الموضوع: إشعار بموافقة جهاز طبي مغروس
Orthopedic Internal Fixation Systems, Spinal, Facet Wedge Trial Implants with Small Cannulated Rasp.

الجهاز المعني بالمتابعة:

- Orthopedic Internal Fixation Systems, Spinal, Facet Wedge Trial Implants with Small Cannulated Rasp.
- Trade Mark: Synthes Inc.
- Local Representative:

بناء على التقرير الصادر عن الشركة المصنعة
والذي يتضمن إلى وجود خلل في عمل الصفن المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنيه.

مرفق ربطا:
التقرير الصادر عن الشركة المصنعة

*Bilal A. El Amm*,
مدير عام الصحة

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Rue de la Musée - Imm. Hussein Manosour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb
To the ATTENTION of:
Operating room manager

16 October 2012

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Part Description</th>
<th>Lot Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>03.630.130</td>
<td>FACET WEDGE Trial Implant w/Rasp small cannulated</td>
<td>1219945</td>
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</table>

Dear Sir/Madam

Synthes is initiating a Medical Device Product Removal related to the above mentioned medical device.

Complaints were received stating that the Trial / Rasp for FACET WEDGE small (03.630.130) broke in-situ leading to remaining part in the facet joint. The remaining part could be removed and patient adequately treated with FACET WEDGE. The removal part caused an extension of the OR time. No patient harm has been noted.

A new, improved design will be available within the next few weeks.

Synthes is requesting that you immediately cease using the product and please examine your inventory for the above part numbers and remove them.

If you have any questions, please contact your Synthes Sales Consultant.

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.
Synthes GmbH
Manager Complaint Handling Unit

Cc:

Director Quality EMEA