لاحة: إشعار بمتابعة جهاز طبي معروض

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

بناء على التقرير الصادر من الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
وتوصية الصادرة عن الشركة المصنعة والتي تفيد بخطر استعمال الحرف الوردي أثناء العمل الجراحي، نرجو منكم متابعة هذا الموضوع مع الأطباء الأسنان والعمل بموقع التوصيات الصادرة عن الشركة المصنعة.

نرجو تمام هذه النشرة على المستشفيات المعنية والعقل بموقع التوصيات الصادرة عن الشركة المصنعة.

مرفق برطان:
- التوصية الصادرة عن الشركة المصنعة.

兵力
- دائرة البرامج والمشاريع
- المحفوظات

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


The affected models and lot numbers can be found below:

<table>
<thead>
<tr>
<th>Part Description</th>
<th>Part Number</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemostatic Bone Putty</td>
<td>08.901.001.97S</td>
<td>ALL</td>
</tr>
<tr>
<td></td>
<td>08.901.001.98S</td>
<td></td>
</tr>
<tr>
<td></td>
<td>08.901.001.99S</td>
<td></td>
</tr>
<tr>
<td></td>
<td>08.901.001D</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VB1025.10S</td>
<td></td>
</tr>
</tbody>
</table>

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 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.

Accessibility Contact FDA Careers FDA Basics FOIA No Fear Act Site Map Transparency Website Policies
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

For Government For Press
Combination Products Advisory Committees Science & Research Regulatory Information
Safety Emergency Preparedness International Programs News & Events Training and
Continuing Education Inspections/Compliance State & Local Officials Consumers Industry
Health Professionals

U.S. Department of Health & Human Services

Links on this page: