

Safety Communication

Hemodialysis Venous Catheter Components May Disengage during Routine Use, Quickly Causing Patient Harm or Death

Device/ Product Description:	Hemodialysis Venous Catheter Components
Brand Name:	Multiple Brands
Lot numbers/Serials:	N/A
Manufacturer:	Multiple Manufacturers
Problem:	<ul style="list-style-type: none"> • Hemodialysis venous catheter components can disengage during routine use, quickly causing patient harm or death. • Scenarios that can cause partial or full component disengagement from the catheter include: <ul style="list-style-type: none"> ➤ A person tripping on a fluid line connected to the catheter ➤ A person stepping on a suspended fluid line ➤ A fluid line snagging on an object during patient locomotion ➤ Administration set attachment to, or removal from, a hemodialysis catheter that is also indicated for IV infusion ➤ Patient motion causing sufficient tension to disengage one or more components ➤ A pressurized catheter that can push an adapter out of the tubing • Potential consequences of problem occurring include: <ul style="list-style-type: none"> ➤ Air embolism, which can quickly cause patient injury (e.g., pulmonary embolism, stroke) or death ➤ Rapid patient blood loss ➤ Minor or moderate blood loss may require transfusion ➤ Significant blood loss can cause patient death ➤ Catheter colonization with skin pathogens ➤ If a clinician notices an adapter is loose, they may push it flush ➤ This could cause catheter colonization if pathogens are present on hands ➤ Premature catheter removal and replacement

**Recommendation/
Actions:**

Nephrologists and relevant administrators:

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 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.
 - 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.

You **should** be aware of the mentioned risks in the notice and **contact** the Authorized Representative of your product for corrective action.

Healthcare Professionals should **report any adverse events** suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.

Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority
4904 northern ring branch rd - Hitteen Dist.
RIYADH 13513 - 7148
Tel: +966 (11) 2038222 Ext: 2995, 2952
Fax: +966 (11) 2757245

Or

Saudi Vigilance

For latest published FSCAs, please visit ([NCMDR Website](#))

Sincerely,
NCMDR Team