REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
THE DIRECTOR GENERAL

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ١/٢٨
رقم الصادر: ٢٠١٢/٤/١٣٤٦٤
بيروت، في: ٢٤ آب ٢٠١٢

جانب شركة: Intermedic S.A.L.

الموضوع: إشعار بمتابعة جهاز طبي مغروس.

الجهاز المعني بالمتابعة:

- Surgical instruments, implant impactor, Trabecular Metal reverse shoulder instrumentation liner impactor
- Trade Mark: Zimmer inc
- Local Representative: Intermedic S.A.L.

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مشاكل في عمل مفصل الكتف الإصطناعي الوارد أعلاه، نطلب 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
- المحفوظات

مدير عام الصحة

د. وليد عمار

الجمهورية اللبنانية - المديرية العامة - قلم الديوان - وزارة الصحة العامة

وثيقة مطابقة للأصل
بيروت في ٢٧ آب ٢٠١٢
رئيس قسم امانة السر
عناية غصن

الجمهورية اللبنانية - وزارة الصحة العامة

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July 19, 2012

To: **Risk Managers at Facilities using the Zimmer Trabecular Metal™ Reverse Shoulder Instrumentation Liner Impactor**

Subject: URGENT MEDICAL DEVICE RECALL-LOT SPECIFIC

Affected Product: **Zimmer Trabecular Metal™ Reverse Shoulder Instrumentation Liner Impactor**

Dear Risk Manager:

Zimmer is initiating a lot specific recall of the Trabecular Metal Reverse Shoulder Liner Impactors due to reports of alignment peg fractures occurring in approximately 0.4% of surgeries. See Figure 1 for a representative picture of a fractured alignment peg. The affected item and lot numbers can be found in Attachment 1. The specific lot numbers being recalled were manufactured from 455 stainless steel, which is the material that all of the reported fractured instruments were manufactured from. The remainder of the lot numbers that are not affected by this recall are manufactured from 13-8 stainless steel and have never had a report of an alignment peg fracture. Zimmer distributors have been instructed to remove the affected lot numbers from all user facilities.

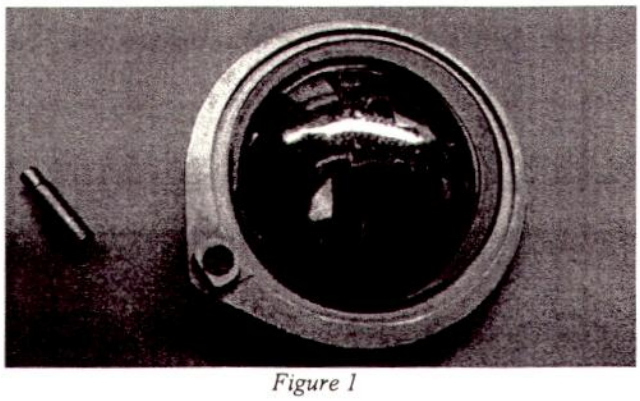

Figure 1

Risks:

Immediate:

- There may be a delay in surgery to locate an additional instrument to complete the surgery or to remove the fragment from the surgical site.
- The fragment may interfere with the placement of the liner implant.

Long term:

- If the alignment peg is left in the patient, there is a risk of an autoimmune reaction.
- In the event that the liner implant is not seated fully, this could result in premature wear and failure.

Your Responsibilities

1. Review the notification and ensure affected personnel are aware of the contents.
2. If you find any product from this lot, quarantine the product and notify your distributor.
3. Complete the acknowledgement certification (Attachment 2) and return it, via fax, to 1-574/372-4265.
4. Please ensure the recalled devices are cleaned and sterilized prior to returning them to your distributor. Complete the form Certificate of Sterilization (Attachment 3) when providing the units to them.
5. Your local Zimmer representative will remove the recalled product from your facility

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Other Information:

This voluntary recall will be reported to the U.S. Food and Drug Administration. The FDA will also receive from Zimmer progress reports on the implementation of this correction. Your urgent cooperation is requested.

MedWatch Reporting: Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

Under 21 CFR Part 803, manufacturers are also 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.

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. 6 to the local health authority in your country.

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ATTACHMENT 1
Affected Item and Lot Numbers

Item	Lot	Item	Lot
00-4309-028-00	60443178	00-4309-028-01	60529860
	60545332		60574377
	60549563		60589079
	60605851		60605856
	60612791		60616574
	60720047		60684774
	60758647		60739623
	60773944		60842967
	60836577		60896979
	60896973		60936815
	60973522		61019785
	61019783		61051017
	61024158		
Item	**Lot**	**Item**	**Lot**
00-4309-029-00	60444332	00-4309-029-01	60535162
	60537066		60545338
	60549565		60576488
	60605852		60605855
	60612792		60637022
	60633381		60689253
	60708954		60772974
	60743404		60875277
	60773946		60918060
	60870480		60989817
	60915146		61011689
	60979391		61024161
	61004027		61051024