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	HeartWare Ventricular Assist Device (HVAD)™ System	
Affected Devices	**Device Model**	**Description**
	1104	HVAD Pump Implant Kit
	MCS1705PU	HVAD Pump Implant Kit
	1125	HVAD Pump Outflow Graft
	MCS1725OG	HVAD Pump Outflow Graft
	1153	HVAD Pump Implant Accessories
	MCS1753AK	HVAD Pump Implant Accessories
	100	Driveline Extension Cable
Manufacturer	Medtronic	
Country of Origin	Netherlands	
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-stops-distribution-and-sale-heartware-hvad-system-due-risk-neurological-adverse-events#:~:text=Reason%20for%20Recall,restarting%20or%20fail%20to%20restart.	
Device picture		

For more information please contact Medical_Devices@nhra.bh

Recall 2021 0055

Reason of Recall	NHRA initiated is FSN due to an issue where the HVAD™ pump may experience a delay to restart or a failure to restart. Medtronic has not been able to pinpoint a root cause for each pump restart failure, this failure could lead to serious patient harm or death.
Action should be taken	Please stop using the above mentioned implants and contact the authorized representative **Cigala Gulf Medical** at sayed@cgmed.com to take the necessary action for replacement.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh