

Urgent Field Safety Notice
InterStim® Test Stimulation Lead Kit
Model 3065USC
Recall

22 February 2016

Medtronic reference: FA701

Dear Risk/Inventory Manager,

Medtronic is voluntarily initiating a recall for 6 lot numbers of the InterStim® Test Stimulation Lead Kit Model 3065USC that potentially have not been used to date. The Model 3065USC Kit is used with the Model 3625 Test Stimulator during trial screening InterStim® therapy. This action is being conducted due to the potential for a breach in the sterile barrier that may have been caused during transportation. The primary Peripheral Nerve Evaluation (PNE) lead and cable components have an additional sterile barrier separate from the tray. Sterility of additional kit components used during the PNE lead implant procedure however may be compromised in case of a breach. This recall is intended to mitigate the risk for infection as a result of a potential breach in the sterile barrier. Through 12 February 2016, Medtronic has not received any complaint reports related to this issue.

Your action is only required for Model 3065USC lot numbers identified below:

Lot Numbers

N478119	N478170	N478559
N478167	N478441	N478643

Action Required for Risk/Inventory Manager:

Included is a list of affected Model 3065USC product lot numbers.

- Immediately identify and quarantine all affected unused inventory.
- Your Medtronic representative will assist with the return process and ordering currently available trial screening product as needed.
- If any potentially affected devices have been transferred to others within your organization, please share this notification as appropriate.
- Note that no action is required from Healthcare Professionals. This product is used for temporary trial screening of patients and is not chronically implanted.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We appreciate your assistance with this matter and apologize for the disruption and inconvenience. Our field team is responsible for the removal of potentially affected units and we will strive to facilitate an efficient process. If you have questions, please contact your Medtronic Sales Representative directly or via Tel no 353 1 511 1400.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland