

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 directly or via Tel No. 01923 212213.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland