Class I Medical Device Recall: DePuy Orthopaedics, Inc. - LPS Diaphyseal Sleeve

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: February 15, 2013

Product: LPS (Limb Preservation System) Diaphyseal Sleeve

Manufacturing and Distribution Dates: 2008 to July 20, 2012

Product Codes and Lot Numbers:

Part #	Lot #
1987-20-018	ALL
1987-20-020	ALL
1987-20-024	ALL
1987-20-028	ALL

Use: The LPS Diaphyseal Sleeve is intended for use with the LPS System which is an end-stage revision knee product that allows surgeons to reconstruct severe soft tissue and bony defects. The diaphyseal sleeve is intended to enhance the fit and fill of the diaphyseal femoral canal with femoral and tibial replacements.

Recalling Firm:
DePuy Orthopaedic, Inc
700 Orthopaedic Drive
Warsaw, IN 46581

Reason for Recall:
The LPS Diaphyseal Sleeve to Diaphyseal Sleeve Base taper connection may not be sufficient to accommodate potential physiologic loads that may be transferred to the junction during normal gait activities by some patients. This may result in fracture of the sleeve at the taper joint which may also lead to loss of function or loss of limb, infection, compromised soft tissue or death.

Public Contact: Questions should be directed to DePuy Orthopaedics at 574-372-7136.

FDA District: Detroit

FDA Comments:
On Jan. 4, 2013, DePuy issued an Urgent Medical Device Recall informing hospitals and surgeons of the problem and to immediately stop distributing or using the

recalled lots. If a medical facility has the affected product in stock, it should be returned to DePuy.

DePuy is not recommending revision or additional follow up in the absence of symptoms of patients with this implanted device. However, DePuy is encouraging surgeons to communicate with patients who received these implants and discuss the risks of the implant fracture and the method for detecting implant failure if the patient begins experiencing symptoms.

The FDA has received a total of 10 reports (6 fractures and 4 reports of loosening that may or may not be attributed to the same device design issue) of incidents in which the device has malfunctioned.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

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http://www.mdtmag.com/news/2013/02/class-i-medical-device-recall-depuy-orthopaedics-inc-lps-diaphyseal-sleeve

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm