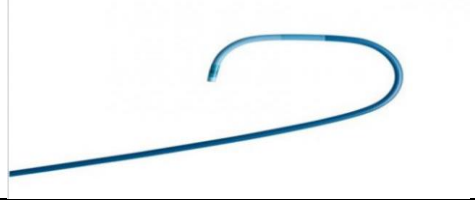
Medical Devices Safety Notice

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	6 French Sherpa NX Active Guide Catheters
Device Model	All
Manufacturer	Medtronic
Country of Origin	USA
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/medtronic-recalls-6-french-sherpa-nx-active-guide-catheters-due-separation-and-fragmentation-issue
Device picture	
Reason of Recall	NHRA initiates this FSN due to the risk of the outer material separating from the device resulting in detached fragments that could result in the underlying stainless-steel braid wires being exposed. These fragments could be left inside the patient's bloodstream, and this or the attempts made to retrieve the fractured pieces, can cause other serious adverse health consequences such as continued blockage of blood vessels, injury to blood vessel walls, development of blood clots, embolism, heart attack or death.
Action should be taken	In case of having the above defected medical device, please stop using it and contact your local agent 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