Medtronic

URGENT MEDICAL DEVICE RECALL
FIBERNET® Embolic Protection System
Model Numbers and Lot Numbers: See Below

March 3, 2014

Medtronic Reference # FA608

Dear Healthcare Professional (Hospital Administrator, OR Manager, and Risk Manager),

Medtronic has identified the potential for an issue with a specific subset of lot numbers of the FIBERNET® Embolic Protection System (EPS) where the yellow polyimide tube on the FIBERNET EPS was not removed from the FIBERNET EPS during the manufacturing process and subsequently may remain on the FIBERNET EPS. This recall is limited to (79) potentially affected units globally and is limited to the following model and lot numbers:

Model Number	Lot number
FBC350500190	1E029174
FBC500600190	1E029176
FBC600700190	1E029750
FBN350500190	1E012912
FBN500600190	1E012914
FBN600700190	1E012916 and 1E017817

Through February 26, 2014, Medtronic has received two reports from customers regarding this issue, with no reported patient injuries or adverse effects. In the two reports, the physician detected and removed the polyimide tube from the FIBERNET EPS and the device functioned normally. Medtronic is recommending all potentially affected units from the lots above be returned immediately to Medtronic.

Use of a FIBERNET EPS without removal of the polyimide tube may result in vessel damage and embolic event if the polyimide tube dislodges and remains in vivo. For affected product that has been used, no action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.

Our records show that your facility has received one or more of these FIBERNET EPS, as shown in the attachment to this notification. Consequently, Medtronic requests you immediately take the following actions:

1. Immediately remove and quarantine all potentially affected product that remains in your inventory.
2. Return these units to Medtronic. Your local Medtronic representative will assist you with this device return. If the product is hospital owned your Medtronic representative can assist you with receiving financial credit.

Medtronic has taken the necessary steps to prevent any future shipment of the potentially affected product. Regulatory agencies will be notified about this recall as applicable.

Please share this notification with others in your organization as appropriate. If any FIBERNET EPS within the scope of this recall have been forwarded to another facility, please notify that facility accordingly and facilitate the retrieval of the affected product.

Medtronic

We apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern. Should you have any questions, please contact your Medtronic representative /Al Haya Medical 9661 465 5075

Sincerely,

Hussein Hammoud
Business Manager, Middle East & North Africa
Medtronic Endovascular Therapies