



Urgent Field Safety Notice

Specify™ 5-6-5 Surgical Lead and Specify™ 2x8 Surgical Lead Model 39565 and 39286 Upcoming Labeling Updates for Spinal Cord Stimulation

6 January 2016

Medtronic reference: FA691

Dear Healthcare Professional,

The purpose of this letter is to notify you that labeling is being updated to clarify that the Specify™ 5-6-5 and 2x8 surgical leads are not intended for interoperative trial evaluation use (i.e., trialing/screening outside of the operating room with an external neurostimulator). Some of the current Specify™ 5-6-5 and 2x8 surgical lead product labeling does not distinguish between intraoperative stimulation testing with a permanent surgical lead and interoperative trial evaluation use.

Action:

Ensure you and your staff are aware that the Specify™ 5-6-5 and 2x8 surgical leads are not intended for interoperative trial evaluation use (i.e., trialing/screening outside of the operating room with an external neurostimulator). Please share this notification with others in your organization as appropriate and retain this letter for your records.

Additional Information:

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

If you have questions regarding SCS therapy or current labeling, please contact your Medtronic representative at Gulf Medical +966 12 2852828

Sincerely,

Ziad Kassir
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