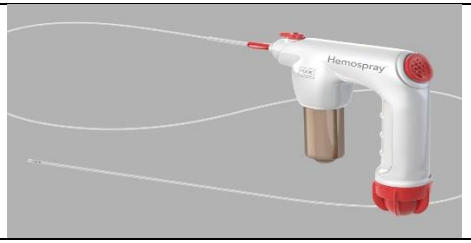
Medical Devices Safety Notice

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	Hemospray Endoscopic Hemostat
Device Model	HEMO-7-EU
Lot No.	W3915373 – 3, W3991856 – 1, W4163471 – 6, W4163796 – 10, W4049196 - 1
Manufacturer	Cook Endoscopy/Wilson-Cook Medical, Inc.
Country of Origin	USA
Reference	https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/72371r-eng.php#reason-motif
Device picture	
Reason of Recall	NHRA initiates this FSN due to the handle and/or activation knob on Hemospray Endoscopic Hemostat devices have broken or cracked when the device is activated, prior to and during use. This has led to the carbon dioxide cartridge exiting the handle.
Action should be taken	Please stop using the above defected medical device, and contact the authorized representative **YMH** at me.regulatory@ymh.com.bh to take the necessary action for withdrawal.

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

For more information please contact Medical_Devices@nhra.bh