


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	CIRRUS2 NEBULISER, ADULT, INTERSURGICAL ECOLITE MASK KIT WITH TUBE, 2.1M
Lot No.	32052973 / 32053276 / 3205352
Manufacturer	Intersurgical Ltd
Country of Origin	UK
Reference	https://mhra.gov.filecamp.com/s/ECw5oPYZcnnvScTdP/d
Device picture	 <p>(1) Mask without Vents (2) Correct Mask with Vents</p>
Reason of Recall	NHRA initiates this FSN due to Adult Ecolite™ Aerosol Mask with vents (Picture 1), has been found to contain a similar mask without vents (Picture 2), this would prevent the patient breathing normally. This could result in distress or some form of harm to the patient if unnoticed. It would also prevent the intended treatment being provided to the patient.
Action should be taken	Please stop using the defected medical device and contact the authorized representative General Medicals at Registration.medics@intercol.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