

URGENT FIELD SAFETY NOTICE

Medtronic Spinal Cord Stimulation (SCS) Therapy

Labeling Update for Epidural Mass Causing Spinal Cord Compression

Medtronic Reference: FA601

17 February 2014

Dear Healthcare Professional,

This letter is to inform you of upcoming changes to the adverse event labeling for Medtronic spinal cord stimulation therapy. Current labeling¹ addresses the potential for neurological complications associated with the surgical implant procedure; however, they do not address the potential for epidural mass formation and subsequent spinal cord compression.

Issue Description:

Medtronic has identified 14 reports over the last 30 years describing delayed spinal cord compression due to an epidural mass around a Medtronic SCS lead. All patients had neurological deficits and required surgical intervention to remove the mass. Histologically, the epidural masses consisted of reactive tissue (granulomatous and/or fibrous tissue). The reported time to onset of neurological symptoms after lead implant ranged from weeks to 17 years. The severity ranged from muscle weakness to progressive quadriplegia. In several of the cases, only one side of the body was affected. The appearance of neurological symptoms was often preceded by a loss of therapy effect. The reported outcomes in these patients were full recovery (9 reports), permanent impairment (2 reports), and unknown (3 reports). There has not been a report of a patient death associated with this issue.

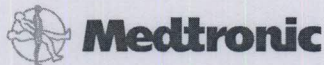
Occurrence:

The number of reports corresponds to an estimated rate of occurrence of less than 1 in 10,000 patients. The reports involved various models (8 surgical leads, 6 percutaneous leads). The data indicate that this issue is not limited to specific lead models or lead location (8 cervical, 3 thoracic, and 3 unknown). The frequency of spinal cord compression due to this issue was found to be significantly higher with the use of surgical leads and significantly higher with cervical lead location, but at least one case occurred with a percutaneous lead placed in a thoracic location.

Recommendations:

- Medtronic **does not** recommend prophylactic removal of SCS leads. Awareness of this adverse event can lead to early detection and prevention of permanent neurological impairment.
- If a patient with an SCS lead presents with a new neurological deficit, spinal cord compression due to reactive tissue mass formation should be considered as a potential cause.
- If an asymptomatic epidural mass is identified, periodic monitoring should be considered.

¹ See attached list of product model numbers associated with the labeling update.



Medtronic has notified the Competent Authority of your country of this field safety corrective action. Please share this notification with others in your organization as appropriate.

We are committed to continuing to improve our product performance and services to enable you to manage your patients in a safe and effective manner.

If you have questions, please contact your Medtronic sales representative Gulf Medical at: +96614633399

Sincerely,

Ayman Doughan
Business Manager
Neuromodulation MENA

List of Product Models associated with the Labeling Update for Epidural Mass Causing Spinal Cord Compression

Spinal Cord Stimulation Neurostimulators (Model)

- ITREL®3 (7425)
- SYNERGY (7427)
- SYNERGY VERSITREL (7427V)
- RESTOREPRIME® (37701)
- RESTOREPRIME® Advanced (37702)
- ITREL®4 (37703 and 37704)
- RESTORE® (37711)
- RESTOREULTRA® (37712)
- RESOTREADVANCED® (37713)
- RESTORESENSOR® (37714)
- PRIMEADVANCED® SURESCAN® MRI (97702)
- RESTOREULTRA® SURESCAN® MRI (97712)
- RESTOREADVANCED® SURESCAN® MRI (97713)
- RESTORESENSOR® SURESCAN® MRI (97714)

Spinal Cord Stimulation Leads (Model)

- PISCES™ Quad (3487A)
- RESUME® II (3587A)
- 1 x 8 Sub-Compact (3776)
- 1 x 8 Standard (3777)
- 1 x 8 Compact (3778)
- 1 x 8 Standard (3873)
- 1 x 8 Compact (3874)
- 1 x 8 Sub-Compact (3875)
- 1x8 Sub-Compact Lead w/Perc Ext (3876)
- 1x8 Standard Lead w/Perc Ext (3877)
- 1x8 Compact Lead w/Perc Ext (3878)
- 1x8 Subcompact SURESCAN® MRI Perc (977A1)
- 1x8 Compact SURESCAN® MRI Perc (977A2)
- PISCES™ Quad Compact (3887)
- PISCES™ Quad Plus (3888)
- SymMix In-Line Connector Lead Kit for SCS (3982A)
- RESUME TL® (3986A)
- SPECIFY® (3998)
- SPECIFY® 2x4 Hinged (3999)
- SPECIFY® 2x8 (39286)
- SPECIFY® 5-6-5 (39565)
- 1x8 Subcompact SURESCAN® MRI Trialing Perc (977D160)
- 1x8 Compact SURESCAN® MRI Trialing Perc (977D260)

Kits

- Models 7719, 7729, 3550-22 and 3550-23

Patient Programmers

- Models 7434A, 7435, 37744, 37746 and 97740