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Class 2 Device Recall Juggerknot Long Flex Drill Bit

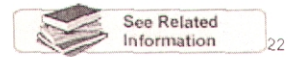


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Class 2 Device Recall Juggerknot Long Flex Drill Bit



Date Initiated by Firm	August 03, 2018
Create Date	September 26, 2018
Recall Status¹	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. 56 E Bell Dr Warsaw IN 46582-6989
For Additional Information Contact	SAME 574-372-1687
Manufacturer Reason for Recall	Expiration date incorrectly listed on the label
FDA Determined Cause²	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