FDA Home Medical Devices Databases

Class 2 Device Recall Biomet

Date Initiated by Firm: April 18, 2019
Create Date: June 06, 2019
Recall Status: Open, Classified
Recall Number: Z-1741-2019
Recall Event ID: 82818

Product Classification: Orthopedic manual surgical instrument - Product Code LXH

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: Nonconforming Material/Component

Action: Zimmer Biomet issued URGENT MEDICAL DEVICE RECALL notification to distributors and

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=172762
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

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.

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.

Links on this page:
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmncfm
8. /scripts/cdrh/cfdocs/cfpmndenovo.cfm

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=172762
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
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12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
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/tplc.cfm
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