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Class 2 Device Recall Fortex Pedicle Screw System



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Class 2 Device Recall Fortex Pedicle Screw System



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Date Initiated by Firm	April 12, 2017
Create Date	April 27, 2017
Recall Status¹	Open ³ , Classified
Recall Number	Z-1884-2017
Recall Event ID	76842 ²³
510(K)Number	K120832 ²⁴
Product Classification	Orthosis, spondylolisthesis spinal fixation ²⁵ - Product Code MNH ²⁶
Product	5.5mm Diameter x 500mm CoCr Straight Rod, Model number X077-0420. The product is packaged in plastic bags with one piece per bag. Product Usage: The 5.5mm dia. X 500 mm CoCr Straight Rod is an accessory to the Fortex Pedicle Screw System. It is a straight rod connected between two or more pedicle screws to create a pedicle screw construct. Indications for Use: The Fortex Pedicle Screw System is indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion. In addition, the system is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).
Code Information	Part number X077-0420, lot number 041218
Recalling Firm/Manufacturer	XTANT MEDICAL INC 664 Cruiser Ln Belgrade MT 59714-9719
Manufacturer Reason for Recall	The material type on the label may incorrectly state Ti6Al-4V ELI. The rods are composed of Cobalt Chromium.
FDA Determined Cause²	Labeling mix-ups
Action	XTANT sent an Urgent Medical Device Removal letter dated 4/12/2017 to customers with a Return Response Acknowledgement and Receipt form. The letter identified the affected product, problem and actions to be taken. For questions call 406-570-7028.
Quantity in Commerce	97 units
Distribution	Worldwide distribution - US Nationwide in the states of: AZ, CA, CT, GA, LA, NV, OH, TX and in the country of Mexico.
Total Product Life Cycle	TPLC Device Report ²⁷