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

CareLinc Medical Equipment and Supply
Grand Rapids MI 49548

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.

c. 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

Immediate Action Requested

Attachment A: Ballard Closed Suction System Field Removal / Return Response Form

REF NUMBER	LOT NUMBER	QTY RECEIVED	QTY TO BE RETURNED	QTY TO BE DESTROYED

Please check ALL appropriate boxes.

- ☐ I have read and understand the removal instructions provided in the letter sent March 19, 2025
- ☐ I have checked my inventory.
  - ☐ I do not have any affected products.
  - ☐ I am returning the affected product.
  - ☐ I have destroyed and disposed of the affected product. (Complete and return Attachment B)
- ☐ I have further distributed the affected device and have notified the receiving facility by (**specify date & method of notification**): _____

Have any adverse events been reported to you regarding the affected product? ☐ Yes ☐ No

If yes, please explain: _____

_____

Contact Name: _____

Title: _____

Facility Name: _____

Address: _____

City/State/Zip Code: _____

Telephone Number: _____Email: _____

PLEASE SEND COMPLETED RESPONSE FORM(S) TO:

E-MAIL TO: **productquality@myairlife.com**

Received Letter from Distributor? ☐ Yes ☐ No

If yes, please add name of distributor: _____

Immediate Action Requested

Attachment B – Certificate of Destruction Form

Required when product disposition designation is **Discard/Destroy**

Name of Consignee/Company: _____

I have read and understand the recall instructions provided in the March 19, 2025, letter.

Yes, _____No _____

Complete the following and send completed form with completed Attachment A form.

Product disposition:

Product catalog number: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Lot number: _____ QTY Destroyed: _____

Destroyed by Signature: _____ Date: _____

Print Name: _____

Witnessed by Signature: _____ Date: _____

Print Name: _____

Immediate Action Requested