June 2013

URGENT FIELD SAFETY NOTICE

Potential Lead Damage Associated with the DBS Lead Cap

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

RECALL

Medtronic Reference: FA565 Phase II

Dear Healthcare Professional,

This letter is a follow-up to Medtronic's February 2013 letter to physicians regarding potential lead damage associated with use of the Deep Brain Stimulation (DBS) and Dystonia Lead Cap. The February 2013 letter provided details regarding potential damage to the connector end of the lead due to twisting of the setscrew connector block within the lead cap, and provided modified instructions to mitigate the potential for damage to the lead.

Medtronic has implemented manufacturing process changes that address the twisting of the setscrew connector block within the lead cap and is now removing any unused product that was distributed to customers prior to implementing this change.

Your sales representative will review your inventory and remove any lead kits that were manufactured prior to the change.

In June 2013 Medtronic began distributing lead kits manufactured after the process changes. Lead kits manufactured after the process changes can be identified by the UPN number located on the shelf box side label and on the device registration stickers. A document identifying new product UPN's and their location on the package is attached. Please note that the UPN is the only way to identify the corrected product.

For future orders of the Medtronic DBS lead kit, OCD kit, or Dystonia Kit, please follow your typical order process. Any new orders placed will receive the corrected product. It is no longer necessary to follow the modified instructions provided in the February 2013 notification.

The Competent Authority of your country has been notified of this action.
This notice needs to be passed on all those who need to be aware within your organization.

If you have any questions related to this recall, please contact your Medtronic representative at (insert phone number). We apologize for any inconvenience this may cause, and we thank you for your continued business. Medtronic is committed to providing you with the highest quality products, services, and ongoing support as you care for your patients.

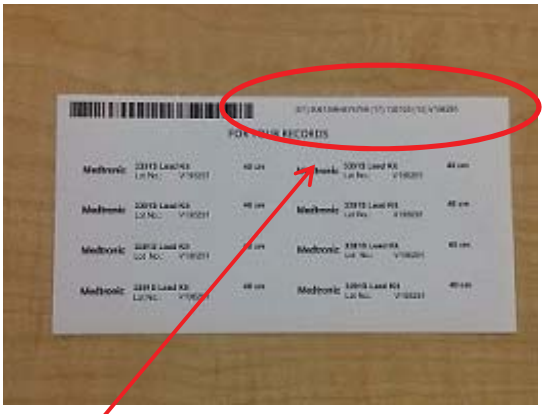
Sincerely,

Attachment: *UPN Summary – Corrected DBS Lead Kit Identification*

UPN Summary
Corrected DBS Lead Kit Identification

International Model Configurations

The UPN number is located on the DBS Kit box side label, and on the registration stickers inside the box:



UPN Number (Enlarged Below)

The following DBS Lead Kits (Identified by UPN) were manufactured using the updated manufacturing process.

If a DBS Lead Kit has a UPN <u>not</u> on this list, it is being retrieved by Medtronic.

Model	New UPN	Supported Languages
3387-28	00643169326484	CS,EN,PL,RU,SK
	00643169326477	DA,EN,NO,SV
	00643169326460	DE,EN,FR,IT,NL
	00643169326453	EL,EN,HU,RO,TR
	00643169326446	EN,ES,FR,PT

Model	New UPN	Supported Languages
3391-28	00643169326170	EN,SV
	00643169326200	DA,EN,NO
	00643169326194	DE,FR,IT
	00643169326187	DE,FR,NL
	00643169326231	EN,FR
	00643169326217	EN,RU

Model	New UPN	Supported Languages
3387-40	00643169326422	CS,EN,PL,RU,SK
	00643169326415	DA,EN,NO,SV
	00643169326408	DE,EN,FR,IT,NL
	00643169326392	EL,EN,HU,RO,TR
	00643169326385	EN,ES,FR,PT
3389-28	00643169326361	CS,EN,PL,RU,SK
	00643169326354	DA,EN,NO,SV
	00643169326347	DE,EN,FR,IT,NL
	00643169326330	EL,EN,HU,RO,TR
	00643169326323	EN,ES,FR,PT
3389-40	00643169326316	CS,EN,PL,RU,SK
	00643169326309	DA,EN,NO,SV
	00643169326293	DE,EN,FR,IT,NL
	00643169326286	EL,EN,HU,RO,TR
	00643169326279	EN,ES,FR,PT
3391-28 (continued)	00643169326248	EN,ES,PT
	00643169326262	CS,PL,SK
	00643169326224	EN,HU,RO
	00643169326255	EL,EN,TR
3391-40	00643169326071	EN,SV
	00643169326101	DA,EN,NO
	00643169326095	DE,FR,IT
	00643169326088	DE,FR,NL
	00643169326132	EN,FR
	00643169326118	EN,RU
	00643169326149	EN,ES,PT
	00643169326163	CS,PL,SK
	00643169326125	EN,HU,RO
	00643169326156	EL,EN,TR
	00643169326156	EL,EN,TR