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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٤٨١٠٥
رقم الصادر: ١٣/١/١٥٦٨٣
بيروت، في: ٩ أيار ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Retractor access system, NexPosure Portal System, placement of posterior spinal fixation implants

الجهاز المعني بالمتابعة:

- Retractor access system, NexPosure Portal System, placement of posterior spinal fixation implants
- Trade Mark: Zimmer Inc
- Local Representative: Intermedic

بناء على التقرير الصادر عن وكالة ال FDA

والذي يشير الى سحب هذا الصنف المذكور اعلاه من الأسواق وعدم استعماله، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

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- دائرة البرامج والمشاريع
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مدير عام الصحة
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U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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Class 2 Recall
NexPosure Portal System

Date Posted	April 01, 2013
Recall Number	Z-1045-2013
Product	Zimmer NexPosure, retractor portals of the NexPosure MIS Access System, Part Numbers or REF numbers: N1830R80-100, N1830R80-090®, N1830R80-080®, N1830R80-070®, N1830R80-060, N1830R50-100, N1830R50-090, N1830R50-080, ® N1830R50-070, N1830R50-060, N1830L80-100, N1830L80-090, N1830L80-080, N1830L80-070, N1830L80-060, N1830L50-100, N1830L50-090, N1830L50-080, N1830L50-070, N1830L50-060, ® N182450-085, N182450-075, N182450-065, N182450-055, N182450-045.® Retractor access system that allows placement of posterior spinal fixation implants.
Code Information	Lot Number 61225572 61664689 61664689 61657007 61657015 61657015 61267745 61267745 61267750 61267750 61267753 61267753 61657016 61657016 61801814 61895685 61657017 61657018 61657018 61267756 61267756 61267759 61267759 61267760 61267760 61267761 61267761 61267761 61267761 61873348 61657019 61657019 61657031 61657031
Recalling Firm/ Manufacturer	Zimmer, Inc. 345 E Main St Warsaw, Indiana 46580-2746
Reason for Recall	Possibility that the inner pouch may be compromised. The product is packaged in two pouches - a sterile inner pouch within an external pouch. NexPosure Retractors contained in a breached inner pouch have an increased risk of contamination (i.e.; loss of product sterility) if proper aseptic technique is not followed when transferring the inner package into the sterile field. Patient infection may o
Action	Consignees were sent on 2/8/13 a Zimmer Spine "Urgent Medical Device Recall" letter dated February 08, 2013. The letter was sent to Surgeons and Facilities using the NexPosure MIS Access System. The letter described the product involved in the recall and the problem. Advised consignees to discontinue the use of the product and to contact their sales representative for removal. A consignee letter dated February 8, 2013 was also sent to Distributors, Sales Representatives, and Distribution Operation Managers Distributing the NexPosure® MIS Access System. The letter contained instructions if they had the affected product or not and the steps to follow.
Quantity In Commerce	58
Distribution	Nationwide Distribution including the states of AZ, CO, DE, FL, ID, LMA, MI, NH, NJ, NM, PA, RI, TX, and VA.

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