Safety Alert: Medtronic Spinal Cord Stimulation (SCS) Therapy
Labeling Update for Epidural Mass Causing Spinal Cord Compression

Dear Healthcare Professional,

This letter is to inform you of upcoming changes to the adverse event labeling for Medtronic spinal cord stimulation therapy. Current labeling\(^1\) 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.

**Action in Response to this Letter:**
Acknowledge receipt of this letter by completing the attached reply form and returning it to Medtronic using the contact details on the reply form.

**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.

Medtronic is communicating this information to the appropriate regulatory agencies globally. 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 Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CST. Please report any malfunction or adverse event related to a device to Medtronic Neuromodulation Technical Services and to FDA’s MedWatch Program (www.fda.gov/medwatch).

Sincerely,

\[Signature\]

Mike Crader
Vice President Quality
Medtronic Neuromodulation

\(^1\) See attached summary for the product model numbers associated with the labeling update.
Summary of the 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)
- 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, 355022 and 355023

**Patient Programmers**
- Models 7435, 37744, 37746 and 97740