

**URGENT MEDICAL DEVICE CORRECTION NOTIFICATION**

*Rev'd 10/21/25 JS*

October 9, 2025

Dear Valued McKesson Customer:

Cardinal has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Product Correction Notice regarding all lot(s) of their Salem Sump Products. This notice has been issued to provide additional guidance on how to properly use the Anti-Reflux Valve (ARV). Affected product first shipped August 1, 2020.

A review of our records indicates that your company may have purchased items included in the attached manufacturer's notification.

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

| MMS #   | MFG Catalog # | Description                                           | Affected Lot(s) |
|---------|---------------|-------------------------------------------------------|-----------------|
| 160733  | 8888264911    | TUBE, SALEM SUMP STR 10FR 36" (50/CS) KENDAL          | ALL             |
| 160734  | 8888264929    | TUBE, SALEM SUMP STR 12FR 48" (50/CS) KENDAL          | ALL             |
| 160735  | 8888264945    | TUBE, SALEM SUMP STR 14FR 48" (50/CS) KENDAL          | ALL             |
| 160736  | 8888264960    | TUBE, SALEM SUMP STR 16FR 48" (50/CS) KENDAL          | ALL             |
| 185659  | 8888266106    | DRAIN, SUMP W/ANTI REFLUX VALVE 10FR 36" KENDAL       | ALL             |
| 185660  | 8888266114    | TUBING, SCTN W/ANTI-REFLUX VLV12FR 48" (50/CS) KENDAL | ALL             |
| 185661  | 8888266122    | DRAIN, SUMP W/ANTI REFLUX VALVE 14FR 48" KENDAL       | ALL             |
| 185662  | 8888266130    | DRAIN, SUMP W/ANTI REFLUX VALVE 16FR 48" KENDAL       | ALL             |
| 185663  | 8888266148    | DRAIN, SUMP W/ANTI REFLUX VALVE 18FR 48" KENDAL       | ALL             |
| 1045549 | 8888264986E   | TUBE, SALEM SUMP STR 18FR 48" (50/CS)                 | ALL             |
| 201488  | 8888266262    | TUBE, SALEM SUMP SIL W/RFLX 16FR (10/CS) KENDAL       | ALL             |
| 201489  | 8888266288    | TUBE, SALEM SUMP SIL W/RFLX 18FR (10/CS) KENDAL       | ALL             |
| 1045543 | 8888268086E   | TUBE, SALEM SUMP 8FR 30" (10/CS)                      | ALL             |
| 1045542 | 8888268060E   | TUBE, SALEM SUMP 6FR 24" (10/CS)                      | ALL             |
| 1045545 | 8888264911E   | TUBE, SALEM SUMP STR 10FR 36" (50/CS)                 | ALL             |
| 1006292 | 8888266197    | VALVE, ANTI-REFLUX KEITH ARV (10/CS)                  | ALL             |
| 161239  | 8888264986    | TUBE, SALEM SUMP STR 18FR 48" (50/CS) KENDAL          | ALL             |
| 161240  | 8888265108    | TUBE, SALEM SUMP SIL STR 10FR 36" (10/CS) KENDAL      | ALL             |
| 161241  | 8888265116    | TUBE, SALEM SUMP SIL STR 12FR 48" (10/CS) KENDAL      | ALL             |
| 161242  | 8888265124    | TUBE, SALEM SUMP SIL STR 14FR 48" (10/CS) KENDAL      | ALL             |
| 161243  | 8888265132    | TUBE, SALEM SUMP SIL STR 16FR 48" (10/CS) KENDAL      | ALL             |
| 161244  | 8888265140    | TUBE, SALEM SUMP SIL STR 18FR 48" (10/CS) KENDAL      | ALL             |
| 204163  | 8888266247    | VALVE, ANTI-REFLUX SALEM SUMP 14FR (10/CS) KENDAL     | ALL             |
| 417984  | 8888268086    | TUBE, SALEM SUMP 8FR 30" (10/CS) KENDAL               | ALL             |
| 205251  | 8888266221    | TUBE, SALEM SUMP 12FR (10/CS) KENDAL                  | ALL             |
| 205252  | 8888266213    | TUBE, SALEM SUMP 10FR (10/CS) KENDAL                  | ALL             |

McKesson Medical-Surgical Inc.

|         |             |                                                             |   |     |
|---------|-------------|-------------------------------------------------------------|---|-----|
| 1045548 | 8888264960E | TUBE, SALEM SUMP STR 16FR 48" (50/CS)                       |   | ALL |
| 417983  | 8888268060  | TUBE, SALEM SUMP 6FR 30" (10/CS) KENDAL                     | X | ALL |
| 1272818 | 8888264929E | TUBE, STOMACH SALEM SUMP DUAL LUMEN W/ENFIT CONNECT (50/CS) | Y | ALL |
| 181833  | 8888264960  | TUBE, SALEM SUMP 16FR (SB CO MED CTR) KENDAL                | X | ALL |
| 181834  | 8888264986  | TUBE, SALEM SUMP 18FR (SB CO MED CTR) KENDAL                | Y | ALL |
| 187124  | 8888264945  | TUBE, SALEM SUMP 14FR 48" (SBCMC) (50/CS) KENDAL            | Y | ALL |
| 187125  | 8888264929  | TUBE, SALEM SUMP 12FR 48" (SBCMC) (50/CS) KENDAL            | X | ALL |
| 187126  | 8888264911  | TUBE, SALEM SUMP 10FR 48" (SBCMC) (50/CS) KENDAL            | X | ALL |
| 362974  | 8888266197  | VALVE, ANTI-REFLUX KEITH ARV (10/BX) KENDAL                 | X | ALL |
| 167062  | 8888266197  | VALVE, ANTI-REFLUX KEITH ARV (10/BX) KENDAL                 | X | ALL |
| 1045547 | 8888264945E | TUBE, SALEM SUMP STR 14FR 48" (50/CS)                       | X | ALL |
| 1045575 | 8888266122E | DRAIN, SUMP W/ANTI REFLUX VALVE 14FR 48"                    | Y | ALL |
| 1045546 | 8888264929E | TUBE, SALEM SUMP STR 12FR 48" (50/CS)                       | Y | ALL |
| 1045797 | 266130CN    | TUBE, SALEM SUMP W/ARV & IRR CONNECTION 16FR (50/CS)        | X | ALL |
| 1045576 | 8888266130E | DRAIN, SUMP W/ANTI REFLUX VALVE 16FR 48"                    | X | ALL |
| 1045573 | 8888266106E | DRAIN, SUMP W/ANTI REFLUX VALVE 10FR 36"                    | X | ALL |
| 1045574 | 8888266114E | TUBING, SALEM SUMP W/ANTI-REFLUX VLV 12FR 48" (50/CS)       | X | ALL |
| 1045577 | 8888266148E | DRAIN, SALEM SUMP W/ANTI REFLUX VALVE 18FR 48"              | X | ALL |
| 1239996 | 8888268086  | TUBE, SALEM SUMP 8FR 30" (GLADDEN) (10/CS)                  | Y | ALL |
| 1239997 | 8888268060  | TUBE, SALEM SUMP 6FR 30" (GLADDEN) (10/CS)                  | X | ALL |
| 1240003 | 8888264911  | TUBE, SALEM SUMP STR 10FR 36" (GLADDEN) (50/CS)             | X | ALL |

**Please note:** This is *not* a recall. **Product returns will not be accepted.** Carefully review the information in the attached Urgent Medical Device Correction Notification, and follow the instructions provided by Cardinal. If you have any questions regarding this notification, please contact Cardinal via phone at **(888) 444-5440**. 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 notification may have caused you and your staff.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.



**CardinalHealth**

## URGENT MEDICAL DEVICE PRODUCT CORRECTION UPDATE

September 18, 2025

**PLEASE SEE ATTACHMENT 1 FOR AFFECTED PRODUCT**

Dear Valued Customer:

Cardinal Health is issuing an update to the urgent medical device product correction originally issued in July 2024 (Event-2024-06342), on all lots of Salem Sump™ product codes listed on Attachment 1 that were manufactured from August 1, 2020. These are listed as under the 'Original Notice' column. In addition, updated products have been included in Attachment 1 under the column 'Updated Notice.'

|                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Purpose of this letter:</b>            | <p>The purpose of this letter is to provide additional guidance on how to properly use the Anti-Reflux Valve (ARV).</p> <p><b><u>Important Instructions:</u></b></p> <p>After placement of the Salem Sump tube, always inject 10ml-20ml of air before seating the Anti Reflux Valve (ARV) into the blue sump vent lumen.</p> <p>Instructions:</p> <ol style="list-style-type: none"> <li>1. Seat the BLUE END of the ARV into the blue sump vent lumen of the Salem Sump tube. Insert the ARV gently into the Salem Sump tube to avoid difficult removal.</li> <li>2. To cap tube, seat the WHITE END of the ARV into the suction lumen. Insert the ARV gently into the Salem Sump tube to avoid difficult removal.</li> <li>3. To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve.</li> </ol> <p>Please visit <a href="https://www.mycardinalmsds.com">https://www.mycardinalmsds.com</a> for updated electronic IFUs.</p> |
| <b>Reason for the Product Correction:</b> | <p>Cardinal Health received complaints regarding the Anti-Reflux Valve (ARV) breaking due to use error. The ARV failures are attributed to excessive force during use. Based on this, Cardinal Health is providing additional guidance when using these products.</p> <p>Please visit <a href="https://www.mycardinalmsds.com">https://www.mycardinalmsds.com</a> for an electronic version of the IFU.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Risk to Health:</b>                    | <p>ARV breakage may require the user to remove and replace the Salem Sump Dual Lumen Stomach Tubes, thus exposing the patient to additional analgesic/sedative medications for replacement, and to additional radiation as a result of further imaging to confirm correct anatomical placement of the device. To date, Cardinal Health has received 125 complaints of ARV stuck and/or breakage. Of these reports, one situation resulted in a serious injury in relation to the number of attempts to replace the device, following ARV breakage, not from the device breakage itself.</p>                                                                                                                                                                                                                                                                                                                                                                                           |



|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
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|  | <p>The primary health risk associated with breakage of the Anti-Reflux Valve (ARV) within a Salem sump tube is device revision or replacement—major severity—to maintain proper suction functionality. The clinical impact of ARV breakage depends on its location within the tubing:</p> <p>ARV breakage in the sump side (blue port):<br/>Suction functionality is preserved, significantly reducing the risk of harm to the patient. The device can continue to operate effectively without immediate intervention.</p> <p>ARV breakage in the main port (clear port):<br/>Tube replacement is required to restore suction. However, the ARV is only placed in this port when the patient is clinically appropriate to be capped—such as during transitions off suction or for transport—thereby minimizing exposure to high-risk Patients.</p> <p>The Salem Sumps and ARVs are used in hospital settings, where replacement tubes and clinical resources are readily available, further mitigating the risk.</p> <p><b>Medical Safety summary:</b></p> <p>While the Anti-Reflux Valve (ARV) plays a significant role in the safety and functionality of the Salem sump tube, the tube can still operate without it. In fact, it can function without the blue sump side, which reduces the overall risk to the patient. The primary concern arises when the ARV breaks off in the clear main Port.</p> <p>The ARV is typically placed in the clear port to cap the tube during transitions off suction or when the patient is stable enough for transport without active suction. Therefore, patients with the ARV in the clear port are generally lower-risk and clinically stable, further minimizing the potential for harm.</p> <p>The overall risk to patients is minimal.</p> <p><b><u>How to recognize that the device may fail:</u></b></p> <p>Device failure due to ARV breakage is recognizable by the user through visual inspection and loss of suction.</p> |
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|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Actions Required of the Customer:</b></p> | <ol style="list-style-type: none"> <li>1. <b>REVIEW</b> your inventory for the affected product codes. All lots of inventory are impacted.</li> <li>2. <b>COMMUNICATE</b> the risks and appropriate usage of the ARV with all personnel.</li> <li>3. <b>POST</b> a copy of this notification in your storeroom and clinical areas.</li> <li>4. <b>NOTIFY</b> any customers to whom you may have distributed/forwarded affected product (or to whom you intend to distribute/forward product) about this medical device product correction and share a copy of this notice.</li> <li>5. <b>RETURN</b> the enclosed acknowledgment form via fax to <b>614-652-9648</b> or email to <b>GMB-FieldCorrectiveAction@cardinalhealth.com</b>, whether you have affected product or not.</li> </ol> |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Cardinal Health 200, LLC  
3651 Birchwood Drive  
Waukegan, IL 60085  
cardinalhealth.com



**CardinalHealth**

|                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <b>Available Customer Assistance:</b> | <p><b>CONTACT</b> the appropriate Customer Service group with questions related to this notification.<br/><b>Monday – Friday between 8:00am - 5pm EST:</b></p> <ul style="list-style-type: none"> <li>• Hospital – 800-964-5227</li> <li>• Federal Government – 800-444-1166</li> <li>• Distributor – 800-635-6021</li> <li>• All Other Customers – 888-444-5440</li> </ul> <p>For questions related to this notification and/or acknowledgement form that are not adequately addressed in this letter, please contact the market action team at:<br/><b>GMB-FieldCorrectiveAction@cardinalhealth.com or call 800-292-9332.</b></p> <p>In the event you have experienced quality problems or adverse events related to the products listed, please utilize the contacts above.</p> |
|---------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                      |                                                                                                                                                                                                                                                                                     |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>What Cardinal Health is Doing</b> | <p>We are evaluating the labeling, IFU, &amp; design of the ARV to facilitate proper use, functionality and limit device replacement.</p> <p>Electronic IFUs have been updated and are available at <a href="https://www.mycardinalmsds.com">https://www.mycardinalmsds.com</a></p> |
|--------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Additional Information:</b> | <p><b><u>Adverse Events Reporting Process</u></b></p> <p>Cardinal Health has notified the U.S. Food &amp; Drug Administration that we are taking this action. In the event you have experienced quality problems or adverse events related to the products listed above, please utilize the contact information above.</p> <p>The FDA can be contacted to report any adverse events experienced with these products:<br/>Online at <a href="http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm">http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm</a> (form available to fax or email) or call FDA 1-800-332-1088.</p> |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

We apologize for any inconvenience this communication may cause. We know that you place high value in our products, and we appreciate your cooperation in this matter. Cardinal Health is committed to maintaining your confidence in the safety and quality of the products that we supply.

Respectfully yours,

Hector Rocha



### Attachment 1

| Product Codes<br>(Original Notice) | Product Description                                 | UDI            |
|------------------------------------|-----------------------------------------------------|----------------|
| 8888264929                         | Salem Sump™ PVC Tubes, 12 Fr                        | 10192253012477 |
| 8888266114                         | Salem Sump™ PVC Tubes with Anti-Reflux Valve, 12 Fr | 10192253012781 |
| 8888264945                         | Salem Sump™ PVC Tubes, 14 Fr                        | 10192253012491 |
| 8888266122                         | Salem Sump™ PVC Tubes with Anti-Reflux Valve, 14 Fr | 10192253012804 |
| 8888264960                         | Salem Sump™ PVC Tubes, 16 Fr                        | 10192253012514 |
| 8888266130                         | Salem Sump™ PVC Tubes with Anti-Reflux Valve, 16 Fr | 10192253012828 |
| 8888264986                         | Salem Sump™ PVC Tubes, 18 Fr                        | 10192253012538 |
| 8888266148                         | Salem Sump™ PVC Tubes with Anti-Reflux Valve, 18 Fr | 10192253012842 |

| Product Codes<br>(Updated Notice) | Product Description                                                                                                   | UDI            |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------|----------------|
| 5558264957                        | Salem Sump™ COILED TUBE 16Fr/Ch (5.3 mm)                                                                              | 50192253008171 |
| 5558264965                        | Salem Sump™ TUBE 16 Fr/Ch (5.3 mm)                                                                                    | 50192253008195 |
| 5558264973                        | Salem Sump™ COILED TUBE 18Fr/Ch (6.0 mm)                                                                              | 50192253008201 |
| 5558264981                        | Salem Sump™ TUBE 18 Fr/Ch 18Fr/Ch (6.0 mm)                                                                            | 50192253008218 |
| 266130CN                          | Salem Sump™ Tube 16FR with CONFIRM NOW, Nonsterile                                                                    | 10884521141292 |
| 266148CN                          | Salem Sump™ Tube 8 FR with CONFIRM NOW, Nonsterile                                                                    | 20884521141305 |
| 266197                            | Salem Sump™ Anti-Reflux Valve – CE Marked                                                                             | 10884527022762 |
| 8888266197                        | Salem Sump™ Anti-Reflux Valve                                                                                         | 10192253012866 |
| 266122                            | Salem Sump™ Stomach Tube, Dual Lumen with Anti-Reflux Valve, 14 Fr/Ch (4.7 mm)                                        | 10884521065024 |
| 266130                            | Salem Sump™ Stomach Tube, Dual Lumen with Anti-Reflux Valve, 16 Fr/Ch (5.3 mm)                                        | 10884521065031 |
| 266148                            | Salem Sump™ Stomach Tube, Dual Lumen with Anti-Reflux Valve, 18 Fr/Ch                                                 | 10884521065055 |
| 8888266106                        | Salem Sump™ Dual Lumen Stomach Tube, Anti-Reflux Valve 10 Fr/Ch (3.3 mm), 36"                                         | 20884521004655 |
| 8888266213                        | Salem Sump™ Silicone Dual Lumen Stomach Tube, Anti-Reflux Valve and Radiopaque Line, 10 Fr/Ch (3.3 mm) x 36" (91 cm)  | 10192253012781 |
| 8888266221                        | Salem Sump™ Silicone Dual Lumen Stomach Tube, Anti-Reflux Valve and Radiopaque Line, 12 Fr/Ch (4.0 mm) x 48" (122 cm) | 10884521000803 |
| 8888266247                        | Salem Sump™ Silicone Dual Lumen Stomach Tube, Anti-Reflux Valve and Radiopaque Line, 14 Fr/Ch (4.7 mm) x 48" (122 cm) | 10884521000827 |
| 8888266262                        | Salem Sump™ Silicone Dual Lumen Stomach Tube, Anti-Reflux Valve and Radiopaque Line, 16 Fr/Ch (5.3 mm) x 48" (122 cm) | 10884521000841 |
| 8888266288                        | Salem Sump™ Silicone Dual Lumen Stomach Tube, Anti-Reflux Valve and Radiopaque Line, 18 Fr/Ch (6.0 mm) x 48" (122 cm) | 10884521000858 |
| 8888266106E                       | PVC SALEM SUMP WITH ENFIT & ARV 10FR 36IN                                                                             | 10192253012774 |
| 8888266114E                       | PVC SALEM SUMP WITH ENFIT & ARV 12FR 48IN                                                                             | 10192253012798 |
| 8888266122E                       | PVC SALEM SUMP WITH ENFIT & ARV 14FR 48IN                                                                             | 10192253012811 |
| 8888266130E                       | PVC SALEM SUMP WITH ENFIT & ARV 16FR 48IN                                                                             | 10192253012835 |
| 8888266148E                       | PVC SALEM SUMP WITH ENFIT & ARV 18FR 48IN                                                                             | 10192253012859 |
| 264929                            | Salem Sump™ Stomach Tube, Dual Lumen, 12 Fr/Ch (4.0 mm)                                                               | 10884521067196 |
| 264945                            | Salem Sump™ Stomach Tube, Dual Lumen, 14 Fr/Ch (4.7 mm)                                                               | 10884521067202 |
| 264960                            | Salem Sump™ Stomach Tube, Dual Lumen, 16 Fr/Ch (5.3 mm)                                                               | 10884521067219 |
| 264986                            | Salem Sump™ Stomach Tube, Dual Lumen, 18 Fr/Ch (6.0 mm)                                                               | 10884521067226 |
| 8888268060                        | Salem Sump™ Dual Lumen Stomach Tube 6 Fr/Ch (2.0 mm), 24" (61 cm)                                                     | 10192253012972 |

Cardinal Health 200, LLC  
3651 Birchwood Drive  
Waukegan, IL 60085  
cardinalhealth.com



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|             |                                                                                               |                |
|-------------|-----------------------------------------------------------------------------------------------|----------------|
| 8888268086  | Salem Sump™ Dual Lumen Stomach Tube, 8 Fr/Ch (2.7 mm), 24" (61 cm)                            | 10192253012996 |
| 8888264911  | Salem Sump™ Dual Lumen Stomach Tube, 10 Fr/Ch (3.3 mm), 36" (91 cm)                           | 10192253012453 |
| 8888264804  | Salem Sump PVC Gastroduodenal Tube, 10Fr/Ch (3.3 mm) x 85 cm                                  | 10192253012408 |
| 8888264820  | Salem Sump PVC Gastroduodenal Tube, 12 Fr/Ch (4.0 mm) x 108 cm                                | 10192253012415 |
| 8888264846  | Salem Sump PVC Gastroduodenal Tube, 14 Fr/Ch (4.7mm), 108 cm                                  | 10192253012422 |
| 8888264861  | Salem Sump PVC Gastroduodenal Tube, 16 Fr/Ch (5.3mm), 108 cm                                  | 10192253012439 |
| 8888264887  | Salem Sump PVC Gastroduodenal Tube, 18 Fr/Ch (6.0mm), 108 cm                                  | 10192253012446 |
| 1180264895  | Salem Sump PVC Gastroduodenal Tube, 20 Fr/Ch (3.3mm), 108 cm                                  | 10192253007015 |
| 8888265108  | Salem Sump Silicone Dual Lumen Stomach Tube, Radiopaque Line, 10 Fr/Ch (3.3 mm), 36" (91 cm)  | 10884521000766 |
| 8888265116  | Salem Sump Silicone Dual Lumen Stomach Tube, Radiopaque Line, 12 Fr/Ch (4.0 mm), 48" (122 cm) | 10884521020078 |
| 8888265124  | Salem Sump Silicone Dual Lumen Stomach Tube, Radiopaque Line, 14 Fr/Ch (4.7 mm), 48" (122 cm) | 10884521020085 |
| 8888265132  | Salem Sump Silicone Dual Lumen Stomach Tube, Radiopaque Line, 16 Fr/Ch (5.3 mm), 48" (122 cm) | 10884521020092 |
| 8888265140  | Salem Sump Silicone Dual Lumen Stomach Tube, Radiopaque Line, 18 Fr/Ch (6.0 mm), 48" (122 cm) | 10884521020108 |
| 8888264911E | ENFit™ SALEM SUMP™ PVC TUBE 10FR 36IN                                                         | 10884521779419 |
| 8888264929E | ENFit™ SALEM SUMP™ PVC TUBE 12FR 48IN                                                         | 10884521779426 |
| 8888264945E | ENFit™ SALEM SUMP™ PVC TUBE 14FR 48IN                                                         | 10884521779433 |
| 8888264986E | ENFit™ SALEM SUMP™ PVC TUBE 18FR 48IN                                                         | 10884521779457 |
| 8888268060E | ENFit™ SALEM SUMP™ PVC TUBE 6FR 24IN                                                          | 10884521779464 |
| 8888264960E | ENFit™ Salem Sump™ PVC Tube 16Fr 48IN                                                         | 10884521779440 |
| 8888268086E | ENFit™ Salem Sump™ PVC Tube 8Fr 24IN                                                          | 10884521779471 |
| 1180264523  | Salem Sump™ Polyurethane Gastroduodenal Tube, 14 Fr/Ch (4.7 mm) x 114 cm                      | 10192253007060 |
| 1180264531  | Salem Sump™ Polyurethane Gastroduodenal Tube, 16 Fr/Ch (5.3 mm) x 114 cm                      | 10192253006988 |
| 1180264549  | Salem Sump™ Polyurethane Gastroduodenal Tube, 18 Fr/Ch (6.0 mm) x 114 cm                      | 10192253006995 |
| 1180264556  | Salem Sump™ Polyurethane Gastroduodenal Tube, 20 Fr/Ch (6.7 mm) x 114 cm                      | 10192253007008 |
| 1180264408  | Salem Sump™ PVC Gastroduodenal Tube, 10 Fr/Ch (3.3 mm) x 90 cm                                | 10192253006940 |
| 1180264416  | Salem Sump™ PVC Gastroduodenal Tube, 12 Fr/Ch (4.0 mm) x 114 cm                               | 10192253006957 |
| 1180264424  | Salem Sump™ PVC Gastroduodenal Tube, 14 Fr/Ch (4.7 mm) x 114 cm                               | 10192253006964 |
| 1180264432  | Salem Sump™ PVC Gastroduodenal Tube, 16 Fr/Ch (5.3 mm) x 114 cm                               | 10192253006971 |
| 1180264440  | Salem Sump™ PVC Gastroduodenal Tube, 18 Fr/Ch (6.0 mm) x 114 cm                               | 10192253007053 |
| 1180264457  | Salem Sump™ PVC Gastroduodenal Tube, 20 Fr/Ch (6.7 mm) x 114 cm                               | 10192253006568 |



CardinalHealth

CARDINAL HEALTH  
DATE: 9/18/2025  
FILE#: Event-2025-07278

**Urgent Medical Device Product Correction - RESPONSE REQUIRED**

FAX COMPLETED FORM TO 614-652-9648 or email to [gmb-fieldcorrectiveaction@cardinalhealth.com](mailto:gmb-fieldcorrectiveaction@cardinalhealth.com)

1. Did you read and understand the product correction notice for Cardinal Health Salem Sump PVC Tubes as outlined in the attached correction letter?  
\_\_\_\_ YES \_\_\_\_ NO
1. Have you reviewed this notification with your staff as part of the product correction notice?  
\_\_\_\_ YES \_\_\_\_ NO

Name of facility: \_\_\_\_\_

Address of Facility: \_\_\_\_\_  
\_\_\_\_\_

Name/Title of person completing form: \_\_\_\_\_

Signature: \_\_\_\_\_

Email address: \_\_\_\_\_

Phone number: \_\_\_\_\_

**PLEASE FOLLOW INSTRUCTIONS ON THE ENCLOSED NOTICE**