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	BD PCEA Patient Controlled Epidural Analgesia Administration Sets
Affected Devices	19016079 – 19036183 - 19045426
Manufacturer	Becton Dickinson (BD)
Reference	https://www.bd.com/en-us/support/recall-notifications/recall-notification-bd-alaris-pcea-administration-set-and-bd-alaris-pcea-administration-kit
Reason of Recall	NHRA initiates this FSN due to potential leak between the connection of the male luer and the yellow striped tubing. This leak may be observed while priming or during use. The most likely health consequence associated with this leak would be inadequate pain control for the patient due to an under-infusion of medication.
Action should be taken	Please stop using the above-mentioned defected medical device and contact your authorized representative to take the necessary action to recall the device.

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

For more information please contact Medical_Devices@nhra.bh