

Safety Communication

potential leakage may interrupt treatment and expose to hazardous drugs

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| Device/ Product Description: | Closed System Transfer Device | |
| Brand Name: | BD PhaSeal™ C61 Secondary Set | |
| Lot numbers/Serials: | Product Code (REF) | Lot Numbers |
| | 515302 | 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 style="list-style-type: none"> 1. 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. 2. Contact BD local representative, Ahmed.Taha@bd.com (Tel: 00966 11 266 3216) OR Saleh.al.sohibane@bd.com (Mobile: 0544760333), for alternative replacement devices as soon as possible. <p>You can read the complete Safety Alert that includes recommendations from (HERE).</p> | |

Devices/Products photo:



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 **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

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Or

[Saudi Vigilance](#)

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Sincerely,
NCMDR Team