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	Venovo™ Venous Stent System
Affected Devices	Please refer to below link
Manufacturer	BARD GmBh
Country of Origin	Germany
Reference	https://wwwmedia.supplychain.nhs.uk/media/1278-Field-Safety-Notice-Becton-Dickinson-Venovo-Venous-Stent-System-24-May-2021.pdf
Device picture	
Reason of Recall	NHRA initiates this FSN due to potential to exhibit deployment issues whereby the proximal end of the stent may not immediately expand upon deployment. The proximal end of the stent instead remains connected to the stent cushion on the delivery system. Potential harm ranges from prolonging the procedure, damaging or deformity of the stent, potential vascular injury and / or hemodynamic disruption affecting the blood flow and / or a thrombotic event.
Action should be taken	Please stop using the defected medical device and contact the authorized representative **Bahrain pharmacy** at pqc@bahrainpharmacy.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

Recall 2021 0034