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## Class 2 Device Recall Biomet

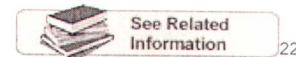


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### Class 2 Device Recall Biomet



<b>Date Initiated by Firm</b>	October 24, 2018
<b>Create Date</b>	December 04, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0553-2019
<b>Recall Event ID</b>	81513 <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K062998</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Prosthesis, hip, semi-constrained, metal/polymer, cemented</a> <sup>25</sup> - <b>Product Code JDI</b> <sup>26</sup>
<b>Product</b>	<p>Biomet 20mm Compress Device Short Anchor Plug With Drill Set / With Pin Inserter Ion Implant Item number: 178562</p> <p>Product Usage: 1. Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement. 2. Tumor resections. 3. Revision of previously failed total joint arthroplasty. 4. Trauma. The Compress<sub>z</sub> Segmental Femoral Replacement System (Short Spindle and Anchor Plug) components are intended for uncemented use only.</p>
<b>Code Information</b>	Lot Number: 608740 UDI Number: (01)00880304461666(17)271113(10)608740
<b>Recalling Firm/Manufacturer</b>	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
<b>For Additional Information Contact</b>	411 Technical Services 574-371-3071
<b>Manufacturer Reason for Recall</b>	Potential metal burrs in the holes of the device preventing the appropriate drill and transverse pins from being inserted
<b>FDA Determined Cause<sup>2</sup></b>	Employee error
<b>Action</b>	Zimmer Biomet initiated recall by letter on 10/24/18 to distributors and hospitals advising of the problem and action to be taken-locate quarantine and return product. Complete Inventory Return Certification Form. Questions or concerns call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday.
<b>Quantity in Commerce</b>	6 units
<b>Distribution</b>	US Nationwide Distribution in the states of IN, DC, MD