



PtoleMedic System

Instructions for Use – T.K.R. Surgical Procedure for the PtoleKnee Surgical Guide

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Instructions for Use

T.K.R. Surgical Procedure



IMPORTANT NOTE FOR THE SURGEON: PLEASE READ THE ENTIRE I.F.U. BEFORE USING THE ***PtoleKnee Surgical*** GUIDES CLINICALLY. THE SURGEON SHOULD BE FAMILIAR WITH THE PERSONALIZED SURGICAL INSTRUMENT CONCEPT.



Warnings:

- The ***PtoleMedic System*** has not been evaluated in a pediatric population; performance in such cases is unknown and not recommended.
- The ***PtoleMedic System*** is a prescription-only medical device.
- The ***PtoleMedic System*** is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on the surgeon's education, training, and experience.
- ***PtoleMedic System*** only provides and documents functional alignment and orientation information based on specific individual anatomic data obtained from current M.R.I. image sources.

- The ***PtoleMedic System*** does not provide an absolute or only solution plan for joint replacement surgery; it only documents one possible approach.
- ***PtoleKnee Surgical*** guides are one-time-use, disposable instruments.
- Do not attempt to reuse, recondition, or re-sterilize.
- Do not alter the custom guides in any way.
- ***PtoleKnee Surgical*** guides are for use by a surgeon experienced in using personalized surgical instruments (PSI-customized guides).
- ***PtoleKnee Surgical*** guides are patient-specific instruments planned and made based on M.R.I. scans for each named patient. New images should be obtained if the patient's anatomy/disease process has changed significantly since obtaining the M.R.I. scan.
- Examine the process and sterilize the ***PtoleKnee Surgical*** guides before use. Do not use the guide if chipped, broken, cracked, or debris is present.



NON-STERILE

- The guides and their packaging are ***non-sterile***.
-  ***PtoleKnee Surgical*** guides may not be reused. They are for **ONE-TIME-USE** only.
-  **DO NOT RE-STERILIZE** the guides.



Cautions:

- The use of aged (>3 months) M.R.I. image files is not recommended. Accuracy of planning and guide fit may diminish with evolving or changing disease processes.



Precautions:

- Use only M.R.I. data of recent origin obtained per established *PtoleMedic System* designated M.R.I. protocols.
- Take care to minimize excessive heat buildup from friction between P.S.I. instruments and other instrumentation, such as drills/saws. Excessive heat buildup can lead to debris or deformation of the *PtoleKnee Surgical* guide.
- Do not place heavy instruments on top of the *PtoleKnee Surgical* guides during sterilization.
- Surgical guides are made for scheduled surgery dates only! Storage conditions only require the guides to remain in their original packaging until processed for surgery. The shelf life of the guides is related to the patient's disease progression. If the patient's surgery is delayed for more than 3 months, the surgeon should determine if new M.R.I. data should be obtained and new guides made.



Limitations

- Metallic implants in or near the affected joint interfere with the M.R.I. images and may yield unreliable or useless images.
- The *PtoleMedic System* planning provides an estimate of implant sizing only. Exact implant size can only be determined during surgery and may differ from sizes projected during planning. Most estimated implant sizes fall within one size of estimation.
- The *PtoleMedic System* is not used in planning revision/replacement surgery in persons already having implants in the affected joints.
- Digital x-ray or C.T. data is not acceptable for guide production; the files must be M.R.I. images.



Contra-indications

- The *PtoleKnee Surgical* guides should not be used when:
- Active infections of the knee or knee joint are present, Hip-Knee-Ankle alignment deformity greater than 6° Varus or valgus, or the case requires "tibia-cut-first" surgical techniques, cases of uni-condylar replacement, and for cases of T.K.R. revision surgery.



NOTICE: *PtoleKnee Surgical* Guides are intended to assist in executing a designated joint replacement (T.K.R.) surgery and must be created using the *PtoleMedic System* web application software. The guides are not reusable or transferable to any other person or surgery type.

Help Desk: For questions, please contact;
Lento Medical, Inc.

Telephone: United States telephone support +1 (510) 413-3230
Internet: If you have access to the Internet, you may reach the
Online Help support:

Web: <http://www.lentomedical.com> or
<http://www.lentomedical.net>



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Help services are available free of charge to all registered customers.



Indications for Use:

The *PtoleKnee Surgical* Guides are for clinical use as a template or guide for use in total knee replacement orthopedic surgery to assist the surgeon in selecting or positioning orthopedic implants and guiding the marking of tissue before cutting or pinning for a specifically named patient.



CAUTION: *United States Federal law restricts this device to sale by or on the order of a Physician*

Acknowledgments:

Lento, Inc. acknowledges the assistance of the following orthopedic surgeon for his expertise, guidance, and time in the development of the surgical protocol:

Benjamin Soo-Il Song, M.D., Diplomat American Board of Orthopaedic Surgery



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Introduction

These instructions cover the use of personalized surgical instruments designed using the *PtoleMedic System* surgical planning software to make T.K.R. femur and tibial component alignment guides.



Important Notes:

PtoleKnee Surgical Guide Inspection: Upon delivery, verify the presence and accuracy of the engraved information on the cutting guides.

- Serial # of *the* guides are in the format K, with five numerals, & an L or R (e.g., K12345L or K12345R)
- Patient's 1st initial & up to 10 letters of the last name
- Patient's Date of Birth

Indications/Contraindications: Review this entire section of all indications, contraindications, warnings, and precautions before ordering *PtoleKnee Surgical* guides.

Start with the femur: Lento does not recommend a tibia-first approach.

Incision Length: M.I.S. incisions are unlikely to provide sufficient access for the use of *PtoleKnee Surgical* guides. A standard incision is essential to ensure accurate placement of the *PtoleKnee Surgical* guides.

Pre-operative Imaging Scan:

The initial step in the *PtoleMedic System* process is a quality M.R.I. scan of the arthritic knee and a scout M.R.I. scan of the hip and the ankle. Lento recommends a 1.5 Tesla or higher magnet obtained from a qualified M.R.I. imaging center. All scans should be obtained at least 14 calendar days before the surgical procedure date and sent electronically to the Lento secure database via the *PtoleMedic System* M.R.I. web interface.

Before submitting scans for the PtoleMedic System knee procedure, pre-qualification of the imaging center by Lento is required. Strict scanning procedures and quality control measures apply to ensure accurate imaging of the patient's knee. Patients with a pacemaker, defibrillator, and large thigh circumference not fitting within the knee or torso coil or the ability to remain motionless for the scan are not recommended for the *PtoleMedic System* procedure.

The *PtoleMedic System*:

The *PtoleMedic System* is a Web-based approach to orthopedic surgical planning that enables surgeons to carefully preplan joint replacement procedures (T.K.R.) and personalize each patient's surgical parameters. Lento's proprietary software provides implant alignment and placement information based on the individual's anatomic data from medical M.R.I. images. It also allows the surgeon to request individualized custom surgical cutting guides for personalized alignment and positioning of the implants during surgery.

Sterilization of *PtoleKnee Surgical* guides:

The Femur and Tibia cutting guides are supplied clean but not sterile. Hospital processing and sterilization recommendations accompany each guide shipment to the hospital or surgical center.

Recommended Saw Blade:

The recommended saw blade thickness is 1.27 mm (0.050 inch), and the saw blade length of 110-120 mm.

Distal and Proximal Cutting Guides:

The distal femoral and proximal tibial cutting guides help set the Varus/valgus, flexion/extension (femoral), posterior slope (tibial), and proximal/distal positions of the planned femoral and tibial components.

Surgical Procedure Overview:

No special or unique surgical approach is required. The guides are functionally useful with almost all standard (non-MIS) surgical incisions and approaches for the knee.

#	Step	Procedure Overview	PST Instruments
1	Knee Exposure	Expose joint using standard approach. Allow enough exposure to allow seating of guide	NONE
2	Excise A.C.L.	1. Excise the ACL	NONE
3	Femur Preparation	2. Place Femur Guide anteriorly on the distal femur and slightly push down	Femur Guide
4	Femur Guide Placement	1. Drill the two condyle pins first 2. Then, drill the two anterior pins 3. Remove the lateral condyle pin 4. Place angled anterior pin (stabilizer pin)	Femur Guide
5	Resect distal femur	1. Verify guide placement and cut distal condyles 2. Remove femur pins and guide	Femur Guide
6	Tibial Exposure	1. Expose tibia & excise meniscus & soft tissue at guide contact points	NONE
7	Tibial Preparation	1. Fix Tibial Guide on anterior surface and tibial plateau	Tibial Guide
8	Tibial Guide Preparation	1. Install two tibia proximal pins 2. Then, install two anterior tibia pins 3. Take out two tibia proximal pins 4. Place anterior pin (stabilizer pin)	Tibial Guide
9	Resect tibia	1. Make proximal tibia cuts. 2. Remove guide & pins	Tibial Guide
10	Standard T.K.R.	Return to standard T.K.R. procedure	NONE

The Surgical Procedure:



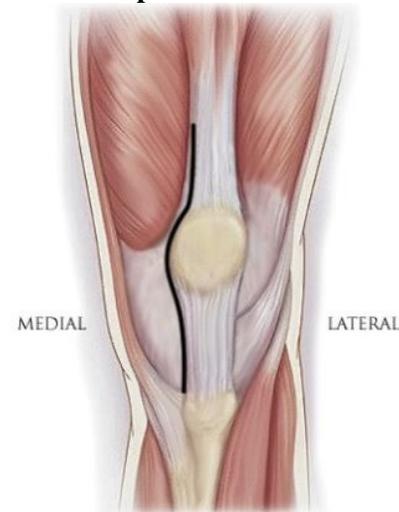
Warning: If the Case ID markings do not match the patient and each other, **do not Use** the *PtoleKnee Surgical* Guides for the surgery. Use

Standard Instruments. Notify Lento as soon as possible after the completion of the case.

Incision:

A median parapatellar incision beginning one or two finger-widths superior to the patella and ending at the approximate location of the medial edge of the tibial tubercle is usually sufficient (see illustration below). However, depending on surgeon preference, the median parapatellar or variations such as mid-vastus, sub-vastus or lateral can be used as long as sufficient exposure results allow proper guide insertion. The smaller actual MIS-type incisions do not provide sufficient surgical exposure for guide insertion.

Parapatellar Incision



The initial step proceeds as typical for T.K.R. procedures, opening, dissecting, and removing adipose, Anterior Cruciate ligament, and capsule tissue. Patellar dislocation is done as you usually would.

Exposure:

With the knee moderately flexed, the medial synovium is released from the mid-point of the patella proximally to a point superior to the trochlear groove. The posterior patellar tendon fat pad is excised from the joint line to the tibial tubercle. With the knee flexed to approximately, 70 degrees retract the quadriceps muscle in the usual fashion to expose-to-expose the anterior femoral cortex. Displace the patella laterally as usual to obtain full exposure.



Osteophytes:

Removal of osteophytes is usually optional. *PtoleKnee Surgical* guides are planned to affix in areas devoid of osteophytes. Their presence is generally not a detriment to the proper fit of the guides.

Placing the Guides:

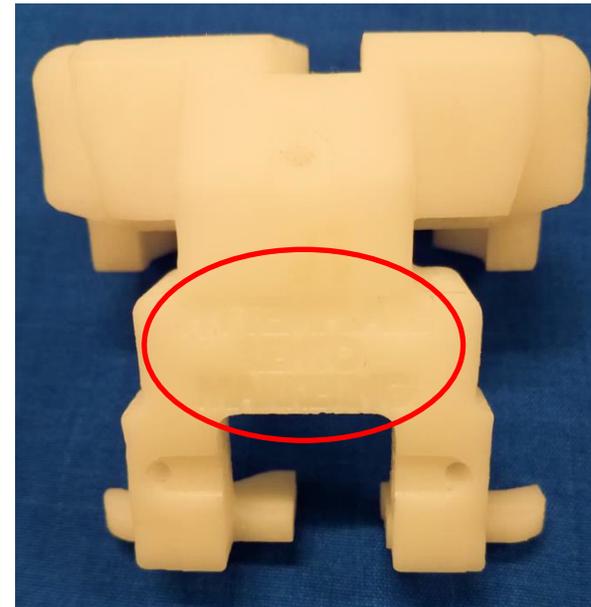
Place the guides sequentially, beginning with the femur and finishing with the tibia. Whenever guides are placed and before any bone cuts are made, it is essential for the surgeon to visually verify and or measure the proposed orientation and angle of the impending cut. Templates and guides are not a substitute for sound clinical judgment. If any potential cut is believed to be inappropriate, the use of the guide

should be abandoned, and the standard manual instruments used without delay to complete the case.

Examine the Femur Guide:

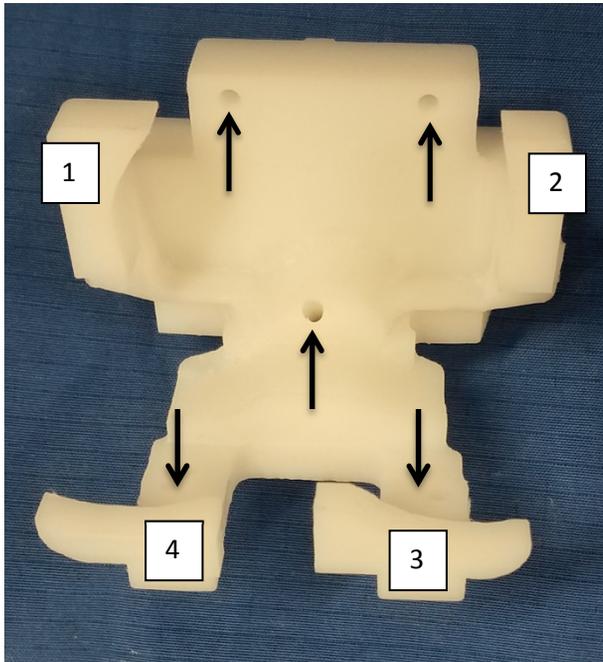
First, ascertain that you have received the correct guide. The face of the *PtoleKnee Surgical* guide contains the case identification information (red oval). Engraved here are the Guide Serial Number, Patient initial, and ten alpha characters of the last name, D.O.B., and knee descriptor.

A.P. View – Face

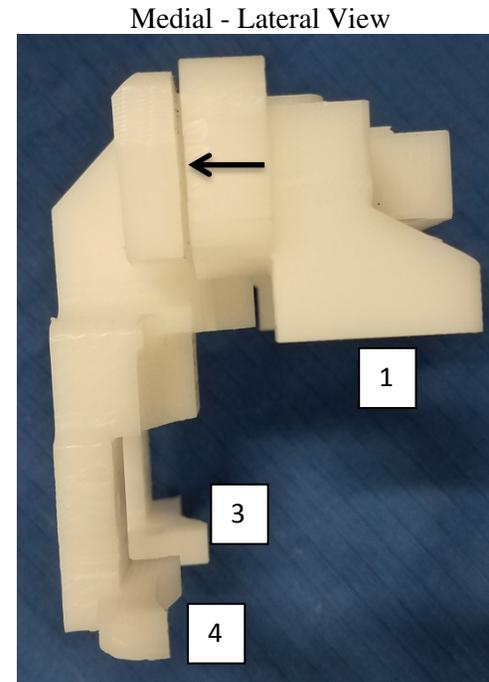


Next, examine the physical properties of the guide.

P.A. View - Interior



The four primary guide contact points are identified in the picture above. The locations of the pinning holes are marked with black arrows. Scrutinize all seven features; they should be smooth and free of debris.

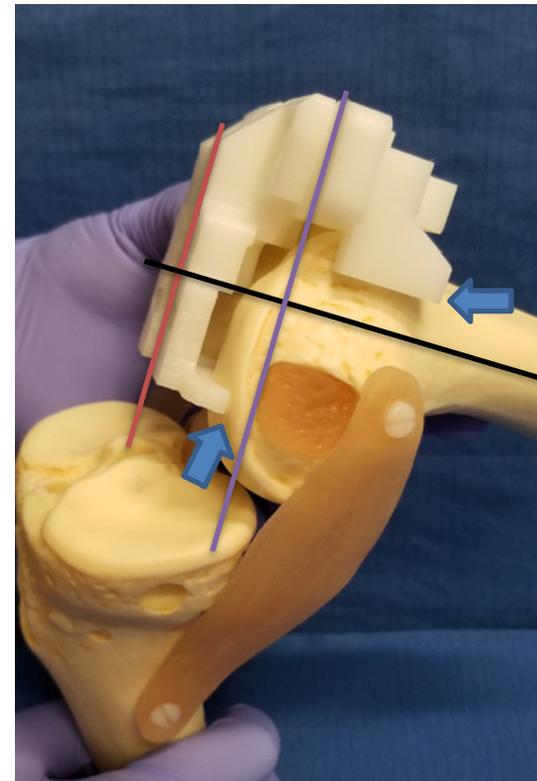
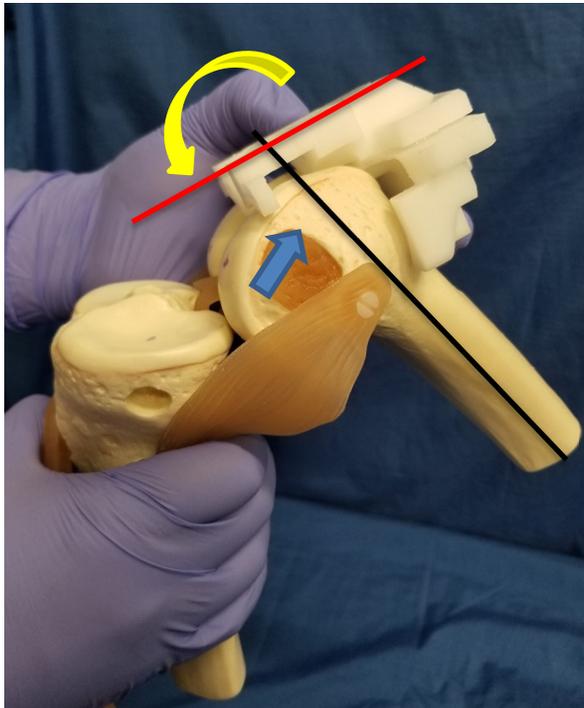


The lateral view above shows the cut slot indicated with a black arrow. Also depicted are the guide contact points. Also, note the contact points from the previous A.P. guide view. Guide contact point (2) is directly behind contact point (1). As explained previously, scrutinize all surfaces and features with particular attention to the cut slot; all should be smooth and free of debris.

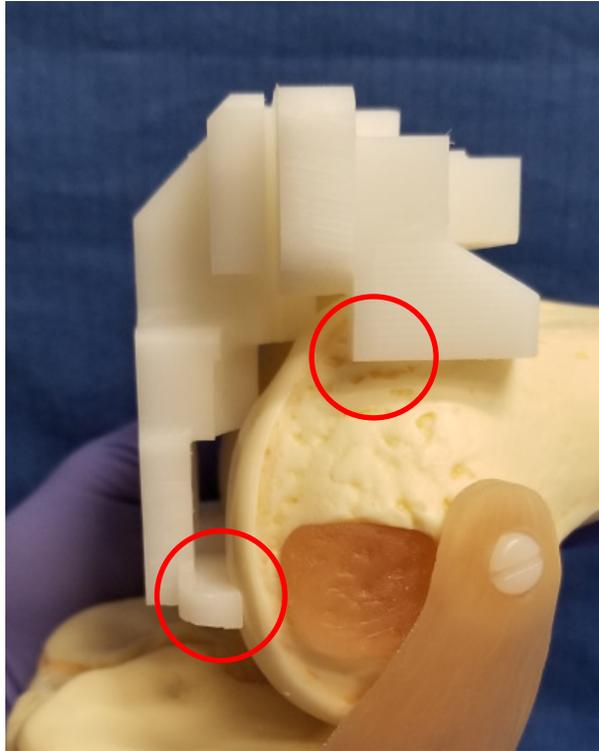
Placing the Femur Guide:

Initial placement of the femur guide is done by orienting the guide and the condyle contact feet slightly above the mid-point of the condylar curve to allow the superior feet to make initial contact slightly distal of the epicondylar area (blue arrow). The face of the guide (red line) should approximate a twenty-degree angle relative to the long axis of the femur (black line).

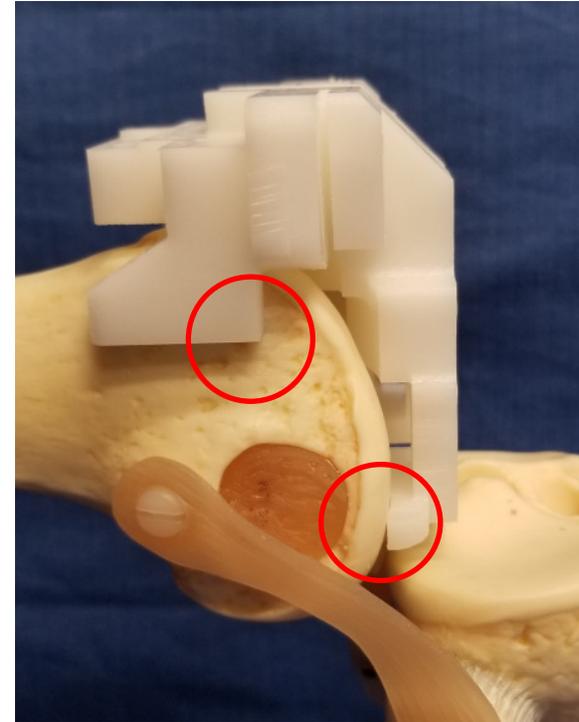
The *PtoleKnee Surgical* Guide should rest initially at a modest angle superiorly as shown. The guide body is centered over and within the trochlear groove with distal condylar feet resting lightly on the distal condyle surfaces. Apply slight downward pressure to allow the guide to rotate distally and posteriorly; the guide can be felt to stick slightly as it locates the intended fixation point.



Once the guide is rotated posteriorly, the anterior and posterior feet of the guide make light contact with the anterior lateral and medial sides of the condyles and the distal condylar surfaces, as shown (blue arrows). When properly positioned, the guide's face (red line) indicates the intended orientation of the cut plain. The black line is perpendicular to the red line and typically approximates the long axis of the femur. The blue line indicates the intended cut plain and indicates the depth of the intended condylar resection.



From the medial side, verify the position of medical guide contact points (red circles). Each contact point should lightly touch the surface of the tissue without using excessive force or excessive direct pressure. A narrow (less than 1.0 mm) gap may sometimes occur along the guide contact point surface.

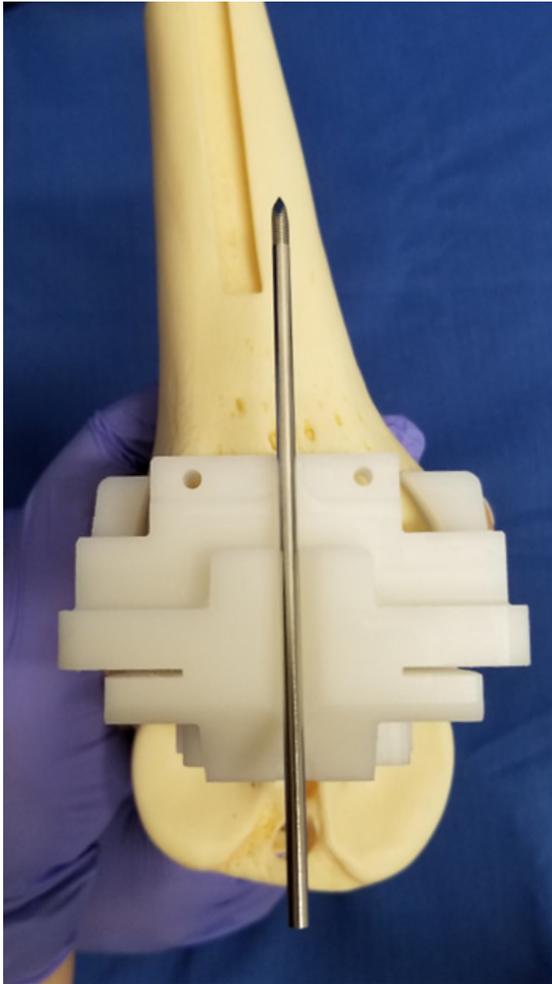


From the lateral side, in the same fashion as the medial side, verify lateral contact points. Both contact points should lightly touch the surface of the tissue without using excessive force or direct pressure. A narrow (less than 1.0 mm) gap may sometimes occur somewhere along the contact point surface.

There are four tissue contact points (2 medial and 2 laterals) and one visual indicator (5th point). Verify the correct placement location of the guide before pinning or making any cuts.

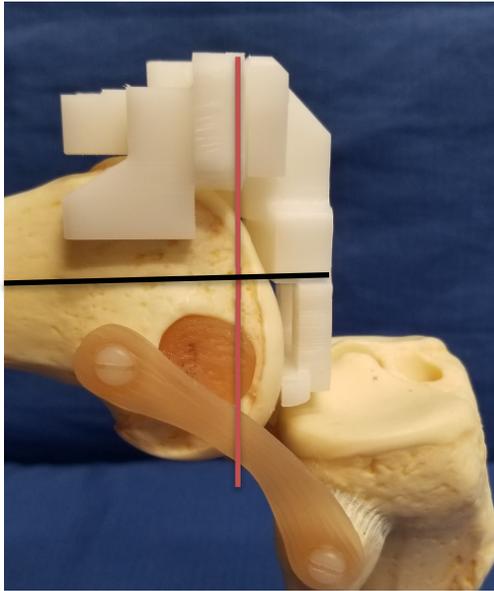
The fifth point (visual indicator) is located over the femoral notch and must be viewed as shown in the two following images. This fifth guide point is a machined notch in the form of a "V" shaped slot aligned so that a pin or rod placed within it points to the center of the femoral

head. When the guide is appropriately placed, the V notch is located over the mid-line of the condylar notch (center of the knee).



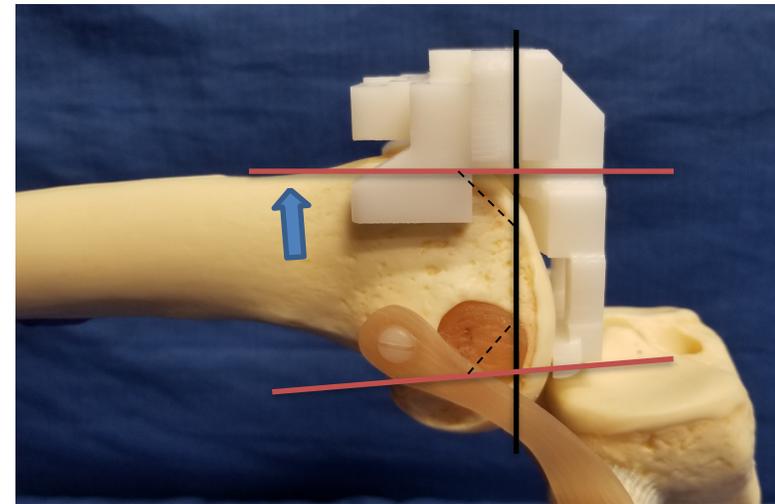
Verification of the potential Varus/valgus angle is made using a fixation pin placed within the "V" notch on the anterior surface of the guide, as shown. The pin should point to the center of the femoral head (black arrow) if the guide placement matches the surgical plan. After

establishing the projected Varus/valgus alignment is as desired, the projected condylar cuts are assessed and may be completed.



Verification of the projected initial cut plane for the medial and lateral condylar cuts (red line) of the distal femur is performed. This cut plane is typically perpendicular to the long axis of the femur (black line) or as dictated by the surgical plan if flex/extension adjustments are planned.

Use a resection checker (angel-wing) to assess the angle and depth of each condylar cut to verify they are as expected. Angle verification is essential; as the initial cut sets the final Varus/valgus angle, flex/extension, and IR/ER of the femur implant. The thickness of each condyle cut should match the surgical plan values. If satisfactory, fixation of the guide can follow.



An additional guide placement verification is performed to assess that the initial cut plane will not ultimately result in a resection that leads to the implant's notch or gapping following the 4:1 (chamfer) cutting block.

The vertical black line above represents the intended cut plane for the distal femur. The horizontal red lines approximate the final anterior and posterior cut planes resulting from a 4:1 chamfer-cutting block. The anterior and posterior cut angles may be nearly parallel or divergent depending on implant brand, as shown. In either case, the final anterior cut plane of the 4:1 cutting block should skim the anterior surface of the femur (blue arrow).

Drill and set the Pins

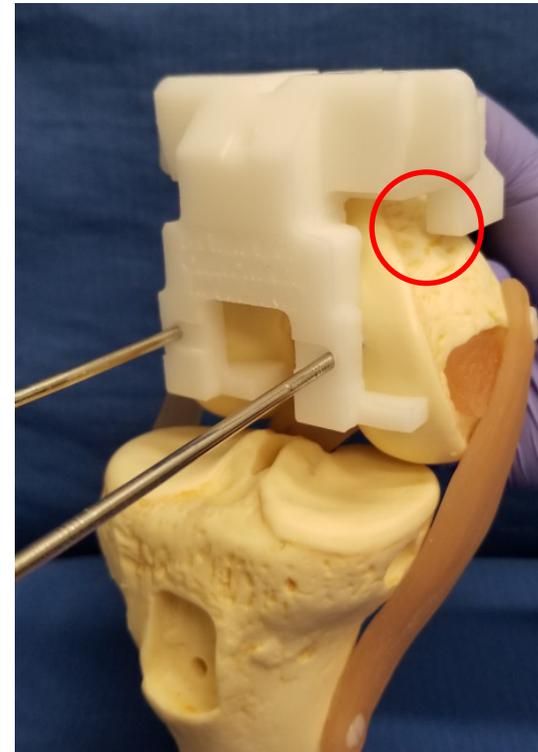
Pre-drilling pilot holes for the pins obtain the most accurate position of the guides. It is recommended that the distal condylar pins should be drilled and set first. The holes are not drilled to maximum depth, only deep enough to pierce the cortical bone. Insertion of the pins after pre-drilling reduces the tendency of threaded or smooth pins to "wander or walk" before they bite in.

With the fingers or thumb of the non-drilling hand, stabilize the guide by moderate pressure on the guide over the trochlear groove area to prevent unwanted movement, maintain pressure until both condylar pinholes are drilled.

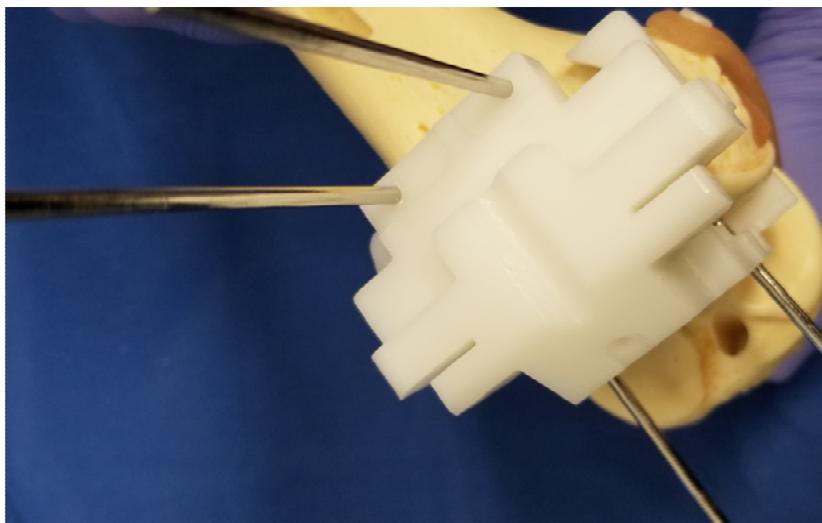
Using an orthopedic 3.2 mm drill, insert the bit into the guide hole before turning on the drill motor, then drill the lateral condyle pin location taking care to minimize contact with the walls of the guide hole. Leave this first drill in place for stability; check *PtoleKnee Surgical Guide* contact points to ensure the guide has not shifted, correct as necessary.

With a second drill bit, drill the second medial pilot hole. Replace this drill with a 3.2 mm bayonet or trocar point pin and impact or screw into place. Remove the lateral drill bit and replace it with a pin in like fashion.

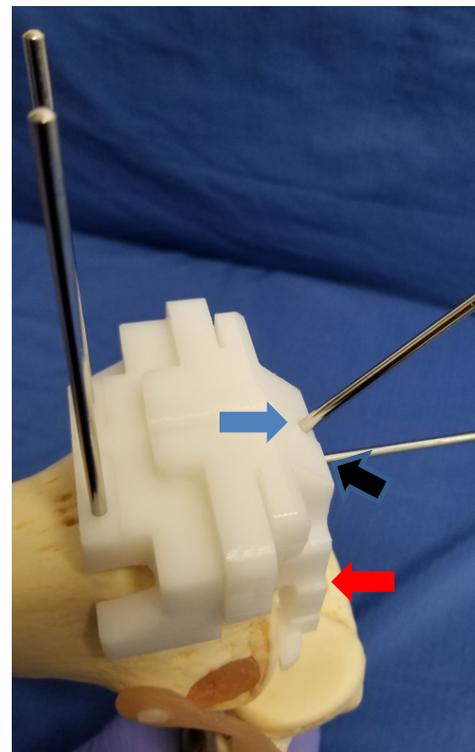
Now re-inspect the distal condyle contact locations of the *PtoleKnee Surgical Guide*; the feet should still be in contact with the condyle surfaces. The anterior, medial, and lateral contact points above the epicondylar area should also be in contact. If needed, slight downward pressure on the anterior guide surface between the anterior pinholes may correct small contact gaps (less than 1.0 mm) (red circle) in the following picture.



Once all four contact point checks are completed, placement of the two anterior pins begins. While still holding the Femur Guide in place, pre-drill the anterior lateral femur pin location, leave the lateral drill bit in place, and drill the medial side with a second drill bit. Replace the medial drill with a 3.2 mm bayonet or trocar point pin and impact or screw into place. Remove the lateral drill bit and replace it with a pin in like fashion. Once all pins are inserted, the guide should be firmly locked in place. Examine the guide again once all pins are in place to verify that the guide has not skewed during pin placement.



With the guide fully pinned, and before cutting, examine the distal resection thickness on the medial and lateral sides using a resection checker (Angel-wing). The tool is standard in T.K.R. instrument sets. Check the potential cut carefully for thickness on both medial and lateral condyles for Varus/valgus angle and flex/extension angle. If potential alignment and cuts are as expected, proceed. The surgical plan provides the expected thickness of each condyle cut.



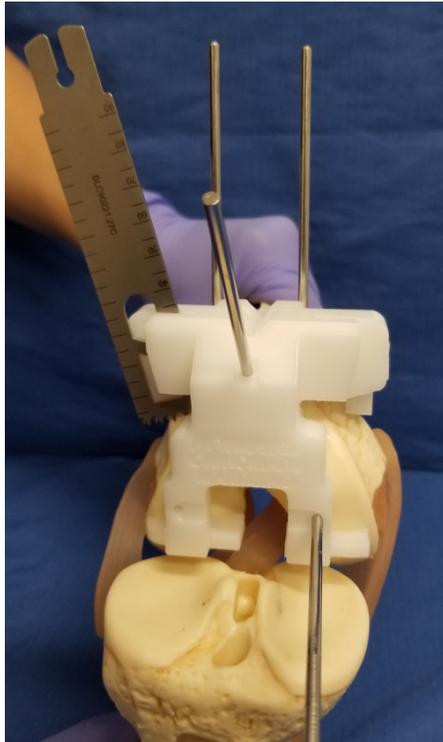
A kerf-less blade 110-120 mm x 1.27 mm is recommended.



Making the first cut:

Remove the lateral condyle distal pin (red arrow location) and save it for reuse. Replace this pin in the diagonal stabilization location as shown (blue arrow) pre-drill and pin as before. The diagonal stabilizer pin helps reduce possible guide shifting due to saw vibration. The

medial pin (black arrow) remains in place until the lateral condyle cut is completed.

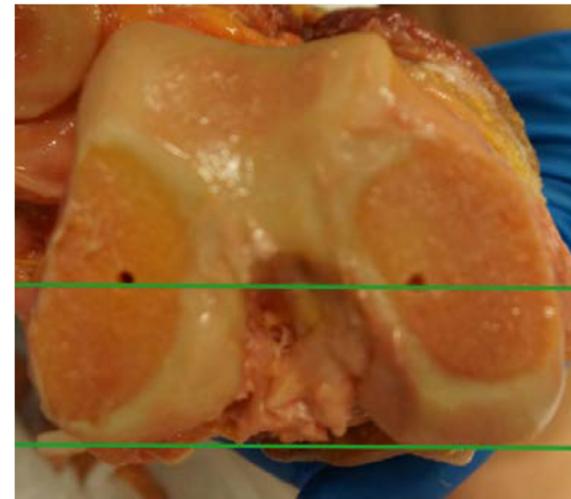


With the lateral femur condyle pin removed, resect the lateral condyle using an orthopedic saw.

If the area occupied by the diagonal stabilization pin requires resection, remove the pin and pass the saw blade across this area to complete the resection. When the lateral condyle is finished, remove the medial stabilization pin and reinsert carefully into the lateral location within the original hole to provide additional stability while cutting the medial condyle. Once both sides are cut, remove all pins and the guide.

Check the flatness of the final cuts. Minor clean-up and smoothing of the cut surfaces may be undertaken if needed.

Sawing cortical bone can generate significant heat and may result in thermal necrosis. Irrigation of the saw blade with saline while cutting help reduce this heat. Multiple slow, smooth passes of the saw also help reduce heat and ensure a more accurate cut with less tendency to skive. When the femur cuts are completed, with the pins and guides removed, the resection appears similar to the photograph following.



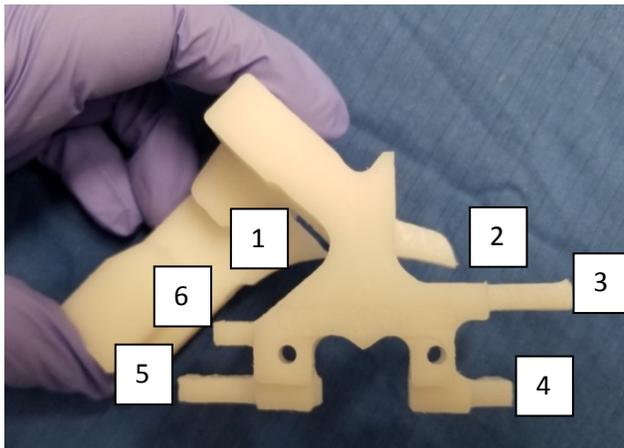
Based on the implant system designated in the plan, the femur chamfer cuts may or may not follow now. Some systems immediately cut the tibia, followed by a resection gap check to assess gap dimensions and knee stability while corrections are still easily made.

Making the chamfer cuts:

Attach the chamfer-cutting (4:1) block after the revision of the femur is verified and found acceptable. Verification of this cut is crucial should conversion to standard manual instruments be necessary.

Correction of varus/valgus or flex-extension angles is difficult or impossible once the femur chamfer cuts are made. Occasionally, the distal holes can be challenging to identify following the initial distal cut. If this occurs, clean and irrigate the pinhole locations. Alternatively, before removing the femur guide, locate and re-clean the drill pinholes manually with a 3.2 mm drill bit by hand using the guide as an alignment tool.

Examine the Tibia Guide:



Shown are the six visible contact feet or points. Points 3, 4, 5 & 6 all contact the proximal surface of the tibial plateau. Points 1 and 2 contact the anterior lip of the tibia. As with the femur guide, inspect all guide surfaces for damage, debris and that the guide serial number and patient identifying, and leg information is correct.

Preparation of the tibia:

Remove all meniscus tissue. Do not remove osteophytes from the tibia unless instructed to do so. Clean the bone around the A.C.L. stump and anterior to the medial tibial lip where the guide fits. Remove any

soft tissue that may interfere with the proper placement of the *PtoleKnee Surgical* Guide. Using a forked distractor/retractor posteriorly may be helpful to expose the tibia better and protect the Posterior Cruciate Ligament (P.C.L.) from additional injury when sawing.

Placing the Tibia Guide:

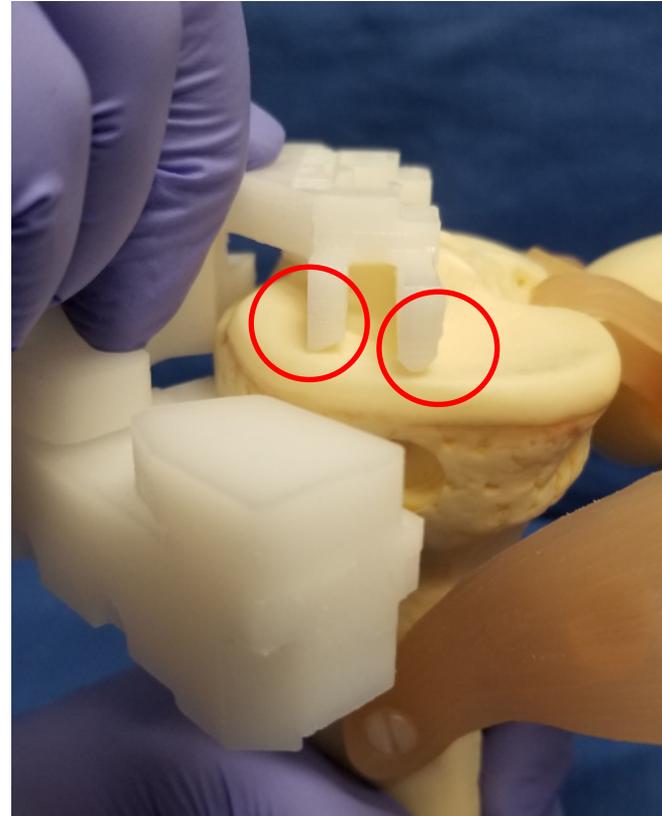


Hold the tibia guide as shown above. The central pointer indicated (red arrow) aligns with the axis of the tibial spine when the guide is placed on the tibia. Orient the tibia guide with the central pointer aligned with the central spine of the tibia as shown (red arrow).

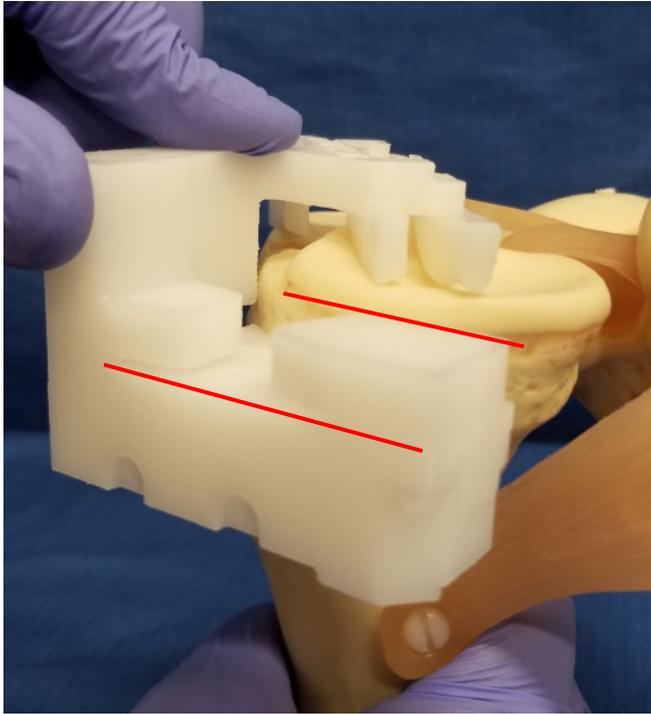
The *PtoleKnee Surgical* guide contacts the anterior lip, and the cut slot extends medially on the tibia. It may be necessary to extend the original incision slightly to provide better guide access medially.



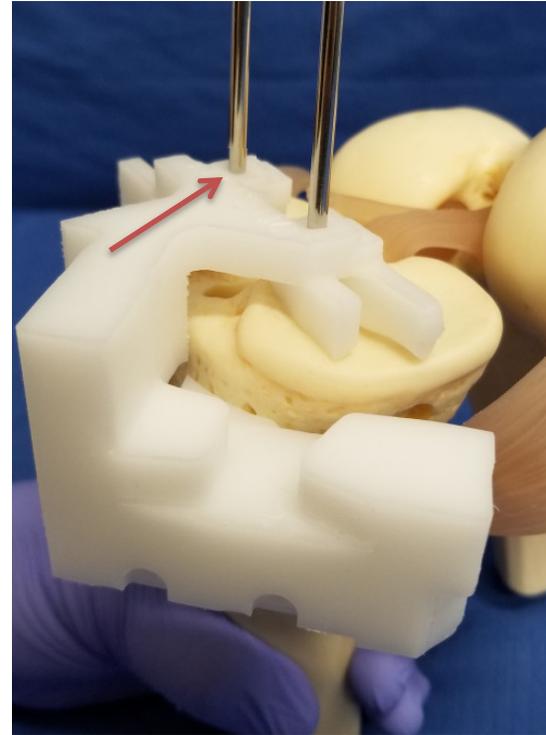
Place tibia guide against the anterior surface with the superior bilateral feet on top of the tibial plateau (pointer toward posterior) as shown. For reference, use the central arrow feature on the tibia guide to point along the central axis of the tibial spine, as shown above.



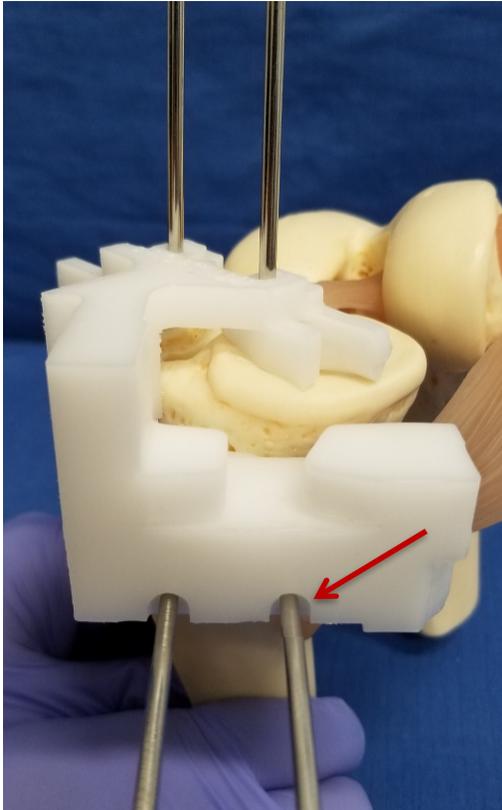
From the medial side, check the contact point of the medial guide feet within the circled area as above. Both feet should lightly touch the surface of the tibial surface along their length. The lateral side is checked in like fashion.



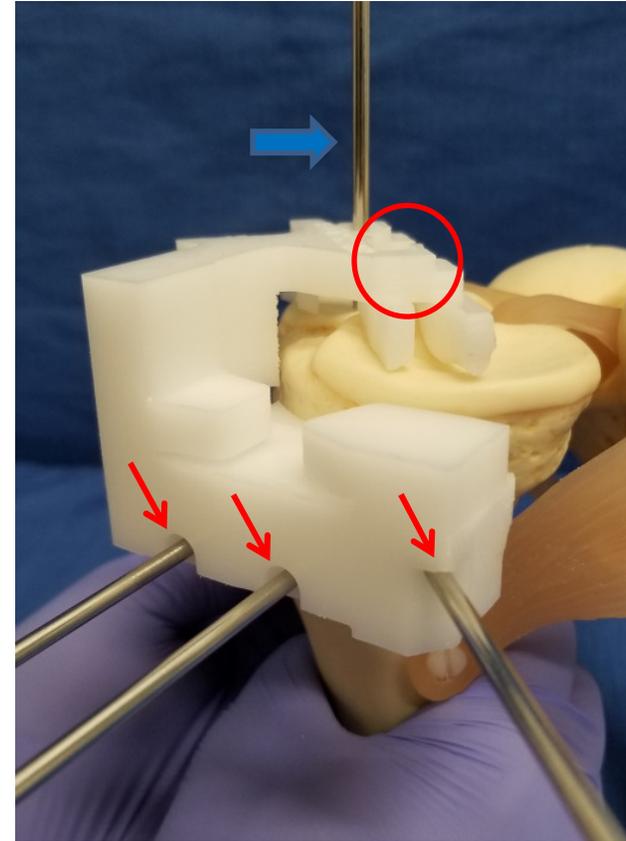
Also, check that the intended cut plane and natural tibial slope are approximately the same from the medial side, as shown above. The exception to this is when a tibial slope changes during planning to a different cut angle. In this case, verify that the new cut slope matches the planned cut slope.



While holding the tibia guide in place, install the two proximal tibia pins one at a time, beginning with the lateral side (red arrow).



After the proximal pins are in place, continue to hold the tibia guide in place and re-verify all five (5) of the tibia guide contact points. If they are all still in contact with joint surfaces, the two 3.2 mm anterior guide pins are placed, beginning with the medial (right) side (red arrow).



Remove one of the two tibia proximal pins (red circle) and reinstall it (red arrow) as the angle stabilizer pin. Once the angle stabilizer pin is in place, remove the remaining proximal pin (blue arrow).

Once the *PtoleKnee Surgical* guide is securely anchored with three (3) anterior pins, as shown above, the last proximal pin is removed.

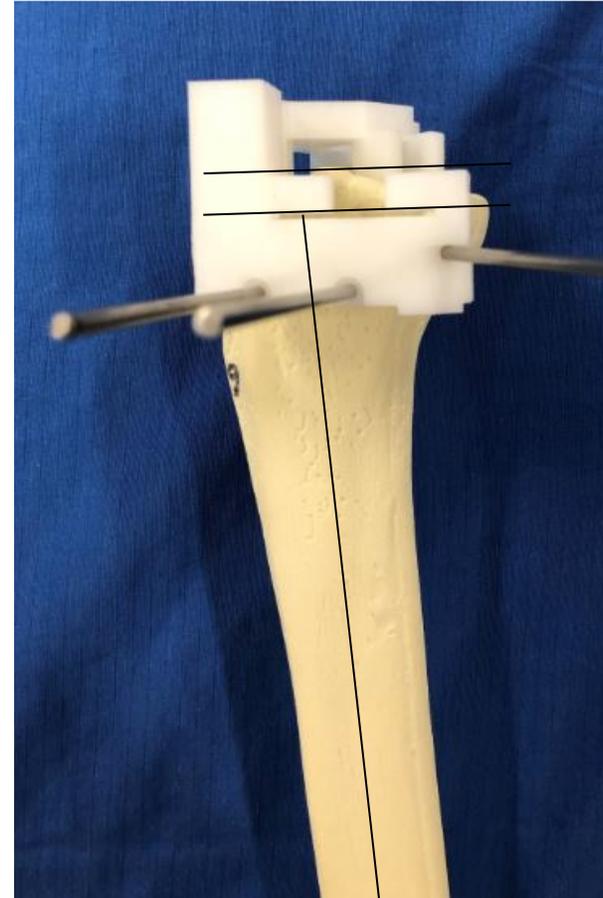
Tibial alignment Check



A 1/4-inch drop rod from the standard instrument set may be placed as shown to verify it points to the center of the ankle.

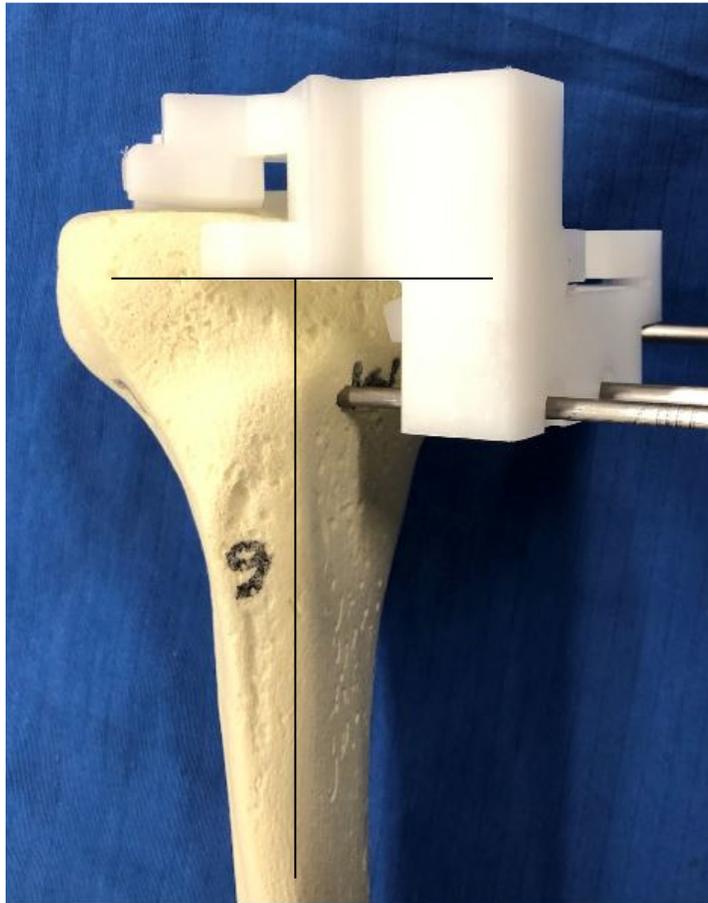
Verification of the tibial cut-plane angle:

An estimate of the final Varus/valgus angle, posterior slope, and depth of cut of the tibial resection is conducted in the example shown below.

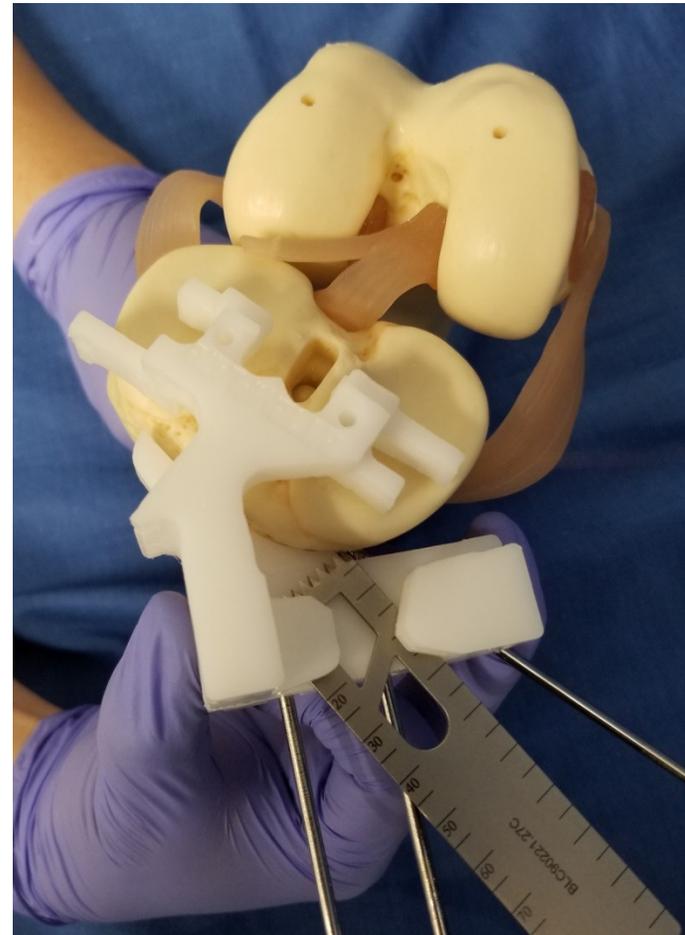


The tibial slope and depth of cut are expected to match the surgeons' plan. In this case, 3 degrees posterior and 11 mm thick.

The varus/valgus angle may be assessed using the long tibia axis and the guide cut plane. In this case, the plan called for zero degrees varus/valgus angle alignment.



If all verification checks match the plan or are as desired, the tibia may be cut with the power saw.



If the pinned guide does not replicate desired angles and slope, do not cut. Remove all the pins and tibia guide and continue with the remainder of the surgery using manual instruments.

Position the *PtoleKnee Surgical* Guide on the tibia as shown. Like the femur guide, careful checking of guide positioning before cutting is essential. Verify all contact anatomic contact points of the *PtoleKnee Surgical* guide. Verify guide stability. Check M/L thickness of the

proposed cuts. Check Varus/valgus angle matches the femur cut. Verify tibial slope matches the plan. If all is satisfactory, complete the tibial cut and proceed with the remainder of the T.K.R. procedure using the standard instruments.

Resuming the standard T.K.R. procedure:

For example, a typical next step verifies that the resection creates a rectangular resection gap between the distal femur and proximal tibia, which are flat and parallel in both flexion and extension.

Inserting a Flex/Extension gap checker from the implant tray allows assessment of the soft tissue tensioning and the final thickness of bone resected in both flexion and extension. Some implant brands assess fit during a "trial reduction." *PtoleMedic System* planning should result in a gap between the two cut surfaces allowing for the thickness of the metallic knee components and the thinnest polyethylene tibial insert. The minimum insert thickness varies by implant brand selected by the physician when setting their brand preference but is typically between 10 & 13 mm.

NOTE: Some Implant systems and surgeons choose to perform an extension gap assessment first before completing the chamfer cutting of the femur. In this case, once the initial extension gap is verified as acceptable, the chamfer cuts are made, and the flexion gap is assessed.