REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧/٢٥
رقم الصادر: ١٢/٧/٨٧٠٧
بيروت، في: ٢ - تموز - ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Non-Sterile fluted surgical drill, Drill Bit

الجهاز المعني بالمتابعة:

- Non-Sterile fluted surgical drill, Drill Bit
- Trade Mark: DePuySynthes
- Local Representative: Asmar Medical

بناء على التقارير الصادرة عن الوكالة البريطانية
Medicine and Health Care Products Regulatory Agency (UK) MHRA
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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DePuy Synthes
Companies of Johnson & Johnson

To the ATTENTION of:
Operating room manager

20 June 2013

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

Part Description / Part Number:

Part Number	Part Description	Lot Number
03.207.001	Drill Bit Ø 5.0/7.3 mm, for SCFE Screw, thread length 10 mm	PE00376 PE00439 PE01391
03.207.008	Drill Bit Ø 5.0/7.3 mm for SCFE Screw, thread length 20 mm	PE00440 PE00377 PE00513 PE01475

Dear Sir/Madam

Synthes is initiating a medical device removal of the above mentioned article and lot numbers of the Drill Bit Ø 5.0/7.3 mm, for SCFE Screw. Our records indicate that you have inventory that is impacted by this removal.

Description of problem:

Synthes received several complaints regarding two failure modes associated with the drill bits used with this system. Failure mode one concerns guide wires sticking in the cannulation of the drill bit. Failure mode two concerns drill bits breaking during surgery.

Cannulation straightness and coaxiality of the drill bit were determined to be the root cause.

placement has been created, the Surgeon may elect to proceed with the procedure and place the screw under fluoroscopy. However, it is possible that the Surgeon would elect to place a new guide wire. There are six guide wires in the SCFE Screw System Instrument set; therefore the surgeon will have replacement wires readily available and the need for additional wires will not further extend the operative procedure. A surgical delay of <15 minutes is not likely to result in patient harm.
Review of the complaint history revealed 4 instances of minor surgical delay related to stuck guide wires, with no reported instances of patient harm.

If a drill bit breaks during the surgical procedure (failure 2), it is likely to result in a surgical delay while the surgeon retracts the drill bit and assesses the surgical site for potential device fragments. If fragments are present, the surgeon may attempt to retrieve them. The SCFE Screw System Instrument set contains 2 drill bits. However, they are of different sizes, and not necessarily interchangeable. If the second drill bit is not an option (due to the different size) or if the second drill bit also breaks, this may extend the surgical delay further, potentially up to 15 minutes or longer, while the surgeon procures an alternate instrument. If no alternate instrument is available, the surgeon may need to change the operative plan and an alternate product may be used. Surgical delays expose the patient to increased anesthesia, an increased potential for medical intervention (IV fluids, medication, blood and/or blood components) and place them at increased risk for infection.

If a drill bit breaks and results in irretrievable device fragments, the patient is at risk for adverse tissue reaction related to the presence of foreign, non-implant grade material. These fragments are less resistant to corrosion; they are ferrous and may potentially interact with diagnostic procedures like MRI, potentially leading to heating, bone necrosis, structural damage and/or surrounding soft tissue damage. The foreign material may also result in a localized inflammatory response. If these conditions are present, the patient will require treatment; it is unlikely that non-surgical treatment will be effective, thereby exposing the patient to additional surgery. However, if the condition is treated timely, no permanent impairment is expected to occur.

DePuy Synthes

Customer immediate actions:

1. Immediately identify and quarantine all products listed above in a manner that ensures the affected product will not be used anymore.
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.
4. Forward this notice to anyone in your facility that needs to be informed.
5. If any product listed above has been forwarded to another facility, contact that facility to arrange return.
6. Maintain awareness of this notice until all products listed above have been returned to Synthes GmbH.
7. Maintain a copy of this notice for your records

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: