Class 2 Device Recall PFC SIGMA Cruciate Retaining (CR); Cemented Femoral devices[6]

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Class 2 Recall
PFC SIGMA Cruciate Retaining (CR); Cemented Femoral devices

See Related Information[21]

Date Posted	February 24, 2014
Recall Status[1]	Open
Recall Number	Z-1077-2014
Recall Event ID	67159[22]
Product	PFC® SIGMA Cruciate Retaining (CR); Cemented Femoral devices; (Size 5/RT) Used during primary total knee arthroplasty to improve patient mobility.
Code Information	Catalog Number 960015 Lot Numbers 7810268 and 7806929 (US) Lot Number 7806934 (OUS)
Recalling Firm/ Manufacturer	DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw, Indiana 46582-3994
For Additional Information Contact	Mindy Tinsley 574-372-7136
Manufacturer Reason for Recall	PFC¿ SIGMA Cruciate Retaining (CR) Cemented Femoral devices, product 960015, lots 7810268 and 7806929, were found to have anomalous microstructure. Due to the manufacturing method employed, there may be the potential for increased levels of porosity, as well as blocky grain boundary carbides in the microstructure when compared to parts manufactured under the current accepted and validated protoc
Action	The recall is extended to the DePuy Distributor, Hospital, and Surgeon levels. The two affected distributors were contacted by telephone. Written communication to the two hospitals and one surgeon who received the devices will be delivered by DePuy Orthopaedics, Inc. via email or regular mail. The one affected surgeon will also be contacted by telephone by the Medical Safety Officer and a metallurgist, who will discuss the surgeon communication with the surgeon. The sales representatives aid customers in the affected device returns, as needed. The devices will be returned through the normal DePuy Returns process, to attention of Returns and marking H13-30C on the outside of the box. All (21) remaining devices have been verified as being returned and in quarantine. Effectiveness will be determined by product reconciliation, receipt of all hospital reconciliation forms, and receipt of international declaration from the International Affiliate. DePuy will follow-up with the affected hospitals until all hospital reconciliation forms are returned, and DePuy will follow-up with the International Affiliate until all international actions are complete and the international declaration is completed and return.
Quantity in Commerce	2
Distribution	Worldwide Distribution-USA including the states of IA, CA, KY, and FL, and the countries of Finland, Germany, Sweden, and Czech Republic.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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