Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the below medical device:

Device Details	
Device Name	BARD SafeStep Huber Needle Sets
Lot No.	REEN3159, REEP3067, REEQ4064, REDS3541, REDV3438, REEN2781, REEN2145, REEP3068, REDY0835, REDZ3103
Manufacturer	Becton Dickinson
Country of Origin	USA
Reference	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=181912
Device picture	
Reason of Recall	NHRA initiates this FSN due to Potential development of cracks or breaks in the tubing near the Luer or Y site of the device. Devices that have developed breaks or cracks can cause leakage resulting in exposure to chemicals such a chemotherapeutics or biohazard material (e.g., blood). A crack or break could result in potential blood loss, catheter occlusion, air embolism, under or interrupted infusion, or site contamination which could lead to infection.
Action should be taken	Please stop using the above defected medical device and contact the supplier to take the necessary action for recall.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh