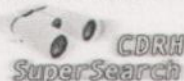


FDA Home³ Medical Devices⁴ Databases⁵
**Class 2 Device Recall TITANIUM END CAP WITH T40 STARDRIVE RECESS, 0MM
 EXTENSION FOR TITANIUM TIBIAL NAILSEX**

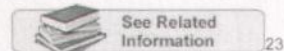


6 510(k) DeNovo⁶ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | HDE¹³ | Classification¹⁴ | Standards¹⁵
 7 | CFR Title 21¹⁶ | Radiation-Emitting Products¹⁷ | X-Ray Assembler¹⁸ | Medsun Reports¹⁹ | CLIA²⁰ | TPLC²¹ | Inspections²²

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



Date Posted	July 08, 2015
Recall Status¹	Open
Recall Number	Z-2051-2015
Recall Event ID	71440²⁴
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 Report²⁷

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁸](#)

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