Medtronic

URGENT FIELD SAFETY NOTICE

Medtronic Interventional Wires and Attain Hybrid® Guidewires
Model and Lot Numbers: See Attached List
Recall

October 21, 2013

Medtronic Reference: FA594

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 Medtronic Interventional Wires and ATTAIN HYBRID® Guidewires where the PTFE (polytetrafluoroethylene) coating could delaminate and detach from the Guidewire. As a result, we are recalling the Guidewires from specific lots as noted in the attached list. This issue affects a subset of the following Medtronic Guidewires manufactured from mid April 2013:

Cougar® NITINOL WORKHORSE GUIDEWIRE	COUGAR® Steerable Guidewire
Zinger® STAINLESS STEEL WORKHORSE GUIDEWIRE	ZINGER® Steerable Guidewire
Thunder®EXTRA-SUPPORT GUIDEWIRE	THUNDER® Steerable Guidewire
ProVia® CROSSING GUIDEWIRE	ATTAIN HYBRID® Guide Wire

Delamination and detachment of the PTFE coating may lead to embolic occlusion and thrombosis in coronary, cerebral, peripheral or pulmonary vasculature. Vascular thrombosis and/or occlusion have the potential to result in irreversible damage or injury to vital organs including myocardial infarction or stroke.

Through October 15, 2013, Medtronic has received a total of four (4) complaints related to this issue. Medtronic has received no reports of patient deaths as a result of this issue.

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 Guidewires, as shown in the attachment to this notification. Consequently, Medtronic requests you immediately take the following actions:
Consequently, Medtronic requests you immediately take the following actions:

1. Remove and quarantine all potentially affected Guidewires that remain in your inventory.
2. Return the potentially affected Guidewires to Medtronic. Your local Medtronic representative will assist you with this device return. If replacement product is needed, please contact your local Medtronic representative **Ameesa- +966 2 653 0306** who can assist you with identifying suitable replacement product.

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 Guidewires 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.

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.

Sincerely,

Amer Sidani
Business Manager Coronary & RDN – MENA