

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/98

Issued: 28 November 2007



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	✓
INFORMATION	

	Section
<p>Medical Device/Equipment: Injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation.</p>	▶ ①
<p>Problem: Inappropriate use, or modification, of cement composition leading to serious complications (an update).</p>	▶ ②
<p>Action by: Clinicians carrying out percutaneous vertebroplasty, balloon kyphoplasty or pedicle screw augmentation</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Note the revised recommendations on percutaneous vertebroplasty and balloon kyphoplasty, which supersede the advice given in MDEA(NI)2004/030 (issued in June 2004). Destroy all copies of MDEA(NI)2004/030. 	▶ ④
<p>Distributed by NIAIC to:</p> <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
<p>Contacts Details of NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation.

2. PROBLEM:

NIAIC issued a Medical Device/Equipment Alert in June 2004 (MDEA(NI)2004/030) in response to reports of adverse incidents during percutaneous vertebroplasty and pedicle screw augmentation procedures. A number of complications can occur due to:

- cement leaking into the paravertebral veins
- use of excessive quantities of cement.

In February 2007, Health Canada (the Canadian Department of Health) issued safety information on bone cements used in vertebroplasty and kyphoplasty procedures. Their notice contained a number of additional recommendations regarding:

- the importance of patient monitoring during procedures
- the increased risk of adverse reaction to bone cement if more than three vertebral levels are treated in one procedure
- the risk of cement leakage in patients undergoing vertebroplasty or kyphoplasty for traumatic burst fractures with disruption of the posterior vertebral body.

MHRA has consulted with relevant clinical experts, and is issuing updated advice in light of their comments.

3. ACTION BY:

Clinicians carrying out percutaneous vertebroplasty, balloon kyphoplasty, or pedicle screw enhancement procedures. These may include:

- Surgeons (orthopaedic, spinal and neuro); Radiologists (interventional, musculoskeletal and neuro); Anaesthetists; Rheumatologists; Pain therapists.

4. ACTION:

NOTE: New action points are in italics.

The MHRA has consulted with the relevant professional associations and royal colleges, and advises that clinicians undertaking percutaneous vertebroplasty, balloon kyphoplasty or pedicle screw augmentation procedures should note the following recommendations:

For percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentations

- perform procedures only after appropriate training
- use only cements specifically recommended by the cement manufacturer for these procedures
- do not alter the cement composition recommended by the cement manufacturer. Note that modification of composition (for example through the addition of radiopacifier or monomer) may leave the clinician (rather than the manufacturer) liable with regard to performance, toxicity, and handling issues arising from such modifications. Increased monomer levels can cause unpredictable handling of the cement dough, increased exposure to the toxic monomer component, increased risk of venous embolisation as the cement polymerises, and unpredictable final mechanical properties
- use high quality motorised C arm fluoroscopy, high quality biplanar fluoroscopy or real-time CT to guide needle insertion*
- use high quality lateral fluoroscopy during cement injection**.

Action (continued):

Specifically for percutaneous vertebroplasty and balloon kyphoplasty

- *closely monitor patient's blood pressure during and immediately after the procedure*
- *be aware that treating multiple levels may increase the risk of sudden drop in blood pressure, particularly if more than three vertebral levels are treated in a single operation*
- give due consideration to other conventional therapies prior to undertaking percutaneous vertebroplasty or kyphoplasty
- do not overfill the vertebral body with cement
- place the needle tip in the anterior third of the vertebral body
- consider carefully the risk/benefit analysis for patients with malignant conditions who also have epidural extension or malignant collapse, in view of risk of precipitating cord compression. Ensure that immediate surgical support is available
- *consider carefully the risk/benefit analysis for patients with traumatic burst fractures with disruption of the posterior vertebral body.*

Specifically for pedicle screw augmentation

- ensure that cement is placed in the proximal part of the screw hole to prevent cement being pumped into the vertebral body during screw placement
- for multilevel pedicle screw augmentation, insert cement and pedicle screws on one side and allow the cement to set prior to inserting cement and pedicle screws on the contralateral side.

In all cases the benefit of radiographic examination should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of The Ionising Radiation (Medical Exposure) Regulations 2000 [IR(ME)R 2000] - SI 2000 No. 1059 and The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 - SI 2006 No. 2523.

* High quality motorised C arm fluoroscopy (where available) is the preferred technique to guide needle insertion as it allows for more rapid and more precise monitoring of needle placement.

** Because bone cement can extrude into the spinal canal during cement injection, it is important to use high quality lateral fluoroscopy during this part of the procedure. Where pulsed fluoroscopy is available, it may be used to reduce patient dose providing the image quality remains adequate for the procedure.

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:

- Anaesthetists
- Clinical governance leads
- Directors of pain clinics
- Interventional radiologists
- Medical directors
- Neurosurgeons
- Orthopaedic surgeons
- Radiologists
- Radiology departments
- Risk managers
- Skeletal radiologists
- Spinal surgeons
- Theatre managers
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to NIAIC should quote reference number MDEA(NI)2007/98 and be addressed to:

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

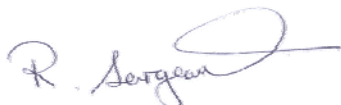
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None required.



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