Medical Device Alert

Ref: MDA/2012/016 Issued: 02 April 2012 at 16:30

Device

Metal-on-metal (MoM) total hip replacements:
MITCH TRH acetabular cups/MITCH TRH modular heads (Finsbury Orthopaedics) when implanted with uncemented Accolade femoral stems (Stryker Orthopaedics).

Problem

Increased rates of revision of metal-on-metal total hip replacements when MITCH TRH acetabular cups/MITCH TRH modular heads are used in combination with uncemented Accolade femoral stems.

Action by

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

Action

- Do not implant MITCH TRH acetabular cups/MITCH TRH modular heads in combination with uncemented Accolade femoral stems.
- Follow up both symptomatic and asymptomatic patients implanted with this combination as detailed in Table 1.
- Report all adverse incidents to the MHRA, DePuy International and Stryker Orthopaedics.

CAS deadlines

Action underway: 11 April 2012

Action complete: 02 May 2012

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

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Problem

The MITCH TRH System is a metal-on-metal hip replacement system consisting of components that can be used in different combinations to carry out either hip resurfacing arthroplasty or total hip replacement. The system was manufactured by Finsbury Orthopaedics and was distributed in the UK by Stryker Orthopaedics between May 2006 and October 2011.*

Analysis of data from the England and Wales National Joint Registry (NJR) up to 10 March 2012 has shown that the cumulative revision rate for MITCH TRH System used in hip resurfacing arthroplasty (revision rate of 3.1 % at 4 years based on 769 patients recorded by the NJR) is in line with relevant guidance from the National Institute for Health and Clinical Excellence (NICE) guidance,[1,2] but that the cumulative revision rate for MITCH TRH System total hip replacements (revision rate of 8.8% at 4 years based on 445 patients recorded by the NJR) is higher than indicated as acceptable by NICE.

MITCH TRH total hip replacements consist of MITCH TRH acetabular cups used with MITCH TRH modular femoral heads and also an appropriate Stryker femoral stem with a V40 taper including Exeter V40 or uncemented Accolade or ABG II.

Further analysis of NJR data by DePuy has now determined that the cumulative revision rate of MITCH TRH System total hip replacements varies considerably depending upon which femoral stem is used:

- MITCH TRH with Exeter V40 – revision rate of 3.7% at 4 years based on 120 patients recorded by the NJR
- MITCH TRH with uncemented Accolade – revision rate of 10.7% at 4 years based on 271 patients recorded by the NJR
- MITCH TRH with ABG II - rate of usage too low to estimate revision rate

*Note: DePuy International acquired Finsbury Orthopaedics in 2009 and they are now responsible for the safety and monitoring of the MITCH TRH hip system.

References:

1. Guidance on the selection of prostheses for primary total hip replacement. National Institute for Health and Clinical Excellence (NICE), 2000. Technology appraisal guidance No. 2
2. Guidance on the use of metal on metal hip resurfacing arthroplasty. National Institute for Health and Clinical Excellence (NICE), 2002. Technology Appraisal Guidance No. 44.

Action

Table 1 - Management recommendations for patients with stemmed MoM total hip replacements – femoral head diameter ≥36mm (originally published in the MHRA's MDA/2012/008).

	Stemmed MoM total hip replacements – femoral head diameter ≥36mm	
	Symptomatic patients	**Asymptomatic patients**
Patient follow-up	Annually for life of implant	Annually for life of implant
Imaging: MARS MRI or ultrasound	Recommended in all cases	Recommended if blood metal ion levels rising
1st blood metal ion level test	**Yes**	**Yes**
Results of 1st blood metal ion level test	*Blood metal ion level >7ppb indicates potential for soft tissue reaction*	*If blood metal ion level >7ppb then second blood test required 3 months later*
2nd blood metal ion level test	**Yes** - 3 months after 1st blood test if result was >7ppb	**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*	*If blood metal ion levels rising - further investigation required including imaging*
Consider need for revision	If imaging is abnormal and/or blood metal ion levels rising	If imaging is abnormal and/or blood metal ion levels rising

Table 1 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.

  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 Laboratories - Scottish Trace Element and Micronutrient Reference Laboratory

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.

Distribution

This MDA has been sent to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters) for information
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Equipment Co-ordinators)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

Onward distribution

Please bring this notice to the attention of relevant employees in your establishment. Below is a suggested list of recipients.

Trusts

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

Primary care trusts

CAS liaison officers for onward distribution to all relevant staff including:

- Directors of public health
- General practitioners (for information only)
- NHS walk-in centres

Independent distribution

Establishments registered with the Care Quality Commission (CQC) (England only)

This alert should be read by:

- Hospitals in the independent sector
- Independent treatment centres
- 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.

Contacts

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England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2012/016** or **2011/009/006/291/004**

Technical 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:
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