

+ Evidence in focus

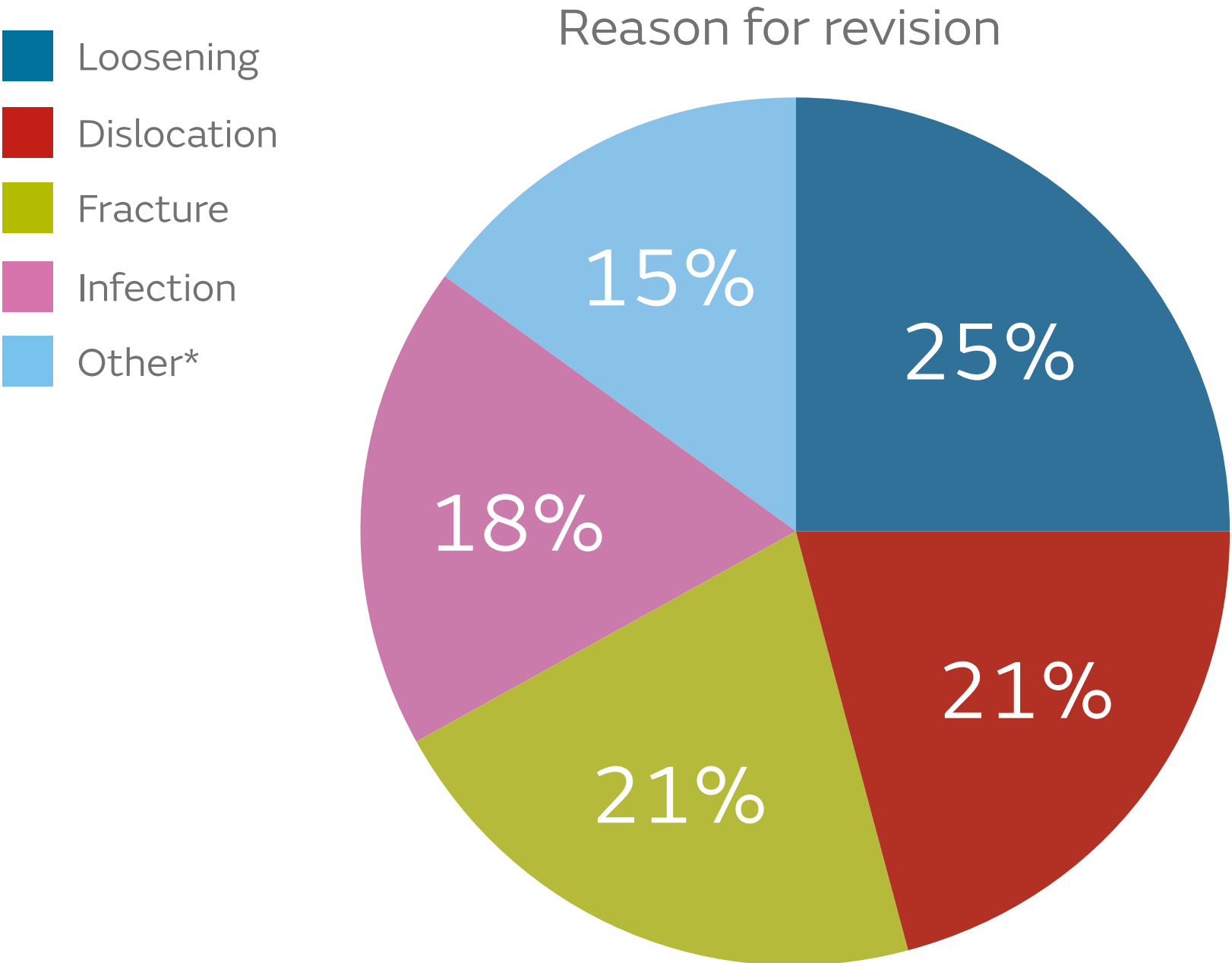
Introducing a new modular dual mobility acetabular component: OR30[◇]



“Despite the success of primary THR, failure and revision continue to pose a major challenge for orthopaedists while persisting as a significant economic burden on the healthcare system.”¹



Dislocation is a leading cause of hip revision²



“Dislocations have a profound effect on patient outcomes and may result in implant damage.”³

Fear of dislocation may result in some patients having to abandon their job or leisure activities.⁴

*Includes lysis, pain, leg length discrepancy, malposition, instability, implant breakage. All less than 2.5%.

Patient-related risk factors for dislocation⁴⁻⁶

Patient-related risk factors

Age >75 years

Female gender aged >70 years

Prior hip surgery

ASA grade* >3

Body mass index >30 kg/m²

Abductor deficiency

Significant pelvic tilt

Preoperative diagnosis

Avascular necrosis

Fractured neck of femur

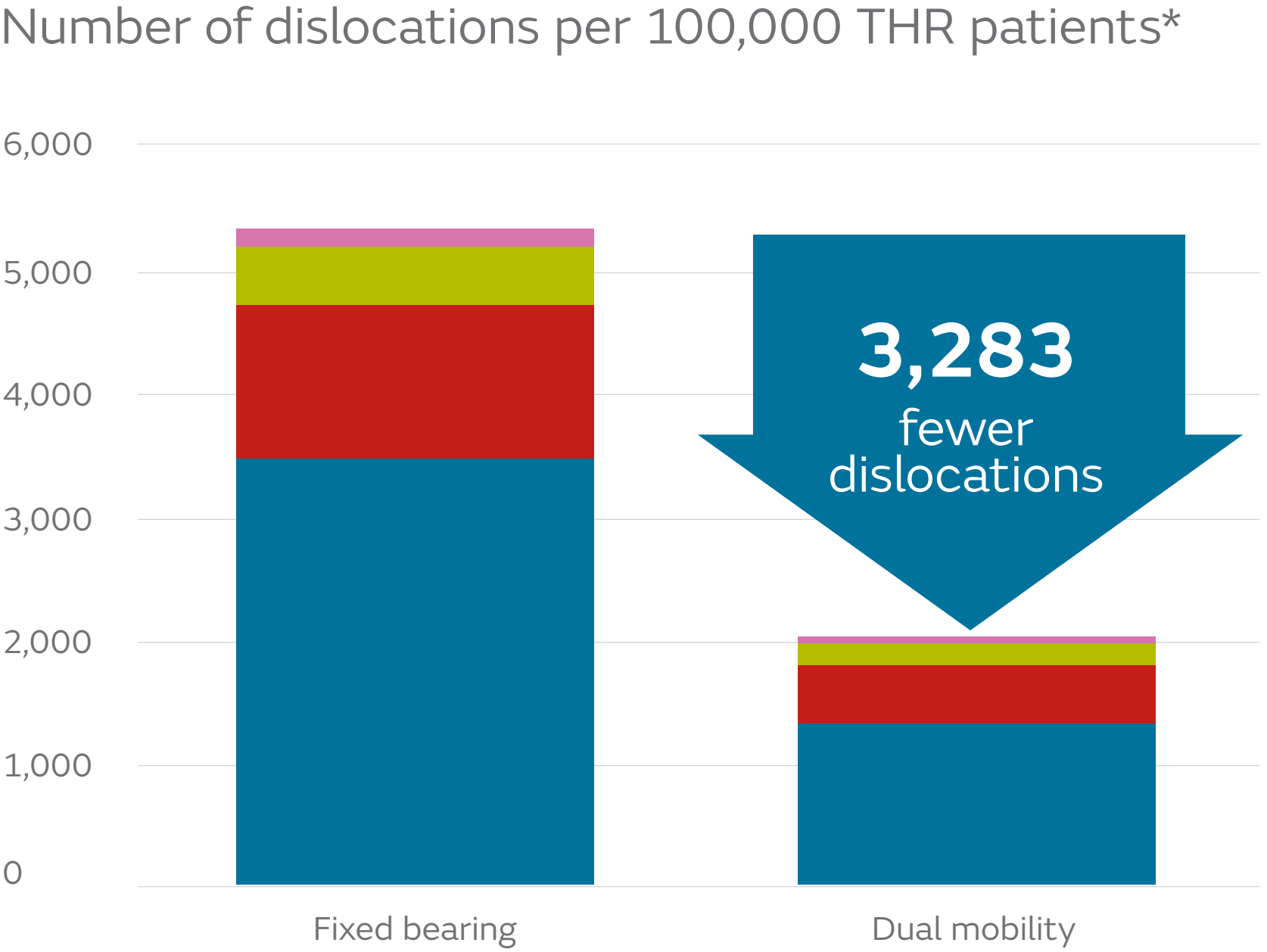
Inflammatory arthropathy

Neuromuscular disease

*American Society of Anesthesiologists' physical status classification system

Dual mobility acetabular components may reduce number of dislocations and revisions compared to fixed bearings⁷

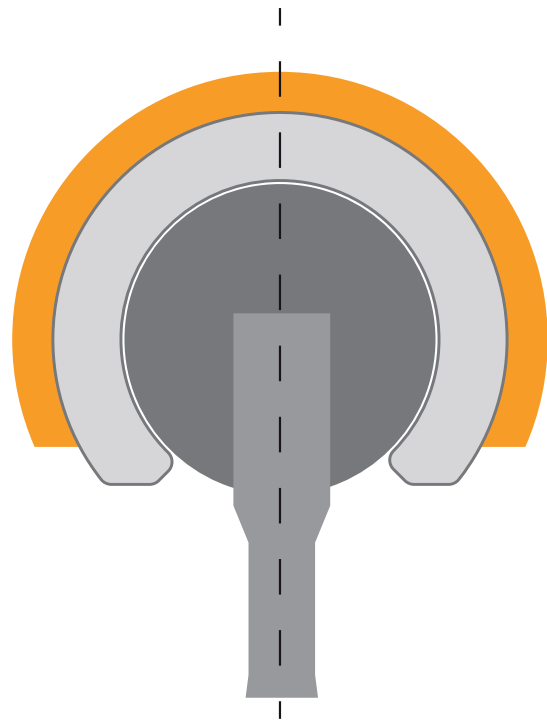
- 4 dislocations
- 3 dislocations
- 2 dislocations
- 1 dislocation



*Based on assuming a relative risk of dislocation of 0.4 for dual mobility vs fixed bearing

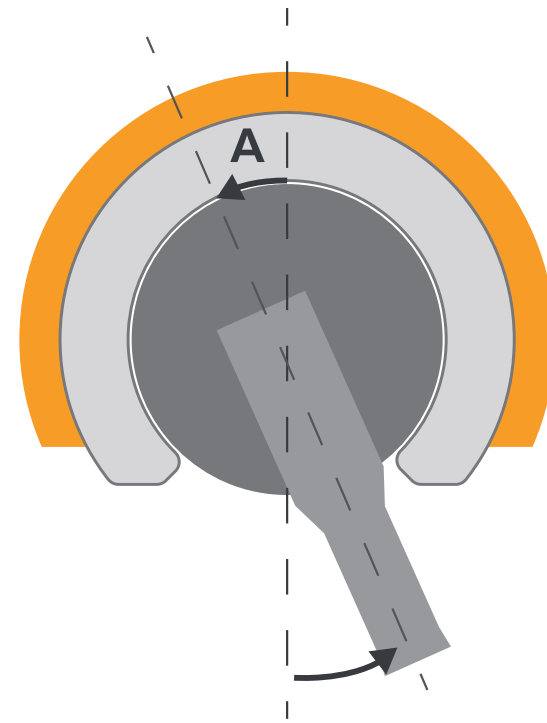
Dual mobility (DM) acetabular components

Designed to deliver increased range of motion with good stability to address dislocation whilst reducing wear⁸



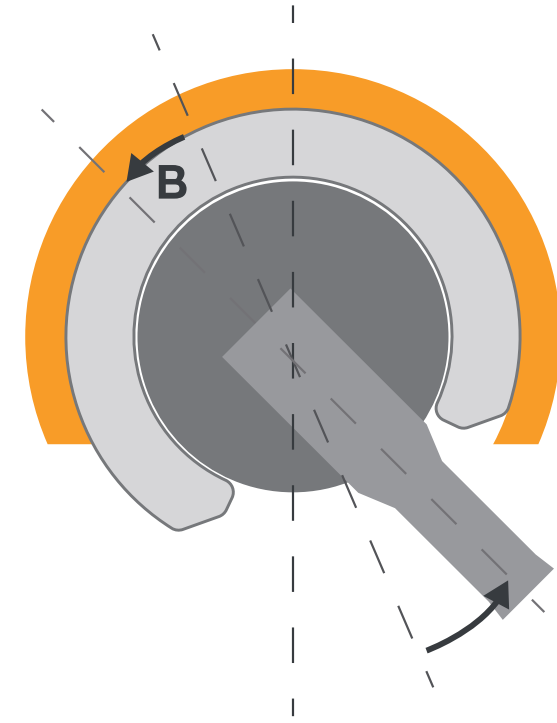
Neutral position

The insert is self-aligning, allowing loading following the path of least resistance



Low level activity

Primary movement occurs in the ball head/insert articulation, allowing the insert to sit in its natural position

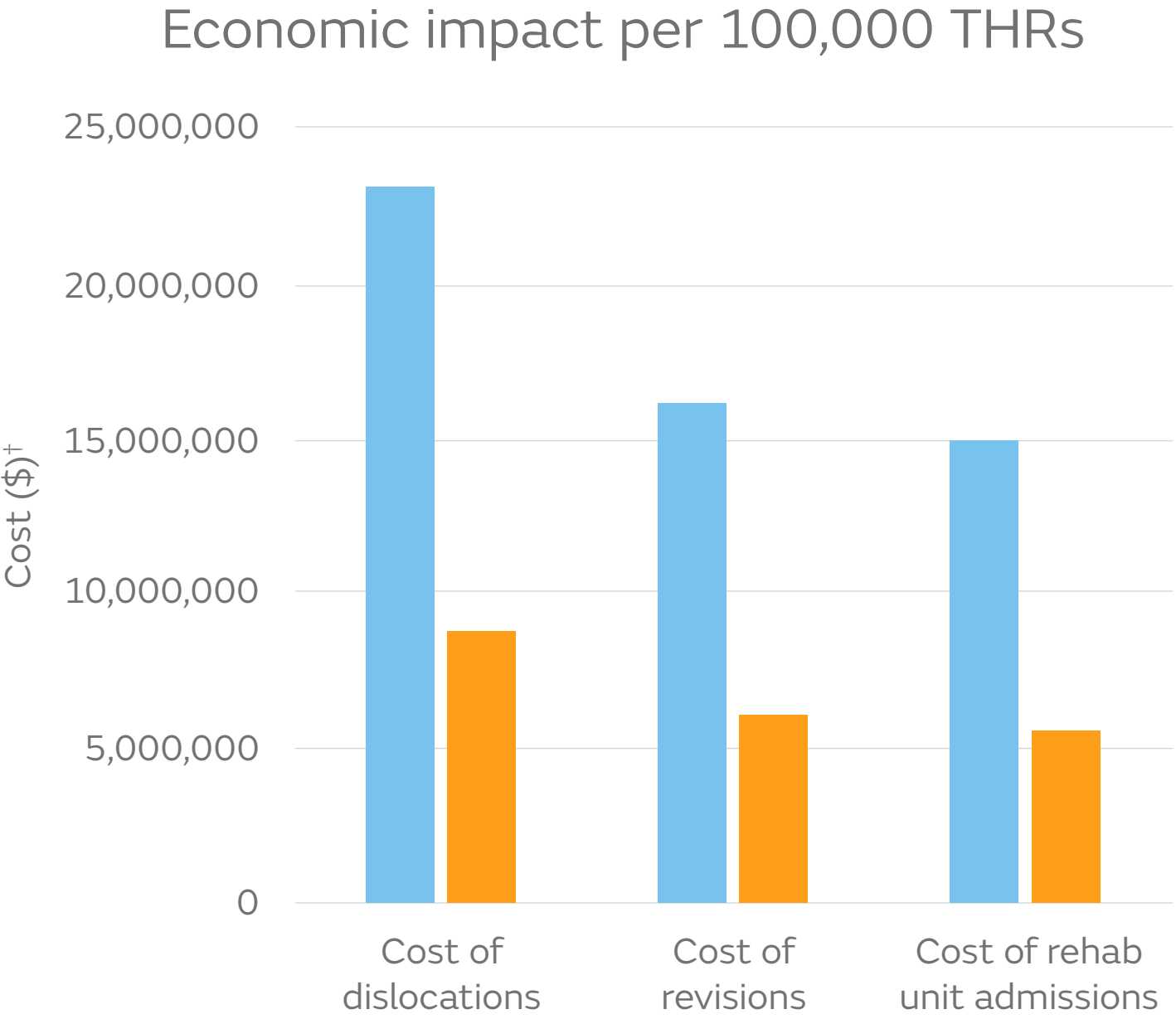


High level activity

Secondary movement occurs in the insert/cup articulation

Potential cost savings with DM cups when used in *all* primary THR patients*⁷

- Fixed bearing
- Dual mobility



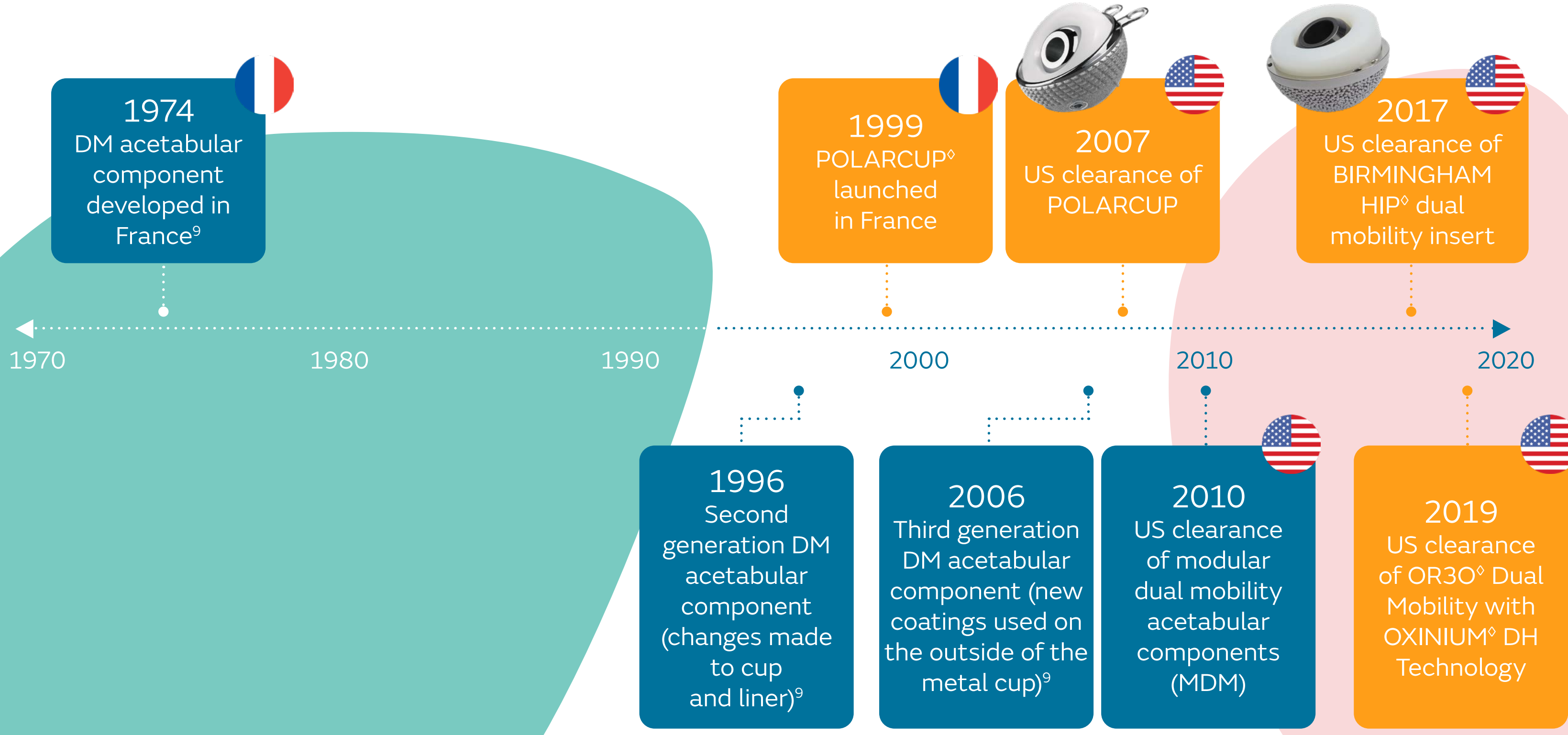
DM cups may result in cost savings per 100,000 primary THRs of **\$33,399,671[†]**

*Compared to fixed bearings
[†]Calculated from €30,276,802 with an exchange rate of 1USD=€0.91 (calculated May 1, 2020)

Dual mobility cups –
building on our strong
heritage



Advances in dual mobility systems



1974
DM acetabular component developed in France⁹

1999
POLARCUP[◇] launched in France

2007
US clearance of POLARCUP

2017
US clearance of BIRMINGHAM HIP[◇] dual mobility insert

1996
Second generation DM acetabular component (changes made to cup and liner)⁹

2006
Third generation DM acetabular component (new coatings used on the outside of the metal cup)⁹

2010
US clearance of modular dual mobility acetabular components (MDM)

2019
US clearance of OR30[◇] Dual Mobility with OXINIUM[◇] DH Technology

POLARCUP[◇] demonstrates excellent clinical and functional outcomes

20+ years of clinical heritage
10A* ODEP rating
POLARCUP Cementless¹⁰

 **7** clinical publications


 **4** Registries

 **200,000** implantations

Clinical results

 Excellent cumulative 10-year survivorship (all cause)¹¹
95.9%
n=502

0 Dislocations¹¹

 Dislocation rate in primary THR:¹¹⁻¹³
0.0 to 0.7%

From monoblock to modular DM cups: OR30[◇] Dual Mobility with OXINIUM[◇] DH Technology



OXINIUM femoral head

Launched in 2002; currently used with POLAR3 and REDAPT[◇] Total Hip Solutions

- Ceramicised metal: oxidized zirconium is a metallic alloy with a ceramic surface that provides wear resistance without brittleness
- OXINIUM minimizes the risk of corrosion and fretting compared to CoCrMo¹⁴
- Biocompatibility: OXINIUM contains very low levels of nickel, cobalt and chromium compared to cobalt chromium molybdenum implants^{15,16}

From monoblock to modular DM cups: OR30[◇] Dual Mobility with OXINIUM[◇] DH Technology



Highly cross-linked polyethylene (XLPE) insert

Launched in 2002; currently used across entire Smith+Nephew hip platform

- 10 Mrad irradiated and remelted XLPE
- Excellent mechanical properties¹⁷
- No measurable free radicals¹⁷
- Oxidation resistance¹⁸
- Low wear rate with a marked reduction in the risk of revision for aseptic loosening¹⁹⁻²¹
- Eccentric polyethylene design; reduces risk of impingement at retentive mouth

From monoblock to modular DM cups: OR30[◇] Dual Mobility with OXINIUM[◇] DH Technology



OXINIUM DH (Diffusion Hardened) liner

Launched in 2020

- Diffusion hardened oxidized zirconium (OXINIUM) designed for hard-on-hard articulation²²
- Comparable abrasion damage resistance to OXINIUM and superior to CoCrMo²³
- Low wear rates under ideal and adverse conditions^{24,25}
- 18 degree taper and alignment peg designed to aid in liner insertion and seating²⁶

From monoblock to modular DM cups: OR30[◇] Dual Mobility with OXINIUM[◇] DH Technology



R3[◇] or REDAPT[◇] Acetabular Systems

- Continuum of care from primary to complex revisions with acetabular platform
- Modular shell designs enabling screw fixation
- Liner removal slot

OR30[◇] delivers...

Low wear rates

OR30 may deliver reduced XLPE wear rates compared to POLARCUP[◇] under idealised conditions (ORS1041) and under adverse subluxation (ORS1012)^{24,25}

Adequate clearance to accommodate deformation

OR30 device has been shown to incorporate adequate clearance between the insert and liner to accommodate acetabular shell/liner deformation that may occur upon implantation; it should perform similarly to POLARCUP (ORS1905)²⁷

Minimal fatigue failure

OR30 insert will withstand stresses anticipated by sub-optimal acetabular cup orientation, and is comparable to POLARCUP (ORS1036)²⁸

Improved corrosion resistance

OR30 may deliver improved corrosion resistance compared to CoCrMo (ORS0528)²⁹

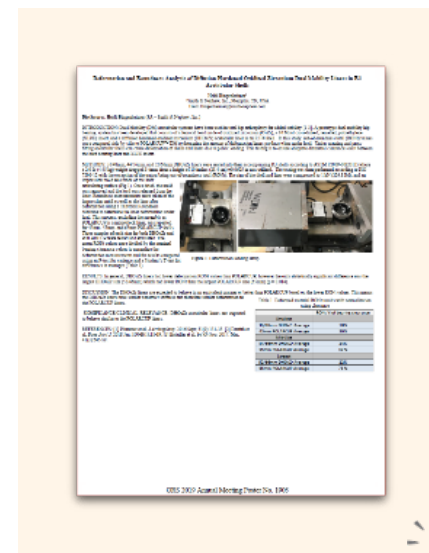
ORS1041



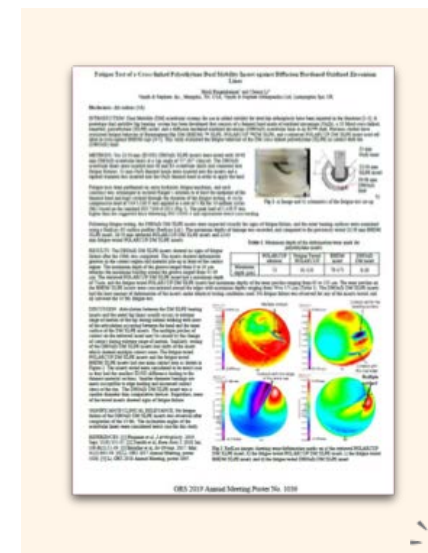
ORS1012



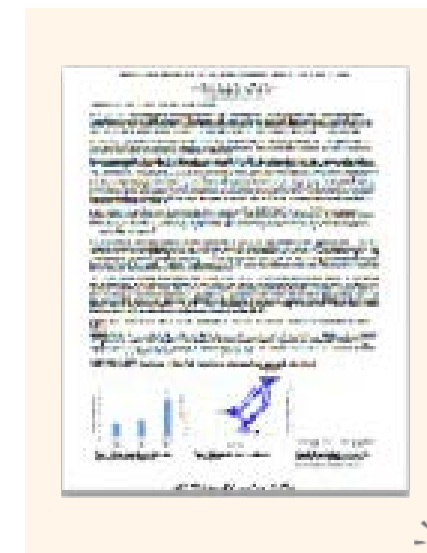
ORS1905



ORS1036



ORS0528



Indications for OR30^{◇*30}

- ✓ Advanced degeneration of the hip joint as a result of degenerative, post-traumatic, or rheumatoid arthritis
- ✓ Fracture or avascular necrosis of the femoral head
- ✓ Failure of previous hip surgery: joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement
- ✓ All forms of osteoarthritis
- ✓ Patients with hips at risk of dislocation (incl. spinal deformity)
- ✓ Femoral neck fracture or proximal hip joint fracture

*This is a full list of the indications for OR30; use of OR30 may not be suitable for all patients and should be decided by the surgeon on a per-patient basis.

Smith+Nephew

OR30[◇]

Dual Mobility with
OXINIUM[◇] DH Technology

✦ **Stability redefined**
In black and white




References

1. Gwam CU, Mistry JB, Mohamed NS, et al. Current Epidemiology of Revision Total Hip Arthroplasty in the United States: National Inpatient Sample 2009 to 2013. *J Arthroplasty*. 2017;32:2088–2092.
2. Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) Hip, Knee & Shoulder Arthroplasty: 2019 Annual Report. Available at: <https://aoanjrr.sahmri.com/annualreports-2019>. Accessed April 30, 2020.
3. Moore C, Orlandini L. The dual mobility concept in total hip arthroplasty. *Bone & Joint Science*. 2012;4:1–4.
4. Blakeney WG, Epinette J-A, Vendittoli P-A. Dual mobility total hip arthroplasty: should everyone get one? *EFORT Open Reviews*. 2019;4:541–547.
5. Jones CW, De Martino I, D’Apolito R, Nocon AA, Sculco PK, Sculco TP. The use of dual-mobility bearings in patients at high risk of dislocation. *Bone Joint J*. 2019;101-B(1 Supple A):41–5.
6. Abdel MP. Simplifying the hip-spine relationship for total hip arthroplasty: when do I use dual-mobility and why does it work? *J Arthroplasty*. 2019;34:S74–S75.
7. Epinette J-A, Lafuma A, Robert J, Doz M. Cost-effectiveness model comparing dual-mobility to fixed-bearing designs for total hip replacement in France. *Orthopaedics & Traumatology: Surgery & Research*. 2016;102:143–148.
8. De Martino I, Triantafyllopoulos GK, Sculco PK, Sculco TP. Dual mobility cups in total hip arthroplasty. *World J Orthop*. 2014;18:180–187.
9. Neri T, Philippot R, Klasan A, et al. Dual mobility acetabular cups for total hip arthroplasty: advantages and drawbacks. *Expert Rev Med Devices*. 2018;15:835–845.
10. Orthopaedic Data Evaluation Panel (ODEP). Available at: <http://www.odep.org.uk>. Accessed March 27, 2020.
11. Cypres A, Fiquet A, Girardin P, et al. Long-term outcomes of a dual-mobility cup and cementless triple-taper femoral stem combination in total hip replacement: a multicenter retrospective analysis. *J Orthop Surg Res*. 2019;14(1):376.
12. Bauchu P, Bonnard O, Cypres A, Fiquet A, Girardin P, Noyer D. The dual-mobility POLARCUP: first results from a multicenter study. *Orthopedics*. 2008;31(12 Suppl 2):97–99.
13. Fiquet A, Noyer D. “Polarsystem” dual mobility hip prosthesis and “minimally invasive surgery” (MIS). *Interactive Surgery*. 2006;22:1–5.
14. Cartner J, Aldinger P, Li C, Collins D. Characterization of femoral head taper corrosion features using a 22-year retrieval database. *HSSJ*. 2017;13:35–41.
15. Hunter G, Dickinson J, Herb B, Graham R. Creation of oxidized zirconium orthopaedic implants. *J ATSM Int*. 2005;2:7.
16. ASTM F75-01. Standard specification for cobalt-28 chromium-6 molybdenum alloy castings and casting alloy for surgical implants (UNS R30075), ASTM International, West Conshohocken, PA, 2012.
17. Morrison M, Jani S. Comparison of sequential and single-dose irradiation effects on the mechanical and physical properties of UHMWPE. Poster 1786 presented at Orthopaedic Research Society Congress; February 14–18, 2007; CA, USA.

References

18. Morrison ML, Jani S. Evaluation of sequentially crosslinked ultra-high molecular weight polyethylene. *J Biomed Mater Res B Appl Biomater*. 2009;90:87–100.
19. Davis ET, Pagkalos J, Kopjar B. Polyethylene manufacturing characteristics have a major effect on the risk of revision surgery in cementless and hybrid total hip arthroplasties: an analysis of the National Joint Registry Of England, Wales, Northern Ireland and The Isle of Man. *Bone Joint J*. 2020;102-B(1):90–101.
20. Jassim S, Patel S, Wardle N, et al. Five-year comparison of wear using oxidised zirconium and cobalt–chrome femoral heads in total hip arthroplasty. *Bone Joint J*. 2015;97:883–889.
21. Parikh A, Hill P, Pawar V. The effect of femoral head diameter and material on the wear of highly crosslinked polyethylene liners. Abstract #042 Presented at Society for Biomaterials Annual Meeting; April 13–16, 2011; FL, USA.
22. Pawar V, Weaver C, Parikh A, Jani S. Evaluation of Diffusion Hardened Oxidized Zr-2.5wt%Nb for Hard-on-Hard Articulation in Total Hip Arthroplasty. *Medical Device Materials VI; Proceedings from the Materials & Processes for Medical Devices Conference 2011 (ASM International)*. 2013;149–152.
23. Parikh A, Weaver C, Sprague J, Pawar V. Abrasion resistance, wear performance, and taper corrosion of a new composition of ceramicised metal. Poster 1910 presented at Orthopaedic Research Society Congress; March 5–8, 2016; FL, USA.
24. Parikh A, Weaver C. Wear testing of a new modular dual mobility system under sublaxation conditions. Poster 1012 presented at Orthopaedic Research Society Congress; February 2–5, 2019; TX, USA.
25. Parikh A, Weaver C. Wear Testing of a New Modular Dual Mobility System. Poster 1041 presented at ORS Congress; February 2–5, 2019; TX, USA.
26. Lee Y-K, Kim K-C, Jo W-L, Ha Y-C, Parvizi J, Koo K-H. Effect of inner taper angle of acetabular metal shell on the malseating and dissociation force of ceramic liner. *J Arthroplasty*. 2017;32:P1360–1362.
27. Bingenheimer H. Deformation and roundness analysis of diffusion hardened oxidized zirconium dual mobility liners in r3 acetabular shells. Poster 1905 presented at Orthopaedic Research Society Congress; February 2–5, 2019; TX, USA.
28. Bingenheimer H, Li C. Fatigue test of a cross-linked polyethylene dual mobility insert against diffusion hardened oxidized zirconium liner. Poster 1056 presented at Orthopaedic Research Society Congress; February 2–5, 2019; TX, USA.
29. US Department of Health and Human Services. 510(k) Summary Smith & Nephew OR30 Dual Mobility System (K191002). Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf19/K191002.pdf. Accessed April 30, 2020.



Smith & Nephew, Inc.
1450 Brooks Road,
Memphis, TN 38116,
USA

www.smith-nephew.com

◇ Trademark of Smith & Nephew
All Trademarks acknowledged
© 2020 Smith & Nephew
24756-en V2 12/20.
Published December 2020.