

Medical Device Alert

Action

Ref: MDA/2010/033 Issued: 22 April 2010 at 14:00

Device
All metal-on-metal (MoM) hip replacements.

Problem	Action
<p>The MHRA has received reports of revisions of MoM hip replacements involving soft tissue reactions. These reactions may be associated with unexplained hip pain.</p>	<p>Put systems in place for the follow-up of patients implanted with MoM hip replacements including, where appropriate, blood metal ion measurements and cross sectional imaging.</p>
Action by	
<ul style="list-style-type: none"> • Medical directors • Orthopaedic departments • Orthopaedic surgeons • Staff involved in the management of patients with joint replacement implants. 	
CAS deadlines	
<p>Action underway: 21 May 2010 Action complete: 17 June 2010</p> <p>Note: These deadlines are for systems to be in place to take actions and not for the completion of patient follow-up and testing.</p>	

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. Early revision of poorly performing MoM hip replacements should give a better revision outcome.

Following extensive consultation with orthopaedic experts and using information from the National Joint Registry for England and Wales, the MHRA is issuing this interim advice to healthcare professionals involved in the management of patients implanted with MoM hip replacements.

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

Action

For patients implanted with MoM hip replacements:

- follow up patients at least annually for five years postoperatively and more frequently in the presence of symptoms. Beyond five years, follow up in accordance with locally agreed protocols
- investigate patients with painful MoM hip replacements. Specific tests should include evaluation of cobalt and chromium ion levels in the patient's blood and cross sectional imaging including MRI or ultrasound scan
- consider measuring cobalt and chromium ion levels in the blood and/or cross sectional imaging for the following patient groups:
 - > patients with radiological features associated with adverse outcomes including component position
 - > patients with small component size (hip resurfacing arthroplasty only)
 - > cases where the patient or surgeon is concerned about the MoM hip replacement
 - > cohorts of patients where there is concern about higher than expected rates of failure
- if either cobalt or chromium ion levels are elevated above seven parts per billion (ppb), then a second test should be performed three months after the first in order to identify patients who require closer surveillance, which may include cross sectional imaging
- if imaging reveals soft tissue reactions, fluid collections or tissue masses then consider revision surgery.

Note: Measurements of cobalt or chromium ions should be carried out by laboratories participating in the Trace Elements External Quality Assessment Scheme (TEQAS) (<http://www.sas-centre.org/home.html>).

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Care Quality Commission (Headquarters)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

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 surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Pathologists
- Radiology departments
- Radiology directors
- Risk managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

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

Primary care trusts to:

- Directors of public health
- General practitioners
- NHS walk-in centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/033 or 2010/004/019/291/007**

Technical aspects

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Clinical aspects

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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.irc@nhs.net

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

Wales

Enquiries in Wales should be addressed to:

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Medical Device Alerts
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