Date: 11 Mar 2024
Reference Number: SG-2403-417-H

قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

رسالة سلامة

Safety Communication

To: Healthcare Provider	**إلى: مقدمي الرعاية الصحية**

Title	Recommendations for Healthcare Providers regarding the safe and effective use of hemodialysis devices to prevent related Venous Needle Dislodgement (VND) and Access-Bloodline Separation (ABLS)	**العنوان**
Medical Device Description	Hemodialysis Devices	**اسم ووصف الجهاز/المستلزم الطبي**
Manufacturer	All	**اسم المصنع**
Authorized Representative	All	**الممثل المعتمد**
Medical Devices Marketing Authorization (MDMA)	All	**إذن التسويق**
Potential /Associated risks	Based on the SFDA's Post-Market Clinical Evaluation study, which examined and highlighted the potential risks of VND and ABLS while using hemodialysis devices in light of their adverse events, risk factors, complications, preventive recommendations, and reporting awareness within Saudi healthcare providers. The study revealed multiple complaints during hemodialysis treatments, including VNDs, ABLSs which caused cases of slight blood loss, hypovolemic shock, and mild hypotension. SFDA found that there are underreporting of the complaints and adverse events related to these issues to the National Center of Medical Devices Reporting (NCMDR).	**المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي**
Recommendations	1. Healthcare providers must use hemodialysis and bloodlines approved by SFDA. 2. Healthcare providers must be specialized, trained, and qualified to use hemodialysis devices along with bloodlines. 3. Healthcare providers must use hemodialysis and bloodlines as trained by the manufacturers. 4. Healthcare providers must inform and educate the patient about VND, ABLS, and associated complications to articulate and prevent the risk of VND and ABLS. 5. Healthcare providers must report any adverse event or complaints they encounter with hemodialysis.	**التوصيات**
For Reporting	SFDA 19999 مركز الاتصال الموحد · NCMDR · تيقظ Saudi Vigilance	**للإبلاغ**