

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/18

Issued: 30 July 2003

For:

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



NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE

	Section
<b>Medical Device/Equipment:</b> Injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation	▶ ①
<b>Problem:</b> Inappropriate use or modification of composition leading to serious complications.	▶ ②
<b>Action by:</b> Clinicians carrying out percutaneous vertebroplasty, balloon kyphoplasty or pedicle screw augmentation.	▶ ③
<b>Action:</b> Note the best practice recommendations described in the following pages.	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers <b>For onward distribution see Section 5</b>	▶ ⑤
<b>Contacts</b> NIAIC contact details	▶ ⑥
<b>Feedback Requirements to NIAIC</b> Please feedback details of any problems found.	▶ 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 has been informed that the Medicines and Healthcare products Regulatory Agency (MHRA) has received reports of the following adverse incidents during percutaneous vertebroplasty and pedicle screw augmentation procedures:

- leakage of cement into the paravertebral veins leading to complications including pulmonary embolism, shortness of breath, and in one case cement accumulation in the right atrium;
- use of excessive quantities of cement leading to vertebral fracture; interference with thoracic aorta, nerve root or spinal cord; and migration of cement to neighbouring vertebrae or extension into an adjacent intervertebral disc with consequent increased risk of fracture of the adjacent vertebra.

MHRA is concerned that these adverse incidents may be exacerbated by:

1. use of bone cements which are not indicated for use in these procedures;
2. use of bone cements which are modified from the composition recommended by the manufacturer (through further additions of monomer/radiopacifier), which may lead to:
  - unpredictable handling of the cement dough;
  - unpredictable final mechanical properties;
  - increased exposure to the toxic monomer component; and
  - increased risk of venous embolisation as the cement polymerises.
3. use of inappropriate quality of X-ray imaging. This has the potential for inadequate imaging of the injected bone cement leading to higher radiation exposure than necessary.

MHRA considers that due to procedural similarities (in particular the use of methacrylate bone cement in vertebral bodies), similar issues may also be relevant to balloon kyphoplasty.

The MHRA has been unable to establish a clear consensus amongst clinicians as to the benefits of pre-flushing the vertebral body with radiopaque dye prior to these procedures. Whilst this practice may have the advantage of helping to identify potential cement leakage paths, this needs to be set against the disadvantages of blurring the radiographic image of the injected cement, and the potential for triggering an adverse patient reaction to the contrast medium.

## **3. ACTION BY:**

Clinicians carrying out percutaneous vertebroplasty, balloon kyphoplasty or pedicle screw enhancement procedures.

This may include:

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

## 4. ACTION:

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 augmentation

- 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, increased X-ray exposure if radiopacifier levels are inappropriate, and unpredictable final mechanical properties;
- use either real-time CT or high quality biplanar fluoroscopy to guide needle insertion;
- use high quality lateral fluoroscopy during cement injection.

### Specifically for percutaneous vertebroplasty and balloon kyphoplasty

- 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 flushing the injection site with radiopaque dye prior to injecting cement if haemorrhage occurs from the needle hub after removal of the central stylet.

### 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 IR(ME)R 2000 (SI 2000 No. 1059 The Ionising Radiation (Medical Exposure) Regulations 2000).

## 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:

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Medical Directors
- Directors of Anaesthetics
- Theatre Managers
- Interventional Radiologists
- Neurosurgeons
- Orthopaedic Surgeons
- Spinal Surgeons
- Directors of Pain Clinics
- Skeletal Radiologists
- Independent Healthcare Providers – Private Clinics

## 6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2003/18 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:

Inform NIAIC and the relevant cement manufacturer of any adverse incident relating to medical device issues during vertebroplasty, balloon kyphoplasty or pedicle screw augmentation.



Brian Godfrey  
NIAIC 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 Safety Notice SN (NI) 2003/01. 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](http://www.dhsspsni.gov.uk/niaic)

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