Class 2 Device Recall Synthes Matrix Mandible Short Cut Plate Cutter

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See Related Information [21]

Date Posted	June 11, 2014
Recall Status[1]	Open
Recall Number	Z-1781-2014
Recall Event ID	68111[22]
Product	Synthes Matrix Mandible Short Cut Plate Cutter Synthes Matrix Mandible Short Cut Plate Cutter is intended for oral, maxillofacial surgery.
Code Information	part number: 03.503.057, lot number 8453237
Recalling Firm/ Manufacturer	Synthes, Inc. 1302 Wrights Ln E West Chester, Pennsylvania 19380-3417
For Additional Information Contact	Customer Support 610-719-5000
Manufacturer Reason for Recall	It was discovered internally that the face of the Synthes Matrix Mandible Short Cut Plate Cutter has the potential for discoloration/corroded material in the affected lot.
Action	Synthes Inc. sent an Urgent Medical Device Recall Notice dated April 22, 2014, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. If you DO have any of the identified devices, please take the following steps: Contact DePuy Synthes at 1-800-479-6329 to obtain a Return Authorization (RA) Number . Complete the Verification Section at the end of this letter by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found. Please include your name, title, telephone number and signature in the spaces provided. Return the Verification Section (page 3 of this letter) with the product to: Credit/Returns, DePuy Synthes, 1101 Synthes Avenue, Monument, CO 80132. Return a copy of the Verification Section (page 3 of this letter) to DePuy Synthes by: Fax: 866-324-3731 or Scan/email: Synthes7726@stericycle.com If you DO NOT have the identified product, please take the following steps: Complete the attached Verification Section at the end of this letter by checking the appropriate box indication that no affecteded product has been located. Please include your name, title, telephone number and signature in the spaces provided this return documentation acknowledges your receipt of medical device removal information. Return the Verification Section (page 3 of this letter) to DePuy Synthes by: Fax: 866-324-3731 or Scan/email: Synthes7726@stericycle.com Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on page 3 of the notification. If you have any questions, please call 610-719-5450 or contact your DePuy Synthes sales consultant.
Quantity in Commerce	14
Distribution	US Distribution including the states of CA, CT, FL, GA, NY, SD and TX.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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