### Class 1 Device Recall

**Hudson RCI Sheridan LTS:**

**Date Initiated by Firm:** July 30, 2019  
**Create Date:** September 09, 2019  
**Recall Status:** Open, Classified  
**Recall Number:** Z-2311-2019  
**Recall Event ID:** 8346123  
**510(K) Number:** K8220824  
**Product Classification:** Tube, tracheal (w/o connector) - Product Code BTR  
**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 73C1600368 73K1600727 73A1700645 73B1700410 73C1700237 73D1700624 73E1700474 73F1700386 73H1700040 73H1700042 73H1700511 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:** 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  

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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  

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.

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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
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29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=BTR&knumber=&applicant=SHERIDAN%20CATHETER%20CORP%2E

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21. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83461
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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=BTR
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