REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٨/٢٥
رقم الصادر: ١٢/١/٢٥٩٢٨
بيروت، في: ٥ - آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Shoulder Retractors, Bigliani/Flatow Fukuda Retractors

الجهاز المعني بالمتابعة:

- Shoulder Retractors, Bigliani/Flatow Fukuda Retractors
- Trade Mark: Zimmer Inc
- Local Representative: Intermedic S.A.L

بناء على التوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الجهاز المذكور أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

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zimmer

June 14, 2013

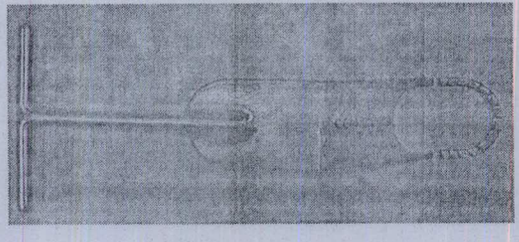
To: Surgeons

Subject: URGENT MEDICAL DEVICE RECALL

Affected Product: Zimmer Bigliani/Flatow® The Complete Shoulder Solution Fukuda Retractors

Item	Lot
00-4305-019-30	61557761
	77000186
	61591732
	61612275
	61614764
00-4305-019-40	61588143
	61612276

In 2010, Zimmer initiated a recall of the Bigliani/Flatow® Fukuda Retractors due to fractures occurring at the grooves around the perimeter of the blades. Zimmer is expanding this recall to include seven lots that were not previously included. The devices are being recalled as they may have been manufactured with an increased grove depth. As a result, there is an increased potential for the retractor to fracture at the groves around the perimeter of the retractor. There have been fifteen reported complaints related to device fracture.



Risks

- Slight delay of surgery to replace the retractor.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. If you find any product from these lots, quarantine the product and notify your Zimmer sales representative.
3. Please ensure the recalled devices are cleaned and sterilized prior to returning them to your Zimmer sales representative. Complete the Certificate of Sterilization (Attachment 2) when providing the units to them.
4. Your local Zimmer sales representative will remove the recalled product from your facility.

This voluntary notification will be reported to the U.S. Food and Drug Administration and local Competent Authority.

Please keep Zimmer informed of any adverse events associated with this device or any other Zimmer product.

Vigilance Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported according to MEDDEV 2.12-1 Rev. 7 to the local health authority in your country.