Medical Device Alert

Immediate action / update

Ref: MDA/2010/069 Issued: 07 September 2010 at 13:00

Device

DePuy ASR™ hip replacement implants.

Problem

Recall of ASR hip replacement implants due to increased rates of revision.

Action

- Do not implant DePuy ASR hip replacements.
- Return all unused ASR hip replacement implants to the manufacturer.
- Inform all patients implanted with ASR hip replacements about this recall and schedule them for a follow-up visit.

Note: the recommendations in this MDA replace the advice given in MDA/2010/044.

Action by

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

CAS deadlines

Action underway: 10 September 2010
Action complete: 05 October 2010

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

Manufacturer
Paul Arnott
DePuy International Ltd
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Device

The DePuy ASR system consists of:
• 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.

DePuy ASR hip replacement implants have been in clinical use in the UK since 2003.

Problem

The manufacturer has informed the MHRA that it is recalling all ASR hip replacement implants. Further background information on this recall is detailed in the manufacturer's Field Safety Notice dated 24 August 2010.

The manufacturer previously issued a Field Safety Notice on 08 March 2010. The MHRA subsequently published a Medical Device Alert (MDA/2010/044) on 25 May 2010 providing advice for patient follow-up and to ensure that these devices are implanted in accordance with the manufacturer's updated instructions for use (Revision C).

The manufacturer has now determined that the revision rate for all devices in the ASR systems at five years is higher than expected across the entire size range and so is recalling all ASR system hip replacement implants. Following consultation with our orthopaedic experts we are updating the advice provided in MDA/2010/044 to ensure appropriate follow-up is considered for all patients already implanted with these hip replacement implants. This advice may change in light of any future developments.

Action

- Follow up all patients implanted with ASR hip replacements with clinical examination at least annually.

- For patients presenting with symptoms of abnormal pain, limping, swelling around the hip, deteriorating hip function or radiological abnormality:
    - consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scan
    - in line with MDA/2010/033, if metal ion levels in whole blood are elevated above 120 nmol/L (cobalt) or 135 nmol/L (chromium) [ie seven parts per billion (ppb) for either metal ion], 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 MRI or ultrasound scan reveals soft tissue reactions, fluid collections or tissue masses then consider revision surgery.

Note**:** 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 Laboratory – http://www.trace-elements.org.uk/Contact.htm

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
- Orthopaedic outpatient clinics
- Outpatient theatre managers
- 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:

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)

Contacts

Manufacturer

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/069 or 2010/003/009/081/036**

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.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:

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
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