Medtronic

# Urgent Field Safety Notice

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

Notification and Recommendation

October 2020

Medtronic Reference: FA933

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.

Sincerely,

Ziad Kassir,

Business Manager, Pain, APS

**Enclosure:** Letter Attachment Recommendation

# OPTIONS FOR MITIGATING PERCUTANEOUS EXTENSION CONNECTOR MIGRATIONS

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The following instructions provide guidance on mitigating migration of the percutaneous extension connector into the tunneling track with the advanced evaluation.

## Solution 1:

**1.** Using a 2-0 or smaller nonabsorbable suture, loop the suture around the percutaneous connector and percutaneous extension body (Figure 1)

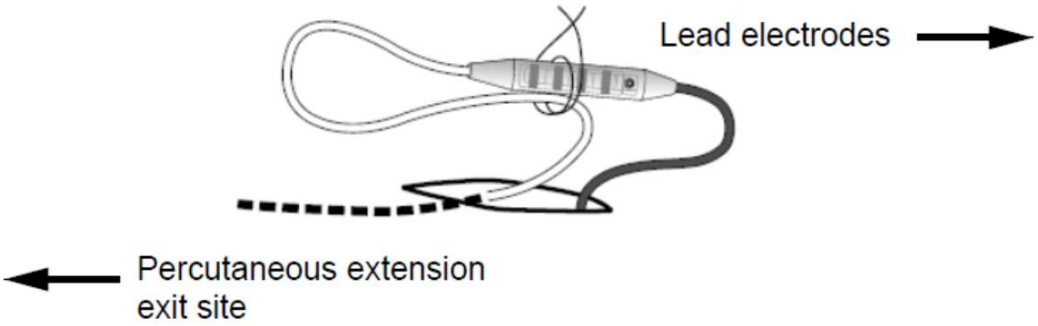


***Figure 1.*** *Suture looped twice around the percutaneous extension connector and extension body*

**2.** Tighten and tie the suture securely around the percutaneous extension connector and extension body (Figure 2)

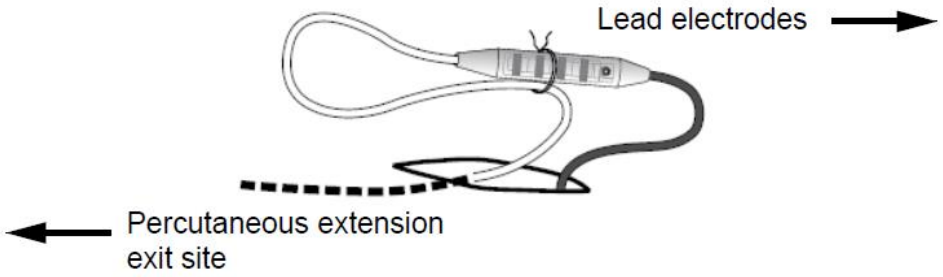


***Figure 2.*** *Suture secured and tied around the percutaneous extension connector and extension body.*

**3.** Create a subcutaneous pocket perpendicular to the percutaneous extension tunneling path to place the percutaneous extension connector and strain relief loops (Figure 3 and 4).

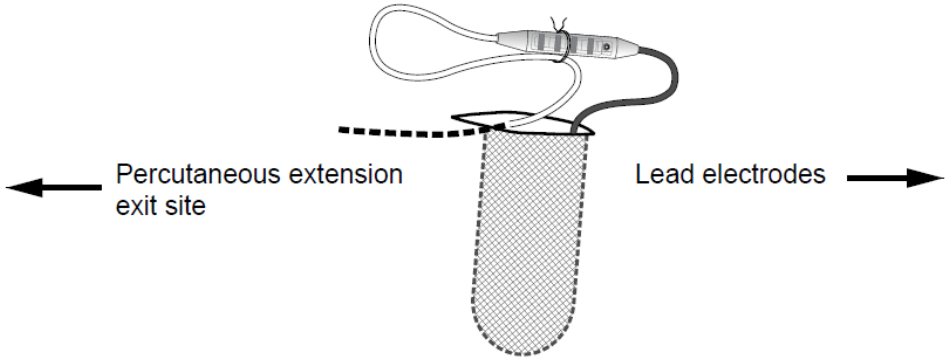


***Figure 3.*** *Enlarged image of the subcutaneous pocket for the percutaneous extension and strain relief loops.*

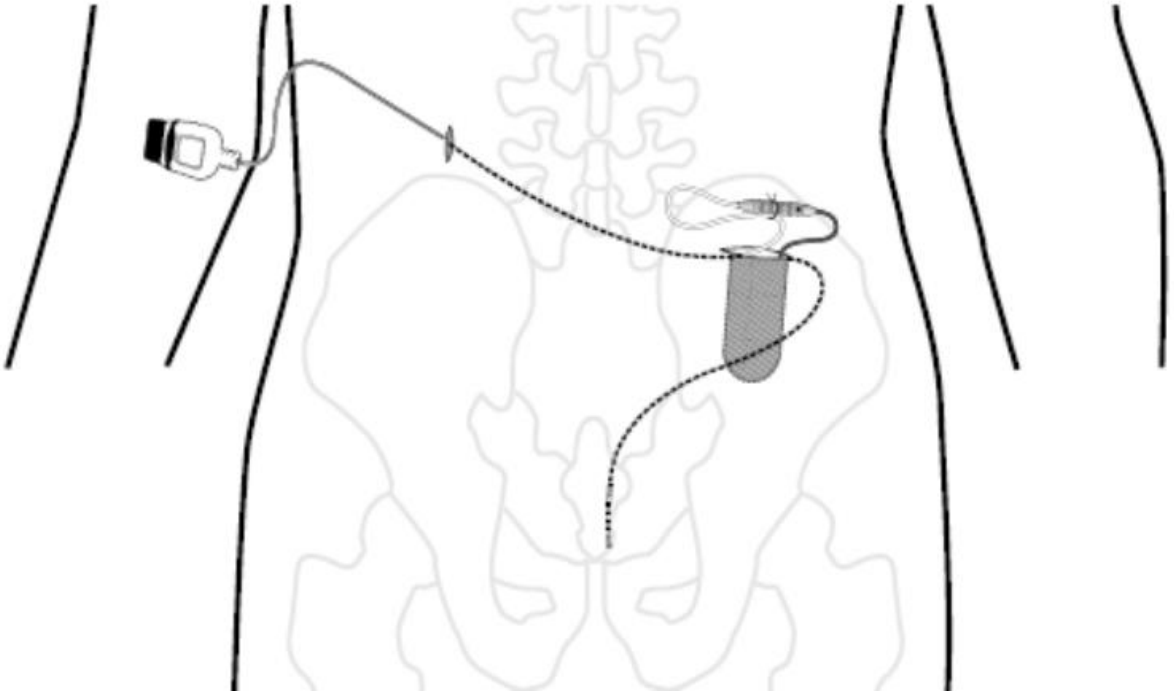

***Figure 4.*** *Subcutaneous pocket for the percutaneous extension and strain relief loops.*

**4.** Rotate the percutaneous extension connector so the set screw block and lead are pointing up, away from the incision and insert the connector block, percutaneous extension body and lead loops into the pocket (Figure 5).

**Note.** Position the lead and extension, avoiding sharp bends or kinks. Fluoroscopic observation may be necessary.

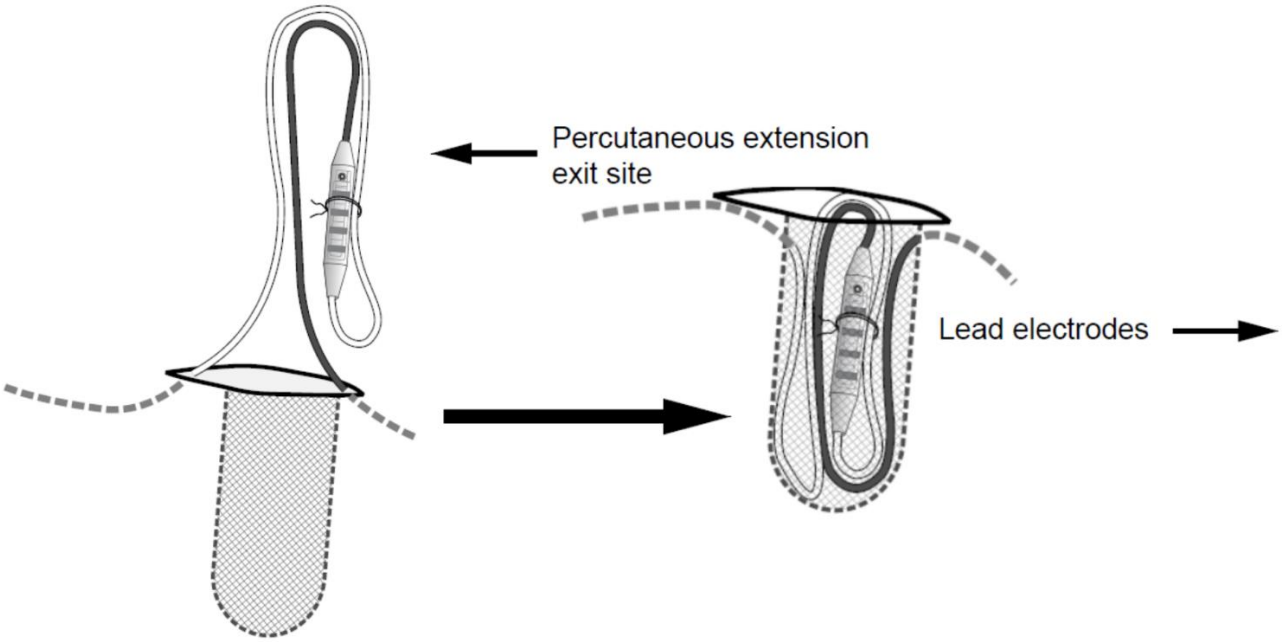


***Figure 5.*** *The lead and percutaneous extension set screw block pointing away from the incision prior to insertion into the subcutaneous pocket; followed by the lead, percutaneous extension connector, and percutaneous extension body strain relief loops in the subcutaneous pocket that is perpendicular to the percutaneous extension tunneling path.*

**Preparing for neurostimulator implant after advanced evaluation**

1. Carefully open the percutaneous extension-lead connector site and expose the lead and connector.
2. Using the torque wrench, loosen the setscrew in the setscrew connector by turning the wrench counterclockwise.
3. Gently remove the lead from the lead connector end of the percutaneous extension.

**Caution:** If resistance is felt when removing the lead from the percutaneous extension, loosen the setscrew slightly to ensure that it clears the lead contacts. Avoid disengaging the setscrew. Inspect the lead contacts for damage (flattening or stretching of lead) if resistance was felt prior to removal. Damaging the lead may result in additional surgical steps.

4. Cut the percutaneous extension near the incision proximal to where it is tied to the connector (Figure 6).

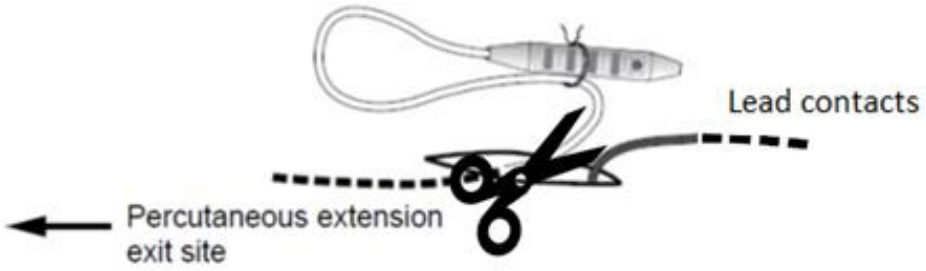


**Figure 6.** Image showing where to cut the percutaneous extension for removal

5. Withdraw the remainder of the percutaneous extension through the contralateral exit site and discard it.

> **Warning:** Ensure sterile field is maintained during removal of the percutaneous extension to minimize the risk of infection.

6. Close the exit site and proceed to connecting the lead to the neurostimulator, refer to product literature packaged with the neurostimulator.

## Solution 2:

1. With the tunneling tool in place and prior to pulling the percutaneous extension to the pocket site, place a resorbable suture in the tissue around the tunneling rod near the entry site from the pocket (Figure 1).

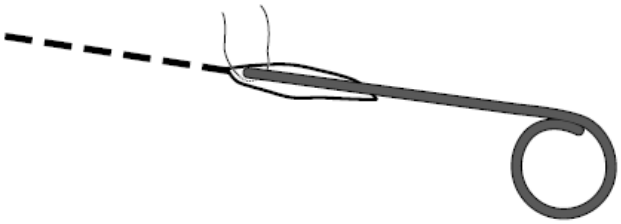

**Figure 1.**

2. Retract the tunneling tool to pull the lead connector end of the percutaneous extension from the percutaneous extension exit site to the pocket site.
3. Remove the percutaneous extension from the carrier tip.
4. Secure the preplaced suture in the tissue around the percutaneous extension closing the tunneling path (Figure 2).

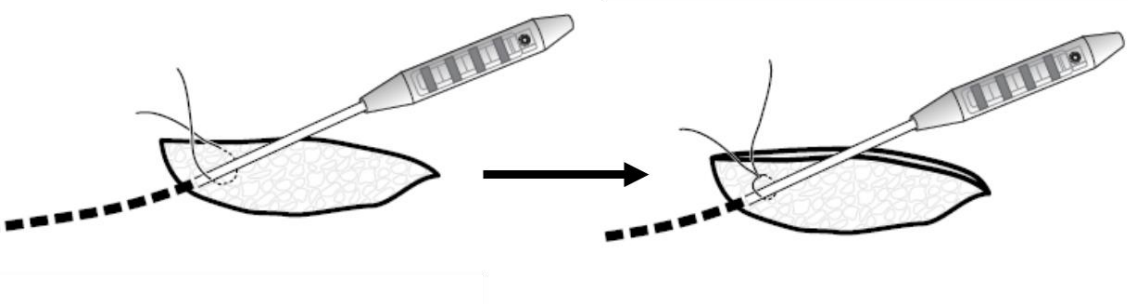

**Figure 2.**

**Note:** Do not overtighten the suture to avoid crushing the extension body.

5. Refer to the lead implant manual to compete the implant process.