said 16 DBS pocket adaptors were returned for high impedance measurements. In two instances, the high impedance was discovered during surgery. The remaining cases were identified after the device was implanted, requiring patients to undergo revision surgery. The company indicated that a subsequent analysis revealed wire fractures located near where the adaptor wire exits the neurostimulation connector block. Roughly 20,000 DBS pocket adaptors have been sold since 2009; the occurrence of wire fractures, thus far, is 0.08 percent, Medtronic indicated. The company notes that it is still investigating the cause of wire fractures.

In light of these findings, the Urgent Field Safety Notice not only cautioned surgeons against implanting DBS devices with sharply bent or kinked wires, but the alert also reiterated device labeling specific to handling the system, as described in implant manuals. The notification further emphasized checking system integrity.

Medtronic has issued similar warnings in the past. In April 2015, the company issued an alert for wire fractures in its DBS Extensions, Models 37085 and 37086. The June 2016 alert notes that the pocket adaptor conductor body is similar in design to the DBS Extensions.

Parker Waichman comments that it will continue to convey medical device updates to consumers. ?Our firm is dedicating to keeping the public informed about safety updates involving drugs and medical devices,? said Melanie H. Muhlstock, a Managing Attorney at Parker Waichman. ?By staying current with the latest medical device news, we hope to detect and prevent medical device injuries.?

Parker Waichman continues to offer free legal consultations to victims who suffered injuries related to the use of Medtronic Deep Brain Stimulation (DBS) Devices. For more information, please visit the firm?s Medtronic DBS Devices page or, for a free case evaluation, call 1-800-LAW-INFO (1-800-529-4636).
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