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 Federal Government Administrative Centre,
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Medical Device / Equipment ALERT: Field Action

Date Issued : 22nd August 2008

Ref:MDB/A/2008/013

IMMEDIATE ACTION	
ACTION	√
UPDATE	
INFORMATION REQUEST	

PRODUCT	Deep Brain Stimulation Lead Kits Model 3387, 3387S, 3389 and 3389S DBS Lead Kits.
CLASS	n/a
USE	Implant – Deep Brain Stimulation Lead Kits.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Field Action Letter dated 15 th August 2008 from Medtronic International Ltd. - Malaysia Branch.
ALERTING / RECALLING FIRM	Medtronic International Limited-Malaysia Branch This document is to provide related physicians with updated instruction for using the lead cap of the above mentioned lead kits.
REASON	<i>*Please refer to attachment for details.</i>
SCENARIO IN MALAYSIA	According to Medtronic International Limited-Malaysia Branch, this field action currently involves 2 physicians in Malaysia.
ACTION	<i>*Please refer to attachment for details.</i>
RECOMMENDATION	Other users of the abovementioned device (not being notified by Medtronic International Limited before) should contact the distributors/supplier of this device (if available) and inform the Medical Device Bureau, Ministry of Health providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number

	c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	<p>Medtronic International Limited-Malaysia Branch</p> <p>Miss Debra Anne Anthony Peter,</p> <p>F-39-7 CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya Selangor Darul Ehsan.</p> <p>Tel:- 03-79534800 Fax:- 03- 79582202</p>
REFERENCES	<i>*Please refer to attachment for details.</i>



Medtronic

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August 15, 2008.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
ENGINEERING SERVICES DIVISION,
Level 2-5, Block E6, Parcel E, Precinct 1,
Federal Government Administration Centre,
62590 Putrajaya,
Malaysia.

Dear Sir,

MODEL 3387, 3387S, 3389, AND 3389S DBS™ LEAD KITS - INSTRUCTIONS FOR USING THE LEAD CAP.

Medtronic International Limited is initiating a field action on Deep Brain Stimulation Lead Kits Model 3387, 3387S, 3389 and 3389S to outline the communication letter to the respective implanting physicians.

The letter is intended to provide physicians with updated instructions for using the lead cap of the above mentioned lead kits. The scope of this field action in Malaysia, involves two physicians from the Hospital Universiti Sains Malaysia and Sunway Medical Centre.

Attached herewith is the medical device correction letter which will be sent to the physicians.

Do consult us should you require additional information.

Thank you and kind regards.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Attachment: Medical Device Correction letter dated August 2008.



August 2008

Urgent: Medical Device Correction

**Model 3387, 3387S, 3389, and 3389S Deep Brain Stimulation (DBS™) Lead Kits
Instructions for Using the Lead Cap**

Dear Healthcare Professional,

This letter is intended to provide you with updated instructions for using the lead cap provided in Medtronic Model 3387, 3387S, 3389, and 3389S Deep Brain Stimulation (DBS™) lead kits. These instructions are being incorporated into the implant manuals provided in these lead kits.

Explanation of the Issue

Medtronic has received reports of DBS leads being damaged at the proximal connector end of the lead (the end of the lead connected to the lead extension) when the lead cap is used in the implant procedure. Analysis of the data collected to date suggests that the lead damage is the result of excessive torsion and/or tensile loading on the proximal connector end of the lead. The data also suggest that excessive torque while tightening or loosening the setscrew may twist the setscrew connector block and damage the proximal connector end of the lead.

Depending on the extent of lead damage and the need to use the affected lead contact(s) and/or conductor(s), lead replacement may be required, exposing the patient to the risks of a second lead implant procedure. To date, there have been no reports of permanent patient impairment, life-threatening injury, or death as a result of this issue. Medtronic estimates the incidence of lead damage caused when the lead cap is used in the implant procedure to be approximately 1.4%.

Recommendations for Implant

Please review and follow the updated instructions for using the lead cap provided in the attachment to this letter. These instructions are being incorporated into the implant manuals provided in the Model 3387, 3387S, 3389, and 3389S DBS lead kits. Failure to follow these instructions may result in damage to the DBS lead and inadequate system performance, and/or the need for lead replacement.

Medtronic is communicating this information to the U.S. Food and Drug Administration (FDA). Report any suspected incidents related to this issue to Medtronic and the FDA using the medical device reporting system at <http://www.fda.gov/medwatch/how.htm>.

We appreciate your assistance with this matter and are sharing this information so you have the resources to provide the best patient care possible. We are committed to providing you with the highest quality products, services and ongoing support as you care for your patients.

If you have any questions or comments, please contact Medtronic Neuromodulation Technical Services at 1-800-707-0933. Your local Medtronic representative will be contacting you to follow-up on this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "George Aram". The signature is fluid and cursive, with a prominent flourish at the end.

George Aram
Vice President of Quality
Neuromodulation Division

Attachment: Updated Instructions for Using the Lead Cap

ATTACHMENT

Updated Instructions for Using the Lead Cap

These instructions are being incorporated into the implant manuals provided in the Model 3387, 3387S, 3389, and 3389S DBS Lead Kits.

Precautions

Handling Components

Handle the implanted components of this system with extreme care. These components may be nicked, cut, or damaged by excessive traction or sharp instruments and may require surgical replacement.

- Do not bend, kink, stretch, or twist the lead body whether or not the stylet is in place. Do not bend or kink the tungsten stylet.
- Do not bend, kink, stretch, or twist the lead body when manipulating the lead in the subgaleal pocket.
- Do not tie a suture directly to the extension or the lead body. Use the burr hole cap and ring provided by Medtronic to secure the lead in place.
- When handling the lead with forceps, use only a rubber-tipped bayonet forceps.

Hex Wrench

Do not overtighten setscrews when using the hex wrench. Excessive torque on setscrews may damage lead contacts. Verify that the sealing grommet has closed on the neurostimulator.

Capping the Lead

If the remainder of the neurostimulation system is not implanted immediately after lead implantation, perform the following steps:

1. Push the connector boot over the exposed end of the lead (Figure 25).



Figure 25: Push connector boot over lead.

2. Insert the exposed end of the lead into the lead cap contained in the lead kit (Figure 26).

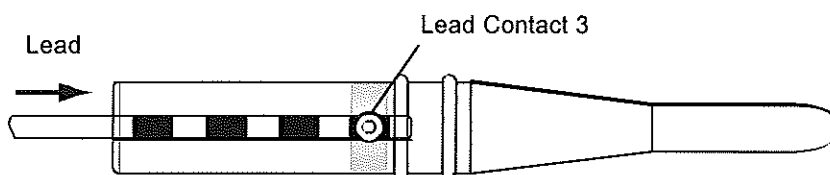


Figure 26: Insert lead into lead cap.

3. Align the number 3 lead contact with the setscrew connector block (Figure 26).
4. Hold the setscrew connector block firmly between thumb and forefinger to prevent rotation (Figure 27).

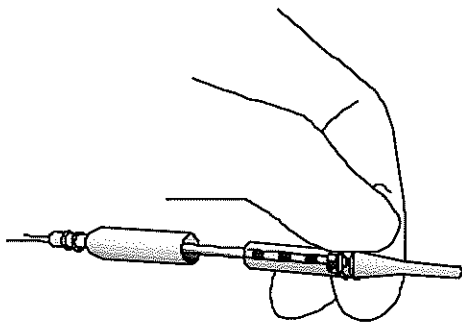


Figure 27: Hold setscrew connector block between thumb and forefinger.

5. Tighten the single setscrew in the setscrew socket on the number 3 lead contact by turning it clockwise with the hex wrench provided (Figure 28). Tighten the setscrew until it touches the contact; then continue tightening for a maximum of 1/4 turn only.

Caution: Excessive torque on setscrew may damage lead contact.

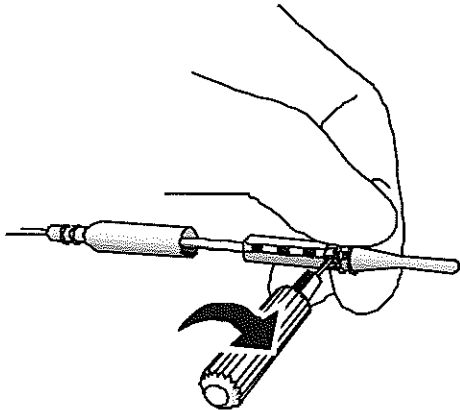


Figure 28: Tighten setscrew.

6. Slide the connector boot over the lead cap (Figure 29).

Note: If it is difficult to position the boot, only sterile water may be used as a lubricant.

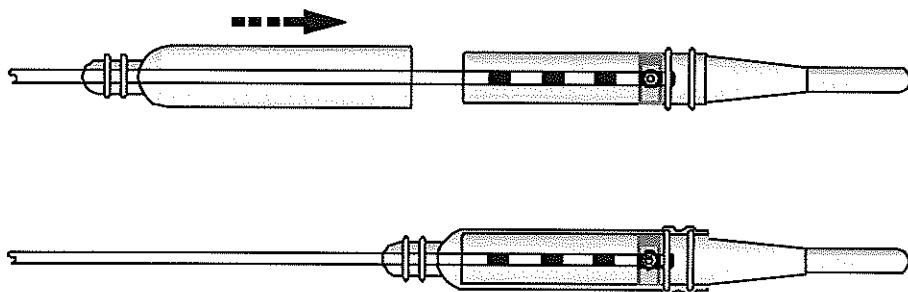


Figure 29: Slide connector boot over lead cap.

7. Place non-absorbable sutures around both ends of the connector boot in the suture channels (Figure 30).

Caution: Do not overtighten sutures because damage may occur to either the connector boot or the lead.

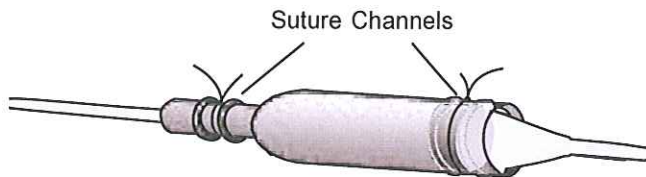


Figure 30: Suture lead/lead cap.

8. Use blunt dissection to create a 50 mm diameter subgaleal pocket and a path to the desired lead-extension connection site (Figure 31).

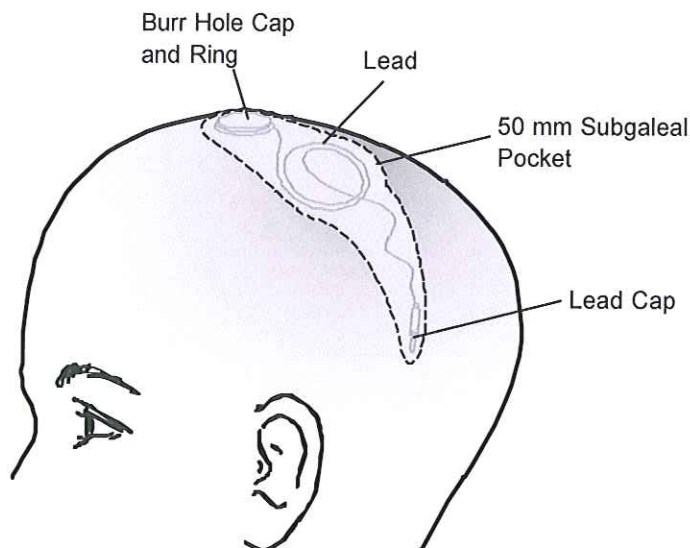


Figure 31: Lead in subgaleal pocket.

9. Deliver the capped end of the lead to the desired temporary location (Figure 31).

Cautions:

1. Be extremely careful when using sharp instruments around the lead body to avoid nicking or damaging the lead.
2. Do not bend, kink, stretch, or twist the lead body when delivering it to the desired temporary location.
3. When handling the lead with forceps, use only a rubber-tipped bayonet forceps and grasp only the lead cap. Do not use the forceps on the lead body.

10. In the subgaleal pocket, coil excess lead in a circle greater than 25 mm in diameter (Figure 31).
Avoid bending or kinking the lead.

11. Close the incision and apply the appropriate dressing.

Removing the Lead Cap

For each implanted lead:

1. Locate the lead cap at the proximal end of the lead.

Note: Use fluoroscopic observation or palpate the area with the fingers to locate the lead cap and confirm access without risk of cutting the lead.

2. Make an incision sufficient to expose the lead and lead cap. Allow room to hold the lead firmly when accessing the lead cap and when connecting the lead to the extension (Figure 32).

Cautions:

1. Be extremely careful when using sharp instruments around the lead body to avoid nicking or damaging the lead.
2. Avoid pulling the lead cap out of the tissue to prevent excess stress on the lead. If more slack is needed, gently grasp the lead body and lift the lead cap out of the tissue. Do not bend, kink, stretch, or twist the lead body when accessing the lead cap.

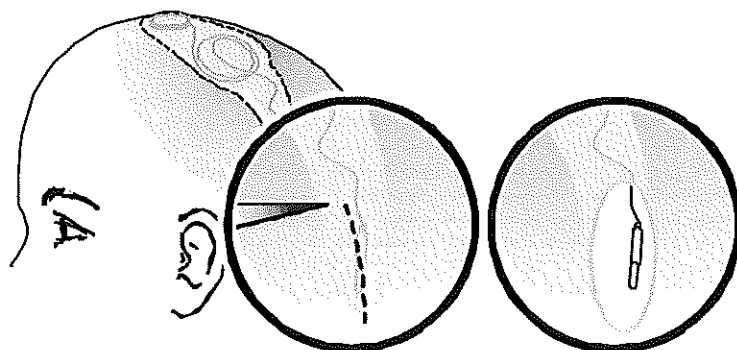


Figure 32: Make incision to expose lead and lead cap.

3. Cut the distal suture over the lead end of the connector boot (Figure 33).

Caution: Do not cut the lead when removing the suture. Cutting the lead's insulation can result in loss of stimulation and lead failure.

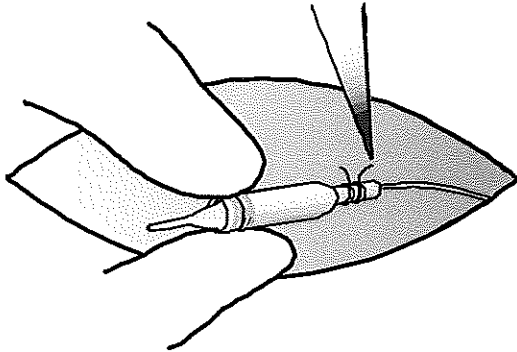


Figure 33: Cut distal suture over lead end of connector boot.

4. Cut the connector boot over the lead cap to expose the setscrew (Figure 34).

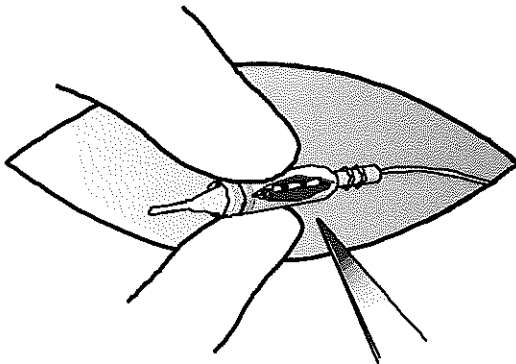


Figure 34: Cut connector boot to expose setscrew.

5. Hold the setscrew connector block firmly between thumb and forefinger to prevent rotation (Figure 35).

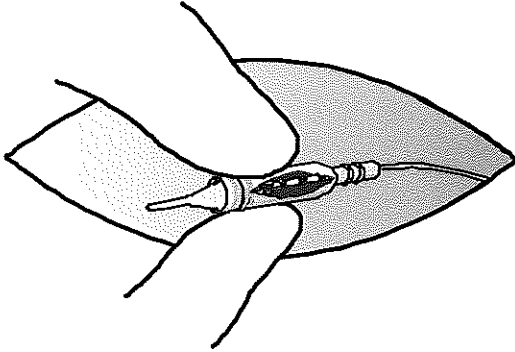


Figure 35: Hold setscrew connector block between thumb and forefinger.

6. Using the hex wrench, loosen the setscrew in the setscrew connector by turning the wrench counterclockwise (approximately one turn) (Figure 36).

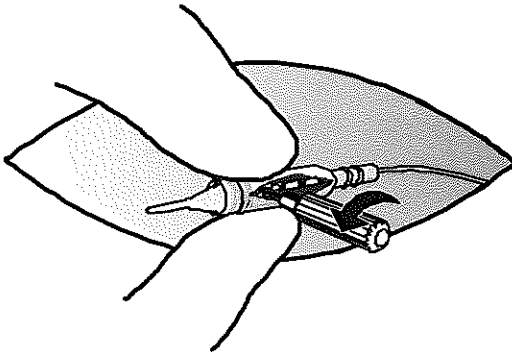


Figure 36: Loosen setscrew.

7. Stabilize the lead and gently remove the lead from the setscrew connector block (Figure 37).

Caution: If resistance is felt when removing the lead from the lead cap, loosen the setscrew slightly to ensure that it clears the lead contact. Avoid disengaging the setscrew. Inspect the lead contact for damage (flattening or stretching of lead) if resistance was felt prior to removal.

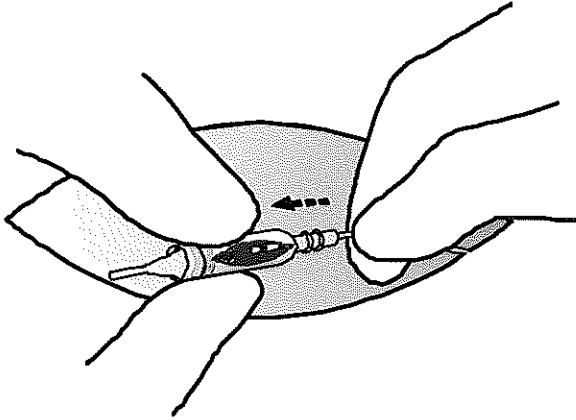


Figure 37: Remove lead from setscrew connector block.

8. Withdraw the lead cap and connector boot through the incision and discard (Figure 38).

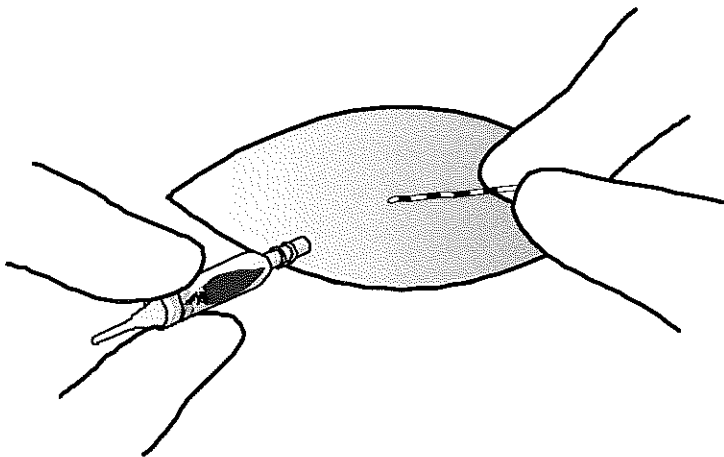


Figure 38: Withdraw lead cap and connector boot.