

Medical Device Alert

Action

Ref: MDA/2009/046 Issued: 20 July 2009 at 14:30

Device

Modular knee/hip replacement systems.
MRS Cemented Stems manufactured by Stryker Orthopaedics.
Specific lots.

Problem

Small diameter stems (8, 9 or 10 mm) may have been incorrectly implanted in the proximal femur and be at risk of fracture.

Action by

- Orthopaedic surgeons.
- Staff in orthopaedic theatres.
- Staff in orthopaedic clinics.

CAS deadlines

Action underway: 03 August 2009
Action complete: 01 September 2009

Action

Review hospital records to identify patients who have had 8, 9 or 10 mm MRS Cemented Stems implanted in the proximal femur.

Consider the need to:

- advise the patient of the additional risk of stem fracture
- advise the patient, particularly if heavier or more active, to avoid excessive impact loading of the affected limb if possible
- offer the patient annual clinical and radiological follow-up where appropriate. For additional radiological examination the benefit should be weighed against the risks from radiation exposure on an individual basis, in line with the requirements of IR(ME)R 2000*
- advise the patient to report any pain or other symptoms as soon as possible.

* SI 2000 No 1769. The Ionising Radiation (Medical Exposure) Regulations 2000.

Contact

Manufacturer/supplier

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[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON051932)

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