Medical Device Alert

Ref: MDA/2013/042 Issued: 19 June 2013 at 15:00

Device

Implantable drug pumps and accessories:

SynchroMed II and SynchroMed EL (all models)

Sutureless connector intrathecal catheter products (models 8709SC, 8731SC, 8596SC, 8578)

Manufactured by Medtronic.

Problem

Risk of drug under- or overdose due to various issues with these drug pumps.

Action

- Be aware that Medtronic has recently issued four Field Safety Notices concerning these products. The MHRA has summarised and prioritised the required actions below.
- Ensure you follow this advice on device and patient management and, also, the return of sutureless catheter connectors to Medtronic.

Action by

All staff who manage patients implanted with drug pumps.

CAS deadlines

Action underway: 03 July 2013

Action complete: 17 July 2013

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Contact

Manufacturer
Lezlie Bridge
Medtronic Ltd
Tel: 07740 899 216
Email: vigilance.eu@medtronic.com

Problem

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

1. The first FSN (Manufacturer reference: FA573) confirms a serious risk associated with the priming bolus function. Unintentional mixing of drug and non-drug fluids (including cerebrospinal fluid and sterile water) during the priming bolus can pose a risk of overdose. A subsequent risk of underdose exists following administration of the priming bolus. Detailed advice on the management of patients during pump priming is provided in FA573.

2. The second FSN (FA574) confirms a risk of an electrical short circuit occurring in the feed-through, which provides an electrically insulated path for current to flow from the electronic circuitry to the motor. This issue typically presents itself as a motor stall or low battery reset / alarm and may result in an underdose. Underdose of drug can lead to return of underlying symptoms and / or withdrawal syndrome, a life-threatening condition for patients receiving intrathecal baclofen therapy. Detailed advice on setting / interpreting alarms and reading alarm event logs is provided in FA574.

3. The third FSN (FA578) has been issued to notify clinicians that the product labelling has been updated to include the advice on pocket fills, which was originally given in an earlier FSN (FA496).

4. The fourth FSN (FA579) confirms the recall of certain connectors manufactured before a recent design improvement. These 'Sutureless Connector Intrathecal Catheter connectors' may exhibit a greater potential for misalignment and subsequent occlusion, which can lead to an underdose. Full details of how to identify devices for return are provided in FA579.

Note: An earlier FSN (FA535, issued in March 2012) relating to erroneous end of service messages, which can result in a drug underdose, also remains relevant as the manufacturer's software solution has not yet been implemented

All these FSNs are available on the MHRA website.

Action

SynchroMed II and EL:

- Prime all new pumps prior to implant in the patient or connection to the catheter to reduce the risk of overdose.
- Monitor all patients closely after initiation of therapy for up to 24 hours, dependent on specific drug guidelines (see FSN FA573).
- Avoid the use of concomitant drugs during therapy initiation that may cause respiratory or CNS depression.
- Consider providing an oral baclofen supplement to patients receiving intrathecal baclofen, until the optimal intrathecal dose is obtained.
- Reinforce with patients and caregivers information on the various pump alarms (see FSN FA574) and on the signs and symptoms of withdrawal due to therapy cessation.
- Continue to monitor patients for the return of baseline symptoms for the life of the implant as this could indicate pump failure due to an electrical short.
- Continue to follow advice on the management of device erroneous end of service messages contained within the earlier FSN (see FSN FA535) until a software upgrade has been installed.

Sutureless catheter products (used with the SynchroMed pump)**:**
Return all sutureless connector intrathecal catheter products that have a use by date preceding 25 August 2014 (see FSN FA579).

Distribution

This MDA has been sent to:

- Care Quality Commission (CQC) (headquarters) for information
- Clinical commissioning groups (CCGs)
- HSC trusts in Northern Ireland (chief executives)
- NHS boards and trusts in Wales (chief executives)
- NHS boards in Scotland (equipment co-ordinators)
- NHS England area teams (for information)
- NHS trusts in England (chief executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment.
Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Chronic pain teams
- Clinical governance leads
- Medical directors
- Neurologists
- Neurosurgeons
- Pain consultants
- Spinal surgeons
- Theatres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

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Email: vigilance.eu@medtronic.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/042** or **2013/005/031/081/018**

Technical aspects
Michelle Kelly or Simon Holmes
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7145 or 7240
Fax: 020 8754 3965

Email: michelle.kelly@mhra.gsi.gov.uk
simon.holmes@mhra.gsi.gov.uk

For clinical aspects please contact the Clinical Team
Medicines & Healthcare Products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7032
Fax: 020 8754 3965

Email: kayleigh.purdon@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk
Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk