



McKesson Medical-Surgical
Quality Assurance
9954 Mayland Drive
Richmond, VA 23233-1464

Rec 10-20-25

MEDICAL DEVICE CORRECTION

MCK50C 6002121 814641807 RC-2025-203 MMSP 6455
VERICOR MEDICAL SYSTEMS, LLC
ATTN: RISK MANAGEMENT
703 WESTERN AVE
HOLMEN WI 54636-9787



URGENT MEDICAL DEVICE CORRECTION NOTIFICATION

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



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.'

Purpose of this letter:	<p>The purpose of this letter is to provide additional guidance on how to properly use the Anti-Reflux Valve (ARV).</p> <p>Important Instructions:</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"> 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. 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. 3. To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve. <p>Please visit https://www.mycardinalmsds.com for updated electronic IFUs.</p>
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Reason for the Product Correction:	<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 https://www.mycardinalmsds.com for an electronic version of the IFU.</p>
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Risk to Health:	<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): 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): 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>Medical Safety summary:</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><u>How to recognize that the device may fail:</u></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>Actions Required of the Customer:</p>	<ol style="list-style-type: none"> 1. REVIEW your inventory for the affected product codes. All lots of inventory are impacted. 2. COMMUNICATE the risks and appropriate usage of the ARV with all personnel. 3. POST a copy of this notification in your storeroom and clinical areas. 4. NOTIFY 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. 5. RETURN the enclosed acknowledgment form via fax to 614-652-9648 or email to GMB-FieldCorrectiveAction@cardinalhealth.com, whether you have affected product or not.
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<p>Available Customer Assistance:</p>	<p>CONTACT the appropriate Customer Service group with questions related to this notification. Monday – Friday between 8:00am - 5pm EST:</p> <ul style="list-style-type: none"> • Hospital – 800-964-5227 • Federal Government – 800-444-1166 • Distributor – 800-635-6021 • All Other Customers – 888-444-5440 <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: GMB-FieldCorrectiveAction@cardinalhealth.com or call 800-292-9332.</p> <p>In the event you have experienced quality problems or adverse events related to the products listed, please utilize the contacts above.</p>
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<p>What Cardinal Health is Doing</p>	<p>We are evaluating the labeling, IFU, & design of the ARV to facilitate proper use, functionality and limit device replacement.</p> <p>Electronic IFUs have been updated and are available at https://www.mycardinalmsds.com</p>
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<p>Additional Information:</p>	<p><u>Adverse Events Reporting Process</u></p> <p>Cardinal Health has notified the U.S. Food & 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: Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email) or call FDA 1-800-332-1088.</p>
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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 (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 (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



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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

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