Class 2 Device Recall Stryker Orthopaedics Specialty Triathlon Tibial Alignment Handle with Secondary Lock

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See Related Information[22]

Recall Date	August 11, 2016
Recall Status[1]	Open
Recall Number	Z-2390-2016
Recall Event ID	74619[23]
510(K)Number	K123486[24]
Product Classification	Prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/[25] - **Product Code** MBH[26]
Product	Stryker Orthopaedics Specialty Triathlon Tibial Alignment Handle with Secondary Lock, Non-Sterile, Used to complement or replace the standard instruments used during the implantation of hip, knee, trauma and upper extremities implants
Code Information	Catalog No: I-K3254TA00 Lot Nos: F6E13243, F6L13864, F6M14078, F6S14667, F6S14831, F6W15444, F6W15406, F7C15943, F7H16099 and F7L16994
Recalling Firm/ Manufacturer	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah NJ 07430-2006
For Additional Information Contact	Mr. Michael Van Ryn 201-831-5000
Manufacturer Reason for Recall	It was reported that the secondary locking mechanism, and its corresponding components, disassociated from the Specialty Triathlon Tibial Alignment Handle with Secondary Lock Assembly during surgery. Upon further investigation, it was discovered that the weld, which was intended to hold the secondary locking mechanism together, did not meet the weld size specified on the engineering drawing.
FDA Determined Cause [2]	Process control
Action	Stryker sent an Urgent Product Recall letter dated June 24, 2016, with a Business Reply Form attached to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were asked to inform users of the Urgent Product Recall letter and forward the notice to all those individuals who need to be aware within their organization. Customers were instructed to return all affected product at their location to: Stryker C/O Stericycle 2670 Executive Dr., Suite A Indianapolis, IN 46241 Customers were also instructed to complete and sign the enclosed Business Reply Form and fax it to 888-912-7352 or email to Stericycle at strykerortho4582@stericycle.com. Customers with questions were advised to call (201) 831-6693. For questions regarding this recall call 201-831-5000.
Quantity in Commerce	47 units
Distribution	Nationwide Distribution to FL, IN, LA, NC, PA, TN and UT