

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	Soft Tissue Retractor, radiolucent
Serial No.	IU 7971-00
Lot No.	ALL
Manufacturer	AAP IMPLANTATE AG
Country of Origin	Germany
Reason of Recall	<p>NHRA initiates this FSN due to the soft tissue retractor is not always removed during the sewing process. This can result in damage to the soft tissue retractor in which abrasion debris can develop and remain in vivo.</p> <p>The biocompatibility of the material of the soft tissue retractor is limited to temporary use. Due to the high risk of the product being used incorrectly during the sewing process.</p>
Action should be taken	Please stop using the above-mentioned defected medical device and contact the authorized representative Bahrain Pharmacy at bahpharm@batelco.com.bh to take the necessary action for withdrawing.

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

For more information please contact Medical_Devices@nhra.bh