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	Valiant Navion™ Thoracic Stent Graft System
Affected devices	V30394285 / V30026013 / V29941659 / V29939761 / V29939760 / V29842210 / V29842175 / V29806012 / V29802237
Manufacturer	Medtronic
Country of Origin	Ireland
Reference	https://newsroom.medtronic.com/news-releases/news-release-details/medtronic-announces-voluntary-recall-unused-valiant-naviontm
Device picture	
Reason of Recall	NHRA initiates this FSN due to serious adverse events associated with use of the mentioned medical device including stent fractures, endoleak and stent ring enlargement which could lead to potentially lead to aneurysm rupture.
Action should be taken	Please stop using the defected medical device and contact the authorized representative **Cigala** at maha@cgmed.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 0015