الموضوع: إشعار بملكيّة جهاز طبي مغروس
Nails, Bone, Trochar Scalpel Instruments

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

FDA

بناءً على التقرير الصادر عن وكالة ال
الذي يشير إلى عدم مطابقة الصفن المذكور أعلاه للمواصفات المطلوبة، نرجو منكم تعميم هذه
النشرة على جميع المستشفيات المعنية.

مرفق ربط:

- التقرير الصادر عن وكالة ال

FDA

- دائره البرامج والمشاريع
- المستشفيات الحكومية
- المحافظات

مدير عام الصحة

Rue de la Musee - Imn. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb
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 PedFixNail™ 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 impeding 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/M
Manufacturer:
OrthoPediatrics Corp
2850 Frontier Dr
Warsaw, Indiana 46582-7001

Consumer Instructions:
Contact the recalling firm for information

For Additional Information Contact:
Greg Teghtsimeyer
574-268-6379

Reason for Recall:
A complaint received from sales representative that a replacement 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.