## Class 1 Device Recall Rusch TracheoFlex Trachostomy Tube

**Date Initiated by Firm**  
August 26, 2016

**Create Date**  
October 18, 2016

**Recall Status**  
Open, Classified

**Recall Number**  
Z-0044-2017

**Recall Event ID**  
750532

**510(K) Number**  
K98405624

**Product Classification**  
Tube trachostomy and tube cuff - Product Code J0H

**Product**  
Willy Rusch GmbH Trachostomy Tube Set

Cannulation of traechotomised patients, particularly in the case of a narrow trachostoma and narrow-lumen tracheas. When using cannulas with curr. For short term intermittent inflation.

**Code Information**  
Lot - 15451, 15291, 15331, 15371, 15501, 15261, 15391, 15421, 15461, 15491

**Recalling Firm/Manufacturer**  
Teleflex Medical  
3015 Carrington Mill Blvd  
Morrisville NC 27560-5437

**For Additional Information Contact**  
Alice K. Harper  
610-378-0131

**Manufacturer Reason for Recall**  
The connector may disconnect from the trachostomy tube during use.

**FDA Determined Cause**  
Unknown/Undetermined by firm

**Action**  
Teleflex sent an Urgent Field Safety Notice dated August 26, 2016, to all affected consignees. The letter requested that consignees cease use and distribution of stock, quarantine immediately, and return the product. Also, the letter requested a sub-recall if the product had been further distributed. The letter included an Acknowledgement Form which is to be returned. Customers with questions were instructed to contact their local sales representative or Customer Service. For questions regarding this recall call 610-378-0131.

**Quantity in Commerce**  
1095 units

**Distribution**  
Worldwide Distribution: US (nationwide) to CA and countries of: Austria, Belgium, France, Germany, Italy, Japan, Poland, and Turkey.

**Total Product Life Cycle**  
TPLC Device Report

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1. A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#).

2. Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[Source](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=149196)  
11/2/2016