Class 2 Device Recall Biomet

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See Related Information 22

Date Initiated by Firm	April 18, 2019
Create Date	June 06, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1741-2019
Recall Event ID	82818[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	Biomet Oxford Partial Knee Phase 3 / Domed Lateral Femoral Drill Guide: Item Number: 32-421930 System Domed Lateral Femoral Drill Guide Small
Code Information	Lot Numbers: ZB160101 ZB160801 ZB160801
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	Incorrect raw material used by the supplier in the manufacturing of the screw component, which could potentially lead to corrosion.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	Zimmer Biomet issued URGENT MEDICAL DEVICE RECALL notification to distributors and

	hospital risk managers on 4/18/19 via FedEX and email. " Distributors letter identifies the issue and responsibilities include locating and removing the product in their territory, as well as identifying hospitals who have previously used the product. " Distributors will return on-hand product to Zimmer Biomet and ensure all of their products are accounted for using the form provided in the letter. " Hospital risk managers will be provided with a letter identifying the issue and their responsibilities. Complete Certificate of Acknowledgement. questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday.
Quantity in Commerce	15
Distribution	CA, IN, LA, NM, NY, TX, WI Foreign: CANADA, AUSTRALIA, JAPAN, NETHERLANDS
Total Product Life Cycle	TPLC Device Report[26]

[1] 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 for a final time when the recall is terminated. Learn more about medical device recalls[27].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] 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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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82818
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LXH
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm

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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82818
24. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=LXH
26. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=LXH
27. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm