Class 2 Device Recall Stryker Vitallium Wire (6 Pack) Non Sterile

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Recall Date	February 23, 2016
Recall Status[1]	Open
Recall Number	Z-0855-2016
Recall Event ID	73042[23]
510(K)Number	K031127[24]
Product Classification	Staple, fixation, bone[25] - **Product Code** JDR[26]
Product	Stryker Vitallium Wire (6 Pack) Non Sterile. For use in bone procedures.
Code Information	All lots of the following Catalog Numbers: 2704-1-024; 2704-3-018; 6703-1-018; 6703-2-120; 6704-1-018; 6704-2-120 and 6704-3-120.
Recalling Firm/ Manufacturer	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah NJ 07430-2006
For Additional Information Contact	Ms. Aminah Crawford 201-831-5272
Manufacturer Reason for Recall	The wire packages are correctly marked with a "NON-STERILE" label, however, the enclosed Instructions For Use (IFU) states the device are sterilized via gamma irradiation and should not be resterilized. Since the IFU states the devices are sterile, no instructions for moist heat sterilization are provided.
FDA Determined Cause [2]	Under Investigation by firm
Action	Stryker Branches/Agents were notified of the action via email on December 23, 2015. Urgent Medical Device Recall Notification Letters/Urgent Medical Device Recall Notification Acknowledgement Forms dated December 23, 2015 were sent to Branches/Agents via UPS on December 28, 2015. Urgent Medical Device Recall Notification Letters/Urgent Medical Device Recall Notification Acknowledgement Forms dated December 23, 2015 were sent to Hospital Risk Managers and doctors via UPS on 12/23/2015. The notification instructed customers of the related issue with the affected product; how to identify affected product; the potential hazards associated with affected product; risk mitigations; and actions needed to be taken. Customers were asked to complete and return the attached Product Recall Acknowledgement Form within 5 days and either email (strykerOrtho7808@stericycle.com or Fax (1-866-672-0627) the response form back. Customers were instructed to return all affected products to Stryker C/O Stericycle, 2670 Executive Drive, Suite A, Indianapolis, IN 46241 (Attn RA2015-120-Event 7808). A point of contact was provided in case the customer had any questions 201.831.5272 .
Quantity in Commerce	3,741 units