



رقم المحفوظات: ٣٨/٢٥  
رقم الصادر: ١٤١٦/١٣١٧  
بيروت، في: ٢٤ نيسان ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي مغروس

Orthopedic Internal Fixation Systems, Spinal, Facet Wedge Trial Implants with Small Cannulated Rasp.

الجهاز المعنى 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 يشير الى وجود خلل في عمل الصنف المذكور أعلاه ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

**مرفق ربطاً:**

- التقرير الصادر عن الشركة المصنعة

**يلغ:**

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة  
وليد أعمار

**To the ATTENTION of:  
Operating room manager**

16 October 2012

## URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number: See attached list

Part Number	Part Description	Lot Number
03.630.130	FACET WEDGE Trial Implant w/Rasp small cannulated	1219945

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.

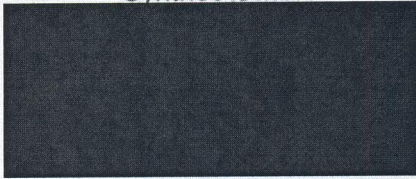
If you have any questions, please contact your Synthes Sales Consultant.

We apologize for the inconvenience caused.

Thank you for your attention and cooperation.



Synthes GmbH



Manager Complaint Handling Unit



Director Quality EMEA

Cc: