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

Date Initiated by Firm: November 29, 2017
Create Date: March 14, 2018
Recall Status: Open, Classified
Recall Number: Z-1059-2018
Recall Event ID: 7876923
510(K) Number: K07110724 K05037025
Product Classification: Prosthesis, knee, patelofemorotibial, semi-constrained, cemented, polymer/metal/polymer - Product Code JWH

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 Unicondylar 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 61843139, 00-5750-016-06 6192898, 00-5750-016-06 62007752, 00-5750-016-06 62094390, 00-5750-016-06 62138249, 00-5750-017-01 56603532, 00-5750-017-01 56706262, 00-5750-017-01 61849015, 00-5750-017-01 11400212, 00-5750-017-01 11400228, 00-5750-017-01 61943192, 00-5750-017-01 61976547, 00-5750-017-01 62036518, 00-5750-017-01 62075567, 00-5750-017-01 62023039, 00-5750-017-01 62134726, 00-5750-017-01 62164340, 00-5750-017-01 62172421, 00-5750-017-01 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 62081697, 00-5750-017-02 62091452, 00-5750-017-02 62146658, 00-5750-017-02 62149586 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726, 00-5750-017-02 62134726.

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 facility's 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\(^2\)

\(^1\) 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\(^1\).

\(^2\) 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.\(^3\)

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

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=162418
3/26/2018