Class 2 Device Recall Stryker Toga

[22]

Date Initiated by Firm	February 23, 2018
Create Date	April 24, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1500-2018
Recall Event ID	79779[23]
510(K)Number	K070078[24]
Product Classification	surgical gown[25] - **Product Code** FYA[26]
Product	T4 Pullover Toga, (S/M); Catalog Number: 0400-710-000 Sterile personal protection garment
Code Information	17071877
Recalling Firm/ Manufacturer	Stryker Instruments Div. of Stryker Corporation 4100 E Milham Ave Portage MI 49002-9704
For Additional Information Contact	Kara Spath 269-323-7700
Manufacturer Reason for Recall	Separation of material layers may occur, causing a potential risk of exposure to contaminants.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On March 7, 2018 Stryker Instruments mailed Urgent Medical Device Recall Notifications to affected customers. Distributors and Sales Representative were notified via e-mail. Customers were instructed to: 1) Immediately review this Recall Notification; 2) Immediately check all stock areas and/or operating room storage for affected products. Quarantine and discontinue use of any affected T4 and T5 Togas; 3) Complete the enclosed Business Reply Form (BRF) to confirm receipt of this Notification and identify how many affected items are currently in your inventory. Please complete and return the BRF even if you dont have any affected product on hand. Fax the completed BRF to Stryker Instruments at 866-521-2762, or email to kara.spath@stryker.com. Note: Your signature on the BRF indicates that you received and understand this Notification and have followed the instructions in the Notification; 4) If you have further distributed this product, please forward this Notification and the attached BRF to all affected locations. Please indicate each location on the BRF; 5) If the BRF for your facility indicates that recalled product is currently on hand, a FedEx label will be emailed to you and should be used to return recalled product. Upon receipt of the recalled product, a credit will be issued to your account. Customer with questions or concerns may call (800)253-3210.
Quantity in Commerce	34,570 total products
Distribution	US Nationwide and Ireland, Japan, South Korea, UK
Total Product Life Cycle	TPLC Device Report[27]