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**Class 2 Device Recall Zimmer Natural Nail System**

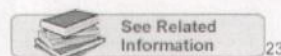


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**Class 2 Recall  
Zimmer Natural Nail System**



<b>Date Posted</b>	July 13, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-2060-2015
<b>Recall Event ID</b>	<a href="#">71530<sup>24</sup></a>
<b>Premarket Notification 510(K) Number</b>	<a href="#">K083497<sup>25</sup></a>
<b>Product Classification</b>	<a href="#">Rod, Fixation, Intramedullary And Accessories<sup>26</sup></a> - <b>Product Code</b> <a href="#">HSB<sup>27</sup></a>
<b>Product</b>	ZNN Antegrade Femoral Nail (ZNN AF). Orthopedic internal fixation device.
<b>Code Information</b>	Part 47-2492-320-10; lot 62763724
<b>Recalling Firm/ Manufacturer</b>	<a href="#">Zimmer, Inc.</a> 1800 W Center St Warsaw, Indiana 46580-2304
<b>For Additional Information Contact</b>	Consumer Relations Call Center 800-447-5633
<b>Manufacturer Reason for Recall</b>	A single distributed ZNN Greater Trochanter Femoral Nail may have been dented. Potential for fatigue of implant prior to sufficient fracture healing, which may result in need for implant removal and revision of fracture fixation to assure proper healing and avoid fracture malunion or nonunion.
<b>FDA Determined Cause<sup>2</sup></b>	PRODUCTION CONTROLS: Process Control
<b>Action</b>	On 6/17/2015, URGENT MEDICAL DEVICE RECALL notifications were sent to the affected distributors and hospital Risk Managers with instructions for returning the affected product. All distributors were notified via electronic mail, and all hospital Risk Managers and distributors with affected inventory were also notified via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. If after reviewing this notification you have further questions or concerns please call the customer call center at 1-877-946-2761. Hours of operation are Monday through Friday, 8 a.m. through 5 p.m. EST.
<b>Quantity in Commerce</b>	8
<b>Distribution</b>	Worldwide distribution. US states of NC and AK; Taiwan, Japan, and Germany.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>28</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>29</sup>](#)

<sup>2</sup> 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 = HSB and Original Applicant = ZIMMER, INC.<sup>30</sup>](#)