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	NEO-FIT NEONATAL ENDOTRACHEAL TUBE GRIP SET
Device Model	42-2540
Lot No.	All
Manufacturer	COOPER SURGICAL
Country of Origin	USA
Reference	https://www.bfarm.de/SharedDocs/Kundeninfos/EN/12/2022/28312-22_kundeninfo_en.pdf;jsessionid=A6D72A2D98EBE69E8DE49DF986DFAE79.internet272?__blob=publicationFile
Reason of Recall	NHRA initiates this FSN due to a potential health risk in which metal clips used to grip the endotracheal tube may fracture and detach from the strap and then be ingested by the patient. If detached metal clips are ingested, there is a potential for laceration to the gastrointestinal tract as the clip passes through the patient's body.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative GULF HOUSE MEDICAL SYSTEM W.L.L at info@gulfhousemedical.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 2022 0045