

Medical Device Alert

Immediate action / update

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

Device

DePuy ASR™ hip replacement implants.

Problem	Action
Recall of ASR hip replacement implants due to increased rates of revision.	- 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.
Action by	Note: the recommendations in this MDA replace the advice given in MDA/2010/044.
- Medical directors. - Orthopaedic surgeons. - Staff involved in the management of patients with joint replacement implants.	
CAS deadlines	Contact
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.	Manufacturer Paul Arnott DePuy International Ltd Tel: 07771 971 930 Fax: 0113 387 6087 Email: parnott@its.jnj.com

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:
 - o consider measuring cobalt and chromium ion levels in whole blood and/or performing cross sectional imaging including MRI or ultrasound scan
 - o 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
 - o 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:

- o 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>
- o 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

Paul Arnott
DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England

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/2010/069** or **2010/003/009/081/036**

Technical aspects

Miss Feza Haque or Dr Crina Cacou or Mr Allan Hilderley
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3066 / 3338 / 3172

Fax: 020 7084 3106

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

Clinical aspects

Dr Nicola Lennard
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Tel: 020 7084 3126
Fax: 020 7084 3111
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.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:

Issued: 07 September 2010 at 13:00

Ref: **MDA/2010/069**

Dr Sara Hayes
Senior Medical Officer
Medical Device Alerts
Welsh Assembly Government
Cathays Park
Cardiff CF10 3NQ
Tel: 029 2082 3922
Email: Haz-Aic@wales.gsi.gov.uk

MHRA is an executive agency of the Department of Health
© Crown Copyright 2010
Addressees may take copies for distribution within their own organisations