

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	ATTUNETM MEASURED SIZING & ROTATION GUIDE INSTRUMENT
Device Model	P/N 254400525
Lot No.	AB4536235, AB4733296, AB4841493, AB4810808, AB4841495, AB4904565, AB4967214, AB5004557, AB5034303
Manufacturer	Depuy synthes - Johnson & Johnson
Country of Origin	Ireland
Reference	https://www.igj.nl/binaries/igj/documenten/waarschuwingen/2022/07/11/depuy-ireland-fa-2126657---attune%E2%84%A2-measured-sizing--rotation-guide-instrument/IT2064512+DePuy+FA+2126657+--ATTUNE_EN.pdf
Reason of Alert	NHRA initiates this FSN due to Nine (9) lots of the subject product had been manufactured with the incorrect grade of steel. The incorrect steel spring material has the potential to oxidize, leading to corrosion.
Action should be taken	<ol style="list-style-type: none"> 1. Examine your inventory immediately for the subject lots and quarantine the products replacement of the spring will be completed by your DePuy Synthes Sales Consultant. 2. Post a copy of this notice in a visible area for awareness and keep a copy for your records. <p>And for more information please contact the authorized representative Gulf corporation for technology at caroline@gctbahrain.com.</p>

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

For more information please contact Medical_Devices@nhra.bh