

FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

**Class 2 Device Recall Continuum Hip Cups**

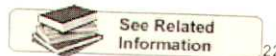


510(k)<sup>7</sup> | DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | Classification<sup>13</sup> | Standards<sup>14</sup>  
 CFR Title | Radiation-Emitting | X-Ray | Medsun | CLIA<sup>19</sup> | TPLC<sup>20</sup> | Inspections<sup>21</sup>  
 21<sup>15</sup> | Products<sup>16</sup> | Assembler<sup>17</sup> | Reports<sup>18</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Recall  
Continuum Hip Cups**



<b>Date Posted</b>	October 20, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-0094-2015
<b>Recall Event ID</b>	<u>69301</u> <sup>23</sup>
<b>Product</b>	Continuum Acetabular System Trabecular Metal Shell with Multi Holes, Porous 68mm, Prosthesis, Hip, Semi-Constrained, Metal/Polymer
<b>Code Information</b>	Part Number: 00-8757-068-02; Lot Number: 62207029
<b>Recalling Firm/ Manufacturer</b>	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
<b>Manufacturer Reason for Recall</b>	The affected products are missing polar boss threads.
<b>Action</b>	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.
<b>Quantity in Commerce</b>	19
<b>Distribution</b>	US Distribution including the states of : IA, CA, NC, AL, WA, FL, TN, MA, AZ, TX, UT, and NV., and Internationally to Japan.

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55](#)<sup>24</sup>

**Links on this page:**

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain>
2. <http://www.addthis.com/bookmark.php>
3. <http://www.fda.gov/default.htm>
4. <http://www.fda.gov/MedicalDevices/default.htm>
5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
7. </scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>
8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>