Medtronic International Limited
- Malaysia Branch (993966-P)
F-39-7, CREST, 3 Two Square,
No. 2, Jalan 19/1, 46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: +60.3.7946.9000 Fax: +60.3.7958.2202

May 19, 2011.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
Level 5, No. 26, Boulevard Plot 3C4,
Precinct 3,
Federal Government Administration Centre,
62675 Putrajaya,
Malaysia

Dear Sir,

URGENT MEDICAL DEVICE RECALL NOTICE:
Medtronic CoreValve® Delivery System (DCS).

This letter is to inform you of an urgent field action being communicated to the healthcare professionals, requesting for the discontinuation of usage and return of the affected lots of the CoreValve® Delivery System (DCS). The CoreValve bioprosthesis is not affected in this field action.

The scope of this field action impacts on the local market and we have located the affected units, and we are in the process of communicating the necessary actions with relevant physicians.

Please find the attached copy of the physician communication letter that provides further insights into this field action.

Do consult us should you require additional information.

Yours Sincerely,

Debra Anne Anthony Peter
Regulatory Affairs Specialist
MEDTRONIC INTERNATIONAL, LTD.

Encl: Customer Communication Letter

Urgent Medical Device Recall Notice

Medtronic CoreValve® Delivery System (DCS)
Field Corrective Action #1201 Rev. 1.0

May XX, 2011

Dear Valued Customer:

Medtronic is informing customers in Germany that we have received reports of 6 (six) instances where the CoreValve® Delivery System (DCS) did not release during deployment. The reports pertain solely to limited manufacturing lots of the delivery system. The CoreValve bioprosthesis is not affected. We have received no reports of adverse patient events, and all patients involved in these reports were successfully implanted with a prosthetic valve when a second DCS was used.

Medtronic has conducted a thorough analysis on these cases and found that this represents low risk to patients. At the request of the German Competent Authority we are removing affected delivery system lots of this product from Germany.

The CoreValve DCS (model DCS-C3-18FR or DCS-C4-18FR) is one of the three parts of the Medtronic CoreValve® Revalving System that also includes a Percutaneous Aortic Valve bioprosthesis and a Compression Loading System. The DCS is used to deliver the Percutaneous Aortic Valve into the aortic annulus.

The root cause of these events has been attributed to a weakened bond between the capsule containing the valve and the delivery shaft. There is no potential for a component to separate from the device (the valve capsule remains connected to the DCS inner lumen). However, the weakened bond could result in the inability to unsheathe and deploy the valve from the capsule. In these instances the DCS has been removed from the patient, and a new DCS used to complete the procedure. There are no additional recommendations for patient care beyond standard practice. We have since improved our manufacturing process to strengthen the bond and have had no reports of events following this change.

Our records show that you have received one or more of the affected DCS units, as listed on the attached Customer Confirmation Form. We ask that you immediately discontinue use of the affected lots of the device and return all affected, unused product. Please complete the attached Customer Confirmation Form and fax it to the number provided.

Any unused, affected product should be returned to Medtronic as instructed on the Customer Confirmation Form. Credit will be issued upon receipt of the returned product. Replacement product is available. Your local Medtronic representative will assist you with this process.

If you need additional information, please contact your local Therapy Delivery Manager or sales representative. Thank you for your patience and your understanding.

Sincerely,