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	Glide Aortic Cannula
Device Model	EZC21A, EZC21TA, EZC24A, EZC24TA, EZF21A, EZF21TA, EZF24A, EZF24TA, EZS21A, EZS21TA, EZS24A, and EZS24TA
Lot No.	Mentioned in below link
Manufacturer	Edwards Lifesciences LLC
Country of Origin	USA
Reference	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/07/2019/14271-19_kundeninfo_en.pdf?__blob=publicationFile&v=1
Device picture	
Reason of Recall	NHRA initiates this FSN due to potential risk of separation of EZ Glide cannula from its connector, causing a breach of the cardiopulmonary bypass (CPB) circuit and loss of blood.
Action should be taken	Please stop using the defected medical device and contact the authorized representative **Gulf Pharmacy** at regulatory@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 2020 0065