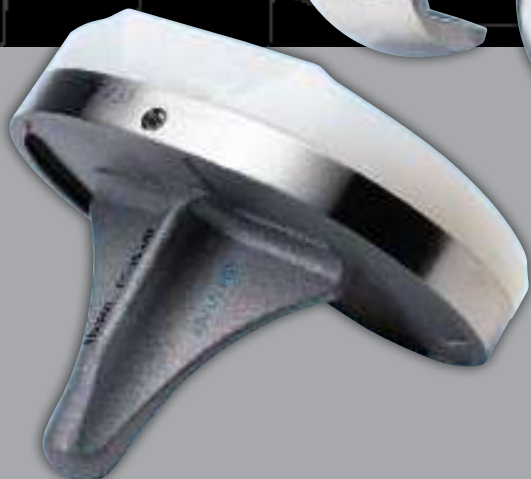




OPTETRAK[®]
A COMPREHENSIVE KNEE SYSTEM



The Right Track

*It's not just a road we're on,
it's a trail we're blazing.*



OPTETRAKTM

A COMPREHENSIVE KNEE SYSTEM

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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.



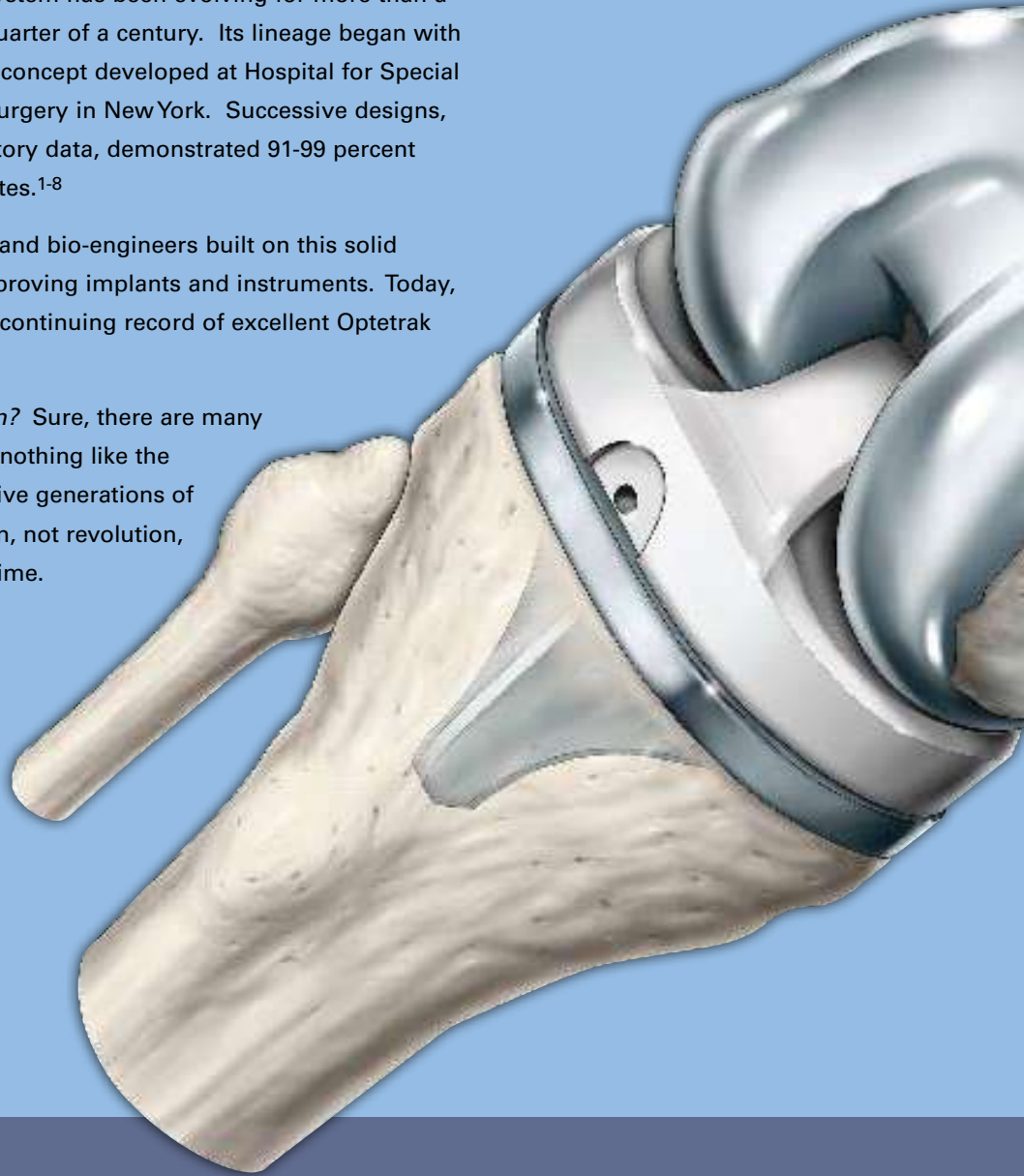
Evolution, Not Revolution.

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 preceding 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

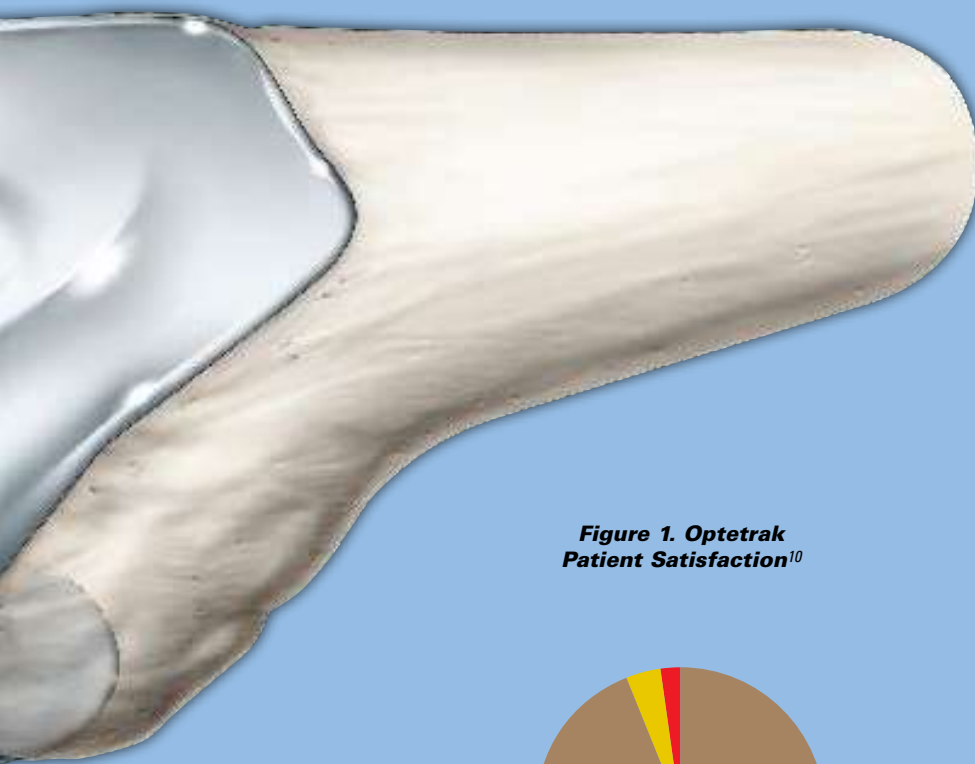
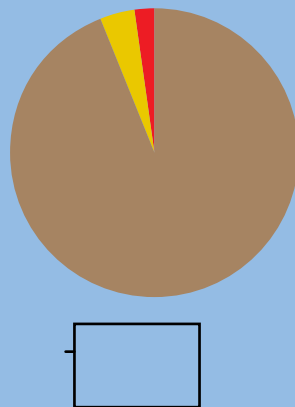


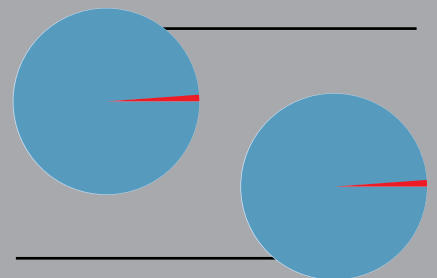
Figure 1. Optetrak Patient Satisfaction¹⁰



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.

Figure 2. Primary Total Knee Arthroplasties



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, non-surgical 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 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



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



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



OPTETRAK, 1994



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.



A 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.

B Enhanced cam/spine mechanism controls femoral roll-back and minimizes subluxation. Bone-sparing PS box changes proportionately with each femoral component size.

C Optetrak is available in both Cruciate Retaining and Posterior Stabilized porous-coated and non-porous options.

D The Optetrak Cruciate Retaining and Posterior Stabilized knees can achieve a full 125-degree range of motion, allowing patients to return to their activities of daily living while maintaining low contact stress.

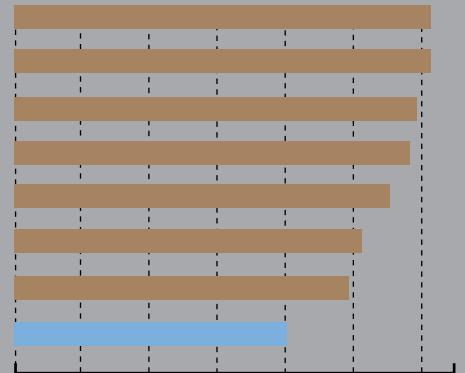


INCREASING CONGRUENCY

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.

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 – its predecessor, the Insall/Burstein II as shown below.¹¹

Contact stress comparison



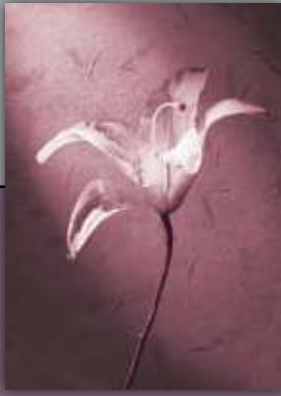
BONE PRESERVING HIGH FLEXION

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™ (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.

E With slight modifications to the cam and spine mechanism and to the tibial insert, Optetrak Hi-Flex maintains excellent congruency, contact pressure and dislocation resistance including high flexion angles of up to 145 degrees.





Let Nature Take Its 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. With a strong lineage, streamlined instrumentation and a proven femoral design, Optetrak keeps your patella on the right track.



A Wide patellar groove (superior region only) provides less constraint to allow for excellent patellar tracking.

B Debulked anterior femoral flange reduces tension in lateral retinaculum and incidence of lateral release.

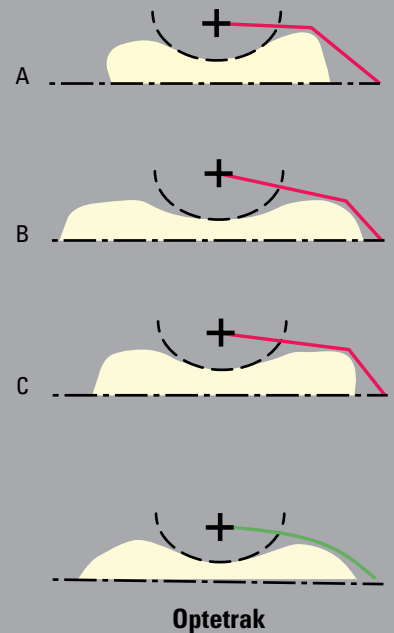
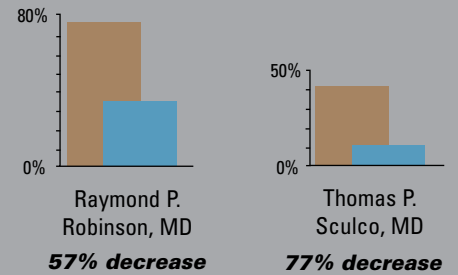


DECREASING LATERAL RETINACULAR RELEASE

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

Optetrak Decreases Lateral Release Rates^{9,13}

Two surgeons, > 2,000 cases
 ■ I/B II ■ Optetrak



Retinacular tissue stretch and patellar component distances¹⁴ produced by other implant designs (shown in red) compared to the Optetrak (green).

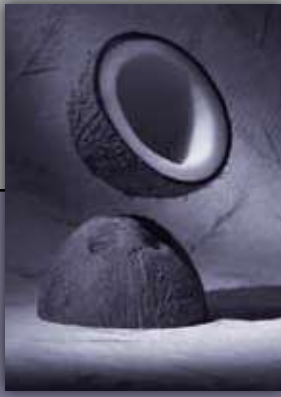
THE "GENDER" ISSUE

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.

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



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 also offers all-polyethylene and molded, metal-backed tibial components—the ultimate in tibial polyethylene stability.

- A** Modular tibial components are available in cemented fin, porous fin or cemented trapezoidal options.
- B** Patented press-in caps provide for polyethylene support to prevent cold flow, as well as debris migration.



- C** The modular tibial components feature a three-part locking mechanism, which prevents tibial insert motion and disassociation.
- D** Undercut cement pockets on the cemented tibial trays allow for a mechanical interlock to provide for excellent stability of the components.



- E** All-polyethylene tibial components maximize poly thickness and are available in either Cruciate Retaining or Posterior Stabilized.
- F** Molded, metal-backed tibial components feature a cemented finned stem and are Posterior Stabilized.

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.^{16,17} In contrast, indicators on Optetrak inserts substantiate its locking mechanism's ability to reduce backside wear.¹⁸



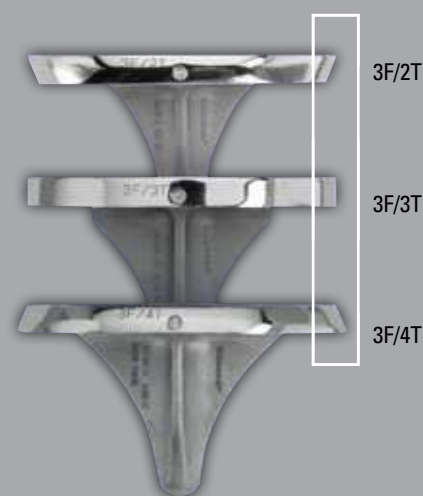
Retrieved Optetrak insert demonstrates minimal wear with no measurable material loss.

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



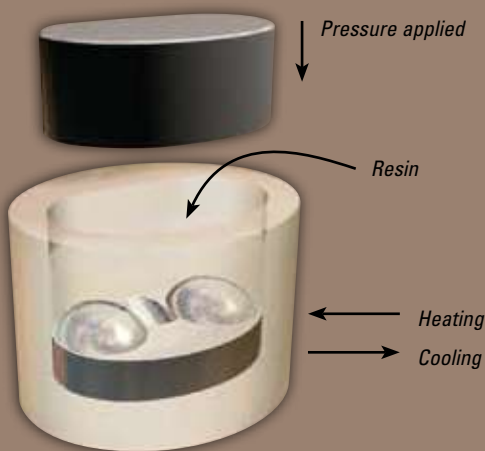


Net Molded, Not Machined.

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.¹⁹



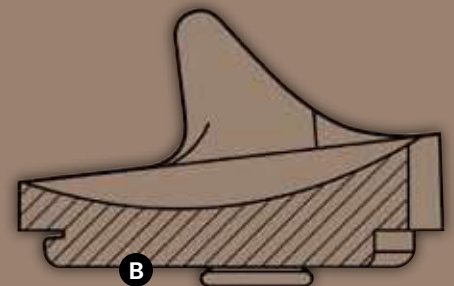
PRODUCING NET COMPRESSION MOLDED POLYETHYLENE

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.



C

BALANCED CROSSLINKING

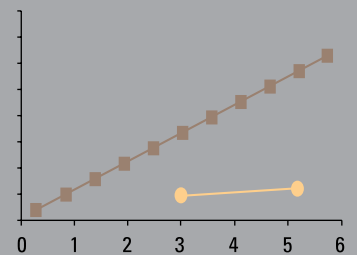
Optetrak's net compression molded polyethylene is sterilized with gamma radiation (2.5-4.0 Mrad) in a vacuum. While the molecular chains of net molded polyethylene are moderately crosslinked due to the irradiation process in the absence of oxygen molecules, this material retains all of its mechanical properties (yield strength, fatigue strength and fracture resistance), avoiding the generation of free radicals. This balances the equation between wear, mechanical properties and oxidation.²⁰

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.¹⁹ 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.

Average Wear Rates



Damage Area

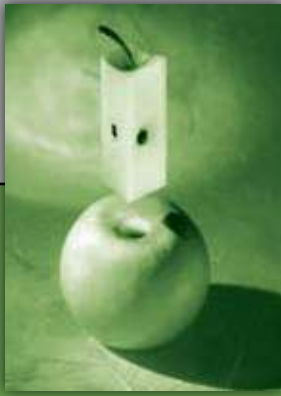


Machined I/B/II



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.¹⁹



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 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.²¹

That's constraint without compromise.

- A** 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.
- B** 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.



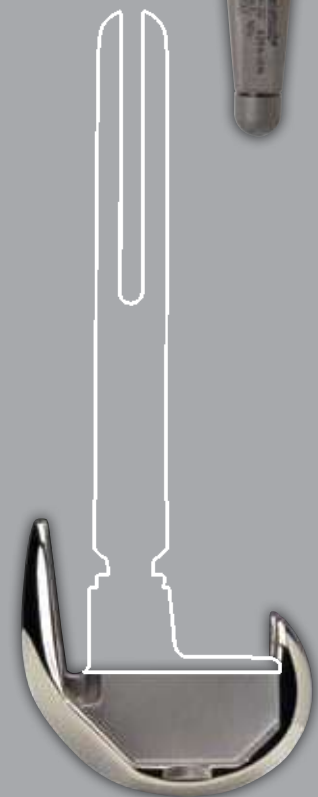


- D** Spherical, all-polyethylene patellar component allows for interchangeability and high congruence throughout range of motion. Available in either three-peg or single-peg fixation options.
- E** Wide patellar groove (superior region only) provides less constraint to allow for excellent patellar tracking.
- F** 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 ± 1.5 degrees of varus/valgus and ± 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 delivers the stability of a constrained condylar without the bone sacrifice required for femoral stem placement.



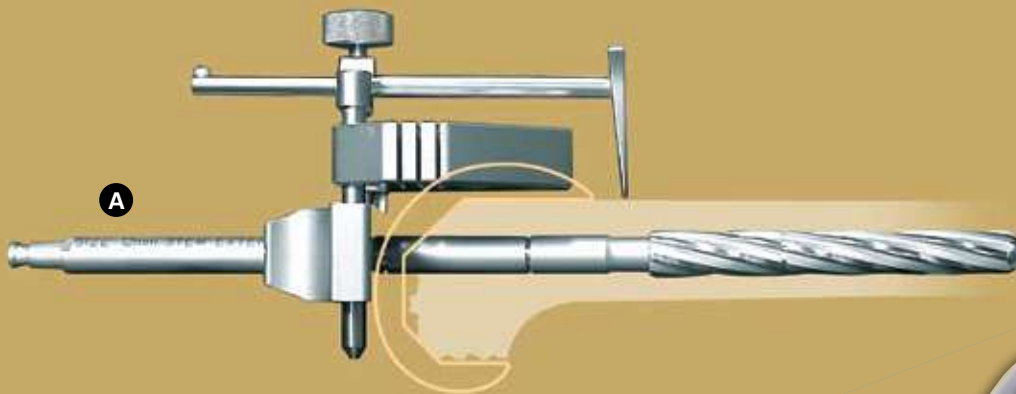
Revision Precision.

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.

If augmentation is required, a wide range of femoral and tibial solutions are available. The CC's unique "box" design provides stability with excellent varus/valgus constraint. Restoration, flexibility, stability and simplicity—that's Optetrak's formula for revision precision.



A The Optetrak Constrained Condylar knee system's Joint Line Referencing Guide takes the guesswork out of maintaining the joint line after the primary implant is removed.

B Stem extensions are common to both the femoral and tibial components and can be cemented or press-fit. Multiple stem diameters and lengths offer solutions to the most difficult revision surgeries.

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



- E** Tibial augments are available in 5, 8 and 11mm thicknesses. One-half as well as bone-sparing one-third options can replace tibial deficiencies.
- F** Independent distal and posterior augmentation blocks provide maximum flexibility for reconstructing deficient femoral bone.

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 ± 2 degrees in rotation and ± 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.²² 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.



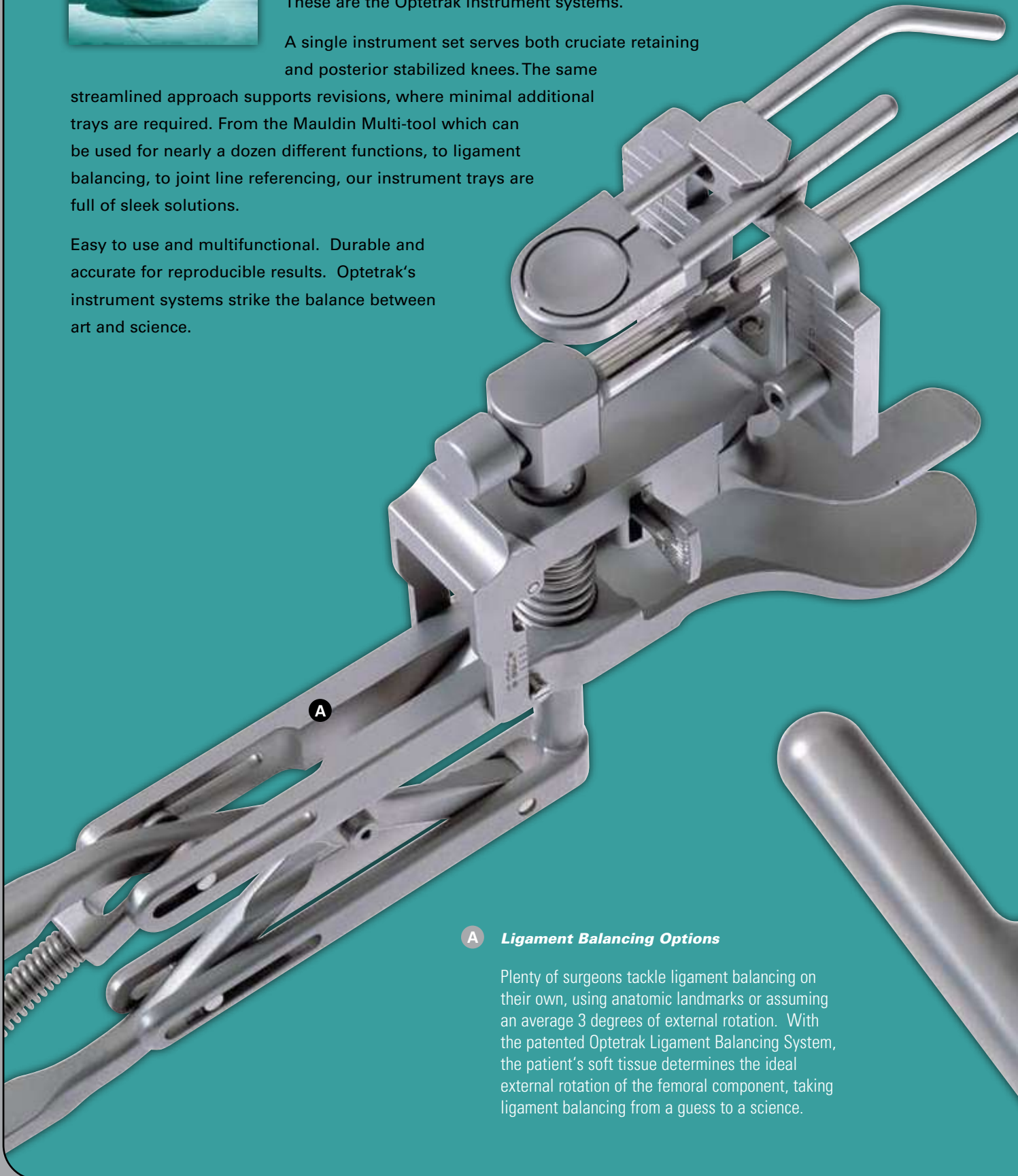
Master the Balancing Act.

Do your instruments support your technique?

Balancing your needs for flexibility and accuracy. Leveraging exact results with efficient use of O.R. time. These are the Optetrak instrument systems.

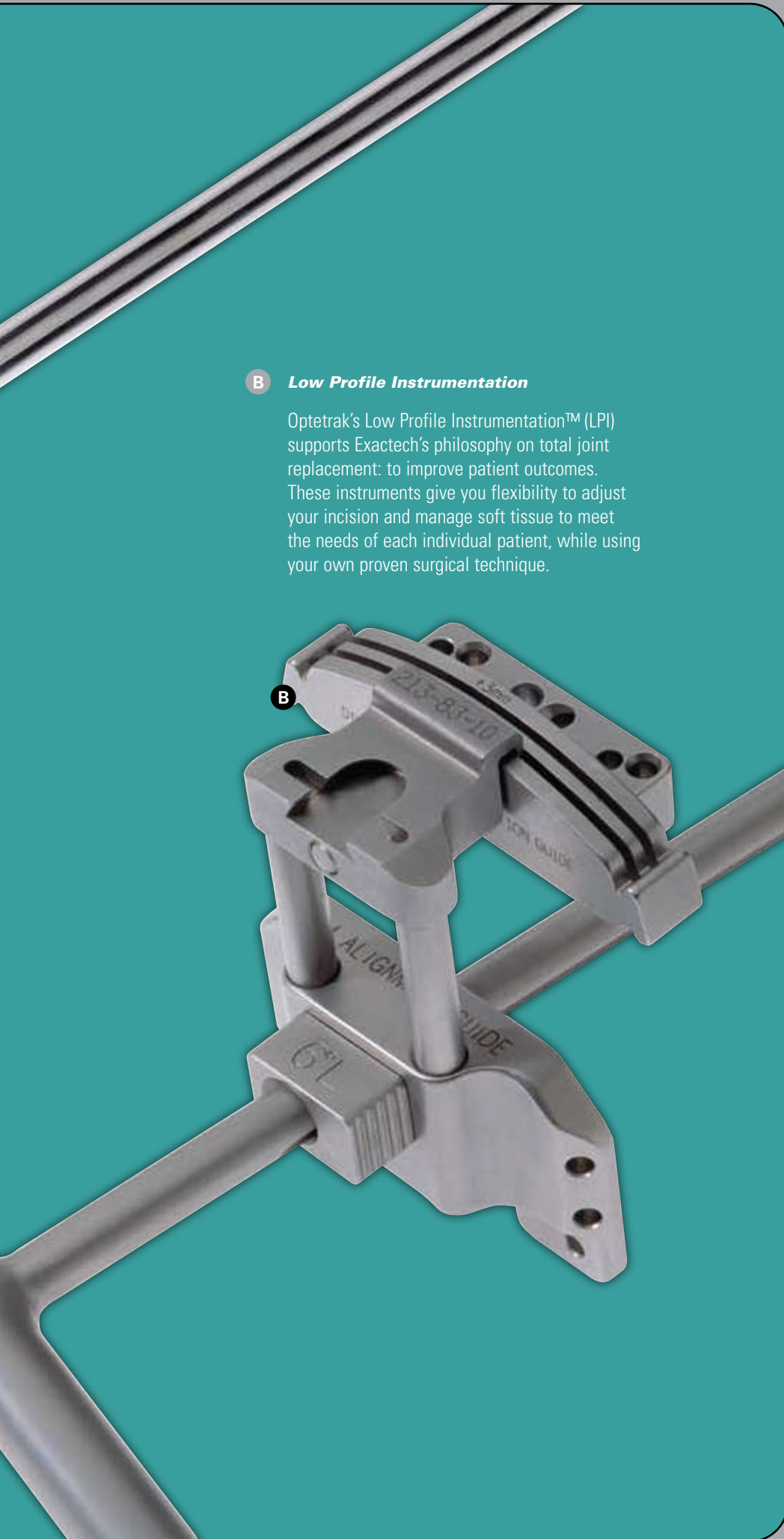
A single instrument set serves both cruciate retaining and posterior stabilized knees. The same streamlined approach supports revisions, where minimal additional trays are required. From the Mauldin Multi-tool which can be used for nearly a dozen different functions, to ligament balancing, to joint line referencing, our instrument trays are full of sleek solutions.

Easy to use and multifunctional. Durable and accurate for reproducible results. Optetrak's instrument systems strike the balance between art and science.



A *Ligament Balancing Options*

Plenty of surgeons tackle ligament balancing on their own, using anatomic landmarks or assuming an average 3 degrees of external rotation. With the patented Optetrak Ligament Balancing System, the patient's soft tissue determines the ideal external rotation of the femoral component, taking ligament balancing from a guess to a science.

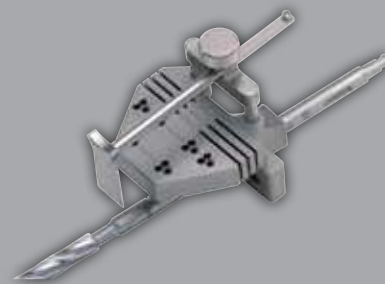


B Low Profile Instrumentation

Optetrak's Low Profile Instrumentation™ (LPI) supports Exactech's philosophy on total joint replacement: to improve patient outcomes. These instruments give you flexibility to adjust your incision and manage soft tissue to meet the needs of each individual patient, while using your own proven surgical technique.

B

INSTRUMENTATION OPTIONS



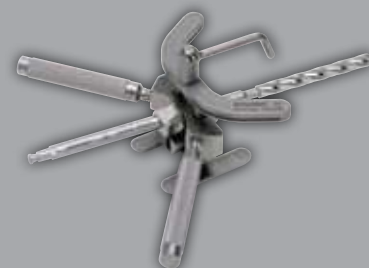
Revision Joint Line Reference and Distal Femoral Cutting Guide

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.



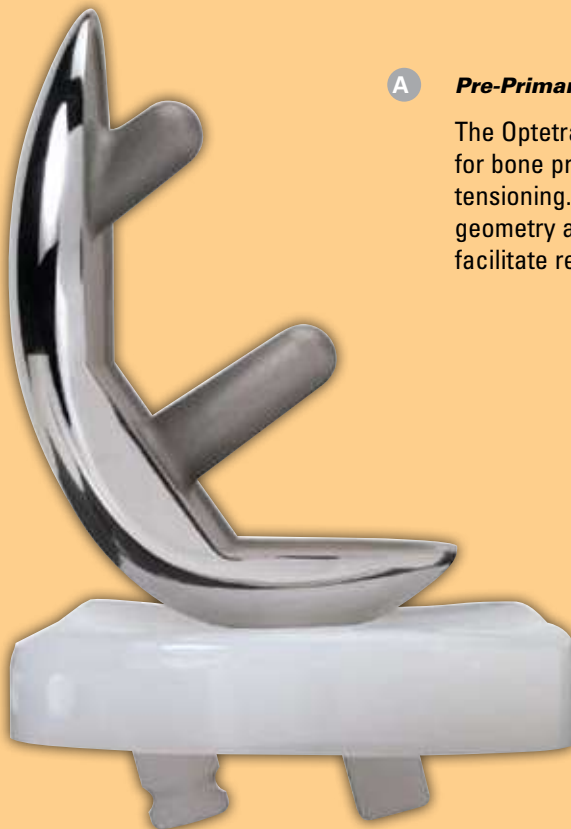
A Great Day in the O.R.SM

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.

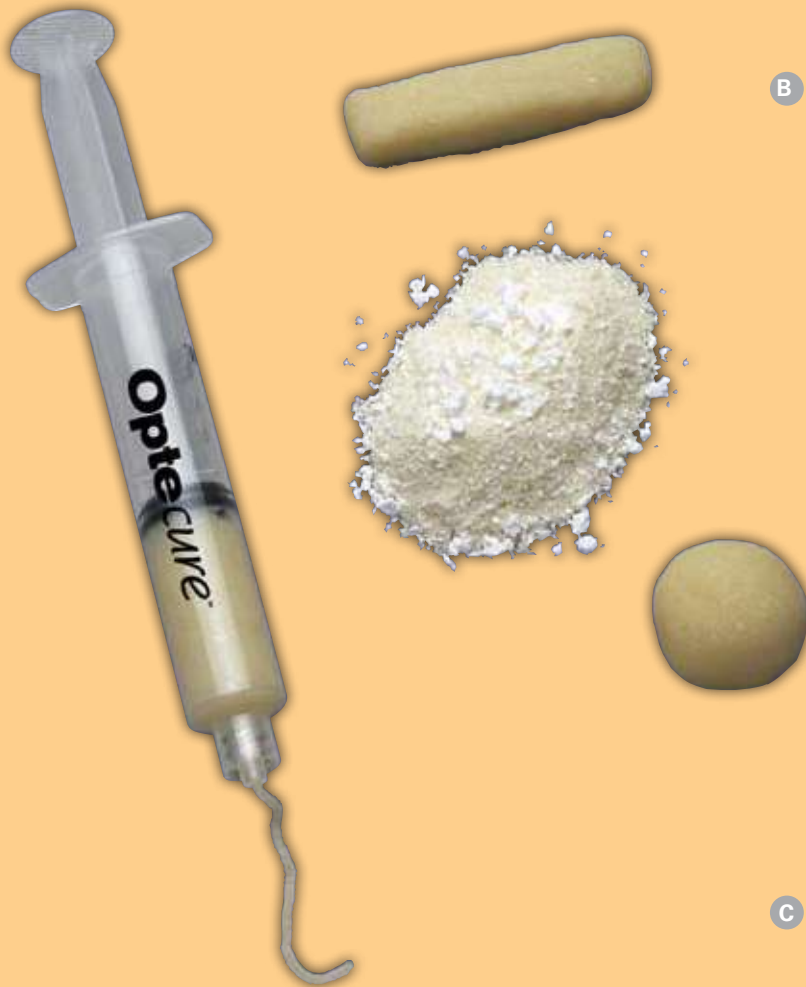
Along with innovative implants and instrumentation for total joint replacement, Exactech provides pre-primary, bone cement and biological solutions to meet your needs throughout the entire case.

Experience Exactech. *A Great Day in the O.R.SM*



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.



B *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. Its ability to speed healing and improve patient outcomes has been well documented.²³ This easy-to-use system provides a fast and convenient method for processing PRP in the operating room from a small amount of patient's blood.



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