Medtronic Ireland Ltd
Block G
Cherrywood Science and Technology Park
Loughlinstown
Co Dublin
Tel. +353 1 5111400

Medtronic

Urgent Field Safety Notice

Integrity Rapid Exchange Coronary Stent System
Recall of specific model and lot numbers (see appendix A)

24 June 2016

Medtronic reference: FA717

Dear Risk Manager or Healthcare Professional:

Medtronic is issuing a Field Safety Notice for a subset of lots for the Integrity Coronary Bare Metal Stent (BMS) System sent to your facility as listed in Appendix A. Medtronic has determined that an external, third-party distributor may have modified the external product labeling to include inaccurate or incomplete information, including, but not limited to, incorrect compliance information. The internal pouch labeling for the product is not impacted.

As of 14-Jun-2016, Medtronic has received three (3) customer complaints related to this issue. There have also been no reports of patient injuries or adverse events related to this new issue.

Of the three (3) potential labeling issues identified with the BMS product, two (2) would have no end user or patient safety issues. Use of a BMS product with a modified label with correct product data or with a local language over-label covering device description information would not result in patient safety risk. Use of a BMS product with a 0,05mm discrepancy in compliance data can result in stent malposition, which, under a worst case scenario (e.g. small vessel), may lead to an occlusion. Use of a BMS product where there is a 1,0 mm discrepancy in the compliance data could result in dissection. Based on the data, the risk of occurrence of occlusion or dissection has been qualitatively estimated per Medtronic procedures as "rare number of occurrences is likely". Patients who have previously been treated with potentially impacted product should continue to be monitored in accordance with your facility's standard care protocols.

Medtronic's records indicate that your facility has received potentially impacted Integrity Coronary Stent System product. As a result, Medtronic is asking that you take the following actions:

- Identify and quarantine all unused product as listed in your inventory.
- Return all listed product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.

Medtronic has sufficient, unaffected product in inventory to meet customer needs and is taking necessary action to prevent future occurrences.

Please share this notification with others in your organization as appropriate, and contact your Medtronic Representative Directly or via Tel No.+353 1 5111 400 with any questions related to this Field Safety Notice.

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

We appreciate your cooperation and apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Keith Taverner Regulatory Affairs Manager UK & Ireland
Appendix A: Attached.