Class 2 Recall TITANIUM END CAP WITH T40 STARDRIVE RECESS, 0MM EXTENSION FOR TITANIUM TIBIAL NAILSEX

See Related Information[23]

Date Posted	July 08, 2015
Recall Status[1]	Open
Recall Number	Z-2051-2015
Recall Event ID	71440[24]
Product Classification	Nail, Fixation, Bone[25] - **Product Code** JDS[26]
Product	TITANIUM END CAP WITH T40 STARDRIVE RECESS, 0MM EXTENSION FOR TITANIUM TIBIAL NAILS-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[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]