Class 2 Recall Stryker Woundcare Tubing Replacement Sets

See Related Information[23]

Date Posted	July 13, 2015
Recall Status[1]	Open
Recall Number	Z-2062-2015
Recall Event ID	71271[24]
Product Classification	Lavage, Jet[25] - **Product Code** FQH[26]
Product	0210-312-000-Woundcare Replacement kit with soft tip; 0210-318-000; Woundcare Replacement with fan tip; 0210-318-100- Woundcare Replacement Kit; 0210-318-200-Woundcare Replacement with retract coax tip. Accessory to Stryker InterPulse Irrigation System, used for wound debridement, soft tissue debridement, and cleansing of medical, clinical, or surgical sites.
Code Information	0210-312-000: 12138012, 12203012, 12229012, 12256012, 12293012, 12314012, 12338012, 13086012, 13140012, 13192012; 0210-318-000: 14140012,14258012; 0210-318-100: 12294012,13051012; 0210-318-200: 12143012, 12293012, 13066012, 14037012, 14112012
Recalling Firm/ Manufacturer	Stryker Instruments Div. of Stryker Corporation 4100 E Milham Ave Portage, Michigan 49002-9704
For Additional Information Contact	Julie Forsyth 269-323-7700
Manufacturer Reason for Recall	Potential sterility breach in the packaging.
FDA Determined Cause [2]	DESIGN: Packaging Design/Selection
Action	Stryker sent Customer Notification Letters on 05/20/2015 through Certified mail via USPS. Customers are asked to do the following: Immediately review this Recall Notification. Immediately check all stock areas and/or operating room storage and quarantine any affected product found. Complete the enclosed Business Reply Form (BRF) to confirm receipt of this notification and identify how many, if any, affected items are currently in your inventory. Please complete and return the BRF even if you do not have any affected product on hand. If you have further distributed this product, please forward this letter and the attached Business Reply Form (BRF) to all affected locations. Please indicate each location on the BRF. Fax (866-521-2762) or email (julie.forsyth@stryker.com) the completed Business Reply Form to Stryker Instruments Regulatory Department. Upon receipt of the Business Reply Form, if you have recalled product on hand, Stryker will email a pre-paid shipper. This shipper can be used to return the recalled WoundCare Replacement kits to Stryker.
Quantity in Commerce	5,328 each (444 boxes)
Distribution	Nationwide Distribution-including the states of FL, IA, IL, IN, LA, MD, MN, MO, NC, NM, NY, PA, TN, TX, VA, and WI.
Total Product Life Cycle	TPLC Device Report[27]