Joint Replacement

Serf Novae® Dual Mobility cups

Product | Novae Dual Mobility cups

Comprehensive

Novae Dual Mobility cups offer multiple variations to accommodate a wide range of patients.

Established[1,2,3]

Novae Dual Mobility cups are the original Dual Mobility cups, backed by over 45 years of clinical history.

Easy to use

Non-anatomic cup combined with streamlined instrumentation

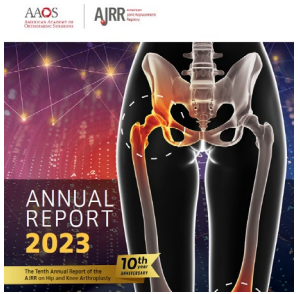
Key Message

Comprehensive

Key message | Comprehensive

Are dislocations still an issue?

- Dislocation continues to be one of the leading causes for Total Hip Replacements. [1,2,3]
- It is the second most common reason for revisions in the NJR and third in the AOANJRR. [2,3]
- Dislocation is even more common when looking at reasons for early revisions. [2]
- Studies have shown significantly higher revision rates for surgeons during their learning curve (50< cases) for direct anterior approach[4], with dislocation being one of the leading causes of revision.[5]



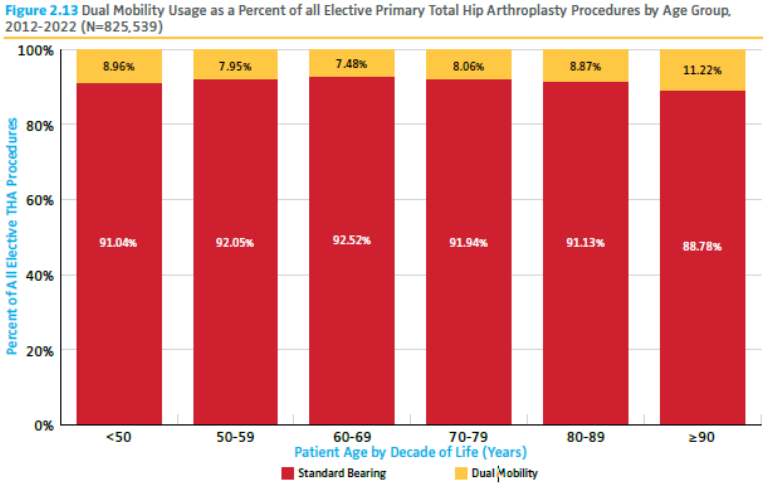
Key message | Comprehensive

Dual mobility market trends

US market (Data from AJRR 2023) :

- AJRR illustrated **a significant increase in dual mobility usage for elective primary hip arthroplasty** procedures when comparing 2012 to 2022 though there was a slight pull-back in 2022.[1]

- These constructs were used **most commonly in the oldest (>90 years) and youngest (<50 years)** patients and least frequently in the 60-69 years age range[1]



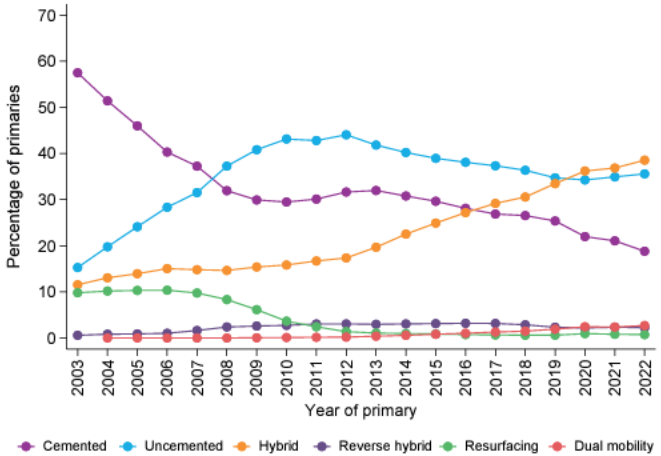
Key message | Comprehensive

Dual mobility market trends

<u>UK Market (Data from NJR 2023) :</u>

- Consistent growing number in dual mobility usage **as a primary hip replacement cup** [2]

Figure 3.H2 (b) Primary hip type percentages by year of replacement, with dual mobility as a separate category.

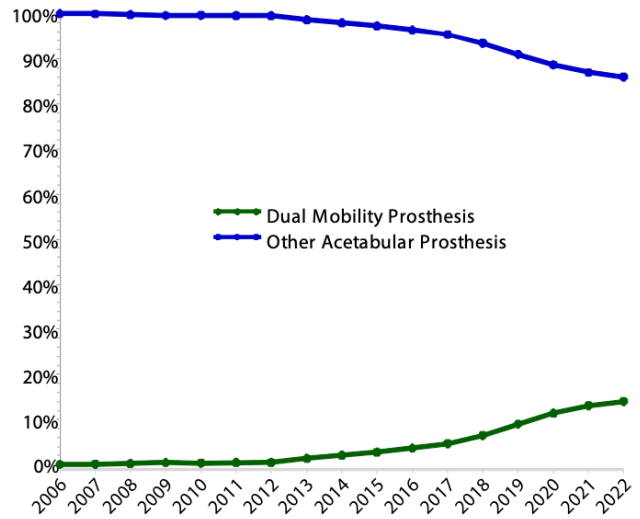


Key message | Comprehensive

Dual mobility market trends

<u>Australian market</u>
<u>(Data from AOANJRR 2023) :</u>

- The Registry has recorded 21,198 primary total conventional hip replacement procedures using dual mobility prostheses; **an increase of 22.3% since 2020**. [3]

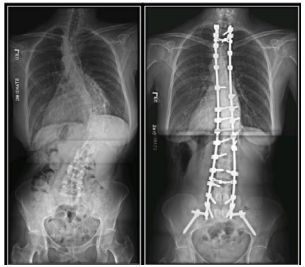


Key message | Comprehensive

Which patients are at higher risk of dislocation?

Primary indications:

- Femoral neck fracture [6]
- Small anatomy, dysplastic hips [7]
- Neuromuscular disease/compliance risk [8]
- High demand/hyper mobile [9]
- Spinal fusion/spine disease [10]

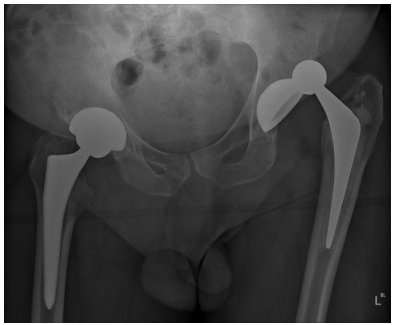


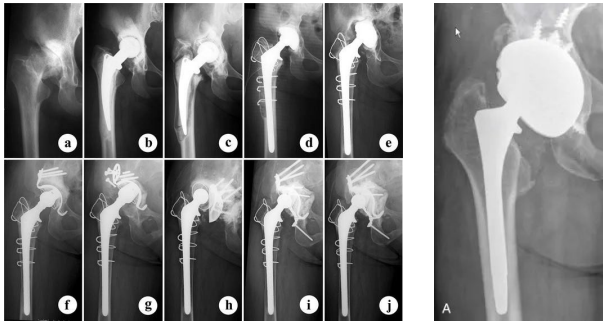
Key message | Comprehensive

Which patients are at higher risk of dislocation?

Revision Indications: [11]

- Instability cases
- Massive bone loss with sub-optimal cup placement
- Well-fixed cup revision
  - Poly wear
  - Dislocation/recurrent dislocation





Key message | Comprehensive

Novae product offering

Novae SunFit TH :
- Dedicated to primary cementless THA
- Press fit fixation & dual coating (Ti+HA)

Novae E TH :
- Dedicated to primary cementless THA or small revision
- Press fit fixation + pegs and screw & dual coating (Ti+HA)

Novae Coptos TH :
- Dedicated to revision cementless THA
- Press fit fixation + pegs and screws & dual coating (Ti+HA)

Novae Stick:
- Cemented dual mobility cup
- Dedicated to acetabular revisions

Key message | Comprehensive

Novae SunFit TH

All of the Novae acetabular cups are hemispherical with a 3 mm cylinder added to form a cylinder-spherical
type shape.

They gradually flatten from the top following a wide radius (0.5 mm maximum), which contributes to absorbing the stress at the bottom of the cup on final impaction.

The internal surface of the cups is completely polished to allow articulation of the dual mobility.

The cementless cups have a peripheral press-fit designed to encourage primary fixation of the implant to the bone.

The secondary fixation is provided by the dual coating of titanium spray (thickness 150±30 µm) and HA coating (thickness 70±20 µm), on the outer surface of the cementless cups.

All the Novae acetabular cementless cups come with their pre-assembled polyethylene cup gripper (single use) and the Novae Stick cup comes with a disposable cup impactor (also single use).

Key message | Comprehensive

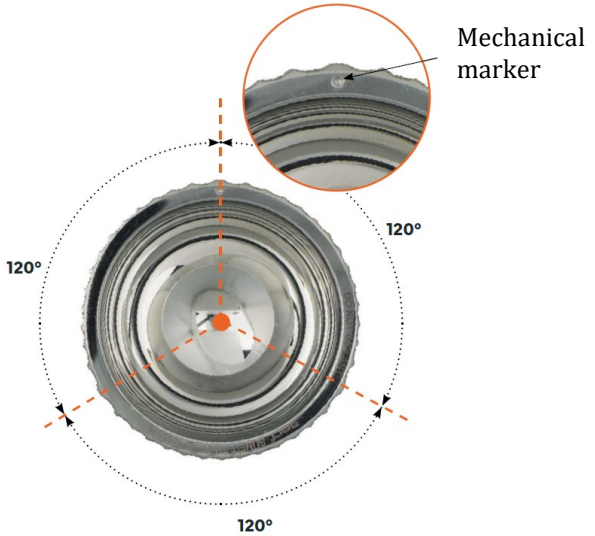
Novae SunFit TH

The Novae SunFit TH cup is an acetabular cementless implant intended for primary total hip replacement (THR).

Designed to promote primary fixation, the cup has 3 points (a few tenths of millimeters higher) that divide the acetabular cup into three 120° segments.

The peripheral press-fit is distributed around these 3 points. The press-fit's height and thickness change according to the cup's diameter (minimum 1.2 mm, maximum 2.1 mm).

A mechanical marker is placed on the implant edge to help locate the ilium attachment point.



Key message | Comprehensive

Novae E TH & Coptos TH

The Novae E TH cup is an acetabular cementless implant intended for primary total hip replacement (THR) and small revision.

Designed to promote primary fixation, the Novae E TH cup has both peripheral press-fit and a tripod attachment system: 1 peg in the ischium, 1 peg in the pubis, and 1 cortical screw in the ilium through the malleable flange. This concept of 3 anchoring points was devised by Prof. Gilles Bousquet with the goal of promoting primary stability during rotation and pull-out of the Novae E TH acetabular cup.

The Novae Coptos TH cup is an acetabular implant intended for cementless acetabular reconstruction.
Primary fixation of the Novae Coptos TH is obtained by equatorial press-fit complemented by 2 pegs, 2 flanges (which can place up to 4 fixation screws in the ilium), and 1 hook. The hook, previously placed in the obturator hole, allows for anatomical repositioning and provides additional mechanical support.
The 2 flanges are malleable and breakable to adapt to different cases of acetabular reconstructions.

Key message | Comprehensive

Novae Stick

The Novae Stick cup is an acetabular implant intended to be attached to the bone with surgical cement.
The external surface has raised reliefs that allow for the evacuation of excess cement and are designed to promote stability when it is polymerized. The Novae Stick cup can be cemented directly through contact with the bone or in a fitting at the bottom of the acetabulum.

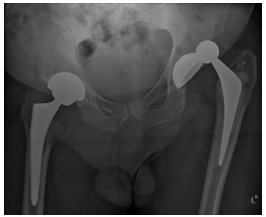
Key message | Comprehensive

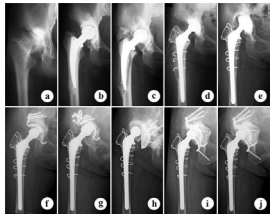
Novae Dual Mobility Cups











Key message | Comprehensive

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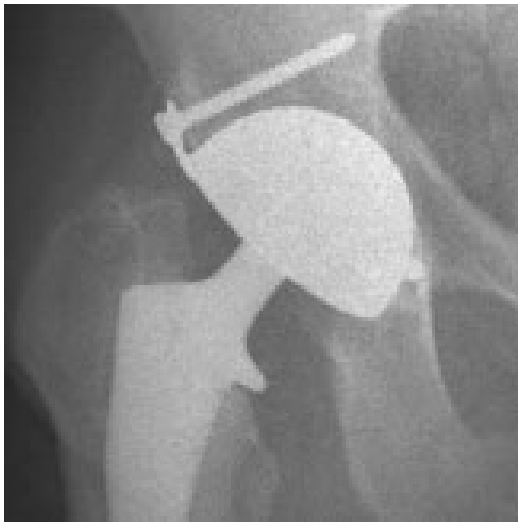

Key message | Comprehensive

Novae Stick

Key Message

Established[1,2,3]

Key message | Established

The original Dual Mobility

Key message | Established

Dual Mobility Concept

Based on the foundation of two orthopaedic concepts:

Charnley low-friction arthroplasty

The Charnley low-friction arthroplasty (LFA) prosthesis has demonstrated both clinically and radiologically that smaller diameter heads produce lower torque forces in the shell and consequently less wear. [12]

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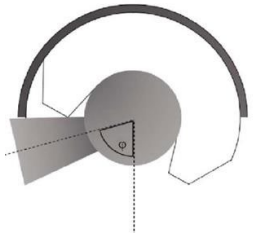
McKee-Farrar large diameter bearing theory

The large diameter bearing concept from McKee-Farrar recognized that a large diameter bearing is inherently more stable than a smaller diameter head. [13]



Key message | Established

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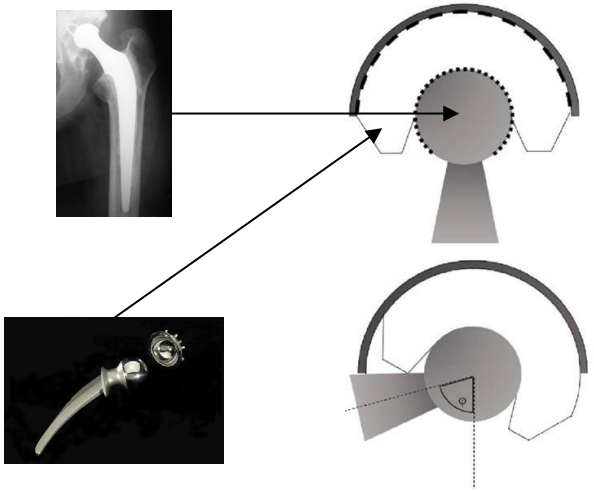


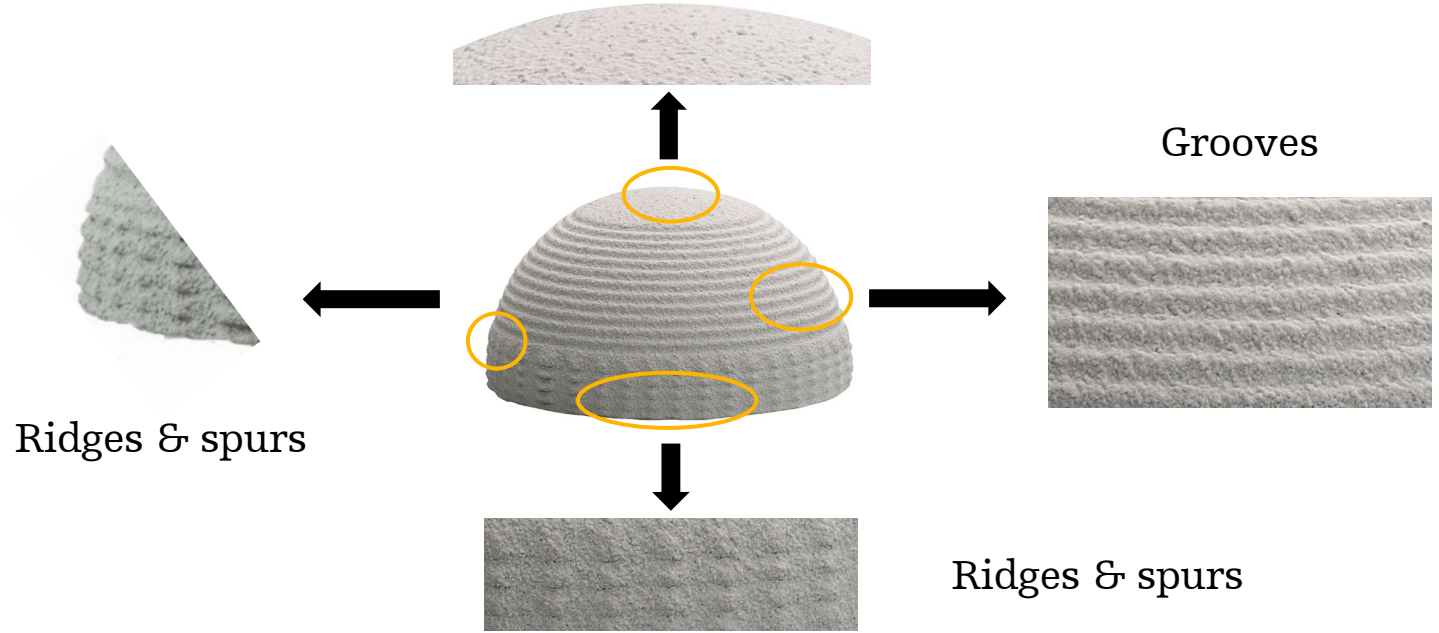
Key message | Established

50 years of continuous improvements

1977	1979	1998	2000	2007	2009
Cemented Fixed pegs	Cementless HA coating Anatomical	Low profile pegs Ridges Spurs		Bi-layer coating (Ti plasma spray + HA)	

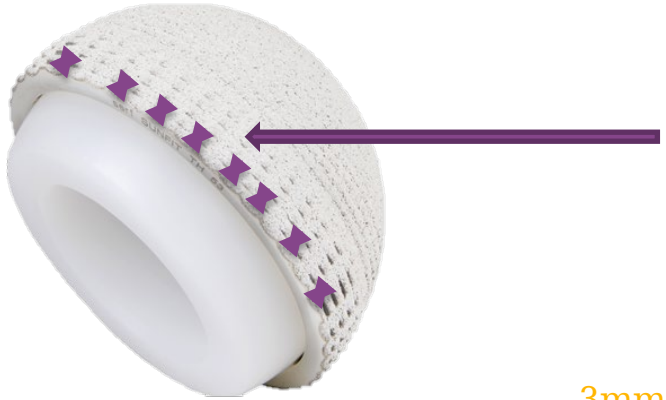
Key message | Established

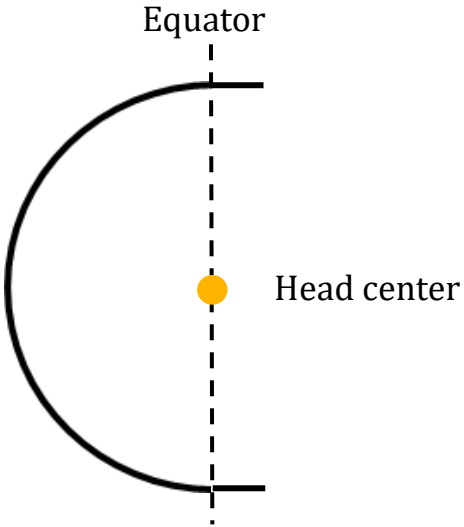
Initial fixation



Key message | Established

Key Product Features





3mm cylindrical extension

Increases jump distance and creates artificial wall[19]

Key message | Established

Cobalt Chrome free

Novae Dual Mobility Cups are made from forged stainless steel, offering a CoCr free dual mobility construct.

Key message | Established

Novae - best selling cup in France

#1 in France [14]

Utilized by **90%** of France's leading **university hospitals** [15]

+450,000 Dual Mobility cup implanted in the past **45+ years** [15]

Over 50,000 implanted globally in 2023 [15]

Distributed in **20 countries** [15]

Key message | Established

ODEP Data*

ODEP 10A

serf

ODEP 10A

serf

*Latest ODEP ratings can be found at www.odep.org.uk

Key message | Established

Registry data – Australian registry[3]

Table HT48 Cumulative Percent Revision of Dual Mobility Primary Total Conventional Hip Replacement by Component (All Diagnoses)

Dual Mobility Insert	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	20 Yrs
2M	22	505	2.2 (1.2, 3.9)	4.2 (2.6, 6.6)	4.9 (3.0, 7.9)			
Active Articulation	129	5774	2.1 (1.8, 2.5)	2.8 (2.3, 3.3)	2.8 (2.4, 3.4)			
Avantage	12	372	2.7 (1.4, 5.2)	3.2 (1.7, 6.0)	4.9 (2.6, 9.2)			
BI-MENTUM	10	401	2.9 (1.5, 5.3)					
MDM (Dual Mobility)	86	3753	1.7 (1.4, 2.2)	2.4 (1.9, 3.1)	3.2 (2.5, 4.1)			
MobiliT CUP	0	61						
Novae E	38	1710	1.0 (0.6, 1.6)	2.0 (1.4, 2.9)	2.3 (1.6, 3.2)			
Polarcup	53	1149	2.6 (1.8, 3.8)	4.2 (3.1, 5.7)	5.0 (3.7, 6.8)	7.3 (5.2, 10.4)		
Restoration	188	5438	2.6 (2.2, 3.0)	3.3 (2.9, 3.9)	4.4 (3.8, 5.2)			
Saturne	32	1353	1.2 (0.8, 2.0)	2.3 (1.6, 3.5)	3.1 (2.0, 4.6)			
SignaSure	5	350	1.1 (0.4, 3.0)					
Trinity	68	4067	1.5 (1.1, 1.9)	1.9 (1.5, 2.5)				
Versafit	54	1755	2.3 (1.7, 3.2)	3.4 (2.6, 4.5)	3.6 (2.7, 4.7)			
Other (4)	1	64	1.6 (0.2, 10.7)					
TOTAL	**698**	**26752**						

The lowest revision rate @ 5Y, 2.3%

Key message | Established

Registry data – American registry[2]

Table 2.5 Unadjusted Cumulative Percent Revision of Cementless Acetabular Components in Hip Arthroplasty Constructs for Primary Total Hip Arthroplasty in Patients ≥65 Years of Age with Primary Osteoarthritis, 2012-2022

Acetabular Shell	N Total	N Revised	1 Yrs	3 Yrs	5 Yrs	7 Yrs	10 Yrs
Trabecular Metal	4,913	160	2.00 (1.63, 2.42)	2.50 (2.09, 2.97)	2.95 (2.49, 3.45)	3.36 (2.86, 3.92)	3.95 (3.26, 4.74)
FMP	4,143	70	1.23 (0.93, 1.60)	1.58 (1.23, 1.99)	1.64 (1.28, 2.07)	1.84 (1.43, 2.34)	1.84 (1.43, 2.34)
Restoration ADM	3,175	72	1.48 (1.10, 1.95)	1.93 (1.50, 2.46)	2.25 (1.76, 2.82)	2.37 (1.86, 2.98)	2.53 (1.95, 3.22)
Trinity	2,668	60	1.73 (1.29, 2.29)	2.10 (1.60, 2.71)	2.53 (1.92, 3.26)	2.75 (2.03, 3.63)	2.75 (2.03, 3.63)
Mpact	2,341	61	1.93 (1.43, 2.55)	2.50 (1.92, 3.21)	2.78 (2.14, 3.55)	2.78 (2.14, 3.55)	—
Dynasty BioFoam	2,306	82	2.00 (1.48, 2.63)	2.98 (2.34, 3.74)	3.49 (2.78, 4.31)	3.75 (3.01, 4.62)	3.75 (3.01, 4.62)
Mallory Head	2,089	30	0.91 (0.57, 1.39)	1.20 (0.80, 1.74)	1.30 (0.88, 1.87)	1.46 (0.99, 2.07)	1.56 (1.06, 2.21)
EMPOWR	2,018	31	1.26 (0.84, 1.83)	1.95 (1.29, 2.85)	—	—	—
Legend	1,966	35	1.38 (0.93, 1.97)	1.82 (1.28, 2.51)	1.91 (1.35, 2.63)	—	—
Novation	1,904	66	1.63 (1.13, 2.28)	2.16 (1.57, 2.89)	3.04 (2.31, 3.93)	4.50 (3.30, 5.95)	8.27 (4.22, 14.04)
RingLoc+	1,761	55	1.99 (1.41, 2.72)	2.45 (1.80, 3.25)	2.99 (2.26, 3.87)	3.19 (2.43, 4.10)	3.19 (2.43, 4.10)
Escalade Acetabular System	1,456	20	0.97 (0.56, 1.59)	1.13 (0.67, 1.79)	1.49 (0.94, 2.25)	1.49 (0.94, 2.25)	—
Regenerex RingLoc+	1,281	35	1.64 (1.05, 2.45)	2.27 (1.55, 3.19)	2.68 (1.89, 3.68)	2.81 (1.99, 3.85)	2.81 (1.99, 3.85)
Ringloc Ranawat-Burstein	1,197	42	2.51 (1.73, 3.51)	3.10 (2.23, 4.20)	3.32 (2.40, 4.46)	3.61 (2.62, 4.84)	4.13 (2.82, 5.80)
Versafitcup DM	969	27	1.96 (1.22, 2.99)	2.38 (1.55, 3.48)	2.48 (1.63, 3.61)	2.85 (1.92, 4.06)	2.85 (1.92, 4.06)
Interface Acetabular System	959	25	1.56 (0.92, 2.51)	2.22 (1.42, 3.32)	2.60 (1.71, 3.78)	2.77 (1.83, 4.00)	2.77 (1.83, 4.00)
PROCOTYL PRIME	857	14	1.17 (0.60, 2.08)	1.68 (0.93, 2.83)	2.27 (1.12, 4.12)	—	—
Consensus	765	24	1.83 (1.05, 2.98)	2.68 (1.69, 4.03)	3.02 (1.94, 4.46)	3.41 (2.24, 4.97)	3.41 (2.24, 4.97)
Logical	749	16	1.74 (0.98, 2.88)	2.05 (1.20, 3.29)	2.05 (1.20, 3.29)	2.54 (1.40, 4.24)	—
Universal	707	16	1.41 (0.73, 2.51)	1.84 (1.03, 3.05)	2.38 (1.41, 3.75)	2.38 (1.41, 3.75)	2.38 (1.41, 3.75)
Restoris PST	690	42	4.06 (2.76, 5.72)	4.78 (3.36, 6.56)	5.51 (3.97, 7.38)	6.10 (4.47, 8.05)	6.10 (4.47, 8.05)
Polarcup	676	15	1.92 (1.08, 3.18)	1.92 (1.08, 3.18)	2.42 (1.40, 3.92)	2.42 (1.40, 3.92)	2.42 (1.40, 3.92)
Reflection	652	24	2.46 (1.46, 3.87)	3.10 (1.96, 4.65)	3.66 (2.38, 5.34)	3.91 (2.56, 5.67)	3.91 (2.56, 5.67)
Provident	541	13	1.66 (0.82, 3.03)	2.05 (1.09, 3.53)	2.26 (1.24, 3.81)	2.66 (1.46, 4.47)	2.66 (1.46, 4.47)
Bencox	521	19	2.13 (1.13, 3.67)	3.83 (2.33, 5.89)	4.57 (2.66, 7.23)	4.57 (2.66, 7.23)	—
Converge	465	10	1.51 (0.67, 2.96)	2.15 (1.11, 3.79)	2.15 (1.11, 3.79)	[illegible]	2.15 (1.11, 3.79)
Novae Sunfit	455	9	1.32 (0.55, 2.73)	1.58 (0.70, 3.10)	1.91 (0.89, 3.6[illegible]	2.36 (1.13, 4.38)	—
Klassic HD	443	6	1.35 (0.57, 2.80)	1.35 (0.57, 2.80)	1.35 (0.57, 2.80)	[illegible]	—
Overall	394,910	8,260	1.43 (1.39, 1.46)	1.89 (1.85, 1.93)	2.18 (2.13, 2.23)	2.40 (2.34, 2.45)	2.66 (2.58, 2.74)

Low revision rate @ 7Y - 2.36%

Key message | Established

Clinical publications

Novae (First generation)

Results of primary total hip replacement with first generation Bousquet dual mobility socket with more than twenty-five years follow up. About a series of two hundred and twelve hips

Neri et al. SICOT, 2017 [16]

@ 25 Y, Cup survivorship for any reason : 90.6% / Cup aseptic loosening rate: 8 % / Dislocation rate : 0%

Novae SunFit TH

Excellent survival of second-generation uncemented dual mobility cups compared with first-generation cups at a minimum of 10 years follow-up in primary total hip arthroplasty.

Duhil et al. SICOT, 2024[17]

@ 14 Y, Cup survivorship for any reason: 99.2 % / Cup aseptic loosening rate: 0.8 % / Dislocation rate: 0.8%

Novae Stick

Low Revision Rates at More Than 10 Years for Dual-Mobility Cups Cemented Into Cages in Complex Revision Total Hip Arthroplasty

Sayac et al. JoA, 2019[18]

@ 10 Y, Cup survivorship for any reason : 92.2 % / Cup aseptic loosening rate: 3.9 % / Dislocation rate : 9.45 %

Key Message

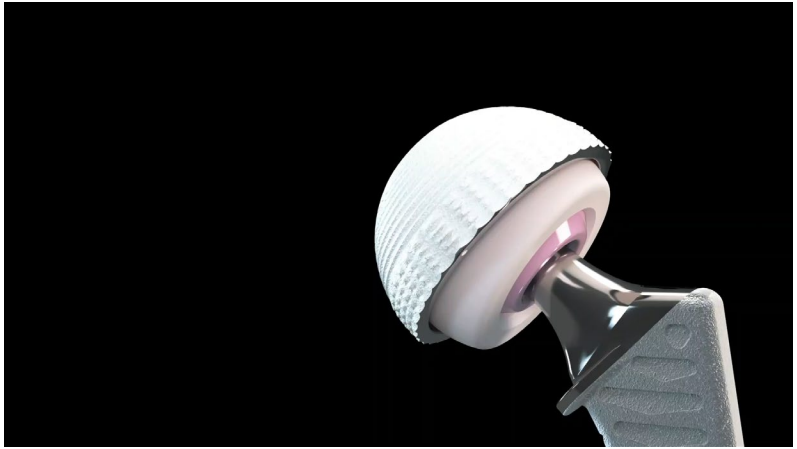
Easy to use

Key message | Easy to use

Simple non-anatomic design

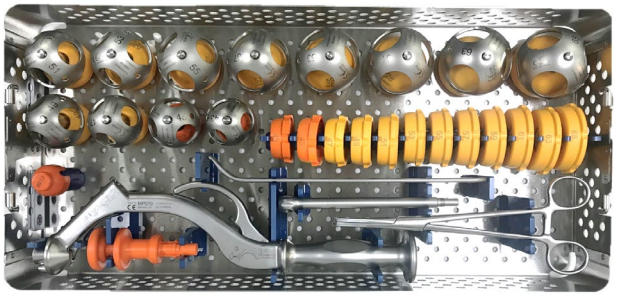
Novae Dual Mobility cups are a simple non-anatomic design

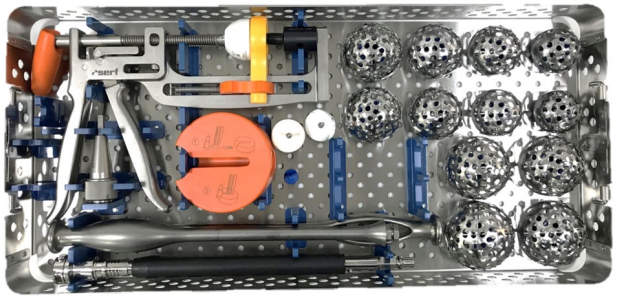
- Allows surgeons to insert the cup without worrying about the rotation of the cup.
- Provides full range of motion in all directions.



Key message | Easy to use

Novae Dual Mobility cups require only 1 instrument tray and 1 reamer tray, making it straightforward and potentially saving OR space and sterilization costs.





Key message | Easy to use

Built with quality and ease of use in mind, Novae Dual Mobility instruments are intuitive and provide reproducible results.[1,2,3]

References

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2. AAOS AJRR Annual Report 2023
3. AOANJRR Annual Report 2023
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