Class 2 Device Recall Regenerex Patella

Date Initiated by Firm  
March 22, 2017

Date Posted  
April 25, 2017

Recall Status  
Open

Recall Number  
Z-2068-2017

Recall Event ID  
77062

510(K)Number  
K083782

Product Classification  
Prosthesis, knee, patello/temprotibial, semi-constrained, un cemented, porous, coated, polymer/metal - Product Code MBH

Product  
Regenerex Patella

- RGX 3 PEG SER A PATELLA 28MM
- RGX 3 PEG SER A PATELLA 31MM
- RGX 3 PEG SER A PATELLA 34MM
- RGX 3 PEG SER A PATELLA 37MM

Product Usage:  
The Regenerex Series A Patella can be used for any non-cemented resurfaced 3-peg patella application within the Vanguard Complete Knee System. 1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved. 2. Correction of varus, valgus, or posttraumatic deformity. 3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure.

Code Information  
All lots of Model #: 141355, 141356, 141357, 141358

Recalling Firm/Manufacturer  
Zimmer Biomet, Inc.

Address  
56 E Bell Dr
Warsaw IN 46582-6989

For Additional Information Contact  
411 Technical Services
574-371-3071

Manufacturer Reason for Recall  
pegs shearing post-operatively

FDA Determined Cause  
Under Investigation by firm

Action  
On 3/22/2017 URGENT MEDICAL DEVICE RECALL REMOVAL notifications were sent to the affected consignees via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. Distributors, Sales Representatives, and Distributor Operation Managers Your Responsibilities 1. Review this notification and ensure affected team members are aware of the contents. 2. Immediately locate and quarantine affected product in your inventory. 3. Complete the Certification of Acknowledgement portion of Attachment 1 Inventory Return Certification Form. a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. 4. Immediately return all affected product from your distributorship and affected hospitals within your territory along
with a completed Attachment 1 Inventory Return Certification Form to Zimmer Biomet. a. Request a Return Authorization Number via email to rgarreque@gmail.com or through FAST/SMS. Be sure to specify "RECALL" as the RGA type when requesting. b. For each return, send a copy of Attachment 1 to corporate equality.postmarket@zimmerbiomet.com. c. Include a hardcopy of Attachment 1 with your shipment for immediate processing. d. Mark the outside of the returns box(es) clearly with "RECALL." 5. Note that any hospitals and surgeons that received direct shipments of this product from Zimmer Biomet or were consigned products, will be sent a copy of the Risk Manager and Surgeon Field Action Notice directly. It is important that you review the list of hospitals and surgeons included with the email notification sent to your facility to identify additional accounts. Zimmer Biomet has not notified. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any additional hospitals and/or surgeons that may have

**Quantity in Commerce** 8154

**Distribution** US Nationwide distribution and Canada.

**Total Product Life Cycle** TPLC Device Report

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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 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.

**510(K) Database**

510(K)s with Product Code = MBH and Original Applicant = BIOMET MANUFACTURING CORP.

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**Links on this page:**

4. http://www.fda.gov/MedicalDevices/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/cfCilia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm