

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/48

Issued: 31 May 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

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	Section
<p>Medical Device/Equipment: Medication cassette reservoir for CADD legacy infusion pumps manufactured by Smiths Medical: model numbers 21-7001-24 and 21-7002-24.</p>	▶ ①
<p>Problem: In certain batches of medication cassette reservoirs there was a change of material formulation, to include calcium carbonate. There have been reports of shifts in pH of medication, discolouration and occlusions, which may or may not be related to this change. Until further evidence is obtained, it is recommended that these batches are not used.</p>	▶ ②
<p>Action by: All nursing, medical and technical staff using these devices and pharmacists.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Identify and locate medication cassette reservoirs from the affected batches (see overleaf for details). Quarantine the affected medication cassette reservoirs until further evidence is obtained regarding their safety. 	▶ ④
<p>Distributed by NIAIC to:</p> <p>Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p> <p>Hospices</p> <p>For onward distribution see Section 5</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC In accordance with PEL(06)17 acknowledgment of assurance should be given:-</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Model number 21-7001-24 has a 50ml reservoir.

Model number 21-7002-24 has a 100ml reservoir.

The batches affected are:

- batches 102X16 to 226X16 for model number 21-7001-24
- batches 081X16 to 229X16 for model number 21-7002-24

2. PROBLEM:

Smiths Medical has received reports associated with the use of the medication cassette reservoirs manufactured using a material containing calcium carbonate:

- Sweden has reported pH increases from pH 3 to 6.9 and yellow discolouration when filled with morphine hydrochloride over a seven day period
- in the USA there have been reports of catheter occlusions during the delivery of Flolan® via the medication cassette reservoir.

Smiths Medical has conducted independent tests, which confirmed that in the affected cassette reservoirs:

- there is an upward pH change of up to 3 units after 24 hours for a non-buffered weak acid solution from pH 3.70 to pH 7.80
- dopamine hydrochloride solution showed a slight yellowing, with pH rising from 3.77 to 6.46 after 48 hours
- an admixture of fentanyl citrate and bupivacaine hydrochloride showed a degradation in drug concentration of 19.7% and 17.2% at 120 hours and pH increase from 4.73 to 6.66 after 24 hours.

Smiths Medical changed their material supplier for the medication cassette reservoirs in March 2006. This new material contained calcium carbonate. In January 2007 they reverted to the original material formulation.

Smiths Medical has informed the MHRA that they are no longer supplying medication cassette reservoirs manufactured with the material containing calcium carbonate.

3. ACTION BY:

All nursing, medical and technical staff using these devices and pharmacists.

4. ACTION:

- Identify and locate medication cassette reservoirs from the affected batches (see overleaf for details).
- Quarantine the affected medication cassette reservoirs until further evidence is obtained regarding their safety.
- Contact Smiths Medical for unaffected medication cassette reservoirs. If unaffected medication cassette reservoirs are not available, consider using an alternative infusion system.

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 departments
- Adult and paediatric intensive care units
- All clinical departments
- All wards
- Anaesthetists
- Chief pharmacists
- Clinical governance leads
- EBME departments
- Outpatient clinics
- Pain teams
- Palliative care teams
- Purchasing managers
- Risk managers
- Special care baby units
- Supplies departments
- Theatres

- Equipment stores
- Health and safety managers
- Hospital at home units
- Hospital pharmacies
- Hospital pharmacists
- IV nurse specialists
- Medical directors
- Nursing executive directors
- Oncology units
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through RQIA
- Community hospitals
- Community nurses
- District nurses
- Equipment libraries and stores
- Palliative care team

6. CONTACTS:

Enquires to the manufacturer should be addressed to:

Jon Charters
Quality Assurance Manager
Smiths Medical International Ltd
Colonial Way
Watford WD24 4LG

Tel: 01923 246 434
E-mail: jon.charters@smiths-medical.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/48 and be addressed to:

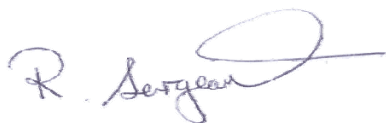
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Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

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7. FEEDBACK:

In accordance with PEL(06)17 the following acknowledgment of assurance should be given:-

Deadline (Email received)	: 04 June 2007
Deadline (action underway)	: 08 June 2007
Deadline (action complete)	: 22 June 2007



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety