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	TM-317 PneumoDart-Pneumothorax Needle
Device Code	NSN 6515-01-655- 9514
Lot No.	190524J69
Manufacturer	Tytek Medical
Country of Origin	USA
Reference	https://www.fda.gov/medical-devices/medical-device-recalls/tytek-medical-recalls-tm-317-pneumodart-pneumothorax-needle-due-fully-and-partially-blocked-needles
Device picture	
Reason of Recall	NHRA initiates this FSN due to the risk of blocked needles. The blockage in the needles is caused by the presence of adhesive from the assembly process. If the needle is blocked, emergency treatment is delayed which can lead to heart or lung failure, or death. An affected device may cause additional injury since the diagnosis of lung injury may be complicated.
Action taken	Please stop using the above defected medical device and contact your authorized representative to take the necessary action for withdrawal.

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

For more information please contact Medical_Devices@nhra.bh