

## Implant Summary Report for:

DePuy

## PFC Sigma Bicondylar Knee (TC3 RP Only)

Comprising REVISION knees implanted up to: 13 June 2020  
NJR Database extract: 12 August 2020

Produced on: 25 August 2020  
Licensed for use until: 25 December 2020

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This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (NJR). It summarises usage and outcomes associated with use of the PFC Sigma Bicondylar Knee (TC3 RP Only) in revision procedures 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. It excludes procedures known to be second (or subsequent) revisions.

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**NJR Recorded Usage**

**Implant Usage**

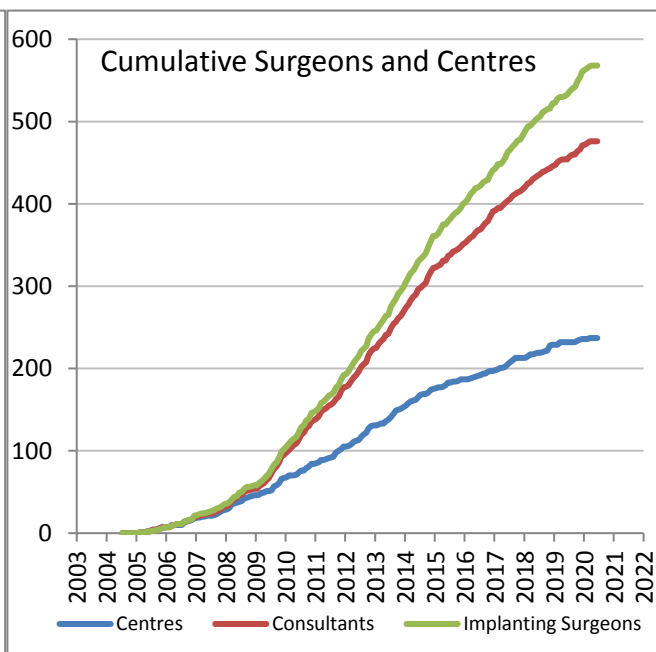
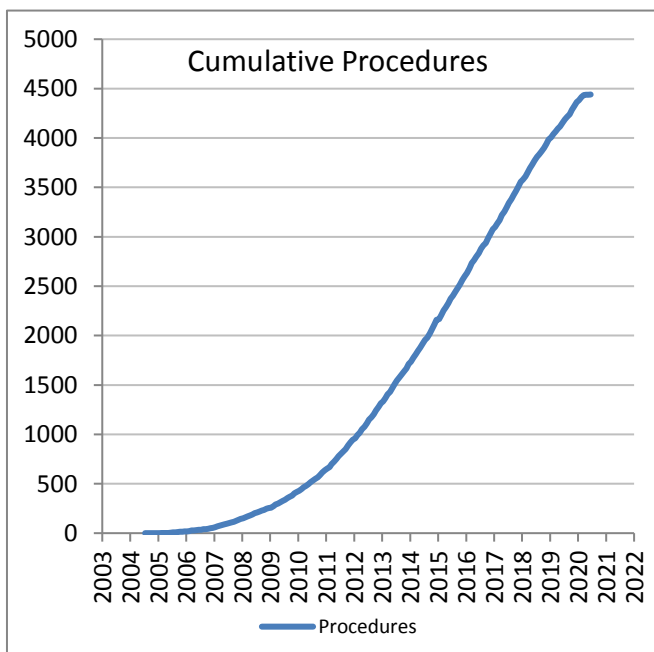
Date of first recorded usage in the NJR: **19 January 2005**

Date of last recorded usage in this dataset: **22 May 2020**

Maximum implantation time: 15.0 years

Mean implantation time: 4.9 years

Totals Recorded in NJR	Cumulative Total
Procedures	4,440
Patients	4,336
Centres	237
Consultants	476
Implanting Surgeons	568



Current Outcome	Year of implantation													Total	%
	Pre-2009	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020		
<b>Death</b>	107	63	64	89	86	67	59	57	20	17	11	3	0	643	14.5%
<b>Revised</b>	28	12	24	20	33	33	30	27	27	20	7	4	0	265	6.0%
<b>Unrevised</b>	123	89	137	198	251	303	347	366	431	442	405	371	69	3532	79.5%
<b>Total</b>	<b>258</b>	<b>164</b>	<b>225</b>	<b>307</b>	<b>370</b>	<b>403</b>	<b>436</b>	<b>450</b>	<b>478</b>	<b>479</b>	<b>423</b>	<b>378</b>	<b>69</b>	<b>4440</b>	<b>100%</b>

## Patient / Procedure Details

## Patient Details

	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR
<b>Total Procedures</b>	4440	26561
<b>Total Patients</b>	4336	25594
<b>Demographics</b>		
Mean age	<b>71.0</b>	<b>69.2</b>
< 50	2.0%	2.9%
50 – 59	10.2%	14.5%
60 – 69	29.8%	31.6%
70 – 79	38.7%	35.7%
≥ 80	19.4%	15.3%
Median BMI	<b>30</b>	<b>31</b>
% BMI information available	67.0%	62.1%
Underweight ( BMI < 18.5)	0.3%	0.2%
Normal (18.5 ≤ BMI < 25)	9.3%	9.4%
Overweight (25 ≤ BMI < 30)	32.6%	31.7%
Obese I (30 ≤ BMI < 35)	32.7%	33.4%
Obese II (35 ≤ BMI < 40)	16.4%	17.8%
Obese III (BMI ≥ 40)	8.7%	7.5%
% Male	51.2%	46.6%
<b>ASA Grades</b>		
P1 - Fit and healthy	4.7%	8.6%
P2 - Mild disease not incapacitating	64.2%	67.3%
P3 - Incapacitating systemic disease	30.2%	23.5%
P4 / P5	0.9%	0.6%
<b>Indications</b>		
Infection	20.3%	12.0%
AsepticLoosening	51.3%	39.1%
Pain	8.7%	14.8%
Instability	19.6%	13.4%
Malalignment	9.5%	8.2%
Stiffness	6.3%	4.7%
Lysis	16.8%	10.0%
DislocationSubluxation	1.7%	2.7%
Wear of Polyethylene Component	17.0%	13.2%
Progressive Arthritis Remaining	1.4%	15.8%
Periprosthetic Fracture	2.3%	2.2%
Other	22.0%	17.1%

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

**Revision and Survivorship**

**Reasons for Re-Revision**

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

Reason for Re-Revision	Re-Revised †	Expected Revisions *	p value
Infection	109	126.24	0.107
Progressive Arthritis Remaining	12	9.10	0.294
Aseptic Loosening Femur	29	33.13	0.528
Aseptic Loosening Tibia	26	46.74	0.001
Aseptic Loosening Patella	6	7.92	0.579
Unexplained Pain	23	27.99	0.375
Stiffness	16	21.48	0.258
Malalignment	4	11.90	0.015
Instability	40	53.98	0.047
Dislocation / Subluxation	13	9.41	0.227
Periprosthetic Fracture	6	8.30	0.582
Wear of Polyethylene Component	7	6.65	0.841
Lysis - Tibia	8	12.01	0.293
Lysis - Femur	5	9.92	0.136
Component Dissociation	5	5.28	1
Implant Fracture	4	2.36	0.295
Other / Not recorded	10	10.90	1
<b>Total Revised</b>	<b>265</b>	<b>300.53</b>	<b>0.032</b>

† multiple reasons may be listed for one revision procedure

\* Based on All TKR in NJR, 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

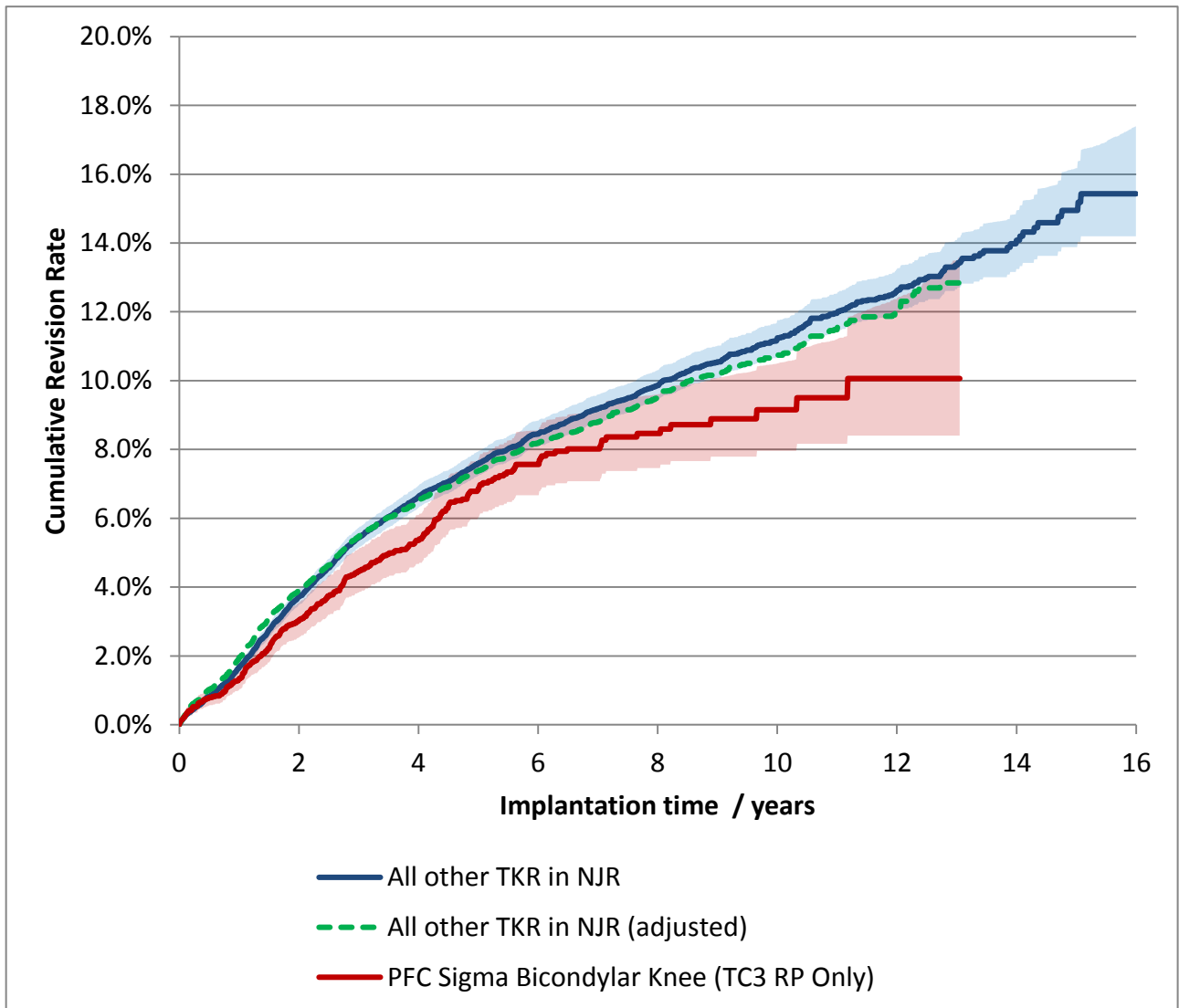


Components Re-Revised	Number of procedures	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR
Femoral and/or Tibial Re-Revision	175	66.0%	79.1%
Isolated bearing exchange	47	17.7%	12.1%
Patella revision / resurfacing only	27	10.2%	5.7%
No component revision recorded	16	6.0%	3.1%

**Revision and Survivorship**

**Cumulative Re-Revision Rate**

Endpoint: All reasons for re-revision



Cox Proportional Hazards model for revision risk ratio of PFC Sigma Bicondylar Knee (TC3 RP Only) / All other TKR in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted.	0.83 (0.73 - 0.94)	0.003
Adjusted for age, gender, year cohort and indications.	0.86 (0.76 - 0.98)	0.026

## Revision and Survivorship

## Cumulative Revision Rate

Endpoint: All revisions

Period /years	At Risk	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR
0	4440	-	-
1	4047	1.3% (1.0% - 1.7%)	1.7% (1.5% - 1.8%)
2	3536	3.0% (2.5% - 3.6%)	3.7% (3.5% - 4.0%)
3	2976	4.4% (3.8% - 5.1%)	5.4% (5.1% - 5.7%)
4	2443	5.4% (4.7% - 6.1%)	6.6% (6.3% - 7.0%)
5	1936	6.8% (6.0% - 7.7%)	7.6% (7.2% - 7.9%)
6	1486	7.6% (6.7% - 8.6%)	8.5% (8.1% - 8.8%)
7	1100	8.0% (7.1% - 9.1%)	9.2% (8.8% - 9.6%)
8	758	8.5% (7.5% - 9.6%)	9.9% (9.4% - 10.3%)
9	505	8.9% (7.8% - 10.1%)	10.5% (10.1% - 11.0%)
10	311	9.1% (8.0% - 10.5%)	11.2% (10.7% - 11.8%)
11	180	9.5% (8.2% - 11.2%)	12.0% (11.4% - 12.5%)
12	94	10.1% (8.4% - 12.4%)	12.6% (12.0% - 13.2%)
13	42	10.1% (8.4% - 13.5%)	13.4% (12.7% - 14.1%)
14		( - )	14.1% (13.2% - 14.9%)
15		( - )	15.0% (13.9% - 16.2%)

Cumulative revision rate with 95% confidence intervals  
Rate is only reported for times where more than 40 remain at risk

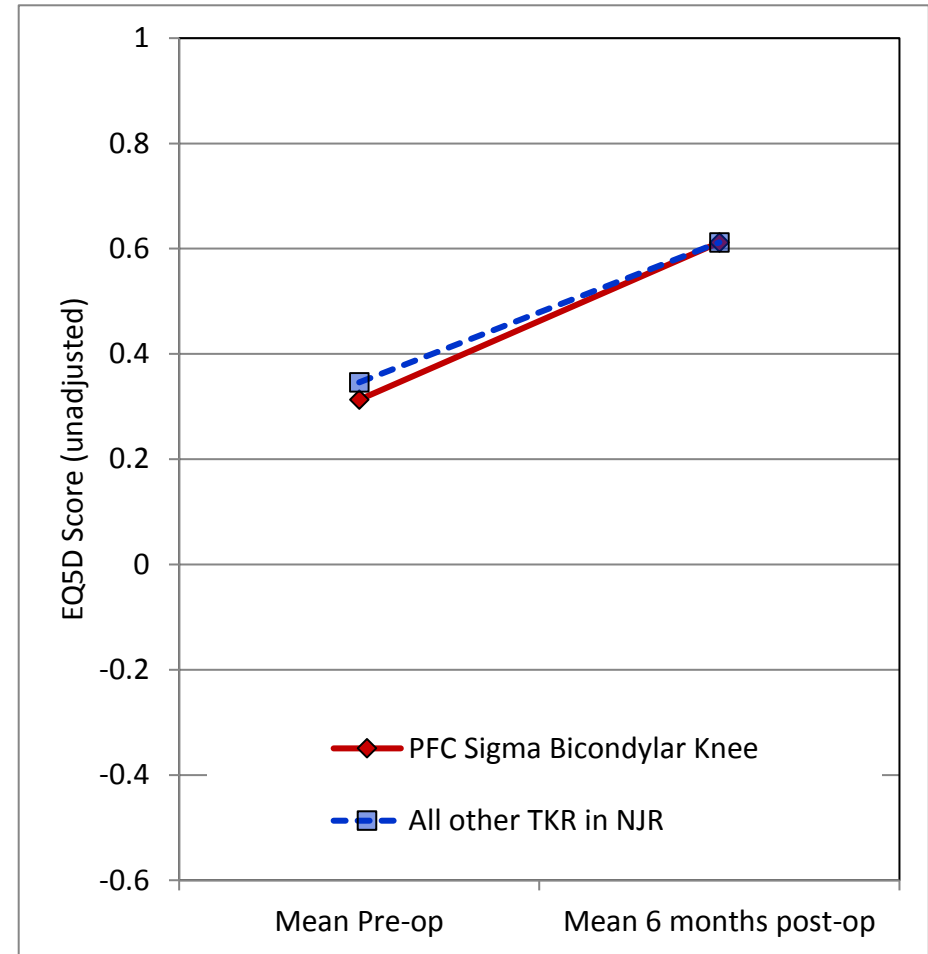
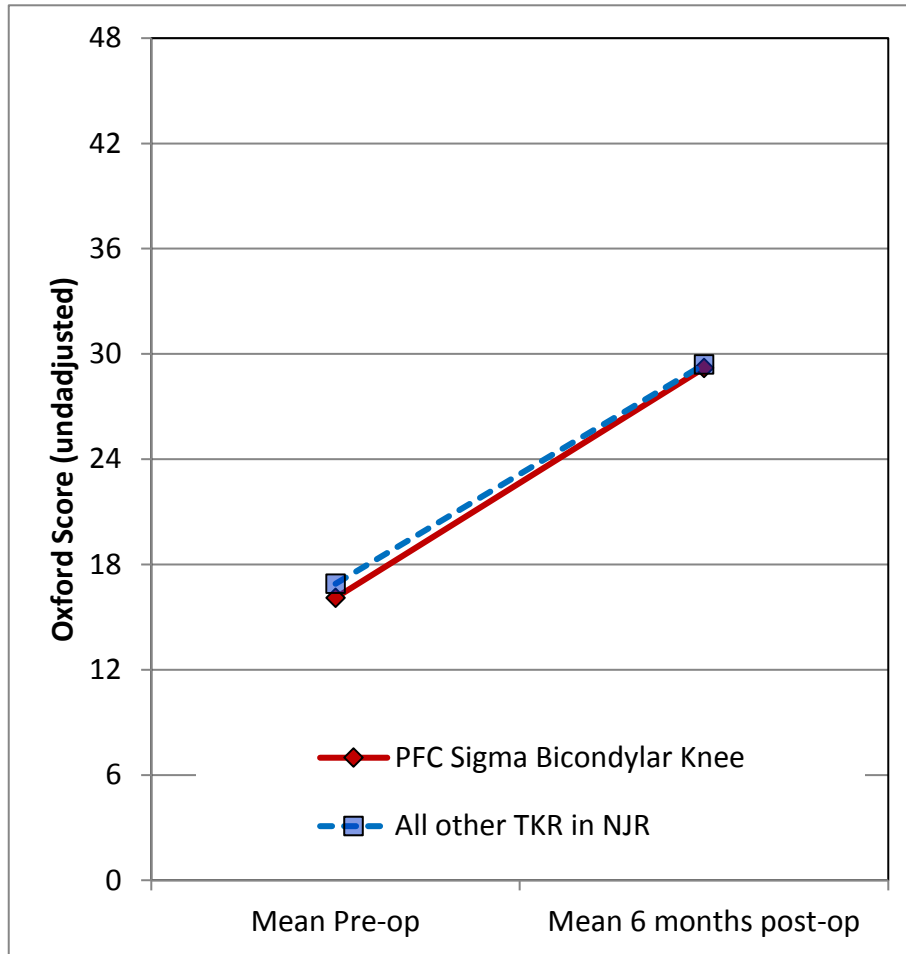
Summary Report for:

PFC Sigma Bicondylar Knee (TC3 RP Only)

## Patient Reported Outcomes

Comprising PROMs data up to and including: 29/03/2018

### PROMs Analysis



## Patient Reported Outcomes

## PROMs Analysis

Comprising PROMs data up to and including: 29/03/2018

Oxford Knee Score (0 - 48)	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR	All Knees in NJR
Paired Records	1,099	5,173	10,933
PreOp score	16.1 (15.7 - 16.6)	16.9 (16.7 - 17.2)	16.6 (16.4 - 16.7)
6 month score	29.2 (28.6 - 29.9)	29.4 (29.1 - 29.7)	28.7 (28.5 - 28.9)
6 month score (adjusted)	29.0 (28.4 - 29.6)	29.2 (29.0 - 29.5)	28.7 (28.5 - 28.9)
Health gain	13.1 (12.5 - 13.7)	12.5 (12.2 - 12.8)	12.1 (11.9 - 12.3)
Health gain (adjusted)	12.4 (11.9 - 13.0)	12.7 (12.4 - 12.9)	12.1 (12.0 - 12.3)
p value (adjusted health gain)	0.7		
Score Improved	87.6%	86.2%	85.6%

EQ-5D Index (-0.59 - 1.00)	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR	All Knees in NJR
Paired Records	1,005	4,741	10,078
PreOp score	0.313 (0.294 - 0.333)	0.346 (0.336 - 0.355)	0.331 (0.324 - 0.337)
6 month score	0.612 (0.594 - 0.630)	0.612 (0.603 - 0.620)	0.596 (0.590 - 0.602)
6 month score (adjusted)	0.609 (0.593 - 0.626)	0.607 (0.600 - 0.615)	0.596 (0.591 - 0.602)
Health gain	0.299 (0.277 - 0.320)	0.266 (0.256 - 0.276)	0.266 (0.259 - 0.273)
Health gain (adjusted)	0.279 (0.262 - 0.295)	0.277 (0.269 - 0.284)	0.266 (0.260 - 0.271)
p value (adjusted health gain)	0.84		
Score Improved	72.8%	71.1%	70.2%

EQ-VAS (0 - 100)	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR	All Knees in NJR
Paired Records	959	4,562	9,672
PreOp score	63.3 (61.9 - 64.6)	65.1 (64.4 - 65.7)	64.6 (64.2 - 65.0)
6 month score	66.0 (64.8 - 67.3)	67.3 (66.7 - 67.9)	66.4 (66.0 - 66.8)
6 month score (adjusted)	66.2 (65.0 - 67.4)	67.0 (66.4 - 67.6)	66.4 (66.0 - 66.8)
Health gain	2.8 (1.3 - 4.2)	2.2 (1.6 - 2.9)	1.8 (1.3 - 2.3)
Health gain (adjusted)	1.6 (0.4 - 2.8)	2.4 (1.8 - 3.0)	1.8 (1.4 - 2.2)
p value (adjusted health gain)	0.099		
Score Improved	48.4%	48.9%	47.5%

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:

PFC Sigma Bicondylar Knee (TC3 RP Only)

Responses are not case mix adjusted

Patient Reported Outcomes



## Patient Reported Outcomes

### Success

Response	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR
Much better	676	2903
A little better	271	1171
About the same	99	555
A little worse	72	378
Much worse	60	339

Answer to 6-months general health question:

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

### Satisfaction

Response	PFC Sigma Bicondylar Knee (TC3 RP Only)	All other TKR in NJR
Excellent	223	886
Very Good	336	1488
Good	327	1383
Fair	203	1068
Poor	82	506

Answer to 6-months general health question:

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

## Disclaimer

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# Appendix A1: Femoral Components

Catalogue Number	Description	Number Implanted
960081	PFC® SIGMA TC3 FEMORAL LEFT SIZE 2	194
960082	PFC® SIGMA TC3 FEMORAL LEFT SIZE 3	699
960083	PFC® SIGMA TC3 FEMORAL LEFT SIZE 4	625
960084	PFC® SIGMA TC3 FEMORAL LEFT SIZE 5	310
960085	PFC® SIGMA TC3 FEMORAL LEFT SIZE 1.5	1
960086	PFC® SIGMA TC3 FEMORAL LEFT SIZE 2.5	235
960087	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 2	230
960088	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 3	753
960089	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 4	745
960090	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 5	352
960091	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 1.5	2
960092	PFC® SIGMA TC3 FEMORAL RIGHT SIZE 2.5	294

## Appendix A2: Tibial Components

Catalogue Number	Description	Number
129435110	MBT REVISION CEM TIB TRAY SZ 1	4
129435115	MBT REVISION CEM TIB TRAY S1.5	17
129435120	MBT REVISION TIBIAL TRAY CEMENTED Size 2	634
129435125	MBT REVISION TIBIAL TRAY CEMENTED Size 2.5	676
129435130	MBT REVISION TIBIAL TRAY CEMENTED Size 3	1362
129435140	MBT REVISION TIBIAL TRAY CEMENTED Size 4	1263
129435150	MBT REVISION TIBIAL TRAY CEMENTED Size 5	419
129435215	MBT REVISION THICK TRAY SIZE 2 +15mm	11
129435225	MBT REVISION THICK TRAY SIZE 2 +25mm	5
129435315	MBT REVISION THICK TRAY SIZE 3 +15mm	21
129435325	MBT REVISION THICK TRAY SIZE 3 +25mm	3
129435415	MBT REVISION THICK TRAY SIZE 4 +15mm	22
129435425	MBT REVISION THICK TRAY SIZE 4 +25mm	3

## Appendix A3: Bearing Components

Catalogue Number	Description	Number
864601	PFC PLI 8MM SZ2	1
864616	PFC PLI 8MM SZ4	1
866042	PFC STB12.5MM SZ1	1
960252	PFC® SIGMA TIBIAL INSERTS SIZE 4 12.5mm	1
960514	PFC® SIGMA TC3 INSERT SIZE 2 20mm	1
960530	PFC® SIGMA TC3 INSERT SIZE 3 10mm	1
960540	PFC® SIGMA TC3 INSERT SIZE 4 10mm	1
960541	PFC® SIGMA TC3 INSERT SIZE 4 12.5mm	1
960542	PFC® SIGMA TC3 INSERT SIZE 4 15mm	1
962111	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 2 10.0mm	1
962121	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 2.5 10.0mm	2
962122	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 2.5 12.5mm	2
962123	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 2.5 15.0mm	1
962124	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 2.5 17.5mm	1
962131	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 3 10.0mm	3
962132	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 3 12.5mm	4
962133	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 3 15.0mm	2
962134	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 3 17.5mm	1
962141	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 4 10.0mm	2
962142	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 4 12.5mm	7
962143	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 4 15.0mm	3
962144	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 4 17.5mm	2
962151	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 5 10.0mm	1
962152	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 5 12.5mm	1
962153	ROTATING PLATFORM STABILISED TIBIAL INSERT SIZE 5 15.0mm	1
962311	TC3 RP Tibial Insert Size 1.5 10mm	4
962321	TC3 RP Tibial Insert Size 2 10mm	104
962322	TC3 RP Tibial Insert Size 2 12.5mm	88
962323	TC3 RP Tibial Insert Size 2 15mm	83
962324	TC3 RP Tibial Insert Size 2 17.5mm	57
962325	TC3 RP Tibial Insert Size 2 20mm	39
962326	TC3 RP Tibial Insert Size 2 22.5mm	26
962327	TC3 RP Tibial Insert Size 2 25mm	15
962328	TC3 RP Tibial Insert Size 2 30mm	2
962331	TC3 RP Tibial Insert Size 2.5 10mm	132
962332	TC3 RP Tibial Insert Size 2.5 12.5mm	120
962333	TC3 RP Tibial Insert Size 2.5 15mm	109
962334	TC3 RP Tibial Insert Size 2.5 17.5mm	68
962335	TC3 RP Tibial Insert Size 2.5 20mm	43
962336	TC3 RP Tibial Insert Size 2.5 22.5mm	25
962337	TC3 RP Tibial Insert Size 2.5 25mm	13
962338	TC3 RP Tibial Insert Size 2.5 30mm	1
962341	TC3 RP Tibial Insert Size 3 10mm	359
962342	TC3 RP Tibial Insert Size 3 12.5mm	285
962343	TC3 RP Tibial Insert Size 3 15mm	290
962344	TC3 RP Tibial Insert Size 3 17.5mm	204

## Appendix A3: Bearing Components

Catalogue Number	Description	Number
962345	TC3 RP Tibial Insert Size 3 20mm	150
962346	TC3 RP Tibial Insert Size 3 22.5mm	58
962347	TC3 RP Tibial Insert Size 3 25mm	43
962348	TC3 RP Tibial Insert Size 3 30mm	13
962351	TC3 RP Tibial Insert Size 4 10mm	334
962352	TC3 RP Tibial Insert Size 4 12.5mm	289
962353	TC3 RP Tibial Insert Size 4 15mm	258
962354	TC3 RP Tibial Insert Size 4 17.5mm	198
962355	TC3 RP Tibial Insert Size 4 20mm	108
962356	TC3 RP Tibial Insert Size 4 22.5mm	62
962357	TC3 RP Tibial Insert Size 4 25mm	37
962358	TC3 RP Tibial Insert Size 4 30mm	9
962361	TC3 RP Tibial Insert Size 5 10mm	161
962362	TC3 RP Tibial Insert Size 5 12.5mm	137
962363	TC3 RP Tibial Insert Size 5 15mm	149
962364	TC3 RP Tibial Insert Size 5 17.5mm	89
962365	TC3 RP Tibial Insert Size 5 20mm	46
962366	TC3 RP Tibial Insert Size 5 22.5mm	20
962367	TC3 RP Tibial Insert Size 5 25mm	15
962368	TC3 RP Tibial Insert Size 5 30mm	3

## Appendix A4: Patella Components

Catalogue Number	Description	Number
151820038	Attune Medialized Dome Patella 38mm	1
5551L299	TRIATHLON ASYMMETRIC PATELLA - 29mm x 9mm	1
5551L350	TRIATHLON ASYMMETRIC PATELLA - 35mm x 10mm	1
71420568	GENESIS II BICONVEX PATELLA 26MM	1
71420570	GENESIS II BICONVEX PATELLA 29MM	1
71420572	GENESIS II BICONVEX PATELLA 32MM	2
960100	PFC® SIGMA OVAL PATELLA 32mm	188
960101	PFC® SIGMA OVAL PATELLA 35mm	513
960102	PFC® SIGMA OVAL PATELLA 38mm	751
960103	PFC® SIGMA OVAL PATELLA 41mm	464
960110	PFC® SIGMA 3 PEG DOME PATELLA 32mm	5
960111	PFC® SIGMA 3 PEG DOME PATELLA 35mm	17
960112	PFC® SIGMA 3 PEG DOME PATELLA 38mm	30
960113	PFC® SIGMA 3 PEG DOME PATELLA 41mm	3
960120	PFC® SIGMA INSET PATELLA 25mm	4

153287-200917 EMEA