



رقم المحفوظات: ٢٨١٢٥
رقم الصادر: ١٣١/١٤٥٦٧
بيروت، في: ٢٧ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Screw fixation system, Biomet Spine Polaris 5.5 Button Lock
screw Inserter

الجهاز المعني بالمتابعة:

- Screw fixation system, Biomet Spine Polaris 5.5 Button Lock screw Inserter
- Trade Mark: Ebi, Llc
- Local Representative: Biomedic

بناء على التقرير الصادر عن وكالة ال FDA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور اعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطا:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
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مدير عام الصحة
د. وليد عمار

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Medical & Radiation Emitting Device Recalls

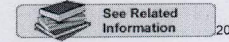


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**Class 2 Recall
Biomet Spine Polaris 5.5 Button
Lock Screw Inserter.**



Date Posted	March 15, 2013
Recall Number	Z-0954-2013
Product	Biomet Spine Polaris 5.5 Button Lock Screw Inserter. Catalog Number 14-500178. The Polaris Spinal System is a non-cervical, pedicle screw spinal fixation device.
Code Information	Catalog Number 14-500178. Lot numbers: 543619, 543853, 543853-1, 543853-2, 544233, 544234-1, 546613 and 546613-1.
Recalling Firm/ Manufacturer	Ebi, Llc 100 Interpace Pkwy Parsippany, New Jersey 07054-1149
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Mr. David M. Talish 973-299-9300 Ext. 2322
Reason for Recall	Increased risk of failure at the driver tip during screw insertion or removal.
Action	Biomet Spine sent a "Urgent Medical Device Recall" notices dated February 6, 2013, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were instructed to immediately locate and remove affected items from circulation and return affected product to EBI, LLC. Please follow the instructions on the enclosed "FAX Back Response Form," and fax a copy of the Response Form to (973) 257-0232, prior to return of the items. Questions related to this notice should be directed to (973) 299-9300 ex. 2322. Monday through Friday, 8am to 5pm.
Quantity in Commerce	59 units.
Distribution	Nationwide Distribution including the states of AL, IN, MO, NE TN and TX.

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