


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	Venflon Pro Safety (VPS) Needle Protected IV Cannula
Device Ref No.	393222 / 393224 / 393226 / 393227 / 393228 / 393229 / 393230 / 393280 / 393281 / 393282 / 393283
Manufacturer	Becton Dickinson
Country of Origin	Switzerland
Reference	https://www.gov.uk/drug-device-alerts/recall-of-bd-venflon-pro-safety-iv-cannula https://www.jazmp.si/fileadmin/datoteka/dokumenti/SMP/Varnostna_obvestila/2021/April/301-40-2021%20Posodobljeno%20varnostno%20obvestilo.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to the potential leakage from the injection port. This leak is undetected and could result in blood loss or inadequate infusion of the infusate and this could result is serious harm or even life-threatening conditions or death. This recall is limited only to the product that has been sterilized by EtO. It does not impact BD Venflon™ Pro Safety (VPS) Needle Protected IV Cannula which has been sterilized by radiation (E-beam).
Action should be taken	Please stop using the above-mentioned medical device and contact the authorized representative Wael Pharmacy at vincent@waelpharmacy.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