Restoration ADM
Anatomic Dual Mobility

Overview of Dual Mobility
Restoration ADM is a dual mobility bearing designed for both Primary and Revision total hip arthroplasty—offering increased stability and range of motion for patients at high risk of hip dislocation due to a history of prior dislocation, bone loss, joint or soft tissue laxity, neuromuscular disease, intra-operative instability or other related complications.

The concept of a dual mobility bearing is a relatively new concept in the U.S. market. However, dual mobility bearings, with designs similar to Restoration ADM, have been used clinically for over 30 years. The first dual mobility concept was defined in the early 1970’s by Gilles Bousquet, Professor in Orthopaedics at the University Hospital of St. Etienne (France); first implantations were in 1975. Bousquet’s historical series shows a dislocation rate of < 0.7%. Given the strong clinical experience of predicate devices with a similar dual mobility design, Restoration ADM has the potential to perform successfully and reduce the risk of dislocation.

Innovative Design and Improved Technology
The introduction of Restoration ADM reflects Stryker’s commitment to continued advancements in product innovation and technology for the improvement of patient quality of life.

With today’s patients living longer and demanding more of their implants, there is an ever growing need for alternative bearings, such as Restoration ADM, that are designed to address the need for stability and implant longevity.

System Component Design – The Restoration ADM construct consists of a cementless, solid back, anatomic cup (left and right), polyethylene insert and a femoral head component. Together, these components result in a dual mobility device with two points of articulation—one between the polyethylene insert and metal cup (external bearing), and the other between the polyethylene insert and femoral head (internal bearing) (Fig 1). Primary point of motion occurs at the internal bearing, providing the opportunity to minimize wear and improve longevity of the implant.

Patented Cup Design – Restoration ADM is the only dual mobility device with an anatomic cup currently available on the market.

The anatomic cup has a rim that closely matches the anatomy of the acetabulum. By doing so, Restoration ADM offers excellent coverage for increased stability, while also potentially reducing the risk of cup and stem impingement; and cup and iliopsoas tendon impingement.

Reducing the risk of cup and stem impingement helps minimize the risk of dislocation, metallosis and/or cup tilting; while reducing the risk of cup and iliopsoas tendon contact helps minimize the risk of groin pain. It is important to note that iliopsoas tendon pain is common with hemispherical cups that are oversized, protrusive or insufficiently placed in the acetabulum. Due to the anatomic nature of the Restoration ADM cup, iliopsoas tendon pain can potentially be avoided.

Clinical Advantage of Restoration ADM
Restoration ADM is designed with the potential to:
• Restore hip stability
• Reduce the risk of dislocation
• Increase range of motion

The insert is available in sizes ranging from 42mm to 58mm outer diameter (OD), providing increased jump distance—the distance a head must travel to dislocate after impingement. The greater the jump distance, the greater the stability of the hip; thus helping to reduce the risk of dislocation.

Based on laboratory testing, when compared to a conventional total hip arthroplasty utilizing the same cup size, Restoration ADM provides greater jump distance and increased range of motion.

Potential Benefits for Hospital
Restoration ADM is designed to provide patients with the potential of improved joint stability – helping to minimize the risk for dislocation and to restore joint mechanics and function. In doing so, Restoration ADM helps to address the rising costs associated with the treatment of hip dislocation after total hip arthroplasty, which helps to minimize the overall expense to hospitals and the U.S. healthcare system.

Hip dislocation, after total hip arthroplasty, occurs in 3.9% of Medicare patients undergoing total hip arthroplasty each year.
Dislocation rates continue to increase at a relatively constant rate and are estimated to represent an annual cost of $74,000,000 to the U.S. healthcare system. In fact, it remains one of the most common complications after a total hip replacement procedure.

The treatment of dislocations after total hip replacement may require the use of expensive hospital resources. A study of hospital costs after primary hip replacement revealed that each dislocation episode treated with closed reduction increased the cost of the primary total hip replacement by 19%. Hospital costs for dislocation after hip arthroplasty is critical not only to minimize patient morbidity, but also to maintain the cost-effectiveness of this surgical procedure by minimizing re-admission. Recommendations to decrease the prevalence of dislocations include, but are not limited to, the use of larger-diameter femoral heads, dual mobility devices, such as Restoration ADM, and careful component positioning.

### Potential Benefits to Surgeon

Restoration ADM provides surgeons with an alternative solution for addressing personalized needs of patients. Offering an indication-based bearing, such as Restoration ADM, can give surgeons another option for managing patients at risk for joint instability.

The concept of an Anatomic Dual Mobility bearing in particular, is an innovative approach that offers a unique solution for surgeons and patients alike.

- **Operating Room Efficiency** - Restoration ADM includes a system of cross-compatible instrumentation to maximize OR efficiency.
- **Instrument Ease-of-Use** - Assembly and use of instrumentation is intuitive, allowing surgeons and OR staff to utilize with ease.
- **Simplicity** - There are many similarities between the surgical procedure of Restoration ADM and a conventional THA.
- **Intra-Operative Alternative** - Same cup size used with Restoration ADM as a conventional THA is designed to allow for a larger bearing for greater stability and ROM.

### Potential Benefits to Patient

Restoration ADM, a differentiated acetabular implant system, is designed to address patient complications associated with the risk of hip dislocation, and the need for moderate constraint and maximized range of motion. This bearing solution may be a suitable alternative for the changing needs of patients who require total hip arthroplasty—offering patients a Personalized Hip Solution specific to their indication, activity and lifestyle.

- **Stability** - The anatomic cup allows for greater coverage of the insert, and the large diameter insert further offers improved hip stability.
- **Mobility** - Increased motion may be achieved with the large diameter insert, which has the potential to experience extended range of motion as a result of the anatomic rim shape of the cup.
- **Longevity** - Primary articulation at the internal bearing reduces polyethylene wear, that may help to prolong the life of the implant.
- **Biocompatibility** - Restoration ADM offers a polyethylene-on-metal bearing that addresses the risk of metal sensitivity—a concern otherwise associated with metal-on-metal articulation.

### Average Institutional Cost for Primary Total Hip Arthroplasty, Closed Reduction, and Revision Surgery for Instability

<table>
<thead>
<tr>
<th></th>
<th>Primary Total Hip Arthroplasty</th>
<th>Each Closed Reduction</th>
<th>Each Revision Surgery</th>
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</thead>
<tbody>
<tr>
<td>Operating room and implants</td>
<td>$5525 (43.0%)</td>
<td>$149 (6.1%)</td>
<td>$4813 (35.1%)</td>
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<tr>
<td>Hospital stay and nursing</td>
<td>$3701 (28.8%)</td>
<td>$1030 (42.3%)</td>
<td>$4008 (29.2%)</td>
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<tr>
<td>Orthopaedic surgeon</td>
<td>$1485 (11.6%)</td>
<td>$664 (27.3%)</td>
<td>$2129 (15.5%)</td>
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<tr>
<td>Pharmacy</td>
<td>$632 (4.9%)</td>
<td>$135 (5.3%)</td>
<td>$708 (5.2%)</td>
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<tr>
<td>Physical therapy</td>
<td>$596 (4.6%)</td>
<td>$19 (0.8%)</td>
<td>$578 (4.2%)</td>
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<tr>
<td>Laboratory medicine</td>
<td>$401 (3.1%)</td>
<td>$80 (3.3%)</td>
<td>$642 (4.7%)</td>
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<tr>
<td>Anesthesia</td>
<td>$162 (1.3%)</td>
<td>$126 (5.2%)</td>
<td>$226 (1.6%)</td>
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<td>Radiology</td>
<td>$180 (1.4%)</td>
<td>$170 (7.0%)</td>
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<td>Central supply</td>
<td>$66 (0.5%)</td>
<td>$29 (1.2%)</td>
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<td>Internal medicine consults</td>
<td>$91 (0.7%)</td>
<td>$31 (1.3%)</td>
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<td>Pathology</td>
<td>$9 (0.1%)</td>
<td>$16 (0.1%)</td>
<td>$166 (1.2%)</td>
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<tr>
<td>Total</td>
<td>$12,648</td>
<td>$2,433 (+19%)</td>
<td>$13,717 (+107%)</td>
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</tbody>
</table>

*All costs are reported in 2003 constant dollars, with the percentage of the total cost of the procedure in parentheses. Only those categories with an average cost of more than five dollars are reported.*