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Urgent Field Safety Notice

InterStim™ System Advanced Evaluation Percutaneous Extension Connector Migration Model Numbers – 3560030, 3560022

Notification and Recommendation

October 2020

Medtronic Reference: FA933, letter update

Dear Healthcare Provider,

This letter is to notify you of the potential for migration of the percutaneous extension connector during an InterStim™ Advanced Evaluation using the Model 3560030 and Model 3560022 percutaneous extension.

Issue Description:
The Medtronic Model 3560030/3560022 percutaneous extension is intended for use with the Model 978A1/978B1 InterStim™ SureScan™ MRI Leads and 3531 Verify ENS during an advanced evaluation to screen potential candidates for chronic sacral neuromodulation therapy.

Medtronic has identified eighteen reports where during the advanced evaluation trial period, the percutaneous extension connector has migrated from the future stimulator pocket site along the tunneling pathway. This resulted in difficulty locating the percutaneous extension connector after the evaluation period when it is necessary to remove the percutaneous extension and external neurostimulator (ENS).

In some cases of reported migration, an additional incision along the tunneling pathway has been required to disconnect the lead from the percutaneous extension. Patients may also be at an increased risk of procedural complications due to delays associated with troubleshooting. Additionally, if the chronic lead is damaged or displaced during the explant of the percutaneous extension, intraoperative replacement of the lead or an additional surgical procedure may be needed.

Recommendation:
Please follow the instructions provided in the attachment that was developed to address the risk of migration of the extension connector. Retain a copy of this letter and attached instructions for your records.

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

We sincerely regret any inconvenience this may have caused you or your patients. We are committed to patient safety and appreciate your prompt attention to this matter.

If you have questions related to this issue, please contact your local Medtronic representative directly or via Tel No:01 511 1400

Sincerely,

Keith Taverner. Regulatory Affairs Manager UK & Ireland

Enclosure: Letter Attachment Recommendation V4 "Options for Mitigating Percutaneous Extension Connector Migrations."