



Teleflex Incorporated Announces Worldwide Voluntary Recall of GaleMed Corporation (third party manufacturer) Babi.Plus® 12.5 cm H₂O Pressure Relief Manifold

October 7, 2019

WAYNE, Pa., Oct. 07, 2019 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX), announced a recall June 14th, 2019 of certain lots of the GaleMed (**third party manufacturer**) Babi.Plus® 12.5 cm H₂O Pressure Relief Manifold. Teleflex receives the product from the manufacturer GaleMed Corporation and is one of its distributors for this product within the United States. GaleMed Corporation is the legal manufacturer of these products.

The recalled products are designed for use with humans with a body mass of less than 10 Kg requiring a pressure limitation system to eliminate excessive pressure should an obstruction occur between gas supply and exhalation port during continuous gas flow therapy up to 12 liters per minute in hospital and transport environments. The most used application of the pressure relief manifold (PRM) is Bubble CPAP therapy. The products involved in this recall are as follows:

Product Name	Product Code	Lot/Batch Number
GaleMed Babi.Plus® 12.5 cm H ₂ O Pressure Relief Manifold	2691	180806 181204
		180910 190225
		181029 190327
		181105

This voluntary recall is due to a Medical Device Recall Notice which Teleflex received from the GaleMed Corporation. GaleMed advises that the Babi.Plus 12.5cm H₂O Pressure Relief Manifold is being recalled because it has been reported that the bubble continuous positive airway pressure (BCPAP) system would not hold pressure as the pressure relief manifold (PRM) internal mechanism was lodged in the upper valve chamber which prevented engagement with the valve seat. This may be easily identified by either visually inspecting the pressure relief valve to confirm that the valve is properly seated on the valve seat and/or performing a pre-patient connection to the BCPAP system or performing a system pressure test, as an affected valve will not allow the system to pressurize.

GaleMed has received two (2) reports of device malfunction in which the device vented gas below the stated pressure. Though no injuries have been reported, use of an affected device with the valve not properly seated on the valve seat could result in lower blood oxygen levels and rebreathing of exhaled carbon dioxide.

These recalled products were distributed from October 2018 to May 2019.

The U.S. Food and Drug Administration (FDA) classified the original recall of the GaleMed Babi.Plus® 12.5 cm H₂O Pressure Relief Manifold 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 discontinue use and return all affected product to Teleflex. The recall notice can be found through the following link: https://p.widencdn.net/ivsxp/AN_ETT_Connector_Customer_Recall_Letter

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 access, interventional cardiology and radiology, anesthesia, emergency medicine, surgical, urology 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®, Rüsçh®, UroLift®, 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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Source:

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