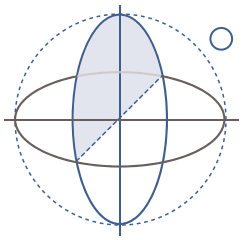

Align 360

UNICOMPARTMENTAL
KNEE SYSTEM

Cardo
Medical

Surgical Technique Contributors:

Marc J. Friedman, M.D.
Southern California Orthopedic Institute
Van Nuys, California

Andrew Yun, M.D.
St. Johns Hospital
Santa Monica, California

Alan L. Valadie, MD
Coastal Orthopedics and Sports Medicine
Director, Joint Replacement Center, LW Blake Medical Center
Bradenton, Florida

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INTRODUCTION

While total knee arthroplasty (TKA) is one of the most predictable procedures in orthopedic surgery, many patients undergoing TKA are excellent candidates for unicompartmental knee arthroplasty (UKA).

Unicompartmental knee arthroplasty offers a quicker surgical procedure, little or no hospitalization, shorter recovery, and less morbidity.[1,2] Current UKA techniques can be intimidating to surgeons for a variety of reasons related to experience, instrumentation and implant design. The **Align 360 Unicompartmental Knee System** was developed to bridge the gap between a sports medicine soft tissue-driven type of surgical technique and traditional total knee arthroplasty techniques.

The **Align 360** System utilizes time proven techniques of gap balancing to create optimal bone cuts for joint resurfacing. The system's flexibility in being able to address unexpected and difficult situations for UKA is unparalleled. The system can be adapted to suit the needs and preferences of surgeon technique and individual patient needs.

The **Align 360** System is the only system on the market which allows the surgeon to make all femoral bone cuts directly off the spacer block with the joint space under optimal tension. The knee is balanced prior to commitment of implant sizing.

The **Align 360** System utilizes a minimally invasive technique which is designed to preserve bone stock, ensure highly reproducible bone cuts and accurately align the components with optimal tension. The system is for cemented use only.

This guide to the surgical technique is a concise step by step procedure written for medial compartment UKA. The same principles can be applied to the lateral compartment, as the system is designed for either compartment. The **Align 360** System design combines an effective, reproducible and easy surgical technique. We hope you find it a most useful addition to your surgical practice.

Patient Selection

Unicompartmental knee arthroplasty is contraindicated in all forms of inflammatory arthritis. The operation is suitable for either medial or lateral compartment arthritis. The patient must have both ACL and PCL intact; deficiency of either cruciate ligament is a contraindication to the procedure. The contralateral compartment should be well preserved with an intact meniscus and full thickness of articular cartilage. This is best demonstrated by the presence of a full thickness joint space visible on AP radiograph. Occasionally, stress x-rays are helpful to assess the joint space. A grade 1 cartilage defect or small marginal osteophytes of the contralateral compartment are not contraindications to unicompartmental arthroplasty. Patellofemoral arthritis is not a contraindication to UKA. It is common to see extensive fibrillation and some full thickness erosions on the trochlear groove and/or patellar facet.

Misalignment of the limb should be passively correctable to neutral. The degree of deformity is less important than the ability to be able to passively correct it with varus or valgus force. UKA has limited ability to correct flexion deformity, thus flexion deformity should be less than 10 degrees. The knee should be able to flex to at least 115 degrees under anesthesia to allow proper bone preparation.

There are no contraindications to the procedure based on patient's age or activity level.

1. Lorio R, Healy WL. Unicompartmental arthritis of the knee. J Bone Joint Surg. Am. 2003;85:1351-64
2. Berger RA et al. Unicompartmental Knee Arthroplasty; Clinical experience at 6-10 year follow-up. Clin Orthop. Relat Res. 1999;367:50-60

COMPONENTS

Femoral Component

The uniquely designed femoral components are made of cast cobalt chromium alloy for optimal strength, wear resistance and biocompatibility. The components are designed for right and left knees and are available in six sizes to provide optimal fit. The thickness of the femoral component is an optimal 7 mm thick and is designed to maintain conformance with varus/valgus angulation of up to 10 degrees. The articulating surface is highly polished. The backside is macrotextured for optimal cement fixation. Figure 1

FIGURE 1

Tibial Tray Component

The tibial components, also made of cast cobalt chromium alloy, are available in six sizes, both right and left. The shape is optimized for maximal tibial bone coverage. A unique locking mechanism for the tibial bearing surface is incorporated into the tibial component. In addition to macrotexturing, the tibial component has 2 pegs and a specialized keel to optimize fixation. Figure 2

FIGURE 2

Tibial Bearing Insert

The tibial bearing insert is made from Ultra High Molecular Weight Polyethylene and is ethylene oxide sterilized. The tibial bearing insert is sized in 1 mm increments from 8 to 14 mm. Figure 3

Any size **Align 360** unicompartmental femoral component is compatible with any size tibial bearing insert.

FIGURE 3

PREOPERATIVE REQUIREMENTS

Preoperative X-ray

A careful preoperative x-ray is necessary to ascertain alignment and provide a precise idea of wear pattern.

Four types of radiographs are recommended:

1. Full length AP radiographs of the lower limb in full weight bearing condition
2. An AP x-ray in full weight bearing condition
3. A lateral x-ray in full weight bearing condition
4. A Sunrise view of the patella-femoral joint

PATIENT PREPARATION AND SURGICAL APPROACH

Positioning

With the patient supine, an ankle support attached to the operating table is helpful to support the foot and maintain position with the knee in flexion.

Surgical Incision

When resurfacing the medial compartment, a 3-4 inch longitudinal incision is made medial to the midline of the knee; the quadriceps can be handled with either a sub-vastus approach or by a mid-vastus incision. Figure 4

When resurfacing the lateral compartment, a midline skin incision is recommended with a lateral parapatellar incision. The capsule is incised and extended proximally along the distal edge of the Vastus Lateralis. It should be noted that the patellar tendon extends fairly far across the lateral compartment. It is important to retract the tendon medially so that the vertical saw cut can be made sufficiently medial for optimum component placement.

Exposure

Depending on which compartment is being resurfaced, release the soft tissues from the very proximal edge of the corresponding plateau to allow insertion of a small retractor. Often it is helpful to remove a small amount of the anterior fat pad. Identify the tibial eminence and mark an AP line using an electrocautery device approximately in the middle between the tip of the eminence and its base.

Tibial Preparation

Tibial alignment is accomplished using the **tibial alignment guide**. The tibial alignment guide is stored in the sterilization case in three sections. Assemble the tibial alignment guide as shown. Figure 5

The **ankle clamp** is used to distally secure the tibial alignment guide to the leg. Open the clamping arms on the ankle clamp and place the "V" section of the ankle clamp over the ankle. Close the clamping arms to secure.

Adjust the length of the tibial alignment guide to allow the proximal portion of the guide to reach the tibial tubercle. A single pin is used to proximally secure the tibial alignment guide to the leg.

Varus/valgus alignment is accomplished by pointing the distal pointer on the tibial alignment guide between the second and third metatarsals. Tighten the thumbscrew to secure varus/valgus alignment. It recommended that the tibial resection slope is set parallel to the anatomic tibial slope. The tibial bearing inserts incorporate a neutral posterior slope.

FIGURE 4

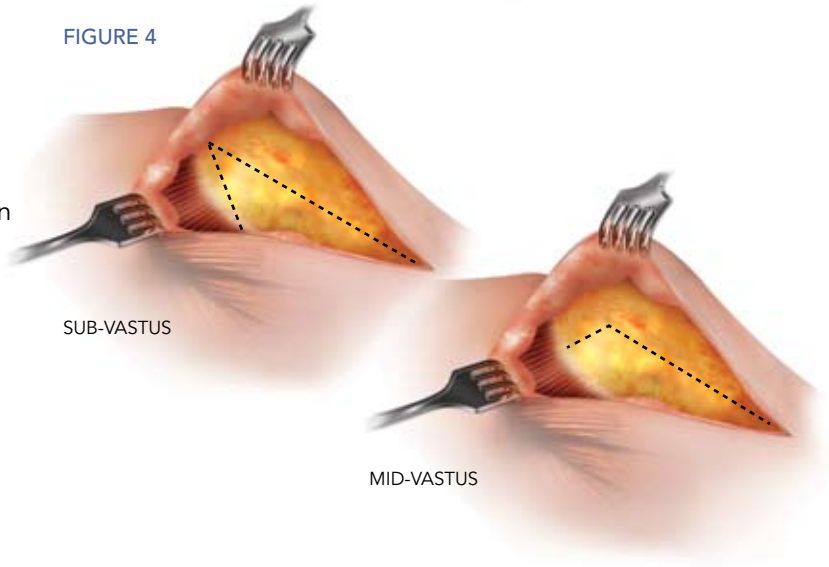
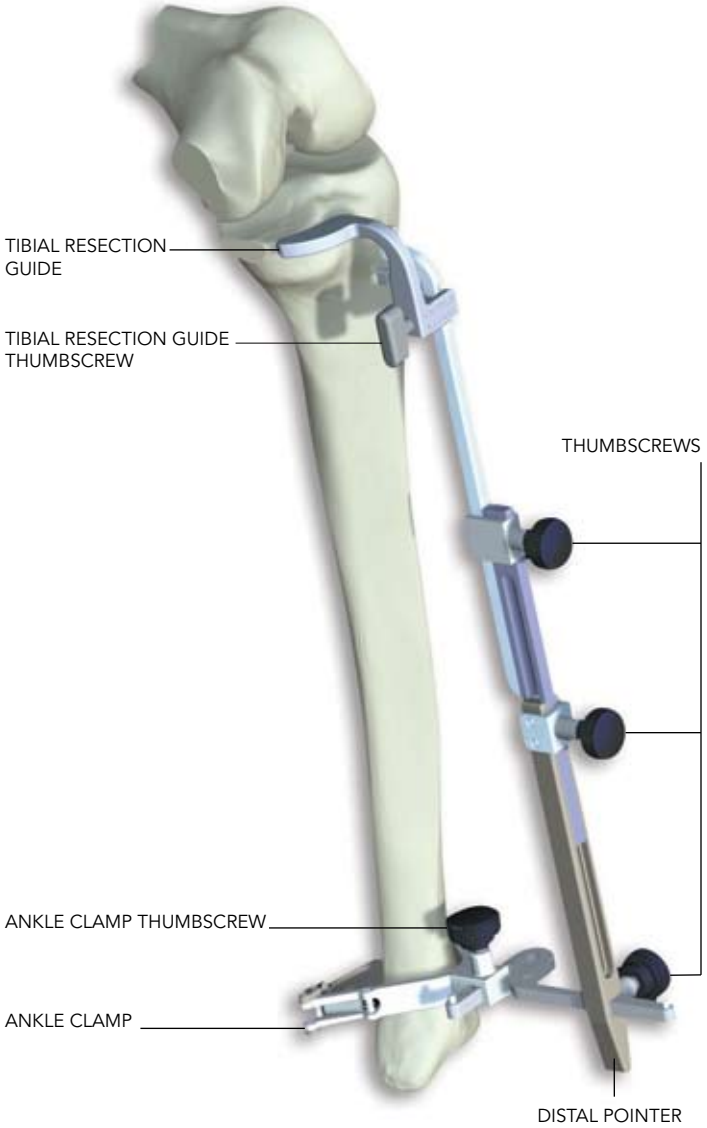


FIGURE 5 TIBIAL ALIGNMENT GUIDE



Attach the appropriate (left-medial or right-medial) **tibial resection guide** to the tibial alignment guide as shown. The curved edge of the tibial resection guide should contact the anterior part of the tibia. Loosen the screw that allows anterior/posterior motion of the tibial alignment guide relative to the ankle clamp, and adjust the alignment guide so that the proximal surface of the tibial alignment guide is parallel to the anatomic slope of the tibia. Tighten the screw to secure tibial slope alignment.

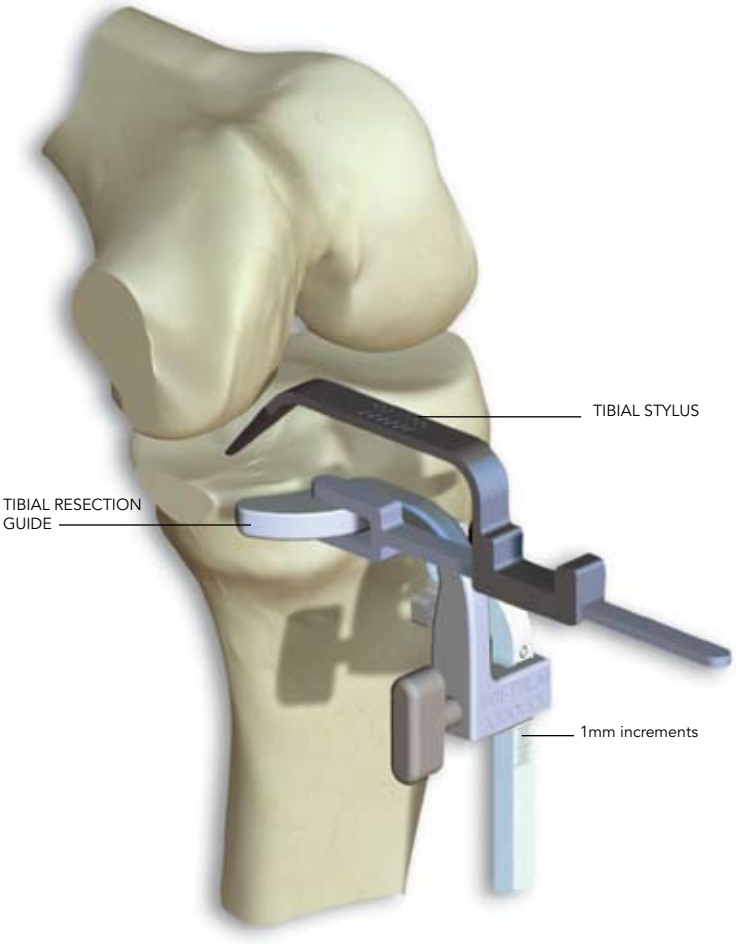
Tibial Resection Depth

Loosen the tibial resection guide thumbscrew so that the resection guide slides proximal/distal on the tibial alignment guide. Slide the **tibial stylus** over the tibial resection guide as shown and place the stylus pointer on the tibia plateau. Figure 6

The tip of the stylus shows the plane the saw will cut through, representing zero resection depth. Lock the tibial resection guide in place on the tibial alignment guide. Remove the tibial stylus by *pulling* on the handle section that attaches to the tibial resection guide while *pushing* on the stylus section.

At this point the tibial resection guide is set to just skim the tibial plateau. Tibial resection depth is adjusted by moving the tibial resection guide distally or proximally on the tibial alignment guide. Each notch on the tibial alignment guide shaft represents 1mm. The tibial resection guide should be lowered to the desired resection depth, and the ankle clamp thumbscrew should be retightened to secure the guide. In some cases it may be desirable to make a **skim cut** at zero resection depth to verify tibial resection slope before making the final tibial resection.

FIGURE 6



Tibial Resection

Vertical Cut

A reciprocating saw is used to make the vertical tibial resection. Make the resection parallel to and located at the edge of the tibial eminence. Typically, this cut is made at the mid-point between the top and bottom of the tibial eminence. Use caution to avoid cutting into the ACL attachment. An electrocautery device is helpful to mark the proper orientation line. There is a tendency with UKA to either medialize or lateralize this vertical cut. Proper attention to this detail is important to create optimal component positioning. Figure 7

Horizontal Cut

The horizontal tibial resection is made using a sagittal saw. The flat surface on the tibial resection guide is used to guide the saw for the sagittal resection. Hold the saw flat against the guide surface while making the resection. Do not flex the blade. Figure 8

Measure Flexion and Extension Space

Flexion and extension space are measured using the **spacer block handle** and **modular spacer blocks**. The modular spacer blocks attach to the spacer block handle magnetically. Figure 9

Extension space is measured with the leg in full extension (or as close as possible) with the leg in proper varus/valgus alignment. Varus/valgus alignment is determined through the use of **alignment rods** used along with the spacer block handle as shown.

Flexion space is measured with the femur in 90° of flexion with the leg in proper varus/valgus alignment. Varus/valgus alignment is determined through the use of **alignment rods** used along with the spacer block handle.

FIGURE 7

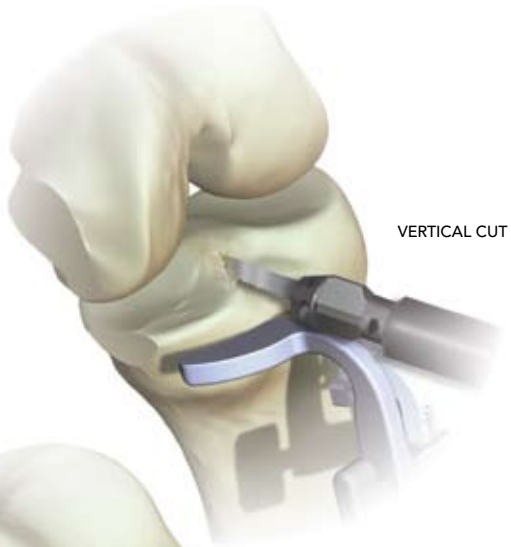


FIGURE 8

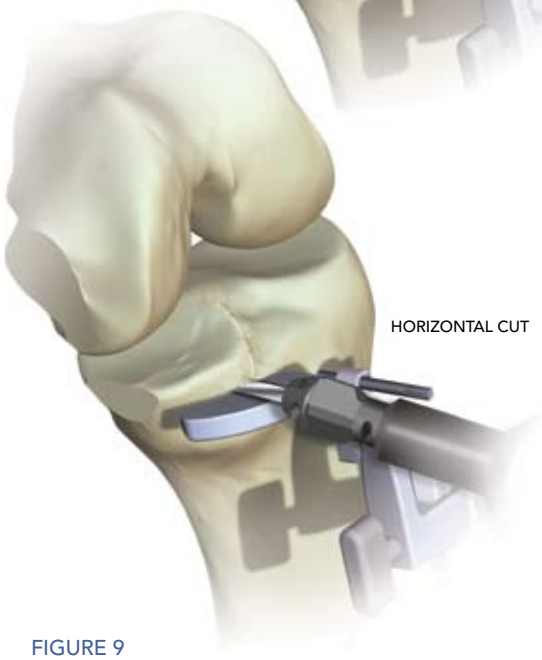
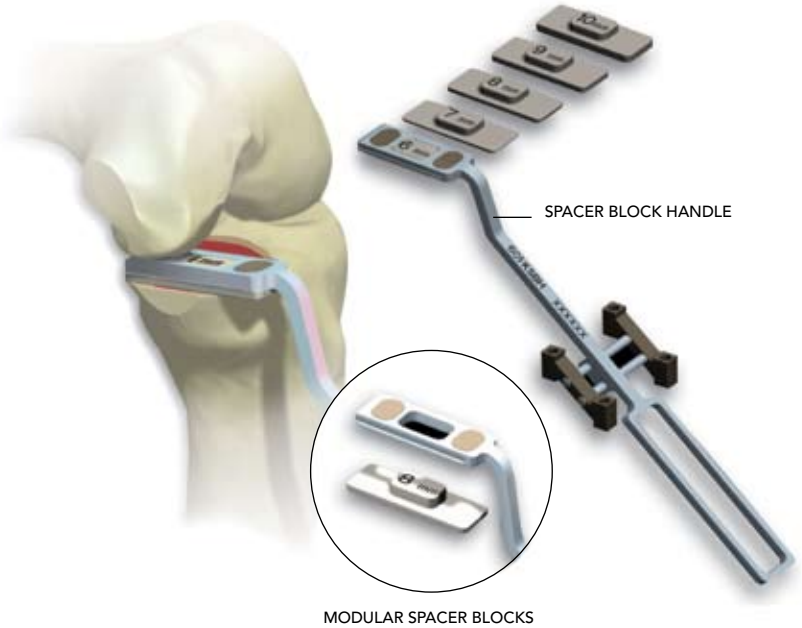


FIGURE 9



Principle of Instrumentation to Achieve Balanced Flexion/Extension Gaps

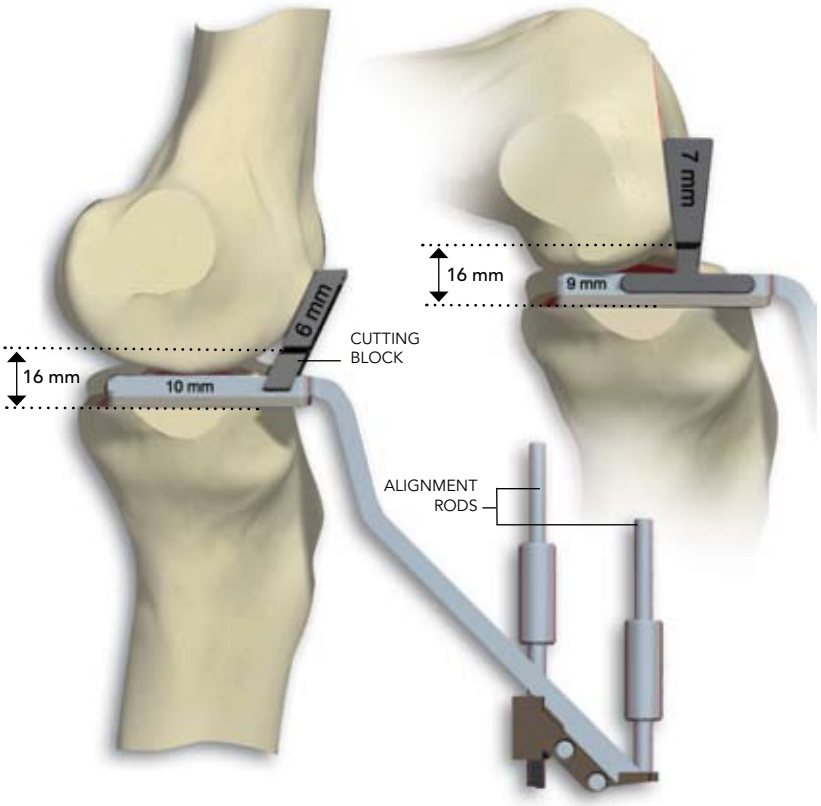
The **Align 360** System allows the surgeon to easily and precisely match gaps in both extension and flexion. The system is designed to create the extension gap first.

Extension balancing is determined by attaching the appropriate size **cutting block** to the spacer block in extension. For example, if the goal is to achieve a 16mm extension gap and the extension space measures 9 mm, after making the tibial cut, a 7 mm cutting block should be placed as shown in Figure 10. This would allow the appropriate amount of bone to be removed in extension to result in a 16mm gap. A 16 mm gap is often desirable as it accomodates the 7 mm thick femoral component articulating with a 9 mm thick tibial component. Figure 10

Flexion balancing is determined in a similar manner. The flexion gap must match the extension gap, so depending on the fit of the spacer block in flexion, the appropriate size posterior block is placed to create the same size gap. For example, if the flexion gap measured 10 mm in flexion, a 6 mm cutting block should be placed to create and match the 16mm extension gap as noted above. Figure 10A

FIGURE 10

FIGURE 10A



Distal Resection

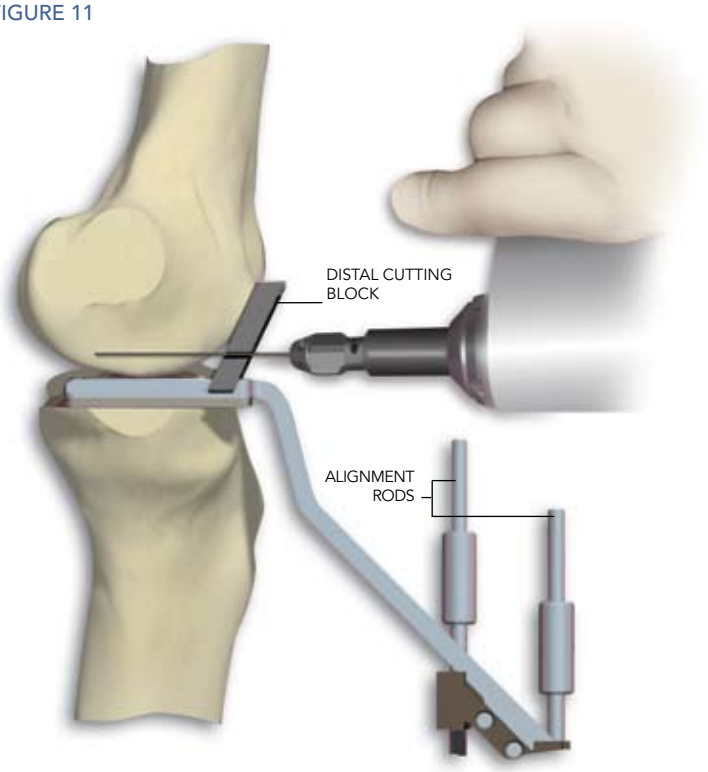
The **distal cutting block** is positioned using the spacer block handle and appropriate spacer block as shown. Figure 11

The spacer block is used to provide appropriate collateral ligament tension and varus/valgus alignment. With the leg in extension, insert the spacer block handle, spacer block and appropriate distal cutting block into the joint between the distal chondyle and tibial resection as shown. Alignment rods can be used to check varus/valgus alignment before the distal resection is made. Figure 11

The distal resection is made using a *1.25mm thick x 12mm wide* sagittal saw. Use of a thinner saw could lead to an inaccurate distal resection and is *not recommended*.

The distal resection can be made with or without pinning the distal cutting block. The spacer block handle along with collateral ligament tension from the spacer block are used to keep the distal cutting block in place. The resection is made in extension in this case, as shown.

FIGURE 11



Posterior Resection

With the leg in flexion, position the **posterior cutting block** using the spacer block handle and appropriate spacer block as shown. The spacer block is used to provide appropriate collateral ligament tension and varus/valgus alignment. The spacer block handle, spacer block and appropriate distal cutting block are inserted into the joint between the distal condyle and tibial resection. The angled surface of the posterior cutting block is placed against the previously made distal resection to provide the correct angle between the posterior and distal resections. Alignment rods can be used to check varus/valgus alignment before the posterior resection is made. Figure 12

The posterior resection is made using a *1.25mm thick x 12mm wide* sagittal saw. Use of a thinner saw could lead to an inaccurate posterior resection and is *not recommended.*

The distal resection can be made with or without pinning the distal cutting block.

If desired, at this point spacer blocks may be utilized to confirm that the flexion and extension gaps are balanced. If the gaps are more than 10 mm the additional 5 and 10 mm shims should be added to make the spacer block the desired thickness. These are held in place on the bottom of the spacer block by magnetic force.

Femoral Sizing

Femoral sizing is performed using the **femoral sizing/ chamfer guide** along with the spacer block handle and spacer blocks. The anterior and posterior profiles of the guide match the profiles of the implants. Place the guide on the distal and posterior resections as shown. When properly sized, there should be 2mm to 3mm of exposed bone above the anterior flange of the guide, with no medial overhang. Figure 13

FIGURE 12

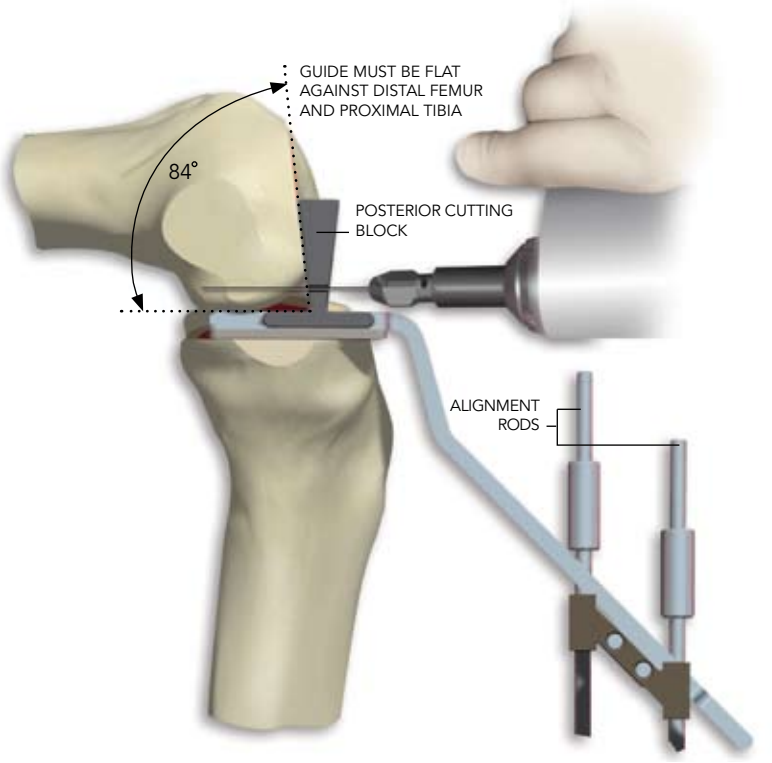
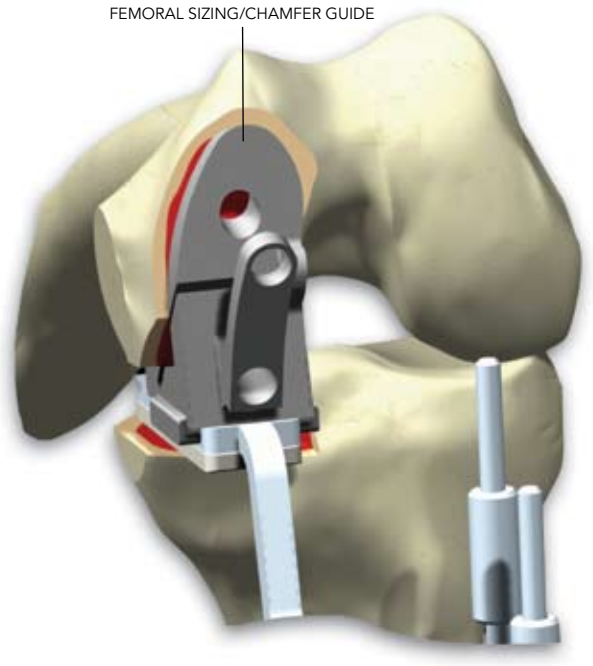


FIGURE 13

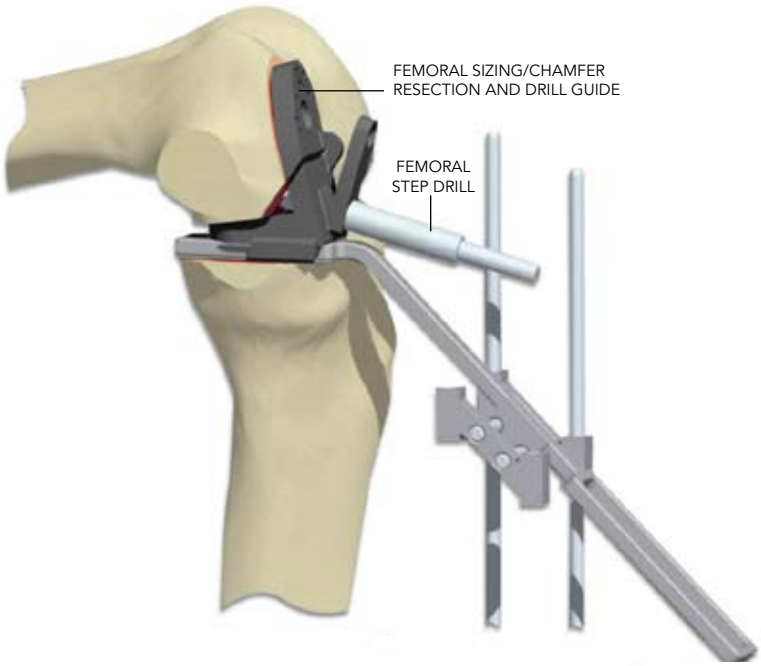


Femoral Peg Holes and Chamfer

The **femoral sizing/chamfer resection and drill guide** attaches to the spacer block handle so that the spacer block handle and spacers can be used to hold the guide in place. This guide can be used in a pinned or pinless manner. A sagittal saw is used to create the chamfer cut. A **femoral step drill** is used to create the lug holes.

The femoral resections can be checked for fit using the appropriate femoral trial. Figure 14

FIGURE 14



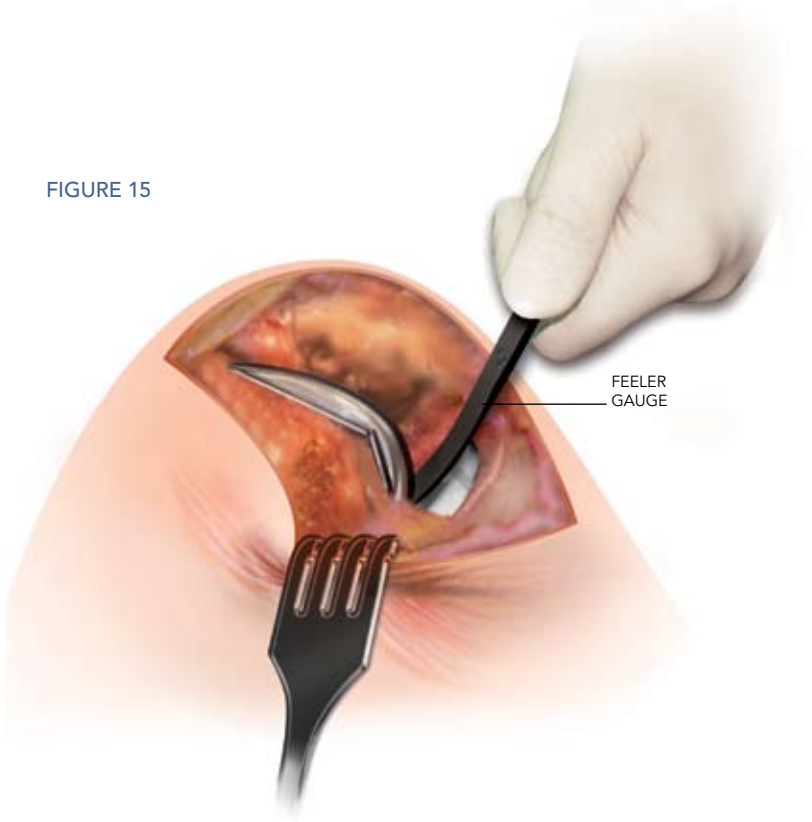
Trial Reduction

Femoral trials and **tibial bearing trials** are used for trial reduction. With the trial components in place, check for proper range of motion and ligament stability.

In extension, the joint should be stable but not excessively tight as this can cause the contralateral compartment to be over-stressed. The bearing thickness selected should provide the correction desired but not over-stress the collateral ligaments. The correct tibial bearing thickness should allow the joint-space to open up 1mm to 2mm under varus/valgus stress. The black **feeler gauge** can be inserted to check optimal tension. Use a thinner tibial bearing or re-cut the tibia to correct excess tightness in extension. Figure 15

In flexion, the joint space should also open up 1mm to 2mm under stress. Another indicator of excess tightness in flexion is if the tibial bearing trial *lifts up anteriorly* during flexion. Re-cut the tibia to increase **slope** if the joint is excessively tight in flexion but *not extension*.

FIGURE 15



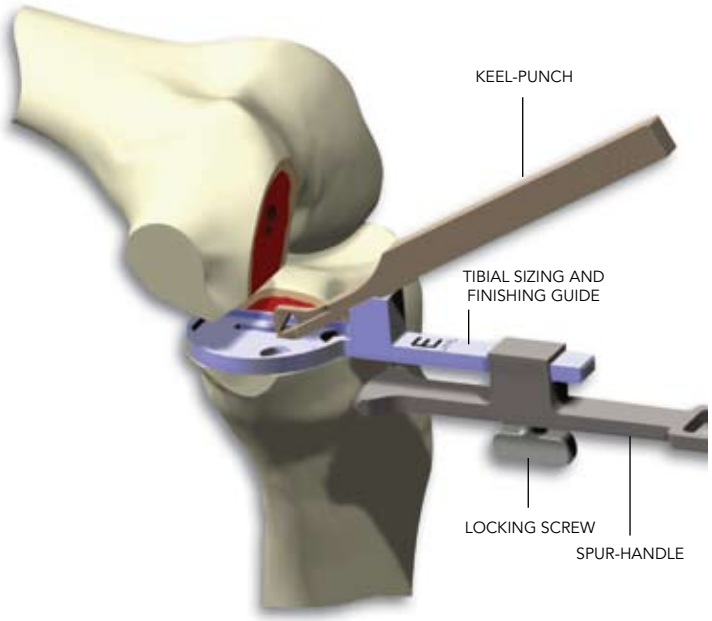
Tibial Sizing and Finishing

Tibial sizing is done using the **tibial sizing** and **finishing guides** as shown in Figure 16. Try several guides to determine which size fits best. Exposed tibia bone should be well covered, but there should be no overhang. The **trial bearing puller** can be used to check posterior coverage.

The appropriate tibial sizing and finishing guide, along with the **spur-handle**, **keel-punch** and **tibial peg step drill**, are used to make the keel preparation and lug holes in the tibia. Insert the guide into the spur-handle and position it on the tibia as shown. Adjust the anteroposterior position of the guide. Lock the guide in the spur-handle using the locking screw. Place the guide and spur-handle onto the tibia, pushing the spur into the anterior tibia bone and simultaneously pushing down into the tibia to hold the guide in place. Use the tibial keel-punch and a mallet to prepare for the keel as shown. Use the tibial peg step drill to drill two tibia lug holes. Figure 16

An alternative method of sizing is to use the **tibial ring trials** which may be preferable for some surgeons in assessing optimal sizing. Figures 17A, 17B and 17C

FIGURE 16



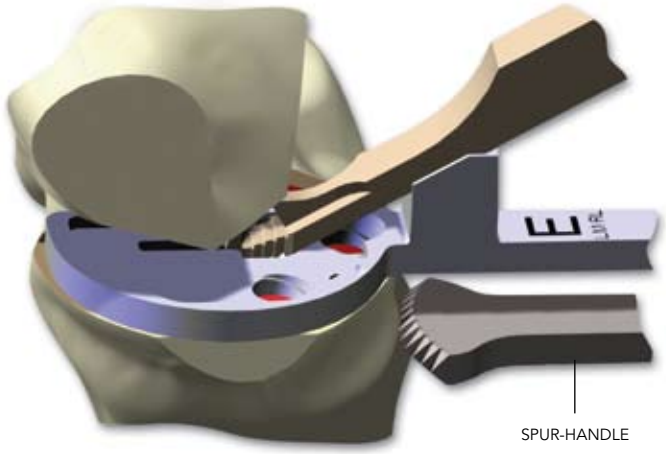
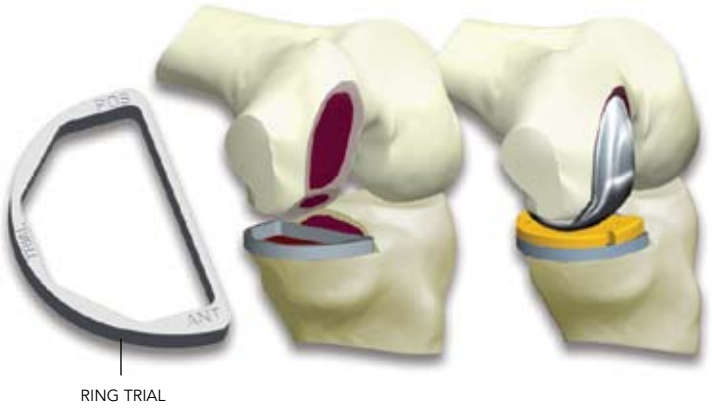


FIGURE 17A FIGURE 17B FIGURE 17C



Implantation

The **tibial component** is implanted first. Flex the knee and rotate the tibia externally to aid insertion. Apply cement and apply the tibial tray component to the prepared tibia. Insert the keel of the tibial tray component into the prepared slot in the tibia, keeping the tibial tray parallel to the tibial resection and pushing the component from anterior to posterior and down into the prepared tibial surface at an angle of approximately 30°. Finish seating the tibial tray component using the **tibial tray impactor**. Remove excess cement from around the component using the **cement remover**.

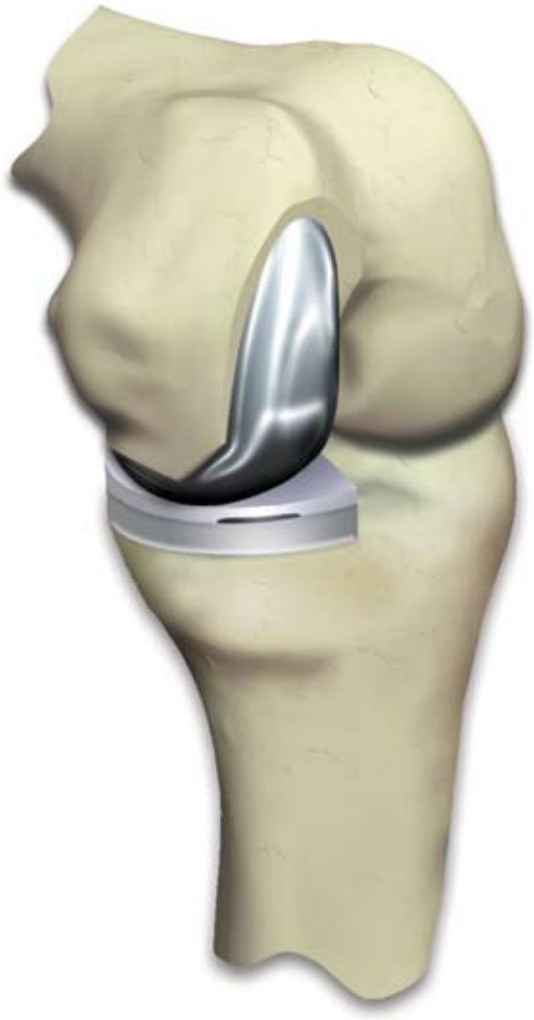
The femoral component is implanted with the leg flexed as much as possible. Apply cement to the component and insert the component manually. Finish seating the femoral component using the **femoral impactor**. Remove excess cement from around the component using the cement remover.

Determine the final thickness of the tibia bearing component by using trial tibial bearing components placed in the definitive tibial tray component. With the correct tibial bearing in place, the joint space should open up 1mm to 2mm under varus/valgus strain, in both flexion and extension, as described previously in the Trial Reduction section. The black feeler gauge can be inserted between the bearing surface and femoral component to confirm tension. Leave the appropriate trial bearing in place to maintain pressure on the femoral and tibial tray components while the cement is curing.

The tibial bearing component is inserted after the cement has fully cured. Remove the tibial bearing trial using the tibial bearing trial puller instrument. Insert the tibial bearing component into the tibial tray component anteriorly, with the articulating surface facing the femoral component. Slide the tibial bearing component posteriorly until the posterior slot on the bearing engages the posterior lip on the tibial tray. Push the anterior edge of the tibial bearing down into the tibial tray component using thumb pressure until it snaps into place.

Knee joint is ready for closure. Figure 18

FIGURE 18



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