

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	AMS 700 with MS Pump	
Item Code	Item Description	Batch No
72404252	AMS 700 LGX MS Pump 1Z (18 cm)	1000387238
72404252	AMS 700 LGX MS Pump 1Z (18 cm)	1000387239
72404251	AMS 700 LGX MS Pump 1Z (18 cm)	1000321545
Manufacturer	Boston Scientific	
Country of Origin	USA	
Reference	http://www.hpra.ie/docs/default-source/field-safety-notice/september-2020/v44778_fsn.pdf?sfvrsn=2	
Reason of Recall	NHRA initiates this FSN due to problem encountered during the initial activation of the device, typically within the first 2 months after an AMS 700 implant procedure, in which the patient and/or physician is unable or has difficulty activating the pump in order to achieve cylinder inflation.	
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Aljishi at reneesh@aljishi.com to take the necessary 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