Class 1 Device Recall Hudson RCI Sheridan LTS:

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Date Initiated by Firm	July 30, 2019
Create Date	September 09, 2019
Recall Status[1]	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 73 numbers: 73K1600368 73K1600727 73A1700645 73B1700410 73C1700237 73D1700624 73E1700474 73F1700386 73H1700040 73H1700482 73H17005 11112 Batch numbers: 73K1600369 73L1600011 73A1700646 73C1700238 73D1700625 73E1700475 73F1700387 73H1700041 73H1700483 73J1700292 73L170050
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 Cause [2]	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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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83461
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K822082
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=BTR
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=BTR&knumber=&applicant=SHERIDAN%20CATHETER%20CORP%2E

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19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83461
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K822082
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=BTR
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
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