Class 2 Device Recall Vanguard XP

Date Initiated by Firm	August 15, 2019
Create Date	September 12, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-2518-2019
Recall Event ID	83594[23]
510(K)Number	K132873[24]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[25] - **Product Code** JWH[26]
Product	XP-XP Tibial Tray - Interlok 83 mm Item # 195759
Code Information	Lot Number 559070 527660 677630 191210 219890 677620 758460 089950 283100 358850 283080 374620 321750 321770 358830 374580 374590 420310
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-371-3071
Manufacturer Reason for Recall	The locking bar not fully engaging
FDA Determined Cause [2]	Manufacturing material removal
Action	Risk Manager Responsibilities: 1.Review this notification and ensure that affected personnel are aware of the contents. 2.If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales 3.Complete Attachment 1 ‼ Certificate of Acknowledgement and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form will be returned even 4.Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility┤s documentation. 5.If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Mo Surgeon Responsibilities: 1.Review this notification for awareness of the contents. 2.There are no specific patient monitoring instructions related to this recall that are recommended beyond your existing follow-up schedule. 3.A visual and audible confirmation should be made to ensure complete locking bar insertion. 4.Complete Attachment 1 ‼ Certificate of Acknowledgement and send to CorporateQuality.PostMarket@zimmerbiomet.com. 5.Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility┤s documentation. 6.If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Mo
Quantity in Commerce	384 units
Distribution	State NY

IN
OH
MI
GA
SC
FL
MO
WI
MN
ND
SD
NE
NJ
PA
MD
IL
IA
CA
VA
NC
DC
WV
AR
AL
MS
AL
MI
WA
OR
ID
LA
FL
KS
TN
MA
KY
OK
TX
TX
CT
AZ
NV
NM
MT
WY
CO
UT
DC
WY

Country:
KOREA
CHINA
CANADA
AUSTRALIA
JAPAN
EMEA
SWEDEN
ITALY

Total Product Life Cycle TPLC Device Report[27]

[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

[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.

510(K) Database 510(K)s with Product Code = JWH and Original Applicant = BIOMET, INC.[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83594
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132873
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JWH
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JWH&knumber=&applicant=BIOMET%2C%20INC%2E

Page Last Updated: 09/16/2019

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive

U.S. Department of Health & Human Services

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. https://www.fda.gov/
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm

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
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=83594
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K132873
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JWH
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JWH&knumber=&applicant=BIOMET%2C%20INC%2E