

Urgent Safety Communication

Potential Risks associated with Vial2Bag Fluid Transfer Sets: May Result in Patient Harm

Device/ Product Name:	<ul style="list-style-type: none"> - Vial2Bag Fluid Transfer Sets - Vial2Bag Direct Connect 13 mm IV Fluid Transfer Sets - Vial2Bag Direct Connect 20 mm IV Fluid Transfer Sets
Lot numbers/Serials:	Several Lots
Manufacturer:	<p>West Pharmaceutical Services, IL, Ltd</p> <p>Also may known under several names:</p> <ul style="list-style-type: none"> - Medline Industries Inc - Medimop Medical Projects Ltd. - Cardinal Health - Progressive Medical
Problem:	<p>SFDA would like to bring your attention to the potential risks associated with the devices mentioned above, which may not adequately transfer drug contents to IV Bag. Potentially resulting in variable or unpredictable dosing. Variable or unpredictable dosing of medication may, in general, lead to overdosing or underdosing, with the effects depending upon the specific drug, specific patient, and the condition for which the drug was ordered.</p>
Recommendation/Actions:	<ul style="list-style-type: none"> • Identify any affected products in your facility. • You should response to this Safety Communication If you have the affected products available in your facility. • Avoid using affected products and use alternate products until further notice. • Report to SFDA any adverse events suspected to be associated with affected Vial2Bag Fluid Transfer Sets

	<ul style="list-style-type: none"> through National Center for Medical Devices Reporting (NCMDR) Or Saudi Vigilance Prompt reporting of adverse events can help the SFDA identify and better understand the risks associated with medical devices.
<p>Devices/Products photo:</p>	

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative for corrective action.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

[National Center for Medical Devices Reporting.](#)

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
Riyadh 13312 - 6288
Tel: +966 (11) 2038222 Ext: 2406, 2479
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Or

[Saudi Vigilance](#)

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Sincerely,
NCMDR Team