

Medical Device Alert

Action

Ref: MDA/2009/062 Issued: 14 October 2009 at 11:30

Device

Knee replacement implant.
PFC Sigma cruciate retaining
non-porous size 5 left femoral
component (part number 960005)
manufactured by DePuy International
Limited. Specific lots.



Problem

A manufacturing defect on the posterior chamfer region may result in fracture of the device.

Action by

Orthopaedic surgeons, orthopaedic departments, and staff involved in the treatment and management of patients with knee joint replacement implants.

CAS deadlines

Action underway: 10 November 2009
Action complete: 13 January 2010

Action

- Identify patients implanted with affected devices.
- Consider undertaking clinical assessment of affected patients.
- Consider informing affected patients and their GPs of this problem.

Contact

Manufacturer/supplier

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DePuy International Limited

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[Link to full Medical Device Alert](http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON059912)

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