Class 2 Device Recall Synthes 5.0mm Unit Stainless Steel Rods for the Synthes Small Stature USS

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Class 2 Recall Synthes 5.0mm Unit Stainless Steel Rods for the Synthes Small Stature USS

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Date Posted	October 17, 2015
Recall Status[1]	Open
Recall Number	Z-0134-2016
Recall Event ID	72134[24]
Premarket Notification 510(K) Number	K020517[25]
Product Classification	Orthosis, Spinal Pedicle Fixation[26] - **Product Code** MNI[27]
Product	5.0mm Unit Rod 270mm, 5.0mm Unit Rod 290mm, 5.0mm Unit Rod 310mm, 5.0mm Unit Rod 330mm, 5.0mm Unit Rod 350mm, 5.0mm Unit Rod 370mm, 5.0mm Unit Rod 390mm, 5.0mm Unit Rod 410mm, 5.0mm Unit Rod 430mm, 5.0mm Unit Rod 450mm; Orthosis, Spinal, Pedicle fixation Intended to provide immobilization and stabilization of spinal segments in skeletally mature patients.
Code Information	Part numbers: 298.269 298.270 298.271 298.272 298.273 298.274 298.275 298.276 298.277 298.278 lot numbers: 4729951; 4841209; 4923651; 4923652; 4987688; 4987750; 5350635; 2002330; 3000595; 4729952; 4841210; 4923653; 4923654; 4987683; 4856248; 4987755; 5153848; 5153853; 1602596; 1880489; 4729953; 4841211; 4923666; 4923667; 4987778; 4856275; 4987761; 5159826; 5157329; 3016224; 4729954; 4841212; 4919162; 4923669; 4987779; 4856250; 4987766; 5153796; 3093619; 4729956; 4923674; 4987825; 4987780; 5066363; 4729958; 4923615; 4987826; 4987781; 5066364; 4729959; 4841213; 4923655; 4936270; 4987684; 4987771; 5153849; 5153854; 4729960; 4835367; 4923656; 4923657; 4984982; 4856246; 4987772; 5159827; 5157330; 4729961; 4835368; 4923658; 4923659; 4987685; 4856249; 4987773; 1602617; 3080451; 4729962; 4835378; 4919165; 4923660; 4987686; 4856252; 4987776; and 5153851.
Recalling Firm/ Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester, Pennsylvania 19380-5986
For Additional Information Contact	Customer Support 610-719-6500
Manufacturer Reason for Recall	This product was produced using a finishing process not identified as part of the manufacturing specification. The process used with the lots subject to this Recall was a bead blast process. (Bead Blasting vs. Shot Peened).
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	An Urgent Notice: Medical Device Recall, dated September 4, 2015, was sent to end users to alert them about the issue and possible risk to patients. Customers were requested to follow the actions to be taken for if they have affected product or not; complete the response form, and return affected product. Customers can call 610-719-5450 or a local Synthes Sales Consultant with any questions.
Quantity in Commerce	492