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Class 2 Device Recall Construx Alum Ankle Clamp

Date Posted: June 09, 2015
Recall Status: Open
Recall Number: Z-1741-2015
Recall Event ID: 7125524
Premarket Notification 510(K) Number: K11137625
Product Classification: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component26 - Product Code KTT27


Code Information: Part 14-450510 Lots:288000, 466170, and 813950
Recalling Firm/Manufacturer: Biomet, Inc.
56 E Bell Dr
Warsaw, Indiana 46582-6989
For Additional Information Contact: Audrey Daenzer
574-372-1570

Manufacturer Reason for Recall: Ankle clamp was assembled incorrectly; the offset of the pin to the pivot point is reversed. This prevents complete range of motion and if pushed too far may loosen the pin from the bone. A revision surgery may be necessary to adequately reconnect the fixator to the bone.

FDA Determined Cause: PRODUCTION CONTROLS: Process Control

Action: Biomet sent an URGENT MEDICAL DEVICE RECALL NOTICE letter dated May 1, 2015 to the affected distributors and implanting surgeons. The recall letter included a description of the reason for the recall, affected product, consignee responsibilities, and distributor instructions for responding to the formal recall notification. Consignees were instructed to return the affected product and continued monitoring of patients. Questions related to this notice should be directed to (574) 372-1570, Monday through Friday, 8 a.m. to 5 p.m.

Quantity in Commerce: 19
Distribution: US Nationwide Distribution in the states of CA, TX, FL, NC, MI, GA.
Total Product Life Cycle: TPLC Device Report26

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 § 5.529
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database: 510(K)s with Product Code = KTT and Original Applicant = EBI, LLC30

6/29/2015