Mako™
Robotic-Arm Assisted Surgery

Value summary
The Institute for Healthcare Improvement Triple Aim Initiative

Better health for the population
Better care for individuals
Lower cost through improvement

In today’s healthcare market, hospital systems in particular are being guided by the Triple Aim Initiative, which is focused on three areas:

- Enhancing the patient care experience – Better care for individuals
- Enhancing the health of populations – Better health for populations
- Reducing per-capita costs of healthcare – Lower costs through improvement

Surgical care currently accounts for an estimated 52% of hospital admission in the US and recently proposed mandated bundled payments for knee and hip procedures have the potential to considerably affect the orthopaedic surgical procedural landscape.

Under the final ruling of the Comprehensive Care for Joint Replacement (CCJR) model, beginning in April 2016 acute care hospitals in 67 geographic areas will receive retrospective bundled payments for episodes of care for hip and knee replacement surgeries. All related care within 90 days of hospital discharge from the joint replacement procedure will be included in the episode of care.

Demand for knee and hip procedures will continue to rise:

- According to a recent study evaluating historical procedure rates and population projections by the US Census Bureau, the projected number of total knee replacements will increase by 673% by 2030 or nearly 3.5 million procedures.
- In this same time period, the demand for primary total hip replacement is projected to increase by 174% or 572,000 procedures.

The Mako Robotic-Arm Assisted System offers a transformational shift in orthopaedic surgery by enabling surgeons to reduce variability within partial knee procedures and total hip procedures potentially driving operational efficiency and thereby enhancing the orthopaedic service line and improving market share and profitability.
Overview of osteoarthritis and approaches to treatment

- Osteoarthritis, the most common form of arthritis, affects more people than any other joint disease and is the most widespread cause of walking-related disability in people over the age of 65 years.25-27 Among adults 60 years and older in the US, an estimated 37.4% have radiographic evidence of the condition.28

- As the fourth-most common cause for hospitalization, a diagnosis of osteoarthritis is attributed to approximately 12 million ambulatory care visits and 85,000 emergency room visits per year.29

- Total knee and hip replacements accounted for more than $42 billion in hospital costs in 2009, with over 905,000 knee and hip replacements performed.29

Current approaches to treatment

For patients who are candidates for total joint procedures, several surgical procedures are available, including total joint replacement procedures, partial joint replacement, manual (traditional) and robotic-assisted techniques. While all surgery carries risk, total joint replacement procedures are major surgical undertakings, with the potential for complications to occur.27

The following table illustrates common complications associated with knee and hip arthroplasty procedures that may lead to failure or a need for revision.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Common Complications</th>
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<tbody>
<tr>
<td>Knee arthroplasty30</td>
<td>• Instability</td>
</tr>
<tr>
<td></td>
<td>• Infection</td>
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<td></td>
<td>• Aseptic loosening</td>
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<td></td>
<td>• Mal-alignment</td>
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<tr>
<td>Hip arthroplasty31</td>
<td>• Early mechanical failures</td>
</tr>
<tr>
<td></td>
<td>• Dislocation</td>
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<tr>
<td></td>
<td>• Prosthetic failures</td>
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<td></td>
<td>(peri-prosthetic fracture, leg length discrepancy)</td>
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The Mako Robotic-Arm Assisted System is at the forefront of providing patients and healthcare providers with an innovative technology that may help to meet the goals of recently proposed policy initiatives.

Mako Robotic-Arm Assisted Surgery has the potential to be:

**Predictable**
Designed to minimize the margin of error to allow for accurate component placement and to enhance accuracy and reproducibility of both partial knee arthroplasty\(^8,10,11,32\) and total hip arthroplasty.\(^14-17\)

**Transformative**
Can help to transform orthopaedic practice and ultimately, patient care, and to deliver value to payers, surgeons, and patients.

**Mako Robotic-Arm Assisted System**

**Enhanced Planning:**
Patient-specific pre-operative plan enables accurate implant sizing and positioning.\(^8-10,13,17\)

**Functional Positioning:**
Surgeon-controlled intra-operative adjustments can be made to optimize implant placements.\(^16\)
The clinical and economic value of the Mako™ Robotic-Arm Assisted System

The Mako Robotic-Arm Assisted System helps to address the challenges in today’s changing orthopaedic landscape and healthcare environment.

### Triple Aim Initiative

| Improving the patient experience of care[^33] | • Mako Partial Knee resulted in lower postoperative pain at day seven and more accurate implant placement than manual PKA in a randomized controlled trial.[^31]
| | • Mako Partial Knee surgery resulted in 92% patient satisfaction at two years.[^34]
| | • Early results showed less physical therapy was required for Mako Partial Knee patients than manual TKA patients to reach the same functional goals.[^35]
| | • Mako Robotic-Arm Assisted THA resulted in higher Harris Hip Scores and higher UCLA Activity Scores at one year post-operative compared to manual THA at minimum one year follow-up.[^34]
| Improving the health of populations[^33] | • Studies have shown robotic-arm assisted PKA to be two to three times more accurate and three times more reproducible than manual partial knee replacement.[^8-10]
| | • In cadaveric studies, Mako Total Hip acetabular cup placement has been shown to be four times more accurate in achieving desired version and six times more accurate in achieving desired inclination than manual total hip arthroplasty (THA).[^12,13]
| | • A cadaveric study has demonstrated excellent accuracy and precision with regard to planned cup position, leg length, and offset.[^13]
| Reducing the per capita cost of health care[^33] | • May allow for more predictable implant selection due to patient-specific planning for robotic-assisted PKA and THA.
| | • Time-neutral for robotic THA when compared to manual THA in a single center study.[^15]
| | • Potential for decreased blood loss.[^14,16]
| | • Allows for more accurate component placement[^8,10,13] and helps to standardize the surgical process across users[^11] for robotic PKA.
| | • Potential decrease in sterilization costs due to fewer trays needed (five trays in manual PKA vs two trays in Mako PKA).
The comprehensive clinical research on Mako Robotic-Arm Assisted Surgery is focused on providing evidence of the clinical, functional, and economic value of the Mako Robotic-Arm System and corresponding partial knee and total hip implant systems, as well as laying a scientific foundation for the support and development of future products and applications.

Potential benefits of Mako partial knee arthroplasty

Partial knee arthroplasty (PKA) for patients with osteoarthritis isolated to only one or two compartments spares the anterior and posterior cruciate ligaments (ACL and PCL, respectively) and healthy bone and tissue. Minimizing tissue disruption may enhance patient outcomes and recovery time after TKA procedures, thereby reducing the risk of complications and associated costs and hospital days. Manual partial knee can be demanding procedures with a restricted field of view and surgeons cannot pre-operatively create a patient specific plan. Poorly implanted PKA may also fail earlier.

- Studies have shown Mako Robotic-Arm Assisted PKA procedures to be associated with two to three times less variability and error compared to manual procedures and results that are closely aligned with the pre-operative plan, allowing for greater accuracy with respect to magnitude of tibial slope, degree of error in the coronal plane, and femoral component placement.

- In a prospective, randomized, controlled single-center blinded trial (n=139 patients), Mako robotic-arm assisted PKA resulted in significantly lower post-operative pain and greater functionality at three months following surgery compared with manual PKA. Patients reported significantly less pain at seven days post-operation (Figure 1) and greater functioning at three months post-operation, as measured by American Knee Society Scores >160 (excellent). Office visits to general practitioners and hospitalizations within 3 months of surgery were also lower for Mako Robotic-arm assisted PKA patients (office visits: 30% vs 45%; hospitalizations: 3% vs 8%). Use of Mako-assisted procedures translated into 54 bed-days saved per 100 patients.

- In a large multicenter retrospective study of six surgeons (n=797 patients; 909 knees), Mako robotic-arm assisted PKA procedures had a cumulative revision rate of 1.2% at two years as well as high patient satisfaction at an average of 29.6 months follow-up (range: 22–52). This revision rate is substantially lower than reported rates for manual PKA of 4.5% and 4.8% at a two-year follow-up (Swedish and Australian national registries, respectively).
Early post-operative pain after PKA

% patients with excellent American Knee Society score (>160) at 3 months

Figure 1. Early post-operative pain (at day seven) (A) and American Knee Society Scores (at three months) (B) after Mako PKA vs manual PKA

Potential benefits of Mako total knee arthroplasty

The Mako Robotic-Arm Assisted System is indicated for use with the market-leading Triathlon Total Knee System. Stryker is excited about the Mako Total Knee and our plans to bring this truly differentiated technology option for Triathlon TKA to our customers. In combination with use in partial knee arthroplasty (PKA) and total hip arthroplasty (THA), the total knee arthroplasty (TKA) application makes the Mako System a comprehensive total joint arthroplasty technology for a provider’s orthopaedic service line. Based on data from validation testing and a safety focused clinical trial, the Mako Total Knee performed within the intended use and met the primary clinical endpoints.

<table>
<thead>
<tr>
<th>Patient-specific pre-operative planning</th>
<th>• Using the patient’s CT scan, a 3D model is created to plan implant size, placement, and alignment specific to each patient’s unique anatomy.</th>
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<tbody>
<tr>
<td>Intra-operative soft-tissue balancing</td>
<td>• Surgeons are provided with real-time data, enabling assessment of ligament tension throughout range of motion and implant articulation.</td>
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<td></td>
<td>• This enables surgeons to fine-tune the plan intraoperatively, if needed, for soft-tissue balance.</td>
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<tr>
<td>Robotic-arm assisted resection</td>
<td>• The Mako system offers visual, auditory, and tactile feedback during bone preparation to help ensure accurate implant fit.</td>
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Potential benefits of Mako total hip arthroplasty

Many reasons for revision total hip arthroplasty can be linked to malpositioned acetabular components including dislocation, impingement, component wear, and liner fracture. Mako robotic-arm assisted procedures may enable surgeons to more accurately plan and place components potentially reducing variability within the THA procedure.

<table>
<thead>
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<th>Predictable</th>
<th>Transformative</th>
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<tr>
<td>• In cadaveric studies, Mako Total Hip acetabular cup placement has been shown to be four times more accurate in achieving desired version and six times more accurate in achieving desired inclination than manual THA.</td>
<td>• Increased accuracy and reduced dislocation rates vs manual THA.</td>
</tr>
<tr>
<td>• A cadaveric study has shown robotic THA provides excellent accuracy and precision with regard to planned cup position, hip length, and offset.</td>
<td>• Potential for decreased blood loss.</td>
</tr>
<tr>
<td>• A matched-pair controlled study determined greater bone stock preservation with robotic THA vs manual THA.</td>
<td>• Mako Robotic-Arm Assisted THA resulted in higher Harris Hip Scores and higher UCLA Activity Scores compared to manual THA at minimum 1-year follow-up.</td>
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</table>
Over 200 Mako Robotic-Arm Assisted Systems are being used to perform surgery today. To date, over 50,000 robotic hip and knee surgeries have been performed with the system. Over 700 orthopaedic surgeons use the technology in practice and over 1,500 surgeons have attended training classes.

Hospitals and surgeons are attracted to the Mako System for its potential ability to expand treatment options, broaden market reach as well drive surgical patient volumes. When comparing average annual knee and hip procedure volumes of 34 institutions two years prior to their Mako System installation with two years post-Mako System installation, a positive impact can be demonstrated (Figure 2).

![Procedure volumes pre/post Mako install – class of 2012](image)

Isolation of 34 currently active Mako systems installed in 2012. Active is defined as having performed at least one procedure with the MAKO system during 2012 and 2013. Overall hospital orthopaedic procedure provided by Aileron Solutions, 2010 to 2013

Case studies have shown a potential for an increase in the number of Mako Robotic-Arm Assisted and conventional knee procedures.\(^{19,20}\)

- One hospital showed a 32% increase in conventional knee arthroplasties two years after adoption of Mako-assisted procedures, and a 77% increase in primary knee arthroplasties\(^{19}\)

- Another hospital showed a 131% increase in all primary knee arthroplasties, and a 14% increase in total knee arthroplasty in the year following implementation of Mako Robotic-Arm Assisted procedures\(^{20}\)

- A 571-bed community hospital experienced 14% increase in TKA. In addition, PKA volume more than tripled, and in the second full year following Mako System implementation, experienced a 22% increase in Mako Partial Knee\(^{23}\)

- Finally, another community hospital experienced a 10-fold growth in PKA procedures and a 14% market share growth for all DRG 470 procedures in the first year following adoption of the Mako technology\(^{18}\)
At Stryker, we are committed to providing an unparalleled variety of high-quality, innovative products and services that create cost-effective solutions for our customers, as well as enhance quality of life for patients. Together with our customers, we are driven to make healthcare better.
Stryker is committed to collaborating with facilities that have the Mako System to offer marketing and strategy expertise, best practices, and marketing tools to generate consumer and professional awareness and to promote patient growth and growth of market share. The Robotic-Arm Destination Program provides facilities with a detailed plan and materials that target internal teams, key hospital stakeholders, consumers, and referring physicians.

The Mako Robotic-Arm Destination Program is committed to helping deliver advanced clinical outcomes and establishing a concrete advantage.

<table>
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<tr>
<th>Strategic advice</th>
<th>Lend marketing expertise and best practices that focus on your market dynamics, goals, and plans</th>
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<tbody>
<tr>
<td>Planning and development</td>
<td>Offer planning and program management tools as well as support in crafting an effective marketing plan</td>
</tr>
<tr>
<td>Execution support</td>
<td>Provide a marketing toolkit and resources to facilitate implementation</td>
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Stryker is one of the world’s leading medical technology companies and together with our customers, we are driven to make healthcare better. From our wide array of innovative medical technologies to our medical education, marketing, and collaboration programs, we are focused on working with our customers to help people lead more active and more satisfying lives.

Clinical and Field Marketing Support: A dedicated implementation team works and assists in educating staff as well as supporting Mako cases to help institutions develop a successful Mako program focused on delivering results.

Medical Education: From Mako surgical observations, to hands-on training to certification courses, Stryker’s comprehensive medical education assists with all areas of product adoption.

Stryker Performance Solutions®: Collaborates with hospitals and physician practices to help improve quality outcomes, patient satisfaction and profitability. Together, they help identify, measure and optimize your performance objectives.

Stryker FlexFinancial®: Offers innovative and flexible payment solutions to meet your budgetary needs and requirements, allowing you to remain competitive in today’s market.
References

17. Esposito CI; Lipman J; Carroll KM; Jerabek SA; Mayman SA; Padgett DE. Acetabular Component Cup Placement Using a Haptically Guided Robotic Technology in Total Hip Arthroplasty. 16th EFORT Congress, May 28-30, 2015, Prague, Czech Republic.
18. DMC Huron Valley – Sinai Hospital, Commerce Township, MI. Stryker Orthopaedics Memo to File #1. October 15, 2015.


A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. The products depicted are CE marked according to the Medical Device Directive 93/42/EEC. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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