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Class 2 Device Recall Titanium Trochanteric Fixation Nail (TFN)

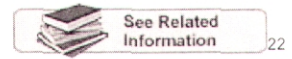


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Class 2 Device Recall Titanium Trochanteric Fixation Nail (TFN)



Date Initiated by Firm	July 21, 2017
Create Date	February 13, 2018
Recall Status ¹	Open ³ , Classified
Recall Number	Z-0604-2018
Recall Event ID	78958 ²³
510(K)Number	K011857 ²⁴
Product Classification	Rod, fixation, intramedullary and accessories ²⁵ - Product Code HSB ²⁶
Product	11MM/130 Degree Titanium Trochanteric Fixation Nail 380MM/Right, Sterile
Code Information	Lot H302839, Expiration Date 31Jan2026
Recalling Firm/Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester PA 19380-5986
Manufacturer Reason for Recall	The locking mechanism and protective cap were missing from the sterile packed nails of the affected lot.
FDA Determined Cause ²	Employee error
Action	The company issued a recall letter on 7/21/2017 asking customers to quarantine affected product and arrange for it to be returned.
Quantity in Commerce	4 units
Distribution	TX, GA, PA, UT and Canada
Total Product Life Cycle	TPLC Device Report ²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated. Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database [510\(K\)s with Product Code = HSB and Original Applicant = SYNTHES \(USA\)](#)²⁹

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1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
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