Class 2 Device Recall Continuum Hip Cups

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See Related Information[22]

Date Posted	October 20, 2014
Recall Status[1]	Open
Recall Number	Z-0094-2015
Recall Event ID	69301[23]
Product	Continuum Acetabular System Trabecular Metal Shell with Multi Holes, Porous 68mm, Prosthesis, Hip, Semi-Constrained, Metal/Polymer
Code Information	Part Number: 00-8757-068-02; Lot Number: 62207029
Recalling Firm/ Manufacturer	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
Manufacturer Reason for Recall	The affected products are missing polar boss threads.
Action	Zimmer sent an "URGENT MEDICAL DEVICE RECALL- LOT SPECIFIC" notifications dated October 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Your Responsibilities 1. Review the notification and ensure affected personnel are aware of the contents. 2. If you find any product from the affected lot , quarantine the product and notify your Zimmer sales representative. 3. Your Zimmer sales representative will remove the recalled product from your facility. 4. For patients that previously had this product implanted, it is recommended that you continue your normal post operative follow up routine. 5. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-800-348-2759 between 8:00 am and 5:00pm EST.
Quantity in Commerce	19
Distribution	US Distribution including the states of : IA, CA, NC, AL, WA, FL, TN, MA, AZ, TX, UT, and NV., and Internationally to Japan.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[24]

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