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: Open, Classified
Recall Number: Z-3144-2017
Recall Event ID: 7741723
510(K) Number: K06290624

Product Classification: Prosthesis, shoulder, non-constrained, metal/polymer cemented - Product Code KWT20

Product: Zimmer Trabecular Metal(TM) Reverse Shoulder System Instrumentation, Drill 2.5 mm Diameter, Item Number/EDI 47430904601, Sterile


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: 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

<table>
<thead>
<tr>
<th>Quantity in Commerce</th>
<th>2825 units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distribution</td>
<td>Nationwide in USA; Internationally to: Australia, Brazil, Canada, China, El Salvador, Germany, Guatemala, India, Japan, Panama, Malaysia, Mexico, Netherlands, South Korea, Singapore, Taiwan &amp; Trinidad.</td>
</tr>
<tr>
<td>Total Product Life Cycle</td>
<td>TPLC Device Report27</td>
</tr>
</tbody>
</table>

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 recalls28.

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

Links on this page:

4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmnm.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
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20. /scripts/cdrh/cfdocs/cfCiaa/Search.cfm
21. /scripts/cdrh/cfdocs/tplc/tplc.cfm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=77417
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K052906
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=KWT