

## **Urgent Field Safety Notice**

Ascenda™ Intrathecal Catheters / Revision Kit  
Specific Serial numbers of Models 8780, 8781, and 8784

### **Updated Recommendations**

30 September 2014

Medtronic reference: FA629 Phase II

Dear Customer,

This is a follow-up to Medtronic Neuromodulation's July 2014 letter titled "*Urgent: Medical Device Removal – Ascenda™ Intrathecal Catheters – Specific Serial numbers of Models 8780, 8781, and 8784*". The July 2014 letter communicated a voluntary removal of specific lots of unused inventory due to a single component of the catheter not meeting our specification criteria. You are receiving this letter because our records identified you as the implanting or managing physician for a patient implanted with one of these catheters prior to the July notification.

Laboratory testing conducted as a part of the investigation is now complete, and we have concluded that patients who were implanted with one of these catheters prior to the notification have:

- No increased risk of unintentional disconnection of the catheter from the pump
- No increased risk of difficulty in disconnecting the catheter from the pump during revision.

As a result, **Medtronic no longer recommends special monitoring of patients** implanted with one of these catheters.

We apologize for any inconvenience this issue has caused you and your patient. If you have questions, please contact your Medtronic representative at <xxxxxx>.

Sincerely,