PtoleMedic System

Instructions for Use – TKR Surgical Procedure for the PtoleKnee Surgical Guide

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PtoleMedic System
Instructions for Use
PtoleKnee Surgical Guides

IMPORTANT NOTE FOR SURGEON: PLEASE READ ENTIRE Instruction for Use BEFORE USING THE ***PtoleKnee Surgical Guides*** CLINICALLY. THE SURGEON SHOULD BE FAMILIAR WITH THE USE OF PERSONALIZED SURGICAL INSTRUMENTS.

Warnings:

The ***PtoleMedic System*** has not been evaluated in a pediatric population, performance in such cases is unknown and not recommended.

The ***PtoleMedic System*** and ***PtoleKnee Surgical Guides*** are prescription only medical devices.

The ***PtoleMedic System*** is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on education, training and experience of the surgeon.

The ***PtoleMedic System*** only provides, and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI image sources.

The ***PtoleMedic System*** does not provide an absolute or only solution plan for joint replacement surgery; it only documents one possible approach.

The ***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.

The ***PtoleKnee Surgical Guides*** are for use by a surgeon experienced in the use of personalized surgical instruments (PSI-customized guides).

The ***PtoleKnee Surgical Guides*** are patient specific instruments planned and made based on MRI scans for each named patient. If the patient's anatomy/disease process has changed significantly since obtaining the MRI scan, new images should be obtained.

Examine process and sterilize the ***PtoleKnee Surgical Guides*** before use. Do not use guide if chipped, broken, cracked or debris is present.

The guides and their packaging are ***non-sterile***.

 ***PtoleKnee Surgical Guides*** may not be re-used. They are for ONE-TIME-USE only.

 DO NOT RESTERILIZE the guides.

Cautions:

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

The guide construction material is extruded acetal copolymer, polyoxymethylene (POM) a common medical instrument material. However, do not use the guides in persons having or suspected of having allergies to this material.

Precautions:

Use only MRI data of recent origin obtained per established ***PtoleMedic System*** designated MRI protocols.

Take care to minimize excessive heat buildup from friction between ***PotleKnee Surgical Guides*** and other instrumentation, such as drills/saws. Excessive heat buildup can lead to debris or deformation of the ***PtoleKnee Surgical Guides***.

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. 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 MRI data should be obtained and new guides made.

Limitations

Metallic implants in or near the affected joint are known to interfere with the MRI 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 will typically fall within one size of estimation.

The ***PtoleMedic System*** is not for use in planning revision/replacement surgery in persons already having implants in the affected joints.

Digital x-ray or CT data is not acceptable for guide production; the files must be MRI 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 larger than 6° Varus or valgus, cases that require "tibia-cut-first" surgical techniques, cases for uni-condylar replacement, and for cases of TKR revision surgery.

NOTICE: ***PtoleKnee Surgical Guides*** are intended to assist in the execution of a Total Knee Replacement (TKR) 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 Innovation, Inc.

Telephone: United States telephone support +1 (510) 413-3230

Internet: If you have access to the Internet, you may reach the

On-line Help support:

Web: http://www.lentomedical.com/contact/

Lento Medical Innovation makes use of cloud based on-line product information. Please refer to all supplied package inserts or go on-line to review them as needed for specific product detail.

Manufacturer:

Lento Medical Innovation, Inc.

15110 Northwest, Freeway, Suite 150

Houston, TX 77040, USA - Telephone +1 (510) 413-3230

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

Indications for Use:

The Lento PtoleMedic System is for use in primary total knee replacement (TKR) procedures only. Revision TKR surgeries are not supported. In addition, the following conditions are contra-indicated for use of the PtoleMedic System and PtoleKnee Surgical Guides:

• Active infections of the knee or knee joint
• Hip-Knee-Ankle alignment deformity larger than 6°
• Varus or valgus, case requiring “tibia-cut-first” surgical techniques
• Uni-condylar knee replacement implants
• No digital x-ray or CT scan images are accepted, only MRI images may be used for guide production
• MIS incisions will not provide sufficient access for use of Lento PtoleKnee Surgical Guides

The Lento PtoleMedic System is an on-line orthopedic surgical planning and instrument design system. The surgical planning software is used pre- operatively to review and plan the surgical placement of the selected components. The system uses physician ordered MRI digital images providing sufficient detail of required anatomical landmarks in guide contact areas. The Lento PtoleMedic System is indicated for TKR patients without severe

bone deformities (greater than 6°) or deformities from fracture of the distal femur or proximal tibia. The PtoleKnee Surgical Guide instrument system assists the surgeon with positioning of knee replacement components. The Lento PtoleMedic System and PtoleKnee Surgical Guides may be used with posterior referencing TKR systems according to their indications and contraindications including Cruciate Retaining and Posterior Stabilized implants. The ***Lento PtoleKnee Surgical Guide*** components are for single-patient-use only.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a Physician only.

Acknowledgements:

Lento Medical Innovation, 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 TKR femur and tibial component alignment guides.

Important Notes:

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

Serial # of *the* guides are in the following format:

K, with five numerals, and an L or R (e.g. K12345L or K12345R)

Patient's 1st initial and 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***.

The PtoleMedic System Supports the following implant systems:

Zimmer	Stryker	Smith & Nephew	DJO Global	Somersault
K193223, Cement indications only. and K171269, K131409, K161828	**K053514, K173849**	**K152726 - Journey II, K200826 Visionaire & K183010 Visionaire**	**K160342 PS Knee System**	**K124051 - Vault System**

Start with the femur: Lento PtoleMedic System and PtoleKnee Surgical Guides do not support a tibia-first approach.

Accessories are not included, but necessary:

- Drill bits, 3.2mm or 1/8 inch
- Threaded or smooth 3.2mm or 1/8 inch orthopedic pins
- Standard surgical instrumentation for joint surgery including powered orthopedic saws and saw blades (0.27mm X 120mm recommended) and angel wings (angle checker) also proprietary instruments specific to the implant brand selected. Brand specific 4:1

cutting/chamfer blocks are essential.

Incision Length: MIS incisions are unlikely to provide sufficient access for 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 MRI scan of the arthritic knee and a scout MRI scan of the hip and the ankle. Lento recommends a 1.5 Tesla or higher magnet obtained from a qualified MRI imaging center. All scans should be obtained at least 14 calendar days prior to the surgical procedure date and sent electronically to the Lento secure database via the ***PtoleMedic System*** MRI web protal interface. Pre-qualification of the imaging center by Lento is required prior to submitting scans for the ***PtoleMedic System*** knee procedure. 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 MRI 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 (TKR) and personalize the surgical approach for each individual patient. Lento's proprietary software provides implant alignment and placement information based on the specific individual's anatomic data from medical MRI images. It also allows the surgeon to request the production of individualized 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 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	PtoleMedic System Instruments
1	Knee Exposure	Expose joint using standard approach. Allow enough exposure to allow seating of guide	NONE
2	Excise ACL	Excise the ACL	NONE
3	Femur Preparation	Place Femur Guide anteriorly on distal femur and slightly push down	PtoleKnee Femur Guide
4	Femur Guide Placement	Drill the two condyle pins first Then, drill the two anterior pins Remove the lateral condyle pin Place angled anterior pin (stabilizer pin)	PtoleKnee Femur Guide
5	Resect distal femur	Verify guide placement and cut distal condyles Remove femur pins and guide	PtoleKnee Femur Guide
6	Tibial Exposure	Expose tibia & excise meniscus & soft tissue at guide contact points	NONE
7	Tibial Preparation	Fix Tibial Guide on anterior surface and tibial plateau	PtoleKnee Tibial Guide
8	Tibial Guide Preparation	Install two tibia proximal pins Then, install two tibia anterior pins Take out two tibia proximal pins Place anterior pin (stabilizer pin)	PtoleKnee Tibial Guide
9	Resect tibia	Make proximal tibia cuts. Remove guide & pins	PtoleKnee Tibial Guide
10	Standard TKR	Return to standard TKR procedure	NONE

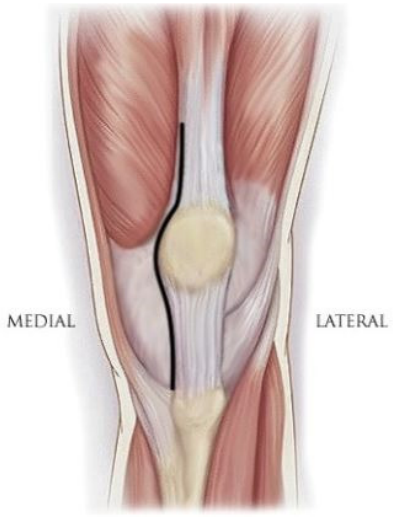
The Surgical Procedure:

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 Medical Innovation as soon as possible after completion of 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 to allow proper guide insertion. The smaller true MIS-type incisions may not provide sufficient surgical exposure for guide insertion.

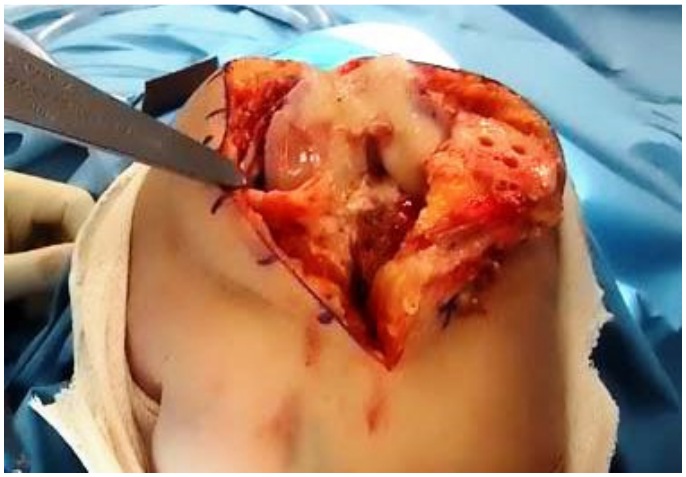
Parapatellar Incision



The initial step proceeds as typical for TKR procedures, opening, dissecting and removing adipose, Anterior Cruciate ligament and capsule tissue. Patellar dislocation is done as normal.

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 to expose the anterior femoral cortex. Displace the patella laterally 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 proper fit of the guides. However, should osteophytes exist at or near location which might interfere with proper fit of the guides, the planning presentation to the surgeon will provide instruction on the location of potential interference resulting from the presence of osteophytes and appropriate notice will be provided to the surgeon to remove them.

PtoleKnee Surgical Guides:

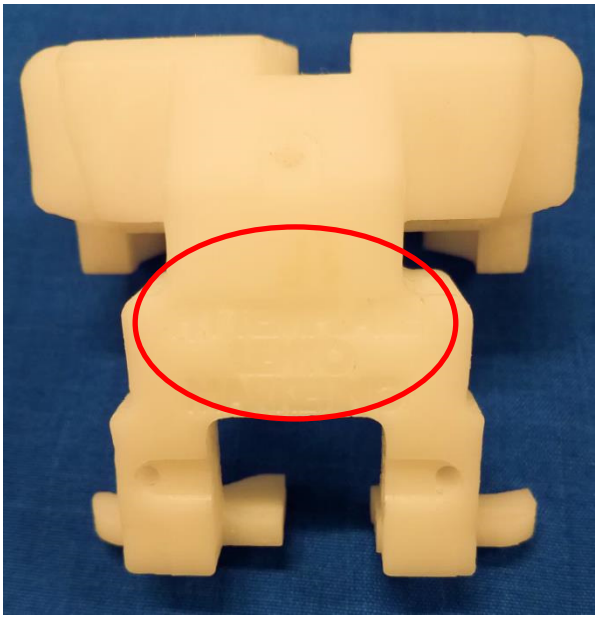
1. Placing the Guides:

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 important 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.

2. Examine the Femur Guide:

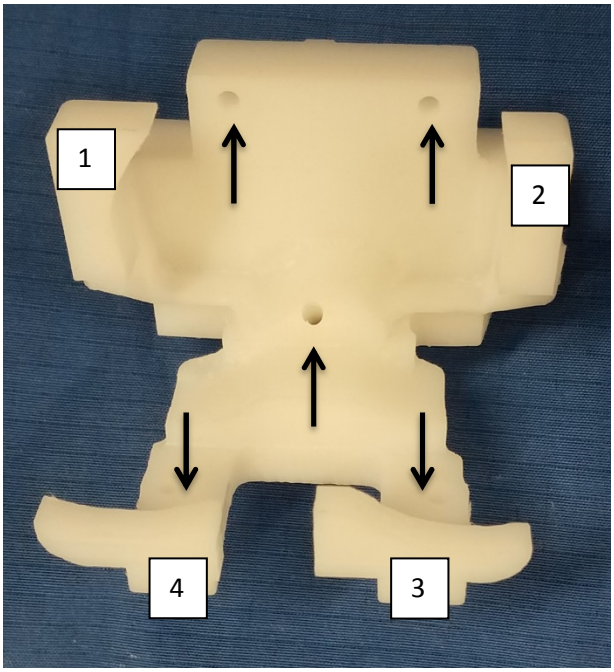
First, ascertain that you have received the correct guide. The face of the ***PtoleKnee Surgical Guide*** contains the case identification information (shown by red oval in the image below). Engraved are: the Guide Serial Number, patient initial and ten alpha characters of the last name, patient's date of birth, and knee descriptor.

AP View – Face



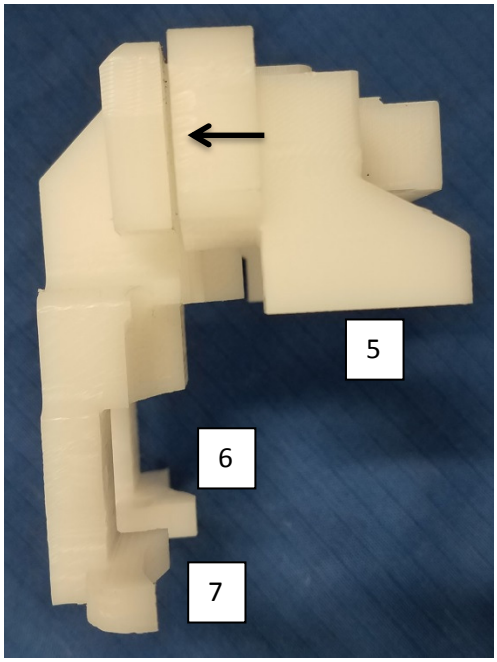
Next, examine the physical properties of the guide.

PA 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. Examine all nine features carefully, they should be smooth and free of debris.

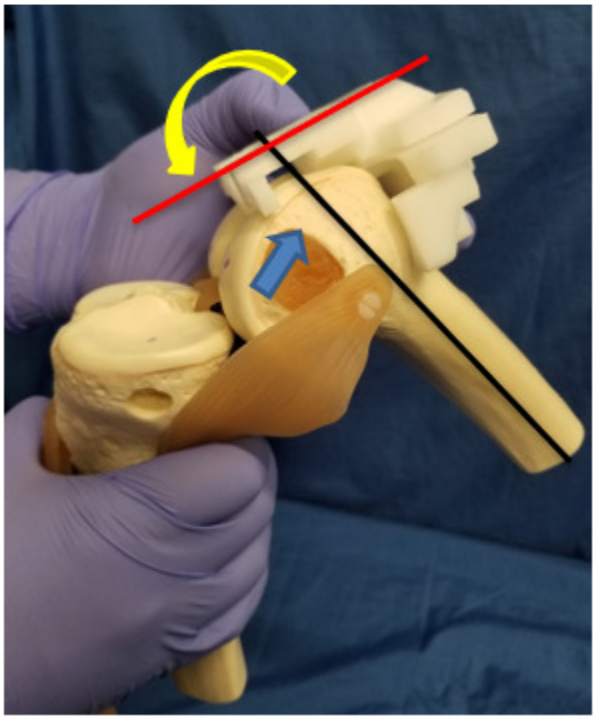
Medial - Lateral View



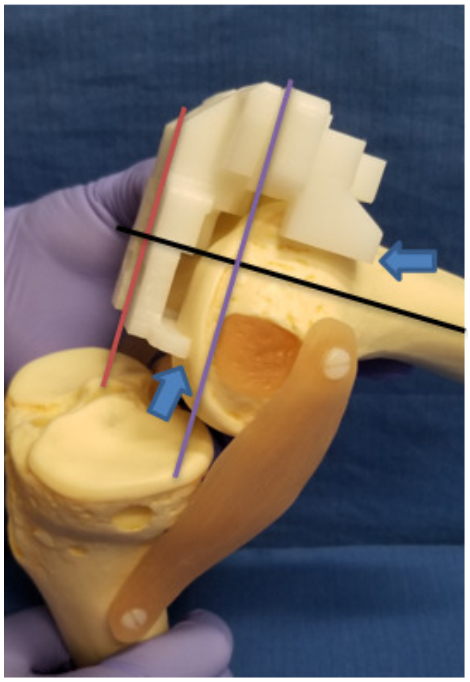
The lateral view above shows the cut slot indicated with a black arrow. Also depicted are the lateral view of the guide contact points (5, 6, 7). Also, note the contact points from the previous AP guide view. Guide contact point (2) is directly behind contact point (1). As explained previously, examine all surfaces and features carefully with special attention to the cut slot, all should be smooth and free of debris.

3. Placing the Femur Guide:

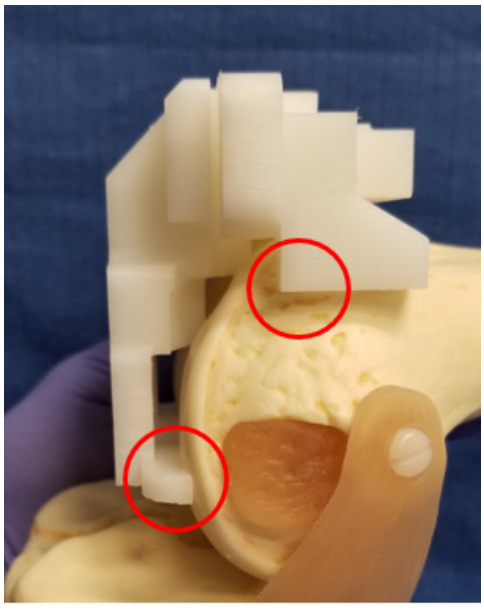
Initial placement of the femur guide is done by orienting the guide and the condyle contact feet slightly above the mid-point of the condylar curve to allow the superior feet to make initial contact slightly distal of the epicondylar area (blue arrow). The face of the guide (red line) should approximate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



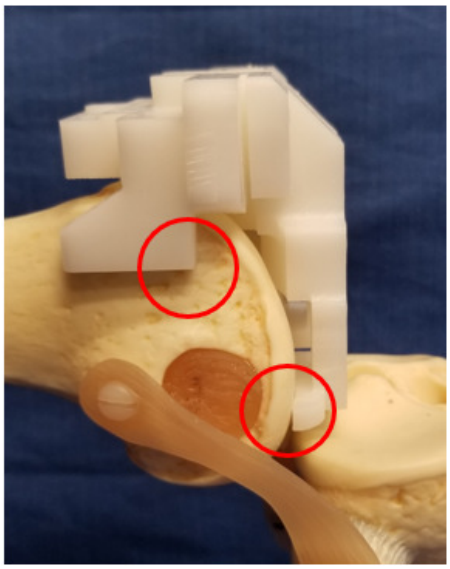
The ***PtoleKnee Surgical Guide*** should rest initially at a modest angle superiorly as shown. The guide body is centered over and within the trochlear groove with distal condylar feet resting lightly on the distal condyle surfaces. Apply slight downward pressure to allow guide to rotate distally and posteriorly, guide can be felt to stick lightly 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 face of the guide (red line) will indicate the intended orientation of the cut plain. The black line is perpendicular to the red line and typically will approximate with the long axis of the femur. The blue line indicates the intended cut plain and indicates the depth of the intended condylar resection.

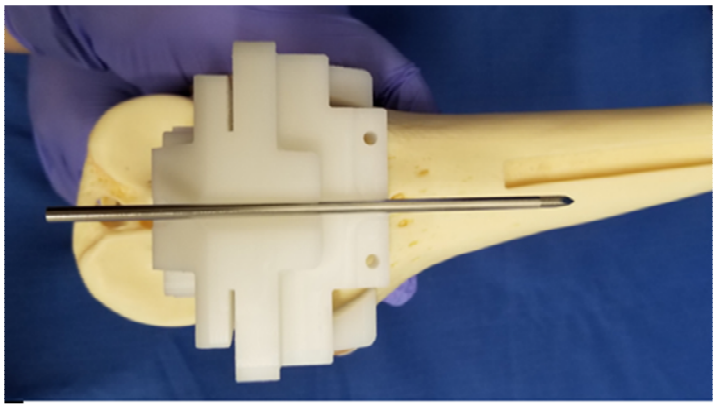


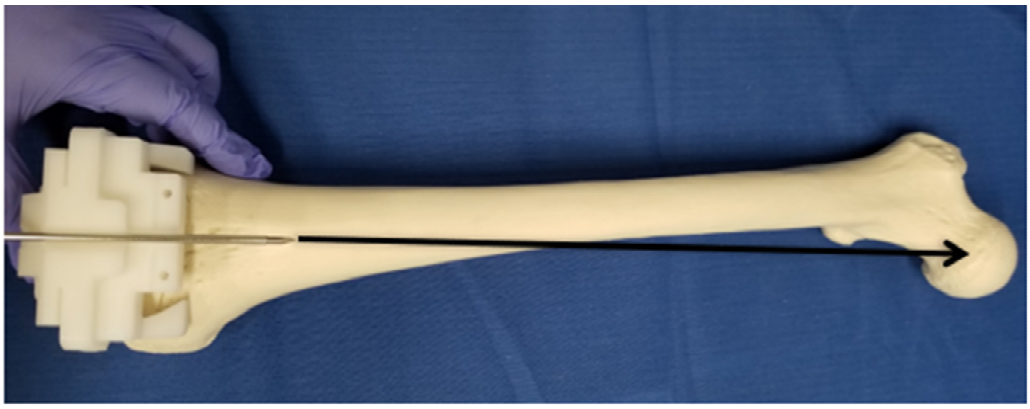
From medial side, verify position of medical guide contact points (red circles). Each contact point should lightly touch the surface of the tissue without using excessive force or excessive direct pressure. A small (less than 1.0 mm) gap may sometimes occur somewhere along the guide contact point surface.



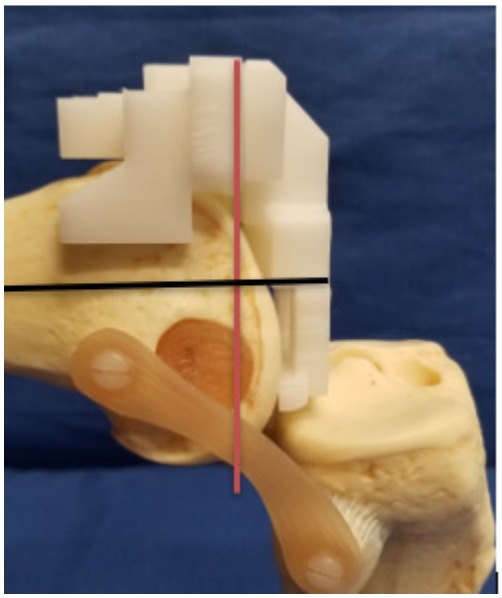
From lateral side, in the same fashion as the medial side, verify lateral contact points. Both contact points should lightly touch the surface of the tissue without using excessive force or direct pressure. A small (less than 1.0 mm) gap may sometimes occur somewhere along the contact point surface.

There are four tissue contact points (2 medial and 2 laterals) and one visual indicator (5^{th} 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 in such a way that a pin or rod placed within it points to the center of the femoral head. When the guide is properly placed, the V notch is located over the mid-line of the condylar notch (center of the knee).





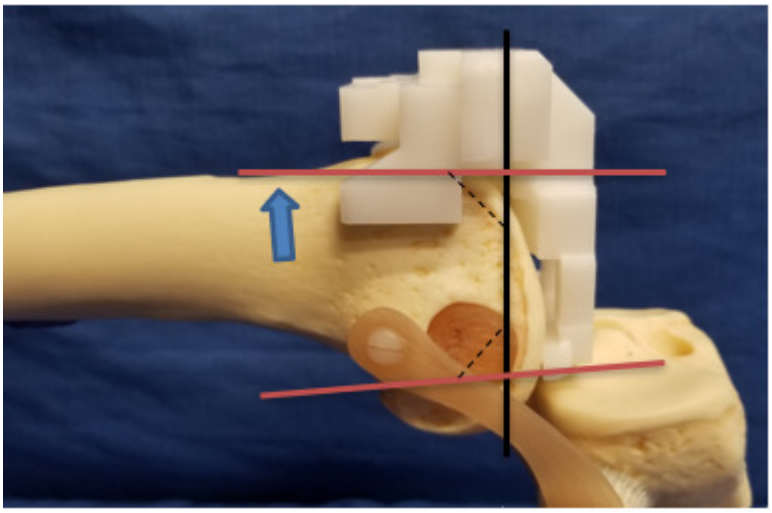
Verification of the potential Varus/valgus angle is made using a fixation pin placed within the “V” notch on the anterior surface of the guide as shown. The pin should point to the center of the femoral head (black arrow) if guide placement matches the surgical plan. After establishing, the projected Varus/valgus alignment is as desired, assessment of the projected condylar cuts is undertaken.



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. This is important; this initial cut sets 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 would lead to notching or gapping of the implant following use of 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 the use of a 4:1 chamfer-cutting block. Depending on implant brand, the anterior and posterior cut angles may be nearly parallel or divergent, as shown. In either case, the final anterior cut plane of the 4:1 cutting block should just skim the anterior surface of the femur (blue arrow).

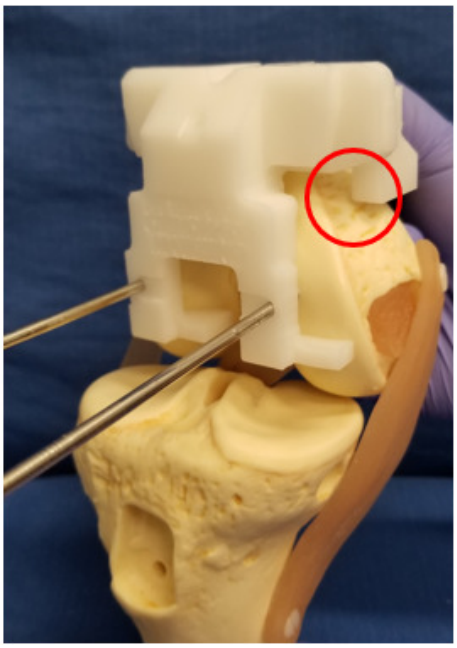
4. Drill and set the Pins

The most accurate position of the guides is obtained by predrilling pilot holes for the pins. It is recommended that the distal condylar pins be drilled and set first. The holes are not drilled to full depth, only deep enough to pierce the cortical bone. Inserting the pins after predrilling reduces the tendency of threaded or smooth pins to "wander or walk" before they bite in. With the fingers or thumb of 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.

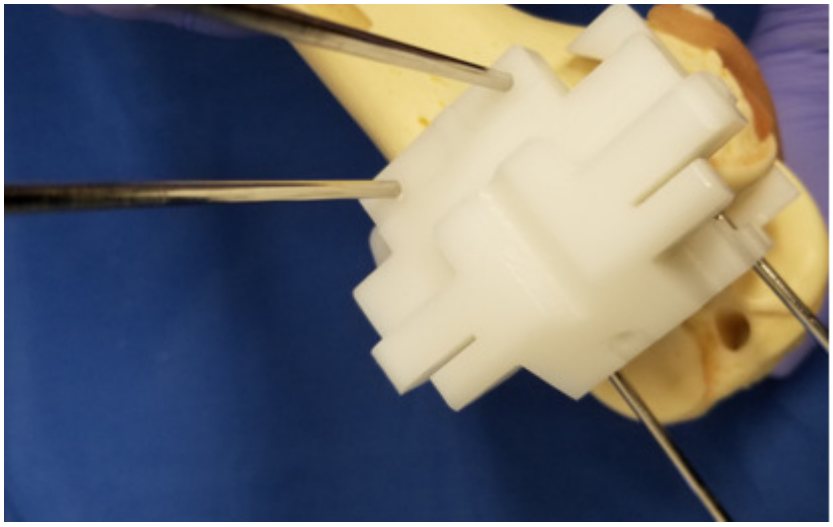
Using an orthopedic 3.2 mm drill, insert the bit into the guide hole before turning on the drill motor then drill the lateral condyle pin location taking care to minimize contact with the walls of the guide hole. Leave this first drill in place for stability, check *PtoleKnee Surgical Guide* contact points to be sure 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 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 guide anterior surface between the anterior pin holes may be used to correct small contact gaps (less than 1.0 mm) (red circle) on the picture following.



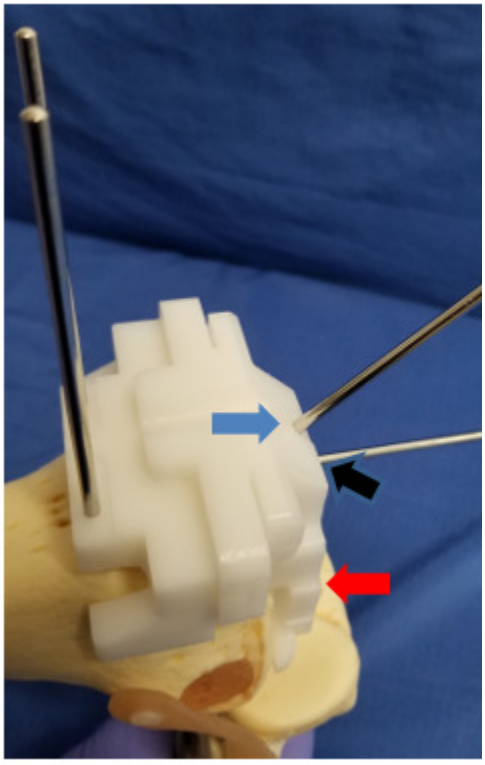
Once all four contact point checks are completed, placement of the two anterior pins begins. While still holding the Femur Guide in place, pre-drill the anterior lateral femur pin location, leave lateral drill bit in place and with a second drill bit, drill the medial side. Replace the medial drill with a 3.2 mm bayonet or trocar point pin and impact or screw into place. Remove the lateral drill bit and replace 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). This tool is standard with TKR instrument sets. Check the potential cut carefully for thickness on both medial and lateral condyles and for Varus/valgus angle and flex/extension angle. If potential alignment and cuts are as expected, proceed. The surgical plan will advise you of the expected thickness of each condyle cut.

5. Making the first cut:

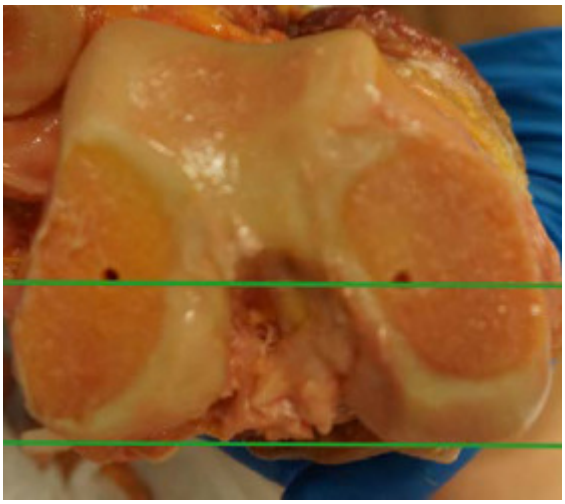
Remove the lateral condyle distal pin (red arrow location) and save for reuse. Replace this pin in the diagonal stabilization location as shown (blue arrow) pre-drill and pin as before. The diagonal stabilizer pin helps reduce possible guide shifting due to saw vibration. The medial pin (black arrow) 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, as well, 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 damage to the bone. Irrigation of the saw blade with saline while cutting may help reduce heat. Sequential slow smooth passes of the saw may also help reduce heat and contribute to more accurate cuts with less tendency to skive. Once the femur cuts are completed the planned thickness of the condylar cuts is accessed. Using a caliper, measure the thickness of the condyle sections removed both medial and lateral. The thickness of the cuts should match the plan. Once complete, the resection will appear like the photograph below. The expected slice thickness in the plan has been adjusted for the Kerf bone loss from saw blade thickness (1.27mm).



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

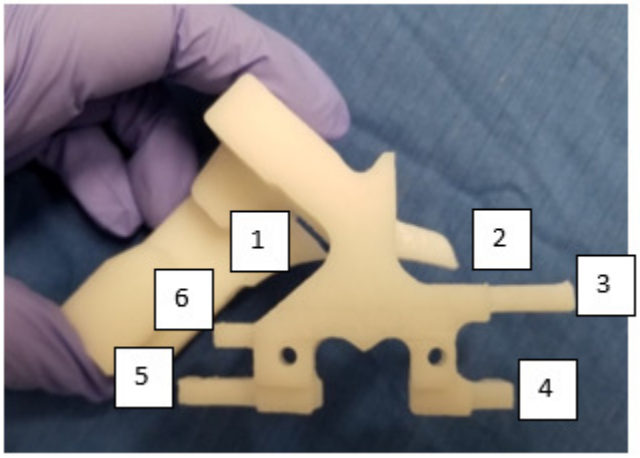
6. Making the chamfer cuts:

Correction of varus/valgus or flex-extension is more difficult after femur chamfer cutting. Occasionally, the pin holes of the PtoleKnee guide can be difficult 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 the alignment tool. The pins and guide are removed at this time.

The recommended size chamfer-cutting (4:1) block is placed once the distal femur cuts are verified and found acceptable. The accuracy of this primary cut is very important when returning to the selected standard TKR instruments. The location of the pin tract holes discussed and shown previously on the cut surface of the condyles may or may not match the spacing of the 4:1 chamfer block pin locations. The pin hole locations are accurate as to IR/ER orientation & AP spacing, however. Thus the 4:1 cutting block may reference these pin tract locations when applied to the cut condyle surfaces.

After placing the 4:1 cutting block, carefully check the block size chosen and the orientation and placement of the projected cuts using the Angel Wing resection checker. If all potential cuts are found acceptable, the cuts may be made. If the projected cuts are not satisfactory, reselect, reorient and adjust the 4:1 cutting block as required to effect the desired cut orientation.

7. Examine the Tibia Guide:

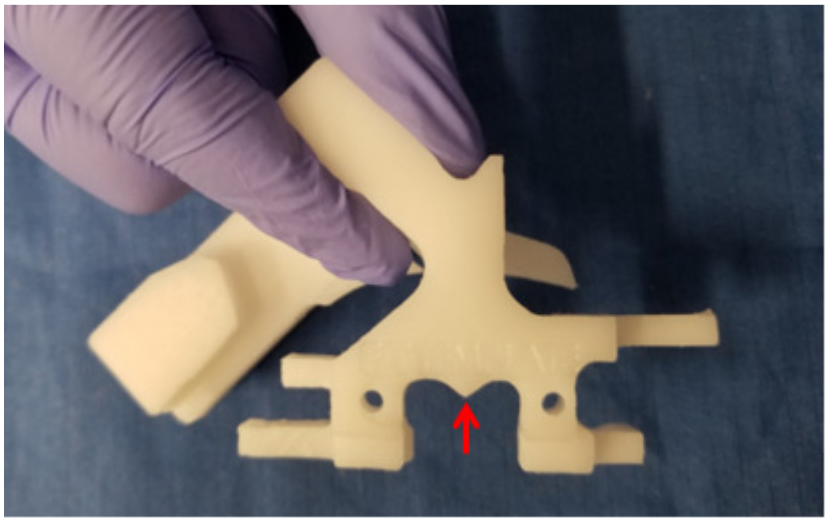


Shown are the six visible contact feet or points. Points 3, 4, 5 & 6 all contact the proximal surface of the tibial plateau. Points 1 and 2 contact the anterior lip of the tibia. As with the femur guide, inspect all guide surfaces for damage, debris and that the guide serial number and patient identifying,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

8. Preparation of the tibia:

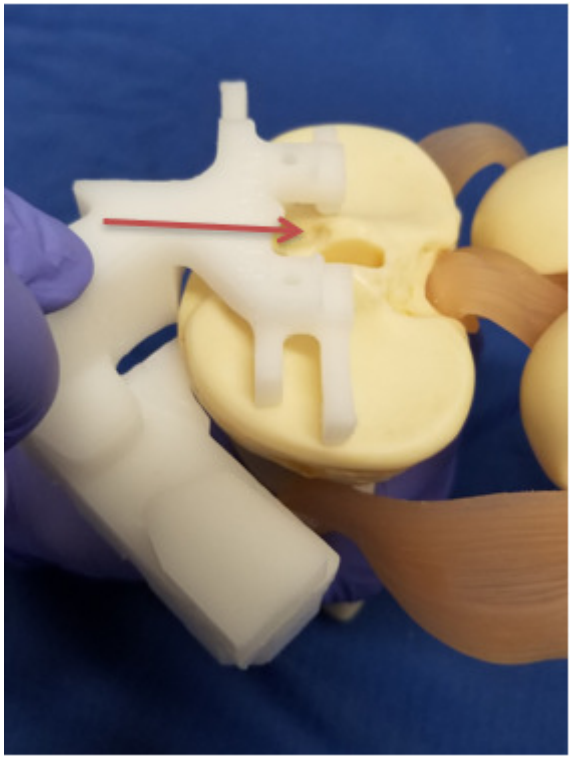
Remove all meniscus tissue. Do not remove osteophytes from the tibia unless instructed to do so. Clean the bone around the ACL stump and anterior to medial tibial lip where the guide fits. Remove any soft tissue that may interfere with proper placement of the ***PtoleKnee Surgical Guide***. It may be helpful to use a forked distractor/retractor posteriorly to better expose tibia and protect the Posterior Cruciate Ligament (PCL) from additional injury when sawing.

9. 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 guide is placed on the tibia. Orient the tibia guide with the central pointer aligned with the central spine of tibia as shown (red arrow).

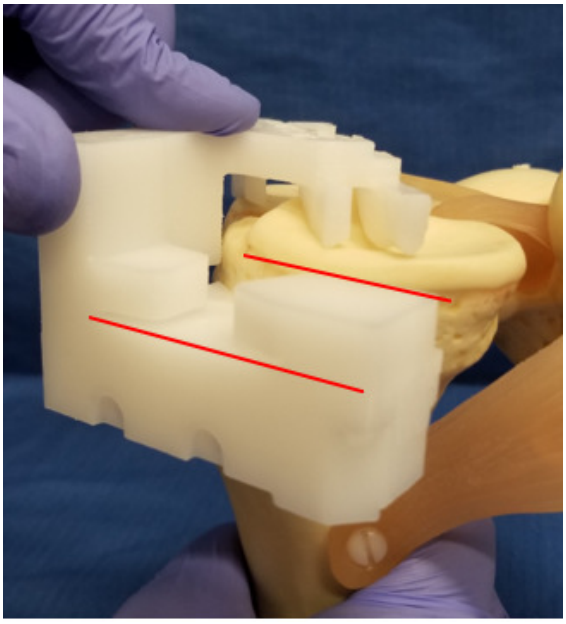
The ***PtoleKnee Surgical Guide*** contacts the anterior lip of the tibia and the cut slots center anteriorly and also extends medially. In some cases it may be necessary to extend the original parapatellar incision slightly to provide better guide access medially.



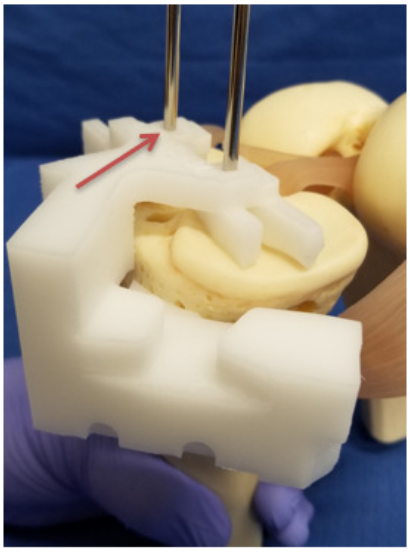
10. Check the contact points

From medial side, check 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.

*Check the Lateral Side as well.

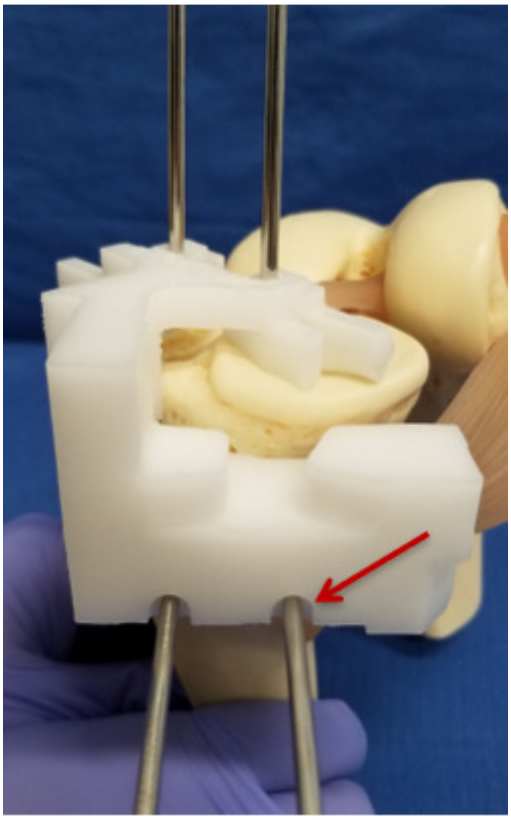


Also, from the medial side, check that the intended cut plane and natural tibial slope are approximately the same, as shown above. The exception to this is when a tibial slope changes during planning to a different cut angle. In this case, verify the new cut slope matches the planned cut slope.



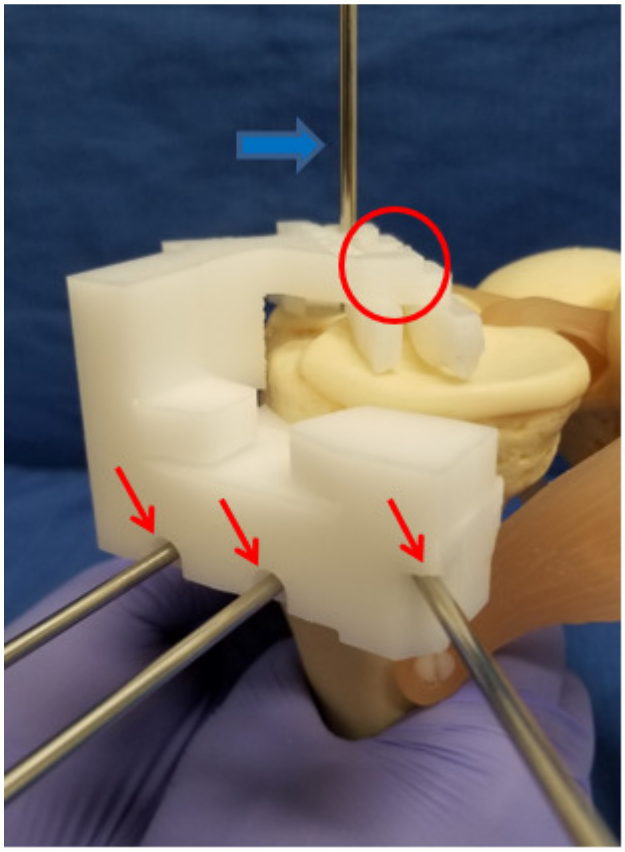
11. Drill and Set Pins for Tibia Guide

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



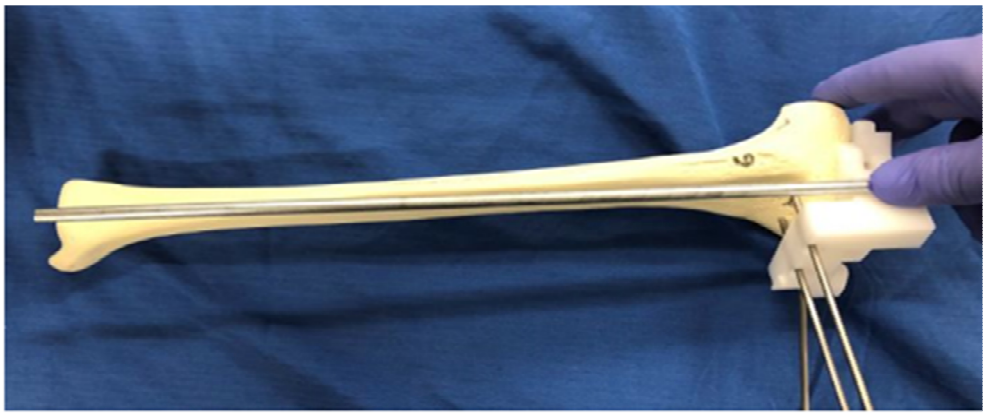
After the proximal pins are in place, continue to hold the tibia guide in place and re-verify all five (5) of the tibia guide contact points. If they are all still correctly in contact with joint surfaces, the two 3.2 mm anterior guide pins are now placed, beginning with the medial side (red arrow).

Setting the diagonal pin.



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.

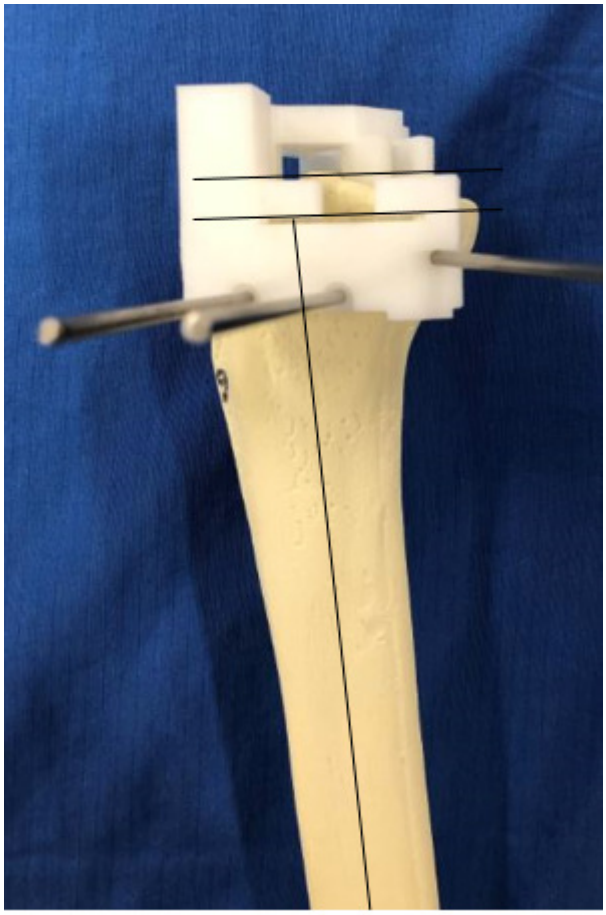
12. Tibial alignment Check



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.

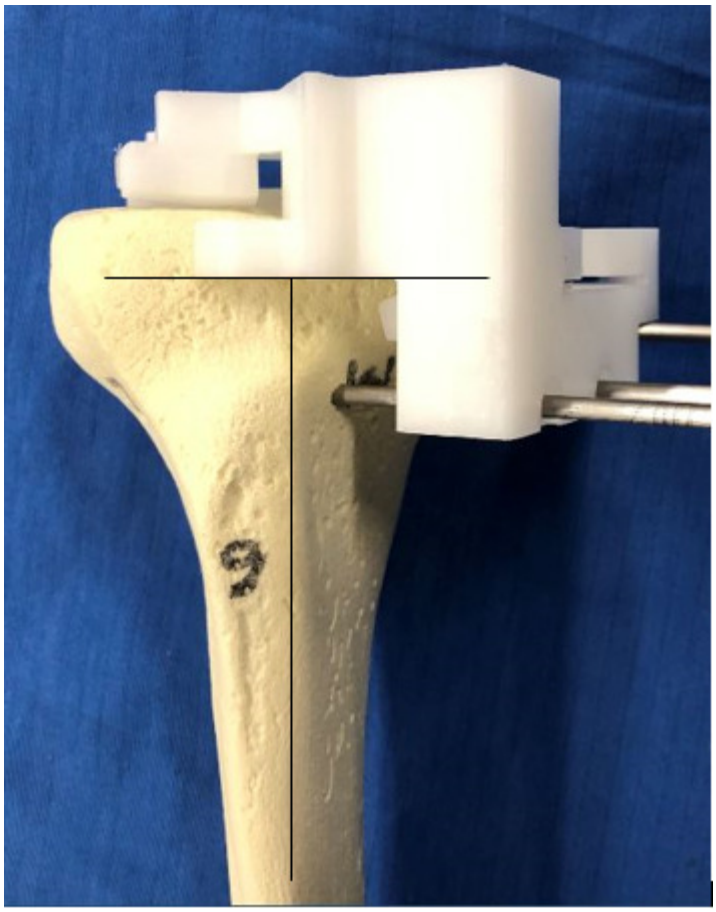
13. Verification of the tibial cut-plain angle:

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

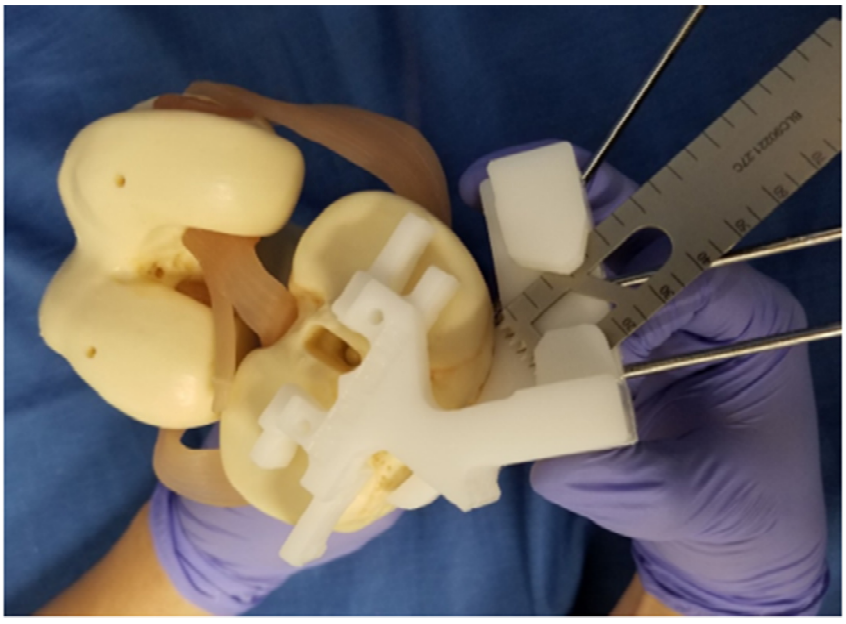


Tibial slope and depth of cut is expected to match the surgeons plan. In this case, 3 degrees posterior and 11 mm thick.

Assessment of the varus/valgus angle may be estimated using the long axis of the tibia 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, cut tibia using 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 remainder of surgery using manual instruments.

Position the ***PtoleKnee Surgical Guide*** on the tibia as shown. Like the femur guide, careful checking of guide positioning prior to cutting is essential. Verify all 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 TKR procedure using the standard instruments.

14. Resuming the standard TKR procedure:

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

Insertion of a Flex/Extension gap checker from the implant tray will allow assessment of the soft tissue tensioning and the final thickness of bone resected in both flexion and extension. Some implant brands will assess this at "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 will vary 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.