FDA

Class 2 Device Recall GENDER SOLUTIONS NATURALKNEE FLEX SYSTEM; NEX GEN COMPLETE KNEE SOLUTION CRFLEX GENDER SOLUTIONS

Class 2 Device Recall GENDER SOLUTIONS NATURALKNEE FLEX SYSTEM; NEX GEN COMPLETE KNEE SOLUTION CRFLEX GENDER SOLUTIONS

See Related Information[22]

Date Initiated by Firm	*November 29, 2017*
Create Date	March 14, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-1059-2018
Recall Event ID	78706[23]
510(K)Number	K071107[24] K060370[25]
Product Classification	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer[26] - **Product Code** JWH[27]
Product	CR-FLEX GSF PRECOAT SZ C-L¿ CR-FLEX GSF PRECOAT SZ C-R¿ CR-FLEX GSF PRECOAT SZ D-L¿ CR-FLEX GSF PRECOAT SZ D-R¿ CR-FLEX GSF PRECOAT SZ E-L¿ CR-FLEX GSF PRECOAT SZ E-R¿ CR-FLEX GSF PRECOAT SZ F-L¿ CR-FLEX GSF PRECOAT SZ F-R¿ CR-FLEX GSF PRECOAT SZ G-L¿ CR-FLEX GSK PRECOAT SZ G-R¿ " These devices are indicated for patients with: - Painful and/or disabling knee joints due to osteoarthritis or traumatic arthritis. - Previous tibial condyle or plateau fractures with loss of anatomy or function. - Varus or valgus deformities. - Revision of previous arthroplasty procedures. " These devices are indicated for cemented use only. " The Zimmer Unicompartmental Knee System is designed for use when load bearing ROM is expected to be less than or equal to 155 degrees.
Code Information	5750-016-02 62138093, 00-5750-016-02 62146939, 00-5750-016-02 62154050, 00-5750-016-02 62163077, 00-5750-016-02 62171794, 00-5750-016-06 61843136, 00-5750-016-06 61982989, 00-5750-016-06 62007752, 00-5750-016-06 62094390, 00-5750-016-06 62138249, 00-5750-017-01 61830532, 00-5750-017-01 61870826, 00-5750-017-01 61889195, 00-5750-017-01 11400212, 00-5750-017-01 11400228, 00-5750-017-01 61943192, 00-5750-017-01 61970695, 00-5750-017-01 61977555, 00-5750-017-01 62003098, 00-5750-017-01 62036516, 00-5750-017-01 62075677, 00-5750-017-01 62134276, 00-5750-017-01 62164340, 00-5750-017-01 62172421, 00-5750-017-05 62134278, 00-5750-017-02 61830533, 00-5750-017-02 61870831, 00-5750-017-02 61890024, 00-5750-017-02 61904207, 00-5750-017-02 61906387, 00-5750-017-02 61926131, 00-5750-017-02 61931674, 00-5750-017-02 61958023, 00-5750-017-02 61963893, 00-5750-017-02 61984229, 00-5750-017-02 62003103, 00-5750-017-02 62036517, 00-5750-017-02 62081907, 00-5750-017-02 62091452, 00-5750-017-02 62146658, 00-5750-017-02 62172422, 00-5750-017-06 62134277, 00-5750-017-06 62173183.
Recalling Firm/	Zimmer Biomet, Inc.

Manufacturer	1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	Kevin W. Escapule 574-372-4487
Manufacturer Reason for Recall	The LDPE bag packaging for various highly polished hip and knee implants may adhere to the highly polished surface, leaving residue or material from the LDPE bag on the implant after it is removed from the bag.
FDA Determined Cause [2]	Packaging
Action	A similar recall was initiated in January 2016 to remove remaining inventory packaged in the old bag. Further evaluation identified additional lots packaged in the old bag that were not included in the January 2016 recall; therefore, resulting in this new recall for the additional lots packaged in the old bag. A firm, Zimmer Biomet, sent an "Urgent Medical Device Recall" notices dated November 29, 2017 and response forms to customers. The notice described the product, problem and actions to be taken. The Customers should take the following 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 representative will remove the affected product from your facility. 3. Complete Attachment 1 Certificate of Acknowledgement and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products at your facility. 4. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facilitys documentation. Distributor Responsibilities: 1. Review this notification and ensure that affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in your inventory. 3. Immediately return all affected product from your distributorship and from affected hospitals within your territory. a. Complete Attachment 1 Inventory Return *Certification Form and send to CorporateQuality.PostMarket@zimmerbiomet.com within* three (3) days. b. For each return, send a copy of Attachment 1 to CorporateQuality.PostMarket@zimmerbiomet.com. c. Include a hardcopy of Attachment 1 in each carton of your return shipment for immediate processing. d. Mark RECALL on the outside of the returned cartons. 4. Return the Additi
Quantity in Commerce	13,227 in total
Distribution	Worldwide Distribution: US (nationwide) and countries of: Argentina, Australia, Brazil, Bolivia, Canada, Chile, China, Colombia, Ecuador, El Salvador, India, Japan, Malaysia, Mexico, Netherlands, New Zealand, Nicaragua, Panama, Seoul-Korea, Singapore, Taiwan, Thailand, and UAE.
Total Product Life Cycle	TPLC Device Report[28]

---

[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[29].
[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 = ZIMMER, INC.[30]

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. http://www.fda.gov/default.htm
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=78706
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K071107
25. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K060370
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
27. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=JWH
28. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=JWH
29. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=JWH&knumber=&applicant=ZIMMER%2C%20INC%2E