



## Teleflex Incorporated Announces Worldwide Voluntary Recall of Select Hudson RCI® Sheridan® Endotracheal Tubes

June 24, 2019

WAYNE, Pa., June 24, 2019 (GLOBE NEWSWIRE) -- Teleflex Incorporated (NYSE: TFX), has announced a worldwide recall of certain lots of Hudson RCI® Sheridan® Endotracheal Tubes. The recalled products are designed for oral or nasal intubation and are indicated for airway management. The products involved in this recall are as follows:

Product Name	Product Code	Product Name	Product Code
Hudson RCI® Sheridan LTS®	5-11112		5-22214
Hudson RCI® Sheridan/CF® 6.0 mm	5-10112	Hudson RCI® Sheridan® Preformed 7.0 mm	5-22314
	5-10212		5-22014
Hudson RCI® Sheridan/CF® 6.5 mm	5-10113		Hudson RCI® Sheridan® Preformed 7.5 mm
	5-10213	5-22215	
Hudson RCI® Sheridan/CF® 7.0 mm	5-10114	Hudson RCI® Sheridan® Preformed 8.0 mm	5-22315
	5-10214		5-22216
Hudson RCI® Sheridan/CF® 7.5 mm	V5-10115		5-22316
	5-10115	Hudson RCI® Sheridan® Preformed 8.5 mm	5-22217
	5-10215	Hudson RCI® Sheridan® Uncuffed 6.0 mm	5-10412
Hudson RCI® Sheridan/CF® 8.0 mm	5-10116	Hudson RCI® Sheridan® Uncuffed 6.5 mm	5-10413
	5-10216	Hudson RCI® Sheridan® Uncuffed 7.0 mm	5-10414
	V5-10116	Hudson RCI® Sheridan®/EZ-ENDO 6.0 mm	5-22512
Hudson RCI® Sheridan/CF® 8.5 mm	5-10117	Hudson RCI® Sheridan®/EZ-ENDO 6.5 mm	5-22513
	5-10217	Hudson RCI® Sheridan®/HVT® 6.0 mm	5-10312
Hudson RCI® Sheridan® EZ-ENDO 7.0 mm	5-22514	Hudson RCI® Sheridan®/HVT® 6.5 mm	5-10313
Hudson RCI® Sheridan® EZ-ENDO 7.5 mm	5-22515	Hudson RCI® Sheridan®/HVT® 7.0 mm	5-10314
Hudson RCI® Sheridan® EZ-ENDO 8.0 mm	5-22516	Hudson RCI® Sheridan®/HVT® 7.5 mm	5-10315
Hudson RCI® Sheridan® EZ-ENDO 8.5 mm	5-22517	Hudson RCI® Sheridan®/HVT® 8.0 mm	5-10316
Hudson RCI® Sheridan® Preformed 6.0 mm	5-22212	Hudson RCI® Sheridan®/HVT® 8.5 mm	5-10317
	5-22312	Sheridan/CF Novaplug® 7.0 mm	V5-10114
	5-22112	Sheridan/HVT® Novaplug® 7.0 mm	V5-10314
	5-22012	Sheridan/HVT® Novaplug® 7.5 mm	V5-10315
Hudson RCI® Sheridan® Preformed 6.5 mm	5-22313	Sheridan/HVT® Novaplug® 8.0 mm	V5-10316
	5-22213	Sheridan/HVT® Novaplug® 8.5 mm	V5-10317
	5-22013		
	5-22113		

These recalled products were distributed from October 2016 to May 2019. Specific lot codes may be found through the following link: [https://p.widencdn.net/ivsxip/AN\\_ETT\\_Connector\\_Customer\\_Recall\\_Letter](https://p.widencdn.net/ivsxip/AN_ETT_Connector_Customer_Recall_Letter)

This voluntary recall is due to reported complaints (<0.0025% of all in scope distributed product) indicating that there is an increased incidence of specific lots of the 15 mm Sheridan connector becoming disconnected from the endotracheal tube (ETT). The immediate consequence for patients is

disconnection from the breathing circuit, which may result in insufficient oxygenation, requiring medical intervention. There have been four reports of death, and additional reports of serious injury where ETT disconnection may have been a factor.

The U.S. Food and Drug Administration (FDA) has classified the recall of Hudson RCI<sup>®</sup> Sheridan<sup>®</sup> Endotracheal Tubes 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 or its distributor. The recall notice, with a list of affected product codes and lot numbers, can be found through the following link: [https://p.widencdn.net/ivsxp/AN\\_FTT\\_Connector\\_Customer\\_Recall\\_Letter](https://p.widencdn.net/ivsxp/AN_FTT_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](mailto: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](http://www.fda.gov/medwatch/report.htm), **or via Regular Mail or Fax** (download form [www.fda.gov/MedWatch/gefforms.htm](http://www.fda.gov/MedWatch/gefforms.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](http://teleflex.com).

Teleflex is the home of Arrow<sup>®</sup>, Deknatel<sup>®</sup>, Hudson RCI<sup>®</sup>, LMA<sup>®</sup>, Pilling<sup>®</sup>, Rüsçh<sup>®</sup>, UroLift<sup>®</sup>, and Weck<sup>®</sup> – 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.

*Teleflex, the Teleflex logo, Arrow, Deknatel, Hudson RCI, LMA, Pilling, Rüsçh, UroLift, and Weck are trademarks or registered trademarks of Teleflex Incorporated or its affiliates, in the U.S. and/or other countries.*

*© 2019 Teleflex Incorporated. All rights reserved.*

#### **Source:**

Teleflex Incorporated  
Jake Elguicze  
Treasurer and Vice President, Investor Relations  
610-948-2836



Source: Teleflex Incorporated