

AN (NI) 2001/05

DATE: 20 August 2001

**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:

**Recall of Specified Batches of Zirconia Ceramic
Femoral Heads for Use in Hip Replacements**

MANUFACTURER/SUPPLIER

Biomet Merck Ltd
DePuy International Ltd
Smith and Nephew Ltd
Stryker Howmedica Osteonics
Zimmer Ltd

PROBLEM

The above manufacturers are recalling some batches of unimplanted zirconic ceramic femoral heads due to increased rates of head fracture.

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
- Nursing Directors
- Trust Pharmacy Managers
- Supplies Staff
- Theatre Managers
- Orthopaedic Surgeons
- Directors of Orthopaedic Surgery
- Private Hospitals and Clinics
- 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 and Private Hospitals and Clinics.

IMMEDIATE ACTION

- Do Not implant zirconia ceramic femoral heads supplied by the above manufacturers until the relevant manufacturer has confirmed which products are affected by the recall;
- Return product affected by the recall to the relevant manufacturer.
- Inform NIAIC of any case of zirconia ceramic femoral head fracture.

Increased follow up of implanted patients as a response to this issue is not recommended at this stage as there is no predictive test to determine if a zirconia ceramic femoral head will fracture.

ADVISE

NOTICE

BACKGROUND

The French Health Authorities have advised the Medical Devices Agency (MDA) of 61 reports (all outside the UK), of fracture of zirconia ceramic femoral heads manufactured by St Gobain Advanced Ceramics Desmarquest (St Gobain). The problem is believed to be due to a change in manufacturing technique in 1998, the failure rate of products made since then is around 0.03%.

St Gobain have supplied the affected zirconia ceramic heads to five orthopaedic manufacturers supplying UK hospitals. These manufacturers are recalling affected products and have issued advice to hospitals in receipt of these products. MDA and DHSSPS supports this action and recommends that zirconia ceramic femoral heads supplied by these manufacturers should not be implanted until the manufacturer has confirmed which products are affected by the recall.

This notice does not affect zirconia ceramic heads supplied by other manufacturers or any alumina ceramic femoral heads.

Fracture of zirconia ceramic heads leads to pain, immobility and the need for a revision operation. Patients experiencing such a fracture will therefore present to their orthopaedic team. There is no predictive test to determine whether any particular zirconia ceramic head will fail. As the failure rate is low, MDA is not advising elective revision surgery at this time; the recall is confined to non-implanted stock.

Details of the affected product batches is available from the relevant manufacturer (see the details below).

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Bernard Cope,
Biomet Merck Ltd,
Waterton Industrial
Estate,
Bridgend,
CF31 3XA
Tel: 01656 655221
Fax: 01656 645454

Paul Arnott,
DePuy
International Ltd,
St Anthony's
Road,
Leeds.
LS11 8DT
Tel: 0113 270 0461
Fax: 0113 272
4101

Dr M Eyre,
Smith and Nephew
Healthcare,
Healthcare House,
Goulton Street,
Hull.
HU3 4DJ
Tel: 01482 673620
Fax: 01482 22211

Maria Giansoldati,
Stryker
Howmedica
Osteonics,
Stryker House,
Hambridge Road,
Newbury,
Berkshire.
RG14 5EG
Tel: 01635 262400
Fax: 01635 580300

Ann Matlock,
Zimmer Ltd,
The Courtyard,
Lancaster Place,
South Marston
Park,
Swindon
SN3 4FP
Tel: 01793 584578
Fax: 01793 585636

Enquires to the NIAIC should quote the reference number AN (NI) 2001/05 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) 2001/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

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



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