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URGENT FIELD SAFETY NOTICE
Medtronic Engager™ Transapical Delivery System
Recall

Lot Numbers:

0006894721	0006907013	0006924532	0006926124	0006926126	0006926136	0006949676
0006949678	0006949707	0006949713	0006964157	0006964163	0007006454	0007076535

Medtronic reference: FA618

May 2014

Dear Health Care Professional,

Medtronic is initiating a voluntary Urgent Medical Device Recall for specific lots of Engager™ Transapical (TA) Delivery Systems (ME-TA2-DS23, ME-TA2-DS26) due to distribution of potentially non-sterile product. This issue was identified during Medtronic routine sterilization testing and is limited to the 14 lots (see lot numbers above) of this product manufactured since the last successful sterility audit, i.e. 299 units manufactured from 1 October 2013 to 1 April 2014. **Medtronic has received no reports of patient injury or illness related to this issue.**

Medtronic analysis has determined that of the potentially affected 299 units that underwent the sterilization process, between zero and two potentially non-sterile units may have been distributed to customers.

Test results have identified the non-sterile micro-organism to be Deinococcus wulumuquiensis/xibeiensis, which are species within the Deinococcus genus. There is no known evidence of the micro-organism being pathogenic or causing a human infection.

While there is no known evidence of this micro-organism causing infection or endocarditis, Medtronic is not excluding this as a potential patient harm for immunocompromised patients who become exposed to a non-sterile Medtronic Engager Delivery System. If you have implanted a valve using a potentially affected delivery system, Medtronic recommends you continue to follow your routine protocol for follow-up and post-operative care.

Our records indicate that your facility has received potentially affected product. As a result, Medtronic is asking that you take the following actions:

1. Immediately identify and quarantine affected product in your inventory.

2. Return all affected product in your inventory to Medtronic. Your Medtronic representative will visit you to assist with this process and will also be able to assist with ordering replacement product as they become available.

Medtronic

Medtronic has taken action to prevent any additional distribution of potentially affected product, and it is important to note that Engager TA Delivery Systems are currently unavailable for purchase. Medtronic is taking action to restore full availability of sterilized Engager TA Delivery Systems.

Medtronic has notified the Medicines and Healthcare products Regulatory Agency (MHRA) of this action. Please share this notification with others in your organization as appropriate or with any organization where the potentially affected devices have been transferred. We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause.

Please contact your Medtronic representative for any questions you may have related to this product recall.

Yours sincerely,

L J Bridge

Lezlie Bridge BSc. DMS
Regulatory Affairs Manager – UK & Ireland