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**Class 2 Device Recall Persona Trabecular Metal Tibial Plate / Persona TM Tibia**

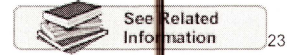


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**Class 2 Recall  
Persona Trabecular Metal Tibial  
Plate / Persona TM Tibia**



<b>Date Posted</b>	March 12, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1266-2015
<b>Recall Event ID</b>	<u>70523</u> <sup>24</sup>
<b>Premarket Notification 510(K) Number</b>	<u>K121771</u> <sup>25</sup>
<b>Product Classification</b>	<u>Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer</u> <sup>26</sup> - <b>Product Code MBH</b> <sup>27</sup>
<b>Product</b>	Persona Trabecular Metal Tibial Plate / Persona TM Tibia-Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer For use in either posterior cruciate retaining or sacrificing surgical procedures.
<b>Code Information</b>	All lots and sizes; Sizes C-J Left and Right.
<b>Recalling Firm/ Manufacturer</b>	Zimmer, Inc. 1800 W Center St Warsaw, Indiana 46580-2304
<b>Manufacturer Reason for Recall</b>	An increase in complaints of loosening and radiolucent lines.
<b>FDA Determined Cause<sup>2</sup></b>	OTHER/UNDETERMINED: Under Investigation by the firm
<b>Action</b>	Zimmer Inc. is initiating a voluntary recall of Persona Trabecular Metal Tibial following an increase in complaints of radiolucent lines and loosening. All sizes and lots of the affected devices are being removed from distribution. Urgent Medical Device Recall notices were issued to affected distributors, hospitals, and surgeons on 2/16/2015 via mail. Customers are asked to review the notification and ensure affected personnel are aware of the contents. All affected product are to be located and quarantined immediately. The Inventory Return Certification Form should be completed and returned along with the recalled product. Customers may contact the following with any questions: 1-877-946-2761 between 8:00 am and 5:00pm EST.
<b>Quantity in Commerce</b>	11,658
<b>Distribution</b>	Worldwide Distribution -- US, including the states of AK, AL, AZ, CA, CO, FL, IL, IN, KS, MA, MI, MN, MO, NC, NJ, NY, OH, OK, PA, TN, TX, UT, VA, WA, and WI; Foreign:Canada, Australia, New Zealand, Korea, Austria, Belgium, Germany, Italy, Luxembourg, Netherlands, South Africa, Sweden, Switzerland, and United Arab Emirates. DOD/VA: HOSPITAL-VA MAINE HLT CR SYTM (402) VA MROC (402) ATTN: PROSTHETICS DEPT TOGUS ME 04330 207-672-9425 HOSPITAL VA MED CTR (438) 2501 W 22 SIOUX FALLS, SD 57105 605-336-8922 HOSPITAL VA MED CTR (509)1 FREEDOM WAY AUGUSTA , GA 30904 706-721-6892 HOSPITAL VA MED CTR (521) 700 S 19TH ST, BIRMINGHAM, AL 35233 378-962-1599 HOSPITAL VA MED CTR (523) 1400 VFW PARKWAY, WEST ROXBURY, MA 02132 617-862-5977 HOSPITAL VA MED CTR (528) 3495 BAILEY AVENUE BUFFALO, NY 14215 716-898-6922 HOSPITAL VA MED CTR (552) 4100 WEST 3RD STREET BLDG #