

URGENT FIELD SAFETY NOTICE

Event-2025-07278

Manufacturer SRN: US-MF-000006765

October 7th, 2025

PLEASE SEE ATTACHMENT 1 FOR AFFECTED PRODUCT

Dear Valued Customer:

Cardinal Health is issuing a Field Safety Corrective Action for all lots of Salem Sump™ product codes listed on Attachment 1 that were manufactured from August 1, 2020 to present.

Purpose of this letter:	The purpose of this letter is to provide additional guidance on how to properly use the Anti-Reflux Valve (ARV). <u>Important Instructions:</u> 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. Instructions: 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. Our electronic IFUs are in the process of being updated with this additional verbiage and will be posted on our website in the coming weeks (https://www.mycardinalmsds.com).
Reason for the Product Correction:	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.
Risk to Health:	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.



	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: 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. 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. The Salem Sumps and ARVs are used in hospital settings, where replacement tubes and clinical resources are readily available, further mitigating the risk. Medical Safety summary: 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. 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. The overall risk to patients is minimal. <u>How to recognize that the device has failed:</u> Device failure due to ARV breakage is recognizable by the user through visual inspection and loss of suction.
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Actions Required of the Customer:	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 Field Safety Corrective Action and share a copy of this notice. 5. RETURN the enclosed acknowledgment form by following the directions on the Form, whether you have affected product or not.
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Available Customer Assistance:	CONTACT the appropriate Customer Service group or local sales office with questions related to this notification.
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What Cardinal Health is Doing	We are evaluating the labeling, IFU, & design of the ARV to facilitate proper use, functionality and limit device replacement. Electronic IFUs are in the process of been updated and will be available in the coming weeks at https://www.mycardinalmsds.com
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Additional Information:	<u>Adverse Events Reporting Process</u> Cardinal Health has notified the U.S. Food & Drug Administration and other applicable Global Regulatory Authorities 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.
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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,

A handwritten signature in black ink, appearing to read "Hector Rocha".

Hector Rocha



Attachment 1

Product Codes	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	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™ TM 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™ TM 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™ TM 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™ TM 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™ TM 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
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"	10192253012453



	(91 cm)	
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