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Urgent Field Safety Notice

Percept™ PC Implantable Neurostimulator (INS) Model B35200

Unable to be Interrogated

Notification

March 2022

Medtronic Reference: FA1231

Dear Healthcare Professional,

The purpose of this letter is to inform you that in rare instances (0.044%) the Percept™ PC Implantable Neurostimulator (INS) Model B35200 cannot communicate with the clinician programmer and/or the patient programmer system (HH90 Handset and TM91 Communicator). In these instances, the INS will continue to provide therapy to the patient within programmed parameters. While the occurrence is rare, Medtronic is raising awareness to inform and serve our customers.

Issue Description:

This occurrence may present in the following way:

- *If the clinician programmer is not able to communicate with the INS, the clinician programmer will display "Searching for Device".*
- *If the patient programmer system was set up, it will continue to communicate with the INS and allows therapy adjustments and group changes to be made within the clinician set limits; however, the patient programmer system will not be able to turn therapy off.*
 - *If the patient has previously been given the ability to turn their device off without requiring close communication, their ability to do so will be maintained.*

- *If the patient has a bipolar group set up previously, they will maintain the ability to put the device into MRI mode.*
- *If there is no communication with the INS during the implant procedure, troubleshooting may delay the surgical procedure, and may require a replacement INS. There have been no reports of this occurring during implant.*
- *If there is no communication with the INS post procedure, it might not be possible to adjust therapy and may cause the patient to experience inadequate therapy (i.e., return of underlying disease symptoms). If communication cannot be restored to the INS (refer to recommended mitigation below), an unanticipated surgical intervention may be needed to explant and replace the INS.*

Since the launch of Percept PC in January 2020 through the end of February 2022, Medtronic has received six (6) confirmed reports of this issue. Five (5) of these reports occurred within the United States of America and one (1) event occurred in Switzerland. Two (2) devices were explanted as a result of not being able to connect with the INS. Medtronic can perform an INS diagnostic and communication reset should this issue occur and is investigating changes to prevent the occurrence.

Recommended Mitigation:

If the INS cannot communicate with the clinician programmer and/or patient programmer system, contact your Medtronic Representative. If needed, Medtronic will schedule an in-field service appointment with the managing DBS physician and the patient to diagnose and reset the INS.

This diagnostic and communication reset is possible only if the patient's programmer system is set up and working. If the communicator is not working, lost, or never provided to the patient, the INS cannot be reset and would need to be explanted.

Required Actions:

- At the patient's initial programming session, ensure the patient programmer system is set up to communicate with the patient's INS.
- If a patient's INS cannot communicate with the clinician programmer and/or patient programmer system, and it is not possible to make therapy adjustments or turn stimulation off, contact your Medtronic Representative.

Additional Information:

The Competent Authority of your country has been notified of this action.

We regret any difficulties this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative directly or via Tel no: 01 511 1400

Sincerely,



Keith Taverner: Regulatory Affairs Manager UK & Ireland