**Class 2 Recall**
**OsteoClage Stainless Steel Bone Plate**

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<th>Date Posted</th>
<th>April 25, 2014</th>
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<td>Recall Status</td>
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<td>Recall Event ID</td>
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<td>Premarket Notification 510(K) Number</td>
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**Product Classification:** Pin, Fixation, Smooth - **Product Code** HTY

**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 00-0222-S 8, 11 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, rigid stainless steel plate. It is used in conjunction with 4.5mm Cortical bone screws to provide compression across bone fractures. The Osteo-Clage Cervical Wire Crimp sleeve is used in conjunction with the bone plate in cervical distraction procedures.

**Code Information**
2.0mm x 80mm SS cable/sleeve: Lot # 220078, 232175, 245032, 254368, 261903, 270659, 284155, 297281, 2.0mm SS sleeve only: Lot # 247553, 267489, 280871, 313281, 8, 11 hole SS compression plate: Lot # 300381, 10, 9 hole SS compression plate: Lot # 299641.

**Recalling Firm/Manufacturer**
Acumed LLC
5965 NW Cornelius Pass Rd
Hillsboro, Oregon 97124-5432

**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**
COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE): Nonconforming Material/Component

**Action**
Acumed sent an Urgent Medical Device Recall letter dated March 29, 2014 to all affected customers. The letter identified the affected products, problems 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 WV. Product was distributed outside the US to: Australia, China, Fiji, France, Great Britain, Italy, Japan, Korea, Maylasia, Sweden, South Africa, Spain.

**Total Product Life Cycle**
TPLC Device Report

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21, §5.27
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.