

Implant Summary Report for:

Heraeus Medical

Knees using Palacos Antibiotic Cement

Comprising PRIMARY knees implanted up to:

01 November 2022

NJR Database extract:

31 December 2022

Produced on:

15 February 2023

Licensed for use until:

15 February 2024

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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

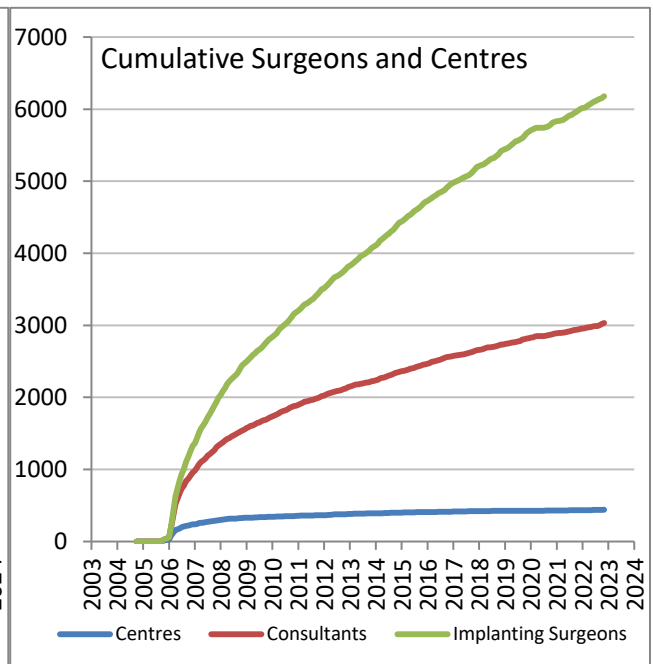
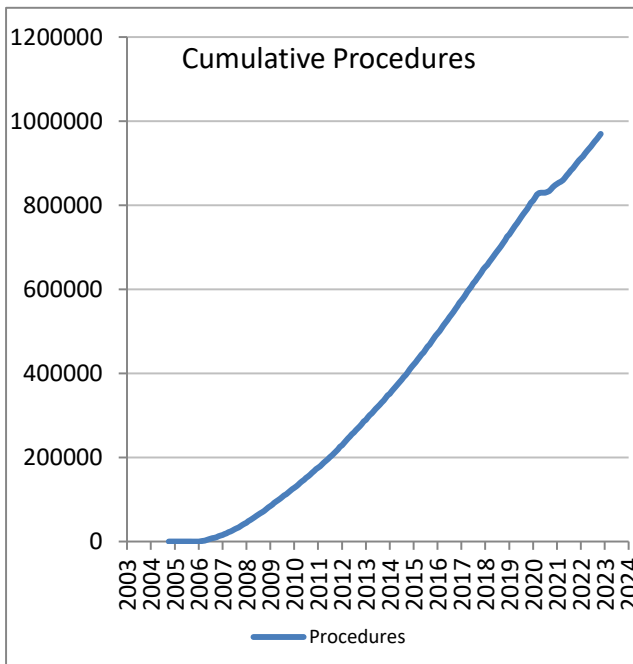
Date of first recorded usage in the NJR: **01 September 2005**

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

Maximum implantation time: 17.2 years

Mean implantation time: 6.4 years

Totals Recorded in NJR	Cumulative Total
Procedures	969,909
Patients	796,606
Centres	441
Consultants	3,033
Implanting Surgeons	6,180



Current Outcome	Year of implantation														Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022			
Death	67408	15075	14588	12332	11573	9926	8324	6214	4427	3245	900	532	116	154660	15.9%	
Revised	8289	2087	2233	2189	2152	2048	1743	1537	1163	864	288	289	114	24996	2.6%	
Unrevised	99533	36502	43857	47262	55329	62055	68453	71875	71960	76830	38521	59437	58639	790253	81.5%	
Total	2E+05	53664	60678	61783	69054	74029	78520	79626	77550	80939	39709	60258	58869	969909	100%	

Patient / Procedure Details

Patient Details

	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Total Procedures	969,909	373,814
Total Patients	796,606	319,915
Demographics		
Mean age	69.6	69.7
< 50	2.4%	2.7%
50 – 59	13.8%	13.3%
60 – 69	33.1%	32.4%
70 – 79	37.0%	37.4%
≥ 80	13.7%	14.2%
Median BMI	30	30
% BMI information available	72.6%	61.8%
Underweight (BMI < 18.5)	0.2%	0.2%
Normal (18.5 ≤ BMI < 25)	10.2%	10.9%
Overweight (25 ≤ BMI < 30)	34.2%	34.7%
Obese I (30 ≤ BMI < 35)	32.6%	31.5%
Obese II (35 ≤ BMI < 40)	16.3%	16.1%
Obese III (BMI ≥ 40)	6.5%	6.6%
% Male	43.3%	42.8%
ASA Grades		
P1 - Fit and healthy	9.5%	12.0%
P2 - Mild disease not incapacitating	73.0%	70.7%
P3 - Incapacitating systemic disease	17.2%	16.9%
P4 / P5	0.3%	0.4%
Indications		
Osteoarthritis	97.58%	97.06%
Rheumatoid Arthritis	1.24%	1.65%
Other Inflammatory Arthropathy	0.68%	0.65%
Previous Trauma	0.63%	0.75%
Avascular Necrosis	0.39%	0.41%
Other	0.37%	0.47%

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	5428	5543.47	0.005
Progressive Arthritis Remaining	4017	4196.80	<0.001
Aseptic Loosening Femur	2120	2222.04	<0.001
Aseptic Loosening Tibia	4424	4444.63	0.612
Aseptic Loosening Patella	748	752.58	0.775
Unexplained Pain	3292	3329.11	0.278
Stiffness	1646	1660.08	0.534
Malalignment	1743	1792.46	0.042
Instability	3577	3666.60	0.011
Dislocation / Subluxation	758	806.22	0.004
Periprosthetic Fracture	1035	1046.05	0.553
Wear of Polyethylene Component	1031	1105.96	<0.001
Lysis - Tibia	986	1013.19	0.169
Lysis - Femur	599	642.93	0.007
Component Dissociation	283	305.80	0.031
Implant Fracture	133	134.80	0.836
Other / Not recorded	1750	1766.99	0.485
Total Revised	24996	25490.61	<0.001

† 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

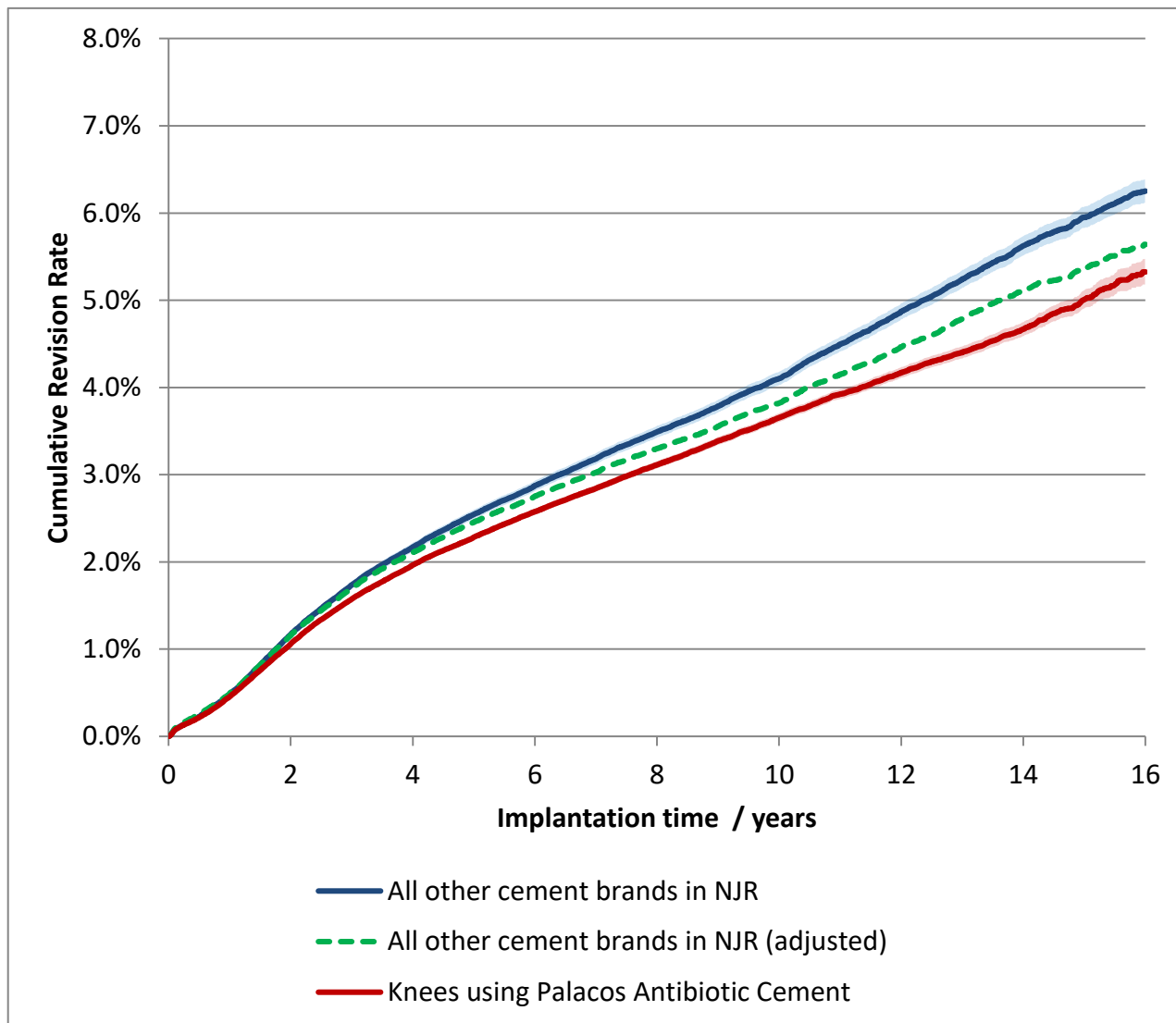


Components Revised	Number of procedures	Knees using Palacos Antibiotic Cement	All other cement brands in NJR
Femoral and/or Tibial Revision	17948	71.8%	78.9%
Isolated bearing exchange	3482	13.9%	10.3%
Patella revision / resurfacing only	3325	13.3%	10.0%
No component revision recorded	241	1.0%	0.7%

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.	0.87 ‡ (0.86 - 0.89)	<0.001 ‡
Adjusted for age, gender, year cohort and indications.	0.93 (0.91 - 0.95)	<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	969909	-	-
1	887889	0.5% (0.4% - 0.5%)	0.5% (0.5% - 0.5%)
2	816421	1.1% (1.0% - 1.1%)	1.2% (1.1% - 1.2%)
3	756450	1.6% (1.5% - 1.6%)	1.7% (1.7% - 1.8%)
4	662624	2.0% (1.9% - 2.0%)	2.2% (2.1% - 2.2%)
5	573885	2.3% (2.3% - 2.3%)	2.5% (2.5% - 2.6%)
6	485443	2.6% (2.5% - 2.6%)	2.9% (2.8% - 2.9%)
7	402220	2.8% (2.8% - 2.9%)	3.2% (3.1% - 3.2%)
8	326933	3.1% (3.1% - 3.2%)	3.5% (3.4% - 3.6%)
9	259853	3.4% (3.3% - 3.4%)	3.8% (3.7% - 3.9%)
10	201825	3.7% (3.6% - 3.7%)	4.1% (4.0% - 4.2%)
11	148859	3.9% (3.9% - 4.0%)	4.5% (4.4% - 4.6%)
12	106670	4.2% (4.1% - 4.2%)	4.9% (4.8% - 5.0%)
13	71232	4.4% (4.3% - 4.5%)	5.2% (5.1% - 5.3%)
14	41854	4.7% (4.6% - 4.7%)	5.6% (5.5% - 5.7%)
15	19577	5.0% (4.9% - 5.1%)	5.9% (5.8% - 6.1%)

Cumulative revision rate with 95% confidence intervals

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

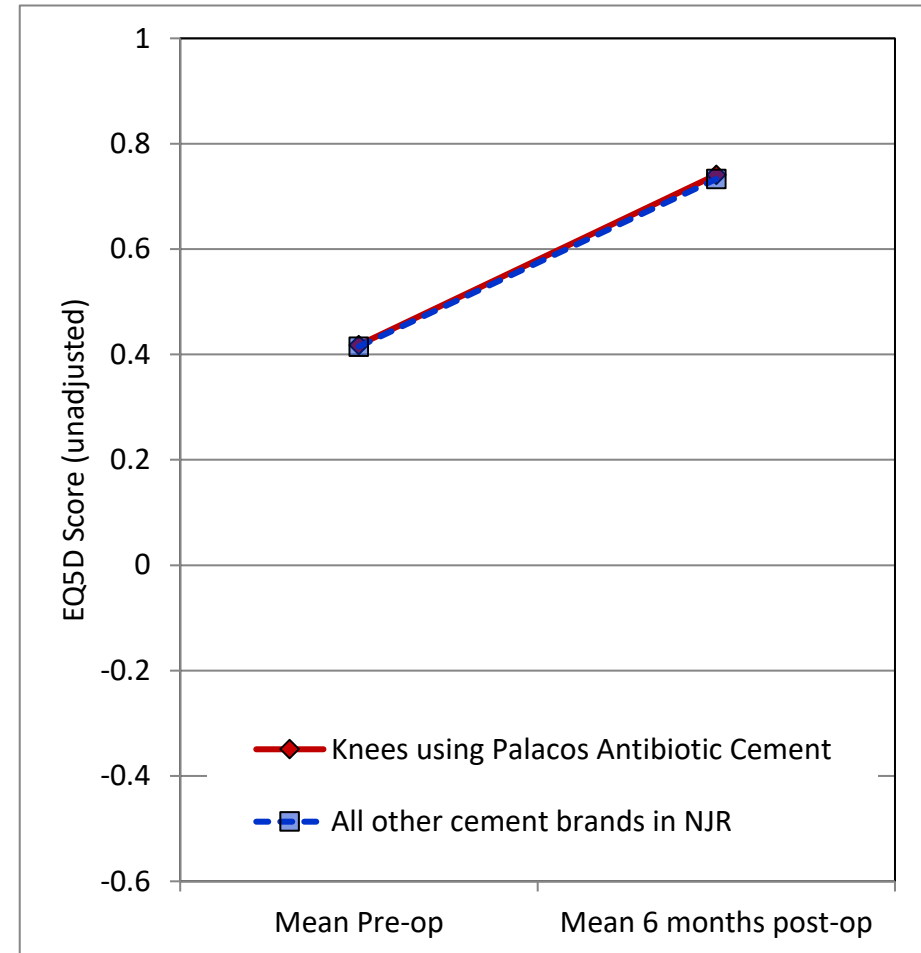
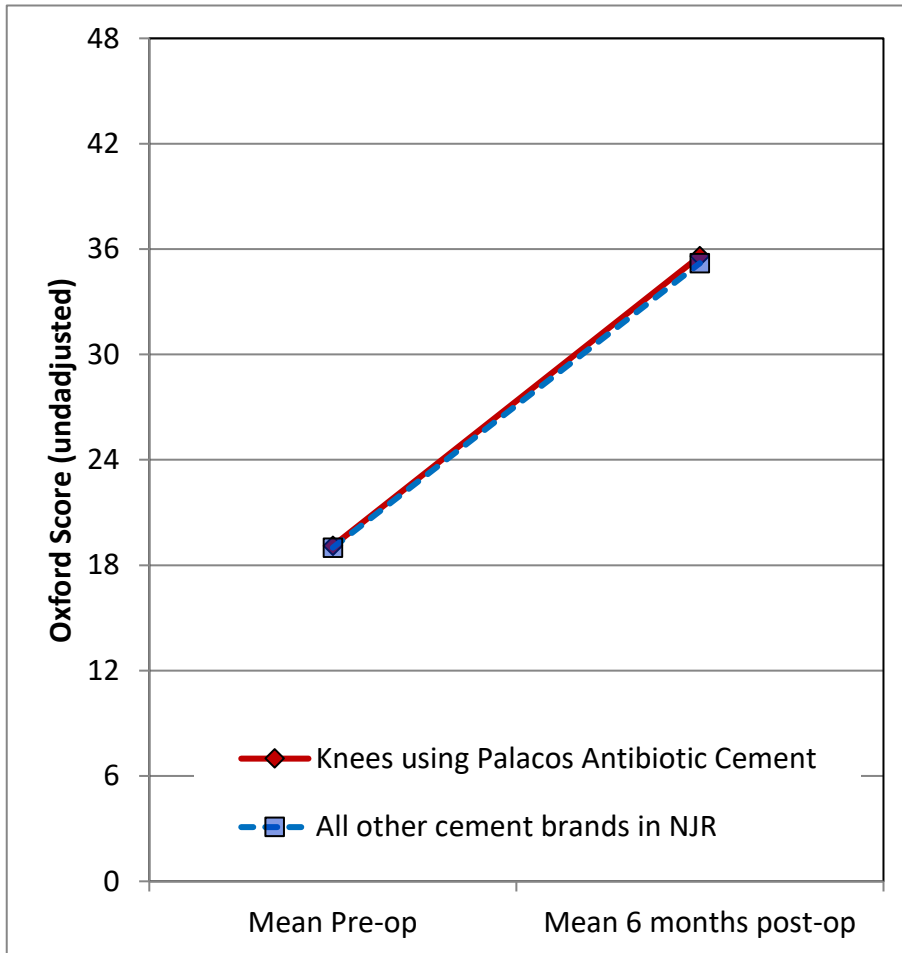
Summary Report for:

Knees using Palacos Antibiotic Cement

Patient Reported Outcomes

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

PROMs Analysis



Patient Reported Outcomes

PROMs Analysis

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

Oxford Knee Score (0 - 48)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	269,018	91,991	382,034
PreOp score	19.1 (19.1 - 19.1)	19.0 (19.0 - 19.1)	19.1 (19.1 - 19.1)
6 month score	35.6 (35.6 - 35.6)	35.2 (35.2 - 35.3)	35.5 (35.5 - 35.5)
6 month score (adjusted)	35.6 (35.5 - 35.6)	35.3 (35.3 - 35.4)	35.5 (35.5 - 35.5)
Health gain	16.5 (16.4 - 16.5)	16.2 (16.1 - 16.3)	16.4 (16.4 - 16.4)
Health gain (adjusted)	16.5 (16.4 - 16.5)	16.2 (16.2 - 16.3)	16.4 (16.4 - 16.4)
p value (adjusted health gain)	< 0.001		
Score Improved	94.1%	93.7%	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	249,774	85,161	354,535
PreOp score	0.418 (0.416 - 0.419)	0.415 (0.413 - 0.417)	0.417 (0.416 - 0.418)
6 month score	0.741 (0.740 - 0.742)	0.733 (0.731 - 0.735)	0.739 (0.738 - 0.740)
6 month score (adjusted)	0.741 (0.740 - 0.742)	0.735 (0.734 - 0.737)	0.739 (0.738 - 0.740)
Health gain	0.324 (0.323 - 0.325)	0.318 (0.316 - 0.320)	0.322 (0.321 - 0.323)
Health gain (adjusted)	0.323 (0.323 - 0.324)	0.318 (0.316 - 0.320)	0.322 (0.321 - 0.322)
p value (adjusted health gain)	< 0.001		
Score Improved	81.6%	80.9%	81.4%

EQ-VAS (0 - 100)	Knees using Palacos Antibiotic Cement	All other cement brands in NJR	All Knees in NJR
Paired Records	239,141	81,995	340,143
PreOp score	68.0 (67.9 - 68.0)	68.0 (67.9 - 68.2)	68.0 (67.9 - 68.1)
6 month score	74.3 (74.2 - 74.4)	73.7 (73.6 - 73.8)	74.1 (74.1 - 74.2)
6 month score (adjusted)	74.3 (74.2 - 74.3)	73.8 (73.7 - 74.0)	74.1 (74.1 - 74.2)
Health gain	6.3 (6.3 - 6.4)	5.7 (5.6 - 5.8)	6.2 (6.1 - 6.2)
Health gain (adjusted)	6.3 (6.2 - 6.4)	5.9 (5.7 - 6.0)	6.2 (6.1 - 6.2)
p value (adjusted health gain)	< 0.001		
Score Improved	56.9%	55.3%	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:

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	204583	69513
A little better	43739	15261
About the same	12296	4291
A little worse	9182	3376
Much worse	6037	2242

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	71789	24653
Very Good	99000	33494
Good	66077	22731
Fair	29737	10341
Poor	8712	3220

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
Cement		
66017569	PALACOS R +G 2x40 g	786707
66017771	PALACOS R +G 1x40 g	22333
66017772	PALACOS R +G 1x60 g	36385
66017773	PALACOS R +G 2x20 g	36025
66017776	PALACOS R +G 2x10 g	32
66017787	PALACOS LV +G 1x40 g	1847
66031993	PALACOS MV+G 1x40g	341
66031995	PALACOS MV+G 2x40 g	2863
66031996	PALACOS MV+G 1x20g	7
66031998	PALACOS MV+G 2x20 g	32
66032000	PALACOS MV+G 1x60 g	1
66037894	PALACOS LV+G 1x20g	2
66044274	PALACOS R+G Pro 75 cement	2
Multiple Found	Multiple Found	83332