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الجمهورية اللبنانية
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المدير العام

رقم المحفوظات: ٣٧/٢٥
رقم الصادر: ١٢/١/٤٩٠٧
بيروت، في: ١٧ ايار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Bone Matrix Implants, Hemostatic Bone Putty
  Trade Mark: Synthes Inc
  Local Representative:

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بخطر استعمال الصنف الوارد أعلاه أثناء العمل الجراحي، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

نرجو تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المحفوظات

الجمهورية اللبنانية
المديرية العامة
قلم الديوان
وزارة الصحة العامة

وثيقة مصادقة للأصل
بيروت في ٢٠ ايار ٢٠١٢
مصلحة أمانة السر

مدير عام الصحة

د. وليد عمار

Medical Devices

Synthes Hemostatic Bone Putty

Recall Class: Class I

Date Recall Initiated: July 5, 2012

Product: Synthes Hemostatic Bone Putty

Manufacturing Dates: July 6, 2011 - December 14, 2011

Distribution Dates: December 22, 2011 - June 25, 2012

The affected models and lot numbers can be found below:

Part Description	Part Number	Lot Number
Hemostatic Bone Putty	08.901.001.97S 08.901.001.98S 08.901.001.99S 08.901.001D VB1025.10S	**ALL**

Use: Hemostatic Bone Putty stops bone bleeding by establishing a physical barrier along the edges of bones that have been damaged by trauma or cut during a surgical procedure.

Recalling Firm:
Synthes USA HQ, Inc.
1302 Wrights Lane East
West Chester, PA 19380

Reason for Recall: There is the potential for Hemostatic Bone Putty to ignite if contacted with electrosurgical cautery systems under certain conditions during surgery.

Public Contact: Questions should be directed to Synthes at 1-610-719-5450, Monday through Friday from 7:45 am to 5:30 pm, Eastern Time.

FDA District: Philadelphia

FDA Comments:
On July 5, 2012, Synthes issued a Medical Device Recall letter requesting medical facilities to examine their inventory and immediately stop using the identified part and lot numbers of the Hemostatic Bone Putty.

If a facility had the affected product in stock, they were asked to call 1-800-479-6329 to obtain a Return Authorization Number, complete the verification form and return both the form and identified product to Synthes.

Facilities that did not have the identified product in stock were asked to complete and return the verification form to Synthes acknowledging receipt of the Medical Device Recall letter.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch: The FDA Safety Information and Adverse Event Reporting Program[1] either online, by regular mail or by FAX.

Page Last Updated: 08/21/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

Links on this page:

1. http://www.fda.gov/Safety/MedWatch/default.htm