

## **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

