Class 2 Recall Construx Alum Ankle Clamp

See Related Information[23]

Date Posted	June 09, 2015
Recall Status[1]	Open
Recall Number	Z-1741-2015
Recall Event ID	71255[24]
Premarket Notification 510(K) Number	K111376[25]
Product Classification	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component[26] - **Product Code** KTT[27]
Product	Unilateral external fixation ankle clamp Product Usage: Unilateral external fixation for use treatment of bone conditions amenable to treatment by use of external fixation modality
Code Information	Part 14-450510 Lots:268000, 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 [2]	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 Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[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, LLC[30]

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