Medtronic International Limited
- Malaysia Branch (993966-P)
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Tel: +60.3.7946.9000 Fax: +60.3.7958.220

February 22, 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 PRODUCT SAFETY ADVISORY:
ALCOHOL PREP PADS MANUFACTURED BY TRIAD GROUP CO-PACKAGED WITH MEDTRONIC EXTERNAL NASAL SPLINTS

Recall of Triad Group Alcohol Prep Pad due to Potential Microbial Contamination in External Nasal Splint Kits (REF: 1528116 (small), 1528126 (medium), 528136 (large); All lots since Jan 2008) **or Thermasplint Kits**: (REF: 1529100 (small), 1529110 (medium) and 1529120 (large); All lots since Jan 2008)

This letter is to inform you of a product safety advisory which is being communicated to the healthcare professionals. The scope of this field action impacts on the local market and we have located all the units and are notifying the relevant customers on this field action.

Please find the attached copy of the communication letter 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.

Encl: Customer Communication Letter

Medtronic

URGENT
Product Safety Advisory

January 31, 2011

Subject: **URGENT PRODUCT SAFETY ADVISORY –**
ALCOHOL PREP PADS MANUFACTURED BY TRIAD GROUP CO-PACKAGED WITH MEDTRONIC EXTERNAL NASAL SPLINTS

Dear Healthcare Professional:

Recall of Triad Group Alcohol Prep Pad due to Potential Microbial Contamination in External Nasal Splint Kits REF: 1528116 (small), 1528126 (medium), 1528136 (large); **or Thermasplint Kits**: REF: 1529100 (small), 1529110 (medium) and 1529120 (large);

All lots received since Jan 2008

Issue Description:

Medtronic Xomed Inc. has been informed by our supplier, Cardinal Health, of a voluntary recall involving all lots of alcohol prep pads manufactured by the Triad Group and marketed under the Cardinal Health brand name. The Cardinal Health alcohol prep pads are co-packaged with Medtronic Xomed Inc External Nasal Splints and Thermasplints.

This recall has been initiated due to concerns from a Triad Group customer about potential contamination of the products with an objectionable organism, namely *Bacillus cereus*. This recall involves those Medtronic nasal splint products marked as non-sterile. As indicated on the FDA website in regard to this recall: "Use of contaminated alcohol prep pads could lead to life-threatening infections, especially in at-risk populations, including immune suppressed and surgical patients."

Medtronic recommends that you **immediately discontinue using the co-packaged alcohol prep pads.** The prep pads should be disposed of in the trash. When administering the external nasal splint products, healthcare providers should use an alternative alcohol prep product that is not involved with this recall or alternatively use a sterile gauze pad in conjunction with isopropyl alcohol from the splint site prior to administration.

It is important to note that (with the exception of the alcohol prep pads) the packaged **Medtronic products and components are not contaminated and may continue to be used** in accordance with the package insert.

Medtronic

Action Requested:
Check your inventories for the affected products:

- Immediately discontinue use of the alcohol prep pads packaged with these devices and dispose of all affected alcohol prep pads identified in this notification in the trash.

Medtronic Xomed regrets any inconvenience this matter may cause; however, we want to make sure that the products we provide you are of the highest quality and reliability. We therefore ask for your cooperation in helping us to comply with this safety advisory. **If you are a distributor or have provided further distribution of this item, please forward this letter or a similar communication to the appropriate recipient.** Please do not hesitate to contact me at 904-279-7532 if you have any questions regarding the subject action or the content of this letter.

Sincerely,

David M. Timlin
Director, Regulatory Affairs