

## SUMMARY OF ADVERSE EVENTS TABLE

**PRODUCT CODE: KWA**

Event Sequence	Device Manufacturer	Device 510K Number	Date FDA Received Notification	Unique Report Number	Adverse Event
1	Sulzer Orthopedic, Inc	K993569	5/24/2000	2935620-2000-00012	Disassociation of anti-rotational pin from insert.
2	Sulzer Orthopedic, Inc	K974728	7/5/2000	2935620-2000-00022	Deep infection resulting in explant of device.
3	Sulzer Orthopedic, Inc	K993569	8/17/2000	2935620-2000-00030	Revision due to impingement between femoral stem and acetabular insert.
4	Sulzer Orthopedic, Inc	K993569	12/1/2000	2935620-2000-00062	Pin insert came out after 1.5 years.
5	Sulzer Orthopedic, Inc	K993569	1/5/2001	2935620-2000-00075	Multiple dislocations, patient revised 3 times.
6	Sulzer Orthopedic, Inc	K993569	2/22/2001	2935620-2001-00003	Disassociation of Metasul insert from APRII shell. Patient also experienced two heavy falls previously.
7	Sulzer Orthopedic, Inc	K993569	6/8/2001	2935620-2001-01058	Doctor impacted the insert into the shell but it did not seat. When he pulled the insert out to inspect, the locking pin was missing and located in one of the slots. Resulted in a 30-minute delay in surgery.
8	Sulzer Orthopedic, Inc	K974728	6/13/2001	2935620-2001-01060	Patient complaining of hearing a "pop" and feeling a "pop" and thinks they have dislocated their hip. Physician notified.
9	Sulzer Orthopedic, Inc	K974728	7/6/2001	2935620-2001-01186	Revision of femoral head at 7 weeks.
10	Sulzer Orthopedic, Inc	K993569	7/18/2001	2935620-2001-01162	Metasul insert dislocated after 4 years implantation, significant metallosis. Severe pain.
11	Sulzer Orthopedic, Inc	K993569	9/18/2001	2935620-2001-01531	APR Metasul insert disengaged nine months after surgery.
12	Sulzer Orthopedic, Inc	K993569	12/18/2001	2935620-2001-01765	Disassociation of liner from cup.
13	Sulzer Orthopedic, Inc	K993569	1/7/2002	2935620-2001-01806	Anti-rotational pin dislocated from the insert.

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14	Encore Orthopedics, Inc	K003250	1/9/2002	1644408-2002-00001	Surgery time extended due to failure to properly assemble acetabular liner into shell.
15	Sulzer Orthopedic, Inc	K993569	2/6/2002	2935620-2001-01841	Doctor reported patient with pain, disassociation of liner from shell.
16	Sulzer Orthopedic, Inc	K993569	2/27/2002	2935620-2002-00026	Disassociation of APR Metasul acetabular insert, size 59mm. Patient fell 2001.
17	Sulzer Orthopedic, Inc	K993569	3/19/2002	2935620-2002-00069	APR Metasul acetabular liner disassociation, patient revised in 2002.
18	Sulzer Orthopedic, Inc	K993569	4/12/2002	2935620-2002-00105	Disassociation of APR Metasul insert.
19	Sulzer Orthopedic, Inc	K993569	4/12/2002	2935620-2002-00106	Reported pain and breakage of implant.
20	Sulzer Orthopedic, Inc	K993569	5/1/2002	2935260-2002-00141	Disassociation of insert 2 years 9 months after initial surgery.
21	Sulzer Orthopedic, Inc	K974728	6/26/2002	2935620-2002-00178	Patient was revised due to dislocation of the hip.
22	Biomet Inc.	K011110	11/20/2002	1825034-2002-00129	Eleven total joint and/or revision procedures performed with five of these cases resulting in postoperative infection. Various implant components implanted. Concluded not to be related to implants because similar reports of infections have not been reported from other user facilities for any of the listed manufacturing lots.
23	Centerpulse Orthopedics, Inc	K974728	12/17/2002	2935620-2002-00393	Second revision required because of instability of the hip. First revision was on a recall shell.
24	Biomet, Inc	K011110	1/7/2003	1825035-2003-00001	Following total hip arthroplasty performed in 2002, patient continued to experience hip pain. Patient underwent additional surgery 1 month later, where osteophytes were removed and modular head component was exchanged.
25	DePuy International, LTD	K003523	1/10/2003	1818910-2003-00019	The package was split – inner plastic portion.

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26	DePuy International, LTD	K003523	3/27/2003	1818910-2003-00178	The metal insert was locked into the shell off-axis. Insert could not be removed from acetabular shell.
27	Centerpulse Orthopedics, Inc	K993569	6/25/2003	2935620-2003-00135	Patient felt pain due to dislocation. Patient was revised.
28	Centerpulse Orthopedics, Inc	K993569	7/16/2003	2935620-2003-00143	Dislocation of APR Metasul insert.
29	Centerpulse Orthopedics, Inc	K993569	7/17/2003	2935620-2003-00142	Patient had a dislocation and was revised.
30	Centerpulse Orthopedics, Inc	K974728	10/14/2003	2935620-2003-00246	Delay in surgery.
31	Centerpulse Orthopedics, Inc	K993569	12/16/2003	2935620-2003-00279	Patient was revised.
32	Centerpulse Orthopedics, Inc	K993569	12/23/2003	2935620-2003-00282	Patient was revised in 2003.
33	DePuy Orthopaedics, Inc	K003523	1/16/2004	1818910-2004-00044	Metal insert did not seat properly. Surgery was extended by 30 minutes due to the product problem.
34	DePuy Orthopaedics, Inc	K924492	1/9/2004	1818910-2004-00050	Ring broken, worn liner. Revised liner only to non-constrained.
35	DePuy Orthopaedics, Inc	K924492	2/24/2004	1818910-2004-00147	Revised due to premature polyethylene failure.
36	DePuy Orthopaedics, Inc	K851421	5/4/2004	1818910-2004-00322	Insert was broken around to insert locking pin.
37	DePuy Orthopaedics, Inc	K924492	5/25/2004	1818910-2004-00385	Surgeon claims polyethylene wear started to appear on x-rays 3 years after THA.
38	Zimmer Austin, Inc	K993569	6/24/2004	2935620-2004-00061	It was reported: pt was revised in 2004.
39	Zimmer Austin, Inc	K974728	7/2/2004	2935620-2004-00063	It was reported: pt was revised in 2001.
40	DePuy Orthopaedics, Inc	K003523	7/2/2004	1818910-2004-00417	Pt was revised die to infection. Surgeon wanted to replace liner but could not get it out, causing a 30 minute delay.

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41	Wright Medical Technology, Inc	K021349	7/23/2004	1043534-2004-00118	Pt was in rehab and having a tremendous amount of pain. No trauma was involved. X-ray allegedly revealed that acetabulum had migrated. Revision surgery performed.
42	Wright Medical Technology, Inc	K021349	7/26/2004	1043534-2004-00112	Original surgery in 1994. Allegedly pain and polyethylene wear.
43	Zimmer Austin, Inc	K974728	7/30/2004	2935620-2004-00074	Pt revised in 2002.
44	Biomet, Inc	K993438	8/17/2004	1825034-2004-00071	Pt underwent right THA in 2000. Operative report indicates that loose acetabular components were replaced during revision surgery in 2003.
45	Biomet, Inc	K993438	8/17/2004	1825034-2004-00070	Pt underwent right THA in 2000. Operative report indicates that loose acetabular components were replaced during revision surgery in 2003.
46	Biomet, Inc	K011110	8/20/2004	1825034-2004-00075	It was reported that pt underwent THA in 2000. Due to loosening, revision performed in 2004 to replace acetabular components.
47	Wright Medical Technology, Inc	K021349	8/20/2004	1043534-2004-00117	Investigation is not complete. This is the same event as 1043534-2004-00018. MedWatch 3500a has not been received from user facility.
48	Biomet, Inc	K993438	8/20/2004	1825034-2004-00074	It is reported that pt underwent THA in 2000. Due to loosening, revision performed in 2004 to replace acetabular components
49	Biomet, Inc	K993438	8/20/2004	1825034-2004-00073	It is reported that pt underwent THA in 2000. Due to loosening, revision performed in 2004 to replace acetabular components
50	Zimmer Austin, Inc	K974728	9/27/2004	2935620-2004-00092	Pt was revised in 1999.
51	Zimmer Austin, Inc	K993569	12/17/2004	2935620-2004-00113	Pt was revised in 2004.
52	Zimmer Austin, Inc	K993569	12/17/2004	2935620-2004-00114	Pt was revised in 2004.

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53	Biomet, Inc	K011110	12/21/2004	1825034-2004-00107	Pt underwent THA in 2001. Due to dislocation, closed reduction performed in January 2004. Following multiple dislocations, left revision THA was performed 2 weeks later. Metallosis of the adjacent tissue noted and acetabular components replaced.
54	Biomet, Inc	K011110	01/07/2005	1825034-2005-00002	Patient had persistent groin pain following right THR in 2004. During revision performed about 8 months later, acetabular components were found to be loose and implants were replaced.
55	Biomet, Inc	K011110	01/04/2005	1825034-2005-00009 1825034-2005-00010	It was reported that pt underwent total hip arthroplasty in 2002. Due to multiple dislocations, revision was performed twelve days later. Acetabular components were replaced.
56	DePuy International, Ltd.	K003523	03/14/2005	1818910-2005-00283	Pt was revised due to pain.
57	Biomet, Inc	K993438	03/18/2005	1825034-2005-00019	Pt underwent right total hip arthroplasty in 1998. Onset of right hip pain noted in 2004 and pt underwent revision surgery in 2005. Surgeon noted osteolysis involving the proximal femur and acetabulum.
58	Biomet, Inc	K993438	03/18/2005	1825034-2005-00020	Patient underwent right total hip arthroplasty in 1998. Onset of right hip pain noted in July of 2004 and patient underwent revision surgery in 2005. Surgeon noted osteolysis involving the proximal femur and acetabulum.
59	DePuy-Cork, A Division Of DePuy Orthopaedics, Inc.	K003523	04/15/2005	1818910-2005-00486	Revised due to persistent pain in the right hip without infection or loosening.
60	DePuy Orthopaedics, Inc.	K003523	05/03/2005	1818910-2005-00611	Pt revised due to disassociation of the liner from the shell of the acetabular component. The shell is a competitor's product.
61	DePuy-Cork, A Division Of DePuy Orthopaedics	K003523	05/03/2005	1818910-2005-00610	Pt was revised due to dislocation.

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62	DePuy International, Ltd.	K003523	05/06/2005	1818910-2005-00638	During primary surgery the metal liner was slightly mal-aligned in the cup, the surgeon removed the cup and liner and replaced with another cup and liner before closing the pt. The surgery was delayed 40 minutes.
63	Wright Medical Technology, Inc.	K021349	05/25/2005	1043534-2005-00077 1043534-2005-00078	Original surgery 2004. Low activity. Allegedly patient was complaining of thigh pain with reduced range of motion. Surgeon noticed at time of revision that there were tears in the abductors.
64	Biomet, Inc.	K011110	06/01/2005	1825034-2005-00040 1825034-2005-00041	It was reported that patient underwent total hip arthroplasty in 2004. The patient had multiple effusions accompanied by pain. Following subsidence of the femoral component, patient underwent revision surgery in 2005.
65	DePuy International, Ltd.	K002883	06/28/2005	1818910-2005-00996	Pt was revised due to pain.
66	DePuy International, Ltd.	K003523	07/01/2005	1818910-2005-01031	The pt was revised due to infection.
67	DePuy International, Ltd.	K003523	07/07/2005	1818910-2005-01088	The patient was revised due to an infection.
68	DePuy International, Ltd.	K003523	07/14/2005	1818910-2005-01132	Legal received litigation papers for a patient whose left hip was revised for unspecified reason.
69	Wright Medical Technology, Inc.	K021349	07/22/2005	1043534-2005-00089 1043534-2005-00090	Original surgery 2005. Allegedly revised due to loosening.
70	DePuy International, Ltd.	K003523	08/04/2005	1818910-2005-01322	The pt was revised due to groin pain and possible adverse reaction but explants were in very good condition when removed.

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71	DePuy International, Ltd.	K001523	08/05/2005	1818910-2005-01335 1818910-2005-01334	Legal department received a phone call from pt's family member claiming they are facing a revision surgery due to metal shavings. They had bi-lateral hip surgery January 2001. Further follow-up is being conducted.
72	Biomet, Inc.	K002379	08/22/2005	1825034-2005-00063	Patient underwent total hip arthroplasty in 2003. Revision procedure performed to replace disassociated liner component in 2005.
73	Biomet, Inc.	K011110	08/24/2005	1825034-2005-00066 1825034-2005-00065	Patient underwent total hip arthroplasty in 2003. Subsequently, revision surgery was performed in 2005 to replace acetabular components due to component loosening.
75	DePuy-Cork, Division Of DePuy Orthopaedics	K002883	08/30/2005	1818910-2005-01536	Patient was revised due to infection.
76	DePuy International, Ltd.	K003523	09/27/2005	1818910-2005-01801	The pt was revised due to pain. No loosening in components, metal bearing exchanged for poly liner. Some tissue staining was evident.
77	DePuy International, Ltd.	K001523	09/27/2005	1818910-2005-01698	The pt was revised due to the cup had loosened.
78	DePuy International, Ltd.	K003523	09/30/2005	1818910-2005-01820	Clinical report states pt had surgical intervention due to deep infection.
79	DePuy International, Ltd.	K003523	11/01/2005	1818910-2005-02113	Pt revised due to chronic dislocation.
80	DePuy International, Ltd.	K023786	11/08/2005	1818910-2005-02532	The patient was revised due to dislocation of the left hip. During surgery the rim of the custom constrained liner folded into the cup because hip was tight. The liner was implanted without delay.
81	Biomet, Inc.	K993438	11/29/2005	1825034-2005-00090 1825034-2005-00091	It was reported that pt underwent total hip arthroplasty utilizing metal on metal acetabular components on January 11, 2002. Pt presented with audible squeak without pain. Revision surgery to replace components was performed on October 27, 2005.

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82	Biomet, Inc	K011110	12/14/2005	1825034-2005-00095 1825034-2005-00096	Patient underwent left total hip arthroplasty in 2002. Irrigation and debridement of the wound performed in 2003 due to infection. Treatment included removal of total hip arthroplasty with insertion of an antibiotic cement spacer. Patient was then treated for six weeks with intravenous antibiotics and surgery to replace prosthesis was performed in 2003.
83	Depuy International, Ltd.	K003525	12/21/2005	1818910-2005-02829 1818910-2005-02831	Examination not possible; devices were not returned. No other reported incidents against the provided product and lot codes since its release. Investigation could not verify or identify any evidence of product contribution to the reported event. Based on the investigation, the need for corrective action is not indicated.
84	Depuy Orthopaedics, Inc.	K003523	12/24/05	1818910-2005-02833	Examination was not possible; devices were not returned. Review of the device history records was also not possible as the lot codes required for retrieval were unavailable. The investigation could not verify or identify any evidence of product contribution to the reported event. Based on the investigation, the need for corrective action is not indicated.
85	Depuy Orthopaedics, Inc.	K003523	01/04/06	1818910-2006-00122	Patient was revised due to chronic dislocation, prosthetic instability. Examination was not possible, as the devices were not returned.
86	Wright Medical Technology, Inc.	K021349	01/09/2006	1043534-2006-00006 1043534-2006-00006	Patient revised due to loose acetabular component.

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87	Wright Medical Technology, Inc.	K021349	01/17/2006	1043534-2006-00011	Original Surgery in 2004. Allegedly implant binding and the rom was not smooth; it was catching.
88	Wright Medical Technology, Inc.	K021349	01/30/2006	1043534-2006-00022 1043534-2006-00023	Original Surgery in 2005. Allegedly doctor felt cup was malpositioned and the patient felt a catching sensation when the hip was manipulated.
89	Depuy International, Ltd.	K003523	02/02/06	1818910-2006-00354	The patient was revised due to pain. Examination not possible as devices were not returned.
90	Wright Medical Technology, Inc.	K021349	02/02/06	1043534-2006-00024	Orig. Surg. 05. Allegedly standard conserve shell appeared to have seated, but "spun out" or dislodged from acetabulum on post-op day 2. Patient returned to operating room on 11/25 for exchange of cup to conserve spiked cup. Investigation is not complete.
91	Biomet, Inc.	K011110	02/17/06	1825034-2006-00016	Patient underwent total his arthroplasty in 2002. Patient returned to surgery in 2006. Upon removal, an area of delamination was observed on the acetabular component.
92	Depuy International Ltd.	K003523	03/03/06	1818910-2006-00620	Mom 54 liner was inserted wrong; liner was not flush. Surgeon cut out liner and implanted 56mm liner and cup. Surgery was
93	Depuy International, Ltd.	K003523	03/06/06	1818910-2006-00720	Patient was revised due to recurrent dislocations due to poor cup position.
94	Wright Medical Technology, Inc.	K021349	03/13/2006	1043534-2006-0026	Cup did not seat—revised to spike cup at time of surgery.
95	Biomet, Inc.	K011110	03/14/06	1825034-2006-00022	Patient underwent total his arthroplasty in 2004. Following dislocation, patient returned to surgery on 2/10/06. Wear was observed on the modular head component and patient had osteolysis of the greater trochanter and surrounding bone.
96	Depuy International, Ltd.	K00353	03/17/06	1818910-2006-00730	Failure of Interlock

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1	Wright Medical Technology, Inc.	K004043	11/04/2002	1043534-2002-00085	Product was in about 1 year. Allegedly patient fell and x-rays shows a suggestion of loosening of the femoral and acetabular components. Pain.
2	Wright Medical Technology, Inc.	K004043	11/04/2002	1043534-2002-00086	Product was in about 1 year. Allegedly patient fell and x-rays shows a suggestion of loosening of the femoral and acetabular components. Pain.
3	Wright Medical Technology, Inc.	K004043	05/06/2004	1043534-2004-00027	Orig. Surg. In 2000. Rev. Surg. In 2004. Allegedly the implant broke while driving pt's car causing the femur to shatter. Rec'd products and x-rays in 2004.
4	Wright Medical Technology, Inc.	K004043	05/06/2004	1043534-2004-00028	Orig. Surg. In 2000. Rev. Surg. In 2004. Allegedly the implant broke while driving pt's car causing the femur to shatter. Rec'd products and x-rays in 2004.
5	Wright Medical Technology, Inc.	K004043	07/28/2005	1043534-2005-00094	Orig. Surg. In 2005 for avascular necrosis of the femoral head. Prior to revision, CT scan revealed fracture at 3 of 4 corners of the stem. The pt's age is 80+ yrs. Product was revised in 2005. Stem was revised due to a blow out fracture of the bone.
6	Wright Medical Technology, Inc.	K004043	11/01/2005	1043534-2005-00123	Corrected data: recurrent dislocation. Allegedly neck would not disassociate from stem, requiring removal of stem. Replacement of head. User facility will not release product for investigation w/o pt. Release. Report will be amended when the investigation is complete. Same event as 1043534-2005-00122,00121.

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