Class 2 Device Recall 10 mm/135 degree Titanium Cannulated Trochanteric Fixation Nail 170 MM Sterile

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Class 2 Recall
10 mm/135 degree Titanium
Cannulated Trochanteric Fixation
Nail 170 MM Sterile

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Date Posted	November 14, 2014
Recall Status[1]	Open
Recall Number	Z-0219-2015
Recall Event ID	69685[23]
Product Classification	Rod, Fixation, Intramedullary And Accessories[24] - **Product Code** HSB[25]
Product	10 mm/135 degree Titanium Cannulated Trochanteric Fixation Nail 170 MM - Sterile: intended to treat stable and unstable fractures of the proximal femur
Code Information	part number: 456.316S, lot number: 7782247
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	Lot 7782247 of the 10 mm/135 degree Titanium Cannulated Trochanteric Fixation Nail 170 MM (Sterile) was assembled incorrectly. If the non conformance goes undetected, it may impact the locking function post-operatively and compromise the bone reduction and construct stability which may lead to non-union/malunion.
Action	An urgent medical device recall notice, dated October 29, 2014, was sent to end users that identified the product, problem and action to be taken. Customers were instructed to return the device to Synthes along with completing the verification section of the notice.
Quantity in Commerce	6
Distribution	AK, FL, OH, OK, TX
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]

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