Teleflex Incorporated Announces Worldwide Voluntary Recall of COMFORT FLO® Humidification System

February 14, 2020

WAYNE, Pa., Feb. 14, 2020 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX), a global provider of medical technologies for critical care and surgery, has announced a worldwide voluntary recall of the COMFORT FLO® Humidification System. The recalled products provide a continuous flow of heated and humidified gas to COMFORT FLO® patients in professional health care environments. The products involved in the recall are as follows:

Product Name	Product Code	Lot Numbers
COMFORT FLO Humidification System	2410	See Appendix 1
COMFORT FLO Humidification System with Remote Port Extension	2414	
Corrugated COMFORT FLO	2415	
Corrugated COMFORT FLO Remote Temp Port	2416	

These recalled products were manufactured from October 2014 through June 2019. Products manufactured after June 2019 are now being packaged with our new COMFORT FLO® columns for high flow therapy. The recalled product can be identified by the presence of only one white reservoir clamp on the feed tube (distinguishing itself from new product which contains two blue reservoir clamps on the feed tube). Specific lot codes may be found through the following link: https://p.widencdn.net/svhco2/EIF-387-Amend-Cust-letter-ack-appx

Teleflex is recalling the above product codes and lots due to the potential for water to flood the column and enter the circuit under circumstances where an abnormal pressure differential is created between the water bottle and the column during high flow oxygen therapy.

The potential health consequence of exposure to water ingress is the aspiration of fluid into the nose and lungs that may result in oxygen desaturation. The company has received 102 complaints of water ingress in which intervention has been required on several patients to prevent serious injury or permanent impairment. The Company has not received any reports of death. In one instance, fluid aspiration and subsequent desaturation required invasive respiratory support including intubation and positive pressure ventilation. In another instance, an infant in a NICU experienced aspiration with desaturation and bradycardia requiring bag mask ventilation. Aspiration in patients requiring supplementary oxygen to prevent hypoxemia also has the potential to result in respiratory arrest, cardiac arrest, permanent brain and/or cardiac injury, and death. The long-range health consequences depend on the degree and duration of desaturation and the rapidity and success of medical interventions to resuscitate the patient.

The U.S. Food and Drug Administration (FDA) has classified the recall of the COMFORT FLO® Humidification System as a Class I recall. FDA defines a Class I recall as, "*a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death*."

Consumers who have affected product should immediately identify all patients that are currently exposed to use of this product, discontinue use, and return all affected product to Teleflex. The recall notice, with a list of affected product codes and lot numbers, can be found through the following link: https://p.widencdn.net/svhco2/EIF-387-Amend-Cust-letter-ack-appx

Consumers with questions may contact the company at 1-866-396-2111; 8am to 7pm, ET, Monday through Friday or email recalls@teleflex.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm, **or via Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

About Teleflex Incorporated
Teleflex is a global provider of medical technologies designed to improve the health and quality of people's lives. We apply purpose driven innovation – a relentless pursuit of identifying unmet clinical needs – to benefit patients and healthcare providers. Our portfolio is diverse, with solutions in the fields of vascular and interventional access, surgical, anesthesia, cardiac care, urology, emergency medicine and respiratory care. Teleflex employees worldwide are united in the understanding that what we do every day makes a difference. For more information, please visit teleflex.com.

Teleflex is the home of Arrow®, Deknatel®, Hudson RCI®, LMA®, Pilling®, Rusch® and Weck® – trusted brands united by a common sense of purpose.

Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements. Any forward-looking statements contained herein are based on our management's current beliefs and expectations, but are subject to a number of risks, uncertainties and changes in circumstances, which may cause actual results or company actions to differ materially from what is expressed or implied by these statements. These risks and uncertainties are identified and described in more detail in our filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K.

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