Date Initiated by Firm: February 23, 2018
Create Date: April 24, 2018
Recall Status: Open, Classified
Recall Number: Z-1500-2018
Recall Event ID: 79779
510(K) Number: K070078
Product Classification: Surgical Gown - Product Code FYA
Product: T4 Pullover Toga, (SI/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 49002-2704
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: 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 don’t 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 (855)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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=163400