FDA

Class 2 Device Recall RECON DRILL 6MM X 439MM

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See Related Information[22]

Date Initiated by Firm	May 16, 2018
Date Posted	June 01, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2241-2018
Recall Event ID	80193[23]
510(K)Number	K831005[24]
Product Classification	Pin, fixation, smooth[25] - **Product Code** HTY[26]
Product	RECON DRILL 6MM X 439MM; 14-443023 Intended to be used as a guide pin for insertion of implants (cannulated screws and/or intramedullary nails). Bone nail guidewire. Intended for drilling bone.
Code Information	001360 008170 106320 330040 952200 924770 446470 446480 337720 032750 971520 957780 295550
Recalling Firm/ Manufacturer	Zimmer Biomet, Inc. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	411 Technical Services 574-372-3071
Manufacturer Reason for Recall	The firm is recalling various trauma guide wires due to insufficient packaging design verification and exceeding the expected occurrence rate of complaints for sterile barrier failure. Guide wires packaged in the affected packaging configuration have the potential for sterile barrier breach, leading to possible risk for infection.
FDA Determined Cause [2]	Under Investigation by firm
Action	The firm, Zimmer Biomet, sent an "URGENT MEDICAL DEVICE RECALL" letter dated May 16, 2018 on May 16, 2018, to affected consignees via email and FedEx. The letter describes the product, problem and actions to be taken. Consignees were informed of the recall and instructed to take the following actions: 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. 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. For each return, send a copy of Attachment 1 to CorporateQuality.PostMarket@zimmerbiomet.com b. International returns, please request an IRA by emailing zimmerbiometintlirarequests@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 Additional Accounts form to CorporateQuality.PostMarket@zimmerbiomet.com. a. Review the list of hospitals included with the email notification sent to your facility, which includes a list of hospitals that have already been notified of this recall. b. Identify whether there are any additional hospitals that Zimmer Biomet has not notified and list these accounts on the Additional Accounts form. Please provide the form in Excel format
Quantity in Commerce	248