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**Class 2 Device Recall Oxford Unicompartmental Knee Phase 3 Shim Size 2**

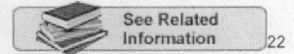


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title 21](#)<sup>16</sup> | [Radiation-Emitting Products](#)<sup>17</sup> | [X-Ray Assembler](#)<sup>18</sup> | [Medsun Reports](#)<sup>19</sup> | [CLIA](#)<sup>20</sup> | [TPLC](#)<sup>21</sup>

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**Class 2 Device Recall Oxford Unicompartmental Knee Phase 3 Shim Size 2**



<b>Date Initiated by Firm</b>	January 05, 2016
<b>Create Date</b>	February 22, 2017
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1169-2017
<b>Recall Event ID</b>	<u>76179</u> <sup>23</sup>
<b>PMA Number</b>	<u>P010014</u> <sup>24</sup>
<b>Product Classification</b>	Orthopedic manual surgical instrument <sup>25</sup> - <b>Product Code LXH</b> <sup>26</sup>
<b>Product</b>	Oxford Unicompartmental Knee Phase 3 Shim Size 2 Product Usage: Instruments for use with the Oxford Uni Partial Knee System
<b>Code Information</b>	Item:32-420664, Lots: ZB160601, ZB160701
<b>Recalling Firm/Manufacturer</b>	Biomet U.K., Ltd. Waterton Industrial Estate Bridgend South Wales United Kingdom
<b>For Additional Information Contact</b>	Kevin Escapule 574-3724487
<b>Manufacturer Reason for Recall</b>	Zimmer Biomet is conducting a medical device field action for various lot-specific Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.
<b>FDA Determined Cause</b> <sup>2</sup>	Nonconforming Material/Component
<b>Action</b>	Zimmer Biomet initiated a voluntary recall of the Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products by mailing letters via FedEx on 01/05/2017. Customers were instructed to Review this notification and ensure affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in their inventory. 3. Complete the Certification of Acknowledgement portion of Attachment 1 Inventory Return Certification Form. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. Immediately return all affected product from your distributorship and affected hospitals within your territory along with a completed Attachment 1 Inventory Return Certification Form and Attachment 2 Certificate of Decontamination to Zimmer Biomet. a. Request a Return Authorization Number via email to rgarequest@zimmerbiomet.com or through FAST/SMS.

Be sure to specify RECALL as the RGA type. b. For each return, send a copy of Attachment 1 and Attachment 3 to [corporatequality.postmarket@zimmerbiomet.com](mailto:corporatequality.postmarket@zimmerbiomet.com). c. Include a hardcopy of Attachment 1 with your shipment for immediate processing. d. Include a hardcopy of Attachment 2 with returned instruments. Mark the outside of the returned boxes clearly with RECALL. 5. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any additional hospitals that may have received or used the affected product. If there are no additional users to notify, please indicate none or NA on the form and return. 6. Retain a copy of your recall acknowledgement and product return forms for your records in the event of a compliance audit of your facility. 7. If after reviewing the recall notice you have further questions or concerns please call the customer call center at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside

<b>Quantity in Commerce</b>	72 units in total
<b>Distribution</b>	Worldwide Distribution in the states of LA, NC, AR, MT, MO, CA, NY, KS, TX, MA, KY, OK, SC, NJ and the countries of Foreign: THAILAND, JAPAN, NETHERLANDS
<b>Total Product Life Cycle</b>	TPLC Device Report <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated a final time when the recall is terminated.

Learn more about [medical device recalls](#)<sup>28</sup>.

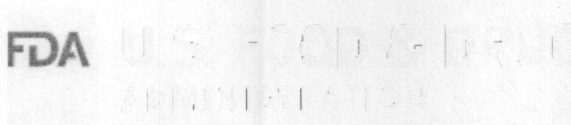
<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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18. </scripts/cdrh/cfdocs/cfAssem/assembler.cfm>
19. </scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>
20. </scripts/cdrh/cfdocs/cfClia/Search.cfm>
21. </scripts/cdrh/cfdocs/cfTPLC/tpic.cfm>
22. <http://www.fda.gov/safety/recalls/enforcementreports/default.htm>
23. [/scripts/cdrh/cfdocs/cfRES/res.cfm?start\\_search=1&event\\_id=76179](/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=76179)
24. </scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P010014>





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**Class 2 Device Recall Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size C**

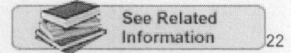


6 510(k)|DeNovo<sup>8</sup> | Registration & | Adverse | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
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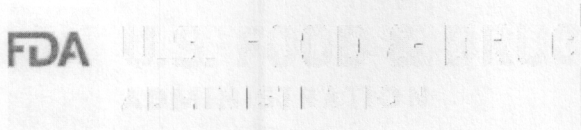
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**Class 2 Device Recall Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size C**



<b>Date Initiated by Firm</b>	January 05, 2016
<b>Create Date</b>	February 22, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1173-2017
<b>Recall Event ID</b>	76179 <sup>23</sup>
<b>PMA Number</b>	P010014 <sup>24</sup>
<b>Product Classification</b>	<u>Prosthesis, knee, femorotibial, unicompartmental, semi-constrained, metal/polymer, mobile bearing<sup>25</sup> - Product Code NRA<sup>26</sup></u>
<b>Product</b>	Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size C Product Usage: Instruments for use with the Oxford Uni Partial Knee System
<b>Code Information</b>	Item:32-420058, Lots: ZB160701
<b>Recalling Firm/Manufacturer</b>	Biomet U.K., Ltd. Waterton Industrial Estate Bridgend South Wales United Kingdom
<b>For Additional Information Contact</b>	Kevin Escapule 574-3724487
<b>Manufacturer Reason for Recall</b>	Zimmer Biomet is conducting a medical device field action for various lot-specific Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	Zimmer Biomet initiated a voluntary recall of the Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products by mailing letters via FedEx on 01/05/2017. Customers were instructed to Review this notification and ensure affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in their inventory. 3. Complete the Certification of Acknowledgement portion of Attachment 1 Inventory Return Certification Form. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. Immediately return all affected product from your distributorship and affected hospitals within your territory along with a completed Attachment 1 Inventory Return Certification Form and Attachment 2 Certificate of Decontamination to Zimmer Biomet. a. Request a Return



FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>  
**Class 2 Device Recall Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size D**

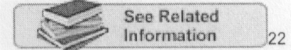


6 510(k)<sup>7</sup>|DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup>|PMA<sup>12</sup>|HDE<sup>13</sup>|Classification<sup>14</sup>|Standards<sup>15</sup>  
 CFR Title 21<sup>16</sup>|Radiation-Emitting Products<sup>17</sup>|X-Ray Assembler<sup>18</sup>|Medsun Reports<sup>19</sup>|CLIA<sup>20</sup>|TPLC<sup>21</sup>

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**Class 2 Device Recall Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size D**



<b>Date Initiated by Firm</b>	January 05, 2016
<b>Create Date</b>	February 22, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1171-2017
<b>Recall Event ID</b>	76179 <sup>23</sup>
<b>PMA Number</b>	<u>P010014</u> <sup>24</sup>
<b>Product Classification</b>	<u>Prosthesis, knee, femorotibial, unicompartmental, semi-constrained, metal/polymer, mobile bearing</u> <sup>25</sup> - <u>Product Code NRA</u> <sup>26</sup>
<b>Product</b>	Oxford Partial Knee System Phase 3 Tibial Template Right Medial Size D  Product Usage: Instruments for use with the Oxford Uni Partial Knee System
<b>Code Information</b>	Item:32-420060, Lots: ZB160701
<b>Recalling Firm/Manufacturer</b>	Biomet U.K., Ltd. Waterton Industrial Estate Bridgend South Wales United Kingdom
<b>For Additional Information Contact</b>	Kevin Escapule 574-3724487
<b>Manufacturer Reason for Recall</b>	Zimmer Biomet is conducting a medical device field action for various lot-specific Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products. Inclusions contained within the finished product could lead to the cracking and separation of the instrument.
<b>FDA Determined Cause<sup>2</sup></b>	Nonconforming Material/Component
<b>Action</b>	Zimmer Biomet initiated a voluntary recall of the Oxford Knee instruments due to potential alumina inclusions in the raw material batch used to produce the affected products by mailing letters via FedEx on 01/05/2017. Customers were instructed to Review this notification and ensure affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in their inventory. 3. Complete the Certification of Acknowledgement portion of Attachment 1 Inventory Return Certification Form. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. Immediately return all affected product from your distributorship and affected hospitals within your territory along with a completed Attachment 1 Inventory Return Certification Form and Attachment 2 Certificate of Decontamination to Zimmer Biomet. a. Request a Return Authorization Number via email to rgarequest@zimmerbiomet.com or through FAST/SMS.