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

الجهاز المعني بالموافقة:
- 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 والنصوصية الصادرة عن الشركة المصنعة والتي تفيد بوجود مشكلة في عملية تعبئة السندن الوارد أعلاه، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:
- النصوصية الصادرة عن الشركة المصنعة.

ينقل:
- دائرة البرامج والمشاريع المستشفيات الحكومية
- المحفوظات

مدير عام الصحة
Thursday 01st August 2013

URGENT

Field Safety Notice
Kimal Procedure Packs

<table>
<thead>
<tr>
<th>Product Code:</th>
<th>Description:</th>
<th>Lot Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>K26310</td>
<td>HCA Harfey Street Cardiac Angio Pack</td>
<td>13E0217</td>
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</table>

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

www.kimal.com