

MEDICAL DEVICE ALERT

Issued: **09 June 2008** at 11:30

Ref: **MDA/2008/038**

<input type="checkbox"/>	Immediate action
<input checked="" type="checkbox"/>	Action
<input type="checkbox"/>	Update
<input type="checkbox"/>	Information request

Device: Implantable drug pumps for intrathecal therapy. All manufacturers.	
Problem: Risk of temporary or permanent neurological impairment due to inflammatory or granulomatous mass formation at the catheter tip.	▶ Page 2
Action by: All healthcare professionals who are involved in the implantation and/or management of patients with implantable intrathecal drug pumps in hospitals and refill clinics.	
Action: <ul style="list-style-type: none"> • Consider inflammatory mass or granuloma formation in the intrathecal space as a possible cause of any new neurological symptoms or loss of analgesic effect in patients receiving intrathecal drug therapy. • Consider prompt diagnostic imaging to confirm the diagnosis of an inflammatory or granulomatous mass in these patients who would then need early neurosurgical referral. • Ensure patient dose remains at minimum level to be clinically effective. • Consider reducing concentration of intrathecal opioids as far as possible. • Follow the patient management and system troubleshooting guidelines given by the pump manufacturer. • Report any incidents involving mass formation to the relevant drug pump manufacturer and the MHRA. 	
Distributed to: NHS trusts in England Healthcare Commission (CHAI) Primary care trusts in England NHS Boards in Scotland	– Chief Executives* – Headquarters – Chief Executives* – Chief Executives * via CE Bulletin
Contacts: Details of MHRA contacts for technical and clinical aspects. Change of address or removal from address list for Healthcare Commission.	▶ Page 3

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 07 July 2008

Deadline (action complete): 09 September 2008

This notice is also on our website: <http://www.mhra.gov.uk>

Problem:

The MHRA is aware of the potential for inflammatory or granulomatous mass formation at or near the distal tip of intrathecal catheters from implantable drug pumps. One study has found the incidence of inflammatory mass to be 3%¹. This is higher than typically cited in the literature.

Although the risk appears to be mainly associated with opioid therapy¹, it has also been reported with other infusions, such as baclofen^{2,3}. The risk of inflammatory mass formation may increase with implantation time and higher concentration of opioids¹. The risk of an individual patient developing an inflammatory mass cannot be predicted. In some patients detailed review may be needed to identify relevant symptoms.

The most frequently observed symptoms associated with this problem are:

- decreased therapeutic response
- pain (either new onset or loss of analgesic effect)
- neurological deficit/dysfunction.

Inflammatory mass formation may result in permanent neurological impairment.

Measures to manage this complication include:

- decreasing or discontinuing drug infusion into the intrathecal space (following the pump manufacturer's recommendations) in order to reduce the size of the mass*
- withdrawal or repositioning of the catheter
- surgical intervention to remove the mass.

Medtronic has already issued advice on this subject in connection with its products⁴. However, it should be noted that this is a known complication associated with the use of intrathecal drugs in general.

* Be aware that serious side effects, including death, can occur on abrupt withdrawal of or decrease in the use of baclofen.

1. Deer, TR. A prospective analysis of intrathecal granuloma in chronic pain patients: a review of the literature and report of a surveillance study. *Pain Physician*. 2004; 7:225-228.
2. Murphy, PM *et al*. Intrathecal catheter granuloma associated with isolated baclofen infusion. *Anesthesia and Analgesia*. 2006; 102:848-852.
3. Deer, TR *et al*. Inflammatory mass of an intrathecal catheter in patients receiving baclofen as a sole agent: a report of two cases and a review of the identification and treatment of the complication. *Pain Medicine*. 2007; 8:259-262.
4. Medtronic Field Safety Notice January 2008
www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON2033876

Distribution:

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- Anaesthetists
- Chief pharmacists
- Clinical governance leads
- Medical directors
- Medical oncologists
- MRI units, directors of
- Neurologists
- Neurosurgeons
- Nurse specialists in multiple sclerosis
- Nursing executive directors
- Oncology nurse specialists
- Paediatric medicine, directors of
- Paediatric nurse specialists
- Paediatric oncologists
- Pain clinics
- Palliative care teams
- Radiographer superintendents
- Radiologists
- Risk managers
- Spinal units

Healthcare Commission (CHAI) to:

Headquarters for onward distribution to:

- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Primary care trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Palliative care team
- Pharmaceutical advisors

Contacts:

Contact your supplier or the manufacturer.

Enquiries to the MHRA should quote reference number **2008/001/023/291/017** and be addressed to:

Technical aspects:

Miss Feza Haque or Miss Katy Hopkins
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3066 / 3176

Fax: 020 7084 3106

E-mail: feza.haque@mhra.gsi.gov.uk
katy.hopkins@mhra.gsi.gov.uk

Clinical aspects:

Dr Christopher Brittain
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3126

Fax: 020 7084 3103

E-mail: christopher.brittain@mhra.gsi.gov.uk

Enquiries for Scotland should be directed to:

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

Tel: 0131 275 7575

Fax: 0131 314 0722

E-mail: iric@shs.csa.scot.nhs.uk

Change of address or removal from address list for Healthcare Commission:

Healthcare Commission
Finsbury Tower
103-105 Bunhill Row
London
EC1Y 8TG

Tel: 020 7448 0842

E-mail: contacts@healthcarecommission.org.uk

How to report adverse incidents

Incidents relating to medical devices must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) as soon as possible.

Further information about reporting incidents; on-line incident reporting facilities; and downloadable report forms are available from MHRA's website (<http://www.mhra.gov.uk>).

Alternatively, further information and printed incident report forms are available from:

MHRA Adverse Incident Centre

Medicines and Healthcare products Regulatory Agency

Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Telephone 020 7084 3080 or Fax 020 7084 3109

or e-mail: aic@mhra.gsi.gov.uk

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the MHRA website: <http://www.mhra.gov.uk>

Further information about **SABS** can be found at www.info.doh.gov.uk/sar2/cmopatie.nsf

MHRA is an executive agency of the Department of Health

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