FDA

Class 2 Device Recall Zimmer Trabecular Metal(TM) Reverse Shoulder System Instrumentation

See Related Information[22]

Class 2 Device Recall Zimmer Trabecular Metal(TM) Reverse Shoulder System Instrumentation

Date Initiated by Firm	May 22, 2017
Create Date	September 22, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3144-2017
Recall Event ID	77417[23]
510(K)Number	K052906[24]
Product Classification	Prosthesis, shoulder, non-constrained, metal/polymer cemented[25] - **Product Code** KWT[26]
Product	Zimmer Trabecular Metal(TM) Reverse Shoulder System Instrumentation, Drill 2.5 mm Diameter, Item Number/EDI 47430904601, Sterile
Code Information	Lot Numbers: 63399406, 63399407, 63413258, 63418122, 63419454, 63421749, 63471169, 63471170, 63471171, 63474753, 63474754, 63484232, 63501370, 63633540, 63649266 & 63655091.
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	411 Technical Services 574-372-4487
Manufacturer Reason for Recall	A raw material anomaly was discovered during inspection at Zimmer Biomet, and an investigation by the supplier determined that 4 lots of raw material could have similar anomalies. The anomaly has the potential to be on or below the surface and can increase the risk of instrument fracture. Accordingly, all products manufactured with the affected raw material are being removed from the field.
FDA Determined Cause [2]	Process control
Action	On 5/22/2017, Zimmer Biomet distributed Urgent Medical Device Recall notices to their customers and distributors. Customers are advised to review the notice and ensure that affected personnel are aware of the contents. All stock should be inspected and product quarantined. A Zimmer Biomet sales representative will remove the affected product from your facility. Customers should complete and return the Certificate of Acknowledgement via email to: corporatequality.postmarket@zimmerbiomet.com and retain the copy for your files. Customers with questions may call the customer call center at 574-371-3071, Monday through Friday 8 am - 5 pm, EST. *For Distributors Your Responsibilities include the following: 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. For

	each return, send a copy of the completed acknowledgement form via email to: corporatequality.postmarket@zimmerbiomet.com. b. Include a hardcopy of Attachment 1 with your shipment for immediate processing. c. Include a copy of Attachment 3 Certificate of Sterilization with returned instruments. d. Mark the outside of the returns box(es) clearly with FIELD ACTION. 5. Note that any hospitals that received direct shipments of this product from Zimmer Biomet will be sent a copy of the Risk Manager Field Action Notice directly. It is important that you review the list of hospitals included with the email notification sent to your facility to identify additional accounts Zimmer
Quantity in Commerce	2825 units
Distribution	Nationwide in USA; Internationally to: Australia, Brazil, Canada, China, El Salvador, Germany, Guatemala, India, Japan, Panama, Malaysia, Mexico, Netherlands, South Korea, Singapore, Taiwan & Trinidad.
Total Product Life Cycle	TPLC Device Report[27]

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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 it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[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 = KWT and Original Applicant = ZIMMER, INC.[29]

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