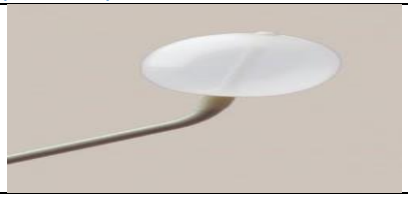
Medical Devices Safety Notice

The National Health Regulatory Authority would like to alert all governmental and private healthcare facilities, local agents and distributors that the following medical device:

Device Details	
Device Name	Miller Balloon Catheter
Device Model	830515F
Lot No.	60618778
Manufacturer	Edward Lifescience
Country of Origin	Puerto Rico
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/edwards-lifesciences-recalls-miller-and-fogarty-atrioseptostomy-dilation-catheters-due-balloon
Device picture	
Reason of Recall	NHRA initiates this FSN due to the possibility of difficulty in balloon deflation after deployment, which may lead to balloon fragmentation or detachment upon attempted retrieval. This may cause serious adverse health consequences including: damage to the heart, the inferior vena cava, and/or the femoral and iliac veins; additional procedures to retrieve the fragments; permanent patient disability; pulmonary embolism; stroke; damage to other organs; or death.
Action taken	In case of having the affected device, please stop using it and contact the local agent **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