



Evolution, Not Revolution 2 4 Congruency Patella-Femoral Articulation 6 Tibial-Polyethylene Stability 8 Net Compression Molded Polyethylene 10 **PCL** Preservation 12 Non-Modular Constrained 14 **Revision Precision** 16 Instrumentation 18 A Great Day in the O.R. 20



OPTETRAK DESIGN TEAM

in cooperation with Hospital for Special Surgery, New York

> Albert Burstein, PhD Donald Bartel, PhD Ivan Gradisar, MD Gary Miller, PhD William Murray, MD William Petty, MD

An approach to total knee arthroplasty that has improved clinical outcomes for patients around the world.



A comprehensive knee system that addresses your concerns for contact stress, patellar tracking, polyethylene wear, joint stability and bone preservation. Streamlined instrumentation lets you work quickly and efficiently.

All from a company that's committed to improving the quality of life for individuals by maintaining their activity and independence.

This is the Optetrak® story.



Evolution, Not Revolution.

How far can your knee system trace its roots?

The design behind the Optetrak knee system has been evolving for more than a quarter of a century. Its lineage began with a concept developed at Hospital for Special Surgery in New York. Successive designs, guided by clinical and laboratory data,

demonstrated 91-99 percent long-term implant survival rates.¹⁻⁸

Exactech's team of surgeons and bio-engineers built on this solid foundation, progressively improving implants and instruments. Today, surgeons are documenting a continuing record of excellent Optetrak clinical results.^{9,10,11}

You say you want a revolution? Sure, there are many choices out there, but there's nothing like the confidence that comes from five generations of proven design. With evolution, not revolution, you can count on the test of time.

OPTETRAK DESIGN DEVELOPMENT TIMELINE

Optetrak builds on a strong lineage of proven designs. The current generation was introduced to orthopaedic surgeons in 1994. Building on the original technology licensed from Hospital for Special Surgery, Exactech has enhanced the system with unique improvements while preserving the proven aspects preceeding designs. In addition, a complete system including the Posterior Stabilized, Cruciate Retaining and Constrained Condylar knee was developed with integrated instrumentation.



DUOCONDYLAR, 1971



DUOPATELLAR, 1974



TOTAL CONDYLAR (TC), 1974

Figure 1. Optetrak Patient Satisfaction¹⁰ 1,526 cases, 5-year follow-up 4% 2% 94% Excellent, Fair Very Good, Poor Good



INSALL/BURSTEIN POSTERIOR STABILIZED (I/B PS), 1978



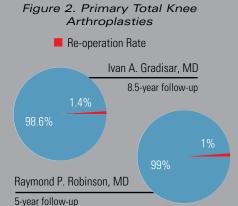
INSALL/BURSTEIN PS II (I/B II), 1988



OPTETRAK, 1994

ORIGINS OF THE OPTETRAK KNEE SYSTEM

The Optetrak design team recognized that surgeons are often reluctant to experiment with "new" knee designs that do not have long-term clinical results. For this reason, under the close direction of Albert Burstein, PhD, the Optetrak design team, in cooperation with engineers at Hospital for Special Surgery and an extensive team of clinical evaluators, developed a knee design based closely on the clinically successful Total Condylar, Insall/Burstein (I/B) and Insall/Burstein II[®] (I/B II) knees.



OPTETRAK CLINICAL RESULTS

Surgeons around the world have documented excellent results with the Optetrak knee system. Dr. Ivan Gradisar reported excellent eight and one-half year results on 1,526 arthroplasties he performed using Optetrak. Independent, nonsurgical investigators evaluated patients at two and five years after surgery using standardized testing tools. Hospital for Special Surgery scores improved from 88 at two years to 91 at five years (Figure 1). Ninety-four percent of the patients reported that the results of their surgery could be best described as excellent, very good or good.¹⁰

The rate of re-operation for any reason was extremely low (1.4 percent). No re-operations were required for either design-related problems, component fault or failure, patellar or tibial-femoral instability, for insufficient motion or for repair or release of collateral or posterior soft tissue (Figure 2).

Dr. Raymond Robinson also reported excellent results after a five-year study of his patients. Despite reduced ratings due to obesity (55 percent of the patients had body mass index greater than 30), 90 percent of the patients were rated good or excellent on both Knee Society and HSS scores. Using aseptic revision of any component as an end point, 99 percent of the implants were predicted to survive at 93 months.¹¹



The Nature of a Good Fit.

Is the congruency of your knee system a cause of stress?

Optetrak's femoral components address a key concern of today's total knee surgeon: contact stress.

Optimized congruency between the femoral and tibial components reduces contact stress, improving polyethylene wear.

The Optetrak comprehensive knee system offers primary femoral components in Cruciate Retaining (CR) as well as a bone-sparing

Posterior Stabilized (PS) design. Cemented and porous coated fixation options allow the surgeon to choose based on bone quality.



- Spherical, all-polyethylene patellar and high congruence throughout range of motion. Available in either three-peg or single-peg fixation options.
- B Enhanced cam/spine mechanism subluxation. Bone-sparing PS box changes proportionately with each

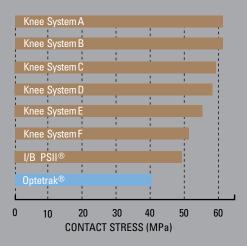


INCREASING CONGRUENCY

The Hospital for Special Surgery (HSS) in New York built upon the clinically successful Insall/Burstein II knee design. By more closely matching femoral and tibial geometries, they achieved an increase in medial/lateral congruency from 0.94 to 0.96. This new knee technology optimized the conformity, stability and kinematics without increasing the stress at the prosthesis-bone interface.¹²

In 1995, Bartel, Rawlinson, Burstein, Ranawat and Flynn conducted additional finite element analysis to compare the differences in the HSS design to other designs on the market at that time. The result was a contact stress profile that was 15 to 20 percent lower than the next lowest design — it's predecessor, the Insall/Burstein II as shown below.¹³

Contact stress comparison



BONE PRESERVING HIGH FLEXION

The patented Optetrak Hi-Flex® total knee design is based on the Optetrak system's more than 10 years of clinical success. Further enhancements in design allow the properly selected patient with high flexion potential the ability to capitalize on Optetrak's excellent range of motion and patellar function. This increased range of motion can be achieved without resecting more posterior bone than is required for the classic Optetrak Posterior Stabilized knee.

The standard surgical technique applies, or use Optetrak's Low Profile Instrumentation (LPI®) with the exception of the Hi-Flex PS notch preparation. Following the Femoral Finishing Guide resections, the corresponding sized Hi-Flex PS Notch Guide is used. Hi-Flex femoral trials, as well as Hi-Flex tibial insert trials, are also required.



Let Nature Take 1ts Course.

Does the patella in your knee system follow the path of least resistance?

From the earliest designs, surgeons have faced challenges with patello-femoral articulation. The Optetrak team of surgeons and bio-engineers have addressed this concern by improving on the clinically successful Insall/Burstein II. The result: a knee system that reduces dislocation, subluxation, tilt and patellar clunk.

Optetrak's contoured femoral flange, the smooth shape in the sagittal plane and a deep femoral groove are design features that reduce strain in retinaculum, allowing for more natural patellar tracking from extension to flexion.

Get in the groove. Optetrak has proven successful in significantly reducing lateral retinacular release rates and the incidence of peripatellar fibrosis.^{9,14} With a strong lineage, streamlined instrumentation and a proven femoral design, Optetrak keeps your patella on the right track.





THE "GENDER" ISSUE

More than three decades ago when the design team first put ideas on paper, they took into account the obvious anatomical differences between narrow, smaller, typically female knees and wider, larger knee dimensions typically seen in men. This is a fact that some other knee system designs are just now addressing.

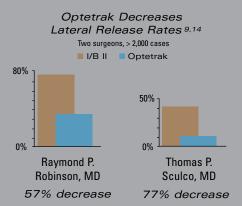
Some implant systems are based simply on an average size of women's and men's knees combined. Optetrak's design team optimized the aspect ratio of its femoral components so every component in every size covers diverse distal femoral morphologies, regardless of gender, without overhang and subsequent soft tissue irritation or alterations in the knee biomechanics.

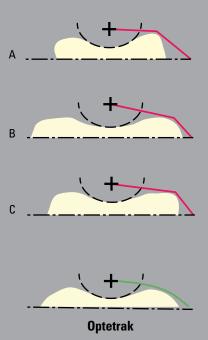
Many factors have been implicated as causes of patello-femoral complications after total knee arthroplasty. One of these factors is seen in female patients or in patients with valgus deformities, whose muscular forces and other soft tissues tend to pull the patella more laterally. Optetrak's wide femoral groove (A) and patented patellar design allow the patient's patella to track naturally (either medially or laterally) during flexion and extension. This design feature has also proven successful in significantly reducing lateral retinacular release rates and the incidence of peripatellar fibrosis.¹⁵

Unlike newer knee systems, Optetrak offers the confidence you can only get from excellent, long-standing clinical results.

DECREASING LATERAL RETINACULAR RELEASE

From the earliest knee designs, surgeons have faced challenges with patello-femoral articulation. Optetrak has proven successful in significantly reducing lateral retinacular release rates and the incidence of peripatellar fibrosis.





Retinacular tissue stretch and patellar component distances¹⁶ produced by other implant designs (shown in red) compared to the Optetrak (green).



Locked in Tight.

How solid is your knee's tibial insert?

Backside wear threatens the function and longevity of total knee replacements. Optetrak's tibial components target backside wear—minimizing polyethylene debris and the risk of component disassociation.

Optetrak's modular tibial components feature a rock-solid locking mechanism with three design elements that keep tibial inserts in place. A continuous

peripheral rim around the tray, posterior feet that couple with precision undercuts in the tray and a central mushroom provide a barrier to insert motion and prevent lift-off.





OPTETRAK'S SOLID RESULTS

Recent studies documenting the backside wear of polyethylene inserts call into question the stability of locking mechanisms in some modular tibial components.^{17,18} In contrast, indicators on Optetrak inserts substantiate its locking mechanism's ability to reduce backside wear.¹⁹



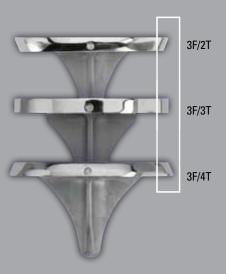
Retrieved Optetrak insert demonstrates minimal wear with no measurable material loss.

MAINTAINING CONTACT

Plenty of knee systems provide tibial up- and down-sizing, but at a cost: increased contact stress. Optetrak tackled this problem where the stress occurs between the femoral component and the tibial insert.

Optetrak maintains its excellent congruency regardless of tibial sizing. The femoral component and the polyethylene insert are a matched pair, with three interchangeable tibial trays to choose from for each femoral size.

Tibial Up- and Down-Sizing





Net Molded, Not Machined.

Is the polyethylene in your knee system wearing on you?

Two main drivers affect polyethylene performance in total knee replacement: design and materials. With its strong lineage, Optetrak's polyethylene tibial inserts benefit from optimized congruency and low contact stress.

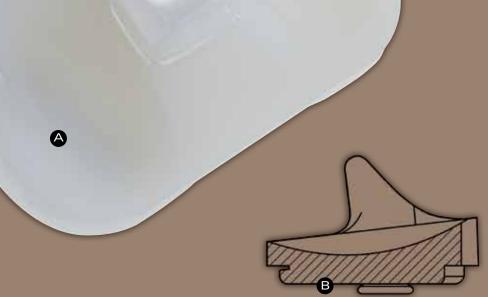
Improvements in materials further enhance Optetrak's excellent performance. Its tibial inserts feature net compression molded polyethylene—no machining is performed on the articulating surface. The result? Less wear debris and less pitting than machined tibial inserts.²⁰



PRODUCING NET COMPRESSION MOLDED POLYETHYLENE

This process is a variation on the traditional molding scheme in which a small mold cavity representing the exact complex shape of the part is created. A precisely calibrated amount of resin is placed in a mold that is heated and cooled in a computer-controlled press. This yields the exact shape of the finished tibial insert's articular surface with exceptional uniformity of material properties.

- A The articular surface of the net molded tibial insert is never machined. The result is a smooth finish, free of machine lines.
- B Precise machining of non-articular surfaces establishes the final thickness and completes the fine details of the locking mechanism to ensure an exacting fit with modular tibial trays.



C The mold used in the net compression molding process forms the surface of the corresponding tibial insert. Each insert is individually produced to ensure the complete and consistent consolidation of resin



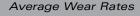
BALANCED CROSSLINKING

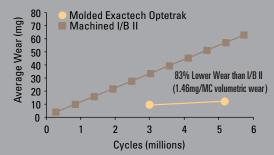
Optetrak's net compression molded polyethylene is sterilized with gamma radiation (2.5-4.0 Mrad) in a vacuum. While the molecular chains of net molded polyethylene are moderately crosslinked due to the irradiation process in the absence of oxygen molecules, this material retains all of its mechanical properties (yield strength, fatigue strength and fracture resistance), avoiding the generation of free radicals. This balances the equation between wear, mechanical properties and oxidation.²¹

A MATERIAL DIFFERENCE IN PERFORMANCE

In a knee simulation study comparing wear rates of net compression molded polyethylene to machined, sheet-molded polyethylene, the Optetrak net compression molded inserts demonstrated volumetric wear of 1.46 mg/MC. That corresponds to an 83 percent reduction in wear rate and 52 percent less damaged area than I/B II extruded tibial inserts.²⁰ That's approximately six times less wear than the traditional I/B II design. This is achieved without sacrificing critical mechanical properties such as fracture toughness.

Through the careful blending of design and materials, Exactech's Optetrak total knee system continues to advance the longevity of knee arthroplasty.





Damage Area



Machined IB/II



Molded Exactech Optetrak

The Optetrak net compression molded tibial inserts demonstrated an 83 percent reduction in wear rate (top) and 52 percent less damaged area (above) than I/B II machined, extruded tibial inserts.²⁰



Preserving your Environment.

Do you ever release the PCL or re-cut more bone to balance tight flexion gaps?

More than 75 percent of tibial resections lead to at least partial compromise of the posterior cruciate ligament (PCL) in the hands of experienced orthopaedic surgeons.²² To truly retain the function of the PCL, one must pay meticulous attention to preserving its anatomy and avoiding releasing PCL fibers – either directly by surgical releases, or indirectly by increasing the slope of the tibial resection.

Exactech is pleased to offer an innovative approach to total knee arthroplasty designed to enhance the precision of the tibial resection and to preserve the integrity of the PCL. The Optetrak CR Slope® patent-pending design enables surgeons to plan and perform PCL-retaining total knee arthroplasty based on the anatomical integrity of the posterior cruciate ligament. User-friendly instrumentation and three different sloped inserts accommodate balancing the flexion and extension gaps.



OPTETRAK CR SLOPE IS DESIGNED TO:23

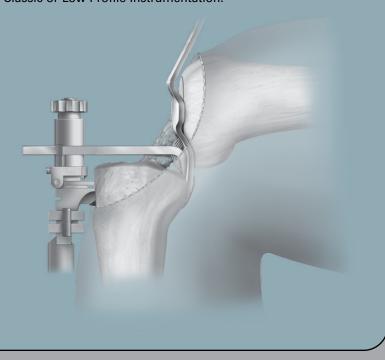
- Identify and protect the anatomical integrity of the PCL
- Provide precise and reproducible bone resections
- Optimize the PCL tension in a predictable manner
- Allow intra-operative tensioning adjustment of the PCL without releasing the PCL, cutting additional tibia slope or downsizing the femur
- Balance flexion/extension gaps independently
- Accommodate variability in patients' anatomies
- Restore knee joint stability throughout the range of motion
- Direct compression molded polyethylene minimizes wear and polyethylene debris.²⁰
- B Wide patellar groove (superior region only) is designed to provide less constraint to allow for excellent patellar tracking.
- C Debulked anterior femoral flange reduces tension in lateral retinaculum and incidence of lateral release. 16

Three insert options allow surgeons the ability to balance flexion and extension gaps, eliminating the need to release the PCL fibers, cut additional tibial slope or downsize the femur.



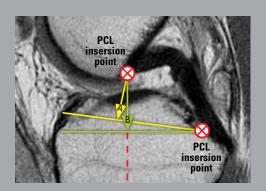
OPERATIVE TECHNIQUE

Femoral preparation is performed using the general Optetrak CR operative technique. The tibia is prepared by referencing the tibial insertion of the PCL rather than the tibial plateau. The Adjustable PCL Stylus, a No-Touch PCL Retractor and insert trials (CR Standard, CR Slope + and CR Slope ++) are used in addition to Optetrak Classic or Low Profile Instrumentation.



DESIGN RATIONALE

The Optetrak CR Slope design team conducted a meticulous MRI study with two goals in mind: (1) to consistently identify the origins of the posterior cruciate ligament (PCL) in both the femur and the tibia and (2) to define the resulting "joint space" depending of the posterior slope of the proximal tibial cut.^{24,25} The study revealed that a reference point at the base of the ligament's tibial attachment points could be consistently identified and measured over a variety of knee sizes and geometries. Additionally, the vertical distance between the PCL femoral insertion and the planned proximal tibial cuts was measured. The data revealed that if the surgeon performed the proximal tibial cut according to the natural posterior slope A, the resultant tibial cut could be too thin (less than 9mm) not leaving sufficient joint space for the implant components. If the surgeon needed to increase the slope of the proximal tibial resection to open up the flexion space, the PCL integrity was most often compromised.



- A Vertical distance between the femoral origin of the PCL and a planned *natural* slope tibial cut
- B Vertical distance between the femoral origin of the PCL and a planned *neutral* slope tibial cut

The results of the study led to the development of unique instrumentation and optimized tibial inserts that comprise the Optetrak CR Slope system. The Posterior Cruciate Referencing Technique was developed, to allow the surgeon to identify and reference the PCL by consistently protecting it intra-operatively. Using the PCL as the reference point, a traditional tibial cut is made according to a neutral slope **B**. Trials and inserts with increased posterior angulation (CR Slope + and CR Slope ++) were added to the standard CR in order to reproduce the natural slope of the tibia. These inserts allow for balance of the flexion gap, reducing the need for soft tissue releases, partial PCL releases or additional tibial bone cuts.²⁶⁻³⁰



Stability Without Sacrifice.

Are you sacrificing femoral bone to address ligament instability?

What do you do when you need a little more stability than a posterior stabilized knee, but good bone quality doesn't demand stems or augments? The answer is typically a constrained condylar prosthesis with its added femoral resection and preparation of the intra-medullary canal. That is, unless you choose Optetrak.

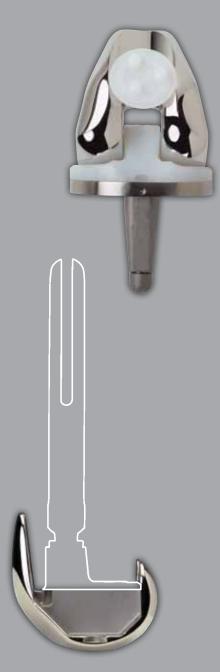
the intra-medullary canal. That is, unless you choose Optetrak. The Optetrak knee system's Non-Modular Constrained (NMC) prosthesis is a solution that uncouples ligament stability from bone issues. Its unique "box" design provides the same varus/valgus constraint as a constrained condylar and greater resistance to subluxation than a posterior stabilized knee, all in a bone-sparing technique. In fact, patients with severe valgus deformity have demonstrated Knee Society score improvement from 46 to 86 points post-operatively with the Optetrak NMC.31 That's constraint without compromise. NMC femoral components, in conjunction with Constrained Condylar inserts, restore stability to the joint without the need for stems or augments on the femoral side. In addition to the constraint that the NMC offers, increased jumping height is allowed as compared to a posterior stabilized total knee. C Tibial trays are modular and require that a stem extension be used with the Constrained Condylar tibial insert. G

Spherical, all-polyethylene patellar component allows for interchangeability and high congruence throughout range of motion. Available in either three-peg or single-peg fixation options. Wide patellar groove (superior region only) provides less constraint to allow for excellent patellar tracking. Debulked anterior femoral flange reduces tension in lateral retinaculum and incidence of lateral release.

EXPERIENCE EXACTECH'S CORE COMPETENCIES

The NMC features the same outstanding congruency, range of motion, patellar tracking and polyethylene wear as the Cruciate Retaining and Posterior Stabilized systems.

In addition, highly controlled tolerances between the box and Constrained Condylar spine provide for \pm 1.5 degrees of varus/valgus and \pm 2 degrees of rotational constraint. This constraint has proven to be bio-mechanically and clinically effective for soft tissue deficiencies.



Optetrak's Non-Modular Constrained knee is designed to deliver the stability of a constrained condylar without the bone sacrifice required for femoral stem placement.

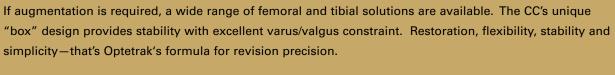


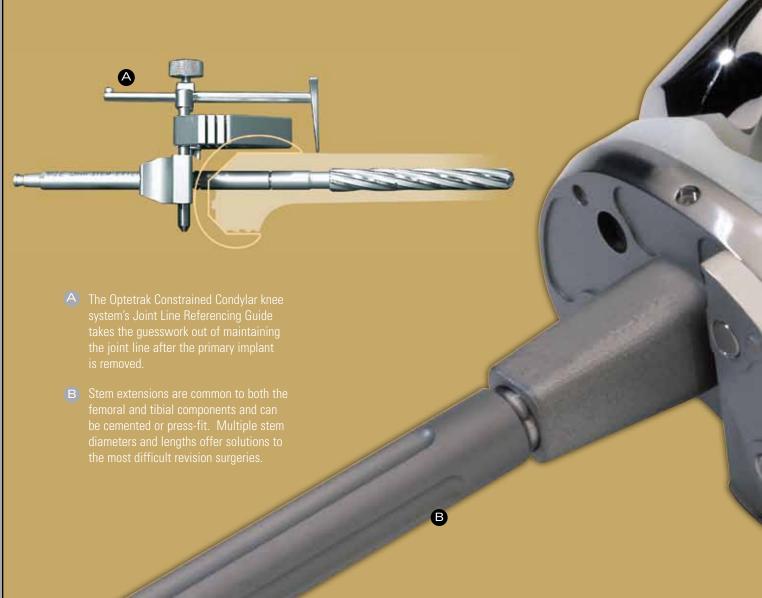
Revision Precision.

Is your technique for revision knee surgery based on precision or approximation?

There is nothing routine about revision knee surgery. It is an art. You never know what you'll find until you get there. Restoring the joint line, augmenting lost bone and providing stabilizing constraint involve guesswork, estimation and frustration.

The Optetrak Constrained Condylar (CC) knee system addresses the art of revision with the science of precision. Its instrumentation allows the surgeon to reproduce the joint line.





When a constrained tibial insert is used, a spine stiffener screw enhances the integrity of the spine and stabilizes the insert, tray and stem extension.

The CC femoral component offers a 2, 5, or 7 degree valgus angle to accommodate a wide range of patients.



BEYOND A SHADOW OF A DOUBT

Optetrak's Joint Line Referencing Guide takes the guesswork out of maintaining the joint line after the primary implant is removed. The surgeon can reproduce—without elevating—the joint line or adjust it if necessary.

The CC features the same outstanding congruency, range of motion, patellar tracking and polyethylene wear as the cruciate retaining and posterior stabilized systems.



CONSTRAINT

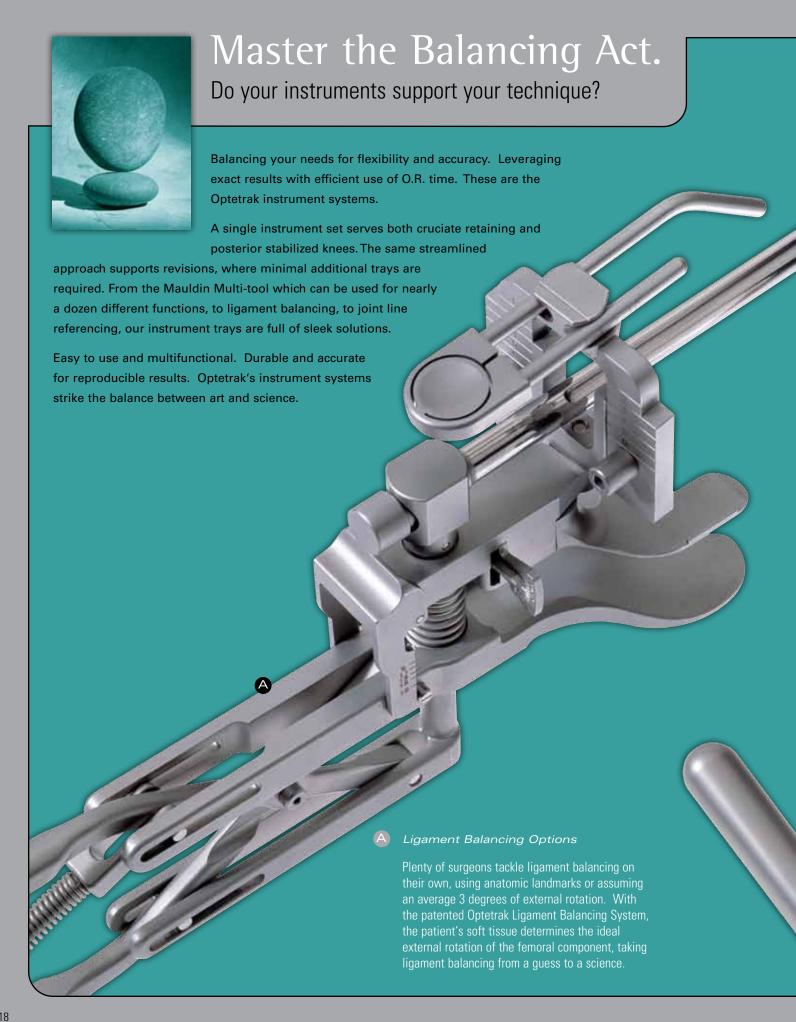
The constraint of the Optetrak Constrained Condylar knee design is \pm 2 degrees in rotation and \pm 1.5 degrees in varus/valgus. This constraint has proven to be bio-mechanically and clinically effective for soft tissue deficiencies.

PROXIMAL TIBIAL COVERAGE

Offset Tibial Trays allow optimal coverage of the tibial plateau while maintaining the integrity of a fixed tibial tray. The proximal offset design offers advantages over offset stems, lessening the chance of cortical impingement.



An anatomic study was conducted in conjunction with Hospital for Special Surgery to gain a thorough understanding of the position of the tibial intra-medullary canal with respect to the center of the tibial plateau.³² It was determined that the optimal offset was medial/lateral and increased with increasing tibial size. The Optetrak Offset Tibial Tray incorporates this data into its design. Along with the standard tibial options, the offset tibial trays provide seven tibial options per femur.





INSTRUMENTATION OPTIONS



Revision Joint Line Reference and Distal Femoral Cutting Guide The Joint Line Referencing Guide allows the surgeon to duplicate, or adjust if needed, the joint line of primary knee implants. Augmentation can be accommodated via captured cutting slots if bone loss is present.



Tibial Instrumentation

Surgeons have varying instrument preferences for preparing the tibia. From extra-medullary to intra-medullary, with posterior slope or without, fixed or adjustable, Optetrak has the special instruments you need to achieve reproducible and accurate results.



HSS Instrumentation

If the surgeon prefers to start with an anterior rough cut, Optetrak offers a special set of femoral instruments designed in conjunction with Hospital for Special Surgery. The HSS instruments have evolved as a continuation of the previous knee systems developed at HSS with improvements and increased reliability.

A Great Day in the O.R.

The commitment that defines the Exactech brand.

Founded by an orthopaedic surgeon and bio-medical engineer, Exactech is committed to making every day a great day in the O.R.—for the surgeon, the O.R. staff and above all, for the patient.

Along with innovative implants and instrumentation for total joint replacement, Exactech provides pre-primary, bone cement and biological solutions to meet your needs throughout the entire case.

Experience Exactech. A Great Day in the O.R.®



A Pre-Primary Total Joint Solutions

The Optetrak Unicondylar Knee system provides for bone preservation through proper ligament tensioning. Its biomechanically-inspired articular geometry and exclusive net-molded polyethylene facilitate restoration of knee function. The OsteoTrac® High Tibial Osteotomy (HTO) Plating System provides adjustable length through a patented design. It allows the surgeon to affix the HTO plate to the osteotomy site before creating/opening the wedge.

Biologic Solutions

Exactech is shaping the future of bone repair. Its full scope of biologic materials features demineralized bone matrix in a thermoplastic carrier, with or without cortical cancellous bone chips. For a bone graft that doesn't wash away, is 100 percent tested and terminally sterilized, Exactech Biologics are the natural choice.



C Accelerate® Platelet Concentrating System

Platelet rich plasma (PRP) gel has global applications in a variety of surgical procedures, including total joint replacement, bone repair and facial cosmetic and reconstruction surgery. Its ability to speed healing and improve patient outcomes has been well documented.³³ This easy-to-use Accelerate Concentrating System provides a fast and convenient method for processing PRP in the operating room from a small amount of patient's blood.



Bone Cement

Cemex® bone cement features a unique low monomer formula that has been clinically proven in Europe for more than two decades.³⁴ Available in a self-contained delivery system or hand mix options, the Cemex family of products are designed to offer surgeons and operating room personnel simplicity, safety and reliability in bone cement.

E Revision Equipment

The AcuDriver® Automated Osteotome System complements Exactech's total joint product line, offering the surgeon efficient, effective instrumentation for removing the components that need replacement in revision hip and revision knee surgery. The AcuDriver system consists of an air-driven impact hand piece, a wide variety of osteotome attachments and a fiber optic illuminator that enhances visualization in the femoral canal.



■ InterSpace[®] Knee Spacer

InterSpace® Knee is a pre-formed, articulating, partial load-bearing structure comprised of Gentamicin-impregnated Cemex PMMA bone cement. It maintains joint space, allows limited mobility and provides for predictable, consistent antibiotic release locally.



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