

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	Single use distal cover
Device Model	MAJ-2315
Lot number	Lower than H2530
Manufacturer	OLYMPUS
Country of Origin	JAPAN
Reference	Link
Reason of Recall	NHRA initiates this FSN due to the fact that the device may cause mucosal injury and/or become cracked and/or detached from the endoscope during use. Consequences of a detached or cracked distal cover could include the risk of aspiration, inhalation, tissue damage or bleeding, or obstruction that will require urgent removal, and/or burns from an uncovered distal end.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Gulf Corporation for Technology at quality@gctbahrain.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