

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2008/042

Issued: 9th June 2008

For:

IMMEDIATE ACTION	
<b>ACTION</b>	✓
UPDATE	
INFORMATION	



**HEALTH ESTATES**

creating healing environments

	Section				
<p><b>Medical Device/Equipment:</b> Implantable drug pumps for intrathecal therapy. All manufacturers.</p>	▶ ①				
<p><b>Problem:</b> Risk of temporary or permanent neurological impairment due to inflammatory or granulomatous mass formation at the catheter tip.</p>	▶ ②				
<p><b>Action by:</b> All healthcare professionals who are involved in the implantation and/or management of patients with implantable intrathecal drug pumps in hospitals and refill clinics.</p>	▶ ③				
<p><b>Action:</b></p> <ul style="list-style-type: none"> <li>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.</li> <li>Consider prompt diagnostic imaging to confirm the diagnosis of an inflammatory or granulomatous mass in these patients who would then need early neurosurgical referral.</li> <li>Ensure patient dose remains at minimum level to be clinically effective.</li> <li>Consider reducing concentration of intrathecal opioids as far as possible.</li> <li>Follow the patient management and system troubleshooting guidelines given by the pump manufacturer.</li> <li>Report any incidents involving mass formation to the relevant drug pump manufacturer and the NIAIC.</li> </ul>	▶ ④				
<p><b>Distributed by NIAIC to:</b></p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Chief Executive of each Agency</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> </table>	Chief Executive of each HSS Board	Chief Executive of each Agency	Chief Executive of each HSS Trust	Hospices	▶ ⑤
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<p><b>Contacts</b> Details of manufacturer and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥				
<p><b>Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)</b></p>					
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;"> <p><b>Acknowledge Receipt of Alert:</b> 11<sup>th</sup> June 2008</p> </td> <td style="width: 33%;"> <p><b>Action Under Way:</b> 11<sup>th</sup> July 2008</p> </td> <td style="width: 33%;"> <p><b>Action Complete:</b> 12<sup>th</sup> September 2008</p> </td> </tr> </table>	<p><b>Acknowledge Receipt of Alert:</b> 11<sup>th</sup> June 2008</p>	<p><b>Action Under Way:</b> 11<sup>th</sup> July 2008</p>	<p><b>Action Complete:</b> 12<sup>th</sup> September 2008</p>	▶ ⑦	
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This Alert is on our web site: <http://sabs.dhsspsni.gov.uk>

## 1. DEVICE/EQUIPMENT:

Implantable drug pumps for intrathecal therapy. All manufacturers.

## 2. 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%<sup>1</sup>. This is higher than typically cited in the literature.

Although the risk appears to be mainly associated with opioid therapy<sup>1</sup>, it has also been reported with other infusions, such as baclofen<sup>2,3</sup>. The risk of inflammatory mass formation may increase with implantation time and higher concentration of opioids<sup>1</sup>. 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 products<sup>4</sup>. 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](http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/FieldSafetyNoticesformedicaldevices/CON2033876)

## 3. 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.

## 4. ACTION:

- 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.

## 5. ONWARD DISTRIBUTION TO:

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

- 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
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

## 6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2008/042 and be addressed to:

Northern Ireland Adverse Incident  
Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US

Tel: 028 9052 3868  
Fax: 028 9052 3900  
Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

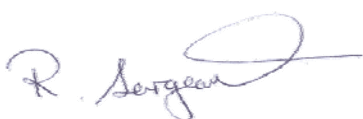
## 7. FEEDBACK:

### Action deadlines for the Safety Alert Broadcast System for HPSS Trusts (SABS)

Acknowledge Receipt of Alert:  
11<sup>th</sup> June 2008

Action Under Way:  
11<sup>th</sup> July 2008

Action Complete:  
12<sup>th</sup> September 2008



Robert Sergeant  
NIAIC Operational Manager