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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
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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.