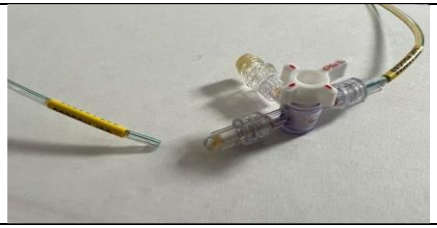
Medical Devices Safety Notice

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	**Duet EDMS BlueCore with VCath**
Device Model	46916
Serial No.	223999043
Manufacturer	Medtronic Inc
Country of Origin	Mexico
Reference	https://portal.mda.gov.my/index.php/documents/recall/2948-duet-external-drainage-and-monitoring-system-pdf/file
Device picture	
Reason of Recall	NHRA initiates this FSN due to the potential for catheter disconnection from the patient line stopcock connectors. If a tubing disconnection occurs, potential harm to patients may include infections, cerebrospinal fluid leakage, overdrainage of cerebrospinal fluid, and abnormality of the ventricles. Uncontrolled overdrainage of cerebral spinal fluid could lead to neurological injury or death if the disconnection is undetected.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Cigala Gulf Medical 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 2024 0003 **13th Feb 2024**