

**URGENT MEDICAL DEVICE RECALL**

Monday, November 5, 2018

Dear Valued Life-Assist Customer,

According to our records you may have purchased a product that has been recalled by the manufacturer. Please examine your inventory to determine if you have the following product, with the affected lot number in your possession.

**ARGYLE® Salem Sump Tube, 10 fr.**

Life-Assist, Inc. Product Code	Manufacturer Product Code	Lot #s
OK4911	8888264911	1812115564

Reason for Recall:

This voluntary recall is being conducted due to incorrect packaging. In the above lot of Salem Sump Dual Lumen Stomach Tubes, the 10Fr product was packaged in a 16Fr labeled pouch.

Please read the enclosed recall notification from the manufacturer for more information.

**Action Required:**

1. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
2. Check your inventory for the specific lot number listed above.
3. Quarantine any product with the affected lot number. If the affected stock has been depleted, you may disregard this notification.
4. Contact Life-Assist Customer Service at 800-824-6016 or [saleservice@life-assist.com](mailto:saleservice@life-assist.com) to obtain a Return Authorization.

We apologize for any inconvenience.



# Urgent: Medical Device Recall

Cardinal Health  
3651 Birchwood Drive  
Waukegan, IL 60085  
800.292.9332 toll free  
847.689.9101 fax



**CardinalHealth**

cardinalhealth.com

October 31, 2018

Event-2018-01707

Dear Valued Customer:

Cardinal Health is voluntarily initiating a product recall of one lot of **Salem Sump Dual Lumen Stomach Tubes** first distributed on 05/10/2018.

Product Code	Product Description	Lot Number
8888264911	Salem Sump Dual Lumen Stomach Tube 10 Fr/Ch (3.3 mm) x 36" (91 cm)	1812115564

### Reason for Recall:

This voluntary recall is being conducted due to incorrect packaging. In the above affected lot of Salem Sump Dual Lumen Stomach Tubes, the 10Fr product was packaged in a 16Fr labeled pouch. Customers can identify the affected product by referring to Attachment A. The use of a 10 Fr Salem Sump Tube when a 16Fr is needed could result in decreased fluid collection, with the potential to affect patient care, particularly in an emergency situation where the correct size is not readily available. Cardinal Health is not aware of any reports of injury or harm related to this issue.

### Action Required:

1. **INSPECT** your inventory for the affected product code and lot number (listed on package)
2. **SEGREGATE and QUARANTINE** all on-hand product
3. **RETURN** the enclosed acknowledgment form via fax to 847-689-9101 or 614-652-9648, whether or not you have affected product, indicating the product code, lot and quantity of product you've quarantined or discarded.
4. **NOTIFY** any customers to whom you may have distributed, or forwarded product affected by this recall
5. **CONTACT** the appropriate Customer Service group to arrange for return and credit of any affected product:
  - Hospital—800-964-5227
  - Federal Government—800-444-1166
  - Distributor—800-635-6021
  - All other customers—888-444-54401

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We request that you contact Cardinal Health if you experienced quality problems or adverse events.

The FDA can be contacted to report any adverse events experienced with the use of these products:

- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm> (form available to fax or email) or call FDA 1-800-332-1088.

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We sincerely apologize for any inconvenience this notice may have caused you and your staff. Should you have any questions, or desire special assistance relating to this product, please feel free to contact Cardinal Health at 800-292-9332. Your cooperation and compliance with the requests in this letter are appreciated.

Sincerely,

A handwritten signature in cursive script that reads "Karl Vahey".

Karl Vahey  
Vice President, QRA Management

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## Attachment A

Figure 1. Shipper carton displayed correct labeling for Product Code 8888264911 Lot Number 812115564



Figure 2. Incorrect pouch indicates 16Fr Salem Sump Silicone Dual Lumen Stomach Tube

