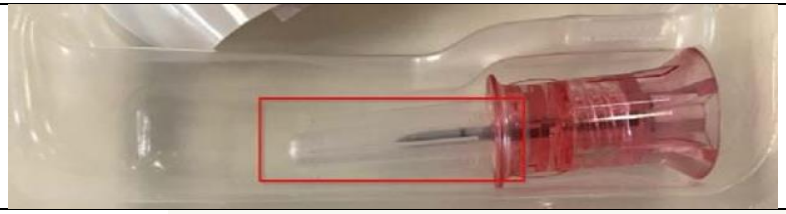
Medical Devices Safety Notice

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	Intraosseous vascular access needle sets (Arrow EZ-IO)
Device Model	9018P-EE-005; 9018P-EU-005; 9018P-ME-005 ;9018P-NO-005; 9018P-VC-005; 9001P-EE-005; 9001P-EU-005; 9001P-ME-005; 9001P-NO-005;9001P-VC-005; 9079P-EE-005; 9079P-EU-005; 9079P-ME-005; 9079P-NO-005; 9079P-VC-005
Manufacturer	Teleflex Medical
Country of Origin	USA
Reference	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177074
Device picture	
Reason of Recall	NHRA initiates this FSN due to the safety cap attached to needles within the needle sets may become dislodged exposing the needle and potentially causing the needle to protrude through the packaging. If this issue is not detected, the immediate risk of exposure to the affected devices is needle stick injury to the clinician or health care professional. In addition, a puncture of the packaging may compromise the sterility of the needle.
Action taken	In case of having the above defected medical device, please contact the authorized representative **Gulf Pharmacy** at regulatory@gctbahrain.com to take the necessary action.

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

For more information please contact Medical_Devices@nhra.bh