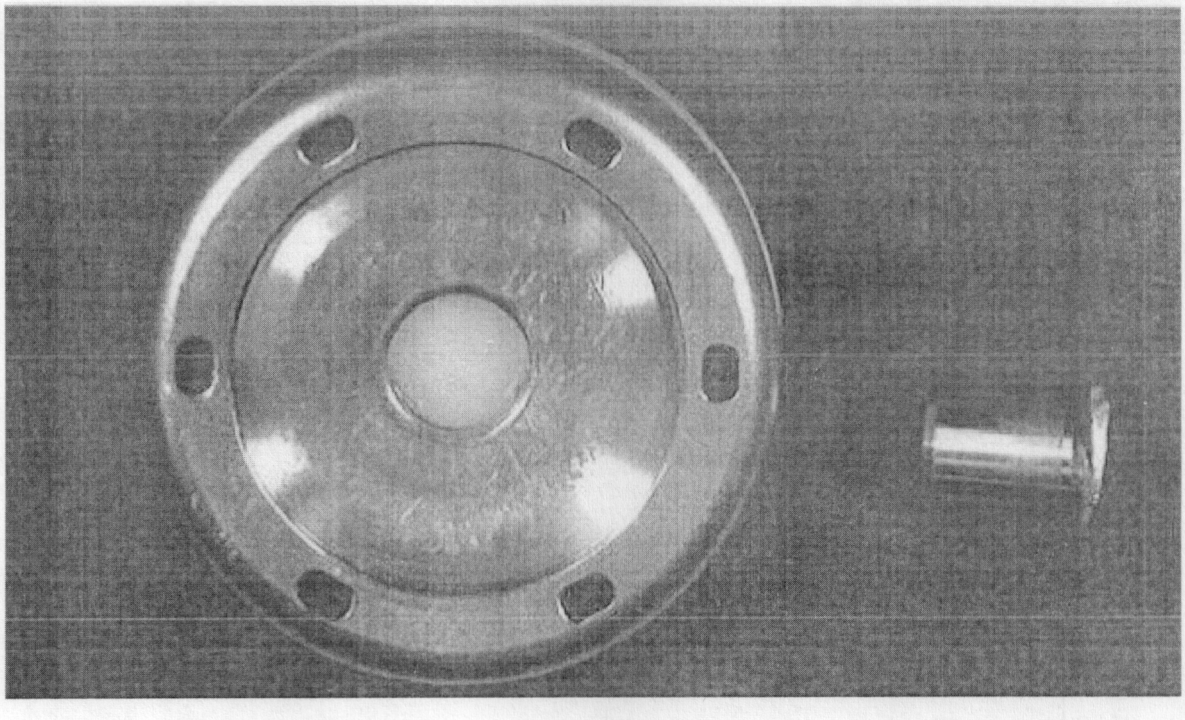
Zimmer Biomet Recalls Comprehensive Reverse Shoulder due to a High Fracture Rate

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Product Description: Comprehensive Reverse Shoulder System Humeral Tray Model 115340
- Trade Name: Biomet Comprehensive Reverse Shoulder Humeral
- Product Code: KWS, PAO
- Lot Numbers: All lots with part number 115340; **See full list of lot numbers**
- Distribution Dates: October, 2008 to September, 2015
- Manufacturing Dates: August 25, 2008 to September 27, 2011
- Devices Recalled: 3662



Device Use

The Comprehensive Reverse Shoulder is a shoulder replacement device that is surgically implanted to help restore arm movement. This device is beneficial for patients with rotator cuff tears who have developed a severe type of shoulder arthritis known as arthropathy and previously failed shoulder joint replacement.

Reason for Recall

Zimmer Biomet is recalling the Comprehensive Reverse Shoulder because these devices are fracturing at a higher rate than is stated in the labeling. Fractures may result in revision surgeries which could cause serious adverse health consequences such as permanent loss of shoulder function, infection, or rarely, death.

Who May be Affected

- Health care providers using this device during reverse shoulder replacement surgeries
- Patients receiving total shoulder replacements using this device

What to Do

On December 20, 2016 Zimmer Biomet sent an Urgent Medical Device Recall Notice and a Certificate of Acknowledgement form to all affected customers. The notice asked customers to:

- Review the safety notice and ensure appropriate staff is aware of the notice.
- Identify and quarantine any affected devices in stock.
- The Zimmer Biomet sales representative will remove the affected device from the facility.
- Complete and return the Certificate of Acknowledgement form within 3 days via email to **corporatequality.postmarket@zimmerbiomet.com (mailto:corporatequality.postmarket@zimmerbiomet.com)**.
- Retain a copy of the Certificate of Acknowledgement form for records in the event of a compliance audit.

The notice also stated that there are no specific patient monitoring instructions related to this recall that are recommended beyond existing surgical follow up protocol.

Contact Information

Health care professionals and consumers with questions are instructed to contact the 411 Technical Services by phone at (574) 371-3071 or by email at **corporatequality.postmarket@zimmerbiomet.com (mailto:corporatequality.postmarket@zimmerbiomet.com)** with any questions related to this recall.

Date Recall Initiated:

December 15, 2016

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm)** either online, by regular mail or by FAX to 1-800-FDA-0178.

Lot Numbers:

041870 041880 041890 052860 060500 070330 079900 085130 118250 118260 118270 118280 118290 118300 118340 118350 118360 118370 118380 118390 132020 132030 153330 153340 153350 153360 153370 153380 153390 153400 153410 153420 153430 159650 159660 161960 172670 215990 216000 216010 256990 257000 257010 257020 278300 278310 278320 278330 278550 278560 278580 278590 300090 300100 300110 300120 300130 300140 300150 310580 310590 310600 310610 310620 329390 349140 349150 351030 351040 367300 367310 367320 367330 367340 367350 367360 367370 367380 372290 372310 372320 385090 402880 411980 413530 415040 415050 415060 415070 415080 415090 420630 424640 424650 424660 424670 424680 424690 424700 424710 424720 424730 424740 436760 436770 440500 457900 492370 492380 492390 492400 492410 492420 492430 492440 492450 501830 551660 556800 556820 557440 557620 557840 558840 558880 558890 558900 558910 558920 561910 562430 563440 568870 569050 569060 569070 569080 569090 569100 569120 569130 569140 569150 569690 578920 595090 597740 607390 607400 607410 607420 607430 609780 613990 630660 633600 634660 634860 635190 637190 637240 641220 641350 641390 641680 648790 648800 648810 648820 648830 648860 659950 659960 659970 659980 659990 660000 660010 660020 660030 660040 668550 668560 668570 668580 668590 668600 668610 668620 668630 668970 674320 677090 677100 677110 677140 677150 677160 677170 677180 677190 677200 680720 680730 680740 680750 680760 697100 697110 697120 697130 697150 697160 697170 697180 697190 697200 704050 704810 706840 712090 715990 716200 723830 723850 723870 723880 725550 725560 725760 726590 726710 734810 745350 762930 764700 765560 765830 765870 767360 767370 771810 788670 788680 788690 791260 791270 791280 818790 839150 846190 846200 846210 846230 846240 846280 846290 846300 846310 846320 846330 848110 848120 848130 848140 848150 848160 848170 848190 848200 848210 848220 848230 848240 848250 848260 848270 848280 848290 848300 848310 848320 854210 854220 854240 854250 854260 854290 854300 854310 854320 863330 889690 908010 950390 950400 963700 974990 981260 981270

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)