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الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٤٤٨٧/١/١٣
بيروت، في: ١١ نيسان ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Surgical instruments, Reamer – Depuy Reclaim reamer extension

الجهاز المعني بالمتابعة:

- Surgical instruments, Reamer – Depuy Reclaim reamer extension
- Trade Mark: DePuy International Limited
- 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 احتمال حدوث مضاعفات جراء استعمال الصنف المذكور اعلاه، 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
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DePuy
a Johnson & Johnson company

Urgent Field Safety Notice (FSN)

Product Name: DePuy ReClaim® Reamer Extension

FSCA-identifier: DVA-107508-HHE

Type of Action: Field Safety Notice

Date: March 2013

Attention: Trust Chief Executives, the Clinical Director-Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers – Private Sector Hospitals

Type of device: Orthopaedic Hip Instrument

Model names: DePuy ReClaim® Reamer Extension

Part Number: 297500500

Batch / lot number of affected devices: See Attachment A.

DePuy Orthopaedics, Inc. is issuing a Field Safety Notice (FSN) for all lots of the ReClaim® Reamer Extensions due to the potential for one or both of the tabs to break off and potentially be left in the patient.

The ReClaim Modular Revision Hip System is used to reconstruct the hip joint in moderate to complex revisions. The ReClaim Distal Reamer Extension attaches to the ReClaim Distal Reamers to lengthen the instrument for improved ease of use during preparation of the femur for implantation of the ReClaim Distal Stem.

This Field Safety Notice provides notification to surgeons currently using the ReClaim Reamer Extensions. The purpose of this FSN is to notify users to reduce the possibility of fragments being left in patients. The reamer extensions are not immediately being removed from the market and may continue to be used until a design change is implemented and new devices are available.

Background: DePuy has identified the potential for the ReClaim Reamer Extension tabs to break off (see Attachment B). DePuy has received 9 complaints reporting tab breakage since 2011. None of the complaints have indicated fragments were left in patients.

DePuy is currently investigating the cause. The Field Safety Notice is intended to inform users that to reduce the possibility of leaving fragments in patients, they should check the condition of the reamer extension tabs on a regular basis, especially before and after usage. Any reamer extensions showing signs of cracks in the tab area or having broken or missing tabs, should be returned to DePuy. When a design change has been implemented, DePuy will conduct a formal trade-out of inventory.

Clinical Implications:

- In remote circumstances, the possible clinical implications related to ReClaim Reamer Extension tabs that break off and are left in the patient may include:
    - Significant surgical delay due to attempted retrieval of remaining fragments
    - Serious surgical delay due to both reamer extensions having broken tabs and where another system may need to be brought in to complete the surgery.
    - Adverse tissue reaction
    - Pain due to potential bone remodeling or during magnetic resonance imaging (MRI)
    - Poor joint mechanics if the remaining fragment is left in the joint space

Use of Reamer Extensions:

- Upon visual inspection, if the reamer extension is found to have one or more tabs broken, please do not use that reamer extension. The reamer extension will still engage with one tab intact and no clinical implications have been identified with the use of the reamer extension with one tab, but DePuy recommends it be returned to DePuy and the alternate reamer extension device be used.
- If both tabs are broken, the reamer extension will not engage and DePuy recommends it be returned and the alternate reamer extension device be used. A reamer extractor is available in the instrument kit for removal of the reamer if necessary.
- In order to reduce the risk of breaking the tabs during surgery, the Reamer Extension should only be used to drive the Distal Reamer axially within the patient's femoral canal. The instrument is NOT intended to be used for side-cutting or lateralizing the femoral canal, therefore, no off-axis force should be applied during distal reaming.

Transmission of this Field Safety Notice:

This notice has been sent to you as records indicate that your organization/hospital has purchased the DePuy ReClaim® Reamer Extension

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where these products may have been transferred.

To confirm receipt of this FSN please complete and return the acknowledgement in Attachment C.

For any enquiries about the DePuy ReClaim® Reamer Extension contact:

Alan O' Sullivan
Recall Co-Ordinator
e-mail – aosulliv@its.jnj.com
Tel no - +353 21 4914149

This FSN has been notified to the appropriate Regulatory Agency.

Sincerely,

Simon Sinclair PhD MB BChir
Worldwide Vice President, Strategic Medical Affairs

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Attachment A: Affected Lot Numbers

Engraved Lot Number	Label Lot Number
J0111	578910
	578913
	R578910
	R578912
	R578913
	In Kit # 2975-50-025
J0211	In Kit # 2975-50-025
J0411	582631
	In Kit # 2975-50-025
J0611	In Kit # 2975-50-025
J0911	592125
	In Kit # 2975-50-025
J1211	000003583
	In Kit # 2975-50-025
NB12649	NB12649
NB12650	NB12650
NB12651	NB12651
NB12652	NB12652
NB12653	NB12653
NB12654	NB12654
NB12655	NB12655
NB12656	NB12656

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Engraved Lot Number	Label Lot Number
NB23480	NB23480
NB23481	NB23481
NB3584	In Kit # 2975-50-025
NB3586	NB3586
NB3587	NB3587
NB3588	In Kit # 2975-50-025
NB3590	NB3590
NB3591	In Kit # 2975-50-025
NB5955	NB5955
NB7894	NB7894
	In Kit # 2975-50-025
NB8016	In Kit # 2975-50-025
NB8017	NB8017
NB8018	NB8018
	In Kit # 2975-50-025
NB8019	In Kit # 2975-50-025
NB8020	NB8020
NB8021	NB8021
NB8022	NB8022
NB8023	NB8023