NSW HEALTH

Safety Alert 003/07

12 September 2007

Distributed to:

- Chief Executives

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Drug and Therapeutic Committees
- Area Directors of Nursing
- Area Directors of Pharmacy
- Clinicians involved in pain management
- Medical staff
- Nurses
- Pharmacists

Deadline for completion of action

28 September 2007

(provide summary of strategy)

Quality and Safety Branch
NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email
quality@doh.health.nsw.gov.au

www.health.nsw.gov.au/quality/sabs/register.html

Medtronic SynchroMed® EL Implantable Pump

Neurological drug delivery pumps

Purpose

The purpose of this Safety Alert is to provide important information of a potential motor stall that affects Medtronic SynchroMed® EL Implantable pumps.

The SynchroMed® EL Implantable pump does not provide an alarm to alert a patient or a clinician to a stalled motor condition.

These pumps are used for:

- Intrathecal pain management
- Hepatic intra-arterial chemotherapy
- Intrathecal baclofen therapy for spinal patients.

The pump motor stall is due to gear shaft wear. If a pump motor stall occurs, drug delivery will stop abruptly and without warning resulting in loss of therapy, return of underlying symptoms, and/or symptoms of drug infusion or withdrawal. Drug withdrawal from intrathecal baclofen therapy can be fatal if not treated promptly and effectively.

Affected Pumps

As at 15 June 2007, Medtronic has received 354 clinicians inquiries/complaints worldwide that have been confirmed, through returned product analysis, to be due to gear shaft wear with the SynchroMed® EL Implantable pumps. Medtronic has advised that 220 of these events are associated with motors manufactured prior to September 1999 and 134 of these events with motors manufactured from September 1999.

In late 1999 changes were made in manufacturing that significantly reduced the incidence of gear shaft wear in the SynchroMed® EL Implantable pumps. Cumulative failure rates (in relation to intrathecal baclofen therapy) were

- Pre September 1999 – 2.2% at seven years
- From September 1999 – 0.5% at seven years

Regardless of the year of manufacture the failure mode is random and hence it is not possible to predict which device may fail.

This specific gear shaft wear issue does not affect the SynchroMed II pump as it has a different motor design.

Action required by Area Health Services

1. AHS are required to provide a summary of their strategy to address this issue
2. AHS are required to recall all affected patients and to replace all SynchroMed® EL Implantable pumps (Model 8626/8627) on a triaged basis.

Category 1 – Intrathecal baclofen administration

Category 2 – Pumps with motors manufactured prior to September 1999

Category 3 – Pumps with motors manufactured on or after September 1999

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Actions to date

- Medtronic has provided the Therapeutic Goods Administration (TGA) with a list of pump recipients
- Medtronic has contacted all specialists known to have implanted the pump requesting a signed acknowledgment
- TGA has issued a Hazard Alert (Reference: RN-2007-0543, dated 2 August 2007) relating to the performance of the SynchroMed® EL Implantable pumps
- TGA advised the NSW Department of Health, on 3 September 2007, that the TGA Hazard Alert now meets the definition of a Class I i.e. defect is potentially life threatening or could cause serious risk to health.