

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/74

Issued: 5th September 2007

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION	



HEALTH ESTATES

creating healing environments

	Section
<p>Medical Device/Equipment: Hip implants for hemiarthroplasty – Austin-Moore, F.R. Thompson and Thompson Modular endoprotheses manufactured by Biomet UK Ltd.</p>	▶ ①
<p>Problem: Recall due to potential failure of sterile barrier packaging which could compromise product sterility.</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 any unimplanted affected devices. • Do not implant 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 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:

Austin-Moore Endoprotheses (catalogue numbers ST609-38 to ST609-55, ST610-38 to ST610-55, ST612-38 to ST612-55, ST613-5 to ST613-95).

F.R. Thompson Endoprotheses (catalogue numbers ST611-38 to ST611-55).

Thompson Modular Endoprotheses modular stems (catalogue numbers 164556 to 164558).

For all the above, affected lot numbers are within the range 388000 to 443000 and expiry dates are between September 2010 (2010-09) and April 2011 (2011-04).

2. PROBLEM:

Biomet UK is recalling certain lots of Austin-Moore, F.R. Thompson and Thompson Modular endoprotheses because the sterile barrier packaging has become brittle with age. Failure of the sterile barrier packaging could compromise product sterility.

The manufacturer has stated that packaging embrittlement is obvious to users and it should be immediately apparent that the product should not be used. Neither the manufacturer nor the MHRA is aware of any reports of adverse patient effects arising from this problem.

Only devices with the lot numbers and expiry dates listed above are affected by this recall.

3. ACTION BY:

- Orthopaedic surgeons
- Supplies managers
- Theatre managers

4. ACTION:

- Identify and quarantine any unimplanted affected devices.
- Do not implant 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 teams
- Medical directors
- Orthopaedic surgeons
- Risk managers
- Supplies managers
- Theatre managers
- Theatres
- Independent Health and Social Care Providers – Private Hospitals and Clinics through RQIA

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Dr Simon Richards
Biomet UK Ltd
Waterton Industrial Estate
Bridgend
CF31 3XA

Tel: 01656 655 221

Fax: 01656 645 454

E-mail: simon.richards@biometeurope.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/074 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

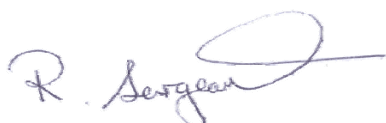
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

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

Deadline (Email received)	: 7th Sept 2007
Deadline (action underway)	: 14th Sept 2007
Deadline (action complete)	: 28th Sept 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

Appendix to MDEA(NI)2007/74



Joint Replacement Cement Trauma Spine Biologics

Biomet UK Ltd

URGENT: - PRODUCT SAFETY INFORMATION **FIELD SAFETY NOTICE**

DATE: 23rd August 2007

SUBJECT: Austin-Moore and Thompson Endoprotheses

REF: Austin-Moore Endoprotheses – ST609-38 to ST609-55, ST610-38 to ST610-55,
ST612-38 to ST612-55 and ST613-5 to ST613-95

F. R. Thompson Endoprotheses – ST611-38 to ST611-55

Thompson Modular Endoprotheses Modular Stems – 164556 to 164558

LOT: Lot Numbers within the range 348000 to 456200 AND Expiry Dates between
September 2010 and May 2011

For the attention of the Heads of Orthopedic Departments / Trauma Departments/Operating Departments / Sterile Services Departments/ Procurement / Supplies / Risk Management

Our records indicate that we have shipped potentially affected units to your hospital. We are requesting that you immediately cease use of product listed in Attachment 1 bearing Lot Numbers within the range LOT 348000 to 456200 (Expiry Date 2010-09 to 2011-05).

Please read the remaining information for an explanation of this request.

Biomet UK has received a small number of reports from customers that the sterile barrier packaging on Austin-Moore and Thompson Endoprotheses has become brittle with age, potentially compromising the sterility of the product. All the complaints received relate to product manufactured over the period September 2000 to April 2001 (with Expiry Dates between 2010-09 and 2011-04).

The nature of the packaging embrittlement would be obvious to the user and it would be immediately apparent that the product should not be used. However as a precautionary measure Biomet UK has taken the decision to voluntarily recall all potentially affected lots that were manufactured during the affected period.

This problem therefore affects a limited number of lots manufactured over the period September 2000 to May 2001 (Lot Numbers within the range 348000 to 456200 with an Expiry Date between 2010-09 to 2011-05).

Only the Item Numbers listed in Appendix 1 with the Lot Numbers and Expiry Dates within the specified range are affected.

Appendix to MDEA(NI)2007/74



Joint Replacement Cement Trauma Spine Biologics

Biomet UK Ltd

What you need to do

To assist us with this action, please locate and immediately quarantine any products listed in this Field Safety Action Notice. Products subject to this Field Safety Notice can be identified by the REF, LOT numbers and Expiry Dates printed on labeling on the unit pack and on the shelf carton.

Complete and return the attached "Fax-Back Response Form" to your Biomet UK or to your local Biomet Europe Distributor. Upon receipt of the "Fax-Back Response Form", we shall quickly contact you to make the necessary arrangements for the replacement of product.

Please pass this information to all in your institution who are using, or ordering these products. Additionally, please ensure that a copy of this letter is provided to any other organisations to which potentially affected products have been transferred.

Biomet UK is taking this action as a conservative measure to ensure patient safety.

Biomet UK has advised relevant Competent Authorities of the issue of this Field Safety Notice and will continue to keep the Competent Authorities apprised of any further action.

Please accept our apologies for the inconvenience caused by this action.

However, we trust that you will agree that this is a sensible measure.

If you have any questions regarding this communication, please contact me on the following Tel: +44 1656 655221, Fax: +44 1656 645454 or e-mail simon.richards@biometeurope.com.

Yours sincerely

Dr Simon Richards
Director of Regulatory Affairs and Quality Assurance
Biomet UK Ltd