REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٣٨/٢٥
رقم الصادر: ١٢/١/٣٥٢٢٤
بيروت، في: ٣١ تشرين الأول ٢٠١٢

## جانب نقيب المستشفيات الخاصة في لبنان

**الموضوع:** إشعار بمتابعة جهاز طبي

Cervical Distractor, right, with adjustable angle, Implant Inserter, Removal Tool for T-PAL, Toothed Rack Retractor, for Matrix

**الجهاز المعني بالمتابعة:**

- Cervical Distractor, right, with adjustable angle, Implant Inserter, Removal Tool for T-PAL, Toothed Rack Retractor, for Matrix
- Trade Mark: DePuySynthes
- Local Representative:

بناء على التوصية الصادرة عن الشركة المصنعة

والتي تشير الى وجود خلل في تصنيع الجهاز 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 الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قلم الديوان
وزارة الصحة العامة

Museum Street - Hussein Mansour Blg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

Synthes GmbH
Luzernstrasse 21
4528 Zuchwil
Switzerland
Tel. +41 32 720 40 60
Fax +41 32 720 40 61
http://www.depuysynthes.com/

DePuy Synthes

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

27 September 2013

## URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

| Part Number | Part Description | Lot Number |
|---|---|---|
| 396.396 | Cervical Distractor, right, with adjustable angle | T989765; T989780 |
| 03.812.005 | Removal Tool for T-PAL | T987734; T988931; T987623 |
| 03.632.087 | Toothed Rack Retractor, for Matrix | T987270 |
| 03.820.129 | Implant Inserter | T988206 |

Dear Sir/Madam

Synthes is initiating a medical device removal regarding the above mentioned lots and article numbers of various instruments which are typically used in spinal and thoracic surgical procedures. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes was informed by one of its suppliers that within one material batch used for production of the affected parts one or several bars were mixed in with an incorrect material. Specified material was 420A and material of the mixed in bar(s) was X20CrMnNi 12 8 6 (which is a non-magnetic austenitic steel grade used for electric generators). The wrong material results in lower than specified hardness and corrosion resistance.

Patient risk:

Instruments that have been manufactured with an incorrect material, as specified above, have the potential to bend or break during use due to lower than specified hardness values. Due to

the material used, the instrument may be more apt to bend under tension. If this occurs intraoperatively, there is the potential for minor surgical delay while the surgeon retrieves an alternate instrument. In a reasonable worst case scenario, the delay may be more substantial, if alternate instruments are not readily available. Surgical delays expose the patient to increased anesthesia, and the potential for increased medical intervention (IV fluids, medications).

If the instrument breaks during the surgical procedure, there is the possibility that device fragments may enter the operative site (interbody disc space; occipital, thoracic space). Retrieval of instrument fragments may require additional medical or surgical intervention (x-ray, fluoroscopy, incision extension). In the case of irretrievable device fragments, the patient may be exposed to non-implant grade material, potentially resulting in an adverse tissue reaction. Additionally, it is possible that the instrument could be corroded, due to lower than specified corrosion resistance, and corrosion residue could be introduced into the operative site. Adverse tissue reactions may include allergic reactions, adverse reaction to metal debris, and/or an inflammatory reaction to foreign debris. If any of these conditions are present, the patient will require treatment, which may include revision surgery or re-operation. However, if this condition is treated on time, no permanent impairment would be expected.

Due to the characteristics of the incorrect metal used, it is more likely that the instruments would experience deformation, rather than breakage. However, since breakage cannot be ruled out, this is considered a reasonable worst case scenario.

Customer immediate actions:

1. Immediately identify and quarantine all products listed above in a manner that ensures the affected products 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

Cc: