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Class 1 Device Recall Rusch TracheoFlex Tracheostomy Tube
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Class 1 Device Recall Rusch TracheoFlex Tracheostomy Tube

See Related Information

Date Initiated by Firm

August 26, 2016

Create Date

October 18, 2016

Recall Status¹

Open³, Classified

Recall Number

Z-0044-2017

Recall Event ID

75053²³

510(K)Number

K964056²⁴

Product Classification

Tube tracheostomy and tube cuff²⁵ - Product Code JOH²⁶

Product

Willy Rusch GmbH Tracheostomy Tube Set

Cannulation of tracheotomised patients, particularly in the case of a narrow tracheostoma 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/

Teleflex Medical

3015 Carrington Mill Blvd Manufacturer Morrisville NC 27560-5437

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

Manufacturer Reason

for Recall

The connector may disconnect from the tracheostomy tube during use.

FDA Determined

Cause 2

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 Report²⁷

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 recalls²⁸.

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