



رقم المحفوظات: ٤٨١ ٢٥
رقم الصادر: ١٤٧/٢٥٥٢٤٩
بيروت، في: ٣٠ تموز ٢٠١٣

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Infusion systems non powered infusion pump.
Easypump C-bloc RA on demand

الجهاز المعني بالمنابعة:

- Infusion systems non powered infusion pump. Easypump C-bloc RA on demand
- Trade Mark: B Braun
- Local Representative:

بناء على التقارير الصادرة عن الوكالة البريطانية

Medicine and Health Care Products Regulatory Agency (UK) MHRA

والتوصية الصادرة عن الشركة المصنعة والتي تشير الى وجود خلل في عمل الصنف الوارد اعلاه مما قد يؤثر على سلامة المريض، 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



18th March 2013

Recall Information

Subject: Easypump C-bloc RA OnDemand
Art.-No.: 4440008
Batches: 152803, 182313, 192472

B Braun Medical Ltd on behalf of I-Flow/Kimberly-Clark (Manufacturer) are recalling the above batches of the Easypump C-bloc RA and would kindly ask that all affected devices are withdrawn from use immediately.

I-Flow/Kimberly-Clark recently determined that in a small quantity of Easypump C-bloc RA pumps with OnDemand bolus button, the button may not lock in the down position when depressed and/or the orange bolus refill indicator may stay in the lowermost position. In this condition, the patient may receive continuous infusion at a rate greater than expected.

I-Flow/Kimberly-Clark's complaint analysis determined that approximately 0.04% of the pumps (i.e., approximately 4 out of 10,000) may develop this condition. If this condition occurs, it may not be detected during filling or priming of the pump. The use of a pump with this condition may result in over medication of the patient and may potentially result in serious patient injury.

According to our records you have received the following stock:

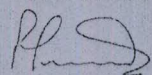
Please contact : Catherine Clulow, Team Leader Quality Complaints , Tel: 0114 2259155.

We will arrange the necessary collection of your stock and immediately issue free of charge replacement stock.

We deeply regret any inconvenience caused by this matter and hope you understand the measures we have to take.

Enclosed you will find an acknowledgement of receipt, we would please request that you sign and send this back to us (fax no 0114 2259136) to confirm that you have received this notice

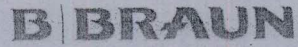
Yours sincerely



Peter Mitchell
Technical and QA Director (R.P.)



Karen Jackson
Medical Affairs Manager



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Field Safety Corrective Action – Product Recall

Subject: Easypump C-bloc RA OnDemand
Art.-No.: 4440008
Batches: 152803, 182313, 192472

PLEASE COMPLETE THIS FORM AND RETURN IT BY FAX TO 0114 2259136

We confirm that we have received and understood the "Recall Notice" in relation to:

- We have received the Recall Notice and have stock to return and will require replacement

| Product Code | Batch | Quantity |
|--------------|-------|----------|
| | | |
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| | | |

- We have received the Recall Notice and do not have any affected stock to return.
- We have received the Recall Notice and have stock to return and require a credit note.

| Product Code | Batch | Quantity |
|--------------|-------|----------|
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- We have received the Recall Notice and the stock has been used without incident.

NAME:

POSITION:

HOSPITAL NAME

DATE:

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