

**Bespoke Report for:****MicroPort Orthopedics  
Profemur L Classic Stem****Produced on:** 19 April 2020**Licensed for use until:** 19 April 2022

## Introduction

This report summarises the outcome of the MicroPort Orthopedics Profemur L Classic Stem in total hip replacement in patients registered in the National Joint Registry. It consists of two parts:

### Part 1

The first part summarises the summarises usage and survival associated with the Profemur L Classic Stem, based upon all data recorded in the NJR for this product combination up to 08/02/2020. The report includes Kaplan Meier survival analysis and Cox Regression analysis, comparing the product with all other cementless hip stems in the NJR, excluding metal on metal. The Cox Regression includes calculation of a Hazard Ratio adjusted for age, gender, year cohort and indications.

### Part 2

The second part summarises the outcomes of an additional Patient Reported Outcome Measures (PROMs) study requested by MicroPort Orthopedics on the Profemur L Classic Stem using Oxford Hip scores, EQ-5D-5L scores, and EQ-VAS scores at a range of time intervals following surgery.

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# PART 1: All-NJR Survival Analysis

## Bespoke Report for:

### Profemur L Classic Stem

Comprising PRIMARY hips implanted up to:  
NJR Database extract:

08 February 2020  
08 April 2020

This report section summarises usage and outcomes associated with the Profemur L Classic Stem, based on data collected by the NJR up to the specified date, for the following femoral stem components used in primary hip arthroplasty, in combination with any acetabular component:

Part Number	Description
PHAE5502	PROFEMUR L Classic Extended Offset Fixed NECK Size 1
PHAE5504	PROFEMUR L Classic Extended Offset Fixed NECK Size 2
PHAE5506	PROFEMUR L Classic Extended Offset Fixed NECK Size 3
PHAE5508	PROFEMUR L Classic Extended Offset Fixed NECK Size 4
PHAE5510	PROFEMUR L Classic Extended Offset Fixed NECK Size 5
PHAE5512	PROFEMUR L Classic Extended Offset Fixed NECK Size 6
PHAE5514	PROFEMUR L Classic Extended Offset Fixed NECK Size 7
PHAE5516	PROFEMUR L Classic Extended Offset Fixed NECK Size 8
PHAE5518	PROFEMUR L Classic Extended Offset Fixed NECK Size 9
PHAS5502	PROFEMUR L Classic Fixed NECK Size 1
PHAS5504	PROFEMUR L Classic Fixed NECK Size 2
PHAS5506	PROFEMUR L Classic Fixed NECK Size 3
PHAS5508	PROFEMUR L Classic Fixed NECK Size 4
PHAS5510	PROFEMUR L Classic Fixed NECK Size 5
PHAS5512	PROFEMUR L Classic Fixed NECK Size 6
PHAS5514	PROFEMUR L Classic Fixed NECK Size 7
PHAS5516	PROFEMUR L Classic Fixed NECK Size 8
PHAS5518	PROFEMUR L Classic Fixed NECK Size 9
PHAS5520	PROFEMUR L Classic Fixed NECK Size 10

Appendix A lists numbers of all Profemur L Classic Stem components included in this part of the report.

**NJR Recorded Usage**

**Implant Usage**

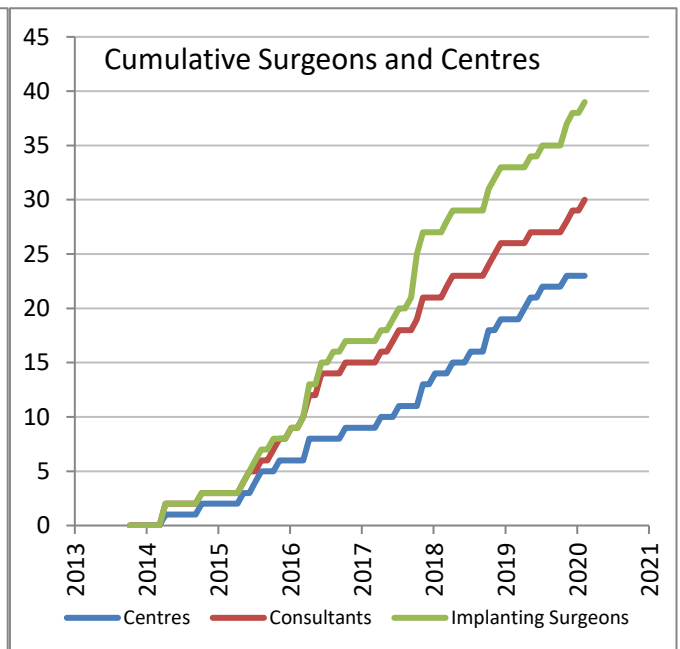
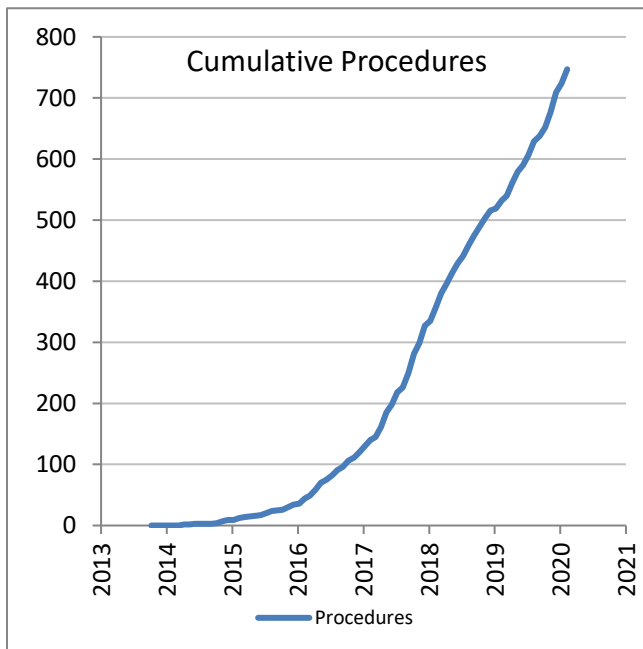
Date of first recorded usage in the NJR: **24 March 2014**

Date of last recorded usage in this dataset: **05 February 2020**

Maximum implantation time: 5.9 years

Mean implantation time: 1.9 years

Totals Recorded in NJR	Cumulative Total
Procedures	747
Patients	704
Centres	23
Consultants	30
Implanting Surgeons	39



Current Outcome	Year of implantation														Total	%
	Pre-2009	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020			
Death	0	0	0	0	0	0	1	1	2	2	1	0	0	7	0.9%	
Revised	0	0	0	0	0	0	0	0	3	2	2	2	0	9	1.2%	
Unrevised	0	0	0	0	0	0	8	26	86	203	182	199	27	731	97.9%	
<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>9</b>	<b>27</b>	<b>91</b>	<b>207</b>	<b>185</b>	<b>201</b>	<b>27</b>	<b>747</b>	<b>100%</b>	

## Patient / Procedure Details

## Patient Details

	Profemur L Classic Stem	All other Cementless Stems in NJR	All NJR hip replacement
<b>Total Procedures</b>	747	493,015	1,221,920
<b>Total Patients</b>	704	425,034	1,031,666
<b>Demographics</b>			
Mean age	<b>61.2</b>	<b>65.3</b>	<b>68.6</b>
< 50	15.9%	8.4%	6.0%
50 – 59	23.6%	19.2%	13.8%
60 – 69	34.8%	34.8%	29.0%
70 – 79	21.6%	28.4%	34.7%
≥ 80	4.1%	9.2%	16.6%
Median BMI	<b>28</b>	<b>28</b>	<b>28</b>
% BMI information available	90.0%	64.2%	62.2%
Underweight ( BMI < 18.5)	0.3%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	21.0%	18.8%	20.7%
Overweight (25 ≤ BMI < 30)	42.6%	39.1%	39.6%
Obese I (30 ≤ BMI < 35)	27.2%	26.9%	25.8%
Obese II (35 ≤ BMI < 40)	6.5%	10.8%	9.7%
Obese III (BMI ≥ 40)	2.4%	3.7%	3.3%
% Male	47.4%	44.3%	40.2%
<b>ASA Grades</b>			
P1 - Fit and healthy	24.5%	18.1%	15.6%
P2 - Mild disease not incapacitating	65.1%	68.9%	67.7%
P3 - Incapacitating systemic disease	10.3%	12.6%	16.1%
P4 / P5	0.1%	0.4%	0.6%
<b>Indications</b>			
Osteoarthritis	95.85%	93.04%	91.46%
Rheumatoid Arthritis	0.67%	1.22%	1.32%
Avascular Necrosis	2.14%	2.56%	2.50%
Fractured Neck of Femur	0.13%	1.85%	3.49%
CDH/DDH	2.68%	2.08%	1.57%
Other	0.67%	1.79%	2.12%

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 all primary procedures in which the implant was used.

Reason for Revision	Revised <sup>†</sup>	Expected Revisions <sup>*</sup>	p value
Unexplained Pain	2	0.41	0.064
Dislocation / Subluxation	1	2.02	0.729
Adverse Soft Tissue Reaction	0	0.13	1
Infection	2	1.70	0.69
Aseptic Loosening - Stem	0	1.03	0.632
Aseptic Loosening - Socket	1	0.34	0.287
Periprosthetic Fracture Stem	1	1.07	1
Periprosthetic Fracture Socket	0	0.09	1
Malalignment Stem	0	0.40	1
Malalignment Socket	1	0.47	0.378
Wear Of Acetabular Component	0	0.12	1
Lysis Stem	0	0.05	1
Lysis Socket	0	0.04	1
Implant Fracture Stem	1	0.07	0.069
Implant Fracture Socket	0	0.16	1
Implant Fracture Head	0	0.02	1
Dissociation of Liner	0	0.12	1
Other / Not recorded	0	0.43	1
<b>Total Revised</b>	<b>9</b>	<b>7.57</b>	<b>0.582</b>

\* Based on All NJR Cementless Stems (excluding metal on metal), adjusted for agegroup, gender, indications, and implantation year

† multiple reasons may be listed for one revision procedure

Significantly better,  $p < 0.001$

Significantly better,  $p < 0.05$

Significantly worse  $p < 0.05$

Significantly worse  $p < 0.001$



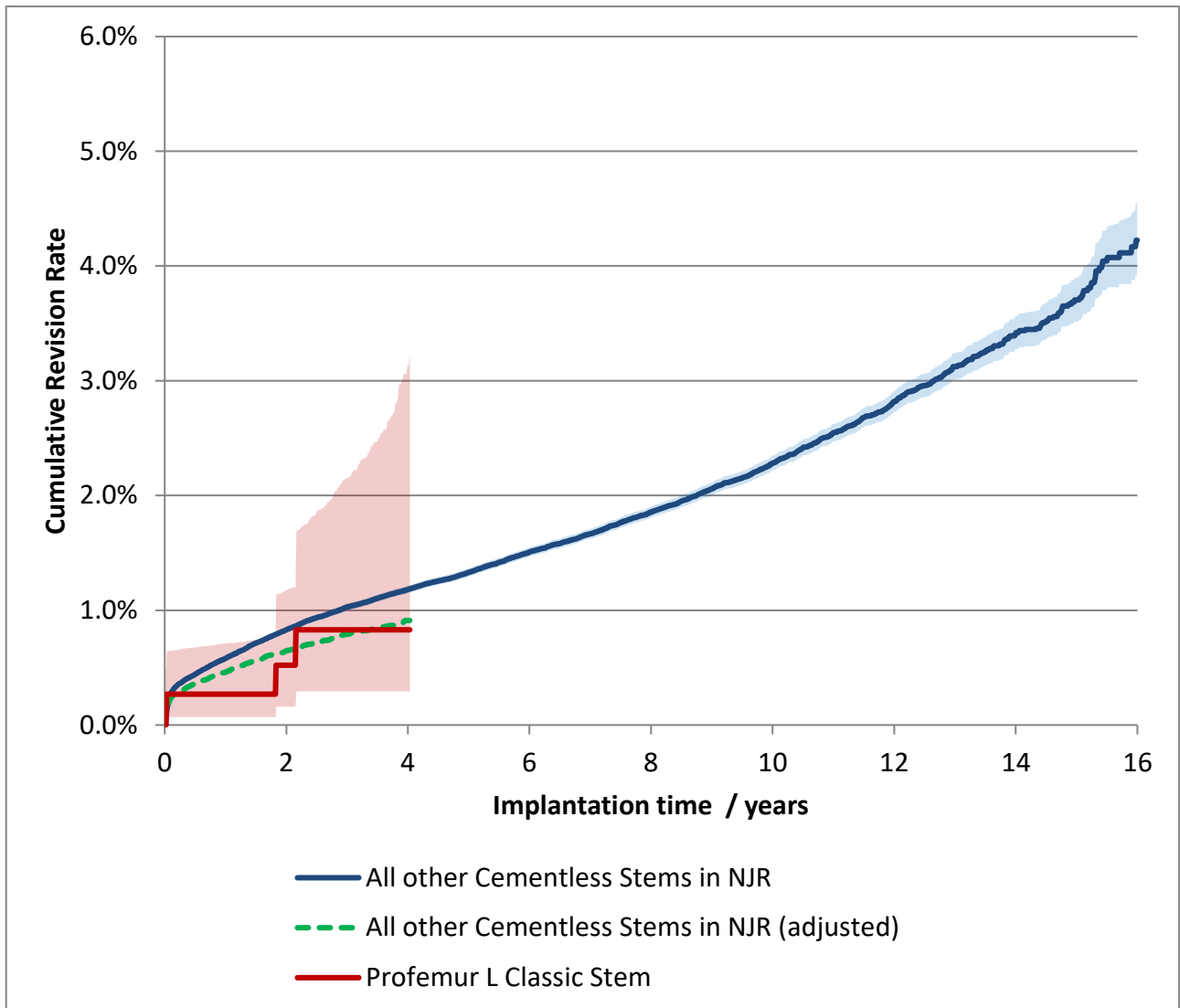
Components Revised	Number of procedures	Profemur L Classic Stem	All other Cementless Stems in NJR
Femoral only	2	22%	31%
Acetabular only	3	33%	26%
Both femoral and acetabular	2	22%	31%
Neither femoral nor acetabular revision recorded *	2	22%	12%

\* includes isolated head and/or liner exchange

**Revision and Survivorship**

**Cumulative Revision Rate**

Endpoint: Femoral Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Profemur L Classic Stem / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	0.70 (0.26 - 1.85)	0.468
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.89 (0.33 - 2.38)	0.821

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Profemur L Classic Stem	All other Cementless Stems in NJR	All THR	At Risk	Profemur L Classic Stem	All other Cementless Stems in NJR	All THR
0	747	-	-	-	747	-	-	-
1	526	0.3% (0.1% - 0.7%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)	526	0.3% (0.1% - 0.7%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	352	0.5% (0.2% - 1.2%)	0.9% (0.8% - 0.9%)	0.7% (0.7% - 0.8%)	352	0.5% (0.2% - 1.2%)	0.8% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	134	0.8% (0.3% - 2.2%)	1.1% (1.0% - 1.1%)	1.0% (1.0% - 1.0%)	134	0.8% (0.3% - 2.2%)	1.0% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	41	0.8% (0.3% - 3.1%)	1.3% (1.2% - 1.3%)	1.2% (1.2% - 1.2%)	41	0.8% (0.3% - 3.1%)	1.2% (1.1% - 1.2%)	1.0% (1.0% - 1.1%)
5		(-)	1.5% (1.4% - 1.5%)	1.4% (1.4% - 1.5%)		(-)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6		(-)	1.7% (1.7% - 1.8%)	1.7% (1.7% - 1.7%)		(-)	1.5% (1.5% - 1.5%)	1.4% (1.3% - 1.4%)
7		(-)	2.0% (1.9% - 2.0%)	2.0% (2.0% - 2.0%)		(-)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.6%)
8		(-)	2.2% (2.2% - 2.3%)	2.3% (2.3% - 2.3%)		(-)	1.9% (1.8% - 1.9%)	1.7% (1.7% - 1.8%)
9		(-)	2.5% (2.5% - 2.6%)	2.6% (2.6% - 2.7%)		(-)	2.1% (2.0% - 2.1%)	2.0% (1.9% - 2.0%)
10		(-)	2.9% (2.8% - 2.9%)	3.0% (2.9% - 3.0%)		(-)	2.3% (2.2% - 2.3%)	2.2% (2.2% - 2.2%)
11		(-)	3.2% (3.1% - 3.3%)	3.4% (3.3% - 3.4%)		(-)	2.5% (2.5% - 2.6%)	2.5% (2.4% - 2.5%)
12		(-)	3.6% (3.5% - 3.7%)	3.8% (3.7% - 3.9%)		(-)	2.8% (2.7% - 2.9%)	2.8% (2.8% - 2.9%)
13		(-)	4.0% (3.8% - 4.1%)	4.2% (4.1% - 4.3%)		(-)	3.1% (3.0% - 3.2%)	3.1% (3.0% - 3.2%)
14		(-)	4.3% (4.2% - 4.4%)	4.6% (4.5% - 4.7%)		(-)	3.4% (3.3% - 3.6%)	3.4% (3.3% - 3.5%)
15		(-)	4.6% (4.4% - 4.8%)	5.1% (4.9% - 5.2%)		(-)	3.7% (3.5% - 3.9%)	3.8% (3.7% - 3.9%)

Cumulative revision rate with 95% confidence intervals

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

## PART 2: PROMs Analysis

Bespoke Report for:

MicroPort Orthopedics  
Profemur L Classic Stem

### Questionnaires and Responses

PROMs questionnaires were mailed out to patients implanted with a Profemur Xm cemented stem. These consisted of Oxford Hip Score and EQ-5D-5L questionnaires. The forms sent to patients are attached as Appendix B. Patients were randomly selected from those with NJR consent and tracing information, and who were known to be alive with the index procedure unrevised.

Oxford Hip Scores were calculated by adding the scores from the 12 questions and subtracting the total from 60. This gives a score range of 0 to 48, where 0 is worst and 48 is best. Where scores were incomplete, a maximum of two unanswered questions were replaced by the mean score of the completed questions.

EQ-5D-5L scores were calculated using the value set for the England. This gives a range -0.285 to 1.00, where 1 corresponds to 'Best imaginable health state' and -0.285 corresponds to 'Worst imaginable health state'. Negative numbers correspond to a self-assessed health state worse than being dead.

EQ-5D-5L responses were also mapped on to an approximate equivalent to EQ-5D-3L (England) scores using a crosswalk valuation. These values have a range of -0.59 (worst possible) to 1 (best possible). Details of both the EQ-5D-5L valuation set for England and the crosswalk valuation are given in Devlin N, Shah K, Feng Y, Mulhern B, van Hout B. Valuing health-related quality of life: An EQ-5D-5L value set for England. Health Economics 2017:1-16, 23-06-2017

For the purpose of analysis, results were grouped by time from the index procedure to completion of the PROMs forms, as follows:

- o Early (<5yrs post op)
- o Midterm (≥5yrs – <8yrs Post Op)
- o Long-term (≥8yrs Post Op)

Questionnaires issued	584	
Responses received	332	57%
Completed Oxford Hip Scores	324	55%
Completed EQ-5D Scores	320	55%
Completed EQ-VAS	329	56%

PROMs responses also were compared with the corresponding measures for primary hips taken from the NHS PROMs programme.



PROMs Scores

Oxford Hip Score			Time post-operation (years)			Oxford Hip Score			
Group	Responses	Complete Scores	Mean	Min	Max	Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
All Profemur L Classic Stem	332	324	2.118	0.386	5.536	43.2	8.3	42.3	44.1
Early (< 5 yrs)	326	319	2.07	0.386	4.884	43.1	8.4	42.2	44.0
Mid-term (5 - 8 years)	6	5	5.196	5.029	5.536	44.8	4.5	37.5	48.0
All NJR primary hips	NA	291858	0.605	0.444	1.177	39.3	8.8	39.3	39.4

EQ-5D-5L			Time post-operation (years)			Oxford Hip Score			
Group	Responses	Complete Scores	Mean	Min	Max	Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
All Profemur L Classic Stem	332	320	2.1	0.4	5.5	<b>0.899</b>	0.178	0.880	0.919
Early (< 5 yrs)	326	315	2.1	0.4	4.9	<b>0.899</b>	0.179	0.879	0.918
Mid-term (5 - 8 years)	6	5	5.2	5.0	5.5	<b>0.935</b>	0.146	0.778	1.000
All NJR primary hips	NA	NA							

EQ-5D Crosswalk			Time post-operation (years)			Oxford Hip Score			
Group	Responses	Complete Scores	Mean	Min	Max	Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
All Profemur L Classic Stem	332	320	2.1	0.4	5.5	<b>0.864</b>	0.196	0.843	0.886
Early (< 5 yrs)	326	315	2.1	0.4	4.9	<b>0.864</b>	0.196	0.842	0.885
Mid-term (5 - 8 years)	6	5	5.2	5.0	5.5	<b>0.924</b>	0.170	0.752	1.000
All NJR primary hips	NA	280376	0.6	0.4	1.2	<b>0.790</b>	0.245	0.789	0.791

EQ-VAS			Time post-operation (years)			Oxford Hip Score			
Group	Responses	Complete Scores	Mean	Min	Max	Mean Score	Std. Dev. Score	Lower 95% CI	Upper 95% CI
All Profemur L Classic Stem	332	329	2.1	0.4	5.5	<b>82.3</b>	15.7	80.6	84.0
Early (< 5 yrs)	326	324	2.1	0.4	4.9	<b>82.3</b>	15.7	80.6	84.0
Mid-term (5 - 8 years)	6	5	5.2	5.0	5.5	<b>84.0</b>	15.6	70.3	97.7
All NJR primary hips	NA	279423	0.6	0.4	1.2	<b>76.7</b>	18.1	76.6	76.7

Oxford Hip scores lie in the range of 0 to 48, where 0 is worst and 48 is best.

The maximum and minimum post-operative times for the "All NJR PROMs" scores were taken as the 0.5% and 99.5% quantiles, to eliminate data-entry outliers.

## Disclaimer

### Disclaimer

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## Appendix A: Component List

Catalogue Number	Description	Number Implanted
PHAE5502	PROFEMUR L Classic Extended Offset Fixed NECK Size 1	32
PHAE5504	PROFEMUR L Classic Extended Offset Fixed NECK Size 2	25
PHAE5506	PROFEMUR L Classic Extended Offset Fixed NECK Size 3	68
PHAE5508	PROFEMUR L Classic Extended Offset Fixed NECK Size 4	87
PHAE5510	PROFEMUR L Classic Extended Offset Fixed NECK Size 5	94
PHAE5512	PROFEMUR L Classic Extended Offset Fixed NECK Size 6	62
PHAE5514	PROFEMUR L Classic Extended Offset Fixed NECK Size 7	32
PHAE5516	PROFEMUR L Classic Extended Offset Fixed NECK Size 8	17
PHAE5518	PROFEMUR L Classic Extended Offset Fixed NECK Size 9	7
PHAE5520	PROFEMUR L Classic Extended Offset Fixed NECK Size 10	1
PHAS5502	PROFEMUR L Classic Fixed NECK Size 1	31
PHAS5504	PROFEMUR L Classic Fixed NECK Size 2	27
PHAS5506	PROFEMUR L Classic Fixed NECK Size 3	38
PHAS5508	PROFEMUR L Classic Fixed NECK Size 4	83
PHAS5510	PROFEMUR L Classic Fixed NECK Size 5	49
PHAS5512	PROFEMUR L Classic Fixed NECK Size 6	48
PHAS5514	PROFEMUR L Classic Fixed NECK Size 7	20
PHAS5516	PROFEMUR L Classic Fixed NECK Size 8	14
PHAS5518	PROFEMUR L Classic Fixed NECK Size 9	6
PHAS5520	PROFEMUR L Classic Fixed NECK Size 10	6

## Appendix A: Component List

Catalogue Number	Description	Number Implanted
2600-0025	TRANSCEND® COCR FEMORAL HEAD 36MM SLT TAPER SHORT NECK	3
2600-0026	TRANSCEND® COCR FEMORAL HEAD 36MM SLT TAPER MEDIUM NECK	3
2600-0027	TRANSCEND® COCR FEMORAL HEAD 36MM SLT TAPER LONG NECK	3
2600-0028	TRANSCEND® COCR FEMORAL HEAD 36MM SLT TAPER X-LONG NECK	3
2601-0007	COCR FEMORAL HEAD 32MM SLT TAPER SHORT NECK	29
2601-0008	COCR FEMORAL HEAD 32MM SLT TAPER MEDIUM NECK	32
2601-0009	COCR FEMORAL HEAD 32MM SLT TAPER LONG NECK	17
2601-0010	COCRFEMORALHEAD32MMSLT TAPERXLONGNECK	4
2601-2801	COCRFEMORALHEAD28MMSLT TAPER3.5MMNECK	3
2601-2802	COCR FEMORAL HEAD28MM SLT TAPER +0MM NECK	5
2601-2803	COCR FEMORAL HEAD28MM SLT TAPER +3.5MM NECK	2
PHA04402	BIOLOX DELTA ceramic head 28mm -3.5mm NECK	8
PHA04404	BIOLOX DELTA ceramic head 28mm 0mm NECK	10
PHA04406	BIOLOX DELTA ceramic head 28mm +3.5mm NECK	3
PHA04408	BIOLOX DELTA ceramic head 32mm -4mm NECK	86
PHA04410	BIOLOX DELTA ceramic head 32mm 0mm NECK	143
PHA04412	BIOLOX DELTA ceramic head 32mm +4mm NECK	85
PHA04413	BIOLOX DELTA ceramic head 32mm X L	2
PHA04414	BIOLOX DELTA ceramic head 36mm -4mm NECK	61
PHA04416	BIOLOX DELTA ceramic head 36mm 0mm NECK	129
PHA04418	BIOLOX DELTA ceramic head 36mm +4mm NECK	104
PHA04419	BIOLOX DELTA ceramic head 36mm XL	5
PHA04420	BIOLOX DELTA ceramic head 40mm -4mm NECK	2
PHA04422	BIOLOX DELTA ceramic head 40mm 0mm NECK	4
PHA04424	BIOLOX DELTA ceramic head 40mm +4mm NECK	1