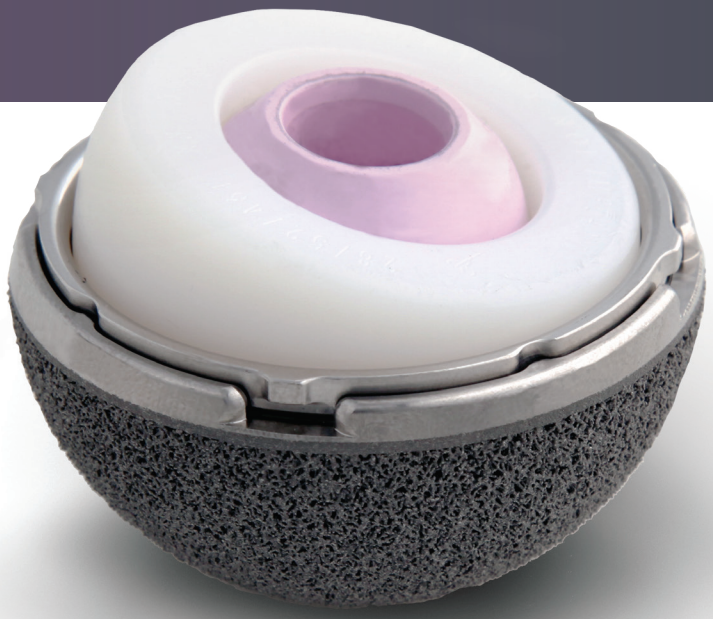
stryker

Modular Dual Mobility
Acetabular System



Design rationale

Addressing instability with dual mobility.

Worldwide patient outcomes are affected by instability, which is a significant complication of total hip arthroplasty (THA)[1]. National joint registries and meta-analyses indicate that hip dislocation is one of the most common causes of THA failure in both primary and revision procedures[1-4]. This has significant implications for future revision burden in a time of increasing numbers of THA performed in increasingly younger patients[1].

Registry data shows that dislocation is the second most common reason for revisions of primary hip procedures[5] and dislocation rates range from 4-30% in revision procedures[3]. The burden to the health economic system is higher when revisions occur, with an average length of stay over 6 days and cost upwards of $54,000 in the US[6].

Constructs such as constrained liners and large femoral heads were designed to help address dislocation due to instability, but have had limited success in decreasing the postoperative dislocation rates[2]. Dual mobility constructs were developed in the 1970s, and have demonstrated success in enhancing the stability of THAs[1-4,7].

2016 Australian Orthopaedic Association National Joint Replacement Registry

Reason for Revision	Number	Percent
Loosening/Lysis	3286	27.6
Prosthesis Dislocation	2803	23.5
Fracture	2230	18.7
Infection	2081	17.5
Pain	220	1.8
Leg Length Discrepancy	164	1.4
Malposition	142	1.2
Instability	119	1.0
Implant Breakage Stem	117	1.0
Metal Related Pathology	104	0.9
Wear Acetabular Insert	96	0.8
Implant Breakage Acetabular Insert	92	0.8
Implant Breakage Acetabular	92	0.8
Incorrect Sizing	90	0.8
Implant Breakage Head	35	0.3
Other	236	2.0
Total	**11907**	**100.0**

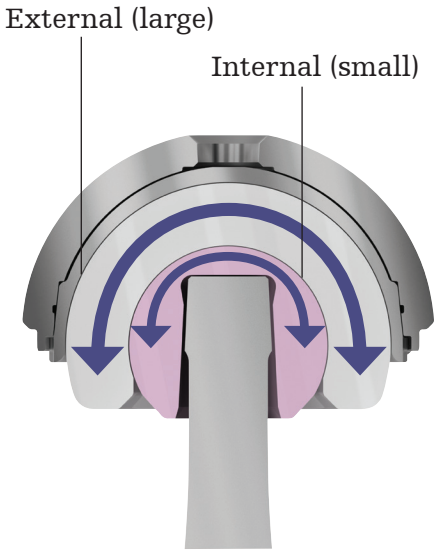
Reference: 5

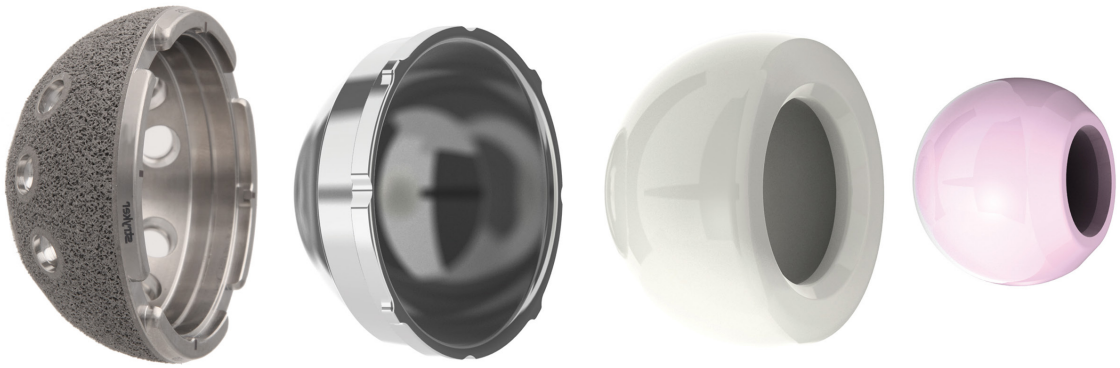
Modular Dual Mobility

Stryker's MDM consists of a modular cobalt chrome liner, a large diameter X3 polyethylene insert, and a femoral head. The highly polished modular cobalt chrome liner can be assembled into any of Stryker's acetabular shells utilizing the Trident Locking Mechanism. X3 polyethylene has demonstrated annual in vivo wear of just 1 micron at 5 years, with no mechanical failures with conventional bearings[8].

Together these components result in a dual mobility device with two points of articulation – one between the X3 polyethylene insert and metal liner (external bearing), and the other between the X3 polyethylene insert and the femoral head (internal bearing). Primary motion occurs at the inner bearing while the outer bearing moves in cases of extreme range of motion, which may minimize wear[9], reduce frictional torque[7], and increase stability[7].

Two Points of Articulation





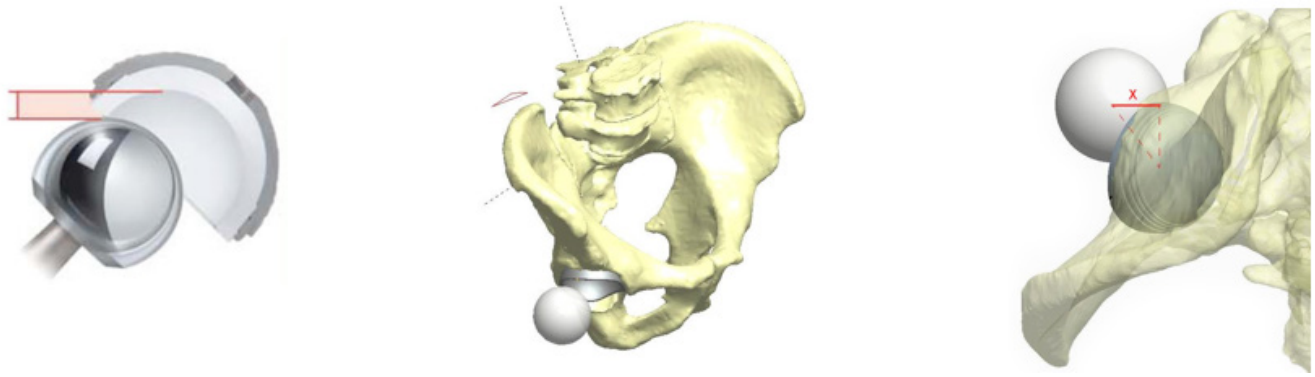
Clinical advantage of MDM:

MDM offers stability[2-3,7] with:

- Versatility
- Clinical proof[1-4,10,11]
- Economic value[12]

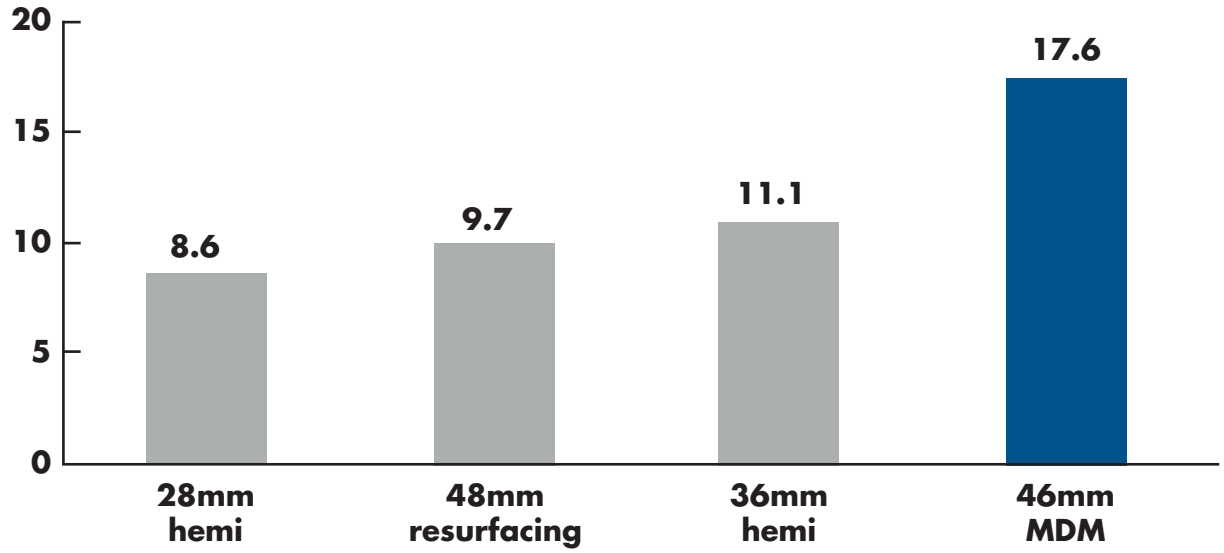
Stability:

- The X3 polyethylene inserts of the MDM system are available in large sizes offering increased jump distance – the distance the femoral head must travel to dislocate[1]. The greater the jump distance, the greater the stability of the hip[13].
- Computer simulations of dislocation demonstrate that for a given shell size the MDM design surpasses the jump height of a traditional fixed bearing[7,14].
- When compared to a conventional THA with a 36mm femoral head, MDM offers a 59% increase in jump distance[7,14].



2-D Jump Height (left) and 3-D Posterior Horizontal Dislocation Distance: denoted X (center and right)[7].

Jump Distance (mm) measured at 26˚ of pelvic tilt with a 54mm shell at 45˚ of inclination and 20˚ of anteversion



Measured in 3D Posterior Horizontal Dislocation Distance; Reference: 7

Versatility:

MDM is a versatile bearing option, as its indications include both primary and revision cases[1-4]. It is a simple construct to use as it does not require a change in surgical technique and may be easily incorporated into a surgeon's practice.

MDM is versatile because it:

- May be used in primary and revision procedures
- Utilizes the Trident Innerchange Locking Mechanism, allowing surgeons the flexibility to trial modular or fixed bearing options intraoperatively
- May be used with Trident II, Trident, Tritanium, or the Restoration Anatomic Shell
- Offers the option to use cancellous bone screws

Potential applications for MDM

Revision:

- Dislocation

High risk primary:

- Mental disability
- Neuromuscular disease
- Acute femoral neck fracture
- Spinal fusions
- Dysplastic hips
- Small acetabulums

Primary:

- High demand patients

Clinical proof:

MDM launched in 2011, and since has had several studies published to show clinical success ranging from outcome data on stability to metal ion levels.

Stability

MDM has been shown to be clinically successful in preventing dislocations[1-4].

"The use of dual-mobility bearings in difficult hip arthroplasty reconstructive cases" – Mont et al.

- In a revision setting, patients with dual mobility had lower dislocation and aseptic loosening rates compared to the control group[2].

"Dual-Mobility Constructs in Revision THA Reduced Dislocation, Re-Revision & Reoperation Compared to Large Femoral Heads" – Abdel et al.

- Revision THA patients with a dual mobility construct had a lower risk of subsequent dislocation, lower risk of re-revision for dislocation, and lower risk of reoperation for any reason at 3.6 years of follow-up when compared to patients treated with a 40mm femoral head[4].
- Surgeons may consider expanding the role of dual mobility constructs in contemporary revision THAs as dual mobility constructs have shown to lower the risk of subsequent dislocation, re-revision, and reoperation[4].

"The use of dual-mobility bearings in difficult hip arthroplasty reconstructive cases" – Mont et al.

- MDM addressed stability in a wide array of indications, ranging from revisions to high risk primary procedures.
- Authors of the study recommend the use of dual mobility in cases of recurrent dislocation, for revision arthroplasties, or for patients at a high risk of dislocation in primary arthroplasty[3].

"Early experience with dual mobility acetabular systems featuring highly cross-linked polyethylene liners for primary hip arthroplasty in patients under fifty five years of age: an international multi-centre preliminary study" – Epinette et al.

- The study evaluated dual mobility constructs in patients 55 years and younger, and concluded that MDM demonstrated excellent clinical data and may reduce stability and wear in the long run[1].

Modularity

Modular junctions are a consideration with implant selection for reasons of strength, material performance, and corrosion. In fact, clinical studies have been shown to demonstrate that the modularity of the MDM liner, metal ions have been shown not to be an issue[10], and no difference has been shown in metal ion levels when compared to conventional constructs[11].

"Metal ion levels in patients with modular acetabular hip components, matching CrCo liners with titanium cups" – Epinette, J.

- This two year study demonstrated that modularity was not an issue with MDM, due to an optimal locking mechanism design[10].

"What are normal metal ion levels after total hip arthroplasty? A serologic Analysis of Four Bearing Surfaces" – Barlow et al.

- This study compared metal ion levels between polyethylene with ceramic and metal heads, ceramic on ceramic and MDM with a ceramic of metal head, and showed that there was no difference in metal ion levels across all bearing options[11].

Economic Value:

MDM exhibited "absolute dominance" with cost effectiveness over conventional THA[12].

"Dual mobility implants are cost-saving for primary THA: A cost-utility analysis using direct and indirect costs" – Barlow et al.

- This study compared outcomes of MDM and conventional constructs, along with costs associated with the implants and the revisions[12].
- MDM was shown to be more cost effective when compared to conventional constructs[12].

How may hospitals benefit when using MDM?

A study has shown that hip instability/dislocation and mechanical loosening are the most common causes for revision THAs in the US[6]. For instance, the cost of treating dislocation has been estimated to represent $74,000,000 annually to the U.S. healthcare system[15]. Prevention of issues such as dislocation and loosening after hip arthroplasty is critical not only to minimize patient morbidity but also to maintain the cost-effectiveness of this surgical procedure.

The MDM system has been designed to help address the most common reasons for failure after THA[1-4], which may help to minimize the overall expense to hospitals and the U.S. healthcare system.

How may surgeons benefit when using MDM?

MDM offers surgeons an alternative solution for addressing individual needs of patients. MDM is designed to offer orthopaedic surgeons increased versatility to allow them to address the wide breadth of reconstructive challenges that they face.

Operating Room Efficiency

- Single set of instrumentation to maximize OR efficiency

Simplicity

- Surgical procedure is similar to conventional THA

Intra-operative Versatility

- MDM uses a conventional acetabular shell offering the surgeon the intraoperative flexibility to utilize a conventional design or the MDM System

How may patients benefit when using MDM?

MDM is designed to allow for the potential for improved joint stability[1-4]. This bearing solution may be a suitable alternative for the changing needs of patients who require THA surgery – allowing surgeons to offer patients a solution to maintain their activity and lifestyle.

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