

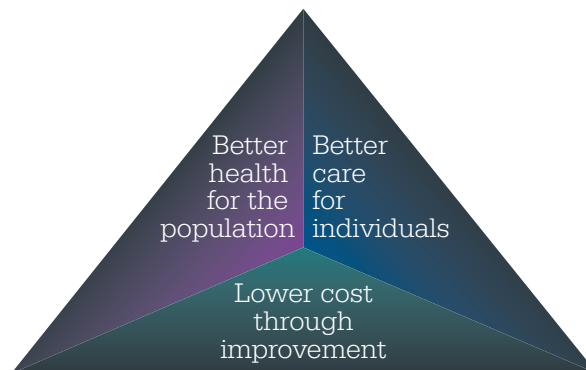
MakoTM

Robotic-Arm Assisted Surgery



Value summary

The future of healthcare reform and changing orthopaedic landscape



The Institute for Healthcare Improvement Triple Aim Initiative¹

- In today's healthcare market, hospital systems in particular are being guided by the Triple Aim Initiative, which is focused on three areas:¹
 - 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^{2,3} and recently proposed mandated bundled payments for knee and hip procedures have the potential to considerably affect the orthopaedic surgical procedural landscape.⁴
- 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.⁵

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.⁶
- In this same time period, the demand for primary total hip replacement is projected to increase by 174% or 572,000 procedures.⁶

The Mako Robotic-Arm Assisted System offers a transformational shift in orthopaedic surgery by enabling surgeons to reduce variability within partial knee procedures⁷⁻¹¹ and total hip procedures¹²⁻¹⁷ potentially driving operational efficiency and thereby enhancing the orthopaedic service line and improving market share and profitability.¹⁸⁻²⁴

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.

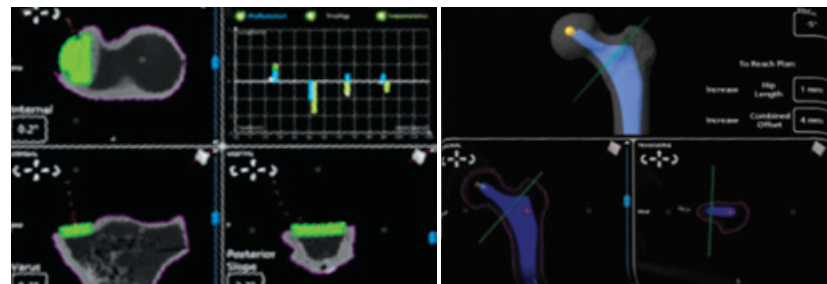
Procedure	Common Complications
Knee arthroplasty ³⁰	• Instability • Infection • Aseptic loosening • Mal-alignment
Hip arthroplasty ³¹	• Early mechanical failures • Dislocation • Prosthetic failures (peri-prosthetic fracture, leg length discrepancy)

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

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

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

Patient-specific pre-operative plan enables accurate implant sizing and positioning.^{8-10, 13,17}



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.¹¹ • 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.¹⁴
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 users¹¹ for robotic PKA. • Potential decrease in sterilization costs due to fewer trays needed (five trays in manual PKA vs two trays in Mako PKA).

Mako™ Robotic-Arm System clinical success

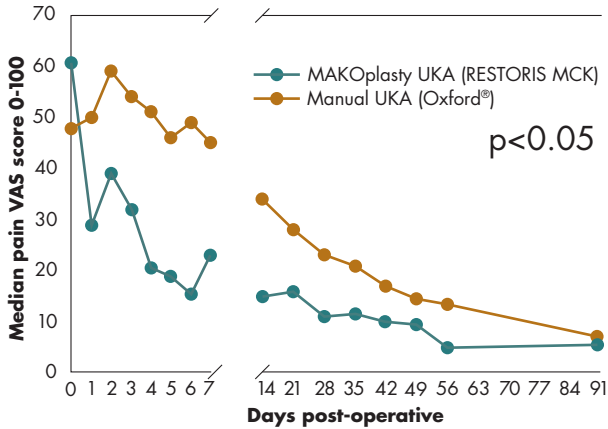
The comprehensive clinical research on Mako Robotic-Arm Assisted Surgery is focused on providing evidence of the clinical, functional, and economic value of the Mako Robotic-Arm System and corresponding partial knee and total hip implant systems, as well as laying a scientific foundation for the support 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.^{36,37} 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.¹¹

- 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.^{7-10,32,38}
- 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.¹¹ 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%).¹¹ Use of Mako-assisted procedures translated into 54 bed-days saved per 100 patients.¹¹
- 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).³⁴ 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).^{39,40}

Early post-operative pain after PKA



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

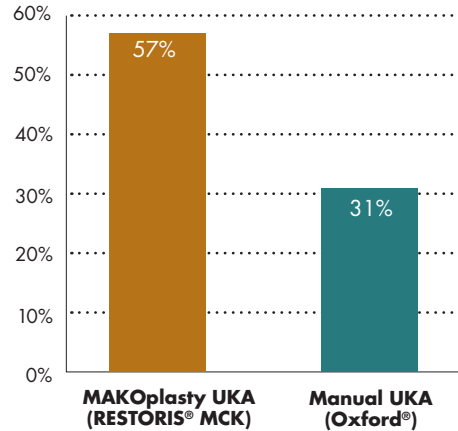


Figure 1. Early post-operative pain (at day seven) (A) and American Knee Society Scores (at three months) (B) after Mako PKA vs manual PKA¹¹

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.

Patient-specific pre-operative planning	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.
Intra-operative soft-tissue balancing	- Surgeons are provided with real-time data, enabling assessment of ligament tension throughout range of motion and implant articulation. - This enables surgeons to fine-tune the plan intraoperatively, if needed, for soft-tissue balance.
Robotic-arm assisted resection	The Mako system offers visual, auditory, and tactile feedback during bone preparation to help ensure accurate implant fit.

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.⁴¹ Mako robotic-arm assisted procedures may enable surgeons to more accurately plan and place components potentially reducing variability within the THA procedure.^{12-15,42}

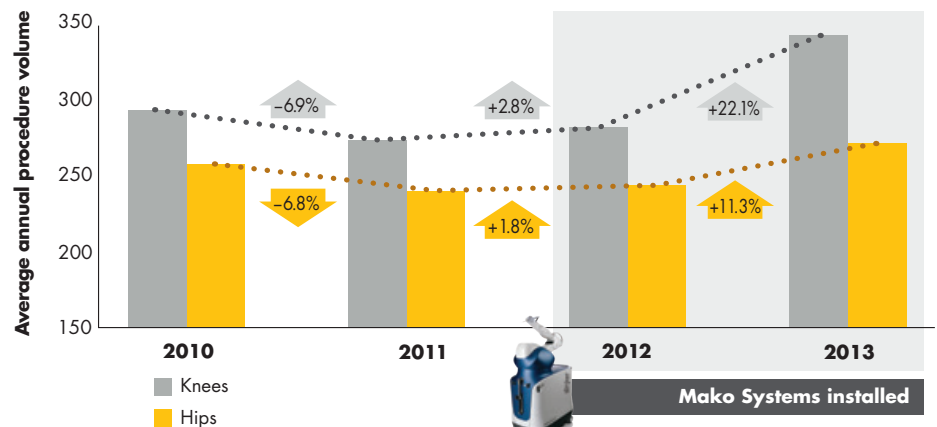
Predictable	Transformative
• In cadaveric studies, Mako Total Hip acetabular cup placement has been shown to be four times more accurate in achieving desired version and six times more accurate in achieving desired inclination than manual THA.^{12,13} • A cadaveric study has shown robotic THA provides excellent accuracy and precision with regard to planned cup position, hip length, and offset.¹³ • A matched-pair controlled study determined greater bone stock preservation with robotic THA vs manual THA.⁴³	• Increased accuracy and reduced dislocation rates vs manual THA.^{14,16} • Potential for decreased blood loss.^{14,16} • 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.¹⁴

Mako Robotic-Arm System return on investment (ROI)

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.)⁴⁴

Procedure volumes pre/post Mako install – class of 2012



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

Figure 2

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 arthroplasties¹⁹
- 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 procedures²⁰
- 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 Knee²³
- 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 technology¹⁸

Stryker's technology continuum in orthopaedics

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's dedication to innovation in orthopaedics



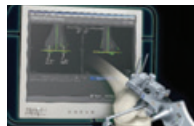
Implant Systems

Ongoing innovation in implant systems offers surgeons more options to restore function and help patients return to their normal daily activities.



Single-Use Instruments

System of single-use cutting blocks and trials is designed to reduce instrumentation and facilitate efficiency before, during and after the surgery.



Navigated Execution

Surgical navigation is used to facilitate decision making for alignment and orientation of instruments, trials and implants before and during surgery.



Freehand Power Tools

Designed to significantly reduce the potential for soft tissue damage⁴⁵ while facilitating precise control for trimming and shaping bone.⁴⁵



Robotic-Arm Assisted Surgery

Mako partial knee, total hip and total knee replacement surgery can help to transform orthopaedic practice and deliver value to providers, patients and payers.

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

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.

Strategic advice	Lend marketing expertise and best practices that focus on your market dynamics, goals, and plans
Planning and development	Offer planning and program management tools as well as support in crafting an effective marketing plan
Execution support	Provide a marketing toolkit and resources to facilitate implementation



Stryker support programs

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.⁴⁶



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

1. Whittington, JW, Nolan K, Lewis N, Torres T. (2015). Pursuing the Triple Aim: The first seven years. *Millbank Quarterly*. 93(2):262-300.
2. Cormier, J.N., Cromwell, K.D., Pollock, R.E. Value-based health care: a surgical oncologist's perspective. *Surgical Oncology Clinics of North America*. 2012. 21:497-506.
3. Fry, D.E., Pine, M., Jones, B.L., Meimban, R.J. The impact of ineffective and inefficient care on the excess costs of elective surgical procedures. *Journal of the American College of Surgeons*, 2011. 212:779-86.
4. Newmarker, C. Why Change is Coming to Hip and Knee Replacements. *Orthopedics*, posted July 10, 2015.
5. <https://www.federalregister.gov/articles/2015/11/24/2015-29438/medicare-program-comprehensive-care-for-joint-replacement-payment-model-for-acute-care-hospitals>. Accessed December 7, 2015.
6. AAOS Total Knee and Hip Replacement Projections 2030. <http://www.prnewswire.com/news-releases/total-knee-and-hip-replacement-surgery-projections-show-meteoriticrise-by-2030-55519727.html>. Accessed June 24, 2015.
7. Citak M, Suero EM, Citak M, Dunbar NJ et al. Unicompartmental knee arthroplasty: Is robotic technology more accurate than conventional technique? *The Knee* 2013; 20:268-271.
8. Dunbar NJ, Roche MW, Park BH, Branch SH; et al. Accuracy of Dynamic Tactile-Guided Unicompartmental Knee Arthroplasty. *Journal of Arthroplasty*. May 2012. 27(5): 803-808.e1.
9. Lonner, JH. Robotic-Arm Assisted Unicompartmental Knee Arthroplasty. *Seminars in Arthroplasty*. 2009. 20(1): 15-22.
10. Lonner JH, John TK, Conditt MA. Robotic Arm-Assisted UKA Improved Tibial Component Alignment: A Pilot Study *Clin Orthop Relat Res*. July 2010. 468(1):141-6.
11. Blyth M, Jones B, MacLean A, Anthony I, Rowe P. Accuracy of UKA implant positioning and early clinical outcomes in a RCT comparing robotic assisted and manual surgery. 13th Annual CAOS Meeting, June 12-15, 2013, Orlando, FL, USA. (Blyth/Jones 2013b).
12. Nawabi DH, Conditt MA, Ranawat AS, Dunbar NJ, et al. Haptically guided robotic technology in total hip arthroplasty: a cadaveric investigation. *Journal of Engineering in Medicine* 2012;227(3):302-309.
13. Jerabek SA, Carroll KM, Maratt JD, Mayman DJ, Padgett DE. Accuracy of Cup Positioning and Achieving Desired Hip Length and Offset Following Robotic THA.; 14th Annual CAOS Meeting, June 18-21, 2014, Milan, Italy.
14. Illgen RL, Bukowski BR, Abiola R. Outcomes after Primary Total Hip Arthroplasty: Manual Compared with Robotic Assisted Techniques. (Illgen 2013a)
15. Domb BG, El Bitar YF, Sadik BS, Stake CE, Botser IB. Comparison of Robotic-assisted and Conventional Acetabular Cup Placement in THA: A Matched-pair Controlled Study. *Clin Orthop Relat Res*. 2014 Jan;472(1):329-36.
16. Illgen R. Robotic Assisted THA: Reduce Outliers and Predictable Outcomes. 43rd Annual Course: Advances in Arthroplasty, October 22-25, 2013, Cambridge, MA. (Illgen 2013b).
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.
19. North Carolina Specialty Hospital, Durham, NC. Stryker Orthopaedics Memo to File #2. October 15, 2015.
20. Oconomowoc Memorial Hospital – Oconomowoc, WI. Stryker Orthopaedics Memo to File #3. October 15, 2015.
21. Pre-Post Mako System Installation Procedure Volumes – Class of 2012 Installations. Aileron Solutions, 2010-2013. Stryker Orthopaedics Memo to File #8. October 16, 2015.
22. St. Michael's Medical Center – Newark, NJ. Stryker Orthopaedics Memo to File #5. October 15, 2015.
23. Holy Cross Hospital – Ft Lauderdale, FL. Stryker Orthopaedics Memo to File #6. October 15, 2015.

24. Mako Economic Case Profile – One Year Review – Central Carolina Hospital. Stryker Orthopaedics Memo to file #7. October 15, 2015.
25. Buckwalter JA, Saltzman C, Brown T. The impact of osteoarthritis: implications for research. *Clin Orthop Relat Res.* 2004;(427 Suppl):S6-S15.
26. Felson DT, Lawrence RC, Dieppe PA, et al. Osteoarthritis: new insights. Part 1: the disease and its risk factors. *Ann Intern Med.* 2000;133(8):635-646.
27. Leopold SS. Minimally invasive total knee arthroplasty for osteoarthritis. *N Engl J Med.* 2009;360(17):1749-1758.
28. Dillon CF, Rasch EK, Gu Q, Hirsch R. Prevalence of knee osteoarthritis in the United States: arthritis data from the Third National Health and Nutrition Examination Survey 1991-94. *J Rheumatol.* 2006;33(11):2271-2279.
29. Murphy L, Helmick CG. The impact of osteoarthritis in the United States: a population-health perspective: A population-based review of the fourth most common cause of hospitalization in U.S. adults. *Orthop Nurs.* 2012;31(2):85-91.
30. Callaghan JJ, O'rourke MR, Saleh KJ. Why knees fail: lessons learned. *J Arthroplasty.* 2004;19(4 Suppl 1):31-34.
31. Tarwala R, Dorr LD. Robotic assisted total hip arthroplasty using the MAKO platform. *Curr Rev Musculoskelet Med.* 2011;4(3):151-156.
32. Plate JF, Mofidi A, Mannava S, Smith BP, et al. Achieving Accurate Ligament Balancing Using Robotic-Assisted Unicompartmental Knee Arthroplasty. *Advances in Orthopedics* 2013(2013): 837167.
33. Institute for Healthcare Improvement Triple Aim Initiative. <http://www.ihl.org/engage/initiatives/tripleaim/Pages/default.aspx>. Accessed October 16, 2015.
34. Coon T, Roche M, Pearle A, Douchis J, Borus T, Buechel Jr F. Short to Mid Term Survivorship of Robotically Assisted UKA: A Multicenter Study. *ICJR 2nd Annual Pan Pacific Orthopaedic Congress*, July 16-29, 2015, Kona, HI (Coon 2014a).
35. Borus T, Robers D, Fairchild P, Christopher J, et al. UKA Patients Return to Function Earlier than TKA Patients. *ISTA 27th Annual Congress*, Sept. 24-27, 2014, Kyoto, Japan.
36. White RE, Allman JK, Trauger JA, Dales BH. Clinical Comparison of the Midvastus and Medial Parapatellar Surgical Approaches. *Clinical Orthopaedics and Related Research.* 1999(367):117-122.
37. Tria AJ, Coon TM. Minimal Incision Total Knee Arthroplasty. *Clinical Orthopaedics and Related Research.* 2003(416):185-190.
38. Blyth M, Smith J, Jones B, MacLean A, Anthony I, Rowe P. A CT based comparison of accuracy of unicompartmental knee arthroplasty (UKA) implant positioning with and without the aid of robotic surgical assistance. *13th Annual CAOS Meeting*, June 12-15, 2013, Orlando, FL, USA. (Blyth/Jones 2013a).
39. The Swedish Knee Arthroplasty Registry. Annual Report 2012. Department of Orthopaedics, Skane University Hospital. Lund, Sweden.
40. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. Adelaide:AOA; 2013.
41. Callanan, M.C et al. The John Charnley award; risk factors for cup malpositioning quality improvement through a joint registry at a tertiary hospital. *Clin Orthop Relt Res*, 2011. 469(2): p. 319-29.
42. Elson L, Douchis J, Illgen R, Marchand R, et al. A multi-centric evaluation of acetabular cut positioning in robotic-arm assisted total hip arthroplasty. *13th Annual CAOS Meeting*, June 12-15, 2013, Orlando, FL, USA.
43. Suarez-Ahedo C, Gui C, Martin TJ, Stake CE, et al. Preservation of Acetabular Bone Stock in Total Hip Arthroplasty Using Conventional vs. Robotic Techniques, A Matched-Pair Controlled Study. *World Arthroplasty Congress*, April 15-18, 2015, Paris, France.
44. Pre-Post Mako System Installation Procedure Volumes – Class of 2012 Installations. Aileron Solutions, 2010-2013. Stryker Orthopaedics Memo to File #8. October 16, 2015.
45. Stryker Instruments, "System 7: Precision Oscillating Tip Saw". Literature Number: 9100-001-581RevB; UnDes/P.S.
46. Stryker Performance Solutions Homepage: www.strykerperformancesolutions.com. Accessed 12/13/2016.



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.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Mako, Stryker. All other trademarks are trademarks of their respective owners or holders.

stryker

Mako[®] Total Knee

**Triathlon Total Knee System
with Tritanium cementless
technology**



**Mako
Robotic-Arm
Assisted Surgery**

Mako Total Knee application

The Mako Total Knee application allows for **functional implant positioning**, which is patient-specific implant placement as a result of the three unique features of the Mako Total Knee procedure: enhanced planning, dynamic joint balancing, and robotic-arm assisted bone preparation. A single study showed Mako Total Knee having significantly lower mean pain ($p < 0.05$) and mean total patient satisfaction scores ($p < 0.05$), indicating greater patient satisfaction and clinical outcome for the Mako cohort compared to manual TKA.³⁰

Enhanced planning

CT data is segmented to create a 3D model of the patient's bony anatomy. The Mako Total Knee application allows you to manipulate the Triathlon implant on the patient's virtual 3D anatomy taking into account the 6 degrees of freedom, implant alignment in all three planes, and consider key anatomic landmarks such as the transepicondylar axis, posterior condylar axis and the mechanical axis during planning. In a single center, prospective study of consecutive cases, patient specific planning has been shown to be able to consistently determine femoral and tibial component sizing within one size of the pre-operative plan.³¹ This has the potential to enhance efficiencies in the operating room by minimizing the number of trays opened, and potentially decreasing revisions due to instability with more accurate sizing and placement of the components to achieve a well aligned and balanced TKA.³¹

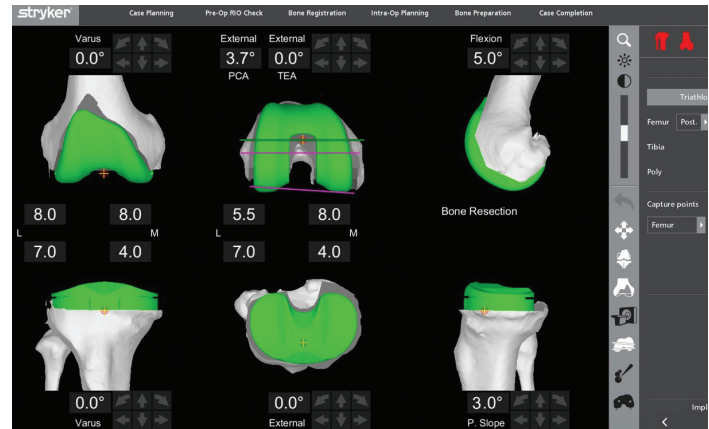


Figure 1: image of the pre-planning screen

Dynamic joint balancing

After assessing the patient's ligament tension, gap analysis, and limb alignment, you can make intraoperative adjustments to the pre-operative plan in both flexion and extension before bone preparation. In a case series of complex TKA cases, Mako Total Knee has been shown to assist surgeons in achieving desired alignment and rotation, even in patients with severe varus/valgus and flexion deformities.³²

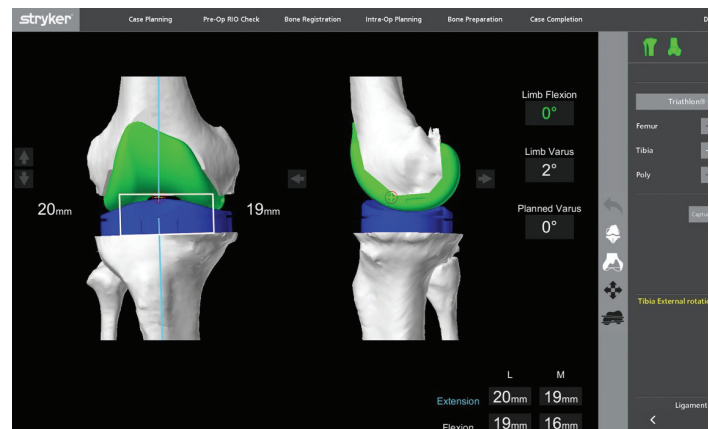


Figure 2: image of the joint balancing screen

Robotic-arm assisted bone preparation

The Mako Total Knee creates a haptic boundary which assists the surgeon in executing both the tibial and femoral bone resections to plan. The haptic boundary has the potential to protect essential anatomical structures of the knee during bone preparation including the PCL and the popliteal artery.³⁴ In a cadaveric study, on average, Mako Total Knee final bone cuts and component positions were 5 and 3 times more precise to plan than the manual TKA control, respectively.¹

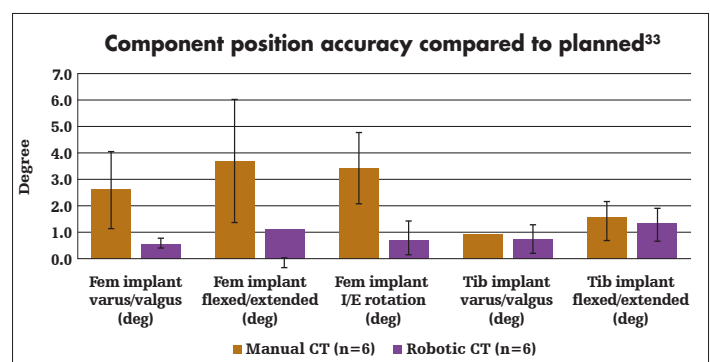


Figure 3: comparison of RATKA and MTKA median variance of implant position to plan

Triathlon Total Knee System

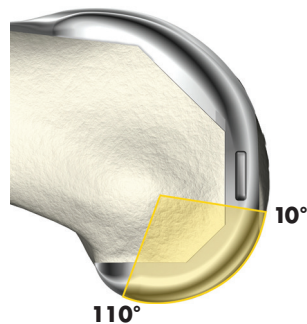
The coupling of the Triathlon primary knee portfolio with the Mako Total Knee application brings you the design and technology that's built on clinical evidence. A wealth of clinical data around the world has largely supported the enhanced survivorship,³⁻⁶ stability,⁷⁻¹¹ and satisfaction^{6,9,12} of the Triathlon design over the past decade.

Triathlon 10-year survivorship	Source
99.0%	Mistry et al. 2016 ³
96.7% (including infection)	2016 National Joint Registry (UK/Wales) ⁴
96.6% (including infection)	2016 Australian Orthopaedic Association Joint Registry ⁵

Triathlon Tritanium 2-year survivorship	Source
99.5% (including infection)	Harwin et al. 2016 ²¹
100%	Buzhardt et al. 2017 ²²

Triathlon design

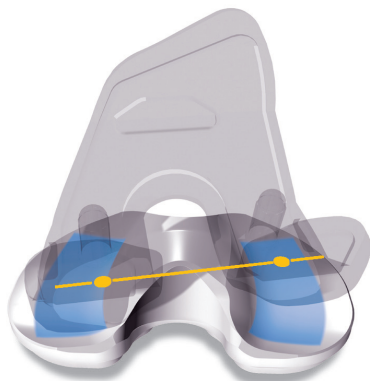
The Triathlon single radius is designed to restore the knee's single center of rotation during active flexion, where most motion occurs.^{15,16} This allows for constant ligament tension and stability in flexion.^{7, 9-11}



In a gait investigation study, patients with the Triathlon knee experienced gait patterns that closely mimicked those of healthy knees.¹⁰ Numerous studies, including a level I study, showed enhanced functional and satisfaction outcomes with the Triathlon knee.⁹⁻¹⁴

Less constraint, more stability

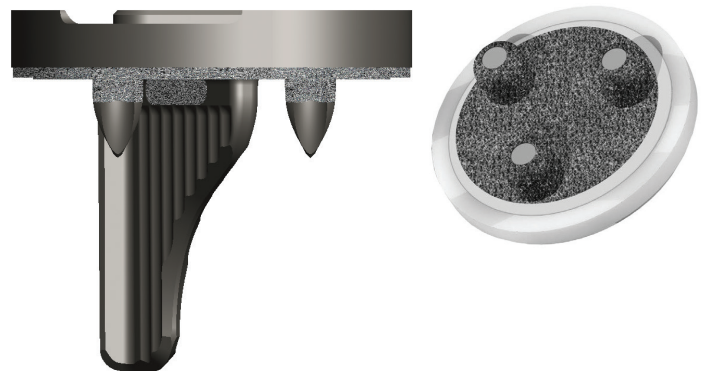
Triathlon is designed to accommodate $\pm 20^\circ$ of rotational freedom. The less constrained the design, the less potential for stresses generated at the articulating surface to be transferred to the bone-implant interface.²⁹



Tritanium technology

Tritanium is a highly porous structure designed for biologic fixation.²³

Initial stability is important for long term fixation in cementless TKA.²⁴ Our additive manufacturing technology enables unique geometries for enhanced initial stability to allow biologic fixation at the bone-implant interface²⁵ and stronger association at the metal-polyethylene interface for the Tritanium metal-backed patella.²⁶



Do more

Tritanium cementless TKA offers the potential for shorter operative time and enhanced procedural efficiency.^{27,28} Demographics show patients are younger, more active, and heavier.¹⁷ These patient subsets have shown higher potential for aseptic loosening.¹⁸ Choosing biologic fixation for your TKAs may assist with these challenging patient demographics.

References:

1. Hampp E, et al. Robotic-Arm Assisted Total Knee Arthroplasty Demonstrated Greater Accuracy to Plan Compared to Manual Technique. Orthopaedic Research Society 2017 Annual Meeting, San Diego, CA. Poster No. 2412. March 20-22, 2017.
2. Sales Data on file at Stryker, 2017.
3. Mistry J, Elmallah R, Chughtai M, Oktem M, Harwin S, Mont M. Long-Term Survivorship and Clinical Outcomes of a Single Radius Total Knee Arthroplasty. International XXVIII.
4. National Joint Registry for England, Wales and Northern Ireland. 13th Annual Report 2016. Excerpt from table 3.28 Kaplan-Meier estimated cumulative percentage probability of first revision (95% CI) of a primary total knee replacement by main type of implant brand at the indicated number of years after primary operation.
5. Australian Orthopaedic Association National Joint Replacement Registry. 2016. KT8 Cumulative Percent Revision of Primary Total Knee Replacement with Cement Fixation. Figure KT29 Cumulative Incidence Revision Diagnosis of Primary Total Knee Replacement by Polyethylene Type (Primary Diagnosis OA).
6. Scott et al. Five-year survivorship and patient-reported outcome of the Triathlon single-radius total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. Published online (2014).
7. Piazza S. Designed to maintain collateral ligament stability throughout the range of motion. Stryker-Initiated Dynamic Computer Simulations of Passive ROM and Oxford Rig Test (2003).
8. Harwin, S., Greene, K., & Hitt, K. (2008). Triathlon Total Knee Arthroplasty – 4-Year Outcomes with a High-Performance Implant. Journal of Knee Surgery, 21(04), 320-326.
9. Cook et al. Functional Outcomes Used to Compare single radius and Multiradius of Curvature Designs in Total Knee Arthroplasty. J Knee Surg (2012) 25:249-254.
10. Larsen et al. Quantitative, Comparative Assessment of Gait Between Single-Radius and Multi-Radius Total Knee Arthroplasty Designs. J Arthroplasty (2015).
11. Shimizu et al. In Vivo Movement of Femoral Flexion Axis of a Single-Radius Total Knee Arthroplasty. J Arthroplasty (2014).
12. Bhowmik-Stoker et al. Mid-Term Results of Patient Satisfaction Following Total Knee Arthroplasty. ICJR (2014).
13. Hamilton, DF “Implant design influences patient outcome after total knee arthroplasty: a prospective double-blind randomised controlled trial”. The Bone & Joint Journal (2015);97-B:64–70.
14. Palmer, Jennifer. “Functional outcomes comparing Triathlon versus Duracon total knee arthroplasty: does the Triathlon outperform its predecessor?” International Orthopaedics (SICOT), 38 (2014), p. 1375.
15. Iwaki et al. Tibiofemoral movement 1: the shapes and relative movements of the femur and tibia in the unloaded cadaveric knee. J Bone Joint Surg [Br] (2000) 82-B:1189-95.
16. Hollister A. The Axes of Rotation of the Knee. Clin Orthop Relat Res. Number 290:259-268.
17. Memtsoudis SG, Della Valle AG, Besculides MC, Gaber L, Laskin R. (2009) Trends in Demographics, Comorbidity Profiles, InHospital Complications and Mortality Associated with Primary Knee Arthroplasty. Journal of Arthroplasty, Jun; 24(4):51827.
18. Abdel, Matthew P, et al. “Increased Aseptic Tibial Failures in Patients With a BMI ≥ 35 and Well-Aligned Total Knee Arthroplasties” The Journal of Arthroplasty, vol. 30, no. 12, 2015, pp. 2181–2184.
19. Whiteside, Leo A. MD. Viganò, Roberto MD. (2007) Young and Heavy Patients with a Cementless TKA Do As Well As Older and Lightweight Patients. Clinical Orthopaedics And Related Research. Number 464, pp. 93–98.
20. Jackson, M. P., Sexton, S. A., Walter, W. L., Walter, W. K., & Zicat, B. A. (2009). The impact of obesity on the mid-term outcome of cementless total knee replacement. Journal of Bone and Joint Surgery - British Volume, 91-B(8), 1044-1048.
21. Harwin S, Elmallah R, Jauregui J, Cherian J, Mont M. Outcomes of a Newer-Generation Cementless Total Knee Arthroplasty Design. ORTHOPEDICS. 2015; 38: 620-624.
22. Buzhardt, P. et al. “Clinical and radiographic results of a highly porous titanium cementless tibial baseplate in TKA.” Bone Joint J 99-B.SUPP 3 (2017): 56. Web. 13 Mar. 2017.
23. Hildebrand T et al. Direct three-dimensional morphometric analysis of human cancellous bone. Journal of Bone and Mineral Research; Vol. 14 Number 7, 1999.
24. Nilsson K et al. Evaluation of Micromotion in Cemented vs Uncemented Knee Arthroplasty in Osteoarthritis and Rheumatoid Arthritis. Journal of Arthroplasty. Vol 6. No 3. September 1991. 265–278.
25. Safia Bhimji, MS, R. Michael Meneghini, MD. Micromotion of Cementless Tibial Baseplates: Keels with Adjuvant Pegs Offer More Stability Than Pegs Alone. The Journal of Arthroplasty; 2014.
26. Stryker Test Report RD-12-044.
27. Chen, Antonia. “Cementless versus Cemented TKA: Shorter Operative Time and Similar Complications” Eastern Orthopaedic Association (EOA) 47th Annual Meeting, New Orleans, Oct. 2016.
28. Masini M. “Surgical And Early Postoperative Outcomes Of A Single Cementless Total Knee System.” The EKS Arthroplasty Conference, London, Apr. 2017.
29. Bhimji S, Kester M, Schmalzried T. Rotational Constraint of Posterior-Stabilized Total Knee Prostheses. J Knee Surgery. 2008; 21: 315-319.
30. Marchand, MD, R., Sodhi, BA, N., Khlopas, MD, A., Sultan, MD, A. A., Harwin, MD, S., Malkani, MD, A. L., & Mont, MD, M. A. (2017). Patient Satisfaction Outcomes after Robotic Arm-Assisted Total Knee Arthroplasty: A Short-Term Evaluation. The Journal of Knee Surgery.
31. Malkani, A. et al. (2017). Accuracy of Preoperative Implant Sizing Using 3D Preplanning Software for Robotic-Assisted Total Knee Arthroplasty. AAHKS. Dallas.
32. Marchand, R. C., Khlopas, A., Sodhi, N., Condrey, C., Piuze, N. S., Patel, R., . . . Mont, M. A. (2017). Difficult Cases in Robotic Arm-Assisted Total Knee Arthroplasty: A Case Series. The Journal of Knee.
33. Mont et. al. The Knee Society 2017. Robotic-Arm Assisted Total Knee Arthroplasty Demonstrated Greater Accuracy to Plan Compared to Manual Technique.
34. Khlopas, Anton, et al. “Robotic-Arm Assisted Total Knee Arthroplasty Demonstrated Soft Tissue Protection. Surg Technol Int. 2017 Jul 25;30:441-446.

Orthopaedics

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's product offerings.

A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. 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 sales representative if you have questions about the availability of products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Mako, Stryker, Triathlon, Tritanium. All other trademarks are trademarks of their respective owners or holders.

Transforming orthopaedics

Mako™ heritage

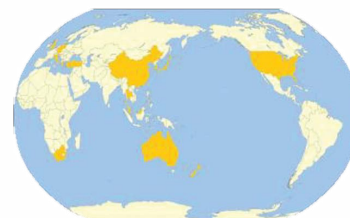
- Acquired by Stryker in December 2013, with a goal of transforming orthopaedics, combining Stryker's market-leading implants (U.S.)² with Mako's proprietary robotic-arm technology
- Ten+ years of robotic-arm experience; 3rd generation robotic-arm platform with multiple generations of knee & hip applications
 - More than 300 U.S. and foreign patents and patent applications
- 300+ systems worldwide¹, with continuing expansion in 19 countries
- Platform technology with uni, patellofemoral and bicompartamental knee, and total hip
- As we continue to prepare for the commercial launch of the Mako Total Knee application, Stryker is actively partnering with surgeons and experts in product user experience to study the operating room work flow and learning curve of the Mako Total Knee application.

Robotic-arm assisted surgery: market leadership with Stryker

- Over 70,000 robotic-arm assisted hip & knee procedures
 - 16,500+ in 2015; >700 active surgeon users¹
 - Over 1500 surgeons attended cadaveric and saw bones training courses
 - The global market leader in robotic-arm assisted PKA
- Patient specific 3D planning & Robotic-Arm Assisted execution:
 - CT derived, patient-specific 3-D modeling enables accurate planning of implant size, orientation and alignment preoperatively³
 - Real-time intra-operative adjustments allow for more correct knee kinematics and soft-tissue balance prior to resection⁴
 - In a cadaveric study, has been shown to provide excellent accuracy and precision with regard to planned cup position, leg length, and offset⁵
 - Allows single stage reaming for the hip⁶

Mako platform clinical success

- Significant primary clinical research conducted on the Mako platform:
 - 50+ peer reviewed clinical publications
 - 350+ scientific abstracts accepted at peer reviewed scientific conferences
- Mako Robotic-Arm Assisted PKA resulted in 92% patient satisfaction at 2 years⁷
- Mako Robotic-Arm Assisted PKA resulted in lower post-operative pain at day seven and more accurate implant placement than manual PKA in a randomized control trial⁸
- Mako Robotic-Arm Assisted THA demonstrated significantly higher modified Harris Hip scores and UCLA activity scores compared to manual THA at minimum one-year follow-up⁹



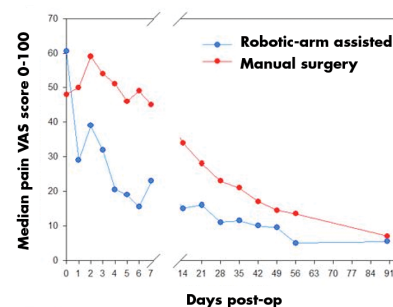
300+ systems worldwide, with continuing expansion in 19 countries¹



Virtual x-ray

**Actual post-op
x-ray**

Pain score results from randomized control trial of manual vs. Robotic-Arm Assisted UKA



References:

1. Data on File.
2. Market data on file: Orthopedic Network News; Volume 26, Number 3 July 2015.
3. Robotic Assisted Unicompartmental Knee Arthroplasty: The MAKO Experience. Roche M. Clin Sports Med. January 2014; 33(1): 123-32.
4. Achieving Accurate Ligament Balancing Using Robotic-Assisted Unicompartmental Knee Arthroplasty. Plate JF, Mofidi A, Mannava S, Smith BF, Lang JE, Poehling GG, Conditt MA, Jinnah RH. Advances in Orthopedics. March 2013. 2013 (ID 837167).
5. Accuracy of Cup Positioning and Achieving Desired Hip Length and Offset Following Robotic THA. Jerabek SA; Carroll KM; Maratt JD; Mayman DJ; Padgett DE; 14th Annual CAOS Meeting, June 18-21, 2014, Milan, Italy.
6. Robotic Arm Assisted THA Improved Accuracy, Reproducibility, and Outcomes Compared to Conventional Technique. Ilgen R. 43rd Annual Course: Advances in Arthroplasty, October 22-25, 2013, Boston, MA.
7. Short to Mid Term Survivorship of Robotically Assisted UKA: A Multicenter Study. Coon T, Roche M, Pearle A, Douchis J, Borus T, Buechel Jr F. ISTA 27th Annual Congress, Sept. 24-27, 2014, Kyoto, Japan.
8. Accuracy of UKA Implant Positioning and Early Clinical Outcomes in a RCT Comparing Robotic Assisted and Manual Surgery. Blyth MJ; Jones B; MacLean A; Anthony I; Rowe P; 13th Annual CAOS Meeting, June 12-15, 2013, Orlando, FL, USA.
9. Bukowski, B.; Abiola, R; Ilgen R. Outcomes after primary total hip arthroplasty: Manual compared with robotic assisted techniques. ; 44th Annual Advances in Arthroplasty; Cambridge, MA. October 7-10 2014.

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's product offerings.

A surgeon must always refer to the package insert, product label and/or instructions for use before using any of Stryker's products. 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 any of Stryker's products in your area.

Stryker Corporation or its divisions or other corporate affiliated entities own, use or have applied for the following trademarks or service marks: Mako, Stryker. All other trademarks are trademarks of their respective owners or holders.

MKOSYM-SS-1 10898

Copyright © 2016 Stryker. Printed in USA