MHRA

Medicines and Healthcare products Regulatory Agency

Safeguarding public health

Medical Device **ALERT**

Ref. MDA/2004/011
Issued: 2 March 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	

	Further Information
DEVICE: ABG I Uncemented Acetabular Cups for Total Hip Replacement	*
PROBLEM: Cup wear and asymptomatic acetabular osteolysis.	*
ACTION BY: Staff involved in the treatment and management of patients with joint replacement implants.	
ACTION: • Identify patients who have received ABG I acetabular cups. • Where the identified patients are already undergoing annual review, including radiographic examination, continue to monitor their progress. • Where the identified patients are not currently undergoing annual review, recall them for clinical assessment, including radiographic examination, on an annual basis. • Radiographic examination should include both A-P and lateral X-rays. Look for evidence of acetabular osteolysis. Where the extent of osteolysis, if present, is unclear from X-rays, consider further investigation using CT.	
DISTRIBUTED to: NHS Trusts (England) – Chief Executives National Care Standards Commission – Headquarters Primary Care Trusts (England) – Chief Executives	*
CONTACTS: Details of distributor contacts, MHRA contacts for technical and clinical aspects. Change of address or removal from address list for services registered under the Care Standards Act 2000.	*
FEEDBACK REQUIREMENTS: Report all cases where ABG I cups have been revised or have been identified as needing revision to MHRA and to Stryker UK.	

* **Further information supplied in the following pages.**

DEVICE:

Approximately 3200 ABG I acetabular cups manufactured by Benoist Girard and distributed by Howmedica International Ltd (both part of Pfizer Medical Technology Group) from 1990 until 4th December 1998 and 61 ABG I acetabular cups distributed by Stryker UK Ltd from 5th December 1998 until 2000, including all of the following components:

- ABG I acetabular shells, catalogue number 4840-00XX
- ABG I acetabular cup liners, catalogue numbers 4840-YYXX and 4841-YYXX

(where XX and YY correspond to the outer and inner diameters in millimetres).

ABG II cups are <u>not</u> affected by this Medical Device Alert. See Appendix for further details.

PROBLEM:

Six hospitals in the UK have informed MHRA of poor results and high revision rates associated with ABG I acetabular cups. Failure modes reported to date include:

- increased wear of the ultra-high molecular weight polyethylene (UHMWPE) acetabular cup liner
- severe, asymptomatic peri-acetabular osteolysis
- cup loosening which in severe cases has led to cup migration into the pelvis.

MHRA is also aware of two UK clinical centres with 'Kaplan Meier survivorship curves' demonstrating ABG I cup survivorship of 90+% at ten years, i.e. less than 10% of the acetabular cups had been revised after ten years. The Scandinavian Joint Registries report similar results associated with this product. Currently available worldwide literature reports both good and poor ABG I cup performance.

MHRA, in co-operation with Stryker UK, has co-ordinated a detailed audit of clinical notes and X-rays at three UK hospitals (two reporting poor results and one reporting good results) to determine the reasons for the mixed performance in the UK. Using two orthopaedic experts' opinion that a cup should 'definitely' or 'probably' be revised as an endpoint, the implant survivorship for all 340 of the ABG I cups reviewed during this audit was 100% at three years and 82.5% at ten years. No one factor could be identified as the initiating factor for higher than anticipated polyethylene wear and poor cup performance (see Appendix for further details).

Although the reason for the variation in performance of ABG I cups is unclear, the MHRA audit demonstrated that unacceptable revision rates have been observed at some UK clinical centres. As the failure mode is asymptomatic, MHRA recommends that all patients implanted with ABG I cups are identified and, where necessary, recalled for clinical and radiological review. All patients with ABG I cups should be reviewed regularly to ensure patients requiring revision are identified at the earliest opportunity. In all cases the benefit of radiographic examination should be weighed against the risks from radiation exposure on an individual basis, in line with the requirements of IR(ME)R 2000[1].

This Medical Device Alert has been distributed to GPs for information, in the event that any of their patients have received an ABG I acetabular cup.

References

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

DISTRIBUTION:

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

TRUSTS to:

- Liaison officers (for onward distribution)
- Clinical governance leads
- Directors of orthopaedics
- Medical directors
- Nursing executive directors
- Orthopaedic surgeons
- Orthopaedic wards and outpatient departments
- Physiotherapists
- Risk managers
- Theatre managers

NATIONAL CARE STANDARDS COMMISSION to:

- Headquarters (for onward distribution)
- Hospitals in the independent sector

PRIMARY CARE TRUSTS to:

- Liaison officers (for onward distribution)
- Directors of public health
- General medical practitioners (for information only)

CONTACTS:

Stryker UK has set up an information line to respond to queries from patients, hospitals and clinicians. All queries for either Stryker UK or Pfizer should therefore be addressed to:

ABG I Cup Information Line

Tel: 0845 600 9682
Fax: 0161 931 5614

Enquiries to the MHRA should quote reference number **20020417.012-4** and be addressed to:

Technical aspects:
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Change of address or removal from list for services registered under the Care Standards Act 2000.
NCSC Customer Service Unit
St Nicholas Building
St Nicholas Street
Newcastle-upon-Tyne
NE1 1NB

Tel: 0191 233 3556

E-mail: enquiries@ncsc.gsi.gov.uk

Appendix to MDA/2004/011

Background Information

1. Distribution of the ABG I Cup in the UK

The uncemented ABG I modular hip system was manufactured by Benoist Girard and distributed by Howmedica International Ltd (both part of Pfizer Medical Technology Group) until 4th December 1998 and was distributed by Stryker UK after 4th December 1998. The ABG I system was first placed on the UK market in October 1990 by Howmedica International Ltd. and was gradually replaced by the ABG II hip system after 1995. ABG I acetabular shells were last sold in the UK in 2000. Approximately 3260 ABG I acetabular cups were distributed to approximately 100 hospitals in the UK between 1990 and 2000.

ABG I cup liners were sterilized using γ–irradiation in air until the late 1990s. ABG I cup liners sterilized in an inert environment are still available for use in revision surgery where the acetabular shell is still well fixed but the cup liner is worn.

ABG II cups are not affected by this Medical Device Alert. ABG II components can be identified as follows:

- ABG II acetabular shells, catalogue numbers 4840-10XX, 4840-20XX
- ABG II acetabular cup liners, catalogue numbers 4842-YYXX, 4843-YYXX, 4844-YYXX, 4845-YYXX

where XX and YY correspond to the outer and inner diameters in millimetres.

2. Incidents reported to MHRA

MHRA has received reports of asymptomatic acetabular osteolysis associated with the ABG I cup from six clinical centres and of two cases of cup migration into the pelvis. Cup migration may require major reconstructive surgery; where there is extensive osteolysis, revision surgery is more difficult.

3. Clinical Audit of three ABG I Implanting Centres in the UK

MHRA, in co-operation with Stryker UK and two orthopaedic experts completed a detailed audit of clinical notes and X-rays at two UK hospitals reporting poor results and one UK hospital reporting good results with the ABG I cup. 340 ABG I cups were reviewed in total during this process.

Using the experts' opinion that a cup should 'definitely' or 'probably' be revised as an endpoint, the cumulative survivorship for ABG I cups at all three centres combined was 100% at three years and 82.5% at ten years. For the centres individually, the cumulative implant survivorships were 63.9, 70.9 and 93.8% at ten years. The average patient age at implantation for all three centres was 52 years (range 22 to 71 years).

It was the opinion of the orthopaedic experts that thresholds for actual revision at each centre were appropriate and that surgical technique had not in their view contributed to the failure rates where poor cup performance was reported.

An in-depth statistical analysis of the effect of various surgeon, patient and implant related variables on the performance of the 340 ABG I cups reviewed was undertaken. Variables evaluated included implanting surgeon, patient age/gender, use of zirconia femoral heads, cup size, and time between sterilization and implantation of the UHMWPE cup liner. Where high polyethylene wear and/or acetabular osteolysis were observed, the cause appears to be multifactorial; no one factor could be identified as the primary cause of poor cup performance.