REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH
The Director General

الجمهورية اللبنانية
وزارة الصحة العامة
المدير العام

رقم المحفوظات: ٢٧١٢٥
رقم الصادر : ١٣/٧/٢٨٤٢٢
بيروت، في :
٢٩ آب ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي
Surgical Instruments, Miscellaneous Surgical Instrument Procedure Pack.

الجهاز المعني بالمتابعة:

- Surgical Instruments, Miscellaneous Surgical Instrument Procedure Pack.
  Trade Mark: Kimal plc
  Local Representative: Novamed S.A.R.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 مشكلة في عملية تعقيم الصنف الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربطاً:

- التوصية الصادرة عن الشركة المصنعة.

يبلغ:

- دائرة البرامج والمشاريع
- المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
د. وليد عمار

الجمهورية اللبنانية
المديرية العامة
قسم الديوان
وزارة الصحة العامة

Museum Street - Hussein Mansour Bldg. - Beirut, Lebanon - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: dirctorgeneral@moph.gov.lb

Thursday 01st August 2013

KIMAL
delivering healthcare innovation

URGENT

Field Safety Notice
Kimal Procedure Packs

Product Code:	Description:	Lot Number:
K26310	HCA Harley Street Cardiac Angio Pack	13E0217

Kimal Plc has identified during investigations, that the sterility of the referenced pack has been compromised. This issue was highlighted during routine sterility testing.

Dear Sir / Madam,

KIMAL plc. is issuing this notice due to a potential issue of sterility with a batch of procedure packs.

We are therefore conducting a product recall as detailed in the attached Urgent Field Safety Corrective Action (Appendix 2).

Our records indicate that you have received the product range affected by this notice and we draw your attention to the following instructions:

- Please review the specific instructions within the attached Field Safety Corrective Action.
- For distributors, please notify Kimal plc within 5 working days on the quantities and location of where these have been shipped, including contact details.
- Please forward this Field Safety Corrective Action immediately to any health care professionals within your organisation that needs to be aware of this notice and to any third party where the affected product may have been used.
- Please complete the attached Product Recall Confirmation Form (Appendix 1) and either fax or email to Kimal plc for the attention of Mr Ben Albutt, Device Vigilance Department on +44(0)1527 572314 or ben.albutt@kimal.co.uk
- Please discontinue use, isolate, label and quarantine any stock to prevent continued use.
- Please contact Mr Ben Albutt in our Device Vigilance Department who will arrange for free of charge replacement stock unaffected by this problem. Contact details ben.albutt@kimal.co.uk or +44(0)1527 572314

Since the problem became known, appropriate measures have been introduced to prevent recurrence. We apologise for the inconvenience caused by this action, taken to safeguard your patients and users.

If you have any concerns or queries, then please do not hesitate to contact Mr Ben Albutt, Compliance/Vigilance Co-ordinator, contact details; +44(0)1527 572314.

Yours sincerely
KIMAL PLC

Attachments:
Appendix 1 – Product Recall Confirmation Form
Appendix 2 – Field Safety Corrective Action