


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	Intraluminal Staplers
Device Lot No.	ECS21A, ECS25A, ECS29A, ECS33A, CDH21A, CDH25A, CDH29A, CDH33A
Manufacturer	Ethicon Endo-Surgery, LLC
Country of Origin	
Reference	https://www.hpra.ie/docs/default-source/field-safety-notices/march-2019/v39460_fsn.pdf?sfvrsn=2 http://www.hpra.ie/docs/default-source/Safety-Notices/sn201911_4_ethicon_intraluminalstaplers_v39460.pdf?sfvrsn=2
Device picture	
Reason of Recall	NHRA initiates this FSN due to occurrence of uncut washers and malformed staples with their intraluminal circular staplers, which can compromise staple line integrity. If a problem with the staple line is not adequately addressed or is not recognized, there is a potential risk of postoperative anastomotic leak, gastrointestinal injury, haemorrhage, or haemorrhagic shock.
Action required	In case of having the affected devices, please stop using them and return them back to the local agent Gulf Pharmacy regulatory@gctbahrain.com to take the necessary action.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh