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	Arrow® QuickFlash® Radial Artery Catheterisation Kits and Sets & Arrow® QuickFlash® Radial Artery/Arterial Line Catheterisation Kit
Device Model	RA-04220
Lot No.	14F23F0377 , 14F23H0087
Manufacturer	Teleflex Medical
Country of Origin	Ireland
Reference	https://azuksappnpdsa01.blob.core.windows.net/datashare/2433-Field-Safety-Notice-Teleflex-15-February-2024.pdf
Reason of Recall	NHRA initiates this FSN due to reports received indicating a potentially defective component. The complaints received are related to resistance of the guidewire handle/chamber during use. The possible immediate health consequences of the component issue are arterial vasospasm and vessel injury arising from multiple arterial punctures with repeated attempts
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative **Gulf Corporation of Technology** at Quality@gctbahrain.com 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

Recall 2024 0004

18th Feb 2024