

TO WHOM IT MAY CONCERN

Your reference

Our reference

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Date

RECALL 2015-08-11 LS/DJ**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:

Article Number	Article Name	Batch
4540016	EASYPUMP II LT 100-50-S	14L01GE261

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).

Chairman of Supervisory Board:
Prof. Dr. h.c. Ludwig Georg BraunExecutive Board:
Prof. Dr. Heinz-Walter Große
(Chairman)
Dr. Annette Beller
Otto Philipp BraunProf. Dr. Hanns-Peter Knaebel
Dr. Meinrad Lugin
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34212 Melsungen
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Page 2 to the letter of August 11, 2015 to
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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,

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Appendix 1

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



Flow rate 2 ml/h

2 $\frac{\text{ml}}{\text{h}}$

Flow rate 10 ml/h

10 $\frac{\text{ml}}{\text{h}}$