



رقم المحفوظات: ٥٨٢٥  
رقم الصادر: ١٣/١٢٠٥٧  
بيروت، في:  
٥ - آب - ٢٠١٢

جانب نقيب المستشفيات الخاصة في لبنان

الموضوع: إشعار بمتابعة جهاز طبي

Dialysis, haemodialysis filter, Diacap Ultra dialysis fluid filter

الجهاز المعنى بالمتابعة:

- Dialysis, haemodialysis filter, Diacap Ultra dialysis fluid filter
- Trade Mark: B Braun Medical Inc
- 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  
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





12th June 2013

## Follow-Up Field Safety Notice

Subject: Diacap® Ultra Dialysis Fluid Filter,  
Article Code 7107366

Dear Sir / Madam,

We would like to update you on the status of the field safety notice issued 22nd February 2013 in relation to the Diacap Ultra dialysis fluid filter - Article Code 7107366.

The FIELD SAFETY NOTICE dated 22nd February 2013 had the following information:

### *Problem description, root cause*

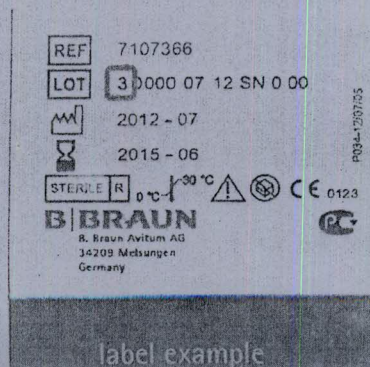
*Over time the residual moisture of the Diacap Ultra membrane can be reduced resulting to a reduction of membrane permeability (ultrafiltration coefficient). During treatment this may lead to a gradually evolving additional ultrafiltration of maximum 230 ml per hour at maximum dialysate flow in single cases. This may cause symptoms in hypotensive-prone patients during dialysis treatment. Only Diacap Ultra older than 10 months after date of manufacture are affected by this non-conformity.*

We have now implemented the corrective measures and Diacap Ultra without any restriction and the shelf life of 3 years is available again.

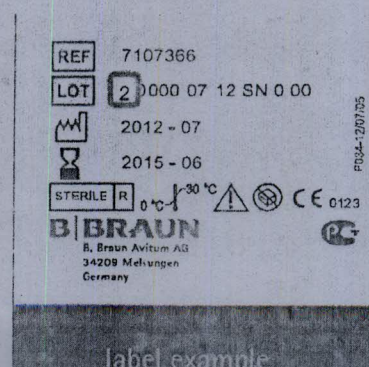
You will be contacted shortly to facilitate the exchange of the affected Diacap Ultra on your stock. Diacap Ultra that are currently in use according to the previous Field Safety Notice, DO NOT have to be replaced.

Products can be identified by the first digit of the Lot number printed on the product label as well as on the carton label:

### OLD LOTS



### NEW LOTS





**B | BRAUN**

B. Braun Medical Ltd  
Thornccliffe Park  
Sheffield S35 2PW  
Tel (0114) 225 9000  
Fax (0114) 225 9111  
<http://www.obraun.com>

Action to be taken:

- Please determine your demand for the exchange of the Diacap Ultra.
- Please ensure that all Diacap Ultra beginning with the Lot. No. 3 on stock are located and quarantined.
- For all issues relating to return/replacement for stock, please contact Catherine Clulow - 0114 2259155. We would kindly ask that you complete the attached form and fax to 0114 2259111 stating the exact quantity to be exchanged and to confirm receipt of this notice.
- Please read the Diacap Ultra Instruction for Use (IFU) as it has been updated. (attachment)

Please make sure that all users of the above mentioned products in your organisation and other concerned persons are informed about this **Follow-Up Field Safety Notice**. If you have forwarded the products to a third party, please forward a copy of the Follow-Up Field Safety Notice to them or inform the contact person mentioned below.

Please retain this Follow-Up Field Safety Notice until you have completed all the above measures. Until all measure are completed, please follow the previous Field Safety Notice.

The MHRA has been notified of the Follow-Up Field Safety Corrective Action.

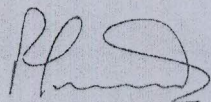
We are available to personally answer any questions you may have regarding this issue and the proposed actions. Please contact

Christine McCabe - 07808 716080

We kindly ask you to confirm the receipt of this information by completing the attached form and returning it by fax to the indicated fax number.

We apologize for the inconvenience caused.

Yours sincerely



Peter Mitchell  
Technical, QM & Environmental Director (R.P.)



Catherine Clulow  
Team Leader Product Complaints