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

Your reference:
Our reference: 2016-10-21 RECALL DG/CB

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Date: October 24, 2016

TO WHOM IT MAY CONCERN

Urgent FIELD SAFETY NOTICE – UREOFIX 500 CLASSIC

To whom it may concern,

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

Article Number	Article Name	Batch
4417930	UREOFIX 500 CLASSIC, EB.2.0L, TUBE 120CM	16F01E8SUA
4417920	UREOFIX 500 CLASSIC, EB.1.5L, TUBE 170CM	16F02E8SUA
4417910	UREOFIX 500 CLASSIC, EB.1.5L, TUBE 120CM	16F06E8SUA

Reason for the Recall
In the course of complaints analyses we identified a defect in UREOFIX 500 Classic. The 1st compartment empties itself in the second one before being full which makes the reading of the diuresis more difficult. Three (3) batches show this defect.

Actions to be taken by the USER
Our records show that your hospital has received potentially affected UREOFIX 500 Classic products 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.

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If more information is needed, please contact

Local contact 1
Name
Title
Email
telephone

Local contact 2

Kindly accept our apologies for any inconveniences.

Yours sincerely,