Medical Device Alert

MDA/2015/024 Issued: 25 June 2015 at 14:00

Metal-on-metal (MoM) hip replacements: Birmingham Hip™ Resurfacing (BHR) system (Smith & Nephew Orthopaedics)

Summary

Higher than expected revision rate for certain patient groups implanted with the Birmingham Hip Resurfacing (BHR) system. Guidance provided on implantation and patient management.

Action

- Do not implant BHR devices in:
  - > female patients
  - > patients requiring femoral heads sized 46mm or smaller.
- Only use 48mm BHR heads in the specific circumstance of intra-operative downsizing from a pre-operatively templated 50mm to a measured 48mm at the time of surgery.
- Return all unused BHR femoral heads sized 46mm and smaller and their corresponding acetabular and dysplasia cups to the manufacturer.
- Follow up patients implanted with BHR hips that fall within the scope of this Medical Device Alert i.e.:
  - > all symptomatic patients
  - > all female patients
  - > all patients implanted with head sizes 46mm or smaller

  in line with recommendations in the table below **(based on the advice given in MDA/2012/036)**

	Management recommendations for patients implanted with BHR hips that fall within the scope of this Medical Device Alert
Patient follow-up	Annually for the life of the implant
Imaging: MARS MRI or ultrasound	Recommended in all cases
1st blood metal ion level test	**Yes**
Results of 1st blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction
2nd blood metal ion level test	**Yes** - 3 months after 1st blood test if result was >7ppb
Results of 2nd blood metal ion level test	Blood metal ion level >7ppb indicates potential for soft tissue reaction especially if greater than previously
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising

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.

Action by

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

Deadlines for actions

Actions underway: 10 July 2015
Actions complete: 24 July 2015

Device details

Catalogue number	Unique Device Identifier (GS1)
BHR head	
74121138	03596010502766
74123140	03596010552402
74121142	03596010502773
74123144	03596010552419
74121146	03596010502780
BHR acetabular cup	
74120144	03596010502537
74120146	03596010502544
74122146	03596010565792
74122148	03596010552266
74120148	03596010502551
74120150	03596010502568
74122150	03596010552273
74122152	03596010552280
74120152	03596010502575
74120154	03596010502582
BHR dysplasia cup	
74120246	03596010502650
74122248	03596010552358
74120250	03596010502667
74122252	03596010552365
74120254	03596010502674

Problem / background

Smith & Nephew has identified that certain groups of patients implanted with the BHR system are at a higher risk of revision compared to other groups. This comes from analysis of recent data from the National Joint Registry (NJR) for England, Wales and Northern Ireland.

Smith & Nephew has advised not to use femoral head components sized 46mm in diameter and smaller, and their corresponding acetabular and dysplasia cups; these will be withdrawn from the market.

In addition, Smith & Nephew will update the instructions for use for these devices with the following changes:

- BHR will be contraindicated for all female patients
- a warning will be added regarding the restrictions in place for implanting femoral head components sized 48mm in male patients

Smith & Nephew issued a Field Safety Notice dated 3 June 2015 to communicate these changes to users.

Manufacturer contacts

Bill Aubrey
Smith & Nephew Orthopaedics Ltd
Tel: 01926 482 385
Email: bill.aubrey@smith-nephew.com

Distribution

Trusts (NHS boards in Scotland)
CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Clinical pathologists
- Clinical pathology directors
- NHS walk-in centres
- Nursing executive directors
- Orthopaedic surgeons
- Outpatient clinics
- Outpatient theatre managers
- Outpatient theatre nurses
- Purchasing managers
- Radiology departments
- Radiology directors
- Risk managers
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Walk-in centres

Public Health England
Directors for onward distribution to:
- Collaborating centres
- Consultants in communicable disease control
- Divisional directors
- Heads of department
- Heads of health, safety and quality
- Health protection nurses
- HPA laboratories
- Laboratory managers
- Regional business managers
- Regional directors
- Regional epidemiologists
- Regional leads
- Regional microbiologists
- Risk manager
- Safety officers

NHS England area teams
CAS liaison officers for onward distribution to all relevant staff including:
- General practitioners
- General practice managers
- General practice nurses

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)
- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- 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.

Enquiries

England
Send enquiries about this notice to MHRA, quoting reference number **MDA/2015/024** or **2015/006/005/291/012**.

Technical aspects
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Clinical aspects

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Reporting adverse incidents in England

Through Yellow Card https://yellowcard.mhra.gov.uk/

Northern Ireland

Alerts in Northern Ireland are distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868
Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

Reporting adverse incidents in Northern Ireland

Please report directly to NIAIC using the forms on our website.

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

Reporting adverse incidents in Scotland

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

Wales

Enquiries in Wales should be addressed to:
Healthcare Quality Division, Welsh Government

Tel: 01267 225278 / 02920 825510

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

Reporting adverse incidents in Wales

Report to MHRA through Yellow Card https://yellowcard.mhra.gov.uk/ and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).