



رقم المحفوظات: ٤٨/٢٥
رقم الصادر: ١٣/٧/٢٥٩٢٥
بيروت، في: ٥ - آب - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Pin-sleeve orthopaedic bone screw, Dynamic Locking Screw Stardrive,
5 and 3.7mm

الجهاز المعني بالمتابعة:

- Pin-sleeve orthopaedic bone screw, Dynamic Locking Screw Stardrive, 5 and 3.7mm
- Trade Mark: Synthes Inc
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير إلى وجود خلل في عمل الصنف المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

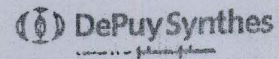
- التوصية الصادرة عن الشركة المصنعة
- يبلغ:
- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام
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To the ATTENTION of:
Operating room manager

11 June 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
09.213.022S — 09.213.070S	Dynamic Locking Screw Stardrive® Ø 3,7 mm, self-tapping, length 22 - 70 mm, Cobalt-Chrome Alloy (CoCrMo), sterile	all lots
09.223.032S — 09.223.090S	Dynamic Locking Screw Stardrive® Ø 5,0 mm, self-tapping, length 32 - 80 mm, Cobalt-Chrome Alloy (CoCrMo), sterile	all lots

Dear Sir/Madam

Synthes is initiating a voluntary recall of all lots of the Dynamic Locking Screws (DLS) Ø 3.7 mm and the Dynamic Locking Screws Ø 5.0 mm. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

The voluntary recall is being initiated following customer complaints of DLS 3.7 and 5.0 mm breakages at the distal tip of the pin identified after successful healing and during planned implant removal of the whole construct.

Instruments and implants
approved by the AO
Foundation

Instrumente und Implantate
geprüft und freigegeben von
der AO Foundation

Instruments et implants
approuvés par l'AO
Foundation

Instrumentos e implantes
aprobados por la AO
Foundation

Strumenti ed impianti
approvati dalla
AO Foundation

Patient risk:

There have been no reports of permanent impairment associated with the reason for this recall to date. However, DePuy Synthes is aware that significant elongation of surgical time has occurred in planned implant removals which involved a broken DLS screw. Additional information is available for the Health Care Providers in your institution; please provide the attached letter to those health care providers who have used DLS.

Patients who have had procedures using the Synthes DLS 3.7 and 5.0mm should be followed under routine standard of care at their institution.

Customer immediate actions:

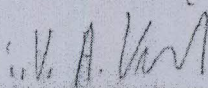
1. Immediately identify and quarantine all unused product listed above in a manner that ensures the affected product will not be used.
2. Review, complete, sign and return the attached reply form to your local Synthes sales organisation in accordance with the directions on the form within 5 business days of receipt of this notification.
3. Return any affected product within 30 business days. Credit or replacement will be provided based on product availability.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed below has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed below have been returned to Synthes GmbH.
7. Maintain a copy of this notice with the affected product

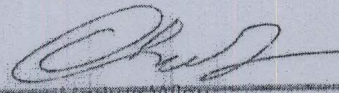
The applicable regulatory agencies are being notified. Synthes GmbH is voluntarily taking this action.

We apologise for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any queries please do not hesitate to contact your Synthes sales representative.

Thank you for your attention and cooperation.

Synthes GmbH


~~Claudia Allemann
Field Action Manager~~


~~Markus Wien
Director Quality Assurance Operations~~

*CHARLES GOLDSON
FOR MARKUS WIEN*

6/11/13

Cc: