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Class 1 Device Recall Hudson RCI Sheridan LTS:



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Class 1 Device Recall Hudson RCI Sheridan LTS:

Date Initiated by Firm	July 30, 2019
Create Date	September 09, 2019
Recall Status¹	Open ³ , Classified
Recall Number	Z-2311-2019
Recall Event ID	83461 ²³
510(K)Number	K822082 ²⁴
Product Classification	Tube, tracheal (w/wo connector) ²⁵ - Product Code BTR ²⁶
Product	Hudson RCI Sheridan LTS: a) 4.0 mm, REF 5-11108 b) 5.0 mm, REF 5-11110 c) 6.0 mm, REF 5-11112 Product Usage: Tracheal tube/airway management
Code Information	a) REF 5-11108 Batch numbers: 73L1600010 73A1700644 73C1700236 73D1700438 73E1700473 73F1700385 73K1700066 73L1700501 73B1800123 73C1700066 73D1700066 73E1700066 73F1700066 73G1700066 73H1700066 73I1700066 73J1700066 73K1700066 73L1700066 73M1700066 73N1700066 73O1700066 73P1700066 73Q1700066 73R1700066 73S1700066 73T1700066 73U1700066 73V1700066 73W1700066 73X1700066 73Y1700066 73Z1700066 b) REF 5-11110 Batch numbers: 73K1600368 73K1600727 73A1700645 73B1700410 73C1700237 73D1700624 73E1700474 73F1700386 73H1700040 73H1700482 73H1700511 73H1700512 c) REF 5-11112 Batch numbers: 73K1600369 73L1600011 73A1700646 73C1700238 73D1700625 73E1700475 73F1700387 73H1700041 73H1700483 73J1700292 73L1700501
Recalling Firm/Manufacturer	Teleflex Medical 3015 Carrington Mill Blvd Morrisville NC 27560-5437
Manufacturer Reason for Recall	Reported complaints indicate an increased incidence of specific lots of the 15 mm Sheridan connector becoming disconnected from the endotracheal tube (
FDA Determined Cause²	Process control
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated July 30, 2019 to affected customers. The letter explains the problem and requests the products. For questions, contact your local sales representative or Customer Service at 1-866-396-2111.
Quantity in Commerce	7963 units
Distribution	US Nationwide Distribution
Total Product Life Cycle	TPLC Device Report ²⁷

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

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

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database

[510\(K\)s with Product Code = BTR and Original Applicant = SHERIDAN CATHETER CORP.](#)²⁹

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