



رقم المحفوظات: ٧٨ / ٢٥
رقم الصادر: ١٤٥٧ / ١٣
بيروت، في: ٢٧ نيران ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس

Surgical instruments, implant, Specialist 2 Intramedullary Rod
(SP2IM Rod)

الجهاز المعنى بالمتابعة:

- Surgical instruments, implant, Specialist 2 Intramedullary Rod (SP2IM Rod)
- Trade Mark: DePuy Orthopaedics, Inc
- Local Representative: Asmar Medical

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK)-MHRA

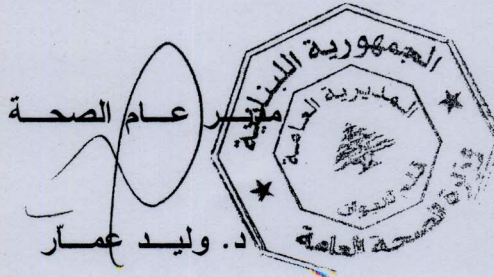
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى احتمال تعرض الجهاز للكسر بعد تركيبه مما يعرض المريض الى مضاعفات، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

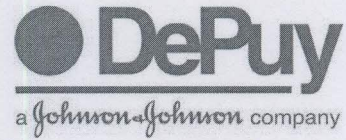
مرفق ربطا:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





Urgent Field Safety Notice (FSN)

Product Name: DePuy Specialist 2 Intramedullary Rod (SP2 IM Rod)

FSCA-identifier: DVA-107305-HHE

Type of Action: Field Safety Notice

Date: Feb 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 Knee Instrument

Model names: DePuy Specialist 2 Intramedullary Rod (SP2 IM Rod)

Part Number: 966120

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

DePuy Orthopaedics, Inc. is issuing a Field Safety Notice (FSN) for specific lots of the Specialist 2 (SP2) Intramedullary (IM) Rod due to the potential for the rod to break, leaving fragments in the patient.

The SP2 IM Rod is used in both primary and revision Sigma knee procedures to align the femoral locating device and distal femoral cutting block. It can also be used with the IM tibial resection.

The SP2 IM rods are not being removed from the market. The purpose of this Field Safety Notice is to provide additional information on how to use the SP2 IM rods to minimize the potential for breakage.

Background: DePuy has identified the potential for the SP2 IM Rod to fail due to fatigue when excess leverage is applied at the tip. There is a deep J shaped groove at the tip of the rod, which allows a sleeve to lock into place when used in revision cases (see picture Appendix B). It is at the top of this groove that fracture can occur. DePuy has received 9 complaints since 2008 regarding the tip breaking with 8 complaints where the tip was left in the patient.

DePuy is currently investigating a material change to the rod to reduce the possibility of the tip fracturing. Changes have/will be made to the Surgical Techniques to include the guidance below.

