

**Manufacturer name:**

Cardinal Health



**About the Recall:**

This notice has been issued due to reported incidences of improper use of the device, which can lead to breakage of the Salem Sump Anti-Reflux Valve (ARV) and an increased risk to patients.

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 because of further imaging to confirm correct anatomical placement of the devices. To date Cardinal Health has received 28 reports of ARV breakage, of these reports one resulted in a serious injury relation to the number of attempts to replace the device.

**Products(s) numbers/models that are affected:**

MMS #	MFG Catalog #	Description	Affected Lot(s)
181833	8888264960	TUBE, SALEM SUMP 16FR (SB CO MED CTR) KENDAL	All Lots
181834	8888264986	TUBE, SALEM SUMP 18FR (SB CO MED CTR) KENDAL	
185660	8888266114	TUBING, SCTN W/ANTI-REFLUX VLV12FR 48" (50/CS) KENDAL	
185661	8888266122	DRAIN, SUMP W/ANTI REFLUX VALVE 14FR 48" KENDAL	
185662	8888266130	DRAIN, SUMP W/ANTI REFLUX VALVE 16FR 48" KENDAL	
185663	8888266148	DRAIN, SUMP W/ANTI REFLUX VALVE 18FR 48" KENDAL	
187124	8888264945	TUBE, SALEM SUMP 14FR 48" (SBCMC) (50/CS KENDAL	
187125	8888264929	TUBE, SALEM SUMP 12FR 48" (SBCMC) (50/CS) KENDAL	
160734	8888264929	TUBE, SALEM SUMP STR 12FR 48" (50/CS) KENDAL	
160735	8888264945	TUBE, SALEM SUMP STR 14FR 48" (50/CS) KENDAL	
160736	8888264960	TUBE, SALEM SUMP STR 16FR 48" (50/CS) KENDAL	
161239	8888264986	TUBE, SALEM SUMP STR 18FR 48" (50/CS) KENDAL	

Product Code	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

**URL Link(s) to Manufacturer Notice/Web Site:**

cardinalhealth.com  
(888) 444-5440

<b>Actions to be taken by customer/Patient:</b>	<p>To mitigate the risk of improper use of the device, Cardinal Health has revised the product labeling to instruct users to seat the BLUE END of the ARV firmly into the sump vent lumen and the WHITE END of the ARV into the suction lumen of the Salem Sump™ tube. Refer to the “Set-Up of the Tube” section of the eIFU. These revised instructions can be accessed electronically via the Cardinal Health website at <a href="http://mycardinalmsds.com">mycardinalmsds.com</a>. Cardinal Health has also added the eIFU symbol to the packaging labels, instructing users to reference the electronic instructions for use so as to increase adherence to proper device usage and decrease the risk of potential patient harm. This labeling change is being implemented on future production lots.</p>