**Medtronic International Ltd.** - Malaysia Branch
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No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

February 27, 2010.

**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,**

**MEDICAL DEVICE RECALL: Epicardial Lead Models 5071, 4965, 4968 Sterile Tray.**

This letter is to inform you on the medical device recall being carried out by Medtronic on a subset of Epicardial Lead Models 5071, 4965, and 4968, due to packaging issue.

The scope of this recall does not cover products which have already been used. In Malaysia, only the model 5071 is affected, and the two unimplanted units have been retrieved.

The communication letters is as attached, to provide 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.

*Attachment:* Customer Communication Letter

## IMPORTANT MEDICAL DEVICE RECALL

February 2010

### Epicardial Lead Models 5071, 4965, and 4968 Sterile Tray

Medtronic has identified a packaging issue for a subset of Epicardial Lead Models 5071, 4965, and 4968. We have determined that specific package seals could be compromised. This is a packaging issue that is not related to the lead design.

Medtronic is not aware of any patient injury due to this packaging issue, and our evaluation indicates the risk of patient injury is remote. However, a compromised package seal could potentially affect product sterility. For products already used, no additional patient follow up is recommended. Patients should be managed in accordance with your standard patient management protocol.

Medtronic's records show that your facility has received potentially affected product. Medtronic requests that you immediately remove the affected leads from inventory per attached customer detail report. Call Medtronic Customer Service at <+603-79469000> for instructions on how to return the affected product to Medtronic for credit. Please contact your Medtronic representative if you would like their assistance in returning product or registering implanted leads.

Medtronic is communicating this information to FDA.

We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause.

Sincerely,

Tim Samsel