B BRAUN

B. Braun Medical Ltd
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22nd February 2013

URGENT FIELD SAFETY NOTICE

Diacap® Ultra Dialysis Fluid Filter
R-2013-001

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

We would like to inform you about a non-conformity in relation to the Diacap Ultra dialysis fluid filter Article Code 7107366 that have been involved in recent customer complaints without patient harm.

Problem description, root cause and corrective action

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 are currently implementing measures to solve this problem. These Diacap Ultra are expected to be available beginning of June 2013.

Until the corrective action is completed, the following steps must be followed:

1. Do not use Diacap Ultra older than 10 months after date of manufacture.
2. All Diacap Ultra older than 10 months currently in use shall be replaced.
3. Please ensure that all Diacap Ultra older than 10 months are located and quarantined.

Products can be identified by the date of manufacture printed on the product label as well as the carton label.

Example:
Product manufactured in 2012-07 can be used up to end of month 2013-04

= date of manufacture (year-month)

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You will be contacted shortly to facilitate the return and replacement of the affected Diacap Ultra. - For all issues relating to return/replacement for stock, please contact Catherine Clulow - 0114 2259155.

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

Please retain this Field Safety Notice until you have completed all the above measures. You will be informed as soon as the modified product is available.

The MHRA has been notified of the 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 - Commercial Manager - 0780871608

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.)
0114 2259200

Catherine Clulow
Team Leader Product Complaints
0114 2259155

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Confirmation of Receipt of Field Safety Notice R-2013-001

Subject **Diacap® Ultra Dialysate Fluid Filter**
Article Code 7107366

Please fill in this form and return it by fax immediately to the fax number

0114 2259111

☐ We hereby confirm that we are aware of the Field Safety Notice from 22nd February 2013 concerning the Diacap Ultra, Article Code 7107366 the Field Safety Notice was communicated within our organization.

Name: _____

Telephone Number _____

Date and Signature: _____

Stamp: