Class 2 Device Recall Cobalt HV Bone Cement with Gentamicin

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See Related Information[22]

Date Initiated by Firm	June 26, 2017
Create Date	November 06, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0067-2018
Recall Event ID	77801[23]
510(K)Number	K051496[24]
Product Classification	Bone cement[25] - **Product Code** LOD[26]
Product	Cobalt HV with Gentamicin, Cobalt Bone Cement 40GM, REF 402283, QTY 1, STERILE, Rx Only, Mfgr: BIOMET ORTHOPEDICS Cobalt MV and HV Bone Cement is indicated for use as bone cement in arthroplastic procedures of the hip, knee and other joints to fix plastic and metal prosthetic parts to living bone when reconstructions is necessary because of osteoarthritis, rheumatoid arthritis, traumatic arthritis, avascular necrosis, nonunion of fractures of the neck of the femur, sickle cell anemia osteoporosis, secondary severe joint destruction following trauma or other conditions (also far fixation of unstable fractures in metastatic malignancies), and revision of previous arthroplasty procedures
Code Information	Lot Numbers: 189690, 189760, 199180, 424740, 508240, 560290, 595660, 638280, 786630, 959650, 959700
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional Information Contact	Neeta Sharma 512-832-9500
Manufacturer Reason for Recall	Loss of the seal on the sterile Tyvek packaging used with this Cobalt Bone Cement.
FDA Determined Cause [2]	Vendor change control
Action	Zimmer Biomet sent an Urgent Medical Device Recall Notice dated April 2017 to all affected customers. The firm initiated their recall to their distributors on 06/26/2017 requesting that they destroy any product on hand. The firm then expanded their recall on 09/14/2017, beginning their notification by email and following with letters to hospitals delivered on 09/21 and 09/22/2017. The firm requested the following actions: "1. Complete the Acknowledgement/Questionnaire provided with this lot specific field safety notice and return to Stericycle by email to DJO5504@stericycle.com or by fax to 866-608-3939. If you have any questions or issues related to sending this information, please call 877-551-7153. 2. Quarantine this affected product. Arrangements will be made to finalize the handling of the product as well as coordinate the replacement product where applicable. 3. If packaging issues are found, please contact DJO Surgical Customer Service to initiate a product complaint." Customers with questions were instructed to call 512-834-6255.