RÉPUBLIQUE LIBANAISE
MINISTÈRE DE LA SANTÉ PUBLIQUE
Le Directeur Général

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ٩٩/ص/١٣
بيروت، في: ١٢ تشرين الثاني ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Prostheses, Joint, Elbow, Synthes Radial Head Prosthesis:
Trial Radial Head

الجهاز المعني بالمتابعة:

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

بناء على التقرير الصادر عن وكالة ال FDA

الذي يشير الى وجود خلل في عملية تصنيع الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن وكالة ال FDA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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Class 2 Recall
Synthes Radial Head Prosthesis: Trial Radial Head

See Related Information[20]

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-situ 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

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