Medical Device Alert

Ref: MDA/2013/010 Issued: 12 March 2013 at 14:00

Device

Metal-on-metal (MoM) total hip replacements:

ADEPT® 12/14 modular head (Finsbury Orthopaedics Ltd).

All lots.

Problem

Higher than expected revision rate for the ADEPT® 12/14 modular head components when used in a total hip arthroplasty.

Action by

- Medical directors.
- Orthopaedic departments.
- Orthopaedic surgeons.
- Staff involved in the management of patients with joint replacement implants.

Action

- Do not implant ADEPT® 12/14 modular head devices.
- Return all affected devices to DePuy International Ltd.
- Follow up both symptomatic and asymptomatic patients implanted with these devices in line with recommendations in the table on page 2.
- Report all adverse incidents to the MHRA and DePuy International.

CAS deadlines

Action underway: 19 March 2013

Action complete: 26 March 2013

Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.

Contact

DePuy International Ltd
Paul Arnott
Complaints & Vigilance Manager
Tel: 07771 971 930
Email: parnott@its.jnj.com

Device

The ADEPT® 12/14 modular head used in MoM total hip arthroplasty, manufactured by Finsbury Orthopaedics Ltd. Finsbury was acquired by DePuy in December 2009. This device was commercially available from Finsbury or DePuy from 2004 to September 2011.

Note: This alert does not apply to ADEPT® hip resurfacing femoral components, which are not implanted in total hip arthroplasty procedures.

Problem

Analysis of data from the National Joint Registry (NJR) for England and Wales since 11 November 2012 has shown a higher than expected cumulative revision rate for the ADEPT® 12/14 modular head when used in conventional total hip arthroplasty (12.1% at seven years).

Further information on the revision rates for specific stems used with the ADEPT® 12/14 modular head can be found in DePuy's Field Safety Notice recalling the affected modular heads (issued 15 January 2013).

Action

Management recommendations for patients with stemmed MoM total hip replacements – femoral head diameter ≥36mm (extracted from the table within the MHRA's MDA/2012/036)

	Stemmed MoM total hip replacements – femoral head diameter ≥36mm	
	Symptomatic patients	**Asymptomatic patients**
Patient follow-up	Annually for the life of the implant	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases	Recommended if blood metal ion levels rising
1st blood metal ion level test	**Yes**	**Yes**
Results of 1st blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction	If blood metal ion level >7ppb then second blood test required 3 months later
2nd blood metal ion level test	**Yes** - 3 months after 1st blood test if result was >7ppb	**Yes** - 3 months after 1st blood test if result was >7ppb
Results of 2nd blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously	If blood metal ion levels rising - further investigation required including imaging
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising

Table footnotes:

- Blood metal ion testing to be in whole blood.
- 7 parts per billion (ppb) equals 119 nmol/l cobalt or 134.5 nmol/l chromium.

Measurements of cobalt or chromium ions should be carried out:

- in England, Northern Ireland or Wales, by laboratories participating in the Trace Elements External Quality Assessment Scheme (TEQAS) - http://www.sas-centre.org/home.html
- in Scotland, by the Scottish Trace Element and Micronutrient Reference Laboratories - Scottish Trace Element and Micronutrient Reference Laboratory - http://www.trace-elements.co.uk/

Guidance notes:

- On the basis of current knowledge, this chart has been produced as a guide to the management of these patients. It will not necessarily cover all clinical situations and each patient must be judged individually.
- MARS MRI scans (or ultrasound scans) should carry more weight in decision making than blood ion levels alone.
- Patients with muscle or bone damage on MARS MRI are those of most concern. A fluid collection alone around the joint in an asymptomatic patient, unless it is very large can be safely observed with interval scanning.
- Local symptoms include pain and limping.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Medical directors
- Nursing executive directors
- Orthopaedic departments
- Orthopaedic outpatient clinics
- Orthopaedic surgeons
- Outpatient theatre nurses
- Pathologists
- Procurement managers
- Purchasing managers
- Radiology departments
- Radiology directors
- Risk managers
- Theatre managers

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- General practitioners (for information only)
- NHS walk-in centres (for information only)

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: safetyalerts@dh.gsi.gov.uk and requesting this facility.

Contacts

DePuy International Ltd
Paul Arnott
Complaints & Vigilance Manager
St Anthony's Road
Leeds
LS11 8DT

Tel: 07771 971 930
Fax: 0113 387 6087

Email: parnott@its.jnj.com

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2013/010** or **2013/001/008/291/010**

Technical aspects
Miss Feza Haque and Dr Crina Cacou
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7066 / 7338
Fax: 020 8754 3965

Email: feza.haque@mhra.gsi.gov.uk
crina.cacou@mhra.gsi.gov.uk

Clinical aspects
Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ

Tel: 020 3080 7126
Fax: 020 8754 3965

Email: nicola.lennard@mhra.gsi.gov.uk

How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic
Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:
Improving Patient Safety Team
Medical Directorate
Welsh Government
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

Email: Haz-Aic@wales.gsi.gov.uk