# Medical Device Alert

Ref: MDA/2012/036   Issued: 25 June 2012 at 11:00

## Device

**All metal-on-metal (MoM) hip replacements**

## Problem

The MHRA is issuing updated information and advice about the follow-up of patients implanted with metal-on-metal (MoM) hip replacements.

## Action

- **Put updated** systems in place for the follow-up and investigation of patients implanted with MoM hip replacements (see appendix).

  Note: The recommendations in this Medical Device Alert (MDA) replace the advice previously given in MDA/2010/033, MDA/2010/069 and MDA/2012/008.

## Action by

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

## CAS deadlines

- Action underway: 25 July 2012
- Action complete: 28 August 2012
Problem
The majority of patients implanted with MoM hip replacements have well functioning hips and are thought to be at a low risk of developing serious problems.

A small number of patients implanted with these hips may, however, develop progressive soft tissue reactions to the wear debris associated with MoM articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery. The MHRA’s clinical orthopaedic experts are of the opinion that early revision of poorly performing MoM hip replacements should give a better revision outcome.

Following extensive consultation with the MHRA’s clinical orthopaedic experts, the MHRA is issuing this updated advice to healthcare professionals involved in the management of patients implanted with MoM hip replacements. This advice updates the recommendations for patient follow-up previously given in MDA/2010/033, MDA/2010/069 and MDA/2012/008. In particular it incorporates updated advice on the duration of follow-up of symptomatic patients implanted with:
- MoM hip resurfacing (no stem)
- stemmed MoM total hip replacements that have a femoral head diameter <36mm.

The MHRA is continuing to monitor the situation in consultation with orthopaedic experts and may issue further advice.

Action
Follow the advice given in the table in the appendix for the management of patients implanted with MoM hip replacements.

The table in the appendix identifies four groups of MoM hip replacements:
- MoM hip resurfacing implants
- MoM total hip replacements with a head diameter <36mm
- MoM total hip replacements with a head diameter ≥36mm
- DePuy ASR™ hip replacements comprising:
  - ASR™ acetabular cups for hip resurfacing arthroplasty or total hip replacement
  - ASR™ surface replacement heads for hip resurfacing arthroplasty
  - ASR™ XL femoral heads for total hip replacement.

The table provides recommendations for follow-up of both symptomatic and asymptomatic patients implanted with MoM hip replacements in each of the above four groups. These include advice on appropriate imaging (Metal Artefact Reduction Sequence (MARS) MRI / ultrasound), blood metal ion levels and situations where revision may need to be considered.

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/
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)
- Local authorities 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
- 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.

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number MDA/2012/036 or 2010/004/019/291/007

Technical aspects
Miss Feza Haque or 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 Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Floor 4
151 Buckingham Palace Road
London SW1W 9SZ
Tel: 020 3080 6800
Fax: 020 8754 3965
Email: susanne.ludgate@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
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
## Appendix

### Management recommendations for patients with metal-on-metal hip replacement implants

<table>
<thead>
<tr>
<th>Patient follow-up</th>
<th>Imaging: MARS MRI or ultrasound</th>
<th>1st blood metal ion level test</th>
<th>2nd blood metal ion level test</th>
<th>Results of 2nd blood metal ion level test</th>
<th>Consider need for revision</th>
</tr>
</thead>
<tbody>
<tr>
<td>MoM hip resurfacing (no stem)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic patients</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>According to local protocols</td>
<td>Recommended in all cases</td>
<td>No - unless concern exists for cohort or patient becomes symptomatic</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td></td>
</tr>
<tr>
<td>Stemmed MoM total hip replacements – femoral head diameter &lt;36mm</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>According to local protocols</td>
<td>Recommended in all cases</td>
<td>No - unless concern exists for cohort or patient becomes symptomatic</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td></td>
</tr>
<tr>
<td>Stemmed MoM total hip replacements – femoral head diameter ≥36mm</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>No - unless concern exists for cohort or patient becomes symptomatic</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td></td>
</tr>
<tr>
<td>DePuy ASR™ hip replacements (all types)</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
<tr>
<td>Symptomatic patients</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
<tr>
<td>Asymptomatic patients</td>
<td>Annually for the life of the implant</td>
<td>Recommended in all cases</td>
<td>Yes</td>
<td>Blood metal ion level &gt;7ppb indicates potential for soft tissue reaction especially if greater than previously</td>
<td>If imaging is abnormal and/or blood metal ion levels rising</td>
</tr>
</tbody>
</table>

**Notes and guidance on next page**
Appendix

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

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.