Class 2 Recall A.L.P.S

See Related Information[23]

Date Posted	July 08, 2015
Recall Status[1]	Open
Recall Number	Z-2046-2015
Recall Event ID	71511[24]
Product Classification	Plate, Fixation, Bone[25] - **Product Code** HRS[26]
Product	A.L.P.S. Foot Locking Calcaneus Plate,Small-Right. Provides the orthopaedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries.
Code Information	Part Number: 816209001; Lots: 015840, 124980, 948210 and P0059, P0076, or P0061 will be etched on the plate itself.
Recalling Firm/ Manufacturer	Biomet, Inc. 56 E Bell Dr Warsaw, Indiana 46582-6989
For Additional Information Contact	Audrey Daenzer 574-267-6639
Manufacturer Reason for Recall	The thread location on one of the thread holes is offset from the axis of the predrill hole. The threads are too deep on one side and too shallow on the other. The locking screw may back out of the plate if it does not achieve proper purchase. This may require a revision surgery to replace or remove the screw and/or plate. The threads, not uniformly loaded, may shear off, causing metal slivers.
Action	On June 4, 2015 an URGENT MEDICAL DEVICE REMOVAL letter was sent to all consignees. This action requires the immediate location and discontinued use of the product and its return to Biomet. The following actions are REQUIRED: Immediately locate and remove the identified device(s) listed below from circulation; Carefully follow the instructions on the enclosed "Response Form"; Email a copy of the Response Form to audrey.daenzer@biomet.com prior to return of product; Use priority carrier for your shipment; and If you have further distributed this product, you MUST notify hospital personnel of this action via the enclosed "Dear Risk/Recall Manager" notice. This letter MUST be given to hospital personnel responsible for receiving recall notices. However, you are charged with the location and return of these products. Please confirm receipt of this notice by sending back the response form within three (3) business days. Thank you in advance for your assistance and prompt attention. On behalf of Biomet, I apologize for any inconvenience this may cause. 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	75 units
Distribution	Distributed in the states of TX, MD, PA, NJ, NC, MA, AZ, GA, FL, and AR. and the countries of Costa Rica CP and The Netherlands.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]