Medtronic

Urgent Field Safety Notice

Medtronic Deep Brain Stimulation (DBS) Therapy

Activa® PC, Activa® SC, Activa® RC, Activa® PC+S, Kinetra®, and Soletra®

Upcoming Labeling Updates Notification

July 2015

Medtronic reference: FA655

Dear Healthcare Professional,

The purpose of this letter is to notify you of information that is being added to the *Warnings* and *Adverse Events* sections of Medtronic's Deep Brain Stimulation (DBS) labeling. These labeling updates result from Medtronic's ongoing monitoring of reported events, clinical trials 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 patients treated with DBS Therapy.

Additional *Warnings* being added to the labeling:

- **DBS Therapy for Dystonia:**
  Status dystonicus – Severe, life-threatening dystonia symptoms, including status dystonicus (also known as dystonic crisis or dystonic storm), during ongoing or loss of DBS Therapy may result in respiratory compromise and rhabdomyolysis. In rare cases, rhabdomyolysis may progress to multi-organ failure and death.

  Monitor patients receiving DBS Therapy for these symptoms. Emphasize the importance of contacting the patient's physician if they experience increased severity of symptoms.

- **DBS Therapy for Epilepsy:**
  Return of symptoms – Cessation or reduction of stimulation may potentially lead to an increase in seizure frequency or severity. Symptoms may return with an intensity greater than was experienced prior to system implant, including the potential for status epilepticus. Emphasize the importance of contacting the patient's physician if they experience worsening of seizure frequency or severity.
  It is also important that the patient or caregiver knows how to use the patient programmer in case the neurostimulator is accidentally turned off.

Additional *Adverse Events* being added to the labeling for all indications of DBS Therapy:

- Meningitis, encephalitis, or brain abscess resulting from infection involving the brain and/or central nervous system
- Focal edema localized to the area around the lead
- Immediate or delayed intracranial hemorrhage or cerebral infarction which could be symptomatic, or which could result in temporary or permanent neurological injury or death
- Aseptic intraparenchymal cyst formation around the distal lead tip

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Action:
Ensure you are aware of the warnings and adverse events associated with DBS Therapy covered in this notification. Please retain this notification for your records until the updated warnings and adverse events are integrated into the labeling for DBS Therapy. This information is being provided to help you with the management of your patients and give you visibility into the upcoming changes for labeling.

Additional Information:
Medtronic has notified the Competent Authority of your country of this action.

If you have questions regarding DBS therapy or labeling, please contact your Medtronic representative.

Sincerely,