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

Date Posted
November 14, 2014

Recall Status
Open

Recall Number
Z-0219-2015

Recall Event ID
6968523

Product Classification
Rod, Fixation, Intramedullary And Accessories24 - Product Code HSB25

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 Report26

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5527

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm