Medtronic

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Medical Device Correction

Upcoming Labeling Updates for Spinal Cord Stimulation

Specify™ 5-6-5 Surgical Lead (model 39565), Specify™ 2x8 Surgical Lead (model 39286)

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 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 staffs 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 retain this letter for your records.

Reporting of Adverse Event:

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions to your local Clinical Representative (Jason at +65 9005 3407 or Shirley at +65 9737 8043). Alternatively, healthcare professionals may report the adverse events to the Vigilance Branch, Health Products Regulatory Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae online. Events that are reported to Medtronic will be investigated and subsequently reported to HSA.

Shirley Loh
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