

Urgent Field Safety Notice

DBS Lead Depth Stop Supplied within Medtronic DBS Lead Kit Models 3387, 3389 and 3391 Recall

August 2017

Medtronic reference: FA761

Dear Health Care Professional, Risk Manager,

The purpose of this letter is to advise you that Medtronic is voluntarily recalling all unused Medtronic Deep Brain Stimulation (DBS) lead kits listed in this letter.

Background:

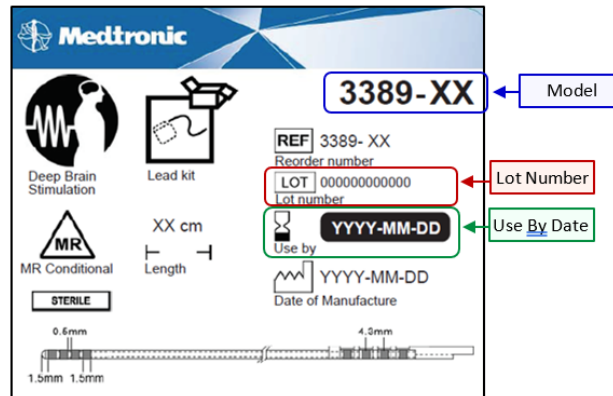
In March 2017, Medtronic notified physicians of safety information regarding the use of the depth stop accessory provided in all Medtronic Deep Brain Stimulation (DBS) lead kits (reference attached letter). Based on potential harm related to product shortage and since Medtronic neurostimulators and extensions are not compatible with non-Medtronic leads, it was recommended to continue using DBS lead kit inventory until replacement product became available.

Affected Product:

Now that sufficient inventory of replacement product is available, the following lead kits are being recalled:

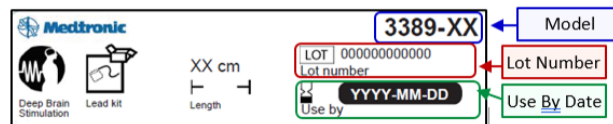
Non-Stimloc DBS Lead Kits in this recall

Model	Lot No.	Recall Note
3387-XX	All	All leads with a Use By Date of 2021-03-01 or earlier
3389-XX		
3391-XX		



Sample box top label for reference

Note: XX represents lead length (e.g. 28 or 40)



Sample box side label for reference

Actions:

- Work with your Medtronic representative to return any unused DBS lead kits listed in this letter. Your Medtronic representative can assist you with ordering replacement product.
- Please communicate to your Neurosurgery department that Medtronic has resolved the issue of the potential for the depth stop to inadequately secure DBS leads (reference attached March 2017 letter).

Medtronic

Please share this notification with others in your organisation as appropriate or to any organization where the affected products have been transferred.

The Competent Authority of your country has been notified of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative at ksa.ra@medtronic.com

Sincerely,

Medtronic Saudi Arabia

Enclosure:

FA761 March 2017 Neurosurgeon Physician Notification Letter