



رقم المحفوظات: ١٤١/٢٨
رقم الصادر: ١٤١/٢٨
بيروت، في: ١٥ تموز/أول ٢٠١٢

جانب شركة Asmar Medical

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعنى بالمتابعة:

- Surgical instruments, implant insertion instrument, Expedium offset spinal system – torque wrench.
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

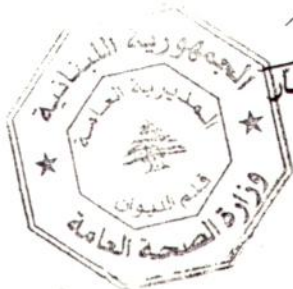
والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود خلل في تصنيع الصنف المذكور أعلاه ، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين والعمل بموجب التوصيات الصادرة عن الشركة المصنعة.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.
- يبلغ:
- دائرة البرامج والمشاريع
- الموقع الالكتروني لوزارة الصحة
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة

د. وليد عامل



وثيقة معبقة للأصل
بيروت في ١٦ تموز/أول ٢٠١٢
د. نيس فهم امانة السر

عناية حسن





URGENT Field Safety Notice

Date: 27 July 2012

Commercial Name of Product: EXPEDIUM® Offset Torque Wrench

FSCA-identifier: DVA-107108-HHE

Type of Action: Field Safety Corrective Action for EXPEDIUM® Offset Torque Wrench

Attention: Theatre Manager, the Safety Liaison Officer, Surgeons using EXPEDIUM® Offset Spinal System – Torque Wrench

Product Description

Torque Wrench, *part of EXPEDIUM® Offset Spinal System*

Catalog Number

2797-29-510

Potentially Affected Product

All Lots Distributed

Summary

A component of the Torque Wrench (pictured below) used during final tightening of an EXPEDIUM® Offset Spinal Construct has been identified to be prematurely wearing, which can potentially result in the instrument recording torque values outside of the specification. Final tightening of the construct applying less than the specified torque could potentially result in construct instability due to hardware loosening which could require an additional surgical procedure.





Action to be Taken

Please remove the torque wrenches described above from service and contact Yoshie Kornmayer in Customer Service via telephone (+41 32 9348442) or email (ykornmay@its.jnj.com) to initiate the product return and to receive a RGA number.

Please discontinue the use of the EXPEDIUM® Offset Spinal System until direction can be provided by DePuy Synthes Spine regarding a replacement torque limiting device.

Further Instruction

Please distribute this information to the appropriate personnel at your facility including surgeons who may have used the product which is the subject of this notice.

If devices have been transferred to other organizations, please provide the organization name and contact information on the Field Correction Acknowledgement Form and forward a copy of this Field Safety Notice to the organization to which the device has been transferred.

If you have further questions or concerns regarding the information contained within this Field Safety Notice, please contact Linda Regan, Complaint Manager, via telephone at +001 508-977-6606 or via email at lregan3@its.jnj.com.

Notice of this Field Safety Corrective Action has been provided to the relevant National Competent Authorities

At DePuy Spine, we are dedicated to delivering products that meet the highest quality standards.

We appreciate your attention to this important notice and assure you that we are working to resolve and prevent such problems from occurring in the future. We apologize for any inconvenience this matter may cause.

We thank you for your cooperation and your patience.

Respectfully,



Linda Regan
Manager, Complaint Department



Field Correction Acknowledgement Form

The undersigned acknowledges receipt of the subject:

*Field Safety Notice in reference to the **EXPEDIUM® Offset Torque Wrench***

FSCA REF: DVA-107108-HHE

Date _____

Hospital Name _____

City and Country _____

Name (please print) _____

Signature _____

Please Indicate All that Apply:

This site does NOT have an EXPEDIUM® Offset Torque Wrench to return to DePuy Synthes Spine, Inc.

This site has transferred an EXPEDIUM® Offset Torque Wrench to another organization

Organization Name _____

City and Country _____

Contact Name _____

Telephone _____

This site has the EXPEDIUM® Offset Torque Wrench in its possession and can return to DePuy Synthes Spine, Inc. Please contact Customer Service- Yoshie Kornmayer at ykornmay@its.jnj.com telephone number +41 32 9348442 to set up the product return and to receive an RGA number.

Please return via fax: + 001 508-828-3762 or e-mail lregan3@its.jnj.com