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	Lasertube (Rubber) Laser resistant tracheal tube, cuffed; Endotracheal tube for laser surgery
Device Model	102004
Lot No.	19071
Manufacturer	Teleflex Medical
Country of Origin	Germany
Reference	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2020/08453-20_kundeninfo_en.pdf;jsessionid=8B15C36A2558732BD1DA33CC84B0E9F1.1_cid319?__blob=publicationFile&v=2
Reason of Recall	NHRA initiated this FSN because the laser guard foil partially separated and/or slightly detached at the edges in the presence of moisture. If the defect is present and is not recognized prior to use, adverse health consequences may result from the use of the device during laser therapy in the trachea and larynx including potential for mucosal cell trauma/bleeding, scarring, infection and pain.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative **Gulf Pharmacy** at regulatory@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

Recall 2021 0003