

Implant Summary Report for: Smith & Nephew

Polarstem Cementless

Comprising PRIMARY hips implanted up to: 09 September 2018

NJR Database extract: 08 November 2018

Produced on: 20 November 2018

Licenced for use until: 20 March 2019

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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 the Polarstem Cementless up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for thefollowing combinations of products:

Femoral components Polarstem Cementless

Acetabular Components Any Acetabular Components manufactured by Smith & Nephew

Appendix A lists details of all Polarstem Cementless components included in this report.

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NJR Recorded Usage

Implant Usage

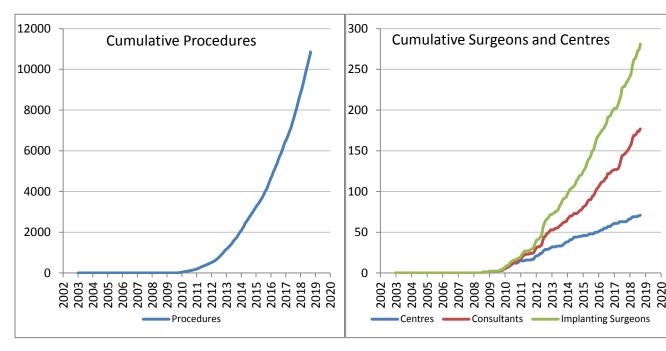
Date of first recorded usage in the NJR: 13 July 2008

Date of last recorded usage in this dataset: 08 September 2018

Maximum implantation time: 10.2 years

Mean implantation time: 2.6 years

Totals Recorded in NJR	Cumulative Total
Procedures	10,854
Patients	9,967
Centres	71
Consultants	177
Implanting Surgeons	281



	Year of implantation														
Current Outcome	Pre- 2007	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	Total	%
Death	0	0	0	9	31	43	63	64	56	35	35	22	5	363	3.3%
Revised	0	0	0	0	0	4	8	7	14	22	13	16	9	93	0.9%
Unrevised	0	0	2	24	124	276	580	844	1092	1354	1794	2280	2028	10398	95.8%
Total	0	0	2	33	155	323	651	915	1162	1411	1842	2318	2042	10854	100%

Patient / Procedure Details

Patient Details

	Polarstem Cementless	All NJR Cementless Stems	All NJR hip replacement
Total Procedures	10,854	435,844	1,070,534
Total Patients	9,967	378,629	912,154
Demographics			
Mean age	65.6	65.4	68.6
< 50	8.3%	8.4%	6.0%
50 – 59	18.5%	18.9%	13.7%
60 – 69	34.1%	35.0%	29.2%
70 – 79	30.6%	28.5%	34.6%
≥ 80	8.5%	9.3%	16.4%
Median BMI	29	28	28
% BMI information available	79.6%	62.1%	59.7%
Underweight (BMI < 18.5)	0.6%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	17.4%	18.9%	20.8%
Overweight (25 ≤ BMI < 30)	39.9%	39.2%	39.7%
Obese I (30 ≤ BMI < 35)	27.5%	26.8%	25.7%
Obese II (35 ≤ BMI < 40)	11.3%	10.7%	9.6%
Obese III (BMI ≥ 40)	3.3%	3.7%	3.3%
% Male	45.8%	44.1%	40.2%
ASA Grades			
P1 - Fit and healthy	15.0%	18.5%	16.3%
P2 - Mild disease not incapacitating	68.8%	68.7%	67.6%
P3 - Incapacitating systemic disease	15.9%	12.4%	15.6%
P4 / P5	0.3%	0.4%	0.6%
Indications			
Osteoarthritis	93.15%	93.04%	91.72%
Rheumatoid Arthritis	1.99%	1.22%	1.32%
Avascular Necrosis	2.09%	2.59%	2.51%
Fractured Neck of Femur	2.11%	1.82%	3.20%
CDH/DDH	1.78%	2.02%	1.55%
Other	1.10%	1.82%	2.13%

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



Reasons for Revision - All bearing types

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	13	26.03	0.007
Dislocation / Subluxation	23	35.27	0.034
Adverse Soft Tissue Reaction	3	16.82	<0.001
Infection	22	29.06	0.223
Aseptic Loosening - Stem	9	27.45	<0.001
Aseptic Loosening - Socket	5	15.21	0.004
Periprosthetic Fracture Stem	24	24.53	1
Periprosthetic Fracture Socket	1	3.47	0.273
Malalignment Stem	1	6.92	0.019
Malalignment Socket	1	11.03	<0.001
Wear Of Acetabular Component	5	6.37	0.84
Lysis Stem	1	2.94	0.381
Lysis Socket	1	2.47	0.528
Implant Fracture Stem	3	2.52	0.743
Implant Fracture Socket	0	3.53	0.055
Implant Fracture Head	0	0.76	1
Dissociation of Liner	1	3.74	0.195
Other / reason not recorded	5	11.80	0.04
Total Revised	93	181.66	<0.001

[†] multiple reasons may be listed for one revision procedure

Significantly better, p < 0.001Significantly better, p < 0.05Significantly worse p < 0.05Significantly worse p < 0.001



Components Revised	Number of procedures	Polarstem Cementless	All other Cementless Stems in NJR
Femoral only	37	40%	22%
Acetabular only	11	12%	34%
Both femoral and acetabular	24	26%	32%
Neither femoral nor acetabular revision recorded *	21	23%	11%

^{*} includes isolated head and/or liner exchange



^{*} Based on All NJR Cementless Stems adjusted for agegroup, gender, and indications

Reasons for Revision - excluding Metal on Metal

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

Reason for Revision	Revised [†]	Expected Revisions [*]	p value
Unexplained Pain	13	18.58	0.24
Dislocation / Subluxation	23	34.97	0.04
Adverse Soft Tissue Reaction	3	4.11	0.804
Infection	22	27.65	0.336
Aseptic Loosening - Stem	9	25.62	<0.001
Aseptic Loosening - Socket	5	11.90	0.04
Periprosthetic Fracture Stem	24	24.53	1
Periprosthetic Fracture Socket	1	3.45	0.273
Malalignment Stem	1	6.61	0.017
Malalignment Socket	1	10.10	<0.001
Wear Of Acetabular Component	5	5.92	1
Lysis Stem	1	2.09	0.729
Lysis Socket	1	1.46	1
Implant Fracture Stem	3	2.39	0.518
Implant Fracture Socket	0	3.75	0.059
Implant Fracture Head	0	0.83	1
Dissociation of Liner	1	3.82	0.195
Other / reason not recorded	5	9.29	0.184
Total Revised	93	158.23	<0.001

[†] multiple reasons may be listed for one revision procedure

Significantly better, p < 0.001Significantly better, p < 0.05Significantly worse p < 0.05Significantly worse p < 0.001

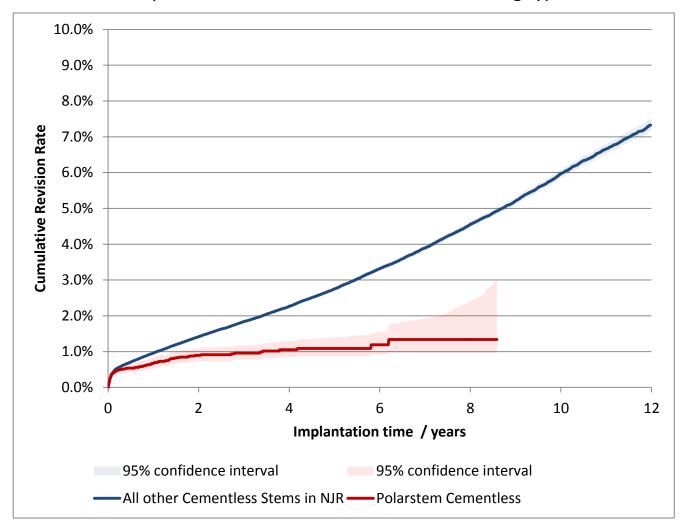


Components Revised	Number of procedures	Polarstem Cementless	All other Cementless Stems in NJR
Femoral only	37	40%	30%
Acetabular only	11	12%	26%
Both femoral and acetabular	24	26%	32%
Neither femoral nor acetabular revision recorded *	21	23%	12%

^{*} Based on All NJR Cementless Stems (excluding metal on metal), adjusted for agegroup, gender, and indications

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types

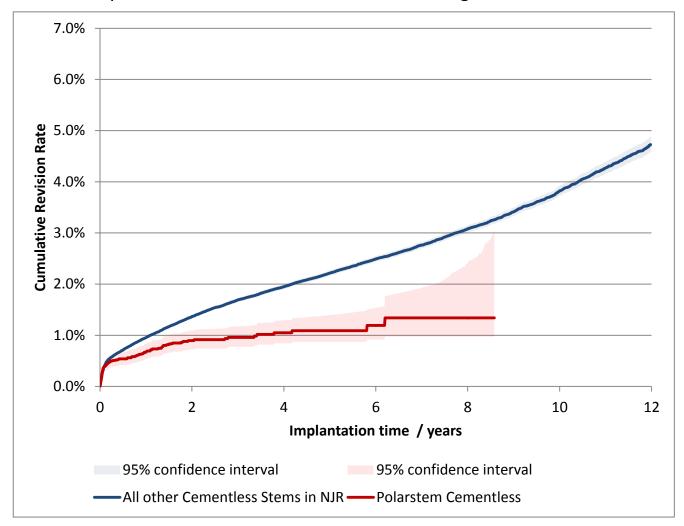


Cox Proportional Hazards model for revision risk ratio of Polarstem Cementless / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.50 (0.41 - 0.62)	<0.001
All bearings. Adjusted for age, gender, year cohort and indications.	0.64 (0.52 - 0.79)	<0.001

Cumulative Revision Rate

Endpoint: All reasons for revision. Excluding Metal-on-Metal

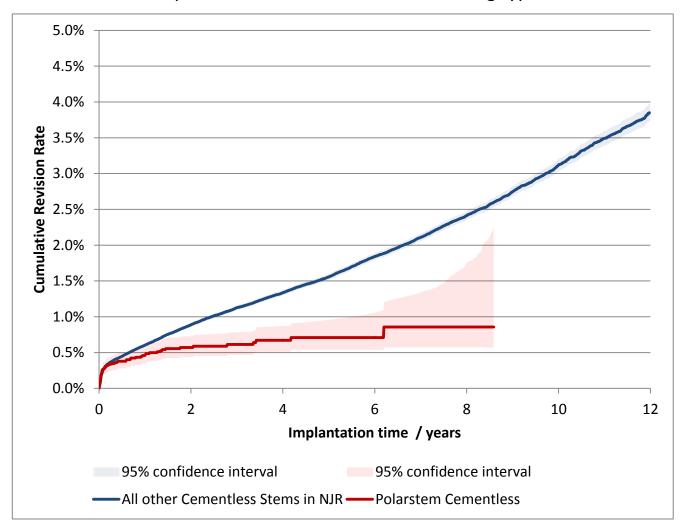


Cox Proportional Hazards model for revision risk ratio of Polarstem Cementless / All other Cementless Stems in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	<i>p</i> -value
Excluding MoM, Unadjusted.	0.58 (0.47 - 0.71)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.65 (0.53 - 0.80)	<0.001

Cumulative Revision Rate

Endpoint: Femoral Revision. All Bearing types

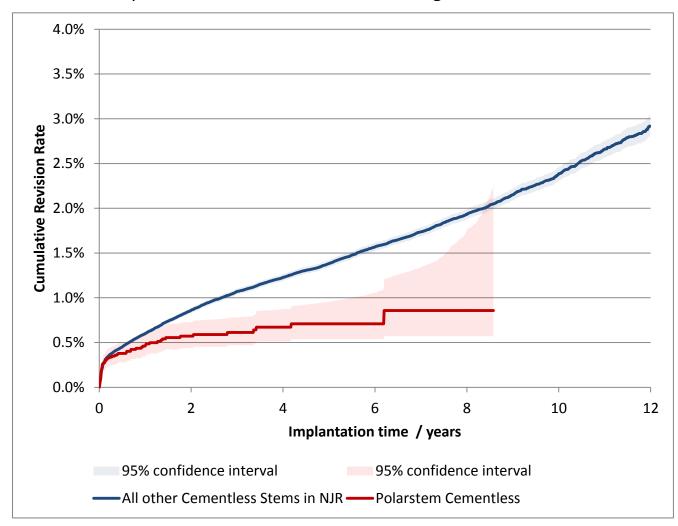


Cox Proportional Hazards model for revision risk ratio of Polarstem Cementless / all other All other Cementless Stems in NJR, with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	<i>p</i> -value
All bearings. Unadjusted.	0.56 (0.43 - 0.72)	<0.001
All bearings. Adjusted for age, gender, year cohort and indications.	0.67 (0.52 - 0.86)	0.002

Cumulative Revision Rate

Endpoint: Femoral Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Polarstem Cementless / All other Cementless Stems in NJR, with endpoint as Femoral revision.

Adjustment	Hazard Ratio (95% CI)	<i>p</i> -value
Excluding MoM, Unadjusted	0.61 (0.47 - 0.78)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.67 (0.52 - 0.87)	0.002

Summary Report for: Polarstem Cementless

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

	All Bearing types				Excluding Metal on Metal Bearings			
Period /years	At Risk	Polarstem Cementless	All NJR Cementless Stems	All THR	At Risk	Polarstem Cementless	All NJR Cementless Stems	All THR
0	10,854	-	-	-	10,852	-	-	-
1	7,851	0.7% (0.5% - 0.8%)	1.0% (0.9% - 1.0%)	0.8% (0.8% - 0.8%)	7,850	0.7% (0.5% - 0.8%)	0.9% (0.9% - 1.0%)	0.8% (0.7% - 0.8%)
2	5,715	0.9% (0.7% - 1.1%)	1.4% (1.4% - 1.4%)	1.2% (1.1% - 1.2%)	5,714	0.9% (0.7% - 1.1%)	1.4% (1.3% - 1.4%)	1.1% (1.1% - 1.1%)
3	3,925	1.0% (0.8% - 1.2%)	1.8% (1.8% - 1.9%)	1.5% (1.5% - 1.5%)	3,924	1.0% (0.8% - 1.2%)	1.7% (1.6% - 1.7%)	1.4% (1.4% - 1.4%)
4	2,728	1.1% (0.8% - 1.3%)	2.2% (2.2% - 2.3%)	1.9% (1.9% - 1.9%)	2,727	1.1% (0.8% - 1.3%)	1.9% (1.9% - 2.0%)	1.6% (1.6% - 1.6%)
5	1,595	1.1% (0.9% - 1.4%)	2.7% (2.7% - 2.8%)	2.3% (2.3% - 2.3%)	1,594	1.1% (0.9% - 1.4%)	2.2% (2.1% - 2.2%)	1.9% (1.8% - 1.9%)
6	817	1.2% (0.9% - 1.5%)	3.3% (3.2% - 3.4%)	2.7% (2.7% - 2.8%)	816	1.2% (0.9% - 1.5%)	2.5% (2.4% - 2.5%)	2.1% (2.1% - 2.2%)
7	348	1.3% (1.0% - 1.9%)	3.9% (3.8% - 3.9%)	3.2% (3.2% - 3.3%)	347	1.3% (1.0% - 1.9%)	2.7% (2.7% - 2.8%)	2.4% (2.3% - 2.4%)
8	105	1.3% (1.0% - 2.4%)	4.5% (4.4% - 4.6%)	3.7% (3.7% - 3.8%)	104	1.3% (1.0% - 2.4%)	3.1% (3.0% - 3.1%)	2.7% (2.6% - 2.7%)
9		(-)	5.2% (5.1% - 5.3%)	4.3% (4.2% - 4.3%)		(-)	3.4% (3.3% - 3.5%)	3.0% (3.0% - 3.1%)
10		(-)	5.9% (5.8% - 6.1%)	4.8% (4.8% - 4.9%)		(-)	3.8% (3.7% - 3.9%)	3.4% (3.3% - 3.4%)
11		(-)	6.6% (6.5% - 6.8%)	5.4% (5.3% - 5.5%)		(-)	4.2% (4.1% - 4.4%)	3.8% (3.8% - 3.9%)
12		(-)	7.3% (7.1% - 7.5%)	6.0% (5.9% - 6.1%)		(-)	4.7% (4.6% - 4.9%)	4.3% (4.2% - 4.4%)
13		(-)	7.9% (7.7% - 8.1%)	6.6% (6.5% - 6.7%)		(-)	5.3% (5.1% - 5.5%)	4.8% (4.7% - 4.9%)
14		(-)	8.6% (8.3% - 8.9%)	7.2% (7.0% - 7.3%)		(-)	5.9% (5.6% - 6.2%)	5.2% (5.1% - 5.4%)
15		(-)	(-)	7.9% (7.6% - 8.1%)		(-)	(-)	6.0% (5.7% - 6.2%)

Cumulative revision rate with 95% confidence intervals

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



Summary Report for: Polarstem Cementless

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Femoral Revision

	All Bearing types				Excluding Metal on Metal Bearings			
Period /years	At Risk	Polarstem Cementless	All NJR Cementless Stems	All THR	At Risk	Polarstem Cementless	All NJR Cementless Stems	All THR
0	10,854	-	-	-	10,852	-	-	-
1	7,851	0.5% (0.3% - 0.6%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)	7,850	0.5% (0.3% - 0.6%)	0.6% (0.6% - 0.6%)	0.5% (0.5% - 0.5%)
2	5,715	0.6% (0.4% - 0.7%)	0.9% (0.9% - 0.9%)	0.8% (0.7% - 0.8%)	5,714	0.6% (0.4% - 0.7%)	0.9% (0.8% - 0.9%)	0.7% (0.7% - 0.7%)
3	3,925	0.6% (0.5% - 0.8%)	1.1% (1.1% - 1.2%)	1.0% (1.0% - 1.0%)	3,924	0.6% (0.5% - 0.8%)	1.1% (1.0% - 1.1%)	0.9% (0.9% - 0.9%)
4	2,728	0.7% (0.5% - 0.9%)	1.3% (1.3% - 1.4%)	1.2% (1.2% - 1.3%)	2,727	0.7% (0.5% - 0.9%)	1.2% (1.2% - 1.3%)	1.0% (1.0% - 1.1%)
5	1,595	0.7% (0.5% - 1.0%)	1.5% (1.5% - 1.6%)	1.5% (1.5% - 1.5%)	1,594	0.7% (0.5% - 1.0%)	1.4% (1.3% - 1.4%)	1.2% (1.2% - 1.2%)
6	817	0.7% (0.5% - 1.1%)	1.8% (1.8% - 1.9%)	1.8% (1.8% - 1.8%)	816	0.7% (0.5% - 1.1%)	1.6% (1.5% - 1.6%)	1.4% (1.4% - 1.4%)
7	348	0.9% (0.6% - 1.3%)	2.1% (2.0% - 2.1%)	2.1% (2.1% - 2.1%)	347	0.9% (0.6% - 1.3%)	1.7% (1.7% - 1.8%)	1.6% (1.5% - 1.6%)
8	105	0.9% (0.6% - 1.7%)	2.4% (2.3% - 2.5%)	2.4% (2.4% - 2.5%)	104	0.9% (0.6% - 1.7%)	1.9% (1.9% - 2.0%)	1.8% (1.7% - 1.8%)
9		(-)	2.7% (2.7% - 2.8%)	2.8% (2.8% - 2.9%)		(-)	2.1% (2.1% - 2.2%)	2.0% (2.0% - 2.1%)
10		(-)	3.1% (3.0% - 3.2%)	3.2% (3.1% - 3.2%)		(-)	2.4% (2.3% - 2.4%)	2.3% (2.2% - 2.3%)
11		(-)	3.5% (3.4% - 3.6%)	3.6% (3.5% - 3.7%)		(-)	2.6% (2.6% - 2.7%)	2.6% (2.5% - 2.6%)
12		(-)	3.8% (3.7% - 4.0%)	4.0% (4.0% - 4.1%)		(-)	2.9% (2.8% - 3.0%)	2.9% (2.8% - 2.9%)
13		(-)	4.2% (4.1% - 4.4%)	4.5% (4.4% - 4.5%)		(-)	3.3% (3.1% - 3.4%)	3.2% (3.1% - 3.3%)
14		(-)	4.5% (4.3% - 4.7%)	4.9% (4.7% - 5.0%)		(-)	3.5% (3.3% - 3.7%)	3.5% (3.4% - 3.6%)
15		(-)	(-)	5.3% (5.2% - 5.5%)		(-)	(-)	4.0% (3.8% - 4.2%)

Cumulative revision rate with 95% confidence intervals

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



Patient Reported Outcomes

PROMs Analysis

Comprising PROMs data up to and including: 31/12/2016

Oxford Hip Score (0 - 48)	Polarstem Cementless	All NJR Cementless Stems	All THR in NJR
Paired Records	2,366	111,055	247,104
PreOp score	18.1 (17.8 - 18.4)	18.5 (18.5 - 18.6)	18.1 (18.1 - 18.1)
6 month score	40.9 (40.6 - 41.2)	39.7 (39.7 - 39.8)	39.2 (39.2 - 39.3)
6 month score (adjusted)	40.7 (40.3 - 41.0)	39.3 (39.3 - 39.4)	39.2 (39.2 - 39.3)
Health gain	22.8 (22.4 - 23.2)	21.2 (21.1 - 21.3)	21.1 (21.1 - 21.2)
Health gain (adjusted)	22.6 (22.2 - 22.9)	21.2 (21.2 - 21.3)	21.1 (21.1 - 21.2)
p value (adjusted health gain)	< 0.00)1	
Score Improved	97.5%	97.0%	97.1%

EQ-5D Index (-0.59 - 1.00)	Polarstem Cementless	All NJR Cementless Stems	All THR in NJR
Paired Records	2,204	102,448	226,875
PreOp score	0.368 (0.355 - 0.382)	0.372 (0.370 - 0.374)	0.357 (0.356 - 0.359)
6 month score	0.822 (0.812 - 0.832)	0.798 (0.797 - 0.800)	0.789 (0.788 - 0.790)
6 month score (adjusted)	0.818 (0.809 - 0.827)	0.792 (0.790 - 0.793)	0.789 (0.788 - 0.790)
Health gain	0.453 (0.439 - 0.468)	0.426 (0.424 - 0.428)	0.432 (0.431 - 0.433)
Health gain (adjusted)	0.461 (0.452 - 0.470)	0.434 (0.433 - 0.436)	0.432 (0.431 - 0.433)
p value (adjusted health gain)	< 0.00)1	
Score Improved	91.1%	89.1%	89.2%

EQ-VAS (0 - 100)	Polarstem Cementless	All NJR Cementless Stems	All THR in NJR
Paired Records	2,118	98,610	217,695
PreOp score	65.0 (64.1 - 65.9)	65.6 (65.5 - 65.8)	65.3 (65.2 - 65.4)
6 month score	79.5 (78.8 - 80.3)	77.4 (77.3 - 77.5)	76.6 (76.6 - 76.7)
6 month score (adjusted)	79.2 (78.5 - 79.8)	76.8 (76.7 - 76.9)	76.6 (76.6 - 76.7)
Health gain	14.5 (13.6 - 15.5)	11.7 (11.6 - 11.9)	11.3 (11.2 - 11.4)
Health gain (adjusted)	13.9 (13.2 - 14.5)	11.4 (11.3 - 11.5)	11.3 (11.3 - 11.4)
p value (adjusted health gain)	< 0.00)1	
Score Improved	71.0%	66.1%	65.0%

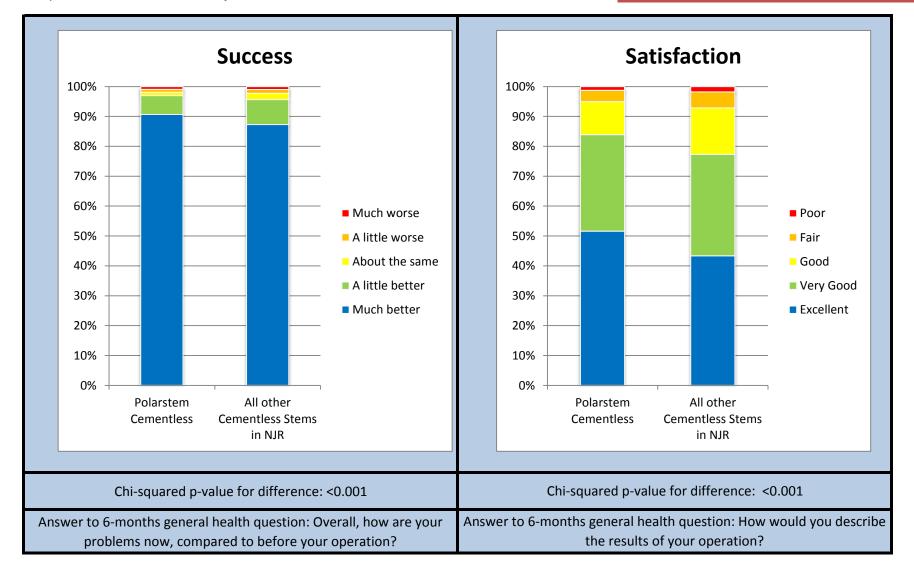
Adjusted scores correspond to the NHS Digital version 3 casemix-adjustment model. This includes patient variables from PROMs, HES, and IMD data.



PMS Report for: Polarstem Cementless

Responses are not case mix adjusted

Patient Reported Outcomes





Summary Report for:

Polarstem Cementless

Disclaimer

Disclaimer

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Appendix A: Component List

Catalogue Number

Description

Number Implanted

11000328	POLARSTEMicementless Standard stem CCD 135 Size 0	1
11000330	standard stem	1
11000331	standard stem	2
11000332	POLARSTEM Stand Offset Ti/HA Stem Sz 4	16
11000334	standard stem	1
11000337	lateral size 1	1
75002069	POLARSTEM cementless standard stem size 0	15
75002070	POLARSTEM cementless standard stem size 1	29
75002071	POLARSTEM cementless standard stem size 2	53
75002072	POLARSTEM cementless standard stem size 3	74
75002073	POLARSTEM cementless standard stem size 4	43
75002074	POLARSTEM cementless standard stem size 5	29
75002075	POLARSTEM cementless standard stem size 6	13
75002076	POLARSTEM cementless standard stem size 7	11
75002077	POLARSTEM cementless standard stem size 8	9
75002078	POLARSTEM cementless lateralised stem size 1	3
75002079	POLARSTEM cementless lateralised stem size 2	1
75002080	POLARSTEM cementless lateralised stem size 3	3
75002081	POLARSTEM cementless lateralised stem size 4	3
75002082	POLARSTEM cementless lateralised stem size 5	4
75002083	POLARSTEM cementless lateralised stem size 6	4
75002084	POLARSTEM cementless lateralised stem size 7	1
75002085	POLARSTEM cementless lateralised stem size 8	1
75002114	POLARSTEM Cementless Stem Std 135 degree Ti.HA Size 3	1
75018112	PLUS POLARSTEM Titanium Stem Std Ti.HA 9	2
75018113	PLUS POLARSTEM Titanium Stem Std Ti.HA10	1
75018399	POLARSTEM Collar standard Ti/HA 01	7
75018400	POLARSTEM Collar standard Ti/HA 0	52
75018401	POLARSTEM Collar standard Ti/HA 1	129
75018402	POLARSTEM Collar standard Ti/HA 2	148
75018403	POLARSTEM Collar standard Ti/HA 3	106
75018404	POLARSTEM Collar standard Ti/HA 4	51
75018405	POLARSTEM Collar standard Ti/HA 5	22
75018406	POLARSTEM Collar standard Ti/HA 6	17
75018407	POLARSTEM Collar standard Ti/HA 7	6
75018408	POLARSTEM Collar standard Ti/HA 8	2
75018409	POLARSTEM Collar standard Ti/HA 9	2
75018412	POLARSTEM Collar lateral Ti/HA 1	25
75018413	POLARSTEM Collar lateral Ti/HA 2	26
75018414	POLARSTEM Collar lateral Ti/HA 3	21
75018415	POLARSTEM Collar lateral Ti/HA 4	13
75018416	POLARSTEM Collar lateral Ti/HA 5	11
75018417	POLARSTEM Collar lateral Ti/HA 6	6
75018418	POLARSTEM Collar lateral Ti/HA 7	3
75100462	Stem Standard with Ti/HA Cone 12/14 Size 01	196
75100463	Smith and Nephew polar stem R stem standard with ti/ha Size 0	637

Appendix A: Component List

Catalogue Number Description

75100464	POLARSTEM Cementless Stem Std Ti.HA 1	1,356
75100465	Smith and Nephew polar stem R stem standard with ti/ha Size 2	1,822
75100466	Smith and Nephew polar stem R stem standard with ti/ha Size 3	1,583
75100467	POLARSTEM Cementless Stem Std Ti.HA 4	885
75100468	POLARSTEM Cementless Stem Std Ti.HA 5	520
75100469	POLARSTEM Cementless Stem Std Ti.HA 6	343
75100470	Smith and Nephew polar stem R stem standard with ti/ha Size 7	198
75100471	Smith and Nephew polar stem R stem standard with ti/ha Size 8	109
75100472	Smith and Nephew polar stem R stem standard with ti/ha Size 9	37
75100473	Smith and Nephew polar stem R stem standard with ti/ha Size 10	7
75100474	POLARSTEM SIZE 1 LATERAL	373
75100475	POLARSTEM SIZE 2 LATERAL	492
75100476	POLARSTEM Cementless Stem Lat Ti.HA 3	517
75100477	POLARSTEM Cementless Stem Lat Ti.HA 4	314
75100478	POLARSTEM LATERAL WITH TI/HA SIZE 5	197
75100479	POLARSTEM lateral with Ti.HA 6	150
75100480	POLARSTEM LATERAL WITH TI/HA	101
75100481	POLARSTEM LATERAL WITH TI/HA SIZE 8 LATERAL	33
75100482	POLARSTEM Cementless Stem Lat Ti.HA 9	14
75102074	POLARSTEM VALGUS TI/HA SIZE 2	1



Number Implanted