Draeger Medical Recalls Breathing Circuits and Anesthesia Sets

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)

- Draeger Medical, Inc. VentStar and ID Breathing Circuits and Anesthesia Sets
- Model/Item Numbers:
  - MP00349, MP00350, MP00351, MP00352, MP00361, MP00374 (VentStar Circuits and Anesthesia Sets)
  - MP01341, MP01348, MP01350 (ID Circuits and Anesthesia Sets)
- Manufacturing Dates: January 2016 to November 2018
- Distribution Dates: April 2016 to December 2018
- Devices Recalled in the U.S.: 1,200

Device Use

Draeger Medical's VentStar and ID Breathing Circuits and Anesthesia Sets are single-use, disposable, accessory devices used with a ventilator or anesthesia machine to provide mechanical ventilation and critical breathing support to infant, child, and adult patients. These devices are designed to be used only under a health care professional's supervision.

Reason for Recall

Draegar Medical is recalling its disposable VentStar and ID Breathing Circuits and Anesthesia Sets due to a risk of the devices being incorrectly assembled, resulting in a short-circuit in the breathing hose. If the breathing hose is short circuited, the patient will not receive the expected breathing support (ventilation). Lack of breathing support may result in irreversible patient harm, up to and including severe oxygen-loss (hypoxia) and death.

Who May be Affected

- Hospitals and health care professionals using the VentStar or ID Breathing Circuit and Anesthesia Set to provide patients with respiratory support.
- Patients receiving respiratory support from a VentStar or ID Breathing Circuit and Anesthesia Set.

What to Do

On December 21, 2018, Draeger Medical sent customers an "Urgent Medical Device Recall Notification" and" Customer Reply and Order Form." The recall notification instructed customers to:

- 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/ReportingAdverseEvents/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)

- Follow the device's Instructions for Use for correct setup of the breathing circuit, and check to ensure the connections are assembled correctly prior to each use.
  - If a short-circuited breathing circuit is not detected during a pre-use check, it will not be possible to ventilate the patient.
- Check whether the breathing circuit is assembled so that the inspiratory and the expiratory connector of the ventilator or anesthesia machine are each connected to the y-piece before each use, and after any temporary disconnection.
- Inspect your existing stock by following the provided inspection instructions and complete and return the "Customer Reply and Order Form" to confirm that inspections have been completed.
- Use the "Customer Reply and Order Form" to order free replacements for any breathing circuits that were pre-assembled incorrectly.
  - An incorrectly pre-assembled breathing circuit can be detected because it will not be a single cohesive hose system but two separate sub-systems.

Contact Information

Customers who have questions or need additional information regarding this recall may contact Michael Kelhart between the hours of 8 AM – 4:30 PM EST at 1-800-437-2437 (press 1 at the prompt, then press 32349).

Date Recall Initiated

December 21, 2018

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