Class 2 Device Recall TITANIUM END CAP WITH T40 STARDRIVE RECESS, 0MM EXTENSION FOR TITANIUM Tibial Nail Sex

Date Posted: July 06, 2015
Recall Status: Open
Recall Number: Z-2051-2015
Recall Event ID: 71440
Product Classification: Nail, Fixation, Bone - Product Code JDS
Product: TITANIUM END CAP WITH T40 STARDRIVE RECESS, 0MM EXTENSION FOR TITANIUM Tibial Nail System EX; Synthes Tibial Nail System EX is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre-and post-isthmic fractures; and tibial malunions and non-unions.
Code Information: Part # 04.004.000, lot # 7950994
Recalling Firm/Manufacturer: Synthes, Inc.
1302 Wrights Ln E
West Chester, Pennsylvania 19380-3417
For Additional Information Contact: Customer Support
610-719-5000
Manufacturer Reason for Recall: A specific part and lot number was packaged and shipped prior to the completion of a required internal inspection.
Action: The firm, DePuy Synthes, sent an "URGENT NOTICE: MEDICAL DEVICE RECALL" notification letter, dated June 3, 2015, to direct accounts/customers. The letter described the product, problem and actions to be taken. The customers were instructed to review your inventory and immediately remove the affected lots from your stock; If you DO have any of the identified devices, please take the following steps: ©Call DePuy Synthes at 1-800-479-6329 to obtain a Return Authorization (RA) Complete and Return the Verification Section with the product to ©Credit/Returns, DePuy Synthes, 1101 Synthes Avenue, Monument, CO 80132. ©Send a copy of the completed Verification Section even if you do not have any product to DePuy Synthes by: ©Fax: (610) 430-7083 or ©Scan/email: Fieldaction@synthes.com Number. If you have any questions, please call 610-719-5450 or contact your DePuy Synthes Sales Consultant.
Quantity in Commerce: 3
Distribution: US Distribution to states of: MO and SC.
Total Product Life Cycle: TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 § 803.30

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8/4/2015