

Field Safety Notice

Commercial Name of the affected product: Demotek Solution Administration IV Set.

Field Safety Corrective Action / Recall – identifier: 16042018

Type of action: Recall

Date:

16th Apr. 2018

Attention:

DRMS (Jordanian Armed Forces)

Details on affected device:

Demotek Solution Administration IV Set

REF: IS08

LOT: 20170215

Description of the problem:

The product has shown leakage on the interconnection between titration needle and lower cover of hard chamber.

Advise on action to be taken by the user:

- Check the product prior to attach a solution
- Do not use if any parts are not connected
- If defected product found identifying and quarantining the device

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those where the potentially affected products have been transferred

Contact reference person:

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The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

