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رقم المحفوظات: ٣٨/٤٥
رقم الصادر: ١٢/١/٤١١٣
بيروت، في: ٢٤ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
LPS Diaphyseal Sleeves

الجهاز المعني بالمتابعة:

- LPS Diaphyseal Sleeves
- Trade Mark: Depuy Orthopaedics, Inc
- Local Representative:

بناء على التقرير الصادر عن وكالة ال FDA
والتوصية الصادرة عن الشركة المصنعة، والتي تشير الى احتمال حدوث عطل في الجهاز مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:
- التقرير الصادر عن وكالة ال FDA

يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

Class 1 Recall
LPS Diaphyseal Sleeves

See Related Information 20

Date Posted	February 15, 2013
Recall Number	Z-0830-2013
Product	LPS Diaphyseal Sleeves Product Usage: The LPS Diaphyseal Sleeves are used with the LPS System which is an end-stage revision knee product that allows surgeons to reconstruct severe soft tissue and bony defects.
Code Information	Part number: 198720024 and Lot numbers: 113812, 123509, 140578, 156210, 171659, 171660, 171661, 171662, 171663, 123509A, B34GE1000, B34GEA000, B4EGR1000, B4EGRA000, B4EGRB000, B4XFL1000, B4XFLA000, B5SH11000, B5SH1A000, B5SH1B, C74J11000, D14KG1000, E4RF21000, EN8CY1000, EN8CYA000, FC1MB1, and FC1MBA.
Recalling Firm/ Manufacturer	DePuy Orthopaedics, Inc. 700 Orthopaedic Dr Warsaw, Indiana 46582-3994
For Additional Information Contact	Mindy Tinsley 574-372-7136
Reason for Recall	DePuy Orthopaedics is initiating a voluntary recall of the LPS Diaphyseal sleeve because the product has the potential for fracture at the taper junction. 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.
Action	DePuy Othopaedics sent an Urgent Information Medical Device Recall Notice letter dated January 4, 2013 to all affected customers. The letter identified the affected products, reason for recall, clinical implications and actions to be taken. The letter instructed customers to check inventory, discontinue use, cease further distribution and return all inventory on hand for credit. Customers were requested to complete and return the Reconciliation Form. For product-related questions contact your local DePuy Othopaedics Sales Representative, clinical questions contact DePuy's Scientific Information Office at 1-888-554-2482 and recall notice information call 574-372-7333.
Quantity in Commerce	162 total units (US) and 102 units total (OUS)
Distribution	Worldwide Distribution - US Nationwide in the states of AL, AZ, CA, CO, FL, GA, ID, IL, MA, MD, MI, MN, NC, NM, NV, NY, OH, PA, SC, SD, TN, TX, VA, WA, WI, and WV and the countries of Holland, Australia, Austria, South Africa and Canada including Veteran Administration hospitals.

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