February 2013

Urgent Field Safety Notice

Deep Brain Stimulation (DBS™) Lead Kits: Models 3387, 3387S, 3389, 3389S, 3391, 3391S

Potential Lead Damage Associated with the DBS Lead Cap: modified instructions

Medtronic reference: FA565

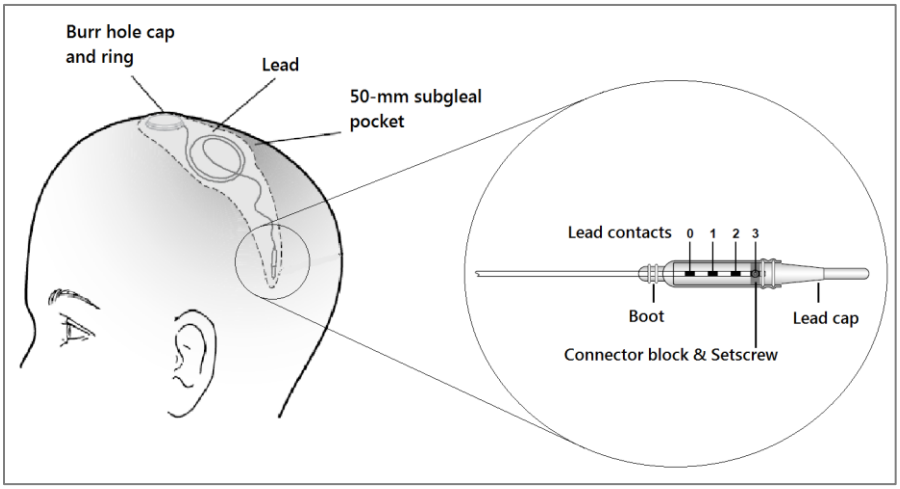
Dear Healthcare Professional,

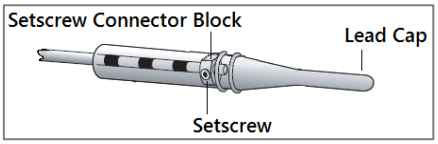
This letter provides information concerning potential lead damage due to the use of the lead cap provided in Medtronic Deep Brain Stimulation (DBS™) lead kits. This lead cap is used to protect the proximal connector end of the lead during implant**.**

- **If you do not use the lead cap in your procedures, this letter does not apply to you and no action is required on your part.**
- **If the DBS lead cap is used, review and follow the modified instructions included in this letter.**

Explanation of the Issue

Medtronic has received reports of DBS leads being damaged at the connector end of the lead when the lead cap is used. The connector end of the lead is the end of the lead connected to the lead extension. Tightening or loosening of the setscrew may twist the setscrew connector block and may damage the proximal connector end of the lead. If this happens, the damage would most likely occur at lead contact #3 which could affect electrode contact #3.





Depending on the extent of lead damage and the need to use electrode #3, lead replacement may be required or optimal therapy may not be provided. Lead damage due to setscrew connector block twisting has been reported with 0.25% of the DBS leads distributed, however, this incidence is lower than the expected actual rate of occurrence since every event is not likely to have been reported and the actual number of uses of lead caps is unknown. . Physicians should recognize that every use of the lead cap provides an opportunity for lead damage to occur. To date, there have been no reports of permanent patient impairment, life-threatening injury, or death as a result of this issue.

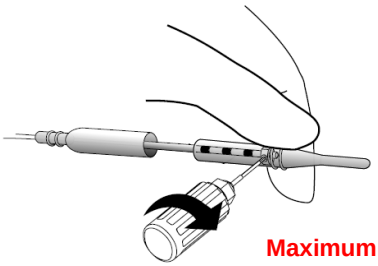
There is no action required for existing patients in the absence of concern over potential lead damage. Medtronic is working on corrective actions to reduce the occurrence of setscrew connector block twisting which may result in lead damage. Until these corrective actions are in place, follow the modified instructions below:

Additional Instructions for Capping the Lead

Follow the instructions in the Implant Manual for capping the lead, *with the exception of* Step 4 and Step 5 (regarding how the setscrew connector block should be held, and tightening the setscrew until clicks are heard), which should be modified as follows:

Regarding Step 4:
Any time you use the torque wrench, hold the setscrew connector block firmly between the thumb and forefinger to prevent rotation of the block.

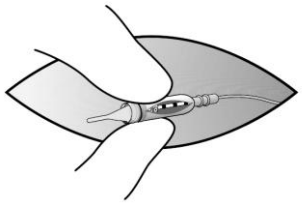
Regarding Step 5:
Tighten the single setscrew in the setscrew socket on the number 3 lead contact by turning it clockwise with the torque wrench provided. **Tighten the setscrew until it touches the contact; then continue tightening for a maximum of ¼ turn only (you may or may not hear the sound of a click)**.



Additional Instructions for Removing the Lead Cap

Follow the instructions in the Implant Manual for removing the lead cap, *with the exception of* Step 5 and Step 6 (regarding how the setscrew connector block should be held), which should be modified as follows:

Regarding Steps 5 & 6:
Hold the setscrew connector block firmly between the thumb and forefinger to prevent rotation. Failure to prevent rotation may break or damage the lead, and may require lead replacement.



If you have any concern that the lead may have been damaged due to twisting of the setscrew connector block, impedance measurement may be used to detect open and/or short circuits. Evaluation of the patient's response to stimulation is also important to evaluate system operation.

Medtronic Neuromodulation is communicating this information to the appropriate regulatory agencies in your country.

This notice needs to be passed on all those who need to be aware within your organization or to any organisation where the potentially affected devices have been transferred.

We regret any inconvenience this may cause you or your patients. If you have questions please contact Medtronic Neuromodulation Technical Services at <insert local contact #>.

Sincerely,

Country Manager