



رقم المحفوظات: ٧٧/٢٥
رقم الصادر: ١٢١١/٢٥٤٦٨
بيروت، في ١ - تمريثا ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

FIAB Ultrasound Transmission and IPL Transparent Gel

الجهاز المعنى بالمتابعة:

- FIAB Ultrasound Transmission and IPL Transparent Gel
- Trade Mark: FIAB SpA
- Local Representative:

بناء على التقرير الصادر عن الوكالة الأسترالية TGA والذي يشير الى احتمال تلوث الصنف الوارد أعلاه ببكتيريا Burkholderia cepacia ، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التقرير الصادر عن الوكالة الأسترالية TGA

يبلغ:

- دائرة البرامج والمشاريع ✓
- المستشفيات الحكومية -
- المحفوظات -

مدير عام الصحة

وليد عمار



Recall detail

Type of Product ⁱ	Medical Device
TGA Recall Reference ⁱⁱ	RC-2013-RN-00165-1
Product Name/Description ⁱⁱⁱ	FIAB Ultrasound Transmission and IPL Transparent Gel Batch number: FG260901 (5L clear), FG240903 (5L blue) and FG180701 (260mL clear) Order codes: WS1G008 (260mL clear), WS1G0084 (5L clear) and WS1G0064 (5L blue) ARTG Number: 161851
Recall Action Level ^{iv}	Retail
Recall Action Classification ^v	Class II
Recall Action Commencement Date ^{vi}	21/02/2013
Responsible Entity ^{vii}	Eastland Medical WA Pty Ltd T/A Westcoast Surgical and Medical Supplies
Reason / Issue ^{viii}	TGA Laboratory testing has identified that these batches may be contaminated with bacteria (<i>Burkholderia cepacia</i>).
Recall Action ^{ix}	Recall
Recall Action Instructions ^x	Westcoast Surgical Supplies have requested their customers to inspect their stock and quarantine any affected units. Recovery and replacement/credit note will be organised for all affected units.
Contact Information ^{xi}	08 9455 6676 - Westcoast Surgical and Medical Supplies

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.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.