



Urgent Field Safety Notice
Activa PC+S Implantable Neurostimulator (INS)
Recall of model 37604

May 2018

Medtronic reference: FA821

Dear Physician-Investigator of an Activa PC+S Clinical Study,

Medtronic is initiating a recall of the Model 37604 Activa PC+S Implantable Neurostimulator (INS). The Model 37604 is currently only being used in physician-sponsored clinical studies.

Background on Issue:

Medtronic is aware of two instances where, after implant, the Activa PC+S device was unable to record and/or retrieve recorded brain sensing data. In both instances, the issue presented at the first attempt to retrieve recorded sensing data, and there was no impact to stimulation functionality. Activa PC, RC, and SC are not affected. The issue has been isolated to an internal memory module that is only used on the Activa PC+S device.

The purpose of this notification is to inform you that the Activa PC+S product in your possession is being retrieved by Medtronic personnel. Due to this retrieval, implants of Activa PC+S for new subjects or device replacements in existing subjects must be postponed until further notice.

Action Required:

1. Provide your Activa PC+S product to Medtronic personnel when s/he visits.
2. Please assess this information for any regulatory reporting requirements that you may have as the Sponsor of your clinical study.

Note: No action is required for patients already implanted with Activa PC+S that have not reported this issue.

We appreciate your assistance with this matter and apologize for the disruption to your clinical studies and inconvenience to your patients.

We are committed to continuing to improve our product performance and services to enable you to manage your patients and conduct your research in a safe and effective manner. Medtronic plans to assess this issue in the retrieved products and will communicate expectations for product availability within the next month.

If you have questions related to the Activa PC+S device sensing memory issue or Activa PC+S product availability, please contact Medtronic's appointed coordinator for this action.

Sincerely,

Medtronic Coordinator