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	SurgiMend® PRS / SurgiMend® PRS Meshed SurgiMend®/ SurgiMend® MP Revize™ / Revize™-X PriMatrix® Dermal Repair Scaffold PriMatrix® Ag Antimicrobial Dermal Repair Scaffold
Device Model / Lot No.	Please refer to below Link
Manufacturer	Integra LifeSciences
Country of Origin	USA
Reference	https://fsca.swissmedic.ch/mep/api/publications/Vk_20230530_03/documents/3
Reason of Recall	NHRA initiates this FSN due to issues with in-process and finished goods endotoxin testing that may result in out of specification endotoxin results. the potential harms due to high levels of endotoxins may include low-grade fever, inflammation, and/or inflammatory response leading to fever (pyrexia), and/or surgical intervention/revision surgery. Per the conclusion of this evaluation, there is a remote possibility of these adverse health consequences occurring.
Action should be taken	Patients who already implanted or used the affected products should be monitored for a fever in the immediate postoperative period according to the standard hospital or clinician protocol. Please stop using the above mentioned medical device and contact the authorized representative 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 2023 0015 **13 / Jun / 2023**