TO WHOM IT MAY CONCERN

Your reference: RECALL 2015-08-11 LS/DJ
Our reference: LS/DJ/150811
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Date: August 11, 2015

Urgent FIELD SAFETY NOTICE – Easypump II Recall

To whom it may concern,

we, the B. Braun Melsungen AG have decided to recall the following product in the context of a FIELD SAFETY CORRECTIVE ACTION from the market:

<table>
<thead>
<tr>
<th>Article Number</th>
<th>Article Name</th>
<th>Batch</th>
</tr>
</thead>
<tbody>
<tr>
<td>4540016</td>
<td>EASYPUMP II LT 100-50-S</td>
<td>14L01GE261</td>
</tr>
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</table>

Reason for the Recall

In the course of our post market surveillance activities we discovered that a low number of Easypumps with a flow rate of 10ml/h may have potentially been packed and distributed as Easypump II LT 100-50-S with a low flow rate of 2ml/h. The mislabeling is limited to article no. 4540016, batch 14L01GE261. The actual flow-rate of an Easypump can be identified directly on the device with a color coded label on its filter (see picture in Appendix 1). Up to now, no harm or any other adverse patient outcome which could be associated to the above described observation has been reported to the B. Braun Melsungen AG.

As the mislabeling, however, bears the risk of serious over-infusion we have decided to recall the affected batch from the market.

Actions to be taken by the USER

Our records show that your hospital has received the potentially affected EASYPUMP II LT 100-50-S as specified in the table above.

We kindly ask you to initiate the following activities immediately and with priority:

- Identify, quarantine and return affected devices.
- Do not use affected devices anymore.
- Running treatments do not need to be interrupted, only check the flow rate sticker on the filter (details see end of this letter).
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- Inform the responsible personnel in the affected facilities.
- Confirm the receipt of this information.

If more information is needed, please contact

Local contact 1                Local contact 2
Name
Title
Email
telephone

Kindly accept our apologies for any inconveniences.

Yours sincerely,
The flow-rate of an Easypump II is labelled on its filter.

<table>
<thead>
<tr>
<th>Flow rate 2 ml/h</th>
<th>2 ml/h</th>
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<tbody>
<tr>
<td>Flow rate 10 ml/h</td>
<td>10 ml/h</td>
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