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

Recall Date
February 23, 2016

Recall Status
Open

Recall Number
Z-0855-2016

Recall Event ID
7304223

510(K) Number
K03112724

Product Classification
Staple, fixation, bone25 - Product Code JDR26

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
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 (Alt R2A2015-120-Event 7808). A point of contact was provided in case the customer had any questions 201.831.5272.

Quantity in Commerce
3,741 units

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=142877
3/15/2016