جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بموافقة جهاز طبي مغروس
Prostheses, Joint, Elbow, Synthes Radial Head Prosthesis: Trial Radial Head

الجهاز العفني بالموافقة:
- Prostheses, Joint, Elbow, Synthes Radial Head Prosthesis: Trial Radial Head
- Trade Mark: Synthes Inc
- Local Representative:

FDA بناء على التقرير الصادر عن وكالة ال
الذي يشير إلى وجود خلل في عملية تصنيع الصفن المذكور أعلاه، نرجو منكم تعميم هذا النشرة
على جميع المستشفيات العفية.

مرفق ربطًا:
- التقرير الصادر عن وكالة FDA

دليل:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

دير عام الصحة
د. ويلي عمار
Date Posted: May 03, 2013
Recall Number: Z-1238-2013
Product: Synthes Radial Head Prosthesis: Trial Radial Head Elbow joint prosthesis: Synthes Radial Head Prosthesis System is a two-piece modular system comprised of titanium alloy stem and cobalt chrome components with an integral screw and side-loading application to allow in-mu assembly.

Code Information: All Lots of Part Numbers: 03.402.018, 03.402.020, 03.402.022, 03.402.024, 03.402.026, 03.402.028, 03.402.218, 03.402.220, 03.402.222, 03.402.224, 03.402.226, 03.402.228, 03.402.418, 03.402.420, 03.402.422, 03.402.424, 03.402.426, 03.402.428, 03.402.618, 03.402.620, 03.402.622, 03.402.624, 03.402.626, and 03.402.628.

Recalling Firm/Manufacturer: Synthes USA HQ, Inc.
1302 Wrights Ln E
West Chester, Pennsylvania 19380-3417

Consumer Instructions: Contact the recalling firm for information

Reason for Recall: The Trial Head may come loose from the implant stem during manipulation of the arm during surgery. To date, no adverse events have been reported related to this issue and this recall is not being initiated as a result of adverse events.

Action: Synthes sent an Urgent Notice: Medical Device Recall letter dated February 22, 2013, to all affected consignees. The letter requested consignees examine their inventory, remove them from use and return them to Synthes. Customers were asked to complete the attached Verification Section at the end of the letter indicating whether or not they have any of the affected product. For questions customers were instructed to call 610-719-5450 or email FieldAction@synthes.com. For questions regarding this recall call 610-719-5000.

Quantity in Commerce: 417

Distribution: Nationwide Distribution including IL, IN, MA, MI, MO, NJ, NY, OH, OR, PA, SC, TX, VA, WA and WI