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الجمهوريـــة اللبنـــانيـــة

وزارة الصحـة العامـة

المديـر العـــام

رقم المحفوظات:

رقـم الصادر :

بيـروت، في : ١٠ شباط ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Nails, Bone, Trochar Scalpel Instruments

الجهاز المعني بالمتابعة:
- Nails, Bone, Trochar Scalpel Instruments
- Trade Mark: OrthoPediatrics Corp
- Local Representative:

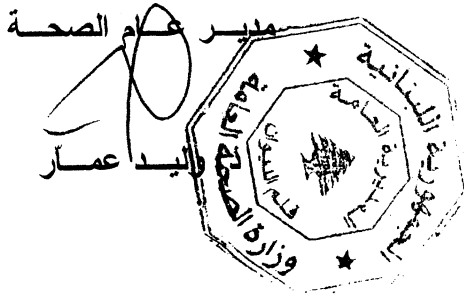بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى عدم مطابقة الصنف المذكور اعلاه للمواصفات المطلوبة، نرجو مـنكم تعمـيم هـذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

– دائرة البرامج والمشاريع

– المستشفيات الحكومية

– المحفوظات

مديـر عـام الصحـة

الـيـد عمـار

U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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Class 2 Recall
Trochar Scalpel Instrument
(Surgical Punch)

Date Posted	November 05, 2012
Recall Number	Z-0207-2013
Product	Trochar Scalpel Instrument (Surgical Punch) OrthoPediatrics intramedullary rods (nails) are generally rod-shaped devices, with screw holes at either end for fixation to bone. This device is intended to be inserted into the medullary canal of the femur for fixation of fractures by aligning and stabilizing the bone fragments. Additional stabilization may be realized by installing transverse screws through holes in the rod. These devices are made of medical grade stainless steel. The OrthoPediatrics PediNail" system is used for pediatric and small stature adult patients as indicated to stabilize fractures of the femoral shaft; subtrochanteric fractures; ipsilateral neck/shaft fractures; prophylactic nailing of impending pathologic fractures; nonunions and malunions; fixation of femurs that have been surgically prepared (osteotomy) for correction of deformity.
Code Information	Part number: 01-1500-9014 and Lot #'s 1466707 and 1466710
Recalling Firm/ Manufacturer	OrthoPediatrics Corp 2850 Frontier Dr Warsaw, Indiana 46582-7001
Consumer Instructions	Contact the recalling firm for information
For Additional Information Contact	Greg Teghtmeyer 574-268-6379
Reason for Recall	A complaint received from sales representative that a replenishment instrument was too short. Upon investigation, it has been determined that the device was not manufactured to design specifications and will not function as intended.
Action	OrthoPediatrics Corp sent an Urgent Recall e-mail dated September 14, 2012, to all affected customers. The e-mail identified the product, the problem, and the action to be taken by the customer. Customers were instructed to quarantine all identified devices from the affected lot numbers immediately. Customers were also asked to complete the Mandatory Reply Form. Customers with questions should call 574-268-6379.
Quantity in Commerce	27
Distribution	Nationwide Distribution including AL, IL, NY, FL, TX, MI, KY, NC, CO, and GA.

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