

AN (NI) 2002/04

DATE: 15 May 2002

**For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency**



**HEALTH ESTATES
ESTATE POLICY**

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

**JRI FURLONG MODULAR CEMENTED TOTAL
HIP REPLACEMENT SYSTEM - ATYPICAL
PAIN ASSOCIATED WITH CORROSION OF
THE POLISHED TITANIUM ALLOY FEMORAL
STEM**

MANUFACTURER/SUPPLIER

Joint Replacement Instrumentation Ltd (JRI Ltd)

PROBLEM

Atypical pain in patients implanted with the polished titanium alloy Furlong Modular cemented femoral stem in the absence of overt infection or femoral loosening. Thickening of the femoral cortices, similar to an osteoid osteoma, on X-ray. Corrosion observed in the retrieved femoral stems.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Nurse Directors
- Directors of Orthopaedic Surgery
- Orthopaedic Surgeons
- Pain Clinics
- Rheumatologists
- Operating Theatre Managers
- Consultants in Rehabilitation Medicine
- Gerontologists
- Nurse-led orthopaedic clinics
- Physiotherapists (Acute and Community)
- General Medical Practitioners

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

Clinicians should:

- be aware of this problem;
- consider the need for implant revision for patients who complain of persistent and severe atypical pain in the absence of overt infection or femoral loosening. The onset of such symptoms may occur a number of years post-operatively;
- inform NIAIC of any such cases with this or other cemented hip implants produced by any manufacturer.

Increased follow up of asymptomatic patients implanted with this device is not recommended at this stage in view of the low incidence of failure.

ADVICE

NOTICE

BACKGROUND

1. The JRI Furlong Modular cemented total hip replacement system was launched in 1979 with a monobloc (one piece) matt finished titanium alloy straight stem. In 1987 JRI changed the stem configuration from monobloc to modular and in 1989 they changed the surface finish of the stem from matt to polished. JRI extended the product range to include the option of a polished conventional stainless steel stem in 1992; a polished high nitrogen stainless steel stem was added to the range in mid-2001.
2. NIAIC has been informed by the Medical Devices Agency (MDA) that they are currently aware of twenty-eight revisions due to pain in nine UK centres where corrosion was confirmed in the polished titanium alloy femoral stem. This represents a confirmed failure rate of 0.14%. MDA is aware of eight further possible cases, of which five are considered by the clinicians involved to have resolved without the need for further surgery.
3. Severe atypical pain at 2-5 years post-implantation, which may be relieved upon movement, is the most common clinical symptom. Thickening of the femoral cortices, which may appear similar to an osteoid osteoma, may be seen on X-ray. Corrosion has been seen along the full length of the explanted stems, but in some cases it is focussed on the distal half of the stem.
4. Extensive testing in five independent biomaterials laboratories has failed to establish categorically why the polished titanium alloy JRI Furlong Modular femoral stem sometimes corrodes in this manner. Titanium alloy is generally considered to be highly corrosion resistant *in-vivo*.
5. MDA is not aware of any cases of corrosion in the original matt finished titanium alloy stem or in either of the stainless steel variants.
6. JRI carried out a survey in 1998 and circulated a letter in 1999 to inform some orthopaedic surgeons of this problem. Since then the number of reported cases has continued to increase. Consequently, NIAIC wishes to ensure that the wide range of clinicians to whom these patients may present are aware of this problem.
7. The orthopaedic literature^{1,2,3} describes sporadic cases of corrosion of other models of polished and unpolished cemented titanium alloy hip implants. However, the polished Furlong Modular cemented stem is the only titanium alloy hip implant reported to MDA as repeatedly exhibiting this problem in the UK.

Literature

1. H-G Willert *et al.* Clinical Orthopaedics and Related Research 1996; 333; 51-73.
2. E Schöll *et al.* Journal of Arthroplasty 2000; 15; 5; 570-575.
3. BF Shahgaldi *et al.* Journal of Bone and Joint Surgery Volume 82-B 2000 Orthopaedic Proceedings Supplement II, 122

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Brian P Jones BA MSc, Director of Scientific Research, Joint Replacement Instrumentation Ltd, 8 Broadstone Place, London W1U 7EP, Tel: 020 7436 1919
Fax: 020 7224 2862

Enquires to the NIAIC should quote the reference number AN (NI) 2002/04 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US, Tel: 02890 523714
Fax: 02890 523900, Email: brian.godfrey@dhsspsni.gov.uk
Brian Godfrey
NIAIC 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 Safety Notice SN (NI) 2002/01. 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

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhíslí Sóisialta agus Sábháilteacht Phoiblí*



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