

AN (NI) 2002/03

DATE: 09 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:

**SCREW-FIT CERAMIC TOE JOINT
(METATARSOPHALANGEAL)
REPLACEMENT PROSTHESIS**

MANUFACTURER/SUPPLIER

Moje Ceramic Implants/Orthosonics Ltd

PROBLEM

Poor clinical performance of screw-fit ceramic toe prosthesis.

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
- Orthopaedic Surgeons
- Medical Directors
- Theatre Managers
- Nurse Directors
- Nurses in Charge – Orthopaedic Theatres
- Clinical Directors of Orthopaedics

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

- Do not implant screw-fit Moje ceramic toe prostheses.
- Isolate any remaining stocks of Moje screw-fit ceramic toe prostheses and return them to the UK distributor.
- Identify patients who have received Moje screw-fit ceramic toe prostheses.
- Where the identified patients are not currently undergoing regular review, recall them for clinical and radiological assessment.
- Report any cases of revision of Moje screw-fit ceramic toe prostheses to NIAIC and the UK distributor.

BACKGROUND

The Moje screw-fit ceramic toe prosthesis was manufactured by Moje Ceramic Implants and distributed in the UK by Orthosonics Ltd. between June 1999 and August 2000. The screw-fit prosthesis consists of two ceramic components fixed distally and proximally at the metatars-ophalangeal joint by a 'screw in screw' technique whereby a titanium locking screw is inserted through the centre of the ceramic articulating component into a pre-placed countersunk titanium bone screw. Screw-fit components have not been supplied by the UK distributor since August 2000.

To simplify the surgical technique and prevent metallosis resulting from loosening of the titanium screws, a press-fit version of the ceramic toe prosthesis was developed by the manufacturer. The press-fit prosthesis was first placed on the market in December 1999 and is not affected by this Advice Notice.

ADVICE

NOTICE



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Between 1999 and 2000, a total of 149 Moje screw-fit ceramic toe prostheses were distributed within the UK. Orthopaedic surgeons in the UK have reported 10 cases of loosening of screw-fit components at the distal/proximal bone screw or locking screw, up to 2 years after implantation. In most instances loose screw-fit components were revised to press-fit components but in some cases an arthrodesis was required. In the UK, loosening of Moje screw-fit ceramic toe components has in some cases been reported to be accompanied by pain, poor bone integration with the ceramic components, bone erosion, bone re-absorption and/or metallosis. Clinical and radiological review is therefore recommended to identify those patients that may require further surgical intervention.

In all cases the benefit of radiographic examination should be weighed against the risks from radiation exposure on an individual patient basis, in line with the requirements of IR(ME)R 2000¹.

Reference

¹ SI 2000 No 1059. The Ionising Radiation (Medical Exposure) Regulations 2000.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Mrs Nikki Palfrey
Orthosonics Ltd
Bremridge House
Bremridge
Ashburton
Devon TQ13 7JX

Tel: 01364 652426
Fax: 01364 653589

Enquires to the NIAIC should quote the reference number AN (NI) 2002/03 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US
Marked for the attention of Mr Brian Godfrey

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

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