Medex Cardio-Pulmonary, doing business as Smiths Medical, Recalls Sterile Saline and Sterile Water for Inhalation Due to Potential Exposure to Infectious Agents as a Result of Leaking Containers

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product(s):

- Select serial and lot numbers of Smiths Medical Sterile Saline and Water (listed below)
- Manufacturing Dates: August 30, 2013, to February 10, 2017
- Distribution Dates: August 30, 2013, to February 10, 2017
- Full list of **affected devices**
- Devices Recalled in the U.S.: 939,364

Device Use

The sterile saline and water are respiratory humidification products used in patients undergoing respiratory therapy, tracheal wash, or wound cleaning.

Reason for Recall

Smiths Medical is recalling the sterile saline and sterile water products for inhalation due to the potential exposure to infectious agents (bacillus infantis and staphylococcus epidermidis) because of damage to the containers used to package the finished products. Use of these products in patients could result in infection and may require treatment with antibiotics. Serious or untreated infections could result in patient death.

The company initiated a voluntary recall on September 5, 2017. That recall covered several products, including some that are outside the scope of this notice. The FDA is auditing the recall to ensure the company has notified all affected customers and that affected product has been returned. Based on the available information, the FDA is now classifying the action regarding the affected products (listed below) as a Class I recall.

Who May be Affected

- Hospitals and health care professionals using Smiths Medical Sterile Saline or Water distributed from August 30, 2013, to February 10, 2017.
- Patients receiving respiratory therapy or tracheal lavage with Smiths Medical Sterile Saline or Water distributed from August 30, 2013, to February 10, 2017.

What to Do

On September 5, 2017, Smiths Medical sent affected customers an "Urgent Medical Device Recall Notice" informing them of affected sterile water and saline product models and directing them to locate, determine the affected sterile saline or water products in their possession, and to complete the “Urgent Medical Device Recall Response Form” attached to the recall notice. Customers were also instructed to return all affected product to Stericycle for processing.

On January 7, 2019, distributer Medline Industries Inc. initiated a sub-recall for privately labeled product models and lots, affected by the September 5, 2017, Smiths Medical recall notice, that were not expired and which may be potentially contaminated with the infectious agents.

The notice asked customers to:

1. Locate the affected Sterile Water, Saline and Eye Wash in their possession by referring to the specific model and lot numbers listed in the Urgent Medical Device Field Recall Response Form.
2. Determine the number of affected devices in their possession and complete the Urgent Medical Device Field Recall Response Form attached to this letter within 10 days of receipt and send it to **smithsmedicalste00100@stericycle.com (mailto:smithsmedicalste00100@stericycle.com)**. The form must be returned even if customers do not have any of the affected Sterile Water, Saline and Eye Wash in their possession. Product credit will be processed once the Urgent Medical Device Field Recall Response Form and affected product is received. All affected devices must be returned to Stericycle for processing. Pre-paid shipping labels were included with the Urgent Medical Device Recall Notice.
3. Package the affected devices and include a copy of the completed Urgent Medical Device Field Recall Response Form inside EACH BOX of the returned devices to obtain credit for the returned devices. Make sure boxes are sealed and labeled with the facility name prior to shipping devices to Stericycle.

Distributors are asked to immediately notify customers who received the affected product of this Recall.

Contact Information

Customers with questions regarding this notification may contact Stericycle via email at **smithsmedicalste00100@stericycle.com (mailto:smithsmedicalste00100@stericycle.com)**.

Date Recall Initiated

September 5, 2017

Full List of Affected Devices

- Portex 350 ml Sterile Water Humidifier w/5psi Adapt (Model # 352 Lot Numbers: A214, A215, Z263,

Z532, and Z555)

- Portex 550 ml Sterile Water Humidifier w/5psi Adapt (Model # 552 Lot Numbers: A054, A089, A090, and Z262)
- Portex 1000 ml Sterile Water USP Pour Bottle (Model # 1065 Lot Numbers: B209 and Z225)
- Portex 500 ml Sterile Water USP Pour Bottle (Model # 1565 Lot Number: Y371)
- Intermed 350 ml Sterile Water Humidifier w/5psi Adapt. (Model # 0352IMJ Lot Numbers: A457, A597, B157, B236, Z589, Z655, Z656, and Z661)
- Portex 550 ml Sterile Water Humidifier w/5psi Adapt. (Model # 0552C Lot Number: Z370)
- Intermed 550 ml Sterile Water Humidifier w/5psi Adapt. (Model # 0552IMJ Lot Numbers: Z588 and Z597)
- Medline 300-350 ml Sterile Water Humidifier w/5psi Adapt. (Model # HCS00300 Lot Number: Y576)
- Medline Prefilled 350 ml Sterile Water (Model # HCS00350 Lot Numbers: A055, A056, A057, A058, A103, A176, A455, B530, B531, B532, B533, Z101, Z534, Z553, and Z554)
- Portex Unit Dose 5 ml Normal Saline (0.9%) (Model # R0059 Lot Number: B360), K820227
- Portex Unit Dose 15 ml Normal Saline (Model # R0159 Lot Numbers: A661, B067, A526, A536, A569, and B201)
- Portex 5ml Normal Saline (0.9%) Unit Dose (Model # UD9005 Lot Number: B515), K820227
- Medline Prefilled 550 ml Sterile Water (Model # HCS00550 Lot Numbers: A092, B205, B534, and Z205)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (/Safety/MedWatch/HowToReport/ucm2007306.htm)**. Health care professionals employed by facilities that are subject to **FDA's user facility reporting requirements (/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverse-Events/ucm2005737.htm)** should follow the reporting procedures established by their facilities.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2019 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm629347.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)