


## 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	Hemodialysis Venous Catheter Components
Brand Name	Multiple Brands
Lot No.	N/A
Manufacturer	Multiple Manufacturers
Country of Origin	Multiple
Reference	<a href="https://www.sfda.gov.sa/ar/medicaldevices/Weekly%20Alerts/(SG-1907-73-H).pdf">https://www.sfda.gov.sa/ar/medicaldevices/Weekly%20Alerts/(SG-1907-73-H).pdf</a>
Device picture	
Reason of Recall	NHRA Initiates this FSN due to fact that Hemodialysis Venous Catheter Components can disengage during routine use, quickly causing patient harm or death.
Action to be taken	<b>In case of having the above medical device, please follow the below instructions:</b> 1. If needed, develop or revise protocols for catheter and line management in facility care areas where hemodialysis is administered. 2. Consider the following for catheter and line management protocols: A. If possible, avoid using hemodialysis venous catheters for purposes

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- other than hemodialysis. Use another vascular access point for other therapies (e.g., IV infusion, apheresis) if available.
- B. Use and care for catheters according to manufacturer device labeling and the instructions for use (IFU).
- C. Patient movement. Consider the addition of strain relief to patient lines and catheters.

**Point-of-care clinicians who administer hemodialysis, such as nephrology nurses and dialysis technicians:**

1. Follow facility policies and procedures for managing catheters and tubing used for hemodialysis.
2. To prevent catheter component disengagement during hemodialysis treatment:
  - A. Make sure that the catheter site remains visible. Remove sheets and blankets from the catheter site if necessary.
  - B. Visually inspect the patient tubing and catheter components frequently.
  - C. Avoid tension on the patient tubing and catheter. Avoid positioning tubing sets where they may be snagged in the bed, chair, or transport equipment.
3. To prevent catheter component disengagement in between hemodialysis treatments:
  - A. Use another access point for other vascular therapies, such as apheresis or IV infusion. If that is not possible, refer to steps described above for preventing catheter component disengagement during hemodialysis treatment.
  - B. Inspect and secure patient catheters that are not in use.
  - C. Notify patients and caregivers to look at catheter connections occasionally and to notify clinical staff if they observe any loose catheter components.

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D. If a loose catheter component is observed, do the following:

- a) Follow facility protocols for aseptic technique.
- b) Push the loose component until it is flush with the adjacent component.
- c) Consider replacing the catheter.

**Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.**

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