

URGENT MEDICAL DEVICE RECALL

March 27, 2025

Dear Valued McKesson Customer:

Airlife has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Notice regarding specific lot(s) of their Ballard Closed Suction Systems. This notice has been issued due to the product shipped was not sterilized through gamma radiation. Affected product first shipped January 9, 2025.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For questions regarding this notification, please contact Airlife at **(800) 433-2797**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
270879	198	CATHETER, SCTN INLINE NEONATE 8FR (20CS)	1561168
538240	20083	CATHETER, TRACH 8FR PED (20/CS)	1555215
538240	20083	CATHETER, TRACH 8FR PED (20/CS)	1555217
281819	220135	SUCTION SYSTEM, CLOSED CATHETER 14FR 12" (20/CS)	1555453
281819	220135	SUCTION SYSTEM, CLOSED CATHETER 14FR 12" (20/CS)	1564227
281915	210	CATHETER, SCTN INLINE NEONATE 10FR (20/CS)	1561165

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above. If you have no product matching the affected item(s) and lot number(s), no further action is needed
- 2.) A copy of the Urgent Medical Device Recall from Airlife has been included for reference.
- 3.) If you have product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days. **Please note:** Credit will only be issued for the affected Lot(s) of the product(s) listed above and entered on the reply form. **Please place a new order for replacement product if there is an immediate need.**
- 4.) Please dispose of any affected product in your possession in accordance with your institution's policies and procedures.
- 5.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
 Medical Device Recall Reply Form: RC-2025-059
 AirLife - Ballard Closed Suction Systems

March 27, 2025

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at **(866) 871-0270** should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____ Ship to Acct Number: _____

Your Name: _____ Email Address: _____

Phone Number: _____ Fax Number: _____

Account Name: _____

Address: _____

City, State Zip: _____

I acknowledge that I DO HAVE product affected by this notification and have disposed of this product in accordance with my institution's policies and procedures.

Qty	Unit of Measure	Affected Lot #(s)	MMS #	MFG Catalog #	Description
			270879	198	CATHETER, SCTN INLINE NEONATE 8FR (20CS)
			538240	20083	CATHETER, TRACH 8FR PED (20/CS)
			281819	220135	SUCTION SYSTEM, CLOSED CATHETER 14FR 12" (20/CS)
			281915	210	CATHETER, SCTN INLINE NEONATE 10FR (20/CS)

*Discard Affected lot numbers only

* The affected lot number(s) are listed on the McKesson customer letter. Please dispose of affected product in accordance with your institution's policies and procedures.

Credit will only be issued for product(s) listed above with affected lots.

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.



URGENT: MEDICAL DEVICE RECALL

**Ballard Closed Suction Systems
(198, 210, 20083, 220135, 2210-5, 2271418-5, and 227-5)**

IMMEDIATE ACTION REQUIRED

1st NOTIFICATION

Date: March 19, 2025

McKesson General Medical
Irving TX 75039

Dear Valued Customer/Distributor,

Purpose of the letter:

The purpose of this letter is to advise you that AirLife (legal manufacturer Avanos) is voluntarily recalling select lots of Ballard Closed Suction Systems (198, 210, 20083, 220135, 2210-5, 2271418-5, and 227-5). We have identified you as a customer who has received the affected lots.

Description of the problem:

Ballard Closed Suction Catheter Systems are intended to be sterile through gamma irradiation. Product that was not sterilized was shipped to consignees/customers.

The table below provides the reference number and lot numbers of the recalled products:

Product Description	REF Number	Lot Number	UDI Information
Ballard Closed Suction System for Neonates/Pediatrics, 8 F, Y-Adapter	198	1561168	Each: 00609038938264 DSP: 10609038938261 Case: 20609038938268
Ballard Closed Suction System for Neonates/Pediatrics, 10 F, Elbow	210	1561165	Each: 00609038938349 DSP: 10609038938346 Case: 20609038938343
Ballard Closed Suction System for Neonates/Pediatrics, 8 F, Elbow	20083	1555215 1555217	Each: 00609038938311 DSP: 10609038938318 Case: 20609038938315

Product Description	REF Number	Lot Number	UDI Information
Ballard Closed Suction System for Adults, 14 F, T-Piece	220135	1555453 1564227	Each: 00609038944920 DSP: 10609038944927 Case: 20609038944924
Ballard Closed Suction System for Adults, 14 F, DSE	2210-5	1555424	Each: 00609038983103 DSP: 10609038983107 Case: 20609038983100
Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, MDI	2271418-5	1555430	Each: 00609038982632 DSP: 10609038982639 Case: 20609038982636
Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE	227-5	1555468	Each: 00609038989655 DSP: 10609038989652 Case: 20609038989659

Risk to Health

Non-sterile suction catheters and equipment can contribute to ventilator-associated pneumonia (VAP) rates. Using a non-sterile suction catheter to suction an endotracheal tube (ETT) can pose several serious risks due to potential contamination. Here are some of the key risks:

- a. Infection: The most significant risk is introducing harmful microorganisms, such as bacteria, viruses, or fungi, into the respiratory tract. This can lead to pneumonia, ventilator-associated pneumonia (VAP), or other respiratory infections. These infections can be particularly severe in patients with weakened immune systems or those on mechanical ventilation.
- b. Airway Injury: A non-sterile catheter might carry debris or contaminants that can cause physical injury to the delicate tissues of the airway. This could lead to inflammation, bleeding, or even more severe damage to the trachea or bronchi.
- c. Prolonged Inflammation: Introduction of non-sterile equipment may lead to a prolonged inflammatory response in the airway, which can complicate recovery or increase the risk of further infections or complications.
- d. Risk of Sepsis: If an infection caused by using non-sterile equipment spreads, it could lead to sepsis, a life-threatening condition where the body's response to infection can cause widespread inflammation and organ failure

Customer immediate actions:

- a. Review the list of affected products above. Please examine your inventory for the mentioned lot(s). No other lots are affected.
- b. Immediately, stop/cease use and quarantine all affected product.

- e. ~~Please complete and return the attached Response Form via e-mail to productquality@myairlife.com as soon as possible. This will enable us to document the amount of product you have on hand for return and/or destruction. It will also allow us to document your receipt of this letter.~~
- d. In addition, if you have further distributed this product, please identify your customers/consignees, and notify them of this product removal. Your notification may be enhanced by including a copy of this removal notification letter.
- e. ~~Once you return and/or confirm destruction of the affected product(s), new replacement product will be sent to you. If you need replacement products to be sent to you urgently, please call AirLife directly at 1-800-433-2797 and we will make every effort to accommodate your needs.~~
- f. Please make sure that all affected personnel in your organization are informed of this removal notice.

AirLife apologizes for any inconvenience this causes. Your satisfaction with AirLife products and with our response to this situation is very important to us. If you have any questions regarding this field action, please call AirLife at **1-800-433-2797**, or e-mail at productquality@myairlife.com.

Adverse reactions or quality problems experienced with the use of these products should be reported to **the FDA's MedWatch Adverse Event Reporting program** either online, by regular mail or by fax.

- **Complete and submit the report Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Attachments:

- ~~A. Ballard Closed Suction System Field Removal/Return Response Form~~
- ~~B. Certificate of Destruction form~~

Should you have any questions, feel free to reach out to your local AirLife Territory Manager, Customer Service at 1.800.433.2797 or productquality@myairlife.com.

Thank you for your attention and cooperation.

Rob Yamashita
AirLife - VP of Regulatory Affairs