Medtronic International, Ltd.
Singapore Branch
49 Changi South Avenue 2
Singapore 486056
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FIELD SAFETY NOTICE

Resolute Integrity Zotarolimus-Eluting Coronary Stent System

Model Number	Lot Number
RSINT25008X	0007270644
RSINT25014X	0007274113
RSINT25018X	0007286314
RSINT27508X	0007266091
RSINT27518X	0007283516
RSINT27522X	0007284835
RSINT30009X	0007277322
RSINT30015X	0007281082
RSINT30022X	0007291706
RSINT30026X	0007274110
RSINT35012X	0007280076
RSINT35015X	0007288265
RSINT35018X	0007281131
RSINT35022X	0007279620
RSINT35026X	0007285080
RSINT40012X	0007269025
RSINT40015X	0007284838
RSINT40018X	0007269026
RSINT40022X	0007274108

May 2016

Dear Risk Manager or Healthcare Professional:

Medtronic is issuing a Field Safety Notice for a subset of lots for the Resolute Integrity Zotarolimus-Eluting Coronary Stent System sent to your facility as listed. Medtronic has determined that an external, third-party distributor may have modified the external product labeling such that the product labeled as Drug Eluting Stents (DES) may actually contain Bare Metal Stents (BMS). The internal pouch labeling for the product is not impacted. This notice is a follow-up communication to a previous, verbal notification provided to your facility in early May 2016.

As of 16-May-2016, Medtronic has received 2 customer complaints related to this issue. **There have also been no reports of patient injuries or adverse events related to this issue.**

Inadvertent use of a bare metal stent when a drug eluting stent is desired can result in a higher restenosis rate, which, under a worst case scenario (e.g. small vessel), may lead to an occlusion. Occlusion may require a re-intervention via Percutaneous Coronary Intervention (PCI) or Coronary Artery Bypass Graft (CABG). 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 Resolute Integrity Zotarolimus-Eluting Coronary Stent System product. As a result, Medtronic is asking that you take the following actions:

1. Per previous communications, ensure all identified, unused product in your inventory has been properly quarantined.

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2. Return all listed product in your inventory to Medtronic. Contact your local Medtronic Representative to initiate a product return and credit. 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. All applicable regulatory agencies have been notified of this issue, as required.

Please share this notification with others in your organization as appropriate, and contact your Medtronic Representative with any questions related to this Field Safety Notice. 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,

Christopher D. Harrold
Vice President, Quality
Medtronic Coronary & Structural Heart