

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	Portex™ Orator Speaking Valve
Device Model	100/550/000
Lot No.	4097683
Manufacturer	Smiths Medical
Country of Origin	UK
Reference	Link
Reason of Recall	NHRA initiates this FSN due to potential packaging seal failures in specific medical devices, which may result in non-sterile products being used, posing a risk of infection.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative BEHZAD MEDICAL EST. W.L.L at info@behzadmedical.com.bh 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