FDA



## Class 2 Device Recall Juggerknot Long Flex Drill Bit

See Related Information[22]

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|---|---|
| **Date Initiated by Firm** | August 03, 2018 |
| **Create Date** | September 26, 2018 |
| **Recall Status[1]** | Open[3], Classified |
| **Recall Number** | Z-3252-2018 |
| **Recall Event ID** | 80918[23] |
| **510(K)Number** | K110145[24] |
| **Product Classification** | Fastener, fixation, nondegradable, soft tissue[25] - **Product Code** MBI[26] |
| **Product** | Biomet Sports Medii cine Juggerknot Long Flex Drill Bit with Sleeve Nitinol intended to be used for soft tissue to bone fixation with indications for use in: Shoulder, Foot and Ankle, Knee, Hand and Wrist and Hip repair.Stainless Steel, Sterile Item Number: 110016992 |
| **Code Information** | Lot Numbers: 053940, 545740, 067490, 664610, 165770, 676180, 165830, 688250, 415590, 860050 |
| **Recalling Firm/ Manufacturer** | Zimmer Biomet, Inc.<br>56 E Bell Dr<br>Warsaw IN 46582-6989 |
| **For Additional Information Contact** | SAME<br>574-372-1687 |
| **Manufacturer Reason for Recall** | Expiration date incorrectly listed on the label |
| **FDA Determined Cause [2]** | Device Design |
| **Action** | Zimmer notified distributors on 8/3/18 distributors notified via email. Hospital risk managers, as well as distributors with product, notified via Fed'X. The letter identifies the issue and their responsibilities, locating and removing the product in their territory, as well as identifying hospitals who have fielded inventory. Product to be returned to Zimmer Biomet. Question customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday or to :CorporateQuality.PostMarket@zimmerbiomet.com |
| **Quantity in Commerce** | 217 units |
| **Distribution** | AZ CO FL FL GA LA MA MA MO NY SC TX |
| **Total Product Life Cycle** | TPLC Device Report[27] |

[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