

Operative Technique



Constrained Condylar



Surgeon focused. Patient driven.™



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THE OPTETRAK[®] CONSTRAINED CONDYLAR OPERATIVE TECHNIQUE AND INSTRUMENTS WERE DEVELOPED IN CONSULTATION WITH:

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INTRODUCTION

In the late 1980s, Dr. Albert Burstein of Hospital for Special Surgery, New York, NY, and Dr. Donald Bartel, a colleague from Cornell University, reviewed the clinical performance of total knee replacements and studied the appearance of retrieved prosthesis specimens. This analysis led them to develop an improved articular design that results in very low Ultra High Molecular Weight Polyethylene (UHMWPE) stresses.

The resulting bi-concave contour of Optetrak® results in reduced polyethylene stress in all loading modes. The condylar radii have been precisely machined and matched to reduce stress further, while maintaining proven kinematics.

Optetrak is a comprehensive knee system, based on over 30 years of clinical results from Hospital for Special Surgery, that addresses your concerns for contact stress, patellar tracking, polyethylene wear, joint stability and bone preservation with streamlined instrumentation that lets you work quickly and efficiently.

The Optetrak ComprehensiveTotal Knee system offers total flexibility among its different components. Both Cruciate Retaining (CR) and Posterior Stabilized (PS) prostheses are compatible with and may be upgraded to the Non-Modular Constrained or Constrained Condylar implants if collateral ligament stability is affected.

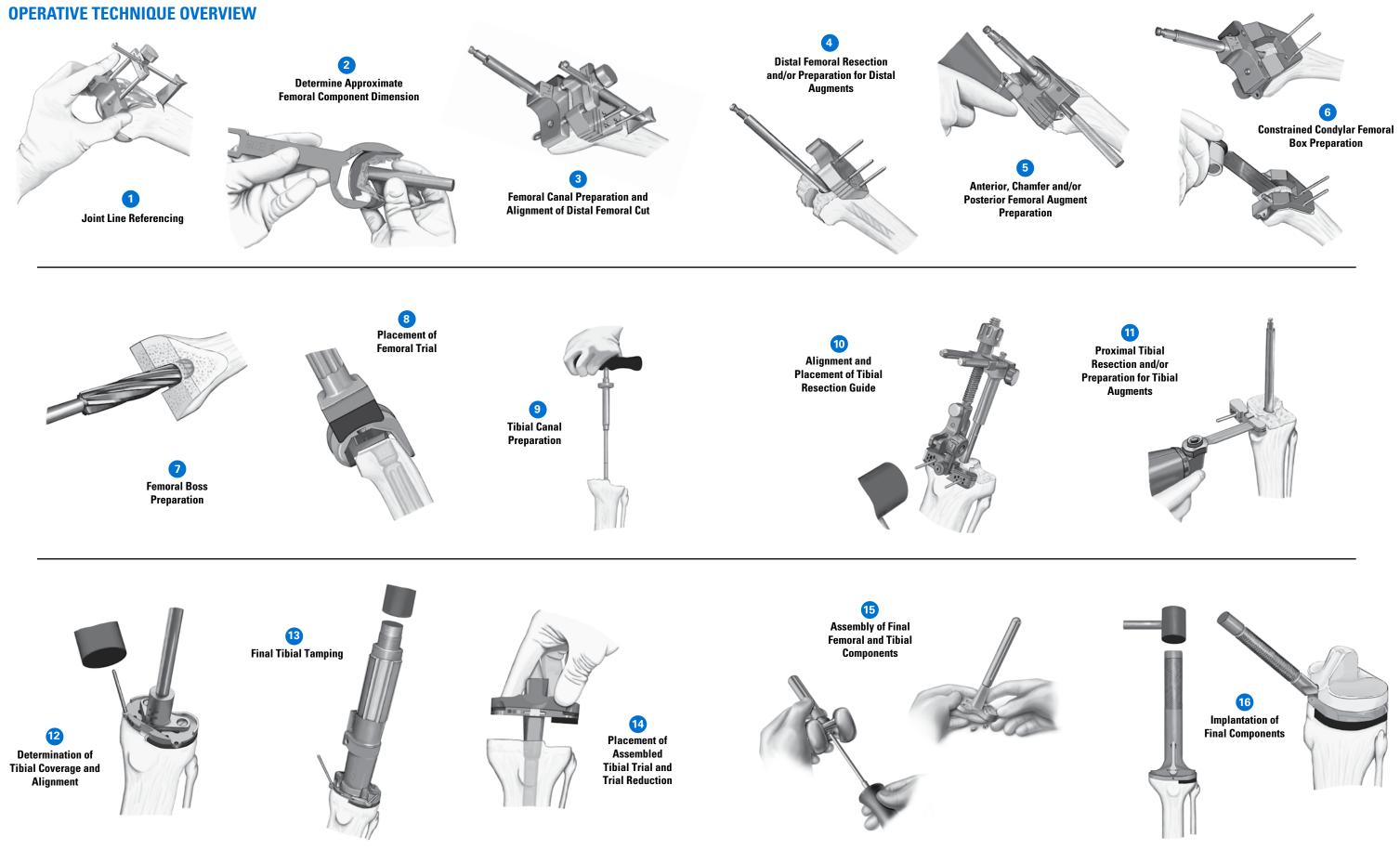
DESIGN RATIONALE

The Optetrak total knee system design team, clinical evaluators and Exactech engineers have collaborated to provide the Optetrak Constrained Condylar knee, a system of implants and instruments that addresses a wide variety of primary and revision knee surgeries. The design includes all the features and benefits of the Optetrak Posterior Stabilized Knee and the heritage of the Total Condylar and Insall/Burstein knee prostheses.

The primary long-term survivorship of these systems has been excellent, with over 90 percent of these knees functioning after 30 years.

The enhancements over other systems are as follows:

- The femoral flange edges of the Optetrak Constrained Condylar knee are beveled to allow a more centralized patellar tracking. The patellar groove is also deeper and additional material has been removed from the extension/flexion transition point to reduce the incidence of "patellar clunk."
- The Optetrak Constrained Condylar stem position is more anterior than other constrained condylar designs. This provides proper positioning of the femoral prosthesis in the sagittal plane. The stem boss has been shortened and designed to allow for a right and left stem position with multiple valgus angle settings.
- The femoral augmentation options of the Optetrak Constrained Condylar knee accommodate independent posterior and distal thicknesses. The femoral augmentation blocks come pre-assembled with a screw. This facilitates attachment to the femoral component.
- The femoral component size is always matched exactly with the corresponding tibial insert to minimize articular stresses and reduce polyethylene wear. The tibial tray design provides for up and down sizing so that the surgeon can optimally fit the tray to the tibial bone.
- The tibial spine fit in the femoral box provides excellent stability to augment deficient medial or lateral collateral soft tissues. The spine provides 1 1/2 degrees of varus/ valgus freedom and two degrees of rotation.
- Instrumentation for the Optetrak Constrained Condylar knee provides reference points for establishing both joint line level and appropriate alignment. A joint line reference instrument can be used to determine the level of distal femoral resection, which positions the joint line anatomically.
- To simplify trial assembly and instrument selection, the CC system uses the same color code scheme as the Optetrak primary system.
- The augmentation trials for the tibial and femoral components have magnets to afford easy assembly.



PRE-OPERATIVE PLANNING

Pre-operative planning is important in knee replacement revision surgery to assist in an adequate management plan for the soft tissues (skin, capsule, ligaments); it also helps recreate the knee joint line properly and allow for the joint to be balanced in flexion and extension.

Pre-operative templating will help the surgeon determine:

- 1. the approximate size femoral component needed.
- 2. the amount of augmentation that may be necessary to restore the normal joint line.
- the length and diameter of femoral and tibial stems. If the contralateral knee has not been replaced, pre-operative templating for determination of these three parameters could also be done on the non-operative side.

DETAILED OPERATIVE TECHNIQUE

PREPARATION OF THE FEMUR

Step 1: Pre-Operative Assessment

The surgeon should pre-operatively determine the proper valgus angle of either five or seven degrees and joint line position by evaluating long limb X-rays.

Step 2: Initial Reference Point

The CC Femoral Reference Coupler and CC Femoral Valgus Angle Adapter are designed to reference the pre-existing joint line position prior to extraction of the existing femoral component. This provides a reference to establish the joint line position for the revision component.

The CC Femoral Reference Coupler is assembled to either the five or seven degree CC Valgus Angle Adapter, with right or left designation facing up, by sliding the two prongs of the CC Femoral Reference Coupler into the two holes in the CC Valgus Angle Adapter (*Figure 1*).

The CC Valgus Angle Adapter face is positioned at the distal extent of the condyles of the previously implanted femoral component (*Figure 2*).



Figure 1 Assembly of Joint Line Reference Instrument

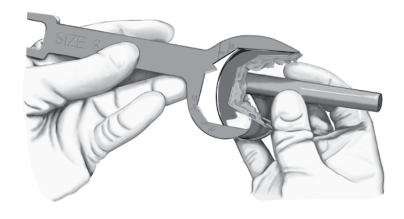
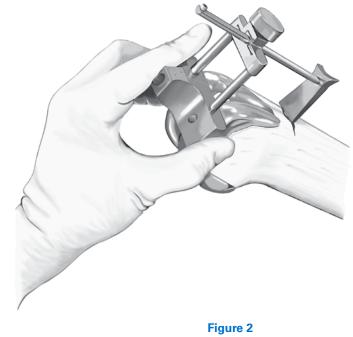


Figure 3 Size Comparison with Removed Implant



Making Initial Joint Line Reference Mark

To be sure the face of the CC Valgus Angle Adapter rests on the most distal position of the femoral condyles, the horizontal stylus shaft of the CC Femoral Reference Coupler is aligned parallel with the shaft of the femur so there is no hyperextension or flexion of the instrument. The proper right or left designation on the CC Valgus Angle Adapter should point anteriorly.

The stylus is adjusted so the tip rests on the anterior femur proximal to the position of the anterior flange of the existing component by approximately 5mm. The stylus is locked firmly in place with the locking knob.

Note: It is important that the knob remains locked until the conclusion of the surgical procedure.

Note: When possible, the stylus should be locked at its shortest position. The "stop" would then allow the stylus position to be reproduced throughout the surgery should the knob become loose.

A mark on the bone is made where the stylus contacts the anterior cortex by using electrocautery or by drilling a small hole. The CC Femoral Reference Coupler assembly is then removed from the operative site.

Note: Take care not to alter the stylus position.

Step 3: Removal of Existing Components

The existing femoral and tibial components should be removed and debridement of the distal femur should be performed. The AcuDriver[®] Automated Osteotome System can be used to loosen and remove the femoral and tibial components. Thin, pneumatic osteotomes will break the cement or porous interface using controlled bursts in either single or multi-shot mode.

Step 4: Sizing of the Femur

Femoral Bone Comparison

With the posterior condyles absent, standard sizing techniques cannot be used. Therefore, it is important to use the existing femoral component as an indicator of the appropriate revision component size. The **CC Femoral Lateral Template** will help the surgeon determine component size.

The extent of bone loss is estimated by comparing the CC Lateral Template to the component removed and to the remaining femoral bone. This enables the surgeon to assess the need for femoral augmentation blocks.

The template is aligned with the lateral aspect of the explanted femoral component for a size-to-size comparison (*Figure 3*).

The handle of the template represents the anterior/posterior (A/P) position of the stem of the constrained femoral component. To visualize the proper A/P position of the femoral component, the centerline point on the handle of the template should be aligned with the center of the femoral canal.

Step 5: Reaming the Femoral Canal

In revision surgery, the intra-medullary canal is often the only reliable landmark for the placement of the instruments. The cutting guides in the Optetrak Constrained Condylar knee use a **Stem Extension Reamer** placed in the intra-medullary canal as their reference point. This Reamer, and subsequently the stem position in the femur, will determine the A/P and medial/lateral (M/L) positions of the femoral component.

Note: Once the proper Reamer is in position within the canal it should not be removed until Step 7.

A **Quick-Release T-Handle** or power reamer may be assembled to the CC Reamers. In addition, the CC Lateral Template may be used to guide the reamer to assure coaxial alignment with the medullary canal (*Figure 4*).

The intra-medullary (IM) canal should be opened with the **Intra-Medullary Pilot Drill** used in the Optetrak Cruciate Retaining/Posterior Stabilized (CR/PS) Operative Technique.

The appropriate size Reamer is one that provides good stability within the canal. When reamer stability is achieved, the Reamer is left in place and disconnected from the T-Handle or power reamer.

Step 6: Resection of the Distal Femoral Bone

The distal femoral resection instrumentation allows for either a minimal distal resection (to freshen the bone surface) or slots to create a freshened surface for any necessary distal augmentation. The reference mark on the anterior cortex created in Step 1 should be used to reestablish the joint line in its original position. Adjustments can be made to move the constrained femoral position more proximal or more distal as desired. A 5- or 7degree valgus angle may be selected.

Begin assembly of the distal femoral resection instrumentation by sliding the CC Femoral Reference Coupler through the two holes in the **CC Distal Femoral Resection Guide**.

The two posts of the CC Femoral Reference Coupler are inserted through the two holes in the CC Valgus Angle Adapter (*Figure 5*).



Figure 4 Reamer Comparison with CC Lateral Template



Figure 6 Placement and Pinning of the CC Distal Femoral Resection Guide



Figure 5 Assembly of CC Reference Coupler to CC Distal Femoral Resection Guide

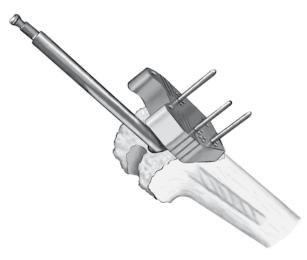


Figure 7 Distal Femoral Cut

The proper right or left designation on the CC Valgus Angle Adapter should point anteriorly.

The assembly is placed onto the reamer with the CC Femoral Reference Coupler and the CC Distal Femoral Resection Guide raised to clear the anterior bone until the tip of the Coupler touches the reference point marked on the bone in Step 1 (*Figure 6*). The CC Distal Femoral Resection Guide is pinned to the bone through the "0" holes.

Note: At least three pins should be used in the resector for stability during cutting.

At this point, the CC Femoral Reference Coupler and CC Valgus Angle Adapter are removed from the Reamer, leaving the Reamer and the CC Distal Femoral Resection Guide in place (*Figure 7*).

The position of the CC Distal Femoral Resection Guide may be changed when headless pins are used if an adjustment to the joint line position is needed. This is done by sliding the CC Distal Femoral Resection Guide onto either the more proximal or the more distal hole positions.

The remaining bone should now be evaluated.

- a) If the distal femur extends to the "0" resection slot on both sides, the bone should be recut through this slot.
- b) If the distal femur is deficient on either the medial or lateral condyle, but extends to the "0" slot on the most preserved side, the augmentation slot should be selected on the deficient side that will provide a freshened surface for a single distal augmentation.
- c) If the distal femur is deficient on both sides, cuts should be made through the augmentation slots on both sides to freshen the bone for two distal augmentations. This will bring the joint line out to the desired position.

The distal cut is completed and the CC Distal Femoral Resection Guide is removed while keeping the Reamer in place.

Step 7: Femoral Finishing Resections

The CC Femoral Finishing Guide uses the Reamer as the reference point for the proper M/L and A/P position. Rotation of the femoral component is determined by the rotation of the CC Femoral Finishing Guide. The surgeon determines the rotation by locating the transepicondylar axis and aligning the CC Femoral Finishing Guide along that axis. If the distal resection level requires augmentation, the magnetic Distal Femoral Augment Trials must be used to provide for a level surface on which the CC Femoral Finishing Guide will rest. These Femoral Augment Trials are colorcoded to match the color indication of the femoral component. The correct valgus angle bushing, determined in the previous step, is used to provide the proper valgus angle. A **Cut Line Predictor** used in the Optetrak CR/PS Operative Technique may be used to assess the remaining bone anteriorly and posteriorly.

The **CC Femoral Finishing Guide Bushing** is inserted into the CC Femoral Finishing Guide, assuring that the proper limb indication, right or left, is facing anteriorly (*Figure 8*).

If the distal resection level requires augmentation, the appropriate magnetic Distal Femoral Augment Trial should be attached to the proximal side of the CC Femoral Finishing Guide. Distal Femoral Augment Trials may be used on both condyles as determined by the distal femoral resection in Step 6 (*Figure 9*).

The CC Femoral Finishing Guide assembly is placed onto the Reamer, rotated to align with the transepicondylar axis (*Figure 10*) and pinned through the side holes with the special **CC Fixation Pins** using the **Pin Inserter**/ **Extractor**.

Note: It is important that the CC Pins are fully seated to prevent interference with the saw blade during the chamfer cuts.



Figure 8 Assembly of the CC Valgus Angle Adapter to the CC Femoral Finishing Guide



Figure 9 Assembly of the Trial Augmentation Block to the CC Femoral Finishing Guide

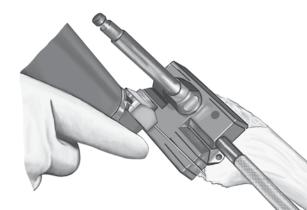


Figure 11 Posterior Augmentation Resection



Figure 12 Assembly of the CC Valgus Angle Adapter to the CC Femoral Notch Guide



Figure 13 Assembly of the Distal Augmentation Block Trial to the CC Femoral Notch Guide



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At this point, the Cut Line Predictor can be used to assess the remaining bone anteriorly and posteriorly.

Cuts should be made through the anterior, anterior chamfer and posterior chamfer slots (*Figure 11*). Posterior bone loss should be evaluated on the medial and lateral posterior condyles. The bone should be freshened through the slots that provide a minimal cut and maximum bone contact independently on the medial and lateral posterior condyles. If the femoral component is to be augmented distally, there may be no chamfer bone to resect.

After all resections have been made, the CC Pins are removed with the Pin Inserter/ Extractor. The CC Femoral Finishing Guide is removed from the Reamer. The Reamer should remain in the femoral canal.

Step 8: Resecting the Intercondylar Box

The **CC Femoral Notch Guide** is placed over the Reamer. The Reamer will position the CC Femoral Notch Guide in line with the IM canal so that the constrained femoral component stem will align with the intercondylar box resection. If both distal condyles have been prepared for augmentation, two Distal Femoral Augment Trials should be attached to the proximal side of the CC Femoral Notch Guide.

The 5-degree or 7-degree CC Valgus Angle Adapter is positioned on the pegs of the CC Femoral Notch Guide (*Figure 12*).

If the bone has been prepared for distal augmentation blocks, magnetic Distal Femoral Augment Trials should be attached to the proximal side of the CC Femoral Notch Guide (*Figure 13*).

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The Notch Guide assembly should be placed on the Reamer. The CC Femoral Notch Guide is pinned through the anterior holes with headless holding pins (Figure 14).

The Reamer and CC Valgus Angle Adapter should be removed before making the box cut. If the Reamer is 18mm or larger, the Notch Guide will interfere with Reamer removal. If this occurs, slide the Notch Guide anteriorly off of the holding pins and remove the CC Valgus Angle Adapter and Reamer. The Notch Guide can now be replaced onto the holding pins. Additional headed pins should be added through the distal angled holes or through the anterior holes of the Notch Guide.

Cuts are made along the three surfaces of the CC Femoral Notch Guide (Figure 15), and the central bone is removed.

Step 9: Final Reaming

The stem boss on the constrained femoral prosthesis is 17mm in diameter. To accommodate the boss in a canal that has been reamed less than 18mm, an 18mm Reamer should be used to ream the distal canal 20mm (2cm) deep to the distal cut (Figure 16).

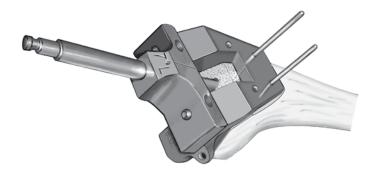


Figure 14 Placement and Pinning of the CC Femoral Notch Guide



Figure 17 Assembly of the CC Taper Adapter Trial to the CC Femoral Trial

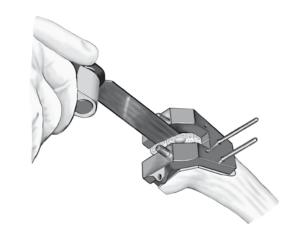
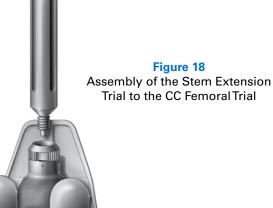


Figure 15 Notch Resection



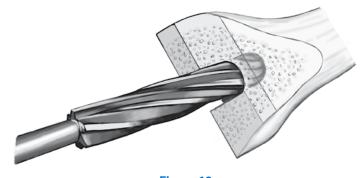


Figure 16 Femoral Boss Preparation



Figure 19 Assembly of the Distal Femoral Augment Trial to the CC Femoral Trial

Step 10: Assembly and Placement of the **Femoral Trial**

The **CC Femoral Trial** provides an opportunity to evaluate fit and function of the femoral component, stem extension and/or any distal or posterior femoral augmentation prior to choosing the actual components.

The CC Femoral Trial that corresponds to the size of the CC Femoral Finishing Guide used in Step 7 should be assembled using either the 5- or 7-degree CC Taper Adapter Trial that corresponds with the valgus angle selected in Step 1. The CC Taper Adapter Trial is inserted into the boss on the CC Femoral Trial by first aligning the engraved angle (5- or 7-degree) on the CCTaper Adapter Trial with the arrow on the femoral Trial boss (Figure 17). The CCTaper Adapter Trial is snapped in place and turned so the engraved letter "L" (left) or "R" (right) is aligned with the arrow on the boss indicating the appropriate patient limb.

The appropriate length and diameter Stem Extension Trial should be screwed into the CC Taper Adapter Trial positioned in the Femoral Trial boss (Figure 18).

If preparation has been made for distal and/ or posterior femoral augmentation in Steps 1 and 6, the appropriate magnetic Femoral Augment Trial should be assembled to the posterior and/or distal areas of the CC Femoral Trial. The color of the Femoral Augment Trial should match the color indicated on the CC Femoral Trial (Figures 19 & 20).



Figure 20 Assembly of the Posterior Femoral Augment Trial to the CC Femoral Trial

The Trial is now ready to be placed on the femur. The CC Femoral Trial should be introduced into the prepared femur and impacted using a Non-Locking Femoral Impactor (Figure 21).

PREPARATION OF THE PATELLA

If the patella requires revision, it should be stabilized with large towel clips or similar instruments. An oscillating saw may be used to cut though the prosthesis/bone interface and through the polyethylene pegs. The remnants of the pegs may be removed using a small curette or burr. The remaining bone should be freshened or recut with an oscillating saw. The surgeon must use care to avoid thinning the patella too much. Patellar diameter may be determined by placing the patellar drill template in either the three-hole or single-hole configuration.

PREPARATION OF THE TIBIA

Step 1: Tibial Reaming

The tibial instruments use the intra-medullary canal as their reference point. This landmark is more reliable if the surgeon has the ability to double-check the alignment with an external rod.

Note: A stem extension on the trapezoid tray is required if a constrained insert is used.

The intra-medullary canal is located with the IM Pilot Drill.

Using the Reamer, ream the canal to a sufficient depth to assure neutral alignment. This depth must be at least as deep as the length of the stem to be used. This is assured when the depth indicator ring aligns with the cut surface of the proximal tibia (Figure 22).

The appropriate size Reamer is one that provides good stability within the canal. When Reamer stability is achieved, the Reamer is left in place and disconnected from the handpiece.



Figure 21 Placement of the CC Femoral Trial



Figure 23 Assembly of the Fixed Tibial IM Resector and Tibial IM Reamer Coupler



Figure 22 Reaming the Tibial Canal



Resector Setup

Step 2: Resection of the Proximal Tibial Bone The Fixed Zero-Degree Slope Tibial Intra-Medullary Resector is used to guide the cut of the proximal tibia. This Fixed Tibial IM Resector is included in the Optetrak CC Standard Instrument Set. The reference point for this guide is the IM canal and Reamer left in place from the previous step. The position of the stem in the IM canal will determine the position of the Tibial Base Plate. Therefore, the proximal tibial cut should be perpendicular to the Reamer. The anterior/posterior and varus/ valgus slope must be in the neutral setting to allow the tibial plate to rest flush on the surface of the proximal tibia when the stem is placed into the intra-medullary canal.

Alternatively, the Optetrak Primary Adjustable Tibial Intra-medullary Resector can be used. If this is the case, the primary reamer guide tube is removed and the Tibial Intramedullary Reamer Coupler is inserted into the Adjustable Tibial IM Resector (Figure 23).

The tibial resection slope is set on the "0" marking. The varus/valgus setting should be in the center or neutral position (Figure 24).

Note: The two previous steps are not necessary when the Fixed Tibial IM Resector is used.

The Tibial Augmentation Block Resection Guide is then attached to the Tibial Resector using the dovetail on the anterior face of the Resection Guide (Figure 25).



Figure 25 Assembly of the Tibial Augmentation Block Resection Guide The tibial resection assembly is placed over the Reamer (*Figure 26*).

The Tibial Augmentation Block Resection Guide should be moved posteriorly until it is touching the anterior tibia. Using the large proximal adjustment knob, the guide depth should be adjusted to allow for a minimal resection. After using the Cut Line Predictor to check the resection depth, the block should be pinned in place with headless pins (*Figure 27*).

If a defect is present, the Tibial Augmentation Block Resection Guide should be used in place of the standard Tibial Resection Guide in order to make the appropriate cut for augmentation. The better (more proximal) surface of the tibia should be aligned with the top surface of the Resection Guide by adjusting the large proximal knob on the Resection Guide. The Resection Guide should be set to resect a minimal amount of bone from the least defective plateau. Either 1/2 or 1/3 blocks may be used (*Figure 28*).

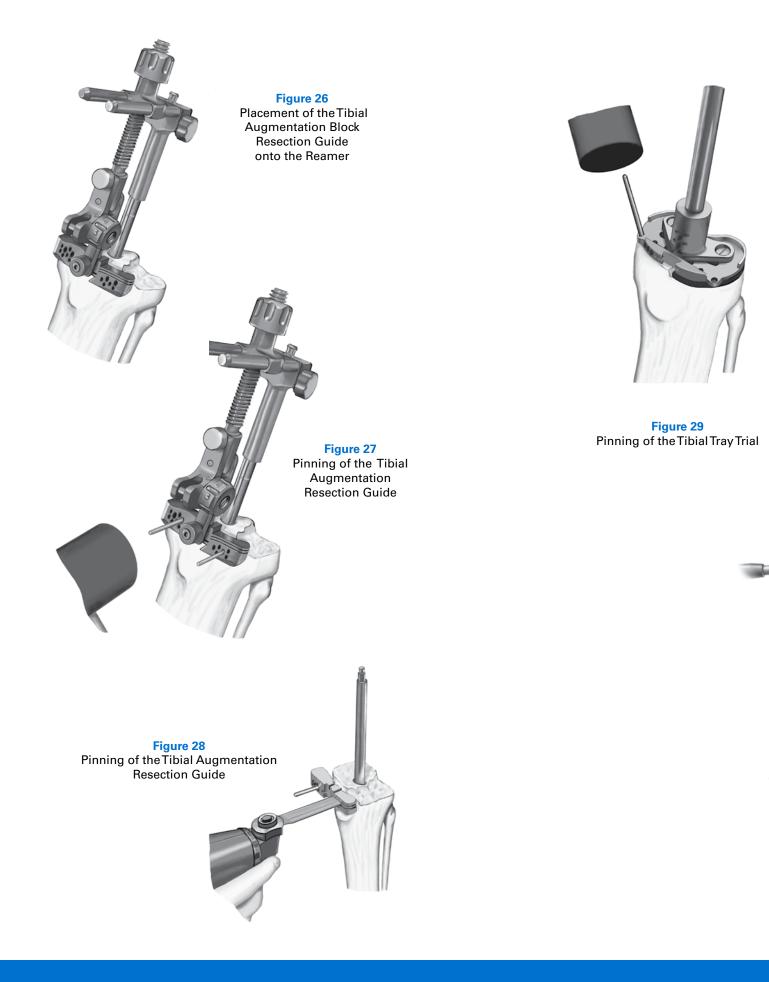
The least defective plateau should be resected from the flat surface of the Resection Guide. The defective plateau should be resected through the slot that removes the least amount of bone.

Step 3: Sizing and Stem Boss Preparation for the Tibial Trials

When the tray and stem assembly is introduced into the canal, its medial/lateral and anterior/ posterior positions will be influenced by the stem fit in the canal. Additionally, the stem of the trapezoid tray is square and must be prepared with the appropriate tamp. Proper placement of the tray relative to the intramedullary canal is determined by using the Reamer and guide bushing as reference points. This will assure that the Trapezoid Tamp is in the correct position.

The **Tibial Tray Trial** is placed on the cut surface of the tibia over the Reamer. Place the **Tibial Stem Extension Drill Guide** over the Reamer. The Tray Trial size is based on the best coverage of the proximal tibia achieved relative to the reamer.

Note: If cuts have been made for tibial augmentation, the appropriate magnetic Tibial Augmentation Block Trial(s) should be attached to the underside of the Tibial Tray Trial. The Tibial Tray Trial should now be pinned in place (Figure 29).



If coverage of the proximal tibial surface is inadequate and/or if there is overhang of the Tibial Trial, an offset tibial component may be needed. Details on the offset tibia preparation can be found on page 16.

The Reamer used in Step 1 is removed. If it was 18mm or larger, the Reamer and assembly should be removed and the Tibial Tray Trial components replaced onto the prepared bone. The **Tibial Tamp Guide** and **Tibial Trapezoid Tamp** should be assembled and used to prepare the bone for the trapezoid tray stem. The Tamp is assembled to the Tamp Guide by setting the dial to the symbol for release. The Tamp is inserted into the Tamp Guide and the dial rotated to the size that matches the tibial tray size chosen (i.e. 1T/2T, 3T/4T or 5T/6T).

The Tamp Guide should be seated on the Tibial Tray Trial and the Tamp driven into the tibia until the stop is reached (*Figure 30*). The appropriate size is marked by a line at the top of the Tamp Guide. This serves as an additional check to indicate when the Tamp is fully seated.

The Tamp should be removed by inserting the small stud on the end of the **Mauldin Multi-Tool** into the hole in the handle of the Tamp, rotating the handle to loosen the Tamp. If needed, a threaded hole is available for attachment of a slap hammer to remove the Tamp. The Guide may now be removed. The fixation pins and the Tibial Tray Trial should also be removed.

Figure 30 Tibial Tamp Insertion



Figure 31 Incomplete Coverage and Overhang of Tibial Trial

PREPARATION OF THE TIBIA – OFFSET TIBIA

Since the position of the tibial component is influenced by the reamer fit and tibial stem position in the canal, it is possible to get an eccentric placement of the horizontal surface of the tibial component in relation to the center of the proximal tibial surface. This can cause overhang of one of the edges of the tibial component and inappropriate coverage of the tibial surface on the other edge (Figure 31). If this becomes an issue during surgery, the Optetrak CC System features an offset trapezoidal tibial component as a solution.

Use the instructions listed above for the standard tibia through the tibial cut, reaming for a stem extension and trial with the existing Tibial Tray Trial and reamer bushings.

Once an "overhang" situation has been established (Figure 31), leave the Reamer inserted in the canal and place the Tibial Tray Trial on the Reamer, substituting the Tibial Drill Guide with the Offset Tibial Bushing of the appropriate size (Figure 32). This Bushing has three hole positions:

- 1. A central position that replicates the same position as the Tibial Drill Guide
- 2. An Alpha position
- 3. A Beta position

Figure 32 Optetrak Tibial Tray Trial with Offset Reamer Bushing





Figure 33 Offset Broach Trial, 80mm Trial Stem Extension and Tibial Impactor/Slap Hammer

Figure 34 Assembly of the Stem Extension Trial to the Tibial Trapezoid Tray Trial



Based on the previous step, the appropriate size Alpha or Beta Offset Broach Trial and Stem Extension Trial that corresponds to the diameter of the last reamer used to prepare the canal are assembled and used to prepare for the offset trapezoidal configuration of the Offset tibial boss (Figure 33). A Offset Tibial Impactor/Slap Hammer is used for impaction and extraction of the Offset Broach Trial.

Note: The Stem Extension Trial must be at least 80mm long.

The Slap Hammer will provide the version control when impacting the Offset BroachTrial.

A Trial insert can be used to perform a trial reduction and assess the stability and range of motion of the joint. After removal of the Offset Broach Trial, the Offset Tibial Implant can be assembled.

Note: If the surgeon prepared the proximal tibia to receive augmentation blocks, make sure to place the corresponding magnetic tibial augmentation block(s) on the lower surface of the Offset Broach Trial before impaction.

Assembly of the Tibial Trial Components

The Tibial Trapezoid Tray Trials provide an opportunity to evaluate fit and function of the tibial tray, stem extension and any tibial augmentations prior to selecting the actual components.

Select the Stem Extension Trial that corresponds with the depth and diameter of the last Reamer used in Step 1. The Stem Extension Trial should be screwed into the base of the Tibial Trapezoid Tray Trial (Figure 34).



The Tibial Augmentation Block Trial used in Step 2 should now be transferred to the Trial Tibial Trapezoid Tray (*Figure 35*).

The appropriate **CC Spine Trial** should be inserted into the chosen Modular Tibial Insert Trial.

Note: The color dot on the CC Spine Trial should match that of the insert Trial, which should match the color of the CC Femoral Trial (Figure 36).

The Tibial Trial may now be placed into the prepared tibia (*Figure 37*).

ASSEMBLY AND IMPLANTATION OF THE FEMORAL COMPONENT

The Optetrak CC femoral component is a symmetrical component. A CC Taper Adapter Trial (available in 5- and 7-degree valgus angles) provides the adjustment necessary for either a left or right knee. The CC Taper Adapter Trial has a taper lock on the inside and outside that will allow the stem to be inserted first into the adapter, and then inserted into the boss of the femoral component.

The Stem Extension is inserted into the CC Taper Adapter Trial and hand tightened (*Figure 38*). If a slotted stem is used, the post of the CC Taper Adapter Trial should be aligned with the slot in the stem. By doing this, the slot will be positioned in the frontal plane.

Note: The CC Taper Adapter Trial is packaged with a femoral stem extension screw that will be used in Step 5 to secure the stem/taper assembly to the CC femoral component.





Figure 35 Assembly of the Tibial Augmentation Block Trial to the Tibial Trapezoid Tray Trial



Figure 36 Assembly of the CC Spine Trial to the Modular Tibial Insert Trial

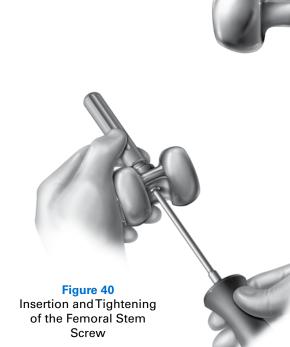




Figure 38 Assembly of the Femoral CCTaper Adapter Trial to the Stem Extension



Figure 39 Assembly of the Stem Extension with CC Taper Adapter Trial into the Femoral Component

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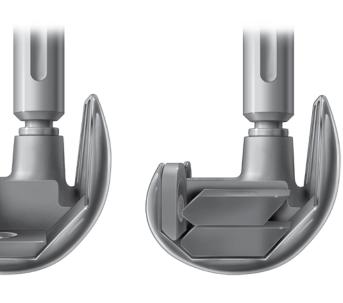
The taper adapter end of the assembly should be inserted into the stem boss of the CC femoral component (*Figure 39*). The stem assembly should be rotated until it is tilted in the direction of the left or right arrow. The assembled femoral implant should be compared with the CC Femoral Trial assembly to confirm the correct stem angle.

The distal condyles of the CC femur should be placed on a padded surface, and the end of the stem should be padded. The end of the stem should be impacted sharply with a mallet. This will lock the mating tapers.

The femoral stem extension screw should be placed in the hole in the intercondylar box of the CC femoral component and tightened using the **Hex Spherical Tip Driver** and **Torque-Limiting Driver Handle** (*Figure 40*). The handle is preset to release when the appropriate torque has been achieved. It is critical to apply this level of torque.

Optetrak CC femoral components feature stackable augmentation blocks. The 5 and 10mm blocks can be stacked up with the use of special locking screws, up to 30mm (3 x10mm blocks). Blocks can be stacked both distally and posteriorly. Whenever blocks are stacked, the ipsilateral aspect of the femoral component only accepts a 5mm block (i.e. 15mm posterior blocks and 5mm distal or 15mm distal blocks and 5mm posterior) (*Figure 41*).

Figure 41 Insertion and Tightening of the Femoral Stem Screw





ASSEMBLY OF THE TIBIAL COMPONENT

The trapezoidal tibial component has been designed to allow for the attachment of augmentation blocks in either a 1/2 or 1/3 size and 5mm, 8mm or 11mm thickness. The tray will also accommodate stem extensions of various lengths and diameters.

The polyethylene plug in the stem of the trapezoidal tray can be removed by inserting a screwdriver through the top of the tray, turning the tray and screwdriver upside down and pressing down until the plug dislodges (Figure 42).

If augmentation blocks or bone screws are to be used, the four screw hole caps should be removed by inserting a screwdriver from the under side of the tibial tray. The caps should be retained so that they may be replaced over the screw heads after the augmentation blocks have been attached or the bone screws implanted (Figure 43).

The trapezoidal tray should be placed face down on a padded table surface and the selected stem extension inserted into the tray stem taper (Figure 44).

The tip of the stem should be protected with padding, and then impacted sharply with a mallet.

If augmentation blocks are necessary, the block type and thickness corresponding with the bone cuts made in Step 2 should be selected. The block size must correspond with the tibial tray size identified by the number on the tray box followed by a "T." (Example: 3F/2T - the appropriate augmentation block for this tray is size 2.) It is necessary to remove the screws from the tibial augmentation block before positioning the block on the under side of the trapezoidal tibial tray (Figure 45).

Figure 42 Removal of the Trapezoid Tray Poly Stem Plug

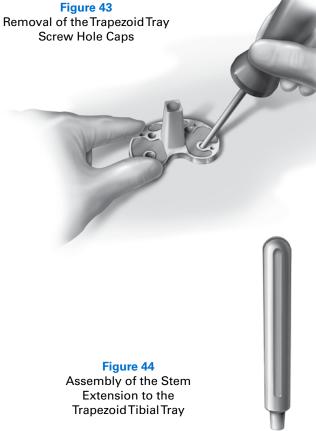
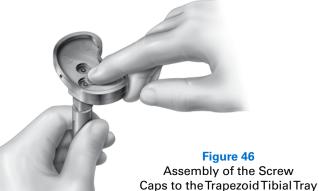








Figure 45 Assembly of the Tibial Augmentation Block to the Trapezoid Tibial Tray





The screws are then placed through the top of the tray and threaded into the augmentation block screw hole. Both screws should be tightened until the Torque-Limiting Driver Handle releases. It is critical to apply this level of torque. The screw caps should now be replaced (Figure 46).

OFFSET TIBIAL IMPLANT ASSEMBLY INSTRUCTIONS

Note: The Offset Tibial Component assembles differently than the Tibial Trapezoidal Tray used with a CCTibial Insert component.

Figure 47 shows the Offset Tibial Component as packaged.

Select and open the size Offset Tibial Component that corresponds with the one used during the preparation of the tibia for an OffsetTray. In addition, select and open the CC Insert that corresponds to the selected size of CC Femoral Component. Discard the standard spine stiffener screw pre-packaged with the CC insert, since it is used with the standard Trapezoid Tray ONLY.

Select the Stem Extension that corresponds to the Stem Extension Trial used during the tibial preparation.



Figure 47 Optetrak Offset Tibial Components as Packaged From left to right: Offset Tibial Screw, Breakaway Screw and Alpha Offset Tibial Component

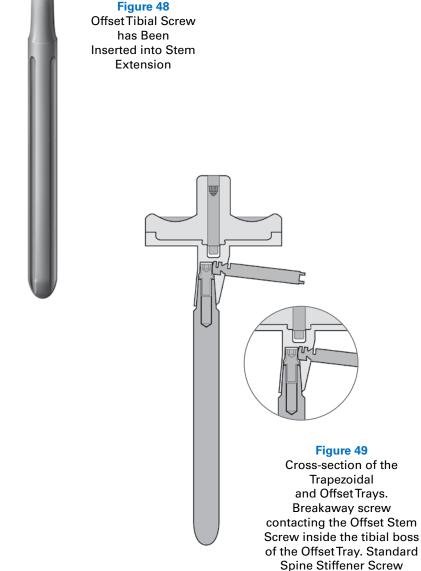
Step 1: Retrieve the Offset Tibial Stem Extension Screw provided in the same package as the Offset tibial component and screw it into the proximal part of the stem extension (*Figure 48*). Assure that the offset stem extension screw is tightened until the screw bottoms out in the stem.

Step 2: Remove the Offset Tibial Tray from the package and insert the stem extension assembly into the tray boss. Place the tray upside-down on a padded surface. Place two, 4x4 gauze pads on top of the stem extension and impact sharply with a mallet. Insert breakaway screw into the side hole on the Offset tray by hand until it engages. Remove the Hex Spherical Tip Driver from the Torque-Limiting Driver Handle.

Place breakaway screw on the Torque-Limiting Driver Handle. Turn clockwise using the handle until the screw breaks free (*Figure 49*). This screw provides additional fixation for the Stem Extension to the Offset Tibial Tray.

Note: If tibial augmentation is required, do not assemble the tibial augment(s) to the tray until after the tibial stem extension and breakaway screw have been assembled. If the augment is attached prior to this, it may block access to the hole for the breakaway screw.

Step 3. The CC Tibial Insert can be assembled to the Offset Tibial Tray using the standard CR/ PS Operative Technique at this stage or after cementation of the component. Insert the offset spine stiffener screw from the chart that corresponds to the thickness of the CC Insert. Use the Torque-Limiting Driver Handle to tighten the spine stiffener screw until the driver releases indicating that the proper torque has been applied (*Table 1*).



shown in Trapezoidal Tray.



Figure 50 Stem Screw Placed through the Center Hole of the Trapezoidal Tibial Tray



Figure 51 Placement of the Tibial Prosthesis and Insert

Table 1	
Offset Spine Stiffner Screw Compatibility Cha	art

Offset Screw Chart		Femoral Sizes				
		1, 1D	2	3	4	5
(9	AA	BB	BB	DD	EE
шш	11	BB	DD	DD	EE	FF
) sse	13	DD	EE	EE	FF	GG
ckne	15	EE	FF	FF	GG	HH
t Thi	18	FF	GG	ΗН	нн	JJ
Iser	22	НН	JJ	JJ	KK	LL
CC Insert Thickness (mm)	26	KK	LL	LL	MM	PP
	30	MM	PP	PP	RR	



IMPLANTATION OF THE TIBIAL COMPONENT

The tibial component may be implanted as a single unit with the tibial insert assembled to the tibial tray, or individually with the tibial tray implanted first and the insert assembled after the cement hardens.

A spine stiffener screw is packaged with the CC Insert, and this is placed into the center of the tibial spine after inserting the assembly into the tray. The spine stiffener screw locks the stem and tibial insert to the tibial tray. In addition, it strengthens the spine of the insert.

Note: A tibial stem extension must be assembled to the tibial tray if a CC insert is used.

Method A: Implantation of Tibial Tray without Insert Attached

If a standard Trapezoidal Tray is used, the gold **CC Tibial Stem Extension Screw Trial** is inserted into the center of the tray and tightened until the head of the screw is below the plate surface (*Figure 50*).

Cement should be applied to the under side of the tray and on the proximal portion of the stem if the surgeon desires. The tibial component should be implanted with the stem screw in place. The Locking Tibial Impactor must be used to impact the tibial component. The locking tibial impactor holds the screw caps in place and will prevent extrusion of the cement into the insert locking area (*Figure 51*).

After the cement has polymerized, the stem screw must be removed. The polyethylene tibial insert is assembled by sliding it into the posterior undercuts in the tibial tray until the anterior edge of the insert is aligned with the anterior edge of the tibial tray. Using the **CC Tibial Insert Impactor**, the tibial insert should be impacted at a 45-degree angle (Figure 51). When seated completely, the anterior edge of the insert will be flush with the anterior rail of the tibial tray. The spine stiffener screw should be inserted into the top of the tibial insert spine. The Torque-Limiting Driver Handle is used to tighten the spine stiffener screw until the driver releases (*Figure 52*). It is critical to apply this level of torque. This will assure that the screw is fully seated in the stem thread hole and the screw head is below the top surface of the insert spine.

Method B: Implantation of Assembled Tibial Tray and Insert

The polyethylene tibial insert is assembled by sliding it into the posterior undercuts until the front edge of the insert is aligned with the anterior edge of the tibial tray. Using the CC Tibial Inserter, the tibial insert should be impacted at a 45-degree angle. When seated completely, the anterior edge of the insert will be flush with the anterior rail of the tibial tray.

The spine stiffener screw should be inserted into the top of the tibial insert spine. A CC Lateral Template can be used to hold the tibial tray while tightening the screw. The Torque-Limiting Driver Handle is used to tighten the spine stiffener screw until the screwdriver releases (*Figure 53*). It is critical to apply this level of torque. This will assure that the screw is fully seated in the stem thread hole and the screw head is below the top surface of the insert spine.



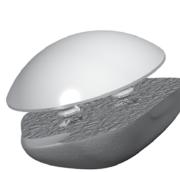
Figure 52 Installation of the Tibial Insert and Spine Stiffener Screw



Figure 54 Implantation of the Tibial Component



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Cement should be applied to the under side of the tray and on the proximal portion of the stem if the surgeon desires. The Tibial Insert Impactor must be used to impact the tibial component (*Figure 54*).

IMPLANTATION OF THE PATELLA

The underside of the patellar component should be coated with cement. After the patellar prosthesis is implanted, it should be held securely with the patellar clamp until cement polymerization (*Figure 55*).

FINAL CHECK

Final check includes the following:

- 1) Removal of any remaining extruded cement
- 2) Final assessment of:

ALIGNMENT STABILITY MOTION and PATELLAR TRACKING

CLOSURE

Standard closure techniques preferred by the surgeon may be used.



Figure 55 Cementation of Patella Component

INSTRUMENT LISTING

Catalog Number	Part Description	Catalog Number	Part Description
101-14-00	Quick Release T-Handle	209-45-05 209-45-07	CC Femoral Valgus Angle Adaptor, 5 Degree CC Femoral Valgus Angle Adaptor, 7 Degree
201-44-00	Mauldin Multi-Tool	209-46-05 209-46-07	CC Femoral Finishing Guide Bushing, 5 Deg CC Femoral Finishing Guide Bushing, 7 Deg
201-57-20	Tibial Resection Guide, Augmentation Block	209-47-01 209-47-02	CC Femoral Lateral Template, Size 1 CC Femoral Lateral Template, Size 2
201-64-00	Femoral Impactor, Non-Locking	209-47-03 209-47-04 209-47-05	CC Femoral Lateral Template, Size 3 CC Femoral Lateral Template, Size 4 CC Femoral Lateral Template, Size 5
201-73-00	Tibial Tamp, Trapezoid	209-51-01 209-51-02 209-51-03	CC Femoral Finishing Guide, Size 1 CC Femoral Finishing Guide, Size 2 CC Femoral Finishing Guide, Size 3
201-74-00	Tibial Tamp Guide	209-51-04 209-51-05	CC Femoral Finishing Guide, Size 4 CC Femoral Finishing Guide, Size 5
201-90-01	CC Tibial Insert Impactor	209-53-01 209-53-02 209-53-03	CC Femoral Notch Guide, Size 1 CC Femoral Notch Guide, Size 2 CC Femoral Notch Guide, Size 3
205-75-01 205-75-02 205-75-03 205-75-04	Tibial Augment Block Template, Size 1 Tibial Augment Block Template, Size 2 Tibial Augment Block Template, Size 3 Tibial Augment Block Template, Size 4	209-53-03 209-53-04 209-53-05	CC Femoral Notch Guide, Size 5 CC Femoral Notch Guide, Size 5 CC Femoral Notch Guide, Size 5
205-75-05 209-30-00	Tibial Augment Block Template, Size 5 Torque-Limiting Driver Handle	209-56-10 209-56-12 209-56-14 209-56-16	Stem Extension Reamer, 10mm Stem Extension Reamer, 12mm Stem Extension Reamer, 14mm Stem Extension Reamer, 16mm
209-30-00		209-56-18 209-56-20 209-56-22 209-56-24	Stem Extension Reamer, 18mm Stem Extension Reamer, 20mm Stem Extension Reamer, 22mm Stem Extension Reamer, 24mm
209-43-00	CC Distal Femoral Resection Guide	•	Hex Spherical Tip Driver
		209-69-00	Pin Inserter/Extractor
209-44-00	CC Femoral Reference Coupler	209-71-10 209-71-12 209-71-14 209-71-16 200-71-18	Tibial Stem Extension Drill Guide, 10mm Tibial Stem Extension Drill Guide, 12mm Tibial Stem Extension Drill Guide, 14mm Tibial Stem Extension Drill Guide, 16mm
		209-71-18	Tibial Stem Extension Drill Guide, 18mm

egrees Degrees

, 5 Degrees , 7 Degrees



INSTRUMENT LISTING

Catalog Number	Part Description		Catalog Number	Part Description
209-78-11	CC Pins			
2007011			205-30-08 205-30-12	Stem Extension Trial, 10mm X 80mm Stem Extension Trial, 10mm X 120mm
209-89-00	Tibial Intra-medullary Resector, Fixed, Zero-Degree Slope		205-32-01 205-32-08 205-32-12	Stem Extension Trial, 12mm X 11mm Stem Extension Trial, 12mm X 80mm Stem Extension Trial, 12mm X 120mm
209-89-05	Tibial Intra-medullary Reamer Coupler		205-34-02 205-34-04 205-34-08 205-34-12	Stem Extension Trial, 14mm X 25mm Stem Extension Trial, 14mm X 40mm Stem Extension Trial, 14mm X 80mm Stem Extension Trial, 14mm X 120mm
209-04-71	OffsetTibial Bushing, Size 1		205-36-08 205-36-12	Stem Extension Trial, 16mm X 80mm Stem Extension Trial, 16mm X 120mm
209-04-72 209-04-73 209-04-74	OffsetTibial Bushing, Size 2 OffsetTibial Bushing, Size 3 OffsetTibial Bushing, Size 4	Conservation Conservation Conservation	205-38-08 205-38-12	Stem Extension Trial, 18mm X 80mm Stem Extension Trial, 18mm X 120mm
209-04-75	OffsetTibial Bushing, Size 5		205-40-08 205-40-12	Stem Extension Trial, 20mm X 80mm Stem Extension Trial, 20mm X 120mm
209-04-90	OffsetTibial Impactor/Slap Hammer		205-46-08	Stem Extension Trial, 22mm X 80mm
			205-48-08	Stem Extension Trial, 24mm X 80mm
213-77-00	Cut Line Predictor	Harrison of	205-41-05 205-41-08 205-41-88 205-41-89	1/3 Block Tibial Augment Trial, Size 1, 5m 1/3 Block Tibial Augment Trial, Size 1, 8m 1/3 Block Tibial Augment Trial, Size 1, 11m 1/3 Block Tibial Augment Trial, Size 1, 11m
201-03-26 201-03-29 201-03-32 201-03-35 201-03-38	One-Peg Patella Trial, Size 26 One-Peg Patella Trial, Size 29 One-Peg Patella Trial, Size 32 One-Peg Patella Trial, Size 35 One-Peg Patella Trial, Size 38		205-42-05 205-42-08 205-42-88 205-42-89	1/3 BlockTibial AugmentTrial, Size 2, 5m 1/3 BlockTibial AugmentTrial, Size 2, 8m 1/3 BlockTibial AugmentTrial, Size 2, 11m 1/3 BlockTibial AugmentTrial, Size 2, 11m
201-03-41 201-21-22 201-21-26 201-21-30	One-Peg Patella Trial, Size 41 Tibial Trial, Modular Insert, Size 1, 22mm ¹ Tibial Trial, Modular Insert, Size 1, 26mm ¹ Tibial Trial, Modular Insert, Size 1, 30mm ¹		205-43-05 205-43-08 205-43-88 205-43-89	1/3 Block Tibial Augment Trial, Size 3, 5m 1/3 Block Tibial Augment Trial, Size 3, 8m 1/3 Block Tibial Augment Trial, Size 3, 11m 1/3 Block Tibial Augment Trial, Size 3, 11m
201-22-22 201-22-26 201-22-30	Tibial Trial, Modular Insert, Size 2, 22mm Tibial Trial, Modular Insert, Size 2, 26mm Tibial Trial, Modular Insert, Size 2, 30mm		205-44-05 205-44-08 205-44-88 205-44-89	1/3 BlockTibial AugmentTrial, Size 4, 5m 1/3 BlockTibial AugmentTrial, Size 4, 8m 1/3 BlockTibial AugmentTrial, Size 4, 11m 1/3 BlockTibial AugmentTrial, Size 4, 11m
201-23-22 201-23-26 201-23-30	Tibial Trial, Modular Insert, Size 3, 22mm Tibial Trial, Modular Insert, Size 3, 26mm Tibial Trial, Modular Insert, Size 3, 30mm	(ALA)	205-45-05 205-45-08 205-45-88	1/3 Block Tibial Augment Trial, Size 5, 5m 1/3 Block Tibial Augment Trial, Size 5, 8m 1/3 Block Tibial Augment Trial, Size 5, 11 1/9 Block Tibial Augment Trial, Size 5, 11
201-24-22 201-24-26 201-24-30	Tibial Trial, Modular Insert, Size 4, 22mm Tibial Trial, Modular Insert, Size 4, 26mm Tibial Trial, Modular Insert, Size 4, 30mm		205-45-89	1/3 BlockTibial AugmentTrial, Size 5, 11m
201-25-22 201-25-26 201-25-30	Tibial Trial, Modular Insert, Size 5, 22mm Tibial Trial, Modular Insert, Size 5, 26mm Tibial Trial, Modular Insert, Size 5, 30mm*			



, 5mm , 8mm , 11mm Right Lateral/ Left Medial , 11mm Right Medial/ Left Lateral

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, 8mm

, 11mm Right Lateral/ Left Medial , 11mm Right Medial/ Left Lateral

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, 8mm

, 11mm Right Lateral/ Left Medial , 11mm Right Medial/ Left Lateral



INSTRUMENT LISTING

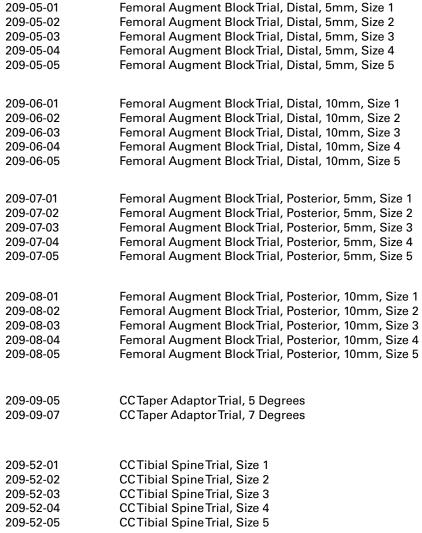
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205-61-89	1/2 Block Tibial Augment Trial, Size 1, 11mm Right Medial/ Left Lateral
205-62-05	1/2 Block Tibial Augment Trial, Size 2, 5mm
205-62-08	1/2 Block Tibial Augment Trial, Size 2, 8mm
205-62-88	1/2 Block Tibial Augment Trial, Size 2, 11mm Right Lateral/ Left Medial
205-62-89	1/2 Block Tibial Augment Trial, Size 2, 11mm Right Medial/ Left Lateral
205-63-05 205-63-08	1/2 Block Tibial Augment Trial, Size 3, 5mm 1/2 Block Tibial Augment Trial, Size 3, 8mm 1/2 Block Tibial Augment Trial, Size 2, 11am Bight Lateral (Left Madia)
205-63-88	1/2 Block Tibial Augment Trial, Size 3, 11mm Right Lateral/ Left Medial
205-63-89	1/2 Block Tibial Augment Trial, Size 3, 11mm Right Medial/ Left Lateral
205-64-05	1/2 Block Tibial Augment Trial, Size 4, 5mm
205-64-08	1/2 Block Tibial Augment Trial, Size 4, 8mm
205-64-88	1/2 Block Tibial Augment Trial, Size 4, 11mm Right Lateral/ Left Medial
205-64-89	1/2 Block Tibial Augment Trial, Size 4, 11mm Right Medial/ Left Lateral
205-65-05	1/2 Block Tibial Augment Trial, Size 5, 5mm
205-65-08	1/2 Block Tibial Augment Trial, Size 5, 8mm
205-65-88	1/2 Block Tibial Augment Trial, Size 5, 11mm Right Lateral/ Left Medial
205-65-89	1/2 Block Tibial Augment Trial, Size 5, 11mm Right Medial/ Left Lateral
205-70-01	Tibial Tray Trial, Trapezoid, Size 1
205-70-02	Tibial Tray Trial, Trapezoid, Size 2
205-70-03	Tibial Tray Trial, Trapezoid, Size 3
205-70-04	Tibial Tray Trial, Trapezoid, Size 4
205-70-05	Tibial Tray Trial, Trapezoid, Size 5
205-70-06	Tibial Tray Trial, Trapezoid, Size 6
209-01-01	CC Femoral Trial, Size 1
209-01-02	CC Femoral Trial, Size 2
209-01-03	CC Femoral Trial, Size 3
209-01-04	CC Femoral Trial, Size 4
209-01-05	CC Femoral Trial, Size 5
209-04-11	Offset Broach Trial, Alpha, Size 1
209-04-12	Offset Broach Trial, Beta, Size 1
209-04-21	Offset Broach Trial, Alpha, Size 2
209-04-22	Offset Broach Trial, Beta, Size 2
209-04-31	Offset Broach Trial, Alpha, Size 3
209-04-32	Offset Broach Trial, Beta, Size 3
209-04-41	Offset Broach Trial, Alpha, Size 4
209-04-42	Offset Broach Trial,, Beta, Size 4
209-04-51	Offset Broach Trial, Alpha, Size 5
209-04-52	Offset Broach Trial, Beta, Size 5











209-58-00

CCTibial Stem Extension ScrewTrial











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Credits

Exactech is grateful to all Optetrak Clinical Evaluators. This group offered many valuable suggestions for the refinement of instrumentation. In addition, Exactech appreciates the original concepts and initial design direction for specific instruments contributed by the following surgeons:

Andrew R Bishop, MD Michael J Christie, MD Ivan A Gradisar, MD	Michael Levine, MD Sam S Messieh, MD Wayne A Moody, MD William B Murray, MD	Calvin Oishi, MD Kenneth P Pohl, MD Albert A Reff, MD Baymand B Babiasan, MD
Edwin A Hissa, MD	William R Murray, MD	Raymond P Robinson, MD

US Patents 5,732,992; 5,688,281; 5,910,143; 6,193,723B1; 5,725,580; 4,298,992; 5,702,458. Other US and foreign patents pending.

Optretrak® A Comprehensive Knee System designed in consultation with:Albert Burstein, PhDGary Miller, PhDDonald Bartel, PhDWilliam Murray, MDIvan Gradisar, MDWilliam Petty, MD

in cooperation with Hospital for Special Surgery, New York.

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Exactech implants are supplied sterile. Prior to use, all packages should be inspected for integrity. If a package is damaged, opened or contaminated in any way, it must not be used.

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