URGENT PRODUCT CORRECTION NOTIFICATION

July 29, 2024

Dear Valued McKesson Customer:

Cardinal Health has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Product Correction Notice regarding all lot(s) of their Salem Sump PVC Tubes. This notice has been issued to notify you that Cardinal Health has updated its product labeling by way of electronic instructions for use (eIFU) for all lot numbers of Salem Sump™ products 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. Affected product first shipped May 1, 2019.

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 #	Description	Affected Lot(s)
1045549	8888264986	TUBE, SALEM SUMP STR 18FR 48" (50/CS)	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
1045548	8888264960	TUBE, SALEM SUMP STR 16FR 48" (50/CS)	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
161239	8888264986	TUBE, SALEM SUMP STR 18FR 48" (50/CS) KENDAL	ALL
1045547	8888264945	TUBE, SALEM SUMP STR 14FR 48" (50/CS)	ALL
1045575	8888266122	DRAIN, SUMP W/ANTI REFLUX VALVE 14FR 48"	ALL
1045576	8888266130	DRAIN, SUMP W/ANTI REFLUX VALVE 16FR 48"	ALL
1045574	8888266114	TUBING, SALEM SUMP W/ANTI-REFLUX VLV 12FR 48" (50/CS)	ALL
1045577	8888266148	DRAIN, SALEM SUMP W/ANTI REFLUX VALVE 18FR 48"	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
1045546	8888264929	TUBE, SALEM SUMP STR 12FR 48" (50/CS)	ALL

Please note: This is ***not*** a recall. **Product returns will not be accepted**. Carefully review the information in the attached Urgent Product Correction Notification, and follow the instructions provided by Cardinal Health. If you have any questions regarding this notification, please contact Cardinal Health 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.

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URGENT MEDICAL DEVICE PRODUCT CORRECTION

July 22, 2024

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

Dear Valued Customer:

Cardinal Health is issuing an urgent medical device product correction on all lots of Salem Sump™ product codes listed in the table above manufactured from May 1, 2019.

Purpose of this letter:	The purpose of this letter is to notify you that Cardinal Health has updated its product labeling by way of electronic instructions for use (eIFU) for the above listed product codes and all lot numbers of Salem Sump™ products 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. 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 mycardinalmsds.com. 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. The revised labeling is attached to this letter at **Attachment A. Cardinal Health recommends customers review the eIFU and updated product labels with the additional eIFU symbol.**

Reason for the Product Correction:	Cardinal Health has created an eIFU for the above-listed product codes and all lots of Salem Sump™ products because of reports of breakage in the ARV due to improper use of the device. These changes to the labeling have been made to increase user awareness of how to use the ARV correctly and to inform users of the new warning.

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 28 reports of ARV 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.

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	Attempts to replace the Salem Sump Dual Lumen Stomach Tubes could lead to patient harm, as patients who experience the ARV breakage issue would still require suctioning. That harm may include: sinusitis, nasopharyngeal discomfort, nasal septum erosion, pressure injury, epistaxis, and blood return through the tube in guidewire withdrawal. Device insertion can also cause pain, discomfort, vomiting and refusal of the procedure by the patient. In addition, device replacement increases the risk of a misplacement of the device. Misplacement of a Salem Sump Dual Lumen Stomach Tube can lead to inadvertent placement in a trachea which may cause pleural injury, pneumothorax, tracheobronchial aspiration, pneumonia, and possible death. How to recognize that the device may fail: Device failure due to ARV breakage is recognizable by the user through visual inspection and loss of suction.

Actions Required of the Customer:	1. **REVIEW** your inventory for the affected product codes. All lots of inventory are impacted. Labeling is included as part of **Attachment A** at the bottom of this notice. 2. **COMMUNICATE** the change to the use instructions with all personnel that utilize Salem Sump™ products. 3. **POST** a copy of **Attachment A** and 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.~~

Available Customer Assistance:	**CONTACT** the appropriate Customer Service group with questions related to this notification. **Monday – Friday between 8:00am - 5pm EST:** • Hospital – 800-965-5227 • Federal Government – 800-444-1166 • Distributor – 800-635-6021 • All Other Customers – 888-444-5440 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.** In the event you have experienced quality problems or adverse events related to the products listed, please utilize the contacts above.

What Cardinal Health is Doing	Cardinal Health has updated its product labeling for the above-listed product codes of Salem Sump™ products in response to reported incidences of improper use of the device, which can lead to breakage of the Salem Sump™ Anti-Reflux Valve (ARV). These changes to the labeling include creation of an electronic IFU and the addition of the eIFU symbol to the packaging labels. These changes will assist in increasing user awareness of proper device usage and decrease the risk of potential patient harm due to device replacement.

Additional Information:	**Adverse Events Reporting Process**

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	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. 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.

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

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Attachment A

[redacted] en –

Description

The SALEM SUMP Dual Lumen Stomach Tube is a sterile, double-lumen tube manufactured from Polyvinylchloride. The larger lumen is for drainage, while the smaller lumen draws in outside air to moderate the amount of suction at the drainage eyes.

Indications for Use

The device is intended to be used for gastric decompression.
The device is intended for patients with age of two and older.

Contraindications

1. Do not use the device in patients with anatomical defects that prohibit safe nasogastric or orogastric tube placement.
2. Do not attempt transpyloric placement of this device.
3. The use of this product is contraindicated in patients with known sensitivities or allergies to its components.
4. Unless the patient is intubated, refrain from utilizing with ingestion of hydrocarbon with a high aspiration potential, or a corrosive substance such as a strong acid or alkali. Assess relevant diagnostic data such as coagulation studies and verify the patient's history.

Warnings:

1. Coughing or any other symptom of respiratory distress would likely indicate that the device had been misplaced in the trachea. If this is suspected, remove the tube and reinsert.
2. At any point during the procedure if continuous resistance is felt the device should be withdrawn and then reinserted. The operator should discontinue all attempts at placement after repetitive unsuccessful attempts.
3. The presence of an endotracheal device tends to guide the feeding tube into the trachea. Should the feeding tube enter the tracheobronchial tree during tube placement, damage to the lung or esophagus could occur. If any resistance is felt during placement, remove the tube and reinsert. Coughing or any other symptom of respiratory distress would likely indicate that the device had been misplaced in the trachea. Misplacement of tubes into the lungs resulting in pneumothorax has been reported in neurologically impaired patients and those with endotracheal tubes in place. The operator should discontinue all attempts at placement after repetitive unsuccessful attempts at device placement.
4. This device should only be inserted by a trained user.
5. This device is disposable intended for single use. Do not reuse.
6. This device is provided in a sterile state. Do not re-sterilize.
7. Maintaining the patient in a High-Fowlers or Semi-Fowlers position may reduce regurgitation or aspiration.
8. Check the outer surfaces of the tube prior to use for rough surfaces or sharp edges. If these are present, do not use the tube.
9. No modification of the equipment is allowed
10. Do not use after the expiration date.

Precautions:

1. Do not autoclave
2. This tube should be flushed frequently to prevent clogging. Flushing after suctioning of gastric fluids is suggested.
3. Only use tap or sterile water to flush. Do not use other solutions to flush or open a clogged feeding tube.
4. The PVC SALEM SUMP is not intended for indwell time beyond 7 days.
5. Monitor patient for nasal erosion, sinusitis, esophagitis, esophagotracheal fistula, gastric erosion and pulmonary & oral infections.

Adverse Events:

Pneumothorax, gastric/esophageal perforation, aspirational pneumonia, bleeding, and mucosal irritation have been reported during the use of this type of device.

Insertion Procedure

1. It is the responsibility of trained clinician to assess and select the proper French Size and length of the SALEM SUMP tube based on age, size, and medical status of the patient.
2. Assemble equipment needed.
3. Use the tube itself to measure the length needed to reach the patient's stomach. Measure the distance from the patient's tragus (ear lobe) to bridge of nose, plus the distance from the bridge of the nose to the bottom of the xiphoid process. Mark this distance with a piece of adhesive tape.
4. Lubricate tube generously for 15 – 20 cm (6 to 8 inches) from distal tip with water-soluble jelly.
5. Insert tube to predetermined distance according to standard naso/orogastric tube insertion technique. (i.e. repeated swallowing movements).
6. Confirm tube position per institutional protocol. These tubes are equipped with a radiopaque material for facilitating radiological (X-ray or fluoroscopic) confirmation.
   Warning: If there is uncertainty of the tube's distal location after institutional placement verification methods have been performed, confirmation by X-ray should be considered.
7. Secure tube.

Set-Up of the Tube

1. Seat the 5-in-1 connector firmly into the suction drainage lumen.
   Note: If using SALEM SUMP Anti-Reflux Valve (ARV), seat the **BLUE END** of the ARV firmly into the **sump vent lumen** of the SALEM SUMP tube.
   Note: To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve.
2. Connect the suction line to the 5-in-1 connector.
   Note: To allow compatibility with syringes or other external suction devices, remove the 5-in-1 connector and insert suction lumen adapter into suction drainage lumen. Position proximal end (connector portion of device) of tube above the level of the patient's stomach, and collection trap below the level of the stomach. All connections should be snug to prevent suction loss.
3. For best results, position connector portion (proximal end) of tube above the level of the patient's stomach, and collection trap below the level of the stomach.

Irrigation

1. To irrigate main lumen or stomach: disconnect SALEM SUMP Tube from suction source. Remove 5-in-1 connector if in use from the main lumen if in use. Connect irrigating syringe to main lumen.
2. To irrigate sump lumen: Insert irrigating syringe in sump vent lumen and leave the suction source on.
3. Follow any irrigation with an injection of air through the sump vent lumen. This assures the patency of the sump lumen.

Suction Settings

1. Always use the lowest suction setting that will effectively decompress the stomach.
2. Intermittent Suction from a Thermotic Pump: Set suction on high setting (e.g. Gomco, 120 mm/Hg).
3. Continuous Suction: Set suction at a low level (30 – 40 mm/Hg) and, if necessary, slightly increase suction until fluid flow or bubbling is observed in SALEM SUMP.
4. Intermittent Suction from a Central Suction Source: Set suction at a low level, as with continuous suction.
5. **Warning:** Do not obstruct or close off the sump vent lumen while suction is applied to the device, as this will render the sump venting action of the device inoperative.

System Closure

a. Connect blue vent lumen to main lumen with 5-in-1 connector when not in use or when transporting patient.
b. To cap tube, fit **WHITE END** of Anti-Reflux Valve into **suction lumen**
   Note: To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve.

Device Removal

1. Ensure SALEM SUMP tube is free of gastric fluids.
2. Disconnect SALEM SUMP tube from all suction connections.
3. Gently withdraw SALEM SUMP tube from patient.
4. Dispose SALEM SUMP tube in accordance with hospital procedure or local guidelines.

Do not use if package is opened or damaged and consult instructions for use. Contains or presence of Phthalate. Do not resterilize. Not made with natural rubber latex.

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STERILE R

LATEX Not made with natural rubber latex

Rx ONLY

PHT DEHP

Do not use if package is opened or damaged.
Ne pas utiliser si l'emballage est ouvert ou endommagé.
No utilizar si la envoltura está abierta o dañada.
Não utilizar se a embalagem estiver aberta ou danificada.

mycardinalmsds.com

cardinalhealth.com/symbolsglossary

WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov

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pdate Description	Example	
ll – eIFU Update		**Set-Up of the Tube** 1. Seat the 5-in-1 connector firmly into the suction drainage lumen. **Note:** If using SALEM SUMP Anti-Reflux Valve (ARV), seat the [redacted] of the ARV firmly into the [redacted] of the SALEM SUMP tube. **Note:** To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve. 2. Connect the suction line to the 5-in-1 connector. **Note:** To allow compatibility with syringes or other external suction devices, remove the 5-in-1 connector and insert suction lumen adapter into suction drainage lumen. Position proximal end (connector portion of device) of tube above the level of the patient's stomach, and collection trap below the level of the stomach. All connections should be snug to prevent suction loss. 3. For best results, position connector portion (proximal end) of tube above the level of the patient's stomach, and collection trap below the level of the stomach. **Irrigation** 1. To irrigate main lumen or stomach: disconnect SALEM SUMP Tube from suction source. Remove 5-in-1 connector if in use from the main lumen if in use. Connect irrigating syringe to main lumen. 2. To irrigate sump lumen: Insert irrigating syringe in sump vent lumen and leave the suction source on. 3. Follow any irrigation with an injection of air through the sump vent lumen. This assures the patency of the sump lumen. **Suction Settings** 1. Always use the lowest suction setting that will effectively decompress the stomach. 2. Intermittent Suction from a Thermotic Pump: Set suction on high setting (e.g. Gomco, 120 mm/Hg). ~~3. Continuous Suction: Set suction at a low level (30 – 40 mm/Hg) and,~~ if necessary, slightly increase suction until fluid flow or bubbling is observed in SALEM SUMP. 4. Intermittent Suction from a Central Suction Source: Set suction at a low level, as with continuous suction. 5. **Warning:** Do not obstruct or close off the sump vent lumen while suction is applied to the device, as this will render the sump venting action of the device inoperative. **System Closure** a. Connect blue vent lumen to main lumen with 5-in-1 connector when not in use or when transporting patient. b. To cap tube, fit [redacted] of Anti-Reflux Valve into [redacted] **Note:** To remove, pull valve in the same direction of assembly. Do not pull at an angle to avoid breaking the valve.

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Update Description	Example
Electronic reference	Add PMD - 12 symbol: Consult electronic instructions for use