FDA

See Related Information[22]

Class 2 Device Recall M/DN Intramedullary Fixation Humeral Guide Wire

Date Initiated by Firm	June 05, 2017
Create Date	February 07, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0547-2018
Recall Event ID	78219[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	M/DN Intramedullary Fixation Humeral Guide Wire - Smooth 2.4 mm Diameter 70 cm Length Single Use Only, Item Number 00-2255-025-00 Product Usage: The Ball Tip and Tear Drop Guide Wires are used during the initial reaming of the intramedullary canal. They also assists in guiding the nail during implantation. The guide wire incorporates either a ball or tapered tip to aid in removal of the intramedullary reamer if it becomes lodged or fails.
Code Information	All Lot Numbers , Expiry Date Before April 2022
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 1800 W Center St Warsaw IN 46580-2304
For Additional Information Contact	Customer Service 574-371-3071
Manufacturer Reason for Recall	The design verification for the previous packaging configuration G928 does not cover the 70cm wires. A design verification has been completed to move the 70cm guide wires to a new packaging configuration. As a result, the products packaged in the previous packaging configuration are being removed.
FDA Determined Cause [2]	Package design/selection
Action	On June 5, 2017, Zimmer Biomet distributed Urgent Medical Device Recall notices to their customers via FedEx and email. **Hospital Risk Managers are advised to:** 1. Review this notification and ensure affected team members are aware of the contents. 2. Complete the Certification of Acknowledgement portion of Attachment 1 a. Return a digital copy to corporatequality.postmarket@zimmerbiomet.com within three (3) days. 3. Assist your Zimmer Biomet sales representative quarantine all affected product. **Distributors are advised to:** 1. Review this notification and ensure affected personnel 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. Note that any hospitals that received direct shipments of this product from Zimmer Biomet will be sent a copy of the Risk Manager 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 Biomet has not notified. Using the Additional Accounts Form provided with the email notice sent to your facility, return contact information for any