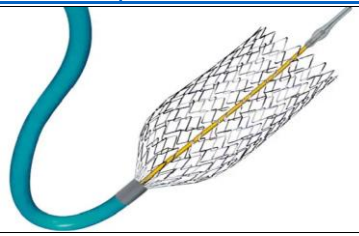
Medical Devices Safety Notice

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	Precise PRO Rx US Carotid System by Cordis
Affected Devices	Please refer to below link
Manufacturer	Cordis Corporation
Country of Origin	USA
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/cordis-recalls-precise-pro-rx-us-carotid-system-due-risk-separation-device-during-use
Device picture	
Reason of Recall	NHRA initiates this FSN due to a risk of separation of the atraumatic distal tip of the sheathed delivery system in patients. If the device separates during use this may cause serious adverse events such as removal of the separated tip from the carotid artery, embolization distally, or stroke.
Action should be taken	Please stop using the above mentioned medical devices and contact your supplier or the manufacturer 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 0028