REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨/ص
رقم الصادر: ١٢/١/ص٩٤٤
بيروت، في: ٥ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Connecting Bolt Trauma Fixation Systems, Phoenix Retrograde Femoral Nail

الجهاز المعني بالمتابعة:

- Connecting Bolt Trauma Fixation Systems, Phoenix Retrograde Femoral Nail
- Trade Mark: Biomet Inc
- Local Representative: Biomedic

بناء على التقرير الصادر عن وكالة ال FDA
والذي يشير الى وجود خلل في عمل الصنف المذكور أعلاه، 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

Museum Street - Hussein Mansour Bldg. - Beirut, Lebanon Tel: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb

Class 2 Recall
Phoenix Retrograde Femoral Nail

Date Posted	June 15, 2013
Recall Number	Z-1547-2013
Product	Biomet Trauma Phoenix Retrograde Femoral Connecting Bolt Trauma Fixation Systems. Product Usage: The Phoenix Retrograde Femoral Nail is indicated for alignment, stabilization, and fixation of fractures caused by trauma or disease and the fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.
Code Information	Catalog number: 14-442021 and lot number:757910
Recalling Firm/ Manufacturer	Biomet, Inc. 56 E Bell Dr Warsaw, Indiana 46582-6989
For Additional Information Contact	Audrey Daenzer 574-267-6639 Ext. 1676
Reason for Recall	Biomet Trauma ("Biomet") has initiated a recall of Retrograde Femoral Connecting Bolt, which involves Part Number 14-442021. The connecting bolt has an undersized diameter specification that may cause an interference fit with the 4mm hex driver (Part Number: 41024) near the edge of the tolerance. If the 4mm hex driver becomes stuck in the connecting bolt it cannot be taken apart and a delay in su
Action	Biomet sent an URGENT MEDICAL DEVICE RECALL notification letter dated April 29, 2013 to all affected customers. The letter identifed the affected product, problem and actions to be taken. The letter instructed customers to: immediately locate and remove the identified affected device (s), carefully follow the instructions on the enclosed "FAX Back Response Form", fax a copy of the Response Form to 574-372-1683 prior to return of product, use priority carrier for your shipment, if you have further distributed this product, you MUST notify hospital personnel of this action via the enclosed "Dear O.R. Manager" notice. For questions call 574-372-1570.
Quantity in Commerce	75
Distribution	Worldwide Distribution - USA Nationwide: CA, TX, NY, PA, NJ, FL, OH, MI, CO, SD, IN, MT, GA, and WI. and the countries of Netherlands, Costa Rica, Japan, and San Juan.

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ../cfPMN/pmn.cfm
8. ../cfRL/rl.cfm
9. ../cfMAUDE/TextSearch.cfm
10. ../cfRES/res.cfm
11. ../cfPMA/pma.cfm
12. ../cfPCD/classification.cfm
13. ../cfStandards/search.cfm
14. ../cfCFR/CFRSearch.cfm
15. ../cfPCD_RH/classification.cfm
16. ../cfAssem/assembler.cfm
17. ../Medsun/searchReportText.cfm
18. ../cfClia/Search.cfm
19. ../cfTPLC/tplc.cfm
20. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/relateditems.cfm?page_title=medical%20device%20recalls&item1_text=medical%20device%20recalls%20&item1_url=www.fda.gov/medicaldevices/safety/recallscorrectionsremovals/listofrecalls/default.htm&item2_text=fda%