Teleflex Medical Announces Worldwide Voluntary Recall of ISIS™ HVT™ Tracheal Tube Cuffed with Subglottic Secretion Suction Port (with and without Preloaded Stylet)

February 12, 2014

LIMERICK, Pa.--(BUSINESS WIRE)--Feb. 12, 2014-- Teleflex Medical Incorporated has announced a worldwide voluntary recall of its ISIS™ HVT™ Tracheal Tube Cuffed with Subglottic Secretion Suction Port (with and without Preloaded Stylet). This recall is being conducted because of complaints that the tracheal tube can kink during patient use. If a tracheal tube kinks, it can deprive the patient of adequate ventilation causing serious injury, including hypoxic injury and/or anoxia.

The U.S. Food and Drug Administration ("FDA") has classified this action as a Class I recall. FDA defines class I recalls 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."

Teleflex initiated this recall by a letter to its U.S. customers on January 6, 2014. In accordance with the instructions provided in the recall letter, customers should immediately discontinue use of the recalled devices and return all unused ISIS products to Teleflex Medical. The affected product codes are:

Product Description	Product Code
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 6.0	5-13012
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 6.5	5-13013
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 7.0	5-13014
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 7.5	5-13015
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 8.0	5-13016
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 8.5	5-13017
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port, 9.0	5-13018
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 6.0	5-14012
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 6.5	5-14013
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 7.0	5-14014
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 7.5	5-14015
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 8.0	5-14016
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 8.5	5-14017
ISIS HVT Tracheal Tube Cuffed with Subglottic Secretion Suction Port and Preloaded Stylet, 9.0	5-14018

A list of product and lot numbers affected by this recall, as well as the original recall notice, can be found at Teleflex's website:

Recall Notice

Consumers with questions may contact the company at 1-866-804-9881; 8am to 8pm, ET, Monday through Friday.

Any adverse reactions experienced with the use of these products, and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

About Teleflex Medical Incorporated

Teleflex Medical Incorporated is a subsidiary of Teleflex Incorporated (NYSE:TFX). Teleflex Incorporated is a leading global provider of specialty medical devices for a range of procedures in critical care and surgery. Our mission is to provide solutions that enable healthcare providers to improve outcomes and enhance patient and provider safety. Headquartered in Limerick, PA, Teleflex employs approximately 11,400 people worldwide and serves healthcare providers in more than 140 countries. For additional information about Teleflex please refer to www.teleflex.com.

Source: Teleflex Medical Incorporated

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