U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Safety

DePuy Orthopaedics LPS Diaphyseal Sleeve: Class I Recall - Taper Connection May Not Accommodate Physiologic Loads

[Posted 02/22/2013]

AUDIENCE: Orthopedics, Surgery, Risk Manager

ISSUE: FDA notified healthcare professionals of a Class I recall of the LPS Diaphyseal Sleeve. 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.

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.

The affected devices were manufactured from 2008 to July 20, 2012. See the Recall notice for a list of affected product codes and lot numbers.

BACKGROUND: 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.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm[1]
- Download form[2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/22/2013 - Recall Notice[3] - FDA]

Page Last Updated: 02/22/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. http://www.fda.gov/MedWatch/report.htm
2. /Safety/MedWatch/HowToReport/DownloadForms/default.htm
3. /MedicalDevices/Safety/ListofRecalls/ucm340708.htm