March 2017

Urgent: Medical Device Correction

Important information regarding the DBS Lead Depth Stop
Supplied within Medtronic Models 3387/3387S, 3389/3389S, and 3391/3391S DBS Lead Kits

Dear Neurosurgeon:

The purpose of this letter is to provide you important safety information regarding the use of the depth stop accessory provided in all Medtronic Deep Brain Stimulation (DBS) lead kits. The Medtronic DBS depth stop, otherwise referred to as the lead holder, is used to establish the implant depth. The depth stop interfaces with parts of the stereotactic system used during surgery to control placement of the DBS lead tip to the target location. This letter provides information regarding a product performance issue that has been identified with this component, potential risk to patients, and actions to take regarding use of the Medtronic depth stop.

If you **do not** use the Medtronic depth stop (for example, if you only use the FHC, Alpha Omega, or Nexdrive depth stop), you are not affected and no actions are needed.

Background:
Medtronic has received three (3) complaints from physicians reporting that the DBS depth stop did not adequately secure to the lead. In two of the three complaints received, this resulted in initial DBS lead placement beyond the intended target, which was identified via intraoperative imaging and corrected with no report of patient harm. In the third instance, the issue was identified prior to lead insertion.


Medtronic DBS depth stop

Analysis of these returned products indicate the threaded area of the depth stop screw did not extend far enough to allow it to fully secure the lead in the depth stop. This caused slippage of the lead through the depth stop. Medtronic's initial investigation indicates that this issue affects less than 2% of all distributed product.

Medtronic is not retrieving affected product at this time as maintaining physician access to Medtronic DBS leads kits is critical for patients who have developed (or are at risk of developing) life-threatening symptoms due to loss of therapy (e.g., patients being treated for Parkinson's disease may experience akinetic crisis, patients being treated for Dystonia may experience dystonic crisis), and require a lead replacement surgery. Since Medtronic neurostimulators and extensions are not compatible with non-Medtronic leads, Medtronic recommends continuing to use current DBS lead kit inventory until replacement product becomes available. Please consider this in accordance with your standards of practice and your assessment of the needs of the patient.

This issue applies only to the depth stop supplied in the Medtronic DBS lead kits. There are no issues with the DBS lead or other components in the DBS lead kits. This issue does not apply to the Nexdrive lead holder or depth stops supplied by Microdrive manufacturers.

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Potential Risk to Patients:
The risks associated with the DBS lead implanted too deeply or in an unintended target may include the following:

1. Lack of therapeutic response, and/or undesirable symptoms associated with stimulation of an unintended target (e.g., new motor, coordination, sensory symptoms).
2. Risks associated with a second surgical procedure to explant and implant another DBS lead (e.g., increased risk of infection, anesthesia risks, intracranial hemorrhage).
3. Life-threatening or fatal intracerebral hemorrhage, life-threatening or fatal cerebral tissue injury (e.g., insertion of lead in the brainstem), and temporary or permanent neurological deficits due to cerebral injury based upon the lead location (e.g., damage to the optic tract resulting in visual impairment).

Actions:
If your surgical procedure involves the use of the Medtronic DBS depth stop, Medtronic recommends the following:

- For implanted product: If product has already been implanted, no action is needed since lead placement at the intended target location is expected to have been confirmed through intraoperative test stimulation, imaging, and/or therapy effectiveness.
- For product not yet implanted: If you suspect that the depth stop is not tightening adequately onto the lead, do not use, and complete the procedure using a depth stop from another Medtronic DBS lead kit. As stated in the DBS lead implant manual, Medtronic recommends that you check the stimulation effect during the implant procedure and use imaging techniques to confirm lead placement.

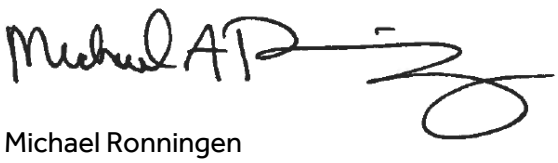
If you have any questions about product functionality or use, you can contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am – 6pm CDT.

Medtronic has implemented manufacturing process changes to address this issue. When sufficient inventory of replacement product becomes available, expected within 2-3 months, Medtronic will retrieve any unused affected products.

Additional Information:
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.

Medtronic is communicating this information to the appropriate regulatory agencies globally, including the U.S. Food and Drug Administration. If you have questions, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933 weekdays 7am - 6pm CDT. 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,



Michael Ronningen
Vice President of Quality

Enclosures:

- *Physician / HCP Reply Form with Postage Paid Return Envelope*