

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/089

Issued: 26th Oct 2007

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Orthopaedic bone cement restrictor instrumentation. DePuy SmartSeal™ pressurisers- femoral and acetabular pressurisers (5 pack) manufactured by DePuy CMW.</p>	▶ ①
<p>Problem: Recall of SmartSeal™ pressuriser as the outer pouch seal may be compromised.</p>	▶ ②
<p>Action by:</p> <ul style="list-style-type: none"> • Orthopaedic surgeons. • Supplies managers. • Theatre managers. 	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Identify and quarantine affected devices. • Do not use affected devices. • Return affected devices to the manufacturer. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical and clinical 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:

DePuy SmartSeal™ pressuriser: femoral and acetabular pressurisers (5 pack) for use with orthopaedic bone cement.

Part numbers

- 3206045 – 45mm acetabular pressuriser
- 3206052 – 52mm acetabular pressuriser
- 3206055 – 55mm acetabular pressuriser
- 3206060 – 60mm acetabular pressuriser
- 3206065 – 65mm acetabular pressuriser

- 3206002 – wedge femoral pressuriser
- 3206005 – standard femoral pressuriser

Lot numbers - all lot numbers are affected by this recall.

Any DePuy SmartSeal pressurisers that have a black tick on the bottom right hand corner of the pouch and on the carton have already been re-inspected by DePuy CMW and the manufacturer has verified that the seals are fully intact. These products are now excluded from the recall.

2. PROBLEM:

DePuy CMW is recalling SmartSeal™ pressurisers used during cemented total hip joint replacement surgery, because the outer peelable pouch seals may be creased and therefore may not be intact. The inner peelable pouch seals are intact and therefore the device is likely to remain sterile.

DePuy CMW is recalling this product as a precautionary measure. The manufacturer is currently investigating the root cause of the packaging problem.

The MHRA is not aware of any incidents associated with these affected devices.

The manufacturer estimates that about 15,000 potentially affected devices have been distributed in the UK since April 2005. The manufacturer wrote to users about this recall in July 2007 (see MHRA website). However, only 5% of the affected devices had been returned to the manufacturer by 04 October 2007.

This notice is intended to facilitate the manufacturer's recall.

3. ACTION BY:

- Orthopaedic surgeons.
- Supplies managers.
- Theatre managers.

4. ACTION:

- Identify and quarantine affected devices.
- Do not use affected devices.
- Return affected devices to the manufacturer.

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:

- Infection control departments
- Infection prevention and control directors
- Medical directors
- Nursing executive directors
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Independent Health and Social Care Providers
– Private Clinics, Residential and Nursing Homes through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

Catherine Holmes
Regulatory Affairs Manager
DePuy International
T/A DePuy CMW
Cornford Road
Blackpool
FY4 4QQ

Tel: 01253 765 167
Fax: 01253 697 431
Email: cholmes@dpygb.inj.com

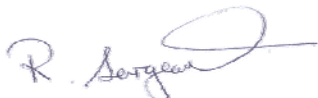
Enquiries to NIAIC should quote reference number MDEA(NI)2007/089 and be addressed to:

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