

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/58

Issued: 14th June 2007



HEALTH ESTATES

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For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	✓

	Section
<p>Medical Device/Equipment: Total hip replacement: DePuy Ultima TPS femoral stem used in combination with Ultima metal-on-metal articulation.</p>	▶ ①
<p>Problem:</p> <ul style="list-style-type: none"> • Unexplained groin pain. • The need for early revision due to periprosthetic soft tissue necrosis. 	▶ ②
<p>Action by: Orthopaedic surgeons.</p>	▶ ③
<p>Action: Refer patients with this implant combination who present with unexplained groin pain for MRI scan. This is in line with the parameters recommended by DePuy (see recommendations for patient management under 'Action' in the appendix). Patients with abnormal signs should be considered for an early revision.</p> <p>Report all revisions of metal-on-metal articulations where corrosion and/or periprosthetic soft tissue reaction are observed to the implant manufacturer and the NIAIC.</p>	▶ ④
<p>Distributed by NIAIC to:</p> <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

DePuy Ultima TPS femoral stem used in combination with Ultima metal-on-metal articulation. These components were only sold in combination in the UK, France and Italy.

2. PROBLEM:

The Ultima TPS femoral stem and Ultima metal-on-metal articulation (femoral head plus metal acetabular cup) is a total hip replacement system that has been on the market in the UK since 1997. The Ultima TPS femoral stem is still available but the Ultima metal-on-metal femoral head and acetabular cup were discontinued in 2005.

Up to April 2007, one UK study has reported 43 revisions (from a cohort of 637 hips) associated with extensive periprosthetic soft tissue necrosis. Some also involved late dislocation or periprosthetic fracture. The revisions were required one to seven years after implantation. There have been no other confirmed reports.

When these stems were explanted, extensive corrosion was observed on the surface of many of them within the area of the cement mantle. This level of corrosion of cemented polished cobalt chromium molybdenum stems has not previously been reported in the orthopaedic literature and the explanation for it is unclear.

DePuy has already communicated this information to UK hospitals that implanted these devices. A copy of their letter, including recommendations for imaging and patient management, is in the appendix.

3. ACTION BY:

Orthopaedic surgeons.

4. ACTION:

Refer patients with this implant combination who present with unexplained groin pain for MRI scan. This is in line with the parameters recommended by DePuy (see recommendations for patient management under 'Action' in the appendix). Patients with abnormal signs should be considered for an early revision.

Report all revisions of metal-on-metal articulations where corrosion and/or periprosthetic soft tissue reaction are observed to the implant manufacturer and the MHRA.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Directors of radiology
- Medical directors
- MR superintendent radiographers
- Orthopaedic surgeons
- Risk managers
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA
- Directors of public health

6. CONTACTS:

Enquires to manufacturer should be addressed to:

Mr Paul Arnott
DePuy International Ltd
Number One
White Rose Office Park
Millshaw Park Lane
Leeds LS11 0EA

Tel: 0113 387 7800

Fax: 0113 387 7890

E-mail: PArnott@dpygb.inj.com

Enquires to NIAIC should quote reference number MDEA(NI)2007/58 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

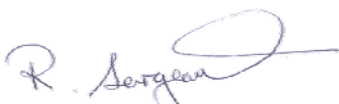
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



Robert Sergeant
NIAIC Operational Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2006/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety



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To all surgeons implanting ULTIMA® TPS femoral stem with the ULTIMA® Metal-on-Metal articulation

8th February 2007

Dear Dr

Re: ULTIMA® TPS femoral stem and ULTIMA® Metal-on-Metal articulation

Our records indicate that you or one of your colleagues has been a past user of the above prosthetic combination of ULTIMA® implants and I would therefore like to draw your attention to the possible adverse performance of this particular combination and action to be taken.

Revision Experience

DePuy is currently aware of a cohort of 637 hips at one centre where 60 revisions (9.4%) at 2 - 9 years follow-up have been required for the Ultima® TPS femoral stem and Ultima® Metal-on-Metal articulation. 21 of these are considered to be "normal" revisions (e.g. for infection, trauma etc.). However, 39 revisions have been associated with extensive periprosthetic soft tissue necrosis, sometimes severe. This represents a failure rate of 3.3% for the revisions exhibiting no reaction and 6.1% for the revisions with a necrotic reaction. Some of these cases with reactions have been associated with late dislocation or peri-prosthetic fracture.

At retrieval, extensive corrosion has been found on the surface of many of the polished stems, within the cement mantle. This level of corrosion has not been reported in the orthopaedic literature before with cobalt chromium molybdenum cemented stems.

Presentation

Patients have presented with the following:

- Groin pain
- Pain with activity and with flexion
- Pain development from intermittent to constant
- Effusion on MRI
- Time to presentation 6 months several years
- Largely normal radiographs (position, migration, cementation, osteolysis)
- Normal inflammatory markers

Action

If you have any patients presenting with groin pain and no obvious explanation, we recommend that the patient be referred for an MRI scan of the peri-prosthetic soft tissue using Metallic Artefact Reduction Sequences (MARS). The MRI should be

performed with spin echo (no spectral fat saturation) and inversion recovery sequences using the maximal bandwidth and matrix size that time will allow.

Artefact will be least in the frequency encoding direction and the selective use of phase and frequency orientation will optimise the imaging of the peri-prosthetic soft tissue. Nearly all symptomatic patients have at least one of a number of abnormalities, including peri-prosthetic inflammatory masses, bone marrow oedema, muscle oedema, and muscle atrophy and avulsion. Patients with abnormal signs should be considered for an early revision, since tissue necrosis may progress rapidly.

BACKGROUND AND INVESTIGATION

The ULTIMA[®] total hip replacement system was introduced in the UK by Johnson & Johnson Orthopaedics in 1987. Implantable components in the system included the ULTIMA[®] TPS modular tapered polished cemented femoral stem and the ULTIMA[®] Metal-on-Metal articulation.

The ULTIMA[®] TPS stem is a tapered polished stem made from wrought cobalt chromium molybdenum alloy. It has been widely implanted in the UK, mainly with the ULTIMA[®] Cemented Cup and Duraloc[®] Cementless Cup to give a metal-on-polyethylene articulation, with excellent results^{1,2,3}.

ULTIMA[®] Metal-on-Metal Articulation

The ULTIMA[®] MOM Cup was a conventional porous coated titanium alloy cementless outer shell with a taper locked cobalt chromium molybdenum liner designed to articulate with a specific superfinished 28mm cobalt chromium molybdenum femoral head. The implant has been discontinued for commercial reasons, having been replaced by the Pinnacle[®] acetabular cup system.

This 28mm MOM bearing was designed after extensive hip simulator testing that investigated diametral clearance, surface roughness, sphericity and metal composition.

The wear properties of the 28mm ULTIMA[®] MOM bearing *in-vivo* were investigated in an independent study by Clarke et al⁴. Serum cobalt and chromium metal ion concentrations for Birmingham Hip Resurfacing components were significantly greater than 28mm ULTIMA[®] MOM THA at a median of 16 months follow-up in a matched pair comparison.

Investigation

An extensive investigation has failed to establish categorically why the ULTIMA[®] TPS tapered polished stem sometimes corrodes in this manner. Cobalt chromium molybdenum alloy is generally considered to be highly corrosion resistant *in-vivo*.

Users of both femoral and acetabular implants at other centres have been contacted, but to date, no others have observed this problem. The clinical performance of the

¹ Shetty NR, Hamer AJ, Kerry RM, et al. Exeter versus Ultima-TPS femoral stem: a randomised early outcomes study. *J Bone Joint Surg* 2006; 88-B Suppl II: 248.

² Downing MR, Ashcroft P, Lawrie D et al. Differing migration patterns of four femoral stems measured using radiostereometric analysis. *J Bone Joint Surg* 2006; 88-B Suppl I: 71.

³ Data on file. 162 TPS stem/Duraloc PE cup cases, 97.4% survival at 7 years.

⁴ Clarke MT, Lee PT, Arora A and Villar RN. Levels of metal ions after small- and large- diameter metal-on-metal hip arthroplasty. *J Bone Joint Surg* 2003; 85B: 913-917.

ULTIMA® TPS stem with metal-on-polyethylene articulations is completely normal. Full details of this problem have been shared with MHRA (Devices).

Following the investigations and retrievals analysis DePuy believes that the necrosis observed at revision is caused by patients reacting to much higher levels of metallic ions than normal in a metal-on-metal articulation, derived principally from the corroded surfaces of the stem, combined with that generated from normal wear of the MOM bearing.

Enquiries

Enquiries regarding this matter should be directed to Paul Arnott, International Vigilance Manager. In accordance with our post marketing surveillance activities, DePuy will continue to monitor the performance of these devices and take any action necessary to ensure patient safety.

Yours sincerely

A handwritten signature in blue ink, appearing to read "Allan Ritchie".

Allan Ritchie MBA, PhD
Vice-President Research & Development