Class 2 Device Recall OsteoClage Stainless Steel Bone Plate

Class 2 Recall
OsteoClage Stainless Steel Bone Plate

See Related Information[21]

Date Posted	April 25, 2014
Recall Status[1]	Open
Recall Number	Z-1515-2014
Recall Event ID	67885[22]
Premarket Notification 510(K) Number	K964500[23]
Product Classification	Pin, Fixation, Smooth[24] - **Product Code** HTY[25]
Product	The Osteo-Clage System consists of stainless steel cable/sleeves and compression plates. . 2.0 mm x 850mm SS Cable/Sleeve; Part Number 01-0020-S 2.0 mm SS Sleeve Only; Part Number 01-0022-S 8, 7 hole, SS compression plate; Part Number 02-2007-S 10, 9 hole, SS compression plate; Part Number 02-2009-S Product Usage: The Osteo-Clage Stainless Steel Bone Plate is an implantable straight, rigid stainless steel plate. It is used in conjunction with 4.5mm Cortical bone screws to provide compression across bone fractures. The Osteo-Clage Cerclage Wire Crimp sleeve is used in conjunction with the bone plate in cerclage dixation procedures
Code Information	2.0mm x 80mm SS cable/sleeve: Lot # 222078, 232175, 245032, 254368, 261903, 270659, 284155, 297281. 2.0mm SS sleeve only: Lot # 247553, 267469, 280871, 313261. 8, 7 hole SS compression plate: Lot # 300381. 10, 9 hole SS compression plate: Lot # 299641.
Recalling Firm/ Manufacturer	Acumed LLC 5885 NW Cornelius Pass Rd Hillsboro, Oregon 97124-9432
Manufacturer Reason for Recall	Acumed is voluntarily recalling specific lot numbers of Osteo-Clage Stainless Steel Bone Plates and Tension Band Pins due to the manufacturing of these devices with a grade of stainless steel that is not within specifications.
FDA Determined Cause [2]	COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component
Action	Acumed sent an Urgent Medical Device Recall letter dated March 26, 2014 to all affected customers. The letter identified the affected products, problem and actions to be taken. Customers are instructed to immediately stop using and/or distributing all lots identified in the letter. Return affected products as instructed in the letter. For questions contact Acumed Business Service via email at BusinessService@acumed.net or via phone at 877-627-9957.
Quantity in Commerce	141 units in the US; 294 units outside the US.
Distribution	US Nationwide Distribution - in the states of CA, CO, FL, GA, LA, MI, MN, MO, OH, OR, PA, PR, TX, UT, VA, WA and WY. Product was distributed outside the US to: Australia, China, Figi, France, Great Britain, Italy, Japan, Korea, Maylasia, Sweden, South Africa, Spain.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.