Vyaire Medical, Inc. Recalls Tri-Flo Subglottic Suction System Due to Risk of Device Breakage

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

- Name: Tri-Flo Subglottic Suction System
- Lot numbers: 0001158835, 0001158836, 0001158837, 0001185564, 0001194114, 0004008255, 0004008256
- Model Number: CM28010
- Manufacturing Dates: Unknown
- Distribution Dates: January 23, 2018 to May 23, 2018
- Devices Recalled in the U.S.: 2,150 units nationwide

Device Use

Health care providers typically place endotracheal tubes into a patient's airway (trachea) to help establish and maintain their airway and to ensure the adequate exchange of oxygen and carbon dioxide. Health care providers use the Tri-Flo Subglottic Suction System to remove liquids or semisolids that block an adult patient's airway when an endotracheal tube is in place.

Reason for Recall

Vyaire Medical, Inc is recalling the Tri-Flo Subglottic Suction System because there is a risk that the distal soft tip of the catheter may break off and enter the patient's lungs.

This may result in serious adverse health consequences including choking, wheezing, additional surgery to remove the tip from the patient's lungs, irritation and reddening of the skin (erythema) of the airways, infections or death.

Who May be Affected

- Health care providers and first responders who use the Tri-Flo Subglottic Suction System devices to provide ventilation to patients advanced airway device.
- Patients who may need manual resuscitation and ventilation after placement of an advanced airway device has been placed.

What to Do

On June 20, 2018, Vyaire Medical, Inc sent an Urgent Tri-Flo Subglottic Suction System Recall

Notification letter to affected customers. The letter asked customers to:

- Inspect current inventory and remove all affected Tri-Flo Subglottic Suction Systems.
- Return all in-stock inventory affected by this recall by calling Vyaire Medical, Inc's Customer Service Support Team at 833-3BREATH (833-327-3284) (Option #1) Monday-Friday 7:00 am Central Standard Time - 5:30 pm Central Standard Time to obtain a pre-paid shipping Return. Goods Authorization (RGA). Requests for credit can be made by providing the original P.O. number for in-stock inventory.
- Complete the Customer Response Form (Appendix 1) and return to GMB-GLB VSFieldActions@Vyaire.com. The letter also included instructions for customers that did not purchase the product directly through Vyaire Medical to work with the distributor to return or receive credit for in-stock inventory affected by this recall.
- Notify customers of this recall if you are a facility that has further distributed affected product.

Contact Information

Customers who have questions or need more information or help with this recall should contact Vyaire Medical, Inc's Customer Service Support Team at (833)327-3284 (Option #1) Monday-Friday 7:00 am Central Standard Time - 5:30 pm Central Standard Time.

Date Recall Initiated

June 20, 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)** 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)

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

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