الموضوع: إشعار بمتابة جهاز طبي مغروس

Connecting Bolt Trauma Fixation Systems, Phoenix Retrograde Femoral Nail

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

FDA

بناء على التقرير الصادر عن وكالة FDA والذي يشير إلى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

المرفق:

FDA التقرير الصادر عن وكالة FDA

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفظة

مدير عام الصنف

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Class 2 Recall
Phoenix Retracto Femoral Nail

Date Posted: June 15, 2013
Recall Number: Z-1547-2013

Product: Bionet Trauma Phoenix Retracto Femoral Connecting Bolt Trauma Fixation Systems. Product Usage: The Phoenix Retracto 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: 14440201 and lot number: 757910.

Recalling Firm/Manufacturer: Bionet, Inc., 56 E. Bell Dr, Warsaw, Indiana 46561-6589.

For Additional Information Contact: Audrey Doenier, 574-267-9639 Ext. 1676.

Reason for Recall: Bionet Trauma ("Bionet") has initiated a recall of Retracto Femoral Connecting Bolt, which involves Part Number 14440201. 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 use.

Action: Bionet sent an URGENT MEDICAL DEVICE RECALL notification dated April 29, 2013 in all affected customers. The letter identified 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 574-372-1663 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 H.R. Manager" notice. For questions call 574-372-1576.

Quantity in Commerce: 75

Distribution: Worldwide Distribution - USA Nationwide CA, TX, NY, PA, NJ, FL, OH, MI, CO, SD, IN, TX, GA, and WI, and the countries of Netherlands, Costa Rica, Japan, and San Juan.

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