

Provider Newsflash July 2025

FDA Recall – Avanos Medical Ballard Closed Suction Systems

Purpose of this communication:

 We are writing to inform you that Avanos Medical, Inc. is recalling Ballard Closed Suction Systems due to a failure in the sterilization process. Ballard Closed Suction Systems are used to remove secretions from the airway in patients receiving mechanical ventilation, minimizing the risks associated with disconnecting the ventilator circuit. Use of the affected product may cause serious adverse health consequences, including infection, airway injury, prolonged inflammation, sepsis, or death. To date, Avanos Medical, Inc. has not reported any serious injuries or deaths associated with this issue.

What do I need to do?

- Please review the following recall notice: <u>https://www.fda.gov/medical-devices/medical-device-recalls/closed-suction-catheter-recall-avanos-medical-inc-removes-ballard-closed-suction-systems-due-risk?utm_medium=email&utm_source=govdelivery</u>
- Notify impacted patients and facilitate the replacement, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.