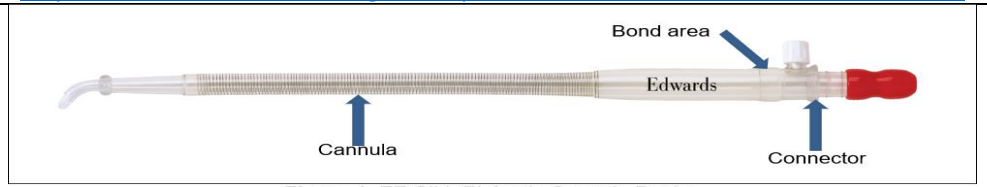
Medical Devices Safety Notice

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	EZ Glide Aortic Perfusion Cannula
Device Model	EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A and EZS24TA.
Lot No.	Refer to FDA link below
Manufacturer	Edward LifeScienes
Country of Origin	Switzerland
Reference	https://www.edwards.com/EZ-Glide-Cannulae-Recall-Information https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=177110
Device picture	 **Figure 1.** EZ Glide™ Aortic Cannula Device
Reason of Recall	NHRA initiates this FSN due to separation of the cannula from its connector causing breach of the cardiopulmonary bypass (CPB) circuit and loss of blood, there is also risk of air embolism and ischemic events.
Action taken	In case of having the above defected medical device, please contact the Authorized Representative **Gulf Pharmacy** at regulatory@gtcbahrain.com to take the necessary action to return the defected devices.

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

For more information please contact Medical_Devices@nhra.bh