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	BioPince TruCore Biopsy Biopince Ultra
Lot No.	11571058
Manufacturer	ARGON MEDICAL DEVICE
Country of Origin	USA
Reference	Link
Reason of Recall	NHRA initiates this FSN due to the identification of holes in 0.29% of the packaging trays of BioPince™, BioPince Ultra™, and TruCore™ II Automatic Biopsy Instruments, compromising the sterile barrier and posing a risk of infection or sepsis to patients.
Action should be taken	Please stop using the above mentioned medical device and contact the authorized representative Union MediScience B.S.C (Closed) at regulatory@unionmediscience.com & info@unionmediscience.com 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