



رقم المحفوظات: ٢٤/٢٥
رقم الصادر: ١٣/١٧.٢٧
بيروت، في: ٢٠ أيار ٢٠١٢

جانب نقيب الاطباء في الشمال/طرابلس

الموضوع: إشعار بمتابعة جهاز طبي

Surgical instruments, implant insertion instrument,
Ardis Interbody system

الجهاز المعنى بالمتابعة:

- Surgical instruments, implant insertion instrument, Ardis Interbody system
- Trade Mark: Zimmer Inc
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

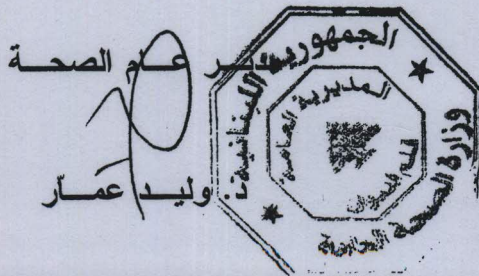
والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف المذكور
أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم متابعة هذا الموضوع مع الاطباء الاختصاصيين.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات





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December 20, 2012

URGENT MEDICAL DEVICE RECALL

To: Surgeons using the Ardis® Interbody System
Subject: *Ardis* Inserter Medical Device Recall
Affected Product: **Ardis Inserter** - used for implanting the *Ardis* PEEK interbody spacer

Dear Surgeon,

Zimmer Spine is initiating a voluntary medical device recall of the Ardis® (PEEK) Inserter. The Ardis Inserter is a surgical instrument used during spinal surgery to implant the Ardis PEEK Interbody Spacer. The inserters are being recalled because Zimmer Spine has received reports of Ardis PEEK Interbody Spacer implant breakage when the implant is subjected to excessive lateral and/or off-axis forces from the inserter during surgery. Intra-operative complaint reports received to date indicate an occurrence rate of 0.52%. No post-operative complaints have been reported that are attributed to a fractured implant.

The Ardis Interbody System was released for commercial use beginning in June 2008. This recall affects 315 inserter instruments worldwide.

Surgeons and hospitals with Ardis (PEEK) Inserter instruments should immediately stop using the inserters and return them to Zimmer Spine. **Surgery using the Ardis PEEK Interbody Spacer cannot be performed per labeling without the aid of the Ardis (PEEK) Inserter instrument.**

Risks

The most probable risk observed is implant breakage that results in surgical delays up to 60 minutes to remove fragments from the patient. The immediate health consequence could be a prolongation of surgery while trying to retrieve the fragment(s) from the surgical site, resulting in a patient's extended exposure to anesthesia. Potential extended surgery time could also expose patients to the standard risks associated with general anesthesia.

In certain occasional cases, fragments have been left in the patient. While no post-operative complaints have been received, the long range health consequence of leaving a fragment in-vivo is unknown. The interbody spacer is made from PEEK material and is considered to be biocompatible for long term implantation. Implant fragments which are not retrieved carry the risk of migrating within the body and could result in pain and the related need for medical intervention. No post-operative reports have been received related to risks associated with fragment migration.

The worst case observed occasional risk is patient injury associated with intra-operative dural tears and blood loss. Sharp edges of the broken implant may contact and damage adjacent structures, requiring surgical intervention

Your responsibilities

1. Immediately discontinue use of the *Ardis* Inserter for implanting *Ardis* PEEK Interbody Spacers.
 - Please note: It is not possible to implant the *Ardis* PEEK Interbody Spacer per labeling without the assistance of the *Ardis* Inserter.
2. Use your best medical judgement to assess the condition of your patients previously implanted with an *Ardis* PEEK Interbody Spacer per standard post-operative monitoring practices. Clinical decisions on patient treatment and follow-up remain the responsibility of the medical team.
3. Contact your Zimmer Representative to arrange for the return of any *Ardis* (PEEK) Inserters you may have in your possession.
 - See list of part numbers in the table below

| | |
|---|---------|
| Inserter in <i>Ardis</i> Instrument Set | 3256-01 |
|---|---------|

Questions and Additional Information

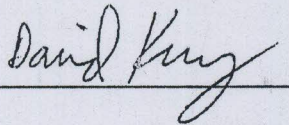
This voluntary action will be reported to the U.S. Food and Drug Administration and Competent Authorities. The FDA and Competent Authorities will also receive from Zimmer progress reports on the implementation of this recall. For any related questions or assistance about this recall, please contact your local Zimmer Spine representative or refer to this website: www.PEEKArdis.Zimmer.com.

MedWatch Reporting

Manufacturers are required to report any serious injuries where a device has contributed to or may have contributed to the event. Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the local competent authorities.

Kind regards



David J. Kunz
Vice-President Quality Assurance & Regulatory Affairs