

REPUBLIQUE LIBANAISE

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الجمهورية اللبنانية

وزارة الصحة العامة

المدير العام

رقم المحفوظات: ٣٧/٢٥

رقم الصادر: ١٢/١/١٤٩٤

بيروت، في:

١٧ أيار ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Implants, ligaments & tendons prosthetic ligaments, Endoscopy - metal (TI) and PEEK (PK) suture anchors - Healicoil, Twinfix, Bioraptor, Footprint-multiple models.
Trade Mark: Smith & Nephew
Local Representative:

بناء على التقرير الصادر عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مشاكل في طريقة توضيب الصنف الوارد أعلاه، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

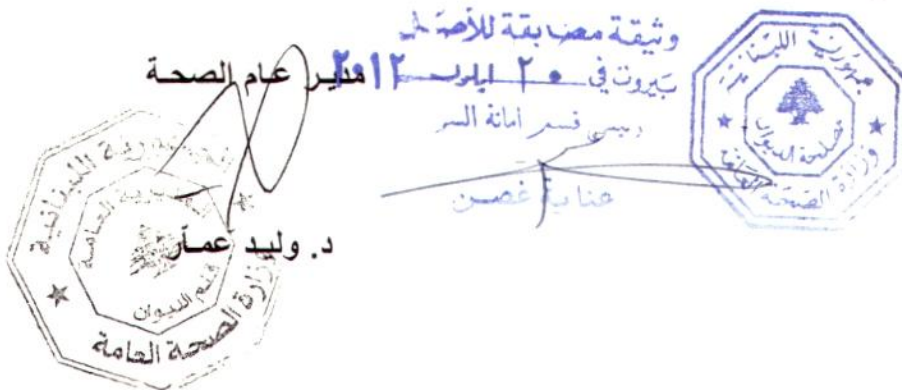
نرجو تعميم هذه النشرة على المستشفيات المعنية والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المحفوظات



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 We are smith&nephew

August 2012

Urgent Medical Device Recall Smith & Nephew Advanced Surgical Devices - Endoscopy metal and peek suture anchors

Dear Customer

This letter is to inform you of a voluntary recall by Smith & Nephew Endoscopy for certain metal and peek suture anchors due to a packaging issue. Specifically, we have identified pin holes in a small number of pouches, which constitutes a breach of the sterile barrier. The affected suture anchors include many from the BIORAPTOR®, FOOTPRINT, HEALICOIL® and TWINFIX® product lines. A full list of affected product is attached, for your reference.

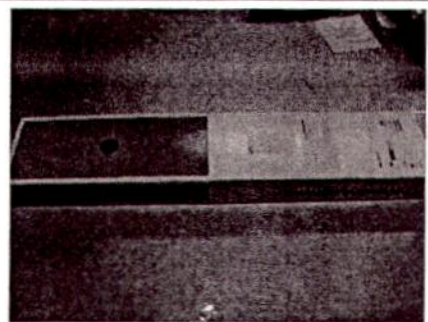
In the most likely scenario, a patient would have no adverse reaction to a device with a pin hole in the package; however, it is possible that, during a surgical procedure, a fixation device is prepared for the procedure, but the physician or prep nurse will overlook a pin hole in the pouch before placing the device into the sterile field. The non-sterile device will then be used during a routine surgical procedure, and may result in an adverse reaction (surgical site infection) that is reversible with aftercare by the physician. In rare instances, there exists the remote possibility that the patient may experience a systemic infection (sepsis) resulting in organ failure and death.

Our records show that this item has been despatched to you recently. If you have any of these devices please remove/isolate the items, and contact Product Services on 01480 423200 (select option 2) who will arrange for the item to be collected and replaced. Please complete the declaration on the following page by inserting the number of items held and return the form as outlined.

Product Unaffected by the Recall:

Product with a blue dot on the carton, has been inspected and is unaffected by the recall. If you receive product with a blue dot, you do not need to return it.

The photo to the right shows what the blue dot looks like and where it is located on each carton.



The Medicines and Healthcare Products Regulatory Agency has been informed of this recall.

Yours sincerely


Tony Horn
Quality & Regulatory Manager
Advanced Surgical Devices – UK/Ireland

DECLARATION

Smith & Nephew Advanced Surgical Devices - Endoscopy metal and peek suture anchors

Fax to Smith & Nephew Endoscopy on 01480 423241. Please return this declaration by 31 August 2012.

I can confirm that I have the following numbers of affected items in our stock.
(please include a zero in the quantity column, if your stock is nil)

Product Code ↓↑	Quantity	...Cont/ Product Code ↑↓	Quantity

Where applicable, these have been segregated awaiting shipping and return instructions from Smith & Nephew Product Services Department, who have been contacted regarding this matter.

Signed

Print Name

Position

Organisation / Hospital

Date