Class 2 Device Recall Stryker Woundcare Tubing Replacement Sets

Date Posted: July 13, 2015
Recall Status: Open
Recall Number: Z-2062-2015
Recall Event ID: 71271
Product Classification: LavaJet 25 - Product Code FQH 26

Product: 0210-312-000-Woundcare Replacement kit with soft tip, 0210-318-000, Woundcare Replacement with flat tip, 0210-318-100, Woundcare Replacement Kit, 0210-318-200, Woundcare Replacement with retractable tip, Accessory to Stryker InterPulse Irrigation System, used for wound debridement, soft tissue debridement, and cleansing of medical, clinical, or surgical sites.


Recalling Firm/Manufacturer: Stryker Instruments Div. of Stryker Corporation
4100 E Milmah Ave
Portage, Michigan 49002-5704

For Additional Information Contact: Julie Forsyth
269-323-7700

Manufacturer Reason for Recall: Potential sterility breach in the packaging.

FDA Determined Cause: 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 (661-521-2762) 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

8/10/2015