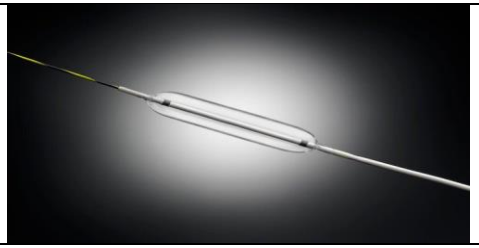
Medical Devices Safety Notice

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	Hurricane™ RX Biliary Balloon Dilatation Catheter
Device Model	M00545890, M00545910, M00545930, M00545890, M00545920, M00545940, M00545900, M00545920, M00545950, M00545960
Lot No.	Please refer to below link
Manufacturer	Boston Scientific
Country of Origin	USA
Reference	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/14/2020/15244-20_kundeninfo_en.pdf?__blob=publicationFile&v=1
Device picture	
Reason of Recall	NHRA initiates this FSN due to complaints reported for pinholes in the balloon. The user may notice that the balloon either rapidly loses pressure or fails to gain or maintain pressure.
Action should be taken	Please stop using the above mentioned defected medical device and contact the authorized representative Gulf Corporation for 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 2021 0064