Medical Devices Bureau, Ministry of Health Malaysia
Level 5, Block E6, Complex E,
Federal Government Administration Centre,
62590 Putrajaya, MALAYSIA.
Tel: 03-8883 2248/2249/2264
Fax: 03-8888 6184

Medical Device / Equipment RECALL

Date Issued : 15 May 2008 **Ref:MDB/R/2008/007**

IMMEDIATE ACTION	√
ACTION	
UPDATE	
INFORMATION REQUEST	

PRODUCT	**Carmeda Coatings Applied to Selected Cardiopulmonary Bypass Products manufactured by Medtronics.**
CLASS	n/a
USE	Disposable products used dusring cardiopulmonary bypass (CPB) for heart surgeries. Product varies from blood oxygenators, reservoirs, pumps, cannulae and tubing packs.
SOURCE OF MEDICAL DEVICE RECALL / ALERT	Medtronic International Limited – Malaysia Branch
ALERTING / RECALLING FIRM	Medtronic International Limited
REASON	**Contaminated Heparin Used in Carmeda Coatings Applied to Selected Cardiopulmonary Bypass Products.** Medtronic is initiating a voluntary and precautionary recall of selected products featuring the Carmeda Bioactive surface. **Please Refer to the attachment for details.*
SCENARIO IN MALAYSIA	**Medtronic Malaysia confirmed that this action does not have any impact on Malaysia market.** For extra precautions, please check whether the device is

	available and contact the distributor.
ACTION	***Action or Recommendations For Healthcare Professionals*** • Ensure that all relevant staff in your institution are informed of this recall • Determine if you have the above products as mentioned. • Locate and cease using product from the mentioned lot numbers. • Determine how much of this product has been used • Follow the distributor / manufacturers recommendations for quarantine and disposal of affected products.
RECOMMENDATION	Users of the abovementioned device should contact the distributors/supplier of this device (if available) and **inform the Medical Devices Bureau, Ministry of Health** providing the following information:- a. Name of healthcare centre/hospital/clinic b. Contact person and contact number c. Numbers of units available
CONTACT/ENQUIRIES IN MALAYSIA	**Medtronic International Limited-Malaysia Branch** F-39-7 CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya Selangor Darul Ehsan. Tel:- 03-79534800 Fax:- 03- 79582202
REFERENCES	NOT AVAILABLE

Medtronic International Ltd. - Malaysia Branch
(993966-P)
F-39-7, CREST,
3 Two Square,
No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

To:

DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
ENGINEERING SERVICES DIVISION,
Level 2-5, Block E6, Parcel E, Precint 1,
Federal Government Administration Centre,
62590 Putrajaya,
Malaysia.

May 12, 2008.

Dear Sir,

Voluntary Recall: Contaminated Heparin Used in Carmeda® Coatings Applied to Selected Cardiopulmonary Bypass Products.

Medtronic is initiating a voluntary and precautionary recall of selected products featuring the Carmeda BioActive surface. The affected devices are disposable products used during cardiopulmonary bypass (CPB) for heart surgeries. Affected products include blood oxygenators, reservoirs, pumps, cannulae, and tubing packs.

Please be informed that this field action does not have any impact on Malaysia, as the affected serial numbers were not distributed locally. This has been confirmed by checking the affected serial number lots against the ones sold in Malaysia.

The physician communication letter is attached herewith, to provide further insights into this voluntary field action.

Do consult us should you require additional information.

Thank you and kind regards.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Copy: Bay Song Chua, COUNTRY MANAGER.

Physician and/or Health Care Provider Communication for OUS

Urgent Medical Device Recall

Contaminated Heparin Used in Carmeda® Coatings Applied to Selected Cardiopulmonary Bypass Products

This letter is to advise you that Medtronic is recalling selected ***Carmeda***®[1]-coated cardiopulmonary bypass (CPB) products (e.g., oxygenators, reservoirs, pumps, cannulae and tubing packs) that were manufactured with contaminated heparin. Medtronic's heparin supplier recently reported that it had provided some batches of heparin to Medtronic that were contaminated with oversulfated chondroitin sulfate (OSCS). Affected CPB products have been distributed since January 24, 2008. Our records show that you have received one or more of these products (see attached product list). We ask that you remove these products from your inventories and place them in quarantine to prevent inadvertent use. Your sales representative will contact you to arrange product return and replacement.

Background

The FDA has recently received numerous adverse event reports potentially caused by contaminated heparin (http://www.fda.gov/cder/drug/infopage/heparin/default.htm) including acute hypotension, allergic response type symptoms and death. On April 8, 2008, FDA issued an important notice to manufacturers of medical devices urging that they re-evaluate their heparin supplies using FDA-recommended test methods.

FDA scientists and independent researchers recently reported a potential biologic mechanism underlying the adverse events associated with OSCS exposure.[2] This work, published in the New England Journal of Medicine, presented in vitro experimentation data in which no biologic response was activated below 0.025 micrograms of OSCS per milliliter of plasma.[2] The applicability of these test results to OSCS exposure in heparin coatings, such as our Carmeda®-coated products, has not been proved. As a precautionary measure, Medtronic has voluntarily decided to recall affected Carmeda® coated products because we were not able to conclusively establish that OSCS exposures resulting from the use of affected products will reliably fall below this threshold.

This investigation is dynamic and ongoing at FDA and within Medtronic. To date, we have not received any complaints related to the presence of OSCS in these affected Carmeda®-coated lots.

Medtronic Trillium® coated CPB products also contain heparin. A separate Medical Device Corrective Action provides information pertaining to Medtronic's Trillium®-coated products.

A listing of affected product lots can be found at www.medtronic.com/heparin. If you have any further questions concerning the execution of this field action, please contact your **Medtronic Sales Representative or CardioVascular Lifeline Technical Support at (800) 638-0218.**

We understand that you depend on us to provide a reliable supply of the highest quality medical devices. We take the trust you place in us very seriously and seek to minimize impact to you and your patients. We apologize for the inconvenience caused by this recall field action.

Sincerely,

Robert W. Perry
Vice President & General Manager
Medtronic CardioVascular
Revascularization & Surgical Therapies

[1]Manufactured under license from Carmeda AB, Sweden

2 Kishimoto TK, Viswanathan K, Ganguly T, et al.Contaminated Heparin Associated with Adverse Clinical Events and Activation of the Contact System. N Engl J Med 2008;358 http://content.nejm.org/cgi/content/full/NEJMoa0803200