



## **Safety Communication**

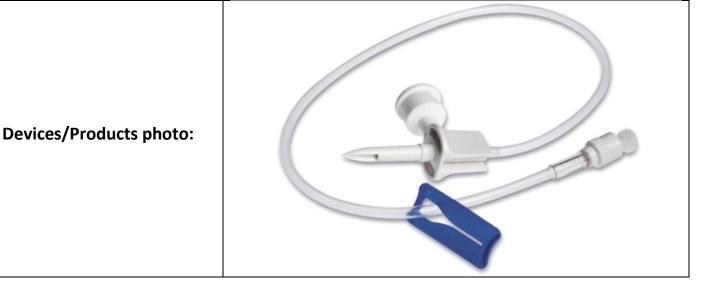
## potential leakage may interrupt treatment and expose to hazardous drugs

Device/ Product Description:	Closed System Transfer Device	
Brand Name:	BD PhaSeal™ C61 Secondary Set	
Lot numbers/Serials:	Product Code (REF) 515302	Lot Numbers 1011102, 1011095, 1011186, 1011412, 1011464, 1011580, 1011753, 1011786, 1011787.
Manufacturer:	Becton Dickinson	
Problem:	Potential leakage at the joint between the tubing and spike components. This leakage could result in delay/interruption in treatment, under infusion and/or exposure of the patient or healthcare worker to hazardous drugs.	
Recommendation/Actions:	<ol> <li>Please inspect your inventory and locate and quarantine any unused device/s of any of the impacted lot numbers of the BD PhaSeal™ C61, REF: 515302. Destroy all impacted devices or return to your BD local representative/distributor to be destroyed.</li> <li>Contact BD local representative, Ahmed.Taha@bd.com (Tel: 00966 11 266 3216) OR Saleh.al.sohibanei@bd.com (Mobile: 0544760333), for alternative replacement devices as soon as possible.</li> <li>You can read the complete Safety Alert that includes recommendations from (HERE).</li> </ol>	

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

Healthcare Professionals should <u>report any adverse events</u> 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

4904 northern ring branch rd - Hitteen Dist.

RIYADH 13513 - 7148

Tel: +966 (11) 2038222 Ext: 2406, 2479

Fax: +966 (11) 2757245

Or

Saudi Vigilance

For latest published Recalls/Alerts, please visit (NCMDR Website)

Sincerely, NCMDR Team



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