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

Medical Device / Equipment RECALL- Field Corrective action

Date Issued : 2 JULY 2008 **Ref:MDB/R/2008/009**

IMMEDIATE ACTION	√
ACTION	
UPDATE	√
INFORMATION REQUEST	

PRODUCT	**SYNCHROMED II IMPLANTABLE INFUSION PUMP – MODELS 8637-20, 8637-40**
CLASS	Not Mentioned
USE	Implantable Infusion Pump
SOURCE OF MEDICAL DEVICE RECALL / ALERT	**Medtronic International Limited – Malaysia Branch**
RECALLING / ALERTING FIRM	Medtronic International Limited
REASON FOR RECALL/ALERT	Small number of SynchroMed II pumps may have been manufactured without propellant, according to reports (***see attachment for details***), eight SynchroMed II pump have been returned to Medtronic and confirmed that the returned device do have a missing propellant. Infusion pumps without a propellant cannot be fully aspirated since a propellant is vital to provide positive pressure to the resevoir from which drug is dispensed. An implanted pump without propellant can initially infuse, and stop infusing without warning or alarm.
SCENARIO IN MALAYSIA	According to Medtronic International Ltd – Malaysia Branch, there was only 1 unit of the affected pump detected locally, and this affected unit has been successfully removed from the customer. (***Please refer attachment for clarification***)

ACTION	***Please Refer to the Device Correction Notification attached.**
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	**Debra Anne Anthony Peter,** **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 FOR DETAILS	***-Please refer attachment-***

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 28, 2008.

Dear Sir,

FCA ON SYNCHROMED® II IMPLANTABLE INFUSION PUMP - MODELS 8637-20, 8637-40.

Medtronic is voluntarily recalling potentially affected SynchroMed® II pumps that have been manufactured without propellant, that **have not** been implanted. Do take not that only one unit of the affected pump was sold locally and this affected **non-implanted** unit has been successfully removed from the customer.

Please find the customer communication letter as attached for detailed explanation on this field corrective action and 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.

Medtronic
When Life Depends on Medical Technology

May 2008

Urgent: Medical Device Recall
SynchroMed® II Implantable Infusion Pump - Models 8637-20, 8637-40

SynchroMed® II Missing Propellant - Physician Letter

Dear Healthcare Professional,

This letter provides important safety information and patient management recommendations related to a small number of SynchroMed II pumps that may have been manufactured without propellant. Medtronic is notifying all physicians who have implanted or are managing a patient with a pump that falls within the parameters of the suspect population.

Medtronic is recalling potentially affected pumps that **have not** been implanted; however, the term "recall" **does not** necessitate the removal of all potentially affected devices that **have** been implanted. Identification and management of implanted pumps affected by the missing propellant condition is described below.

Nature of the device issue:
To date, eight SynchroMed II pumps have been returned to Medtronic and confirmed to be missing propellant. The pump propellant provides positive pressure to the reservoir from which drug is dispensed. Pumps without propellant cannot be fully aspirated. Due to this, the full volume of drug cannot be loaded into the device, and the drug will be diluted by the remaining sterile water that is contained in the reservoir of all new pumps. Additionally, an implanted pump without propellant can initially infuse, and then stop infusing without warning or alarm.

The missing propellant condition can cause drug dilution in the pump reservoir, leading to unknown drug concentration, and inconsistent or variable therapy results.

The clinical manifestations of a pump that is missing propellant may include:

- Inconsistent or variable therapy results
- A clinically significant drug underdose
- A return of underlying symptoms and/or withdrawal symptoms
- Lack of therapeutic effect
- A clinically significant drug overdose

Note: for a detailed description of the effect of the missing propellant condition on device functionality, along with underdose and overdose scenarios, refer to the enclosed "*Effects of Missing Propellant on the SynchroMed Pump*" enclosure.

For underdose and overdose signs and symptoms, please refer to the drug labeling.

Potential severity of the issue:
No death or permanent patient injury has been reported due to this issue. The patient symptoms reported due to this issue are a return of underlying symptoms and/or withdrawal symptoms. Patients receiving intrathecal baclofen therapy (e.g. Lioresal® Intrathecal) are at higher risk for adverse events as baclofen withdrawal can lead to a life threatening condition if not treated promptly and effectively[1].

[1] For complete product information refer to the Lioresal® Intrathecal (baclofen injection) Package Insert, Copyright Medtronic Inc. 2002 http://www.medtronic.com/physician/itb/disclosure-package-insert.html

SynchroMed II Missing Propellant - Physician Letter

Scope and likelihood of the issue:
Medtronic has identified the suspect population as all pumps manufactured prior to the manufacturing process change that was implemented in April 2007 to correct the issue. To date, eight (8) SynchroMed II pumps from the suspect population have been returned to Medtronic and confirmed to be missing propellant. Based on conservative estimates from occurrence modeling, Medtronic estimates that fewer than 21 (0.16%) out of 12,976 devices distributed from the suspect population may be affected by the missing propellant condition.

The enclosed list of pump serial numbers and patient names identifies your patients who, according to our records, are currently implanted with a pump from the suspect population.

The inclusion of a pump in the suspect population does not mean that the pump was manufactured without propellant. Pumps manufactured with propellant ***do not*** lose their propellant over time and are expected to function normally.

How to Identify Pumps Without Propellant:
Pumps without propellant can be identified prior to or after implant. This can be accomplished prior to implant through careful adherence to pre-implant pump preparation instructions as set forth in the labeling, along with awareness of the expected aspiration and fill volumes for each pump. Prior to or after implant, pumps without propellant will present with an inability to fully aspirate the reservoir contents along with an inability to fill the pump to capacity. Please refer to the enclosed "*How to Identify Pumps Without Propellant*" document for details regarding the identification process.

If you ***are*** able to aspirate all expected fluid from the reservoir, and ***can*** fill the reservoir to the labeled capacity of the pump model (i.e., 20 ml or 40 ml), your pump **is not** affected by the missing propellant condition.

Patient Management Recommendations:
As with any surgical procedure, there are risks associated with pump replacement; therefore, before deciding to replace a pump without propellant, physicians should carefully consider the relative risks and discuss them with their patients.

- **Recommendation #1:** Discuss this important information with your patients and their caregivers, reminding them that a pump without propellant can stop infusing without warning, and that the patient may not become aware of the issue until he/she experiences return of underlying symptoms, and/or symptoms of drug withdrawal.

- **Recommendation #2:** Continue to educate patients and caregivers about the signs and symptoms of drug underdose, overdose, and withdrawal. Instruct patients to seek immediate medical assistance in the event that signs or symptoms of drug underdose, overdose, or withdrawal appear.

- **Recommendation #3:** If a pump is identified as lacking propellant, Medtronic recommends the healthcare professional consider immediate pump replacement because proper drug delivery cannot be ensured, and because patient injury may result from drug dilution, underdose, overdose, or abrupt delivery cessation. Refer to the enclosed reimbursement information for details on device warranty and medical expenses.

Medtronic
When Life Depends on Medical Technology

April 2008

SynchroMed II Missing Propellant - Physician Letter

Additional Resources:
For additional information and/or updates, please contact your Medtronic field representative, or contact Medtronic Neuromodulation Technical Services at 1-800-707-0933. This important patient management information is also available on Medtronic's physician web portal: www.medtronicconnect.com, under the heading "Advisories – Implantable Infusion Systems".

Enclosed is a listing of all SynchroMed II pumps within the suspect population for the missing propellant issue. Additionally, the following website can be used to identify (based on pump serial number) whether a specific SynchroMed II pump is potentially affected by the Missing Propellant condition: http://synchromed2propellant.medtronic.com.

Please return any explanted SynchroMed II pump to Medtronic Returned Products Analysis. Contact your Medtronic field representative or Medtronic Neuromodulation Technical Services at 1-800-707-0933 to facilitate the device return procedure.

The US Food and Drug Administration (FDA) has been made aware of this SynchroMed II recall. Please report any malfunction or adverse event related to a device to:

Medtronic Neuromodulation Technical Services: 1-800-707-0933
And
FDA's MedWatch Program:

- Phone: 1-800-FDA-1088,
- Fax: 1-800-FDA-0178,
- Mail: MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787
- Internet: www.fda.gov/medwatch.

Patient safety is Medtronic's highest priority. We are committed to answering your questions and keeping you informed. We appreciate your assistance with this matter and regret any inconvenience this may have caused you or your patients.

Enclosures: Effects of Missing Propellant on the SynchroMed Pump
How to Identify Pumps Without Propellant
Reimbursement Information
Device Serial Numbers Affected By Recall
Physician Patient Detail Report(s)

Sincerely,

George Aram
Vice President Quality
Medtronic Neuromodulation