B|BRAUN

B. Braun Melsungen AG
Division Hospital Care
Safety Officer Medical Devices

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Your reference:
Our reference: RECALL 2016-06-27 LS/STK

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TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE – PERFUSOR LINE

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
8722960	PERFUSOR LINE, PVC, LL, 150 CM	16C03E08SB4

Reason for the Recall

In the course of our post market surveillance activities we observed that the patient connector (male Luer Lock) within one batch was disconnected from the PVC tube. During investigation it turned out that the gluing connection between the PVC tube and the male luer cone was not fully established in all instances. The described failure is limited to the above mentioned product/batch combination.

The disconnection causes the risk of serious patient harm. We therefore recall the affected batch from the market.

Actions to be taken

Our records have shown that your hospital has received Perfusor Lines of the affected batch as mentioned in the table above.

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

- Please identify, quarantine and return affected devices.
- Please do not use affected devices anymore.
- Please inform the responsible personnel/user staff in the affected facilities .
- Please confirm the receipt of this information.

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If more information is needed, please contact

Local contact1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,