

FDA Home³ Medical Devices⁴ Databases⁵
Medical Device Recalls
Class 2 Recall
Synthes

[See Related Information](#)

Date Posted	May 29, 2014
Recall Status¹	Open
Recall Number	Z-1669-2014
Recall Event ID	68190
Product Classification	Bit, Surgical - Product Code GFG
Product	Synthes ProDisc-C 2.0mm Milling Bit, Synthes 2.0mm Milling Bit HXC, Synthes 2.0mm Milling Bit with 2.35mm x 33.5mm Shaft, and Synthes 2.0mm Milling Bit with Flat Coupling. Spinal surgical instrument: The Synthes ProDisc-C 2.0mm Milling Bits are used as a part of the milling option for keel preparation of the vertebral bodies. The milling bits are coupled to a power tool and interface with the milling guide, which is connected to a trial implant for the keel preparation step.
Code Information	part number: 03.820.161s, with lot numbers: 5742507,5755970,5755971,5755972, 5755973,5755974,5828298,6336115, 6338099,6338100,6340029,6340030, 6344199,6344200,6363601,6385892, 6407046,6431260,6431261,6460402, 6503360,6526127,6571070,6571073, 6571074,6601985,6636946,6636947, 6636948,6653819,6653820,6670383, 6691341,6691342,6718933,6718934, 6718935,6740611,6794651,6794652, 6794653,6794654,6794655 part number: 03.820.1638 with lot numbers: 5742506,5755978,5755979,5755980, 5755981,5755982,5828299,5828300, 6320586,6336108,6336110,6336111, 6340033,6344201,6344202,6363602, 6385893,6431262,6431263,6460403, 6503361,6571075,6601986,6601987, 6636949,6636950,6636951,6653810, 6653818,6670382,6691343,6691344, 6718938,6740615,6740616,6745821, 6770474,6770475,6770476,6770477, 6770478,6794657,6794658 part number: 03.820.167S with lot numbers: 5755983,5755984,5755987,5755988, 5755989,5755985,5755986,5755990, 5828302,6338101,6338102,6338103, 6338104,6338106,6338107,6338108, 6338109,6344205,6471089,6670381, 6718939,6718940,6718941,6843907, 6843906,6856252,6856253,6867662, 6867661,6901712,6901713,6919726, 6919727,6919728,6901710,6901711, 6921717,6921718,6940357,6960192, 6960193,6983033,7006496,7055427 part number: 03.820.169S with lot numbers: 6066520,6113671,6113633,6159883, 6180175,6338068,6338098,6344206, 6363603,6407047,6431264,6460404, 6526128,6571078,6670384,6745820, 6770479,6770480
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	Certain lots of the ProDisc-C 2.0mm Milling Bits have an increased potential to break during use.
FDA Determined Cause ²	PRODUCTION CONTROLS: Process Control
Action	DePuy Synthes sent a Recall letter, dated April 29, 2014, to affected customers. The letter identified the affected customers, problem and actions to be taken. The letter instructed customers to discontinue use and distribution of the device and to return affected devices to Synthes. For questions call 610-719-5450.
Quantity in Commerce	6690
Distribution	US Nationwide Distribution