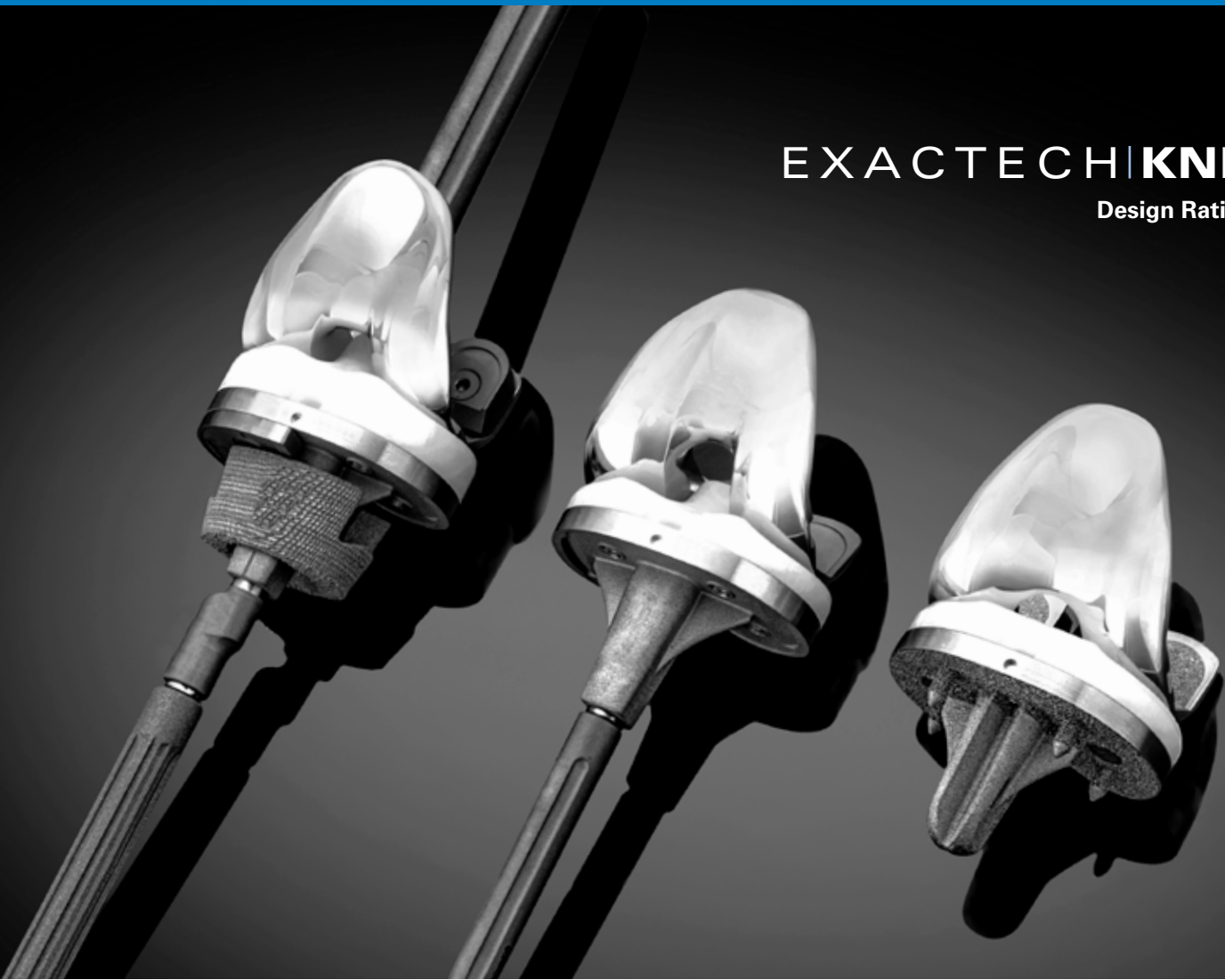


# EXACTECH | KNEE

Design Rationale



**TRULIANT<sup>®</sup>**

Total Knee System



# TRULIANT®

## Total Knee System

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# Introduction

With knee arthroplasty continuing to grow, orthopaedic surgeons are challenged to deliver superior clinical outcomes with ever greater efficiency. The Truliant® Total Knee System offers a high-performance, comprehensive platform that offers solutions to address clinical challenges in primary and revision total knee replacement. Leveraging Exactech's core principles, Truliant applies advanced design philosophies and surgical technologies to help you deliver reproducible clinical outcomes.

The longevity of a total knee implant is often attributed to the combination of excellent design and materials. The Truliant Knee System is the evolution of a clinically successful lineage of implants which began more than four decades ago.





## Design

Truliant maintains many of the proven design features of the Optetrak® and Optetrak Logic® Knee Systems to help minimize contact stresses at the articular surfaces between the femoral and tibial components, thus lowering the potential for surface damage and wear. It has been shown that contact stress at the articular surface is most greatly affected by the medial-lateral radius of the curvature of the femoral and tibial components.<sup>1</sup> Truliant features a full medial-lateral radius of curvature, resulting in an optimized congruency between the two components (*Figures 1a and 1b*). This ideal congruency is never compromised by matching the tibial insert size to the femoral component size. This congruency is essential to the overall kinematic behavior of the knee and by reducing contact stresses helps to minimize polyethylene wear, improving the longevity of the components.<sup>2,4</sup>

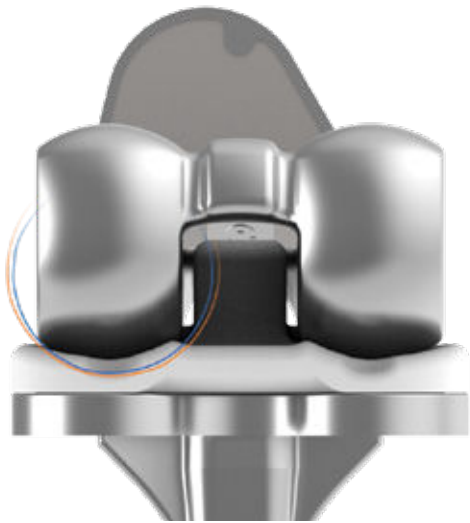


Figure 1a. M/L congruency =  $r_{FML} / r_{TML}$

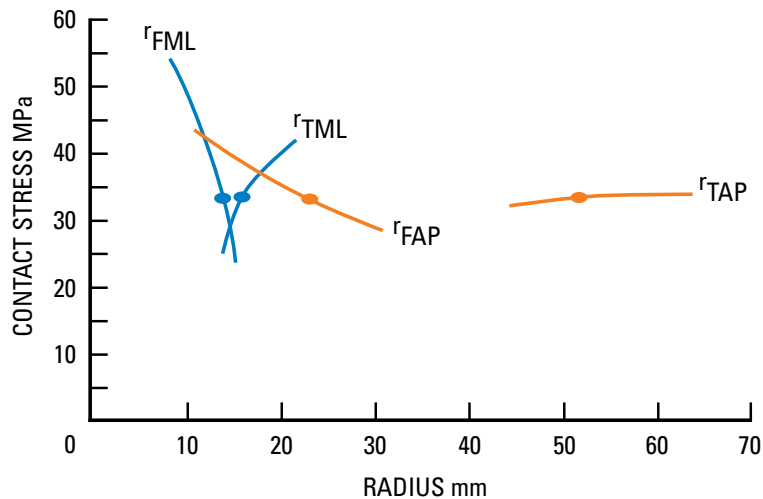


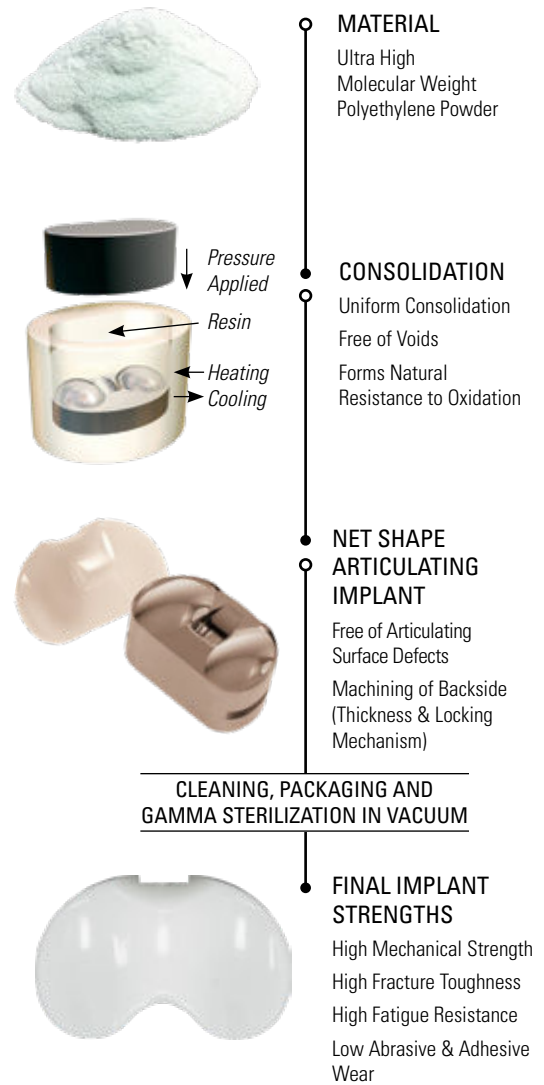
Figure 1b. Optimum Congruency for Minimizing Contact Stress

# Materials

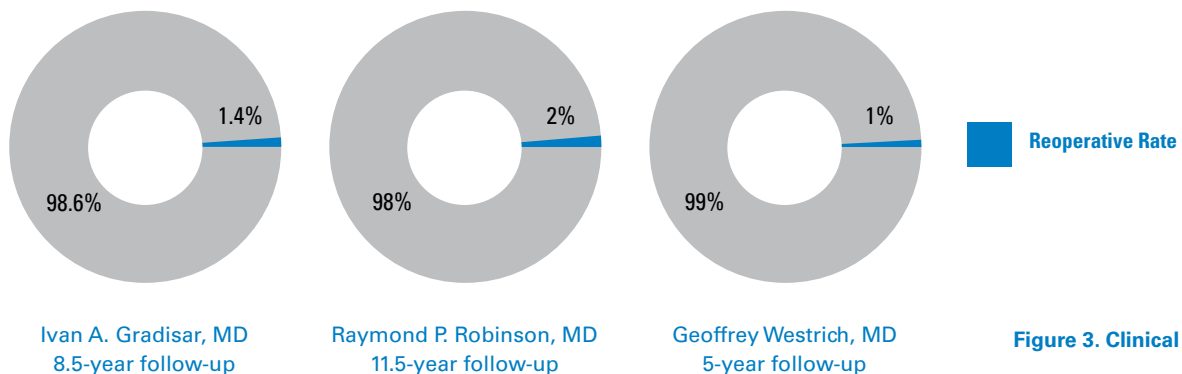
Materials are another key factor in a successful knee implant and Truliant continues to use the gold standard on the market as its predecessors have for many years. Truliant’s polyethylene tibial inserts are net compression molded (NCM), meaning these are molded individually one at a time. This process ensures that the properties are uniform throughout the entire component, resulting in the component being more resistant to oxidation and therefore potential wear (Figure 2). Truliant’s NCM polyethylene has a long clinical history of excellent wear characteristics without the need for any post consolidation treatment.<sup>3</sup> Extensive testing and clinical results of the Truliant legacy designs demonstrated wear rates of 1.46 mg/MC, one of the lowest wear rates in the industry.<sup>4</sup>

# Clinical Results

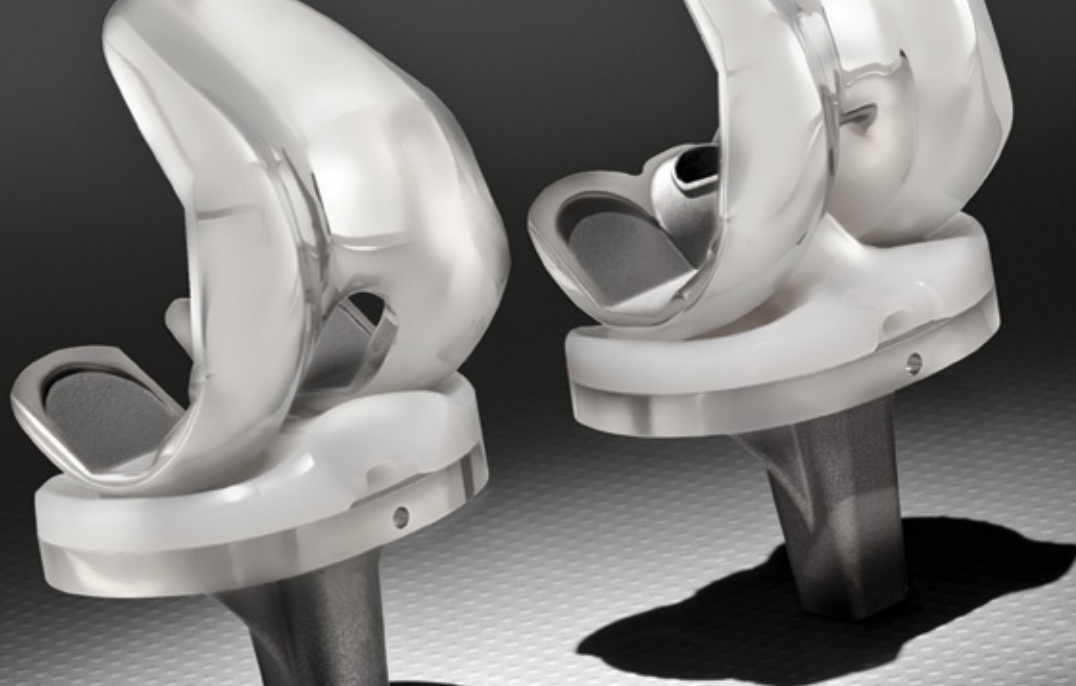
While many competitors are launching new implant designs, there is little to no clinical history on these. Truliant is an evolution of the Optetrak lineage which has demonstrated excellent long-term clinical outcomes.<sup>5,6</sup> There have been some updates to the design and overall scope of product offerings, but the features that are significant to a successful TKA remain constant. Truliant’s predecessor designs have demonstrated 98% or greater survivorship at 11.5 years.<sup>5,6</sup> Recently in a paper published by Geoffrey Westrich MD, a mid-term survivorship of 99% was reported for Optetrak Logic PS knees with significant improvement in pain and function as well as range of motion (Figure 3).<sup>7</sup> Surgeons can feel confident that Truliant was built upon clinically successful designs and that this prosthesis will continue to follow in it these footsteps.



**Figure 2. Manufacturing Process for NCM Polyethylene Inserts**



**Figure 3. Clinical Results**



## Implant Offerings

### TRULIANT CR:

One of the major challenges in a cruciate retaining (CR) TKA is to maintain the PCL during surgery, both structurally and kinematically. The Truliant CR system features several tibial insert options that aid in achieving a well-balanced flexion/extension gap.

The Truliant CR system offers patented sloped tibial insert options in addition to a standard, neutral CR tibial insert (Figure 4). These insert options allow the surgeon to adjust the flexion gap independently from the extension gap. Surgeons now have the flexibility with insert trials to evaluate the effects of an additional three or six degrees of tibial slope without the need of additional bone cuts.

- Truliant CR Standard (neutral)
- Truliant CR Slope + (three degrees of posterior slope)
- Truliant CR Slope ++ (six degrees of posterior slope)

Also available is the Truliant cruciate retaining constrained (CRC) insert, which features an increased anterior lip compared to the CR standard tibial insert (Figure 5). This is designed to provide additional A/P constraint when the integrity of the PCL is in question. There is no additional bone preparation required for use of a CRC tibial insert, allowing for a simple transition intraoperatively from a standard CR to a CRC tibial insert.



Figure 4. Truliant CR Tibial Insert Options

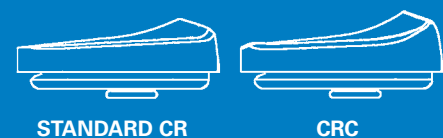
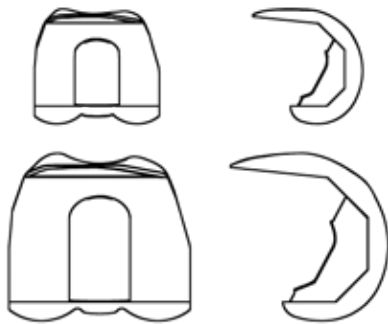


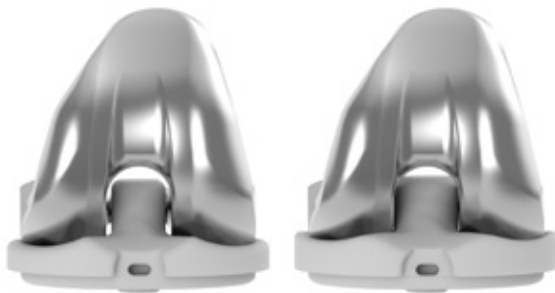
Figure 5. Truliant Standard CR vs Truliant CRC



**Figure 6. Truliant PS Spine/Cam Mechanism at 75, 90, and 120 Degrees**



**Figure 7. Truliant PS Proportional Femoral Notch**



**Figure 8. Truliant PS vs Truliant PSC**

## TRULIANT PS:

Truliant posterior stabilized (PS) is designed to maximize stability and range of motion while providing surgeons an efficient and consistent notch preparation, ultimately aiding in achieving more consistent patient outcomes in a PS TKA.




Truliant PS features an optimized femoral cam/tibial spine mechanism designed to replicate normal femoral rollback while improving joint stability and dislocation resistance. The optimized femoral-tibial congruity along with the patient's own soft tissues stabilize the knee until the cam and spine engage at approximately 75 degrees of flexion, providing controlled rollback for maximum range of motion. This initial engagement begins low on the tibial spine, allowing for increased jump height without increasing the overall height of the spine (*Figure 6*). The anterior femoral cam and tibial spine also feature a rounded geometry, designed for a more congruent contact during various angulations of the joint and reducing potential for deformation.

One of the most notable features of the Truliant PS system is the proportional femoral notch and tibial spine. Since these dimensions vary with each size femoral component, bone resections are minimized for smaller sizes and jump heights are increased for larger sizes (*Figure 7*).

The Truliant PS system also features a posterior stabilized constrained (PSC) tibial insert option when additional constraint is required. With no additional bone preparation, this tibial insert option provides additional rotational and varus/valgus constraint (four degrees and three degrees respectively). This is achieved by through a wider tibial spine on the PSC tibial insert (*Figure 8*).<sup>8</sup> Both insert designs (PS and PSC) are compatible with Truliant PS femoral components as well as Truliant CC femoral components.



**Figure 9. Truliant CC Femoral Component and Femoral Augments**

	Varus/Valgus Constraint	Internal/External Rotational Constraint	
Truliant PS	N/A	N/A	
Truliant PSC	+/- 3°	+/- 4°	
Truliant CC	+/- 1.5°	+/- 2°	

**Table 1. Constraint Options for Truliant CC<sup>®</sup>**



**Figure 10. Truliant Tibial FIT Tray and Tibial Augments**

## TRULIANT CC:

Revision TKA often presents unique challenges that require a broader array of implant offerings than a primary TKA. The Truliant constrained condylar (CC) system provides just that; offering augments, cones, stems, and insert options for easy implant adjustments to treat the needs of each patient. The system is also fully compatible with the Truliant primary system, allowing for a straightforward solution when revision implants are required for a complex primary TKA.

Truliant CC femoral components feature the same anterior/posterior dimensions, including the chamfers, as both the Truliant CR and PS femoral components. It was also designed with the same proportional cylindrical notch as Truliant PS. Truliant CC femoral components accommodate stackable distal and posterior augments (5 and 10mm), allowing for as much as a 30mm stack up if needed (*Figure 9*).

The system features several compatible constraint options for use with the Truliant CC femoral component: Truliant PS, PSC and CC. The ability to use either PS or PSC with a stemmed femoral component provides flexibility when there is poor bone stock requiring a stem and/or femoral augments but adequate collateral ligament stability. The Truliant CC tibial insert allows for two degrees of rotational constraint and one and a half degrees of varus/valgus constraint (*Table 1*).

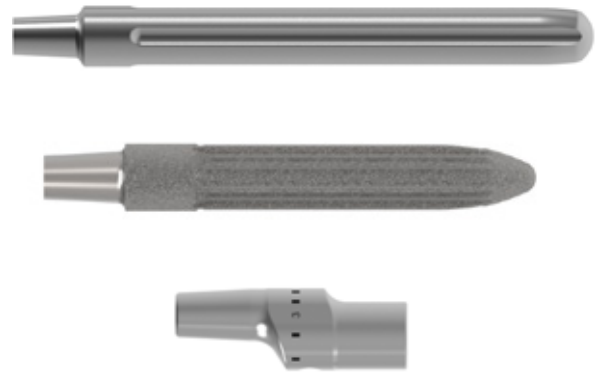
The Truliant FIT tibial trays are accepting of both stem extensions and tibial augments, allowing it to be used for both primary and revision applications. Tibial augments are available in ½ configurations and come in both 5 and 10mm thicknesses. However, they can also be stacked up to 15mm if the defect requires a larger augment. The 10mm augments are side-specific due to the 15-degree taper, designed to match the shape of the tibia and reduce overhang (*Figure 10*).



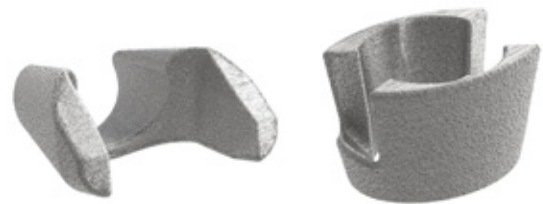
The Truliant CC system features both straight cemented and splined stem extensions as well as offset couplers. The offset couplers provide 2, 4, 6, or 8mm of 360-degree offset which aids the surgeon with achieving optimal bone coverage and manage their flexion/extension gap (*Figure 11*). To provide the appropriate level of fixation, Truliant CC offers:

- Cemented straight stems with 25, 40, 80, 120, and 160mm lengths with diameters ranging from 10-24 mm in 2mm increments.
- Splined straight stems with 80, 120, and 160mm lengths with diameters ranging from 10-24 mm in 1mm increments.

Where bone stock is more severely compromised metaphyseal cones may be required to achieve sufficient metaphyseal fixation. Femoral metaphyseal cones are available in four different sizes (small, medium, large, and x-large), and three different heights (32, 42, and 52mm) for a total of 12 femoral cone offerings. Tibial cones are available in 6 sizes (29, 32, 39, 48, 57, and 65 mm), each with a constant height (*Figure 12*). Both types of cones are manufactured from 3-D printed titanium and have the same parameters as InteGrip®. Comprehensive testing qualifies InteGrip as a three-dimensional, porous material where the porous structure is optimized to enable ingrowth while maximizing material strength properties. It is important to note that these metaphyseal cones feature a line-to-line press-fit when prepared per the operative technique.



**Figure 11. Truliant CC Stem Extensions and Offset Couplers**



**Figure 12. Metaphyseal Femoral and Tibial Cones**

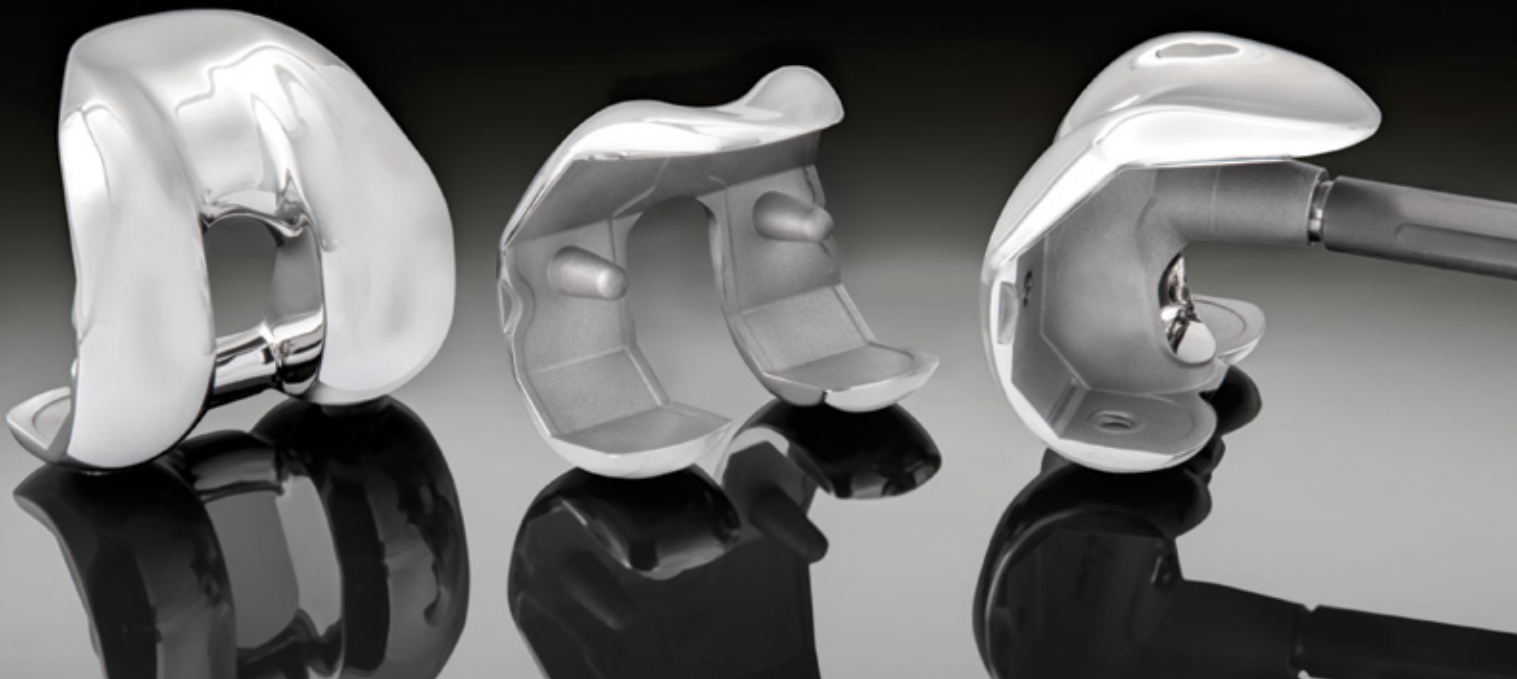




Figure 13. Truliant FIT Tibial Tray Sizing Options

### TIBIAL OPTIONS:

Truliant FIT tibial trays provide the flexibility to optimize tibial bone coverage while maintaining the optimized congruency between the femur and tibial insert. For every femoral-tibial insert pair there are three tibial tray options: same size, up-size, and down-size (Figure 13). The tapered nature of the FIT tibial tray in the up-size and down-size options ensures there is no overhang of the metal on a larger size or of the poly on a smaller size. This allows for optimal tibial bone coverage without increasing stress and wear at the articulating surface.

The Truliant FIT tibial tray was designed to minimize backside wear, which can threaten the function and longevity of total knee replacements. The FIT tray features a clinically successful three-part locking mechanism<sup>9</sup> made up of a continuous peripheral rim, precision undercuts and a central mushroom (Figure 14). These features are designed to prevent backside wear and component disassociation. The FIT tray also features a proportional keel with a geometry intended to provide rotational constraint and tibial plateau support. The FIT tray accepts tibial stem extensions as well as tibial augments, allowing the same tibial tray to be used in both a primary and revision setting. For enhanced cement fixation, the tray also features recessed cement undercuts and blind threaded holes (Figure 15).

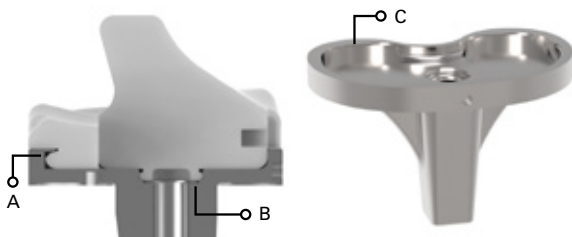


Figure 14. Truliant FIT Tibial Tray 3-part Locking Mechanism



Figure 15. Keel on Truliant FIT Tibial Tray





## TRULIANT POROUS:

The demographics of patients undergoing TKA are evolving to include younger, and more active patients. In addition, surgeons are faced with mounting economic pressures and are looking for solutions to aid in the longevity and durability of implants while decreasing O.R. times. The use of a cementless implant may be beneficial in providing long-term durable biologic fixation while delivering a reproducible and efficient experience for the surgeon. Truliant Porous leverages today's advanced manufacturing techniques to reduce micromotion and aid in potential bony in-growth, providing a durable bonding surface for long-term interface strength.

Truliant Porous offers both femoral and tibial components that are built upon the same design principles as their cemented counterparts (*Figure 16*). Available in CR and PS with the same insert and tibial tray options as cemented, Truliant Porous includes a comprehensive portfolio of options. Fully compatible with the Truliant Primary System, the surgical technique also provides a seamless transition from cemented to press fit.

Truliant Porous femoral components are made of cobalt chrome and feature a porous crushed bead coating that has been clinically proven to provide stable initial fixation.<sup>1</sup> They feature the same anatomical profile as the cemented femur, as well as the same anterior/posterior and chamfer dimensions. The box on Truliant Porous PS was also designed with the same proportional cylindrical notch. Preparation for a Truliant Porous femur is identical to that as a cemented femur so there is no change to surgical flow or additional instrumentation needed.

Truliant Porous tibial components feature a unique design produced by additive manufacturing technology. The component is made entirely of Titanium and the surface structure was designed to mimic the trabecular nature of cancellous bone with an optimized pore size of 425  $\mu\text{m}$  and an average porosity of 65 percent. Pegs allow for stable initial fixation and a channeled keel is designed to increase stability and resistance to micromotion. Additional bone screw fixation options are available for further stability. Preparation for the porous tibial component only requires one additional instrument tray and is compatible with the rest of the Truliant Primary System.



**Figure 16. Porous Tibial Tray Compared to the Cemented Tibial Tray**



## Instrumentation

The Truliant system is a high performance, comprehensive platform that offers intuitive instrumentation designed with the surgeon and O.R. staff in mind.

Great emphasis was placed on the industrial design, ergonomics and overall function of the system (*Figure 17*). The instrumentation features blue accents to indicate touchpoints for adjustability and functionality. The textured grip was designed to accommodate both mechanical and functional needs of the user. The instruments also feature easy-to-read laser markings and are designed to provide surgeons with visual, audible and tactile feedback. Since the system launch in 2017, Truliant has been internationally recognized, winning three different design awards (*Figure 18*).

The Truliant instrumentation was designed for a streamlined technique and the ability to transition simply from primary to revision to navigation. From modular instrumentation to thoughtful tray layouts, the system aims to improve overall efficiency in the O.R. for both the surgeon and staff.

**Figure 17. Industrial Designed Aspects of Truliant Instrumentation**



Figure 18. Truliant System Design Awards

Universal, symmetric femoral trials not only minimize the total number of instruments required but make the intraoperative conversion from CR to PS efficient with only the addition of a size specific notch guide (Figure 19). The instruments also offer a great amount of adjustability, giving surgeons more flexibility to make fine tune adjustments (Figure 20).

The revision system is fully compatible with the primary system, using many of the same instruments for a seamless transition between the two. The instruments feature modular trials similar to the primary system, providing multiple opportunities for femoral augment preparation and features slots for preparing both distal and posterior augments.

The Truliant primary instrumentation consists of only four trays: three core trays plus an additional tray for either CR or PS specific trials. The Truliant revision instrumentation requires only an additional five trays.



Figure 19. Truliant Modular Femoral Trials



Figure 20. Adjustability on the Distal Femoral Alignment Guide

# Navigation

The design foundation for ExactechGPS® is to provide orthopaedic surgeons an innovative technology that redefines total joint replacement surgery. With its active tracker technology, ExactechGPS provides fast, accurate, visual displays within the sterile operative field. Personalized for surgical preferences, ExactechGPS supports goals for accuracy and reproducibility from primary to revision knee arthroplasty. Three applications are available to meet every customer's need:

- TKA Plus allows for precision checking of your orthogonal cuts using the Truliant mechanical instrumentation. This application provides the surgeon with real-time feedback on the placement of the distal femoral and tibial cutting blocks and the ability to make fine-tune adjustments prior to any bone resections (Figure 21).

- TKA Pro offers a more complete navigation platform. This application will not only provide guidance of the orthogonal cuts, but will also determine femoral size and rotation. Additional options are available such as pre- and postoperative kinematics and gap balancing (Figure 22).
- RTKA is designed for revision procedures with the ability to use either the mechanical or anatomical axis for component placement. Real-time feedback aids in re-establishing the joint line, as well as selection of offset position and necessary augments (Figure 23).



Figure 21. TKA Plus Application

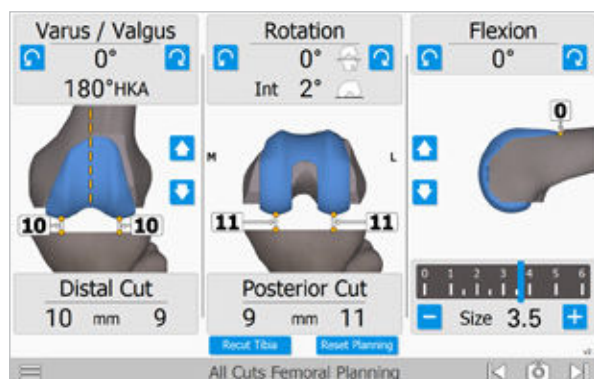


Figure 22. TKA Pro Application

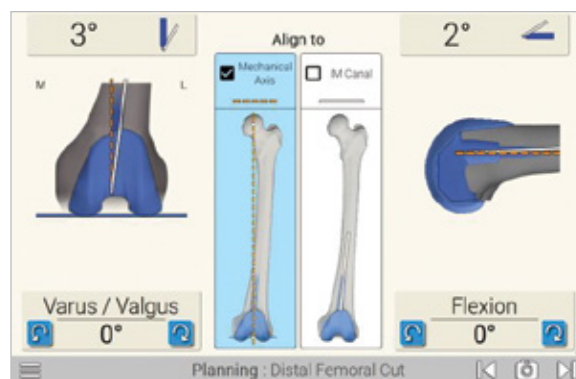
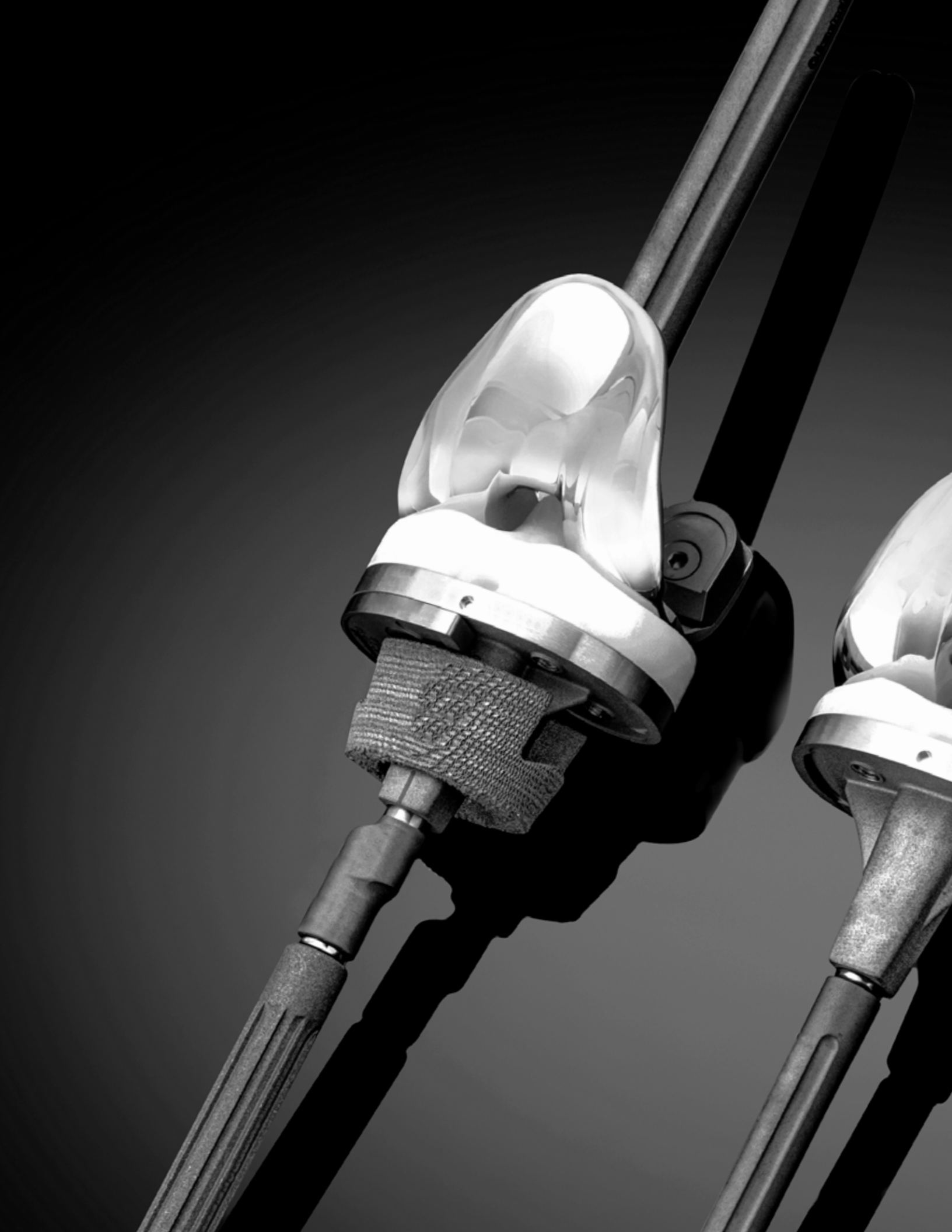


Figure 23. RTKA Application







**TRULIANT**<sup>®</sup>  
TOTAL KNEE SYSTEM



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For additional device information, refer to the Exactech Knee System—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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