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	EEA™ Autosuture™ Circular Stapler
Device Model	EEA25, EEAXL25, EEA2535, and EEAXL2535.
Lot No.	All Lots beginning with “P0”, “P1”, “P7”, “P8”, “P9”
Manufacturer	Medtronic
Country of Origin	USA
Reference	https://mhra-gov.filecamp.com/s/vOXxTrepAW6YK3DX/d
Reason of Recall	NHRA initiates this FSN due to the potential for the staple guide to not be securely attached to the instrument. This could cause the component to disengage and if disengaged, could allow the device to transect tissue without forming staples. This could result in delay of treatment, extended hospital stay, unspecified tissue injury, unintended radiation exposure, unexpected medical intervention, foreign body in patient, failure to anastomose, and hemorrhage.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative **YMH** at me.regulatory@ymh.com.bh 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 0023