REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١٢٥
رقم الصادر : ١٢/١/٢٨٤٢٦
بيروت، في : ٢٩ آب ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي مغروس
Shunts, Pulmonary Artery, Anastaflo Intravascular Shunts

الجهاز المعني بالمتابعة:

- Shunts, Pulmonary Artery, Anastaflo Intravascular Shunts
- Trade Mark: Edwards Lifesciences
- Local Representative: Benta Trading

بناء على التقرير الصادر عن الوكالة الأوسترالية TGA والذي يشير الى وجود خلل في عمل الصنف الوارد أعلاه مما قد يؤثر على سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأوسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

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Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2013-RN-00810-1
Product Name/Description[iii]	Anastaflo Intravascular Shunt (Carotid artery shunt) Model numbers: IVS1512 & IVS2012 All lot numbers ARTG Number: 155725
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Commencement Date[vi]	1/08/2013
Responsible Entity[vii]	Edwards Lifesciences Pty Ltd
Reason / Issue[viii]	Through post market surveillance data review, Edwards Lifesciences has identified a potential health risk to patients undergoing by-pass surgery when an Anastaflo Intravascular Shunt is used. Edwards has received twenty-three complaints concerning excessive adhesive on the shunt body that may interfere with suturing of by-pass grafts. There have been no reports of injuries in any of these complaints. No events have been reported in Australia.
Recall Action[ix]	Recall
Recall Action Instructions[x]	Customers are asked to quarantine affected stock and return all devices with remaining shelf life to Edwards Lifesciences. Customers can contact Edwards Lifesciences to obtain replacement product.
Contact Information[xi]	1800 222 601 - Edwards Lifesciences

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.