

Implant Summary Report for:

Serf

Novae SunFit TH Cup

Comprising PRIMARY hips implanted up to:
NJR Database extract:

02 March 2022
01 May 2022

Produced on:
Licensed for use until:

18 May 2022
18 May 2024

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This report has been produced by the National Joint Registry of England, Wales, Northern Ireland, the Isle of Man and Guernsey (NJR). It summarises usage and outcomes associated with the Novae SunFit TH Cup up to the specified dates. This analysis is based on data collected by the NJR and PROMs data collected by NHS Digital for the following combinations of products:

Acetabular components

Novae SunFit TH Cup

Femoral Component

Any Femoral Component from all manufacturers

Appendix A lists details of all Novae SunFit TH Cup components included in this report.

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NJR Recorded Usage

Implant Usage

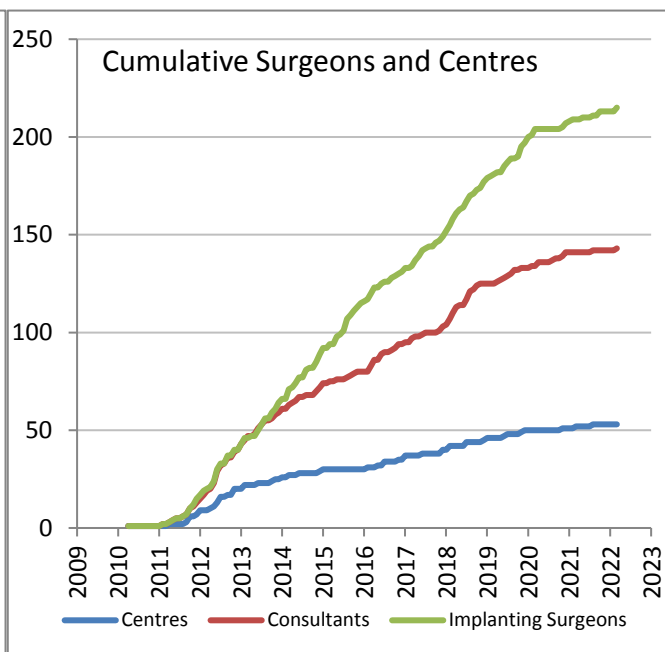
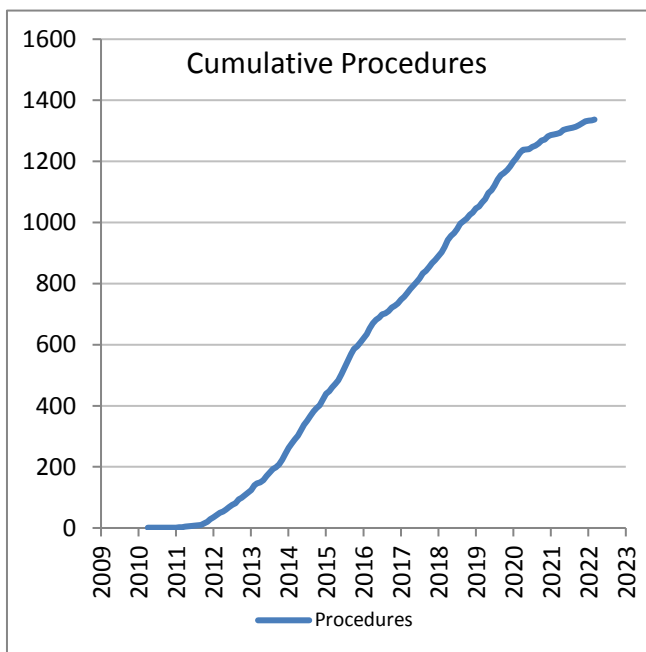
Date of first recorded usage in the NJR: **27 December 2003**

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

Maximum implantation time: 17.0 years

Mean implantation time: 4.5 years

Totals Recorded in NJR	Cumulative Total
Procedures	1,337
Patients	1,299
Centres	53
Consultants	143
Implanting Surgeons	215



Current Outcome	Year of implantation													Total	%
	Pre-2011	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022		
Death	1	19	44	69	73	65	32	33	24	21	4	2	0	387	28.9%
Revised	0	1	5	2	2	8	3	0	0	2	0	1	0	24	1.8%
Unrevised	0	14	40	67	102	109	92	109	131	130	84	44	4	926	69.3%
Total	1	34	89	138	177	182	127	142	155	153	88	47	4	1337	100%

Patient / Procedure Details

Patient Details

	Novae SunFit TH Cup	All other Cementless Cups in NJR	All NJR hip replacement
Total Procedures	1,337	904,055	1,381,725
Total Patients	1,299	764,453	1,157,337
Demographics			
Mean age	73.7	66.2	68.6
< 50	2.9%	8.6%	6.3%
50 – 59	8.2%	18.8%	14.5%
60 – 69	22.1%	32.5%	29.5%
70 – 79	34.4%	29.4%	34.4%
≥ 80	32.4%	10.6%	15.3%
Median BMI	27	28	28
% BMI information available	41.7%	66.0%	63.8%
Underweight (BMI < 18.5)	3.2%	0.7%	0.9%
Normal (18.5 ≤ BMI < 25)	26.2%	20.1%	20.8%
Overweight (25 ≤ BMI < 30)	35.8%	39.3%	39.5%
Obese I (30 ≤ BMI < 35)	23.3%	26.1%	25.8%
Obese II (35 ≤ BMI < 40)	7.5%	10.3%	9.8%
Obese III (BMI ≥ 40)	3.9%	3.5%	3.3%
% Male	34.0%	43.6%	40.2%
ASA Grades			
P1 - Fit and healthy	6.0%	17.6%	15.2%
P2 - Mild disease not incapacitating	54.1%	67.8%	67.7%
P3 - Incapacitating systemic disease	37.8%	14.1%	16.5%
P4 / P5	2.2%	0.4%	0.6%
Indications			
Osteoarthritis	34.18%	91.65%	91.19%
Rheumatoid Arthritis	1.20%	1.27%	1.31%
Avascular Necrosis	2.54%	2.70%	2.57%
Fractured Neck of Femur	55.57%	3.18%	3.79%
CDH/DDH	0.75%	2.07%	1.58%
Other	7.48%	1.92%	2.10%

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 - 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	0	0.95	1
Dislocation / Subluxation	3	8.50	0.057
Adverse Soft Tissue Reaction	0	0.41	1
Infection	5	5.29	1
Aseptic Loosening - Stem	2	2.45	1
Aseptic Loosening - Socket	3	1.71	0.246
Periprosthetic Fracture Stem	11	7.36	0.191
Periprosthetic Fracture Socket	1	1.26	1
Malalignment Stem	1	0.96	0.618
Malalignment Socket	2	1.49	0.665
Wear Of Acetabular Component	1	0.66	0.485
Lysis Stem	1	0.35	0.295
Lysis Socket	0	0.14	1
Implant Fracture Stem	0	0.30	1
Implant Fracture Socket	1	0.27	0.237
Implant Fracture Head	0	0.07	1
Dissociation of Liner	0	0.50	1
Other / reason not recorded	1	1.13	1
Total Revised	24	29.02	0.403

[†] multiple reasons may be listed for one revision procedure^{*} Based on All NJR Cementless Cups, adjusted for agegroup, gender, indications, and implantation yearSignificantly better, $p < 0.001$ Significantly better, $p < 0.05$ Significantly worse $p < 0.05$ Significantly worse $p < 0.001$ 

Components Revised	Number of procedures	Novae SunFit TH Cup	All other Cementless Cups in NJR
Femoral only	9	38%	23%
Acetabular only	3	13%	24%
Both femoral and acetabular	11	46%	42%
Neither femoral nor acetabular revision recorded [*]	1	4%	10%

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

Revision and Survivorship

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	0	0.94	1
Dislocation / Subluxation	3	8.53	0.057
Adverse Soft Tissue Reaction	0	0.38	1
Infection	5	5.31	1
Aseptic Loosening - Stem	2	2.43	1
Aseptic Loosening - Socket	3	1.68	0.236
Periprosthetic Fracture Stem	11	7.36	0.191
Periprosthetic Fracture Socket	1	1.27	1
Malalignment Stem	1	0.96	0.619
Malalignment Socket	2	1.50	0.665
Wear Of Acetabular Component	1	0.67	0.487
Lysis Stem	1	0.35	0.292
Lysis Socket	0	0.14	1
Implant Fracture Stem	0	0.30	1
Implant Fracture Socket	1	0.27	0.239
Implant Fracture Head	0	0.07	1
Dissociation of Liner	0	0.51	1
Other / reason not recorded	1	1.12	1
Total Revised	24	29.00	0.403

* Based on All NJR Cementless Cups (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 $p < 0.001$



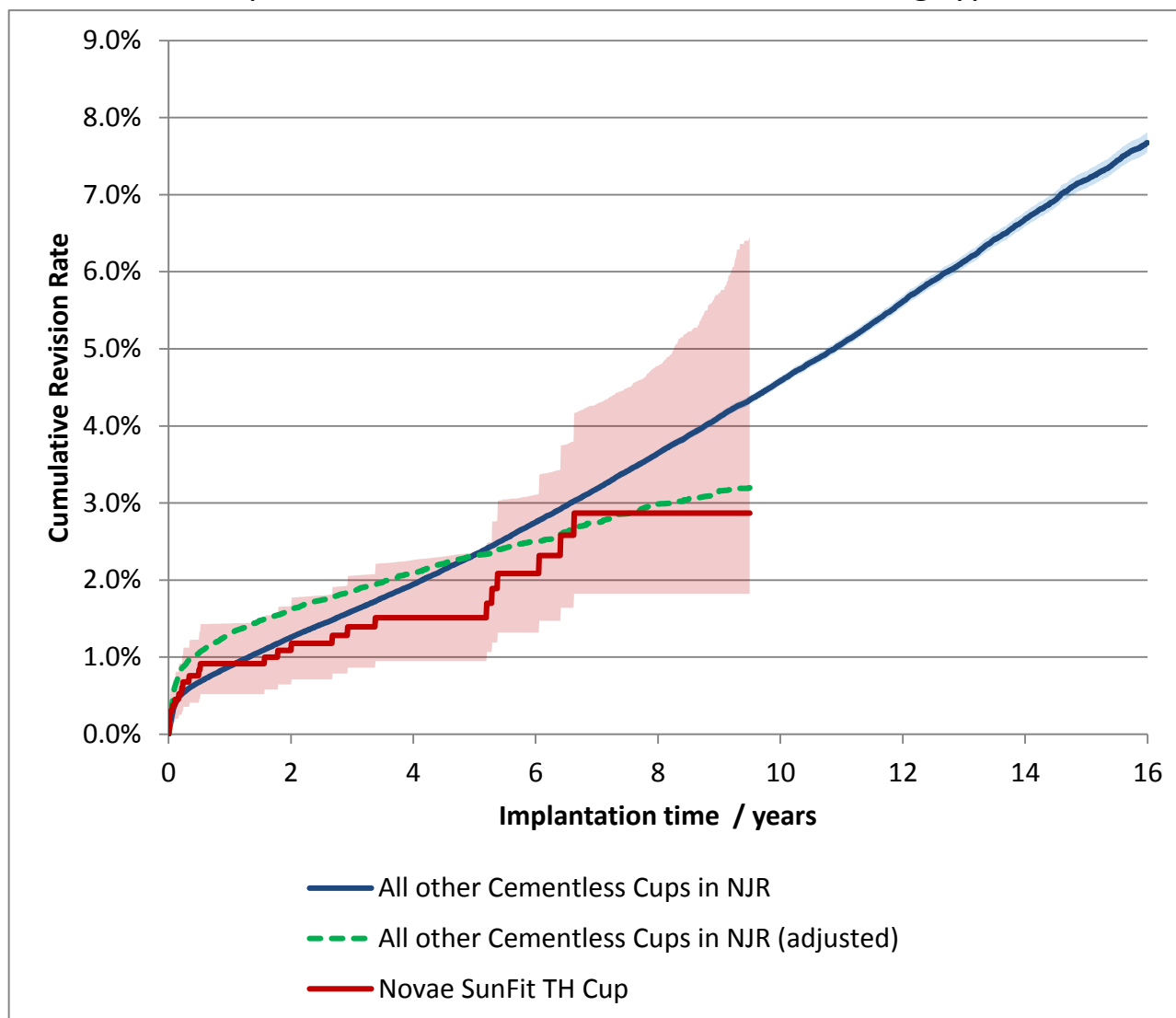
Components Revised	Number of procedures	Novae SunFit TH Cup	All other Cementless Cups in NJR
Femoral only	9	38%	31%
Acetabular only	3	13%	23%
Both femoral and acetabular	11	46%	33%
Neither femoral nor acetabular revision recorded *	1	4%	13%

* includes isolated head and/or liner exchange

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All reasons for revision. All Bearing types



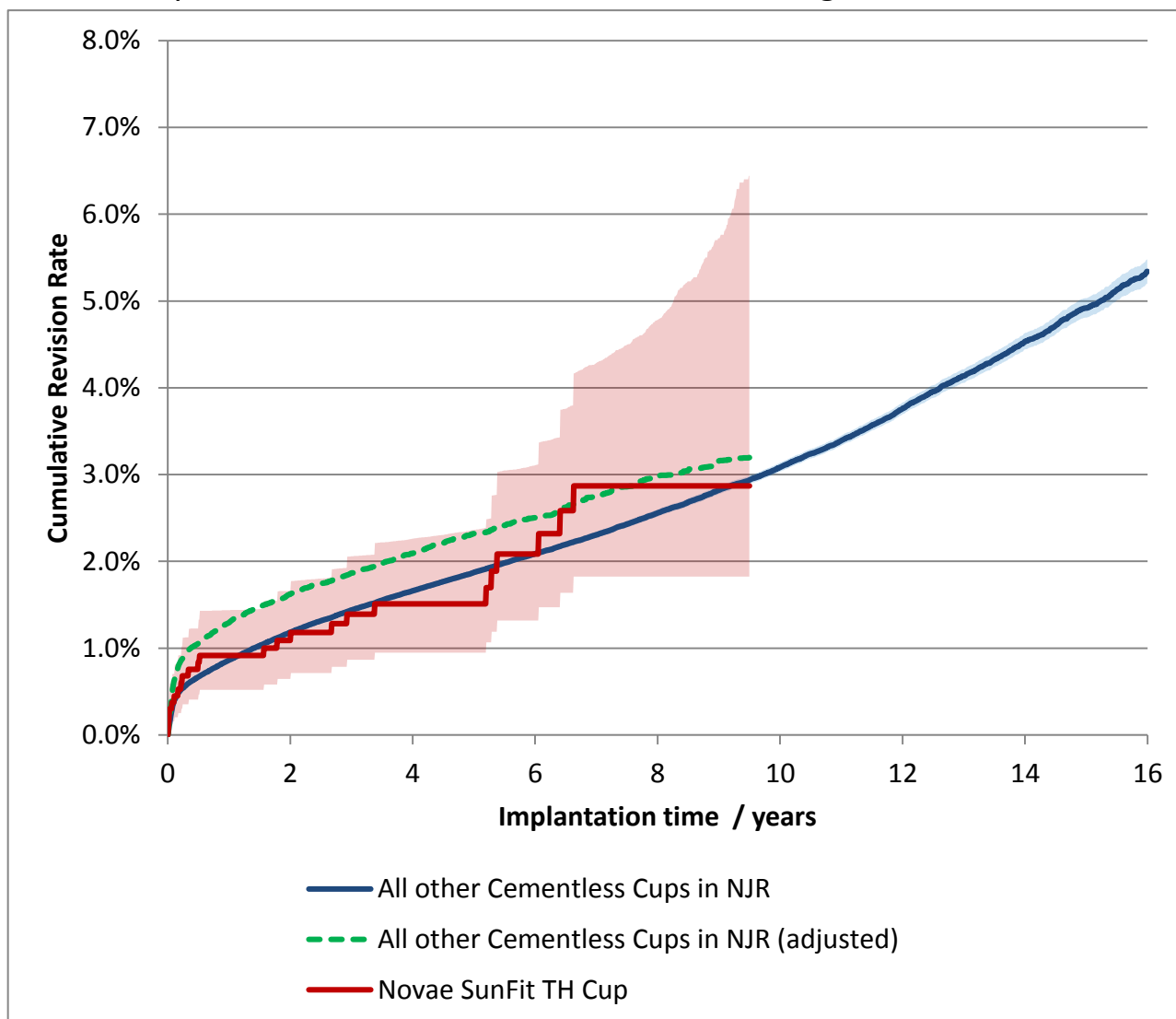
Cox Proportional Hazards model for revision risk ratio of Novae SunFit TH Cup / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.80 (0.53 - 1.19)	0.265
All bearings. Adjusted for age, gender, year cohort and indications.	0.82 (0.55 - 1.23)	0.347

Revision and Survivorship

Cumulative Revision Rate

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



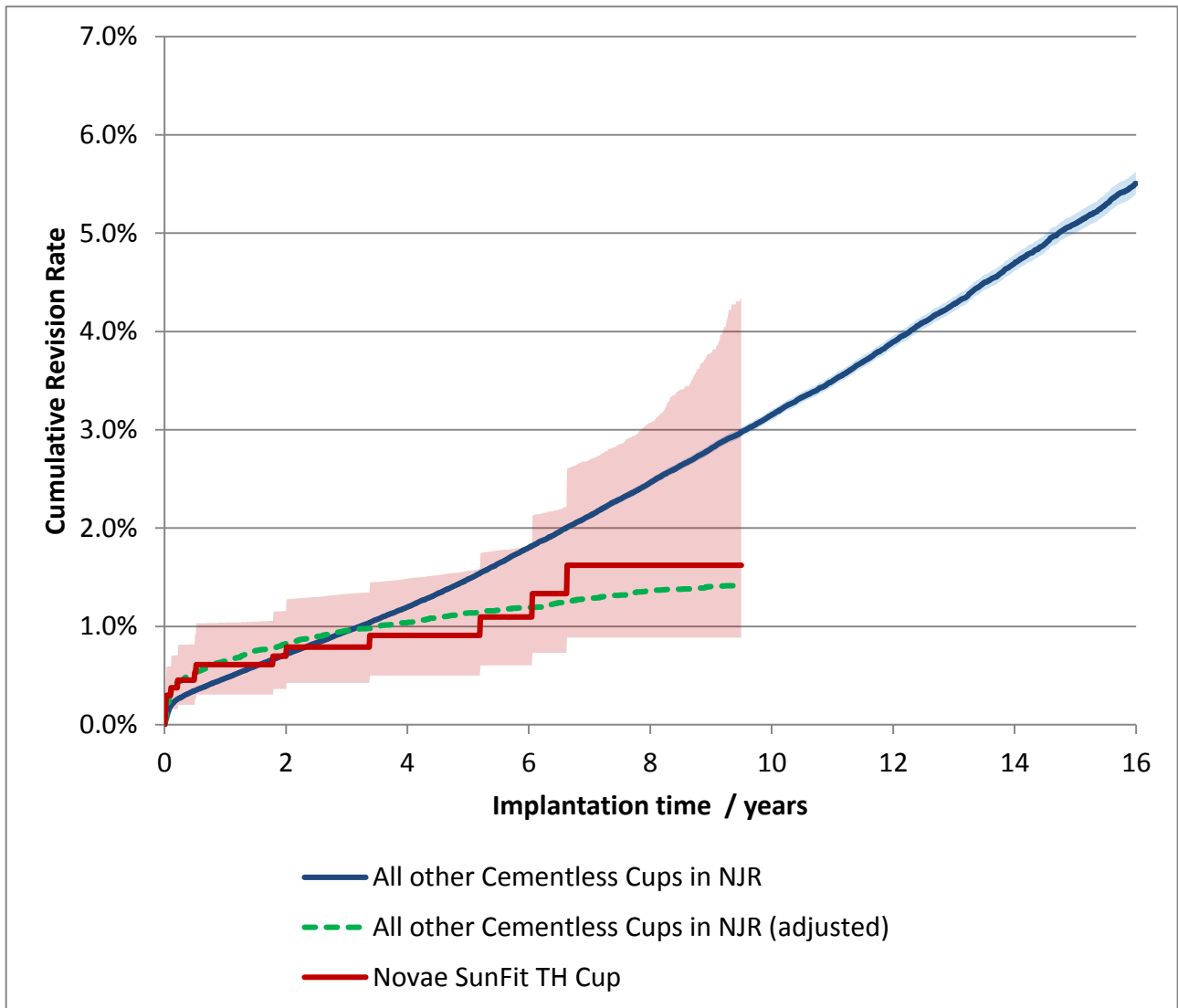
Cox Proportional Hazards model for revision risk ratio of Novae SunFit TH Cup / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.02 (0.68 - 1.52)	0.936
Excluding MoM. Adjusted for age, gender, year cohort and indications.	0.82 (0.55 - 1.23)	0.349

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision. All Bearing types



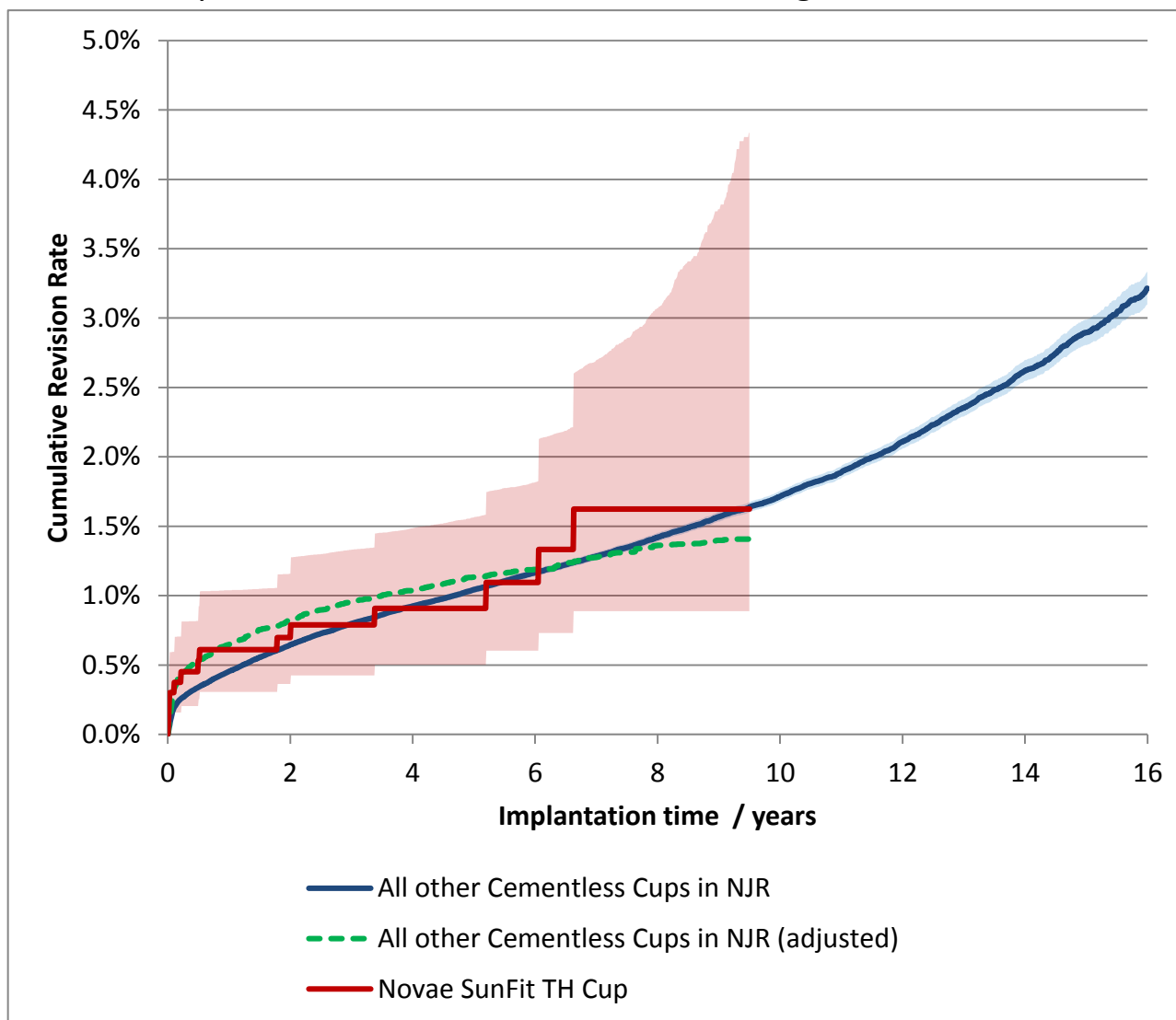
Cox Proportional Hazards model for revision risk ratio of Novae SunFit TH Cup / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
All bearings. Unadjusted.	0.73 (0.43 - 1.23)	0.237
All bearings. Adjusted for age, gender, year cohort and indications.	1.00 (0.59 - 1.70)	0.996

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision. Excluding Metal-on-Metal



Cox Proportional Hazards model for revision risk ratio of Novae SunFit TH Cup / All other Cementless Cups in NJR, with endpoint as any revision.

Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM. Unadjusted.	1.08 (0.64 - 1.82)	0.783
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.00 (0.59 - 1.70)	0.991

Revision and Survivorship

Cumulative Revision Rate

Endpoint: All revisions

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR	At Risk	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR
0	1,337	-	-	-	1,337	-	-	-
1	1,212	0.9% (0.5% - 1.4%)	0.9% (0.9% - 0.9%)	0.8% (0.8% - 0.8%)	1,212	0.9% (0.5% - 1.4%)	0.9% (0.8% - 0.9%)	0.8% (0.7% - 0.8%)
2	1,098	1.1% (0.6% - 1.7%)	1.3% (1.2% - 1.3%)	1.1% (1.1% - 1.1%)	1,098	1.1% (0.6% - 1.7%)	1.2% (1.2% - 1.2%)	1.1% (1.1% - 1.1%)
3	885	1.4% (0.9% - 2.1%)	1.6% (1.6% - 1.6%)	1.4% (1.4% - 1.5%)	885	1.4% (0.9% - 2.1%)	1.4% (1.4% - 1.5%)	1.3% (1.3% - 1.3%)
4	719	1.5% (0.9% - 2.3%)	1.9% (1.9% - 2.0%)	1.7% (1.7% - 1.8%)	719	1.5% (0.9% - 2.3%)	1.7% (1.6% - 1.7%)	1.5% (1.5% - 1.6%)
5	560	1.5% (0.9% - 2.4%)	2.3% (2.3% - 2.4%)	2.1% (2.0% - 2.1%)	560	1.5% (0.9% - 2.4%)	1.9% (1.8% - 1.9%)	1.8% (1.7% - 1.8%)
6	426	2.1% (1.3% - 3.1%)	2.8% (2.7% - 2.8%)	2.4% (2.4% - 2.4%)	426	2.1% (1.3% - 3.1%)	2.1% (2.1% - 2.1%)	2.0% (1.9% - 2.0%)
7	279	2.9% (1.8% - 4.3%)	3.2% (3.1% - 3.2%)	2.8% (2.7% - 2.8%)	279	2.9% (1.8% - 4.3%)	2.3% (2.3% - 2.3%)	2.2% (2.2% - 2.2%)
8	152	2.9% (1.8% - 4.8%)	3.6% (3.6% - 3.7%)	3.2% (3.1% - 3.2%)	152	2.9% (1.8% - 4.8%)	2.6% (2.5% - 2.6%)	2.5% (2.4% - 2.5%)
9	67	2.9% (1.8% - 5.7%)	4.1% (4.1% - 4.2%)	3.6% (3.5% - 3.6%)	67	2.9% (1.8% - 5.7%)	2.8% (2.8% - 2.9%)	2.7% (2.7% - 2.8%)
10		(-)	4.6% (4.5% - 4.6%)	4.0% (3.9% - 4.0%)		(-)	3.1% (3.0% - 3.1%)	3.0% (3.0% - 3.1%)
11		(-)	5.1% (5.0% - 5.1%)	4.4% (4.4% - 4.5%)		(-)	3.4% (3.3% - 3.4%)	3.4% (3.3% - 3.4%)
12		(-)	5.6% (5.5% - 5.7%)	4.9% (4.9% - 5.0%)		(-)	3.8% (3.7% - 3.8%)	3.8% (3.7% - 3.8%)
13		(-)	6.1% (6.1% - 6.2%)	5.4% (5.4% - 5.5%)		(-)	4.1% (4.1% - 4.2%)	4.2% (4.1% - 4.2%)
14		(-)	6.7% (6.6% - 6.8%)	5.9% (5.9% - 6.0%)		(-)	4.5% (4.4% - 4.6%)	4.6% (4.5% - 4.7%)
15		(-)	7.2% (7.1% - 7.3%)	6.4% (6.3% - 6.5%)		(-)	4.9% (4.8% - 5.0%)	5.0% (4.9% - 5.1%)

Cumulative revision rate with 95% confidence intervals

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

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Acetabular Revision

Period /years	All Bearing types				Excluding Metal on Metal Bearings			
	At Risk	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR	At Risk	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR
0	1,337	-	-	-	1,337	-	-	-
1	1,212	0.6% (0.3% - 1.0%)	0.5% (0.5% - 0.5%)	0.4% (0.4% - 0.4%)	1,212	0.6% (0.3% - 1.0%)	0.5% (0.4% - 0.5%)	0.4% (0.4% - 0.4%)
2	1,098	0.7% (0.4% - 1.2%)	0.7% (0.7% - 0.7%)	0.7% (0.7% - 0.7%)	1,098	0.7% (0.4% - 1.2%)	0.6% (0.6% - 0.7%)	0.6% (0.6% - 0.6%)
3	885	0.8% (0.4% - 1.3%)	1.0% (0.9% - 1.0%)	0.9% (0.9% - 0.9%)	885	0.8% (0.4% - 1.3%)	0.8% (0.8% - 0.8%)	0.8% (0.8% - 0.8%)
4	719	0.9% (0.5% - 1.5%)	1.2% (1.2% - 1.2%)	1.1% (1.1% - 1.1%)	719	0.9% (0.5% - 1.5%)	0.9% (0.9% - 0.9%)	0.9% (0.9% - 0.9%)
5	560	0.9% (0.5% - 1.6%)	1.5% (1.5% - 1.5%)	1.3% (1.3% - 1.4%)	560	0.9% (0.5% - 1.6%)	1.0% (1.0% - 1.1%)	1.1% (1.0% - 1.1%)
6	426	1.1% (0.6% - 1.8%)	1.8% (1.8% - 1.8%)	1.6% (1.6% - 1.6%)	426	1.1% (0.6% - 1.8%)	1.2% (1.1% - 1.2%)	1.2% (1.2% - 1.2%)
7	279	1.6% (0.9% - 2.7%)	2.1% (2.1% - 2.2%)	1.9% (1.9% - 1.9%)	279	1.6% (0.9% - 2.7%)	1.3% (1.3% - 1.3%)	1.3% (1.3% - 1.4%)
8	152	1.6% (0.9% - 3.1%)	2.5% (2.4% - 2.5%)	2.2% (2.1% - 2.2%)	152	1.6% (0.9% - 3.1%)	1.4% (1.4% - 1.5%)	1.5% (1.5% - 1.5%)
9	67	1.6% (0.9% - 3.8%)	2.8% (2.8% - 2.9%)	2.5% (2.5% - 2.5%)	67	1.6% (0.9% - 3.8%)	1.6% (1.5% - 1.6%)	1.7% (1.7% - 1.7%)
10		(-)	3.2% (3.1% - 3.2%)	2.8% (2.8% - 2.8%)		(-)	1.7% (1.7% - 1.8%)	1.9% (1.9% - 1.9%)
11		(-)	3.5% (3.4% - 3.6%)	3.1% (3.1% - 3.2%)		(-)	1.9% (1.8% - 1.9%)	2.1% (2.1% - 2.2%)
12		(-)	3.9% (3.8% - 4.0%)	3.5% (3.5% - 3.6%)		(-)	2.1% (2.1% - 2.2%)	2.4% (2.4% - 2.5%)
13		(-)	4.3% (4.2% - 4.4%)	3.9% (3.9% - 4.0%)		(-)	2.4% (2.3% - 2.4%)	2.7% (2.7% - 2.8%)
14		(-)	4.7% (4.6% - 4.8%)	4.3% (4.3% - 4.4%)		(-)	2.6% (2.5% - 2.7%)	3.1% (3.0% - 3.1%)
15		(-)	5.1% (5.0% - 5.2%)	4.7% (4.6% - 4.8%)		(-)	2.9% (2.8% - 3.0%)	3.4% (3.3% - 3.5%)

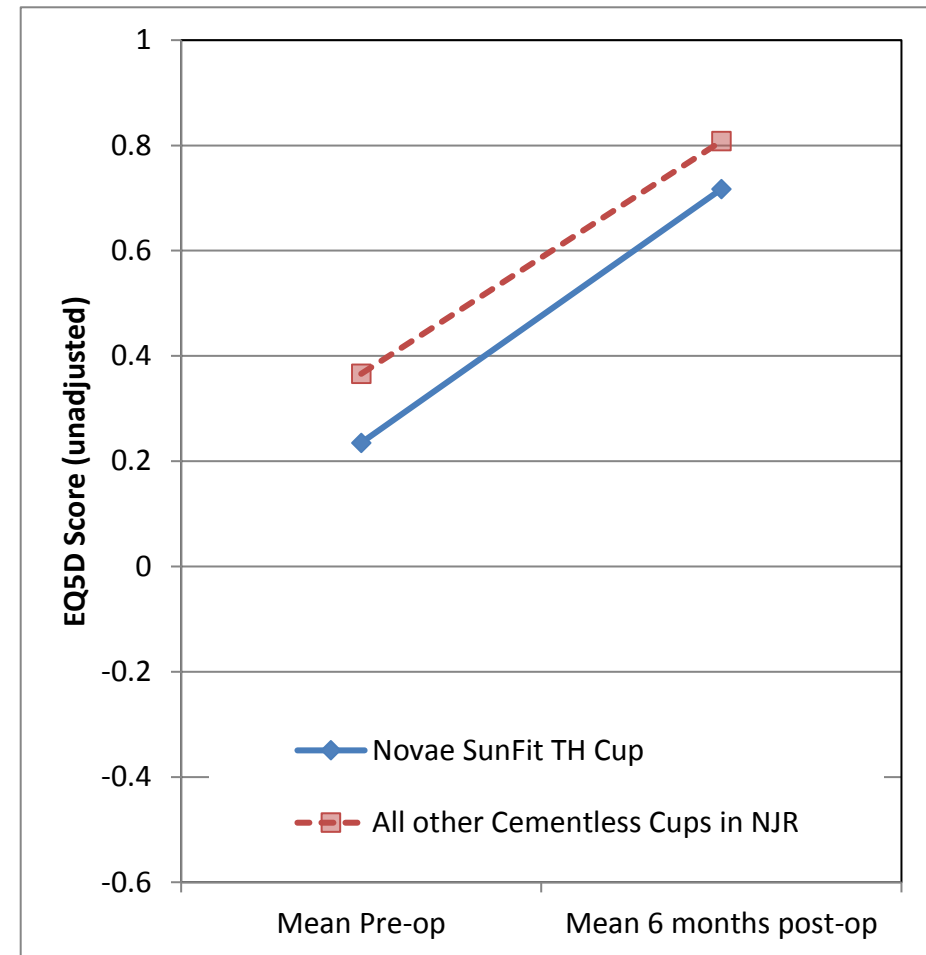
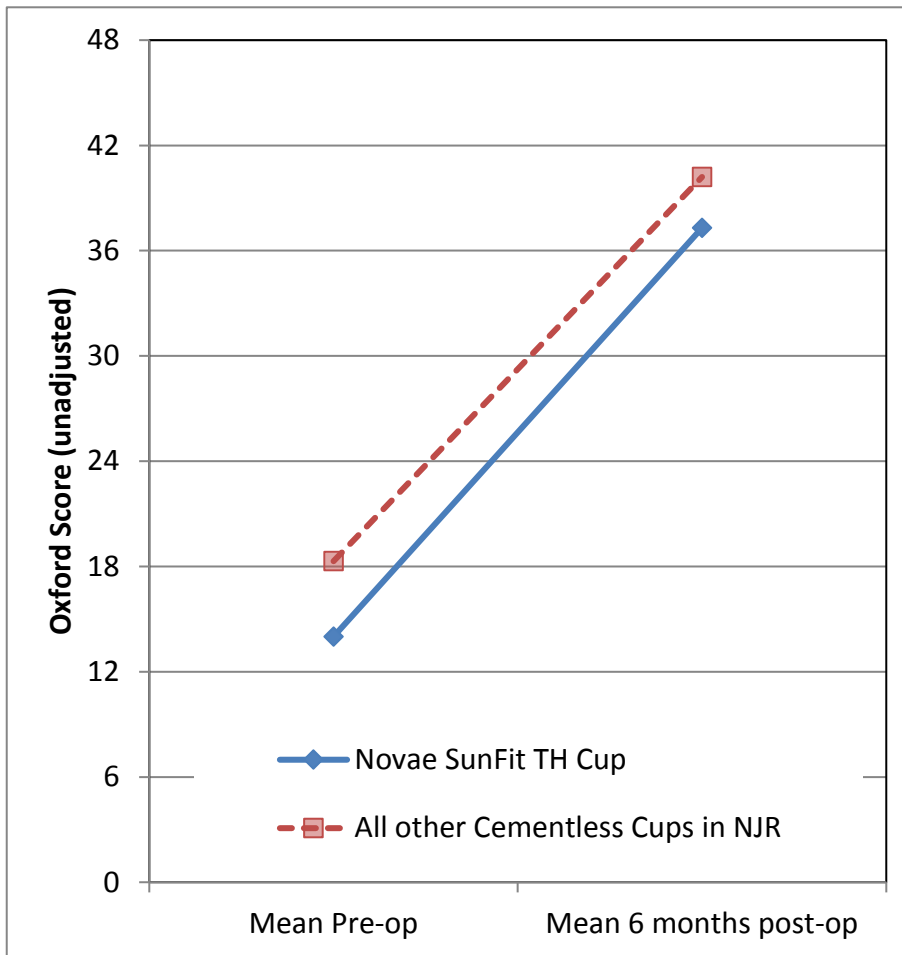
Cumulative revision rate with 95% confidence intervals

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

PROMs Analysis

Patient Reported Outcomes

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



Patient Reported Outcomes

PROMs Analysis

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

Oxford Hip Score (0 - 48)	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	169	226,574	350,400
PreOp score	14.0 (12.7 - 15.2)	18.3 (18.3 - 18.3)	17.9 (17.9 - 18.0)
6 month score	37.3 (35.8 - 38.7)	40.2 (40.2 - 40.2)	39.6 (39.5 - 39.6)
6 month score (adjusted)	40.1 (38.8 - 41.4)	39.9 (39.8 - 39.9)	39.6 (39.5 - 39.6)
Health gain	23.3 (21.8 - 24.8)	21.9 (21.9 - 21.9)	21.6 (21.6 - 21.7)
Health gain (adjusted)	22.2 (20.8 - 23.5)	21.9 (21.9 - 22.0)	21.6 (21.6 - 21.7)
p value (adjusted health gain)	0.35		
Score Improved	98.2%	97.4%	97.3%

EQ-5D Index (-0.59 - 1.00)	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	157	209,772	323,061
PreOp score	0.235 (0.184 - 0.286)	0.366 (0.365 - 0.368)	0.353 (0.352 - 0.354)
6 month score	0.717 (0.671 - 0.763)	0.808 (0.807 - 0.809)	0.795 (0.794 - 0.796)
6 month score (adjusted)	0.780 (0.737 - 0.822)	0.802 (0.801 - 0.803)	0.795 (0.794 - 0.796)
Health gain	0.482 (0.428 - 0.535)	0.442 (0.440 - 0.443)	0.442 (0.441 - 0.443)
Health gain (adjusted)	0.426 (0.384 - 0.468)	0.448 (0.447 - 0.449)	0.442 (0.441 - 0.443)
p value (adjusted health gain)	0.76		
Score Improved	90.4%	90.1%	89.7%

EQ-VAS (0 - 100)	Novae SunFit TH Cup	All other Cementless Cups in NJR	All THR in NJR
Paired Records	150	202,545	310,878
PreOp score	58.2 (54.5 - 61.9)	65.1 (65.0 - 65.2)	64.7 (64.7 - 64.8)
6 month score	69.7 (66.2 - 73.1)	77.9 (77.9 - 78.0)	77.0 (77.0 - 77.1)
6 month score (adjusted)	75.2 (72.0 - 78.4)	77.4 (77.3 - 77.5)	77.0 (77.0 - 77.1)
Health gain	11.5 (7.2 - 15.7)	12.9 (12.8 - 13.0)	12.3 (12.2 - 12.4)
Health gain (adjusted)	10.5 (7.3 - 13.6)	12.6 (12.6 - 12.7)	12.3 (12.3 - 12.4)
p value (adjusted health gain)	0.38		
Score Improved	64.7%	67.8%	66.6%

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:

Novae SunFit TH Cup

Responses are not case mix adjusted

Patient Reported Outcomes



Patient Reported Outcomes

Success

Response	Novae SunFit TH Cup	All other Cementless Cups in NJR
Much better	150	203872
A little better	11	17810
About the same	5	4471
A little worse	5	2715
Much worse	1	2054

Answer to 6-months general health question:

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

Satisfaction

Response	Novae SunFit TH Cup	All other Cementless Cups in NJR
Excellent	72	104738
Very Good	61	77455
Good	22	33665
Fair	13	11195
Poor	4	3572

Answer to 6-months general health question:

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

Disclaimer

Disclaimer

The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the Healthcare Quality Improvement Partnership ("HQIP"). HQIP, the NJR and/or its contractor, NEC Software Solutions (UK) Limited ("NEC") take no responsibility (except as prohibited by law) for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation including any duty of care to third party readers of the data analysis.

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Appendix A: Component List

Catalogue Number	Description	Number Implanted
RM 4532 0002	43mm Novae Sunfit TH Shell	4
RM 4532 0003	45mm Novae Sunfit TH Shell	29
RM 4532 0004	47mm Novae Sunfit TH Shell	166
RM 4532 0005	49mm Novae Sunfit TH Shell	298
RM 4532 0006	51mm Novae Sunfit TH Shell	308
RM 4532 0007	53mm Novae Sunfit TH Shell	218
RM 4532 0008	55mm Novae Sunfit TH Shell	165
RM 4532 0009	57mm Novae Sunfit TH Shell	96
RM 4532 0010	59mm Novae Sunfit TH Shell	32
RM 4532 0011	61mm Novae Sunfit TH Shell	13
RM 4532 0012	63mm Novae Sunfit TH Shell	5
RM 4532 0013	65mm Novae Sunfit TH Shell	3

Appendix A: Component List

Catalogue Number	Description	Number Implanted
RM51100002	DM Novae Poly Insert 22.5mm Size 43	4
RM51100003	DM Novae Poly Insert 22.25mm Size 45	29
RM51100004	DM Novae Poly Insert 22.5mm Size 47	4
RM51100005	DM Novae Poly Insert 22.25mm Size 49	5
RM51100006	DM Novae Poly Insert 22.5mm Size 51	4
RM51100007	DM Novae Poly Insert 22.5mm Size 53	1
RM51100008	DM Novae Poly Insert 22.5mm Size 55	1
RM51100012	DM Novae Poly Insert 22.5mm Size 61	2
RM51100032	DM Novae Poly Insert 28mm Size 47	161
RM51100033	DM Novae Poly Insert 28mm Size 49	291
RM51100034	DM Novae Poly Insert 28mm Size 51	303
RM51100035	DM Novae Poly Insert 28mm Size 53	216
RM51100036	DM Novae Poly Insert 28mm Size 55	163
RM51100037	DM Novae Poly Insert 28mm Size 57	96
RM51100038	DM Novae Poly Insert 28mm Size 59	32
RM51100040	DM Novae Poly Insert 28mm Size 61	11
RM51100041	DM Novae Poly Insert 28mm Size 63	5
RM51100042	DM Novae Poly Insert 28mm Size 65	3
RM51100061	DM Novae Poly Insert 28mm Size 73	1