B|BRAUN

B. Braun Melsungen AG
Division Hospital Care

TO WHOM IT MAY CONCERN

Your reference	Our reference	Tel. +49/56 61/71-	Fax +49/56 61/71-	Date
	RECALL 2014-10-16 LS/STK			2014-10-16

Urgent FIELD SAFETY NOTICE – OMNIFIX 20ML LUER SOLO

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
4616200V	OMNIFIX 20ML LUER SOLO	4H11048

Reason for the Recall

In the course of continuous market surveillance activities we discovered that the above specified batch may contain cracks at a low percentage at the paper side of the primary packaging (blister) of OMNIFIX 20ML LUER SOLO. The cracks were observed at the pressure plate of the plunger. 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. Nevertheless, we have decided to recall the affected products from the market as a precautionary measure.

Actions to be taken by the USER

Our records show that your hospital has received potentially affected devices 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.
- Inform the responsible personnel in the affected facilities.
- Confirm the receipt of this information.
- Replacement is available. Please contact your local distributor.

If more information is needed, please contact

Local contact 1
Name
Title

Local contact 2

. . .

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Email
telephone

Kindly accept our apologies for any inconveniences.

Yours sincerely,