

Implant Summary Report for:

DePuy

Sigma HP (Uni) Unicondylar

Comprising PRIMARY knees implanted up to: 01 November 2022
NJR Database extract: 31 December 2022

Produced on: 15 February 2023
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This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Sigma HP (Uni) Unicondylar up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the components listed in the appendices.

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NJR Recorded Usage

Implant Usage

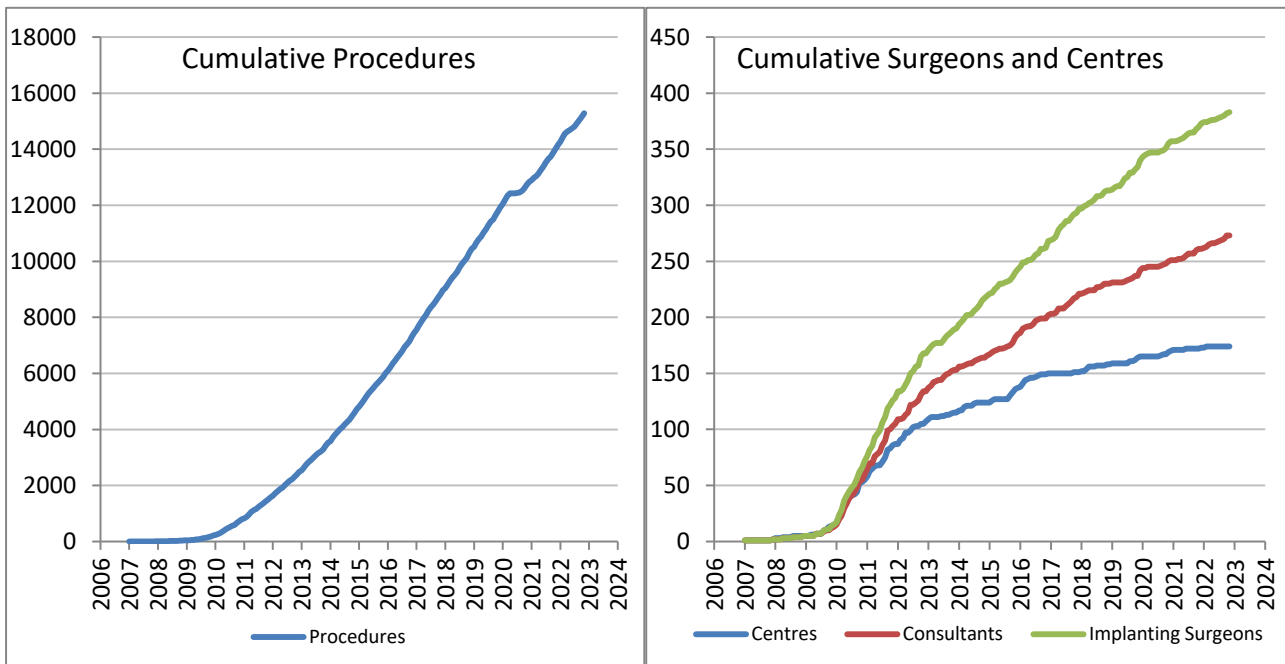
Date of first recorded usage in the NJR: **09 January 2004**

Date of last recorded usage in this dataset: **01 November 2022**

Maximum implantation time: 18.8 years

Mean implantation time: 5.6 years

Totals Recorded in NJR	Cumulative Total
Procedures	15,288
Patients	13,337
Centres	174
Consultants	273
Implanting Surgeons	383



Current Outcome	Year of implantation														Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022			
Death	118	99	91	82	103	72	71	55	38	26	12	3	0	770	5.0%	
Revised	66	67	84	76	78	72	43	46	35	32	6	7	1	613	4.0%	
Unrevised	647	635	737	883	1045	1145	1343	1389	1405	1463	834	1361	1018	13905	91.0%	
Total	831	801	912	1041	1226	1289	1457	1490	1478	1521	852	1371	1019	15288	100%	

Patient / Procedure Details

Patient Details

	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR
Total Procedures	15,288	135,976
Total Patients	13,337	115,996
Demographics		
Mean age	63.9	64.8
< 50	7.4%	5.9%
50 – 59	28.4%	26.6%
60 – 69	35.3%	36.6%
70 – 79	23.8%	24.9%
≥ 80	5.0%	6.1%
Median BMI	29	30
% BMI information available	82.2%	70.0%
Underweight (BMI < 18.5)	0.2%	0.1%
Normal (18.5 ≤ BMI < 25)	11.8%	11.3%
Overweight (25 ≤ BMI < 30)	39.7%	38.2%
Obese I (30 ≤ BMI < 35)	32.1%	32.2%
Obese II (35 ≤ BMI < 40)	12.7%	13.6%
Obese III (BMI ≥ 40)	3.4%	4.6%
% Male	57.5%	53.5%
ASA Grades		
P1 - Fit and healthy	21.5%	19.6%
P2 - Mild disease not incapacitating	71.3%	71.1%
P3 - Incapacitating systemic disease	7.1%	9.3%
P4 / P5	0.1%	0.1%
Indications		
Osteoarthritis	99.09%	98.89%
Rheumatoid Arthritis	0.05%	0.08%
Other Inflammatory Arthropathy	0.05%	0.07%
Previous Trauma	0.39%	0.31%
Avascular Necrosis	0.62%	0.79%
Other	0.25%	0.37%

Total of indications may exceed total number of implants, since more than one indication can be listed per case.

Revision and Survivorship

Reasons for Revision

Reasons for revision of primary procedures in which the implant was used.

Reason for Revision	Revised †	Expected Revisions *	p value
Infection	43	36.89	0.301
Progressive Arthritis Remaining	244	255.08	0.495
Aseptic Loosening Femur	78	75.40	0.723
Aseptic Loosening Tibia	128	112.21	0.13
Aseptic Loosening Patella	5	3.46	0.392
Unexplained Pain	81	103.61	0.022
Stiffness	12	9.90	0.508
Malalignment	31	36.36	0.389
Instability	49	59.76	0.159
Dislocation / Subluxation	6	59.11	<0.001
Periprosthetic Fracture	18	23.39	0.278
Wear of Polyethylene Component	22	40.04	0.002
Lysis - Tibia	18	18.69	1
Lysis - Femur	11	8.52	0.374
Component Dissociation	7	27.09	<0.001
Implant Fracture	1	3.79	0.184
Other / Not recorded	45	55.44	0.166
Total Revised	613	715.95	<0.001

† multiple reasons may be listed for one revision procedure

* Based on All NJR Unicondylar knees, adjusted for agegroup, gender, indications and implantation year

Significantly better, p < 0.001

Significantly better, p < 0.05

Significantly worse p < 0.05

Significantly worse p < 0.001

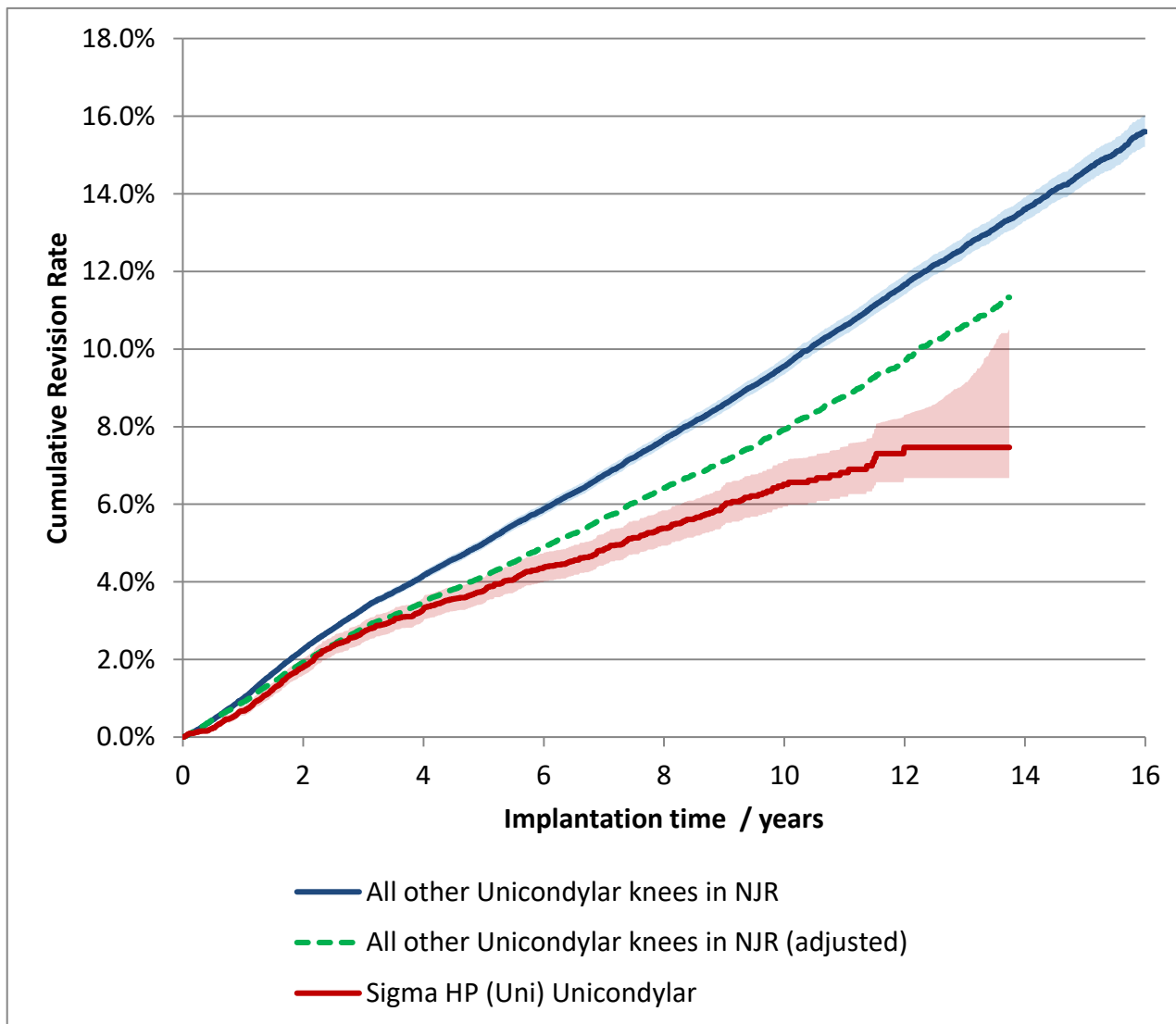


Components Revised	Number of procedures	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR
Femoral and/or Tibial Revision	586	95.6%	91.3%
Isolated bearing exchange	25	4.1%	8.4%
Patella revision / resurfacing only	0	0.0%	0.2%
No component revision recorded	2	0.3%	0.2%

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision



Cox Proportional Hazards model for revision risk ratio of Sigma HP (Uni) Unicondylar / All other Unicondylar knees in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted.	0.70 ‡ (0.64 - 0.76)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	0.84 (0.77 - 0.91)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	At Risk	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR
0	15288	-	-
1	13871	0.7% (0.6% - 0.8%)	1.0% (0.9% - 1.1%)
2	12385	1.8% (1.6% - 2.0%)	2.3% (2.2% - 2.3%)
3	11284	2.7% (2.4% - 3.0%)	3.3% (3.2% - 3.4%)
4	9706	3.3% (3.0% - 3.6%)	4.2% (4.1% - 4.3%)
5	8174	3.8% (3.4% - 4.1%)	5.0% (4.9% - 5.1%)
6	6633	4.4% (4.0% - 4.8%)	5.9% (5.7% - 6.0%)
7	5195	4.8% (4.4% - 5.3%)	6.8% (6.6% - 6.9%)
8	3962	5.4% (4.9% - 5.8%)	7.7% (7.5% - 7.9%)
9	2889	6.0% (5.5% - 6.5%)	8.6% (8.4% - 8.8%)
10	1958	6.5% (5.9% - 7.1%)	9.6% (9.3% - 9.8%)
11	1217	6.8% (6.2% - 7.5%)	10.6% (10.4% - 10.8%)
12	574	7.5% (6.7% - 8.3%)	11.7% (11.4% - 11.9%)
13	142	7.5% (6.7% - 9.1%)	12.6% (12.4% - 12.9%)
14		(-)	13.6% (13.3% - 13.9%)
15		(-)	14.6% (14.2% - 14.9%)

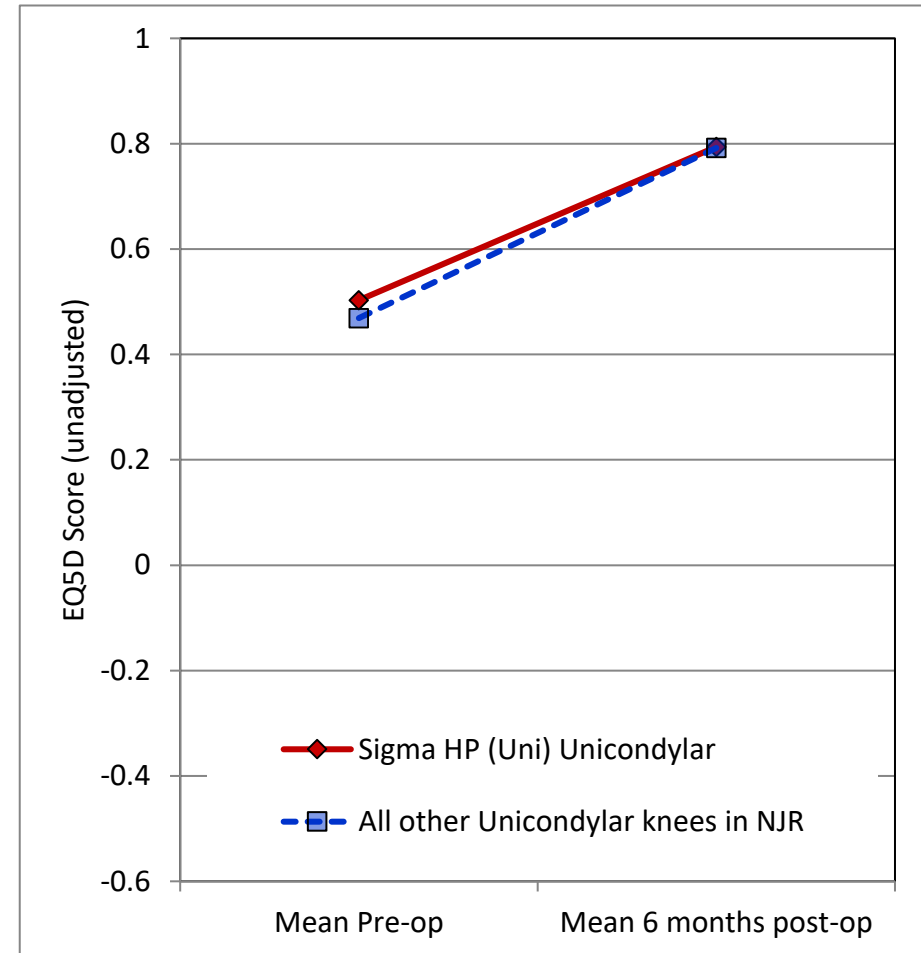
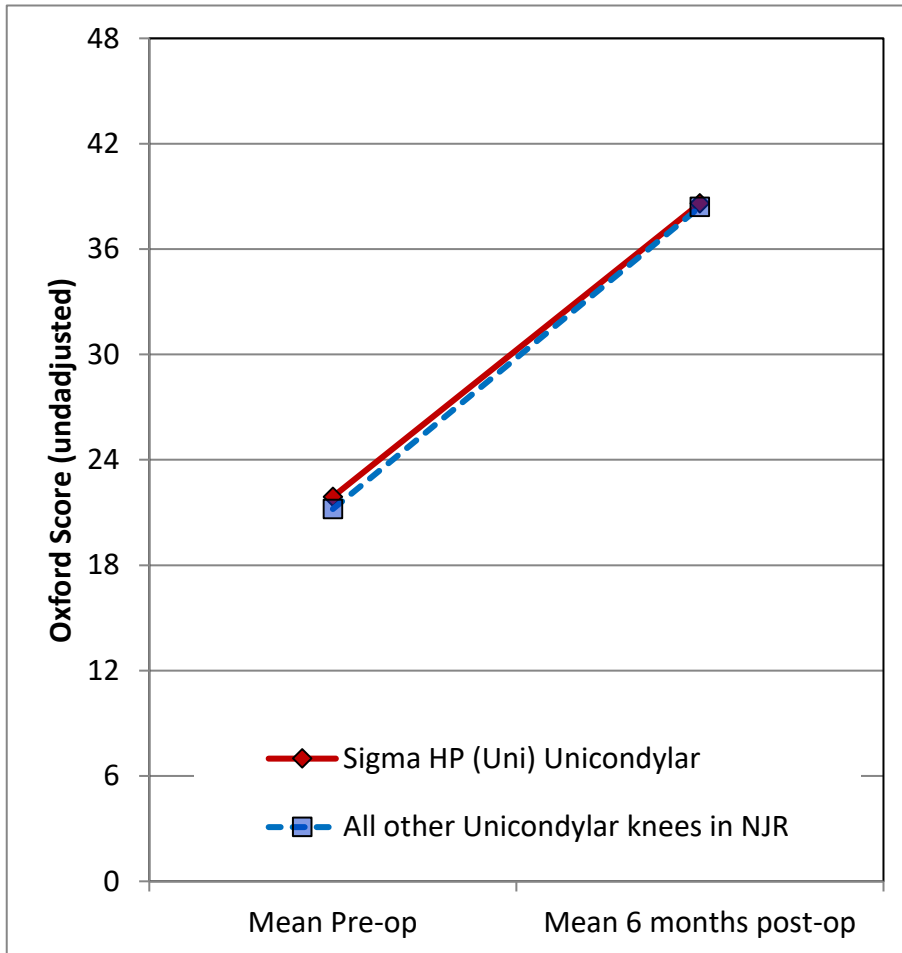
Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

PROMs Analysis

Patient Reported Outcomes

Comprising PROMs data up to and including: 31/12/2020



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2020

Oxford Knee Score (0 - 48)	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR	All Knees in NJR
Paired Records	1,769	11,428	382,034
PreOp score	21.9 (21.5 - 22.2)	21.2 (21.1 - 21.3)	19.1 (19.1 - 19.1)
6 month score	38.6 (38.1 - 39.0)	38.4 (38.3 - 38.6)	35.5 (35.5 - 35.5)
6 month score (adjusted)	37.1 (36.7 - 37.4)	37.3 (37.1 - 37.4)	35.5 (35.5 - 35.5)
Health gain	16.7 (16.2 - 17.1)	17.2 (17.1 - 17.4)	16.4 (16.4 - 16.4)
Health gain (adjusted)	17.9 (17.6 - 18.3)	18.2 (18.0 - 18.3)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	0.13		
Score Improved	94.3%	95.0%	93.9%

EQ-5D Index (-0.59 - 1.00)	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR	All Knees in NJR
Paired Records	1,696	10,760	354,535
PreOp score	0.503 (0.490 - 0.517)	0.469 (0.464 - 0.475)	0.417 (0.416 - 0.418)
6 month score	0.794 (0.783 - 0.805)	0.792 (0.788 - 0.797)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.763 (0.753 - 0.773)	0.771 (0.767 - 0.775)	0.739 (0.738 - 0.740)
Health gain	0.291 (0.276 - 0.305)	0.323 (0.317 - 0.329)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.346 (0.336 - 0.356)	0.354 (0.350 - 0.358)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	0.069		
Score Improved	82.7%	83.9%	81.4%

EQ-VAS (0 - 100)	Sigma HP (Uni) Unicondylar	All other Unicondylar knees in NJR	All Knees in NJR
Paired Records	1,655	10,515	340,143
PreOp score	70.4 (69.5 - 71.4)	69.2 (68.9 - 69.6)	68.0 (67.9 - 68.1)
6 month score	77.8 (77.0 - 78.6)	77.4 (77.1 - 77.8)	74.1 (74.1 - 74.2)
6 month score (adjusted)	75.2 (74.4 - 75.9)	75.6 (75.3 - 75.9)	74.1 (74.1 - 74.2)
Health gain	7.4 (6.4 - 8.4)	8.2 (7.8 - 8.6)	6.2 (6.1 - 6.2)
Health gain (adjusted)	7.2 (6.5 - 7.9)	7.6 (7.3 - 7.9)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	0.18		
Score Improved	58.2%	60.8%	56.4%

Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.

Figures in parentheses represent the 95% confidence interval for the mean

Summary Report for:

Sigma HP (Uni) Unicondylar

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Sigma HP (Uni) Unicodylar	All other Unicodylar knees in NJR
Much better	1379	9045
A little better	263	1605
About the same	69	477
A little worse	41	309
Much worse	40	191

Answer to 6-months general health question:

"Overall, how are your problems now, compared to before your operation?"

Satisfaction

Response	Sigma HP (Uni) Unicodylar	All other Unicodylar knees in NJR
Excellent	534	3762
Very Good	681	4161
Good	357	2309
Fair	162	1063
Poor	55	317

Answer to 6-months general health question:

"How would you describe the results of your operation?"

Disclaimer

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
Femoral Uni		
102407100	SIGMA HP UNI FEMORAL COMP SZ1 LM/RL	283
102407200	SIGMA HP UNI FEMORAL COMP SZ2 LM/RL	1426
102407300	SIGMA HP UNI FEMORAL COMP SZ3 LM/RL	2497
102407400	SIGMA HP UNI FEMORAL COMP SZ4 LM/RL	2360
102407500	SIGMA HP UNI FEMORAL COMP SZ5 LM/RL	1027
102407600	SIGMA HP UNI FEMORAL COMP SZ6 LM/RL	139
102408100	SIGMA HP UNI FEMORAL COMP SZ1 RM/LL	270
102408200	SIGMA HP UNI FEMORAL COMP SZ2 RM/LL	1329
102408300	SIGMA HP UNI FEMORAL COMP SZ3 RM/LL	2471
102408400	SIGMA HP UNI FEMORAL COMP SZ4 RM/LL	2310
102408500	SIGMA HP UNI FEMORAL COMP SZ5 RM/LL	1063
102408600	SIGMA HP UNI FEMORAL COMP SZ6 RM/LL	113
Tibial Tray		
102451100	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ1 LM/RL	440
102451200	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ2 LM/RL	1717
102451300	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ3 LM/RL	2442
102451400	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ4 LM/RL	2061
102451500	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ5 LM/RL	772
102451600	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ6 LM/RL	128
102452100	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ1 RM/LL	424
102452200	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ2 RM/LL	1736
102452300	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ3 RM/LL	2404
102452400	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ4 RM/LL	2010
102452500	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ5 RM/LL	712
102452600	SIGMA HP UNI CEMENTED TIBIAL TRAY SZ6 RM/LL	120
150600007	Attune FB Cemented Tibial Base Size 7	1
158140000	SIGMA MODULAR TIBIAL TRAY CEMENTED COBALT CHROME SIZE 4	1
Meniscal		
102453107	SIGMA HP UNI FIXED BEARING INSERT SZ1 7MM LM/RL	239
102453108	SIGMA HP UNI FIXED BEARING INSERT SZ1 8MM LM/RL	129
102453109	SIGMA HP UNI FIXED BEARING INSERT SZ1 9MM LM/RL	51
102453110	SIGMA HP UNI FIXED BEARING INSERT SZ1 10MM LM/RL	23
102453111	SIGMA HP UNI FIXED BEARING INSERT SZ1 11MM LM/RL	3
102453207	SIGMA HP UNI FIXED BEARING INSERT SZ2 7MM LM/RL	914
102453208	SIGMA HP UNI FIXED BEARING INSERT SZ2 8MM LM/RL	502
102453209	SIGMA HP UNI FIXED BEARING INSERT SZ2 9MM LM/RL	202
102453210	SIGMA HP UNI FIXED BEARING INSERT SZ2 10MM LM/RL	68
102453211	SIGMA HP UNI FIXED BEARING INSERT SZ2 11MM LM/RL	29
102453307	SIGMA HP UNI FIXED BEARING INSERT SZ3 7MM LM/RL	1263
102453308	SIGMA HP UNI FIXED BEARING INSERT SZ3 8MM LM/RL	708
102453309	SIGMA HP UNI FIXED BEARING INSERT SZ3 9MM LM/RL	304
102453310	SIGMA HP UNI FIXED BEARING INSERT SZ3 10MM LM/RL	125
102453311	SIGMA HP UNI FIXED BEARING INSERT SZ3 11MM LM/RL	45

Appendix A: Component List

Catalogue Number	Description	Number Implanted
102453407	SIGMA HP UNI FIXED BEARING INSERT SZ4 7MM LM/RL	1105
102453408	SIGMA HP UNI FIXED BEARING INSERT SZ4 8MM LM/RL	588
102453409	SIGMA HP UNI FIXED BEARING INSERT SZ4 9MM LM/RL	208
102453410	SIGMA HP UNI FIXED BEARING INSERT SZ4 10MM LM/RL	112
102453411	SIGMA HP UNI FIXED BEARING INSERT SZ4 11MM LM/RL	48
102453507	SIGMA HP UNI FIXED BEARING INSERT SZ5 7MM LM/RL	448
102453508	SIGMA HP UNI FIXED BEARING INSERT SZ5 8MM LM/RL	189
102453509	SIGMA HP UNI FIXED BEARING INSERT SZ5 9MM LM/RL	79
102453510	SIGMA HP UNI FIXED BEARING INSERT SZ5 10MM LM/RL	38
102453511	SIGMA HP UNI FIXED BEARING INSERT SZ5 11MM LM/RL	18
102453607	SIGMA HP UNI FIXED BEARING INSERT SZ6 7MM LM/RL	78
102453608	SIGMA HP UNI FIXED BEARING INSERT SZ6 8MM LM/RL	29
102453609	SIGMA HP UNI FIXED BEARING INSERT SZ6 9MM LM/RL	9
102453610	SIGMA HP UNI FIXED BEARING INSERT SZ6 10MM LM/RL	7
102453611	SIGMA HP UNI FIXED BEARING INSERT SZ6 11MM LM/RL	4
102454107	SIGMA HP UNI FIXED BEARING INSERT SZ1 7MM RM/LL	236
102454108	SIGMA HP UNI FIXED BEARING INSERT SZ1 8MM RM/LL	126
102454109	SIGMA HP UNI FIXED BEARING INSERT SZ1 9MM RM/LL	43
102454110	SIGMA HP UNI FIXED BEARING INSERT SZ1 10MM RM/LL	15
102454111	SIGMA HP UNI FIXED BEARING INSERT SZ1 11MM RM/LL	5
102454207	SIGMA HP UNI FIXED BEARING INSERT SZ2 7MM RM/LL	943
102454208	SIGMA HP UNI FIXED BEARING INSERT SZ2 8MM RM/LL	501
102454209	SIGMA HP UNI FIXED BEARING INSERT SZ2 9MM RM/LL	197
102454210	SIGMA HP UNI FIXED BEARING INSERT SZ2 10MM RM/LL	78
102454211	SIGMA HP UNI FIXED BEARING INSERT SZ2 11MM RM/LL	21
102454307	SIGMA HP UNI FIXED BEARING INSERT SZ3 7MM RM/LL	1339
102454308	SIGMA HP UNI FIXED BEARING INSERT SZ3 8MM RM/LL	642
102454309	SIGMA HP UNI FIXED BEARING INSERT SZ3 9MM RM/LL	308
102454310	SIGMA HP UNI FIXED BEARING INSERT SZ3 10MM RM/LL	88
102454311	SIGMA HP UNI FIXED BEARING INSERT SZ3 11MM RM/LL	29
102454407	SIGMA HP UNI FIXED BEARING INSERT SZ4 7MM RM/LL	1061
102454408	SIGMA HP UNI FIXED BEARING INSERT SZ4 8MM RM/LL	582
102454409	SIGMA HP UNI FIXED BEARING INSERT SZ4 9MM RM/LL	221
102454410	SIGMA HP UNI FIXED BEARING INSERT SZ4 10MM RM/LL	102
102454411	SIGMA HP UNI FIXED BEARING INSERT SZ4 11MM RM/LL	42
102454507	SIGMA HP UNI FIXED BEARING INSERT SZ5 7MM RM/LL	405
102454508	SIGMA HP UNI FIXED BEARING INSERT SZ5 8MM RM/LL	190
102454509	SIGMA HP UNI FIXED BEARING INSERT SZ5 9MM RM/LL	73
102454510	SIGMA HP UNI FIXED BEARING INSERT SZ5 10MM RM/LL	38
102454511	SIGMA HP UNI FIXED BEARING INSERT SZ5 11MM RM/LL	11
102454607	SIGMA HP UNI FIXED BEARING INSERT SZ6 7MM RM/LL	64
102454608	SIGMA HP UNI FIXED BEARING INSERT SZ6 8MM RM/LL	29
102454609	SIGMA HP UNI FIXED BEARING INSERT SZ6 9MM RM/LL	15
102454610	SIGMA HP UNI FIXED BEARING INSERT SZ6 10MM RM/LL	7
102454611	SIGMA HP UNI FIXED BEARING INSERT SZ6 11MM RM/LL	3
151640707	Attune PS FB Insert Size 7 7mm	1

Appendix A: Component List

Catalogue Number	Description	Number Implanted
Preassembled Tibial		
102411108	SIGMA HP UNI ALL POLY TIBIAL COMP SZ1 8MM LM/RL	6
102411208	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 8MM LM/RL	28
102411209	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 9MM LM/RL	9
102411210	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 10MM LM/RL	1
102411308	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 8MM LM/RL	45
102411309	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 9MM LM/RL	6
102411310	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 10MM LM/RL	6
102411311	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 11MM LM/RL	2
102411408	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 8MM LM/RL	36
102411409	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 9MM LM/RL	7
102411410	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 10MM LM/RL	3
102411411	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 11MM LM/RL	3
102411508	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 8MM LM/RL	8
102411510	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 10MM LM/RL	1
102411608	SIGMA HP UNI ALL POLY TIBIAL COMP SZ6 8MM LM/RL	1
102412108	SIGMA HP UNI ALL POLY TIBIAL COMP SZ1 8MM RM/LL	9
102412109	SIGMA HP UNI ALL POLY TIBIAL COMP SZ1 9MM RM/LL	1
102412208	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 8MM RM/LL	20
102412209	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 9MM RM/LL	4
102412210	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 10MM RM/LL	2
102412211	SIGMA HP UNI ALL POLY TIBIAL COMP SZ2 11MM RM/LL	1
102412308	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 8MM RM/LL	38
102412309	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 9MM RM/LL	10
102412310	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 10MM RM/LL	6
102412311	SIGMA HP UNI ALL POLY TIBIAL COMP SZ3 11MM RM/LL	1
102412408	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 8MM RM/LL	26
102412409	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 9MM RM/LL	9
102412410	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 10MM RM/LL	3
102412411	SIGMA HP UNI ALL POLY TIBIAL COMP SZ4 11MM RM/LL	1
102412508	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 8MM RM/LL	10
102412509	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 9MM RM/LL	2
102412510	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 10MM RM/LL	3
102412511	SIGMA HP UNI ALL POLY TIBIAL COMP SZ5 11MM RM/LL	1
102412608	SIGMA HP UNI ALL POLY TIBIAL COMP SZ6 8MM RM/LL	1
102412609	SIGMA HP UNI ALL POLY TIBIAL COMP SZ6 9MM RM/LL	1