

SECTION IX - MEDICAL DEVICE REPORTS MOBILE BEARING KNEES

Inclusive Dates: November 15, 1993 to December 31, 2002

A reasonable effort was made to find all adverse reports made for these devices under the Medical Device Reporting (MDR) regulations. A search of the publicly available MDR reporting information on FDA's MAUDE website yielded 385 reports. The search criteria <LCS, DePuy> produced the most hits (385). Searches were also made under the product code <HRY> producing 286 hits (overlapping), and the PMA number P<830055> producing 261 hits (overlapping).

<LCS, DePuy> produced the most hits and the other search criteria produced hits that were redundant with the <LCS, DePuy> hits. Therefore, the 385 reports found under <LCS, DePuy> were used for this petition.

Summary

The search found a total of 385 Medical Device Reports that contained 365 adverse events from one manufacturer. Three hundred and thirty-three (333) reports were submitted as *injuries*, twenty-nine (29) reports were submitted as *malfunctions*, two (2) were submitted as *other/no answer*, and one (1) report was submitted as a *death*.

LISTING OF MDRs

Prosthesis Type Identity Code

LCS PS (Posterior Stabilized)	LCS FEM (Femoral)
LCS RP (Rotating Platform)	LCS TIB (Tibial)
LCS MB (Meniscal Bearing)	LCS PAT (Patella)
LCS UNK (unknown type)	

All reports involved various designs of the DePuy LCS Knee

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
433657	12/20/02	1	Loosening	Y	LCS RP	Injury
433680	12/10/02	1	Metal/Poly Separation	Y	LCS PAT	Injury
433428	12/19/02	1	Loosening	Y	LCS RP	Injury
431199	12/05/02	1	Pain and Hemarthrosis	Y	LCS PS	Injury
429740	11/27/02	1	Bearing Fracture	Y	LCS MB	Injury
429713	11/27/02	1	Bearing Fracture	Y	LCS MB	Injury
428562	11/21/02	1	Loosening	Y	LCS UNK	Injury
428881	11/19/02	1	Metal/Poly Separation	Y	LCS PAT	Injury
428884	11/19/02	1	Effusion	Y	LCS UNK	Injury
427022	11/13/02	1	Loosening	Y	LCS RP	Injury
426521	11/08/02	1	Pain	Y	LCS TIB	Injury
426391	11/07/02	1	Loosening	Y	LCS RP	Injury
426488	11/07/02	1	Loosening	Y	LCS RP	Injury
426495	11/07/02	1	Loosening	Y	LCS RP	Injury
426370	11/07/02	1	Loosening	Y	LCS RP	Injury
426388	11/07/02	1	Loosening	Y	LCS RP	Injury
425115	10/31/02	1	Incorrect Bearing	Y	LCS RP	Injury
423422	10/23/02	1	Physician Error	Y	LCS FEM	Injury
422394	10/16/02	1	Loosening	Y	LCS FEM	Injury
422395	10/16/02	1	Loosening	Y	LCS RP	Injury
422765	10/16/02	1	Loosening	Y	LCS RP	Injury
421346	10/11/02	1	Bearing Fracture	Y	LCS UNK	Injury
417495	09/19/02	1	Loosening	Y	LCS RP	Injury
417165	09/18/02	1	Impingement and Swelling	Y	LCS PS	Injury
415754	09/11/02	1	Loosening	Y	LCS PS	Injury
415710	09/10/02	1	Pain and Effusion	Y	LCS PS	Injury
415723	09/10/02	1	Unknown	Y	LCS PS	Injury
415715	09/10/02	1	Infection	Y	LCS PAT	Injury
414729	09/06/02	1	Pain and Swelling	Y	LCS UNK	Injury
412852	08/27/02	1	Pain and Swelling	Y	LCS PS	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
410681	08/15/02	1	Patella Spin Out	Y	LCS PAT	Injury
410698	08/16/02	1	Poly Wear	Y	LCS MB	Injury
409029	08/07/02	1	Bearing Fracture	Y	LCS MB	Injury
409026	08/07/02	1	Loosening	Y	LCS RP	Injury
409139	08/07/02	1	Loosening	Y	LCS RP	Injury
406941	07/26/02	1	Patella Spin Out	Y	LCS PAT	Injury
406681	07/25/02	1	Pain and Effusion	Y	LCS PS	Injury
406664	07/24/02	1	Pain and Effusion	Y	LCS PS	Injury
405670	07/19/02	1	Loosening	Y	LCS RP	Injury
405672	07/19/02	1	Loosening	Y	LCS TIB	Injury
405073	07/17/02	1	Swelling	Y	LCS UNK	Injury
405076	07/17/02	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
399885	06/17/02	1	Pain, ROM	Y	LCS PS	Injury
399904	06/17/02	1	Poly Wear	Y	LCS RP	Injury
399931	06/17/02	1	Poly Wear	Y	LCS PAT	Injury
397953	06/05/02	1	Infection	Y	LCS FEM	Injury
395705	05/23/02	1	Pain	Y	LCS PS	Injury
395041	05/21/02	1	Pain	Y	LCS TIB	Injury
395045	05/21/02	1	Pain	Y	LCS MB	Injury
395040	05/21/02	1	Pain	Y	LCS FEM	Injury
394647	05/16/02	1	Bearing Fracture	Y	LCS MB	Injury
394384	05/16/02	1	Unknown	Y	LCS UNK	Injury
394634	05/16/02	1	Bearing Fracture	Y	LCS MB	Injury
394170	05/15/02	1	Unknown	?	LCS PAT	Injury
392021	05/07/02	1	Pain, Effusion	Y	LCS PS	Injury
391760	05/06/02	1	Pain, Effusion	Y	LCS PS	Injury
391761	05/06/02	1	Pain, Effusion	Y	LCS PS	Injury
391766	05/06/02	1	Pain	Y	LCS PS	Injury
389285	04/23/02	1	Impingement	Y	LCS PS	Injury
387205	04/09/02	1	Unknown	Y	LCS RP	Injury
386148	04/04/02	1	Polyethylene Defect	Y	LCS PS	Injury
385150	04/01/02	1	Loosening	Y	LCS RP	Injury
385140	04/01/02	1	Loosening	Y	LCS RP	Injury
384697	03/28/02	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
384217	03/26/02	1	Subluxation	Y	LCS MB	Injury
382490	03/19/02	1	Metal/Poly Separation	Y	LCS PAT	Injury
382480	03/19/02	1	Metal/Poly Separation	Y	LCS PAT	Injury
377181	02/20/02	1	Pain, Effusion	Y	LCS PS	Injury
377195	02/20/02	1	Bearing Failure	Y	LCS RP	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
376788	02/19/20	1	Pain, Loosening	Y	LCS PS	Injury
375239	02/05/02	1	Loosening	Y	LCS RP	Injury
374652	01/31/02	1	Metal/Poly Separation	Y	LCS PAT	Injury
369307	01/03/02	1	Pain, Effusion	Y	LCS PS	Injury
367192	12/20/01	1	Pain, Swelling	Y	LCS PS	Injury
366729	12/20/01	1	Patella Locked	Y	LCS PAT	Injury
365404	12/13/01	1	Pain, Effusion	Y	LCS PS	Injury
364277	12/06/01	1	Pain	Y	LCS PS	Injury
362592	11/28/01	1	Pain, Effusion	Y	LCS PS	Injury
361111	11/20/01	1	Pain, Effusion	Y	LCS PS	Injury
360129	11/16/01	1	Poly Wear	Y	LCS RP	Injury
360140	11/16/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
359522	11/06/01	1	Pain, Swelling	Y	LCS PS	Injury
357261	10/23/01	1	Pain, Effusion	Y	LCS PS	Injury
354890	10/09/01	1	Loosening, Wear	Y	LCS RB	Injury
354338	10/03/01	1	Impingement, Wear	Y	LCS PS	Injury
354328	10/03/01	1	Impingement, Wear	Y	LCS PS	Injury
353595	09/27/01	1	Loosening	Y	LCS FEM	Injury
353602	09/27/01	1	Loosening	Y	LCS PAT	Injury
353170	09/25/01	1	Poly Wear	Y	LCS MB	Injury
351216	09/14/01	1	Poly Wear	Y	LCS MB	Injury
348543	08/23/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
348541	08/23/01	1	Pain, Swelling	Y	LCS PS	Injury
348157	08/21/01	1	Fractured Patella	Y	LCS PAT	Injury
348162	08/21/01	1	Broken Meniscal Bearing	Y	LCS MB	Injury
346794	08/13/01	1	Pain, Swelling	Y	LCS PS	Injury
345670	08/07/01	1	Pain	Y	LCS PS	Injury
345625	08/07/01	1	Loosening, Debris	Y	LCS RP	Injury
344084	07/30/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
346323	07/27/01	1	Pain	Y	LCS PS	Injury
342625	07/19/01	1	Poly Wear	Y	LCS MB	Injury
341467	07/12/01	1	Poly Wear	Y	LCS PAT	Injury
341480	07/12/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
341473	07/12/01	1	Poly Fractured	Y	LCS PAT	Injury
341510	07/12/01	1	Pain, Bleeding	Y	LCS PS	Injury
341527	07/12/01	1	Allergic Reaction	Y	LCS UNK	Injury
341504	07/12/01	1	Allergic Reaction	Y	LCS UNK	Injury
341142	07/11/01	1	Pain	Y	LCS PS	Injury
341135	07/11/01	1	Pain	Y	LCS PS	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
340426	07/06/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
340388	07/06/01	1	Edema	?	LCS PAT	Injury
340412	07/06/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
339110	06/25/01	1	Recurrent Bleeding	Y	LCS PS	Injury
338266	06/21/01	1	Swelling, Effusion	Y	LCS PS	Injury
337679	06/15/01	1	Pain, Hemarthrosis	Y	LCS PS	Injury
336200	06/06/01	1	Pain, Effusion	Y	LCS PS	Injury
336205	06/06/01	1	Defective Poly Insert	Y	LCS PS	Injury
336216	06/06/01	1	Hematoma, Delay Healing	Y	LCS PS	Injury
336211	06/06/01	1	Defective Poly Insert	Y	LCS PS	Injury
335023	05/30/01	1	Wear	Y	LCS RP	Injury
335025	05/30/01	1	Bearing Fractured	Y	LCS MB	Injury
335020	05/30/01	1	Pain, Swelling	Y	LCS PS	Injury
334475	05/24/01	1	Pain	Y	LCS FEM	Injury
334488	05/24/01	1	Pain	Y	LCS RP	Injury
331753	05/11/01	1	Failed Tibia	Y	LCS PS	Injury
331550	05/10/01	1	Pain, Effusion, Impinge.	Y	LCS PS	Injury
331438	05/09/01	1	Pain, Swelling, Bleeding	Y	LCS PS	Injury
330089	05/03/01	1	Poly Wear	Y	LCS RP	Injury
329827	05/02/01	1	Pain, Swelling	?	LCS PS	Injury
328878	04/26/01	1	Pain, Fractured Bearing	Y	LCS MB	Injury
328778	04/25/01	1	Effusion	Y	LCS PS	Injury
328841	04/25/01	1	Poly Wear	Y	LCS PAT	Injury
328813	04/25/01	1	Pain, Effusion	Y	LCS PS	Injury
327605	04/19/01	1	Hemarthrosis	?	LCS PS	Injury
327567	04/19/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
327568	04/19/01	1	Recurrent Hemarthrosis	?	LCS PS	Injury
327574	04/19/01	1	Recurrent Hemarthrosis	?	LCS PS	Injury
327599	04/19/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
327499	04/18/01	1	Bloody Effusions	Y	LCS PS	Injury
327508	04/18/01	1	Bleeding	Y	LCS PS	Injury
327534	04/18/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
327491	04/18/01	1	Pain, Inflammation	Y	LCS PS	Injury
326069	04/11/01	1	Bleeding	Y	LCS PS	Injury
326072	04/11/01	1	Loosening	Y	LCS TIB	Injury
321952	03/23/01	1	Broken Bearing	Y	LCS MB	Injury
320899	03/19/01	1	Bloody Effusion	?	LCS PS	Injury
320903	03/19/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
320744	03/16/01	1	Effusion	?	LCS PS	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
320755	03/16/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
320733	03/16/01	1	Bloody Effusion	?	LCS PS	Injury
320749	03/16/01	1	Effusion	?	LCS PS	Injury
320752	03/16/01	1	Infection	Y	LCS PS	Injury
320727	03/16/01	1	Bloody Effusion	?	LCS PS	Injury
320757	03/16/01	1	Loosening, Hemarthrosis	Y	LCS PS	Injury
320761	03/16/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
318825	03/06/01	1	Effusion	?	LCS PS	Injury
318835	03/06/01	1	Pain	Y	LCS PS	Injury
315328	02/09/01	1	Catastrophic Poly Failure	Y	LCS MB	Injury
314996	02/08/01	1	Pain, Effusion	Y	LCS PS	Injury
313660	01/26/01	1	Poly/Metal Separation	Y	LCS PAT	Injury
313410	01/25/01	1	Pain, Effusion	Y	LCS PS	Injury
313308	01/24/01	1	Pain, Effusion	Y	LCS PS	Injury
312338	01/17/01	1	Pain, Bleeding	Y	LCS PS	Injury
312349	01/17/01	2	Pain, Bilateral Revisions	Y	LCS PS	Injury
312363	01/17/01	1	Pain, Effusion	Y	LCS PS	Injury
312341	01/17/01	1	Broken Post	Y	LCS PS	Injury
312355	01/17/01	2	Pain, Bilateral Revisions	Y	LCS PS	Injury
312364	01/17/01	1	Pain, Effusion	Y	LCS PS	Injury
311755	01/11/01	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
311757	01/11/01	1	Pain, Hemarthrosis	Y	LCS PS	Injury
311644	01/11/01	1	Pain, Effusion	Y	LCS PS	Injury
309247	12/21/00	1	Pain, Hemarthrosis	Y	LCS PS	Injury
309259	12/21/00	1	Pain, Hemarthrosis	Y	LCS PS	Injury
309260	12/21/00	1	Pain, Hemarthrosis	Y	LCS PS	Injury
308357	12/13/00	1	Broken Meniscal Bearing	Y	LCS MB	Injury
308359	12/13/00	1	Swelling, Bleeding	Y	LCS PS	Injury
307347	12/06/00	1	Pain	Y	LCS PS	Injury
307351	12/06/01	1	Pain	Y	LCS PS	Injury
306708	12/01/00	1	Effusion	Y	LCS PS	Injury
304873	11/17/00	1	Pain, Effusion	Y	LCS PS	Injury
304417	11/15/00	1	Pain, Effusion	Y	LCS PS	Injury
299777	10/12/00	2	Pain, Effusion	Y	LCS PS	Injury
299084	10/06/00	1	Pain, Effusion	Y	LCS PS	Injury
298943	10/05/00	1	Pain, Effusion	Y	LCS PS	Injury
398945	10/05/00	1	Pain, Effusion	Y	LCS PS	Injury
297687	09/27/00	1	Pain, Effusion	Y	LCS PS	Injury
297689	09/27/00	1	Pain, Effusion	Y	LCS PS	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
297577	09/26/00	1	Pain, Swelling	Y	LCS PS	Injury
295035	09/12/00	1	Poly/Metal Separation	Y	LCS PAT	Injury
293389	08/30/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
292126	08/25/00	1	Infection	Y	LCS PS	Injury
292129	08/25/00	1	Cause Not Reported	Y	LCS PS	Injury
292124	08/25/00	1	Pain	Y	LCS PS	Injury
290121	08/16/00	1	Effusion	?	LCS PS	Injury
289517	08/14/00	1	Pain, Swelling	Y	LCS PS	Injury
289506	08/14/00	1	Pain	Y	LCS PS	Injury
289509	08/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
290631	08/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
288506	08/07/00	1	Hemarthrosis, Pain	Y	LCS PS	Injury
286990	07/26/00	1	Acute Hematoma	Y	LCS PS	Injury
285440	07/21/00	1	Recurrent Hemarthrosis	?	LCS PS	Injury
785438	07/13/00	1	Pain, Effusion	Y	LCS PS	Injury
287184	07/13/00	1	Bleeding, Impingement	?	LCS PS	Injury
285073	07/11/00	1	Pain, Effusion, Poly Wear	Y	LCS RP	Injury
284498	07/06/00	1	Pain, Effusion	Y	LCS PS	Injury
283984	06/30/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
283944	06/30/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
283486	06/28/00	1	Broken Implant	Y	LCS TIB	Injury
282831	06/23/00	1	Pain, Bloody Effusion	Y	LCS PS	Injury
282829	06/23/00	1	Pain, Bloody Effusion	Y	LCS PS	Injury
282833	06/23/00	1	Pain, Swelling	Y	LCS PS	Injury
282838	06/23/00	1	Pain, Bloody Effusion	Y	LCS PS	Injury
282842	06/23/00	1	Pain, Bloody Effusion	Y	LCS PS	Injury
282846	06/23/00	1	Bearing Wear	Y	LCS RP	Injury
282693	06/22/00	1	Bleeding Patella	Y	LCS PS	Injury
282697	06/22/00	1	Bleeding Patella	Y	LCS PS	Injury
281073	06/09/00	1	Bearing Dislocated	Y	LCS RP	Injury
278666	06/07/00	1	Hemarthrosis	Y	LCS PS	Injury
280833	06/07/00	1	Recurrent Hemarthrosis	?	LCS PS	Injury
280886	06/07/00	1	Pain, Bloody Effusions	?	LCS PS	Injury
279364	05/26/00	1	Pain, Swelling	Y	LCS PS	Injury
279179	05/25/00	1	Patella Avulsion Fracture	Y	LCS PS	Injury
279181	05/25/00	1	Pain, Swelling	Y	LCS PS	Injury
279192	05/25/00	1	Pain, Swelling	Y	LCS PS	Injury
279177	05/25/00	1	Pain, Swelling	Y	LCS PS	Injury
278566	05/22/00	1	Severe Swelling	Y	LCS PS	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
278570	05/22/00	1	Pain	Y	LCS PS	Injury
278275	05/19/00	1	Pain, Bleeding	Y	LCS PS	Injury
278352	05/19/00	1	Poly/Metal Separation	Y	LCS PAT	Injury
276127	05/04/00	1	Bearing Fractured	Y	LCS MB	Injury
275007	04/25/00	1	Poly Wear	Y	LCS RP	Injury
273492	04/14/00	1	Pain	Y	LCS PS	Injury
273488	04/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
273496	04/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
273497	04/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
273475	04/14/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
272465	04/07/00	1	Poly Wear	Y	LCS MB	Injury
271848	04/04/00	1	Stiffness, ROM	Y	LCS PS	Injury
271853	04/04/00	1	Revision to Trim 3mm	Y	LCS PS	Injury
271121	03/28/00	1	Poly Wear	Y	LCS MB	Injury
271118	03/28/00	1	Recurrent Hemarthrosis	Y	LCS PS	Injury
270144	03/21/00	1	Fractured Bearing	Y	LCS MB	Injury
268931	03/14/00	1	Pain, Stiffness	Y	LCS PS	Injury
268941	03/14/00	1	Pain, Bleeding	Y	LCS PS	Injury
267821	03/09/00	1	Bearings Disintegrated	Y	LCS MB	Injury
267618	03/08/00	1	Pain, Swelling	Y	LCS PS	Injury
267620	03/08/00	1	Pain, Effusion	Y	LCS PS	Injury
258650	01/24/00	1	Bearing Fractured	Y	LCS MB	Injury
253149	12/10/99	1	Metallosis	Y	LCS MB	Injury
252689	12/08/99	1	Bearing Failure	Y	LCS MB	Injury
250277	11/18/99	1	Bearing Failure	Y	LCS MB	Injury
248823	11/09/99	1	Bearing Failure	Y	LCS RP	Injury
244559	10/14/99	1	Fractured Patella	Y	LCS PAT	Injury
237131	08/26/99	1	Poly Wear	Y	LCS MB	Injury
234617	08/06/99	1	Bearing Failure	Y	LCS MB	Injury
232683	07/23/99	1	Pain, 1 Bearing Failed	Y	LCS MB	Injury
226047	06/08/99	1	Broken Patella Comp.	Y	LCS PAT	Injury
224141	05/21/99	1	Porocoat Separation	Y	LCS FEM	Injury
223897	05/20/99	1	Poly/Metal Separation	Y	LCS PAT	Injury
221072	04/29/99	1	Bearing Fractured	Y	LCS MB	Injury
220901	04/28/99	1	Bearing Fractured	Y	LCS MB	Injury
219967	04/22/99	1	Poly/Metal Separation	Y	LCS PAT	Injury
213250	03/10/99	1	Bearing Fractured	Y	LCS MB	Injury
212186	03/03/99	1	Bearing Wear	Y	LCS MB	Injury
212188	02/26/99	1	Loosening	Y	LCS RP	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
212167	02/26/99	1	Loosening	Y	LCS FEM	Injury
210283	02/18/99	1	Bearing Fractured	Y	LCS MB	Injury
210280	02/18/99	1	Bearing Fractured	Y	LCS MB	Injury
205525	01/12/99	1	Bearing Fractured	Y	LCS RP	Injury
205361	01/05/99	1	Bearing Fractured	Y	LCS MB	Injury
205331	01/05/99	1	Patella Failed	Y	LCS PAT	Injury
200444	11/30/99	1	Bearing Fractured	Y	LCS MB	Injury
200052	11/30/99	1	Bearing Fractured	Y	LCS MB	Injury
200118	11/30/99	1	Poly Wear	Y	LCS MB	Injury
193205	10/23/99	1	Poly Wear	Y	LCS RP	Injury
193229	10/19/99	1	Bearing Fractured	Y	LCS MB	Injury
193233	10/19/99	1	Bearing Failed	Y	LCS MB	Injury
187714	09/15/98	1	Patella Fractured	Y	LCS PAT	Injury
186446	09/08/98	1	Bearing Fractured	Y	LCS MB	Injury
183447	08/18/98	1	Prosthesis Failed	Y	LCS MB	Injury
178007	07/17/98	1	Bearing Track Bent	Y	LCS TIB	Injury
177835	07/16/98	1	Bearing Track Bent	Y	LCS TIB	Injury
177583	07/13/98	1	Bearing Fractured	Y	LCS MB	Injury
168955	05/20/98	1	Bearings Fractured	Y	LCS MB	Injury
167843	05/15/98	1	Bearings Worn	Y	LCS MB	Injury
167904	05/13/98	1	Poly Fractured	Y	LCS PAT	Injury
164014	04/20/98	1	Bearing Fractured	Y	LCS MB	Injury
160969	03/03/98	1	Bearing Dislocated	Y	LCS RP	Injury
160974	03/30/98	1	Bearing Dislocated	Y	LCS RP	Injury
160358	03/30/98	1	Bearing Dislocated	Y	LCS RP	Injury
160361	03/30/98	1	Bearing Dislocated	Y	LCS RP	Injury
159199	03/23/98	1	Tibial Insert Fractured	Y	LCS PAT	Injury
157729	03/16/98	1	Poly Fractured	Y	LCS RP	Injury
155503	03/09/98	1	Bearing Fractured	Y	LCS MB	Injury
154209	03/03/98	1	Bearing Failed	Y	LCS RP	Injury
151925	02/23/98	1	Poly Crumbled	Y	LCS RP	Injury
150159	02/20/98	1	Poly/Metal Separation	Y	LCS PAT	Injury
145306	01/19/98	1	Unknown	?	LCS MB	Injury
141078	12/30/97	1	Loosening	Y	LCS PAT	Injury
130203	11/03/97	1	Bearing Dislocation	Y	LCS FEM	Injury
124137	09/30/97	1	Implant Broken	Y	LCS PAT	Injury
120992	09/18/97	1	Poly Fractured	Y	LCS PAT	Injury
120990	09/16/97	1	Bearings Failed	Y	LCS MB	Injury
117762	09/03/97	1	Knee Prosthesis Failed	Y	LCS UNK	Injury

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
115196	08/21/97	1	Knee Prosthesis Failed	Y	LCS MB	Injury
103437	07/03/97	1	Patella Prosthesis Broke	Y	LCS PAT	Injury
101419	06/27/97	1	Bearing Fractured	Y	LCS RP	Injury
96918	06/06/97	1	Bearing Fractured	Y	LCS RP	Injury
96937	06/04/97	1	Poly/Metal Separation	Y	LCS PAT	Injury
95431	05/29/97	1	Bearing Wear	Y	LCS MB	Injury
91974	05/15/97	1	Bearing Wear	Y	LCS MB	Injury
89841	05/08/97	1	Bearing Fractured	Y	LCS MB	Injury
89873	05/08/97	1	Bearing Fractured	Y	LCS MB	Injury
82554	04/04/97	1	Bearing Fractured	Y	LCS MB	Injury
72906	02/28/97	1	Poly/Metal Separation	Y	LCS PAT	Injury
72449	02/26/97	1	Bearing Fractured	Y	LCS MB	Injury
74368	02/26/97	1	Bearing Fractured	Y	LCS MB	Injury
49662	11/15/96	1	Bearing Fractured	Y	LCS MB	Injury
46559	11/01/96	1	Bearing Fractured	Y	LCS MB	Injury
44851	10/15/96	1	Bearing Fractured	Y	LCS MB	Injury
43751	10/18/96	1	Poly Fractured	Y	LCS PAT	Injury
43523	10/18/96	1	Bearings Failed	Y	LCS MB	Injury
41527	10/03/96	1	Poly Pitted	?	LCS UNK	Injury
40530	09/27/96	1	Bearing Fractured	Y	LCS UNK	Injury
36671	08/30/96	1	Unknown Revision	Y	LCS TIB	Injury
427999	11/14/02	1	Sterile Pouch was cracked	Y	LCS FEM	Malfun
418182	09/20/02	1	Did not bond with bone	Y	LCS RP	Malfun
413124	08/23/02	1	Bearing Fractured	Y	LCS MB	Malfun
394993	05/16/02	1	Bearing Fractured	Y	LCS MB	Malfun
394982	05/16/02	1	Poly Fractured	Y	LCS PAT	Malfun
393564	05/06/02	1	Pain	Y	LCS PS	Malfun
391520	05/01/02	1	Loosening	Y	LCS TIB	Malfun
391522	05/01/02	1	Loosening	Y	LCS TIB	Malfun
363567	12/01/01	1	Implant Defect	?	LCS PAT	Malfun
363563	12/01/01	1	Implant Defect	Y	LCS PAT	Malfun
359692	11/07/01	1	Poly/Metal Separation	Y	LCS PAT	Malfun
354691	10/05/01	1	Bearing Wear	Y	LCS RP	Malfun
320016	03/09/01	1	Poly/Metal Separation	Y	LCS PAT	Malfun
299248	10/06/00	1	Broken Patella	Y	LCS PAT	Malfun
299488	10/06/00	1	Mislabeled	N	LCS MB	Malfun
298248	09/27/00	1	Device Failed	Y	LCS PAT	Malfun
297331	09/21/00	1	Poly/Metal Separation	Y	LCS PAT	Malfun
296156	09/13/00	1	Poly/Metal Separation	Y	LCS PAT	Malfun

MDR Report Key	Date Reported	No. of Occur.	Event Description	Surg. Rev.	Prosthesis Type	Event Type
292521	08/25/00	1	Poly Wear	Y	LCS RP	Malfun
278083	05/17/00	1	Unknown Revision	Y	LCS PAT	Malfun
275237	04/27/00	1	Pain, Impingement	Y	LCS PS	Malfun
264484	02/24/00	1	Device Fractured	Y	LCS PAT	Malfun
259983	01/24/00	1	Mislabeled	N	LCS PS	Malfun
223563	05/14/99	1	Mislabeled	N	LCS MB	Malfun
203076	12/16/98	1	Mislabeled	Y	LCS MB	Malfun
73438	02/27/97	1	Implant Did Not Fit	N	LCS MB	Malfun
69878	01/08/97	1	Package Short 1 Part	N	LCS MB	Malfun
50529	08/16/96	1	Mislabeled	N	LCS UNK	Malfun
398167	06/04/02	1	Malpositioning	Y	LCS RP	Other
342620	07/19/01	1	Swollen, Bloody	Y	LCS PS	Other
38463	08/14/96	1	Bearing Fractured	Y	LCS UNK	Death?