

REPUBLIQUE LIBANAISE

MINISTÈRE DE LA SANTÉ PUBLIQUE

LE DIRECTEUR GÉNÉRAL



الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٢/١/١٥٤٤٤
بيروت، في: ٢٠ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز بآبي مغروس.

الجهاز المعنى بالمتابعة:

- Drills, Bone, Vectra System Graduated 2.5mm Drill Bits and adjustable drill stop.
Trade Mark: Synthes Inc
Local Representative:

بناءً على التوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في عمل الجهاز المذكور أعلاه والذي قد يؤدي الى مضاعفات على المريض، نرجو منكم تعميم هذه النشرة على المستشفيات المعنية.

مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- الموقع الإلكتروني لوزارة الصحة
- المحفوظات

مدير عام الصحة

د. وليد عمار



وثيقة مطابقة للأصل
بيروت ٢٠ أيار ٢٠١٢
د. بسام فهد أمانة السر
عناية غصن



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

14. August 2012

Urgent: Field Safety Corrective Action

Part Description / Part Number:

Part Description	Part Number	Lot Number
Drill Bit Ø 2.5mm, compl., 2-flute	03.613.010	ALL
2.5mm drill bit, graduated 12mm- 26mm adjustable depth.	03.613.011	ALL
Adjustable Drill Stop	03.613.012	ALL

Dear Sir/Madam

Synthes has initiated a recall of the Vectra System graduated 2.5mm drill bit and the adjustable drill stop. 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 2.5mm adjustable drill bit (03.614.011) and the adjustable drill stop (03.613.012) as well as the drill bit complete (03.613.010). The products will be re-introduced once the actions for risk mitigation have been completed.

Please immediately cease use of the 2.5mm adjustable drill bit (03.614.011) and the adjustable drill stop (03.613.012), as well as the drill bit complete (03.613.010). 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



Heinz Gribi
Manager Complaint Handling Unit



Stephan Mueller
Vice President Global Quality Management

Cc: