

## **Urgent Field Safety Notice (FSN)**

**Product Name:** PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral

**FSCA-identifier:** DVA-108564-HHE

**Type of Action:** Field Safety Corrective Action (Recall)

**Date:** Jan 2014

**Attention:** Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

**Type of device:** PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral

**Model names:** PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral

**Part Numbers:** 960015

**Lot #'s affected:** 7806934

DePuy Orthopaedics, Inc. is issuing a voluntary device recall of the PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral Part number: 960015, Lot number: 7806934 because of a possibility that they were manufactured in such a way that could adversely affect material microstructure, leading to decreased strength and a greater risk of device fracture under what would be normally acceptable loads.

### **Reason for Recall**

Due to the manufacturing method employed, there may be the potential for blocky carbides to have formed on the grain boundaries, which could potentially result in a reduction in material properties due to this type of microstructure. This could possibly affect the mechanical performance of the product; therefore a recall is being issued.

### **Depth of Device Correction**

This recall affects Part Number 960015 and Lot Number 7806934



**Clinical Implications**

DePuy Orthopaedics, Inc. believes there are three possible clinical scenarios:

- Little or no impact on clinical performance
- A crack may develop and propagate rapidly with fracture: the patient would likely present with pain, swelling and mechanical symptoms
- A crack may develop and propagate more slowly without fracture: patient would likely present with progressively worsening poly wear, stiffness, pain and swelling

DePuy Orthopaedics, Inc. is not recommending prophylactic revision in the absence of symptoms. We recommend that the surgeon communicate with any patients who have received an affected component and share information regarding any potential clinical implications and risks. Sharing this information will allow the surgeon to make the patient aware of potential symptoms, and to discuss follow up arrangements.

**Transmission of this Field Safety Notice:**

This notice has been sent to you as records indicate that your organization/hospital has received the PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral of the affected part and lot number.

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.

To confirm receipt of this FSN please complete and return the acknowledgement in Appendix A.

For any enquiries about the *PFC® SIGMA Cruciate Retaining (CR) Cemented Femoral* contact:

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This FSN has been notified to the appropriate Regulatory Agency.

Sincerely,



WW VP Medical Affairs