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	Automated Surgical Stapling
Brand Name	Endo GIA, Tri-Staple 2.0
Lot No.	Refer to the following link: https://ncmdr.sfda.gov.sa/FileDownLoad.ashx?f=ca&fid=8274
Manufacturer	Medtronic ltd.
Country of Origin	USA
Reference	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=14366
Device picture	
Reason of Recall	NHRA Initiates this FSN due to fact that there is a potential for a device to be missing one of two pin components that maintain alignment of the device jaws. Use of a product without a pin may result in incomplete staple formation, potentially leading to bleeding, anastomotic leak, peritonitis, or pneumothorax, which can result in the potential for infection and/or sepsis.
Action to be taken	In case of possessing the defected device, please contact the local agent to take the necessary action and in case of an adverse event caused by the defected medical device, please contact NHRA.

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

For more information please contact Medical_Devices@nhra.bh