Class 2 Device Recall Norian Drillable Injects Sterile

See Related Information [22]

Recall Date	June 09, 2016
Recall Status[1]	Open
Recall Number	Z-1944-2016
Recall Event ID	74172[23]
510(K)Number	K102722[24] K073303[25]
Product Classification	Filler, bone void, calcium compound[26] - **Product Code** MQV[27]
Product	Norian Drillable Inject 10 CC-Sterile; catalog # 07.704.010S Intended for bony voids or defects of the extremities and pelvis that are not instrinsic to the stability of the bony structure.
Code Information	Catalog ID 07.704.003S, 07.704.005S and 07.704.010S Lot Numbers: DSC1679, DSC3869, DSC7712, DSC8448, DSC9141, DSD0256, DSD2012, DSD2506, DSD3236, DSC1747, DSC1748, DSC2468, DSC3590, DSC3874, DSC6847, DSC7713, DSC8449, DSC9067, DSC9142, DSD0257, DSD0919, DSD2013, DSD2380, DSD3237. DSC1676, DSC2469, DSC3591, DSC3879, DSC8441, DSC9143, DSD0055, DSD0466, DSD1956, DSD2381
Recalling Firm/ Manufacturer	Synthes (USA) Products LLC 1301 Goshen Pkwy West Chester PA 19380-5986
For Additional Information Contact	Ann Brisson 610-719-6561
Manufacturer Reason for Recall	DePuy Synthes is initiating a voluntary medical device recall of unexpired and unopened part and lot numbers for the Norian Drillable Injects-Sterile due to the rotary pouch within the referenced lots and associated part numbers may potentially be labeled with the incorrect powder volume/size; however, the rotary pouch contains the correct powder volume/size according to the outer label.
FDA Determined Cause [2]	Under Investigation by firm
Action	DePuy Synthes sent an Urgent Medical Device Recall letter dated May 9, 2016, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers with the affected products were asked to call DePuy Synthes at 1-800-479-6329 to obtain a Return Authorization (RA) Number and replacement product(s), Complete the Verification Section (page 3 of this letter) and Return the Verification Section (page 3 of this letter) with the product to: Credit/Returns, DePuy Synthes, 1101 Synthes Avenue, Monument, CO 80132. Send a copy of the completed Verification Section by:Fax: 855-695-8597 or Scan/email: Synthes6797@stericycle.com. If they had any questions they were asked to call 610-719-5450. For questions regarding this recall call 610-719-5443.
Quantity in Commerce	2098 units
Distribution	Worldwide Distribution - Nationwide to AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD., ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, UT, VA, VT, WA, WI, WV, WY and Internationally to Canada...

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See Related Information [22]

Recall Date	June 09, 2016
Recall Status[1]	Open
Recall Number	Z-1942-2016
Recall Event ID	74172[23]
510(K)Number	K102722[24]
Product Classification	Filler, bone void, calcium compound[25] - **Product Code** MQV[26]
Product	Norian Drillable Inject 3 CC-Sterile; catalog # 07.704.003S Intended for bony voids or defects of the extremities and pelvis that are not instrinsic to the stability of the bony structure.
Code Information	Catalog ID 07.704.003S, 07.704.005S and 07.704.010S Lot Numbers: DSC1679, DSC3869, DSC7712, DSC8448, DSC9141, DSD0256, DSD2012, DSC1747, DSC1748, DSC2468, DSC3590, DSC3874, DSC6847, DSC7713, DSC8449, DSC9067, DSC9142, DSD0257, DSD0919, DSD2013, DSC1676, DSC2469, DSC3591, DSC3879, DSC8441, DSC9143, DSD0055, DSD0466, DSD1956, DSD2381
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Quantity in Commerce	1246 units
Distribution	Worldwide Distribution - Nationwide to AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD., ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, UT, VA, VT, WA, WI, WV, WY and Internationally to Canada...
Total Product Life Cycle	TPLC Device Report[27]

Class 2 Device Recall Norian Drillable Injects Sterile

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Class 2 Device Recall Norian Drillable Injects Sterile

See Related Information[22]

Recall Date	June 09, 2016
Recall Status[1]	Open
Recall Number	Z-1943-2016
Recall Event ID	74172[23]
510(K)Number	K102722[24] K073303[25]
Product Classification	Filler, bone void, calcium compound[26] - **Product Code** MQV[27]
Product	Norian Drillable Inject 5 CC-Sterile; catalog # 07.704.005S Intended for bony voids or defects of the extremities and pelvis that are not instrinsic to the stability of the bony structure.
Code Information	Catalog ID 07.704.003S, 07.704.005S and 07.704.010S Lot Numbers: DSC1679, DSC3869, DSC7712, DSC8448, DSC9141, DSD0256, DSD2012, DSD2506, DSD3236, DSC1747, DSC1748, DSC2468, DSC3590, DSC3874, DSC6847, DSC7713, DSC8449, DSC9067, DSC9142, DSD0257, DSD0919, DSD2013, DSD2380, DSD3237. DSC1676, DSC2469, DSC3591, DSC3879, DSC8441, DSC9143, DSD0055, DSD0466, DSD1956, DSD2381
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Quantity in Commerce	2812 units
Distribution	Worldwide Distribution - Nationwide to AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD., ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, SC, SD, TN, UT, VA, VT, WA, WI, WV, WY and Internationally to Canada...