

# ANALYSIS OF TOTAL HIP REPLACEMENT USING BI-MENTUM™ DUAL MOBILITY SYSTEM IN THE NATIONAL JOINT REGISTRY OF ENGLAND, WALES, NORTHERN IRELAND AND THE ISLE OF MAN

National Joint Registries provide valuable information on the revision rates and survivorship of orthopaedic implants. Typically they include large cohorts with data from all surgeons and from all centres, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern Ireland and the Isle of Man (NJR) has been in operation since 2003 and in that time has collected data on over 1,250,000 primary total hip replacements (THR).<sup>1</sup>

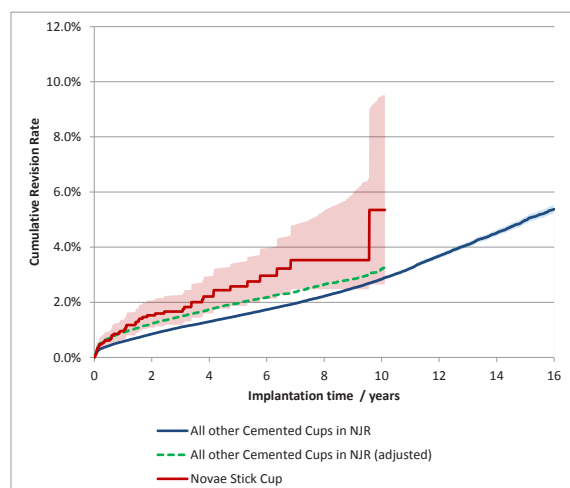
Following a commercial agreement between DePuy Synthes and SERF, BI-MENTUM™ Dual Mobility System is an updated brand-name for the Novae dual mobility system manufactured by SERF. BI-MENTUM Dual Mobility System is available in both cemented and cementless variants. The NJR has recently produced a report analyzing the performance of the cemented Novae system, which, following the re-branding, will be referred to as the cemented BI-MENTUM Dual Mobility System throughout this document.<sup>2</sup> This analysis was commissioned by DePuy Synthes, but conducted and validated by the NJR. The reports details 2,366 cemented BI-MENTUM Dual Mobility System Implantations. In order to better understand the performance of the cemented BI-MENTUM Dual Mobility System the reports provide comparison to all other Cemented Cups on the NJR (n=459,941).

Demographics		Novae cemented	All other Cemented Cups on the NJR
Mean Age		76.0	73.3
ASA Grade	P1 / P2 / P3 / P4&P5 (%)	2.9 / 46.5 / 45.4 / 5.2	10.5 / 67.8 / 20.9 / 0.8
Indication			
	Osteoarthritis	49.58%	90.95%
	Rheumatoid Arthritis	2.70%	1.38%
	Avascular Necrosis	7.73%	2.26%
	Fractured Neck of Femur	27.26%	4.65%
	CDH/DDH	1.31%	0.6%
	Other	18.81%	2.15%

**Table 1.** Demographics

In comparing to all other Cemented Cups, the BI-MENTUM Dual Mobility System cohort is slightly older, has a higher rate of systemic disease and has a much higher proportion of patients with fracture neck of femur as the primary surgical indication. The cumulative revision rates (CRR) are presented on the chart below and include a hazard ratio and an adjusted KM curve (age, gender, diagnosis and year of implantation). The report also includes PROMs at pre-op and 6 months follow up using the Oxford Hip Score (OHS), EQ-5D and EQ-VAS. All Metal-on-Metal articulations were excluded. All reports can be accessed at <https://www.jnjmedtech.com/en-EMEA/corail-pinnacle/resources>

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



Adjustment	Hazard Ratio (95% CI)	p-value
Excluding MoM, Unadjusted.	1.75 (1.32 - 2.32)	<0.001
Excluding MoM. Adjusted for age, gender, year cohort and indications.	1.34 (1.01 - 1.79)	0.042

Oxford Hip Score (0 - 48)	Novae Stick Cup	All other Cemented Cups in NJR
Paired Records	308	120,703
PreOp score	12.9 (12.0 - 13.8)	17.3 (17.2 - 17.3)
6 month score	34.8 (33.7 - 35.8)	38.4 (38.3 - 38.4)
6 month score (adjusted)	39.0 (37.9 - 40.0)	39.0 (39.0 - 39.1)
Health gain	21.9 (20.7 - 23.0)	21.1 (21.1 - 21.2)
Health gain (adjusted)	21.0 (20.0 - 22.0)	21.1 (21.0 - 21.1)
p value (adjusted health gain)		0.79
Score Improved	96.8%	97.1%

EQ-5D Index (-0.59 - 1.00)	Novae Stick Cup	All other Cemented Cups in NJR
Paired Records	280	110,409
PreOp score	0.186 (0.148 - 0.224)	0.330 (0.328 - 0.332)
6 month score	0.671 (0.637 - 0.704)	0.772 (0.770 - 0.773)
6 month score (adjusted)	0.763 (0.734 - 0.793)	0.783 (0.782 - 0.785)
Health gain	0.484 (0.445 - 0.524)	0.442 (0.440 - 0.444)
Health gain (adjusted)	0.410 (0.380 - 0.440)	0.430 (0.429 - 0.431)
p value (adjusted health gain)		0.4
Score Improved	89.3%	89.0%

EQ-VAS (0 - 100)	Novae Stick Cup	All other Cemented Cups in NJR
Paired Records	271	105,556
PreOp score	54.4 (51.4 - 57.4)	64.2 (64.0 - 64.3)
6 month score	68.0 (65.6 - 70.4)	75.4 (75.3 - 75.5)
6 month score (adjusted)	75.6 (73.3 - 77.9)	76.4 (76.3 - 76.5)
Health gain	13.6 (10.3 - 16.9)	11.2 (11.1 - 11.4)
Health gain (adjusted)	10.8 (8.6 - 13.1)	11.7 (11.6 - 11.8)
p value (adjusted health gain)		0.64
Score Improved	64.9%	64.2%

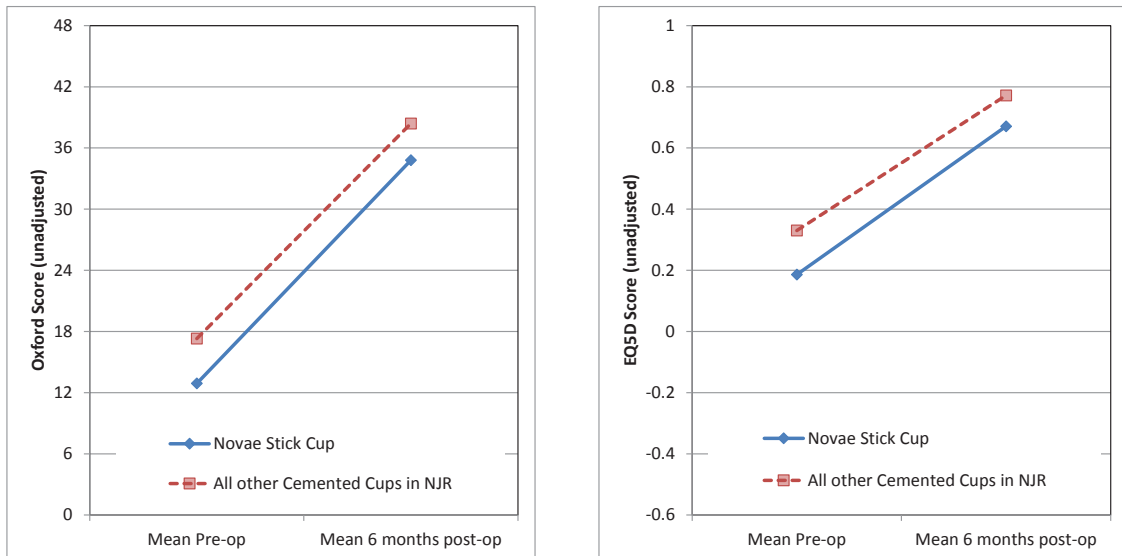


Figure 1. Pre-op and six months PROMs. NJR 2022<sup>2</sup>

The cemented BI-MENTUM Dual Mobility System is typically used in a slightly older patient cohort, with a greater proportion of serious systemic disease and for a surgical indication that is known for a poor outcome versus routine elective procedures. The CRR for the cemented BI-MENTUM Dual Mobility System is 5.4% (2.6, 9.5%) at 10 years. The 10 year CRR for all other Cemented Cups on the NJR is 2.1% (2.1, 2.2%). The 10 year CRR with acetabular revision as the endpoint is 3.9% (1.5, 7.9%) for the cemented BI-MENTUM Dual Mobility System. The adjusted HR is 1.34 (1.01, 1.79)  $p=0.042$ , indicating that there is a slight increase in risk of revision when compared to all other cemented cups on the NJR. The PROMs for the cemented BI-MENTUM Dual Mobility System show comparable adjusted health gains in the OHS ( $p=0.79$ ), EQ-5D ( $p=0.4$ ) and EQ-VAS ( $p=0.64$ ). The much lower pre-operative baseline values (Figure 1) may suggest the patients receiving the cemented BI-MENTUM Dual Mobility System made greater clinical improvements - although it should be acknowledged that pre-operative scores are not adjusted for patient and surgical factors.

### The cemented BI-MENTUM Dual Mobility System

- Is used in a challenging patient population.
- Demonstrates a low revision rate out to 10 years with a slight increase in risk of revision when compared all other cemented cups on the NJR.
- Shows PROMs scores that improve out to six months and are in line with all other cemented cups on the NJR.

### References

1. National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, 18th Annual Report, 2021. Table 3.H1 Available from: [www.njrreports.org.uk](http://www.njrreports.org.uk)
2. Summary Report Novae Stick. Report produced 17 May 2022. Report can be accessed at <https://www.jnjmedtech.com/enEMEA/corail-pinnacle/resources>

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Please refer to the instructions for use for a complete list of indications, contraindications, warnings and precautions.



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