

# Vyair Medical, Inc. Recalls AirLife Resuscitation Devices Due to Manufacturing Error Preventing Oxygen Delivery

*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): AirLife Resuscitation Devices
- Product Codes: 2K8004, 2K8035C2, 2K8017, 2K8005, 2K8018, 2K8008, 2K8036, 2K8001, RE1DK5445D, 2K8035M, 2K8039, 2K8004C2
- Manufacturing Dates: February 5, 2018 to February 28, 2018
- Distribution Dates: February 2, 2018 to April 20, 2018
- Devices Recalled in the U.S.: 15,714 units nationwide

## Device Use:

AirLife manual single-use resuscitation devices provide constant ventilation to adults and children who are not breathing or cannot adequately breathe on their own following placement of an advanced airway device (tracheal or tracheostomy tube). To ventilate the patient, a health care provider squeezes the bag causing oxygen to go through a one-way valve to the patient. The bag is released and automatically refills while an exhalation port valve allows for the patient to exhale and the breath is then repeated.

## Reason for Recall

Vyair Medical, Inc is recalling the AirLife Resuscitation Device due to a manufacturing error which may cause extra plastic material in the oxygen output connection to reduce or block the flow of oxygen to the patient. The blocked connection may result in a delay in or inability to provide necessary ventilation to the patient and potentially result in serious patient injury, such as inadequate oxygen supply (hypoxia), or death. Vyair has received no complaints of this problem; there have been no patient injuries.

## Who is affected?

- Patients who may require manual resuscitation and ventilation after placement of an advanced airway device.
- Health care providers and first responders who use the AirLife Resuscitation devices to provide ventilation to patients after placement of an advanced airway device

## What to Do:

On May 8, 2018 Vyair Medical, Inc sent an Urgent Medical Device Recall notice to affected

customers. The notice asked customers to:

- Review the recall notice and ensure appropriate staff is aware of the notice.
- Identify and remove affected lots of the AirLife Resuscitation Devices
- Destroy all affected product(s) in-stock in accordance with the facility's destruction protocol.
- Complete the Customer Response Form and return to [GMB-GLB-ALFieldActions@Vyair.com](mailto:GMB-GLB-ALFieldActions@Vyair.com) (<mailto:GMB-GLB-ALFieldActions@Vyair.com>).

## Contact Information

Customers who have questions or need additional information or support regarding this recall should contact Lindy Schenning, Clinical Risk Coordinator, at (872)757.0109 or [Lindy.Schenning@Vyair.com](mailto:Lindy.Schenning@Vyair.com) (<mailto:Lindy.Schenning@Vyair.com>).

## Date Recall Initiated

May 8, 2018

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) either online, by regular mail or by FAX to 1-800-FDA-0178.

More in [Medical Device Recalls](#)  
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

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

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

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