

## Implant Summary Report for:

Heraeus Medical

### Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to:	01 July 2024
NJR Database extract:	31 July 2024
Produced on:	15 August 2024
Licensed for use until:	15 August 2025

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This report has been produced by the National Joint Registry (NJR). It summarises usage and outcomes associated with the Knees using Palacos Antibiotic Cement 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**

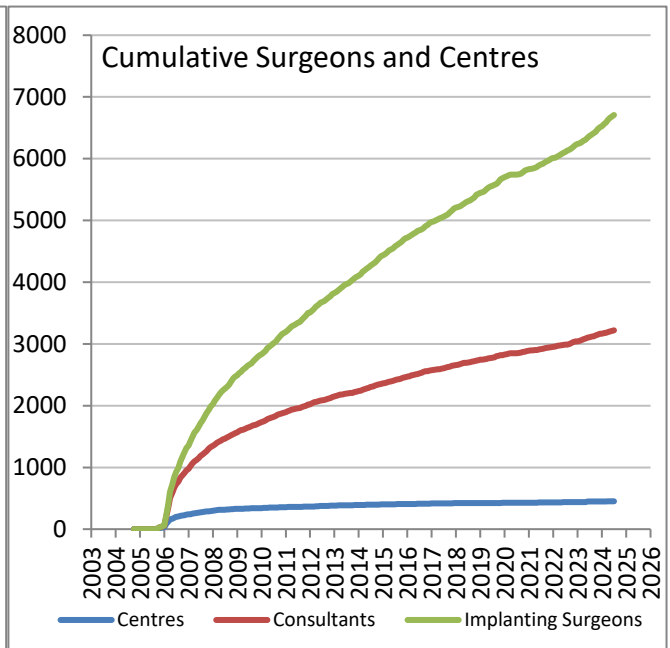
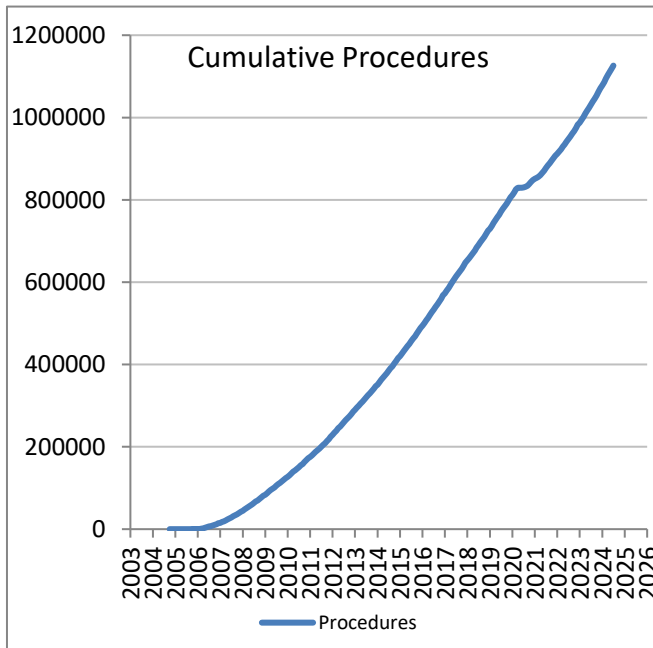
Date of first recorded usage in the NJR: **01 September 2005**

Date of last recorded usage in this dataset: **01 July 2024**

Maximum implantation time: 18.8 years

Mean implantation time: 6.8 years

Totals Recorded in NJR	Cumulative Total
Procedures	1,126,426
Patients	916,553
Centres	451
Consultants	3,221
Implanting Surgeons	6,708



Current Outcome	Year of implantation														Total	%
	Pre-2013	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024			
<b>Death</b>	1E+05	15742	15122	13546	11913	9504	7239	5785	1840	1671	1074	382	26	198172	17.6%	
<b>Revised</b>	13550	2419	2391	2301	2056	1834	1488	1194	493	599	520	365	75	29285	2.6%	
<b>Unrevised</b>	2E+05	43657	51559	58203	64586	68340	68892	74125	37568	58431	74036	89702	48364	898969	79.8%	
<b>Total</b>	<b>3E+05</b>	<b>61818</b>	<b>69072</b>	<b>74050</b>	<b>78555</b>	<b>79678</b>	<b>77619</b>	<b>81104</b>	<b>39901</b>	<b>60701</b>	<b>75630</b>	<b>90449</b>	<b>48465</b>	<b>1126426</b>	<b>100%</b>	

## Patient / Procedure Details

## Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
<b>Total Procedures</b>	1,126,426	479,016
<b>Total Patients</b>	916,553	407,719
<b>Demographics</b>		
Mean age	<b>69.6</b>	<b>69.8</b>
< 50	2.3%	2.6%
50 – 59	13.8%	13.2%
60 – 69	33.0%	32.4%
70 – 79	37.2%	37.6%
≥ 80	13.7%	14.2%
Median BMI	<b>30</b>	<b>30</b>
% BMI information available	73.9%	58.6%
Underweight ( BMI < 18.5)	0.2%	0.2%
Normal (18.5 ≤ BMI < 25)	10.3%	11.1%
Overweight (25 ≤ BMI < 30)	34.1%	34.7%
Obese I (30 ≤ BMI < 35)	32.5%	31.4%
Obese II (35 ≤ BMI < 40)	16.4%	16.0%
Obese III (BMI ≥ 40)	6.4%	6.5%
% Male	43.5%	42.9%
<b>ASA Grades</b>		
P1 - Fit and healthy	8.9%	12.3%
P2 - Mild disease not incapacitating	72.9%	70.4%
P3 - Incapacitating systemic disease	17.9%	16.9%
P4 / P5	0.3%	0.4%
<b>Indications</b>		
Osteoarthritis	97.67%	97.01%
Rheumatoid Arthritis	1.18%	1.68%
Other Inflammatory Arthropathy	0.72%	0.67%
Previous Trauma	0.58%	0.69%
Avascular Necrosis	0.38%	0.39%
Other	0.37%	0.53%

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	6420	6534.00	0.014
Progressive Arthritis Remaining	4975	5188.22	<0.001
Aseptic Loosening Femur	2569	2682.75	0.001
Aseptic Loosening Tibia	5364	5365.53	0.975
Aseptic Loosening Patella	861	865.44	0.804
Unexplained Pain	3511	3572.26	0.11
Stiffness	1860	1875.14	0.551
Malalignment	1970	2035.06	0.018
Instability	4205	4306.27	0.011
Dislocation / Subluxation	925	972.41	0.015
Periprosthetic Fracture	1387	1406.28	0.404
Wear of Polyethylene Component	1367	1500.43	<0.001
Lysis - Tibia	1256	1285.23	0.215
Lysis - Femur	763	815.94	0.006
Component Dissociation	324	345.63	0.073
Implant Fracture	173	177.78	0.609
Other / Not recorded	1846	1850.04	0.882
<b>Total Revised</b>	<b>29285</b>	<b>29875.35</b>	<b>&lt;0.001</b>

† multiple reasons may be listed for one revision procedure

\* Based on All NJR Knees with Cement, 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

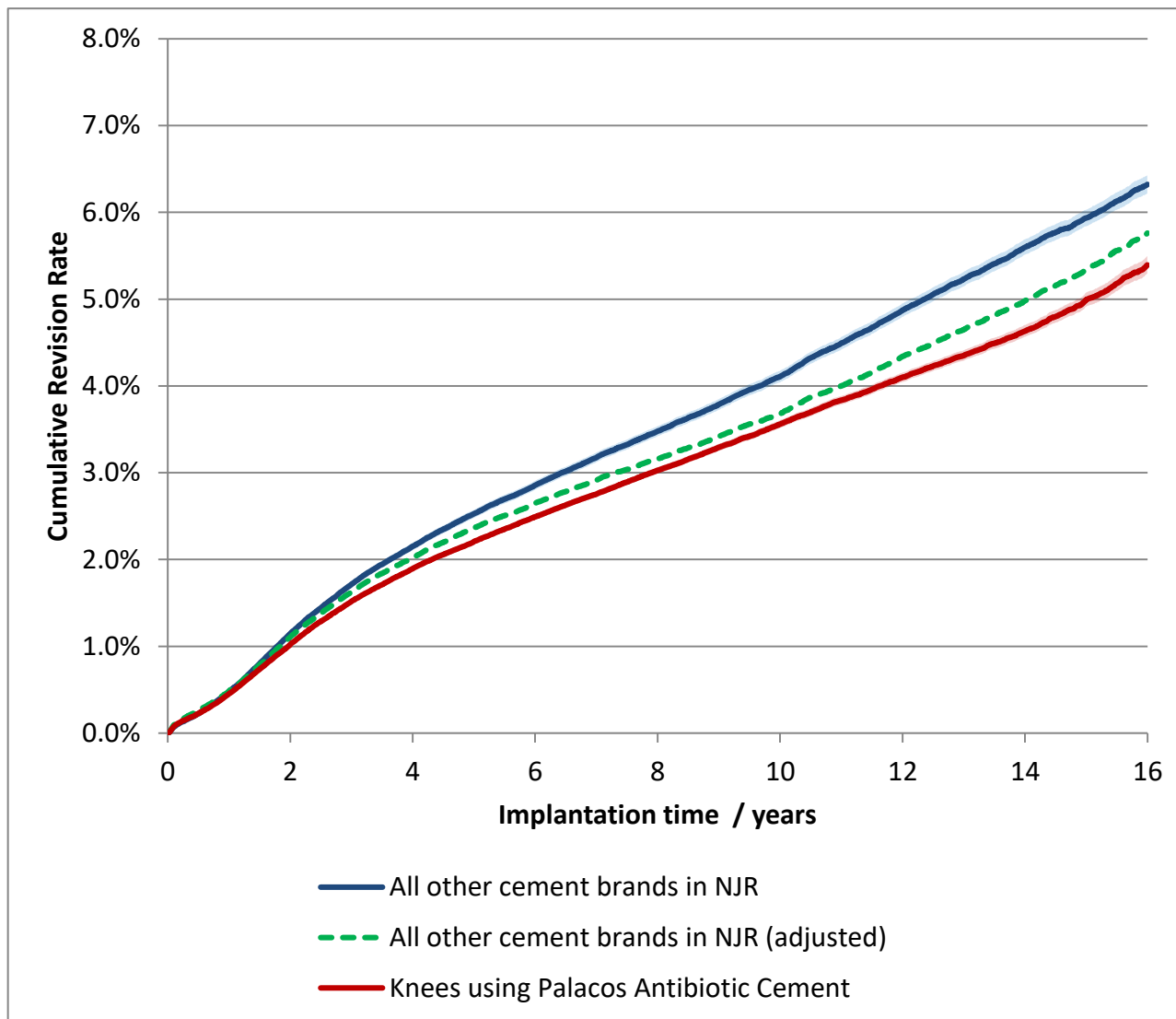


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	21065	71.9%	79.8%
Isolated bearing exchange	4208	14.4%	10.0%
Patella revision / resurfacing only	3737	12.8%	9.5%
No component revision recorded	275	0.9%	0.7%

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision



Cox Proportional Hazards model for revision risk ratio of Knees using Palacos Antibiotic Cement / All other cement brands in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Unadjusted.	0.86 ‡ (0.84 - 0.87)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	0.94 (0.92 - 0.96)	<0.001

‡ Hazard ratio varies with time

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	At Risk	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
0	1126426	-	-
1	1017725	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	918571	1.0% (1.0% - 1.0%)	1.1% (1.1% - 1.2%)
3	831770	1.5% (1.5% - 1.5%)	1.7% (1.7% - 1.8%)
4	767183	1.9% (1.9% - 1.9%)	2.2% (2.1% - 2.2%)
5	692829	2.2% (2.2% - 2.2%)	2.5% (2.5% - 2.6%)
6	599971	2.5% (2.5% - 2.5%)	2.9% (2.8% - 2.9%)
7	513543	2.8% (2.7% - 2.8%)	3.2% (3.1% - 3.2%)
8	427558	3.0% (3.0% - 3.1%)	3.5% (3.4% - 3.5%)
9	348847	3.3% (3.3% - 3.3%)	3.8% (3.7% - 3.8%)
10	278551	3.6% (3.5% - 3.6%)	4.1% (4.0% - 4.2%)
11	218515	3.8% (3.8% - 3.9%)	4.5% (4.4% - 4.6%)
12	166217	4.1% (4.0% - 4.2%)	4.9% (4.8% - 5.0%)
13	119496	4.4% (4.3% - 4.4%)	5.2% (5.1% - 5.3%)
14	83294	4.6% (4.6% - 4.7%)	5.6% (5.5% - 5.7%)
15	53469	5.0% (4.9% - 5.1%)	5.9% (5.8% - 6.0%)

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

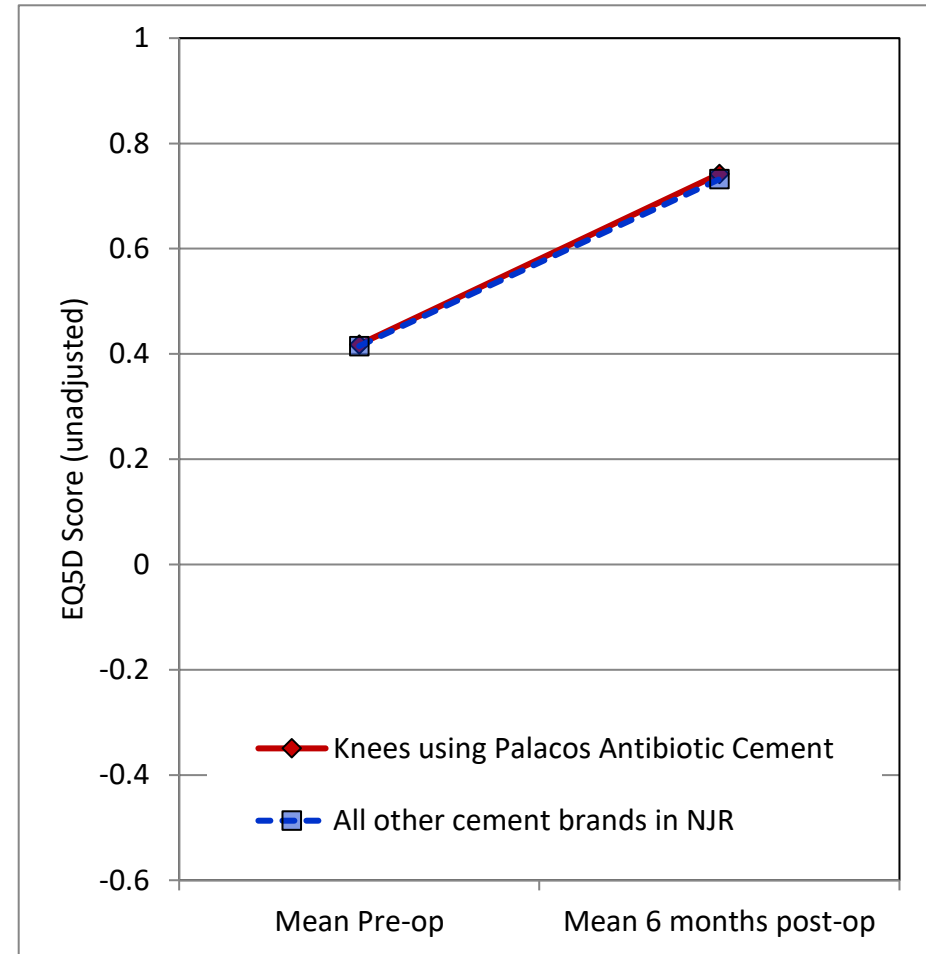
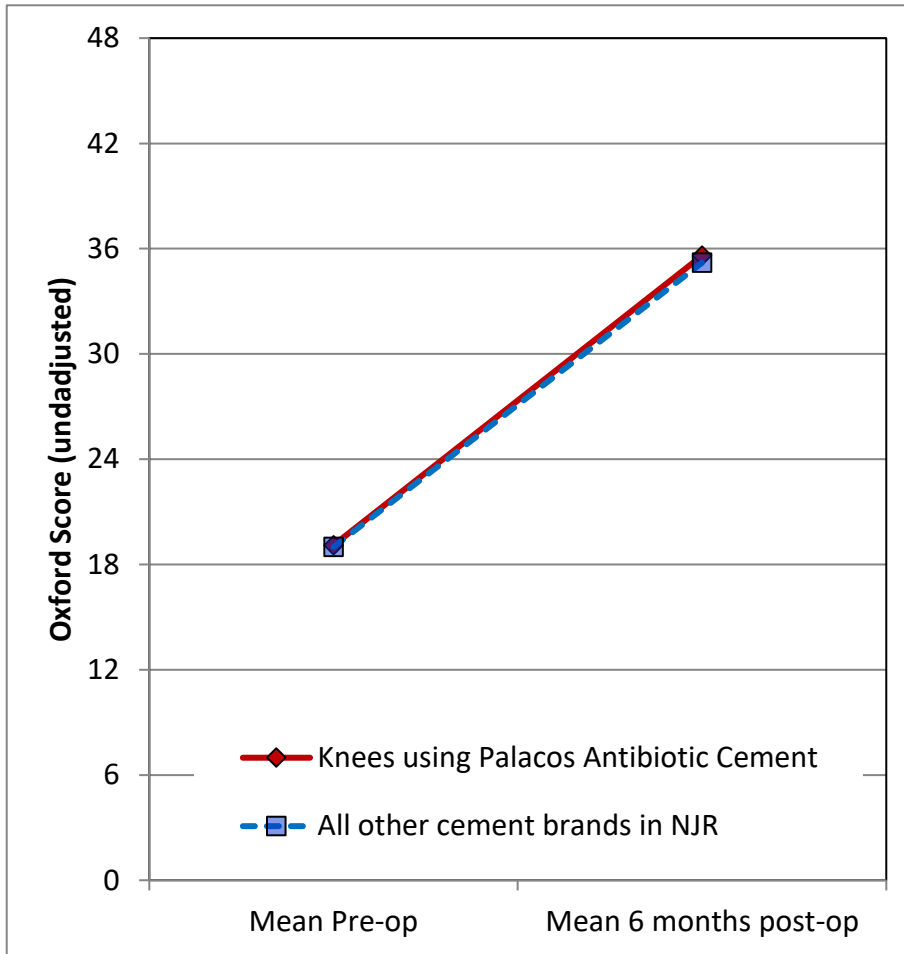
Summary Report for:

Knees using Palacos Antibiotic Cement

## Patient Reported Outcomes

Comprising PROMs data up to and including: 31/03/2022

### PROMs Analysis



## Patient Reported Outcomes

## PROMs Analysis

Comprising PROMs data up to and including: 31/03/2022

Oxford Knee Score (0 - 48)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	282,432	99,631	400,237
PreOp score	19.1 (19.1 - 19.2)	19.0 (19.0 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.6 (35.6 - 35.7)	35.2 (35.1 - 35.3)	35.5 (35.5 - 35.6)
6 month score (adjusted)	35.6 (35.6 - 35.6)	35.3 (35.3 - 35.4)	35.5 (35.5 - 35.6)
Health gain	16.5 (16.5 - 16.6)	16.2 (16.1 - 16.2)	16.4 (16.4 - 16.5)
Health gain (adjusted)	16.5 (16.5 - 16.5)	16.2 (16.1 - 16.3)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	< 0.001		
Score Improved	94.1%	93.6%	93.9%

EQ-5D Index (-0.59 - 1.00)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	262,341	92,253	371,558
PreOp score	0.418 (0.417 - 0.419)	0.415 (0.413 - 0.417)	0.418 (0.417 - 0.419)
6 month score	0.742 (0.741 - 0.743)	0.732 (0.730 - 0.734)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.741 (0.740 - 0.742)	0.735 (0.733 - 0.736)	0.739 (0.738 - 0.740)
Health gain	0.324 (0.322 - 0.325)	0.317 (0.315 - 0.319)	0.322 (0.320 - 0.323)
Health gain (adjusted)	0.323 (0.322 - 0.324)	0.317 (0.315 - 0.318)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	< 0.001		
Score Improved	81.6%	80.8%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	250,807	88,749	355,986
PreOp score	67.9 (67.8 - 68.0)	67.9 (67.8 - 68.1)	67.9 (67.9 - 68.0)
6 month score	74.3 (74.2 - 74.4)	73.6 (73.5 - 73.7)	74.1 (74.1 - 74.2)
6 month score (adjusted)	74.3 (74.2 - 74.3)	73.7 (73.6 - 73.9)	74.1 (74.1 - 74.2)
Health gain	6.4 (6.3 - 6.5)	5.6 (5.5 - 5.8)	6.2 (6.1 - 6.3)
Health gain (adjusted)	6.3 (6.3 - 6.4)	5.8 (5.7 - 5.9)	6.2 (6.2 - 6.3)
p value (adjusted health gain)	< 0.001		
Score Improved	57.0%	55.2%	56.5%

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:

Knees using Palacos Antibiotic Cement

Responses are not case mix adjusted

**Patient Reported Outcomes**



**Patient Reported Outcomes**

**Success**

Response	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Much better	216010	76074
A little better	46098	16744
About the same	12959	4709
A little worse	9679	3752
Much worse	6397	2485

Answer to 6-months general health question:

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

**Satisfaction**

Response	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Excellent	76137	26892
Very Good	104281	36689
Good	69553	24966
Fair	31388	11426
Poor	9227	3535

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**

<b>Catalogue Num</b>	<b>Description</b>	<b>Number</b>
Cement		
66017569	PALACOS R +G 2x40 g	918247
66017771	PALACOS R +G 1x40 g	24513
66017772	PALACOS R +G 1x60 g	43687
66017773	PALACOS R +G 2x20 g	39967
66017776	PALACOS R +G 2x10 g	33
66017787	PALACOS LV +G 1x40 g	1869
66031993	PALACOS MV+G 1x40g	450
66031995	PALACOS MV+G 2x40 g	3764
66031996	PALACOS MV+G 1x20g	9
66031998	PALACOS MV+G 2x20 g	36
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	2
66044274	PALACOS R+G Pro 75 cement	12
Multiple Found	Multiple Found	93836