IRISH MEDICINES BOARD
SAFETY NOTICE

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SynchroMed® II and SynchroMed EL Implantable Drug Pumps

IMB Safety Notice: SN2013(07)
Circulation Date: 11 July 2013

MANUFACTURER/SUPPLIER
Medtronic Limited

TARGET GROUPS
Medical directors
Anaesthetists
Neurologists
Neurosurgeons
Pain Consultants
Spinal Surgeons
Chronic Pain teams
Theatre teams
Risk managers
Emergency Medicine Departments

ISSUE
Four communications to help identify and manage issues that may impact the safe delivery of therapy using the SynchroMed® II and SynchroMed EL Implantable Drug Pumps.

BACKGROUND
Medtronic has recently issued four Field Safety Notices (FSN) related to the SynchroMed II and SynchroMed EL implantable drug pumps and accessories:

The first FSN (FA573) relates to the priming bolus function. Medtronic has identified that when the priming bolus is used, unintentional mixing of drug and non-drug fluids (including cerebrospinal fluid and sterile water) can occur which can pose a risk of overdose or underdose. Detailed advice on the management of patients during pump priming is provided in appendix 1.

The second FSN (FA574) relates to a potential electrical short circuit issue that can occur. This issue can result in a motor stall or low battery reset / alarm which in turn may result in an underdose of medication. Underdose of drug can lead to loss of/or reduction in therapy which may cause underlying symptoms and/or withdrawal symptoms. This can create a life-threatening condition for patients receiving intrathecal baclofen therapy. Detailed advice on the management of patients is provided in appendix 2.

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The third FSN (FA578) advises clinicians of an update to the product labelling. Important reminders are provided concerning the potential for a pocket fill during a SynchroMed implantable drug pump refill procedure. Detailed advice is provided in appendix 3.

The fourth FSN (FA579) confirms the recall of certain 'Sutureless Connector Intrathecal Catheter Products' which may exhibit a greater potential for misalignment and subsequent occlusion at the catheter to pump interface. Details of the recall and how to identify devices are outlined in appendix 4.

ACTION OR RECOMMENDATIONS

The IMB recommends that:

1. Relevant personnel in your organisation are made aware of these potential issues.
2. The device and patient management advice outlined in the Medtronic Communications is followed.
3. Unused sutureless connector catheters with a used by date prior to 25th August 2014 should be returned to Medtronic.
4. This IMB Safety Notice and the attached Field Safety Notices are passed on to any organisation or end user where the potentially affected devices have been transferred.

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: vigilance@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Medtronic Ireland Ltd,
Unit G
Swords Business Campus
Balheary Road
Swords
Co. Dublin

Telephone: 01 511 1400
Fax: 01 807 7220
Contact person: Lezlie Bridge
E-mail: lezlie.j.bridge@medtronic.com