



رقم المحفوظات: ٢٥ / ٨١  
رقم الصادر: ١١ / ٦٦٦٩  
بيروت، في: ١٥ شباط ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي

Drill Bits, The CSLP System  $\varnothing$  3.0mm Drill Bits and the Fixation Sleeve

**الجهاز المعنى بالمتابعة:**

- Drill Bits, The CSLP System  $\varnothing$  3.0mm Drill Bits and the Fixation Sleeve
- Trade Mark: Synthes Inc
- Local Representative:

بناءً على التوصية الصادرة عن الشركة المصنعة،  
والتي تشير الى احتمال حدوث عطل في الجهاز مما قد يؤثر على سلامة المريض، نرجو منكم  
تعميم هذه النشرة على جميع المستشفيات المعنية.

**مرفق رباطاً:**

- التوصية الصادرة عن الشركة المصنعة

**يبلغ:**

دائرة البرامج والمشاريع

- المستشفيات الحكومية

- المحفوظات

الجمهورية اللبنانية  
مدير عام الصحة  
إدارة العامة  
قلم السجون  
وزارة الصحة العامة  
وليد عمار

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

14. August 2012

**Urgent: Field Safety Corrective Action**

Part Description	Part Number	Lot Number
Drill Bit Ø 3.0mm, complete, L 196mm	324.087	ALL
Drill Bit Ø 3.0mm, L 196mm, drilling depth 26mm	324.088	ALL
Fix-Sleeve for Drill Bit	324.089	ALL

Dear Sir/Madam

Synthes has initiated a recall of the CSLP System Drill Bit Ø 3.0mm complete, Drill Bit Ø 3.0mm and the Fixation Sleeve (324.087, 324.088 and 324.089). Although the reported incidence is low, there is the potential for the drill stop to slip on the drill bit resulting in an adverse event. If the drill stop slips on the drill bit, it could result in the penetration of the posterior cortex, dural tear requiring repair, damage to the spinal cord, quadraplegia, and the risk of a potentially life-threatening event.

Having established appropriate actions to mitigate the identified risk, Synthes has decided to recall the Drill Bit Ø 3.0mm complete, Drill Bit Ø 3.0mm and the Fixation Sleeve (324.087, 324.088 and 324.089). The products will be re-introduced once the actions for risk mitigation have been completed.

Please immediately cease use of the Drill Bit Ø 3.0mm complete, Drill Bit Ø 3.0mm and the Fixation Sleeve (324.087, 324.088 and 324.089). Please do not utilize self-tapping screws (20-26mm) in the absence of this drill bit assembly.

In compliance with this product recall, please examine your inventory and remove the above part numbers from your shelves.

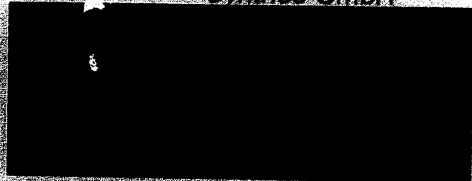
We ask you to send back the affected devices.

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

We apologize for the inconvenience this may cause.

Thank you for your attention and cooperation.

Synthes GmbH



Manager Complaint Handling Unit



Vice President Global Quality Management

Cc: