# Medical Device Alert

**Action**

Ref: MDA/2010/044 Issued: 25 May 2010 at 14:30

## Device

DePuy ASR™ acetabular cups used in hip resurfacing arthroplasty and total hip replacement.

## Problem

The MHRA has received reports of higher than anticipated rates of revision for ASR™ acetabular cups.

## Action by

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

## Action

- Put systems in place for the follow-up of patients already implanted with ASR™ acetabular cups.
- Ensure that ASR™ acetabular cups are implanted in accordance with the manufacturer's instructions for use as amended in 2008 (Revision C).

## CAS deadlines

Action underway: 25 June 2010
Action complete: 25 August 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

Tel: 07771 971 930
Fax: 0113 387 6087

Email: parnott@its.jnj.com

## Device

DePuy ASR™ acetabular cups are used with:

- ASRTM surface replacement heads for hip resurfacing arthroplasty; or
- ASRTM XL femoral heads for total hip replacement.

## Problem

Subsequent to the publication of the MHRA's Medical Device Alert MDA/2010/033 on metal-on-metal hip replacements on 22 April 2010, the National Joint Registry (NJR) of England and Wales informed the MHRA that ASR™ acetabular cups had been identified from registry data as having higher than anticipated rates of revision in hip resurfacing and total hip replacement procedures (see Appendix). The MHRA has also received similar reports from two of the 257 clinical centres in the UK that have implanted these devices.

DePuy produces two different instruction documents for this device: the instructions for use (IFU) supplied with the device, and the surgical technique manual. A cup inclination angle of 45º is recommended for reaming and implantation in all versions of the surgical technique manual. However, the original IFU did not contain reference to specific cup placement angles. Based on post-market experience, in October 2008, the manufacturer added to their IFU (Revision C) a recommended cup inclination angle of between 40º and 45º and distributed a document entitled 'The importance of correct acetabular component positioning' highlighting the importance of cup angles to implanting surgeons from February 2009.

All users were informed of correct cup angles in the manufacturer's Field Safety Notice of 08 March 2010. The FSN did not recommend any additional follow-up for patients in the absence of symptoms. However, the performance of devices implanted outside the manufacturer's currently recommended angle range (40º–45º) is not known.

DePuy ASR™ acetabular cups have been in clinical use in the UK since 2003.

## Action

- Follow up all patients implanted with ASR™ acetabular cups at least annually for five years postoperatively. Beyond five years, follow up in accordance with locally agreed protocols.

- For patients already implanted with ASR™ acetabular cups who are symptomatic or implanted with cup angle greater than 45º and particularly where a small component has been implanted:
  > 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.

- For new patients ensure that ASR™ acetabular cups are implanted in accordance with the manufacturer's most recent IFU (Revision C) and surgical technique (version 3) and in particular that the cup inclination angle is between 40º and 45º.

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**

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/2010/044or 2010/003/009/081/036**.

**Technical aspects**
Miss Feza Haque or Dr Crina Cacou
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3066 / 3338
Fax: 020 7084 3106

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

**Clinical aspects**
Dr Susanne Ludgate
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3123
Fax: 020 7084 3111

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

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
Cathays Park
Cardiff CF10 3NQ

Tel: 029 2082 3922

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



## Appendix

**Background Information**

2,769 primary hip replacements were reported to the NJR for the DePuy ASR™ acetabular cups used with surface replacement heads between 01 April 2001 and 31 March 2010. The NJR prediction for expected revisions for this type of device was 80 but the actual reported revisions were 130.

3,155 primary hip replacements were reported to the NJR for the DePuy ASR™ acetabular cups used with extra large femoral heads between 01 April 2001 and 31 March 2010. The NJR prediction for expected revisions for this type of device was 85 but the actual reported revisions were 126.