Lento PST® System

Instructions for Use – TKR Surgical Procedure

Document ID: LB-73-01-001
Model: Revision C

September 5 , 2019

Author:

Signature: _____ 9/5/2019
Date

Reviewed and Approved by:

Signature: _____ 9/5/2019
Date

Lento
PST System
Instructions for Use
TKR Surgical Procedure

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

Warnings:

- The Lento ***PST System*** has not been evaluated in a pediatric population therefor performance in such cases is unknown.
- The Lento ***PST System*** is a prescription only medical device.
- The Lento ***PST System*** is not a substitute for critical thinking and intra-operative adjustment of surgical goals based on education, training and experience of the surgeon.
- Lento ***PST System*** only provides and documents useful alignment and orientation information based on specific individual anatomic data obtained from current MRI image sources.
- The Lento ***PST System*** does not provide an absolute or only solution plan for joint replacement surgery; it only documents one possible approach.
- ***PST System*** 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.
- Lento ***PST System*** guides are for use by a surgeon experienced in the use of personalized surgical instruments (PSI-customized guides).
- ***PST System*** 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 ***PST System*** guides before use. Do not use guide if chipped, broken, cracked or debris is present.

NON-STERILE

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

Precautions:

- Use only MRI data of recent origin obtained per established Lento ***PST System*** designated MRI protocols.
- Take care to minimize excessive heat buildup from friction between PSI instruments and other instrumentation, such as drills/saws. Excessive heat buildup can lead to debris or deformation of the Lento ***PST System*** guide.
- Do not place heavy instruments on top of the Lento ***PST System*** guides during sterilization.
- PST 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 Lento ***PST 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 Lento ***PST 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 Lento ***PST System*** 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, case requires "tibia-cut-first" surgical techniques, case for uni-condylar replacement and for cases of TKR revision surgery.

NOTICE: Lento ***PST System*** Guides are intended to assist in the execution of a designated joint replacement (TKR) surgery and must be created using the Lento ***PST 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 On-line Help support:
Web:	http://www.lentomedical.com or http://www.lentomedical.net

Manufacturer:

Lento Medical, Inc.
15110 Northwest, Freeway, Suite 150
Houston, TX 77040 - USA
+1 (510) 413-3230

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

Indications for Use:

The Lento ***PST System*** 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 pining for a specifically named patient.

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

Acknowledgements:

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

EC REP

HealthLink Europe BV
De Tweeling 20-22
5215 MC's - Herrogenbosch
The Netherlands
Tel.: +31-13 5479300
Web: www.healthlinkeurope.com

HSA Health Sciences Authority
Singapore Government
Integrity · Service · Excellence

Introduction

These instructions cover the use of personalized surgical instruments designed using the Lento ***PST System*** surgical planning software to make TKR femur and tibial component alignment guides.

Important Notes:

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

- Serial # of *PST System* guides 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 ***PST System*** personalized guides.

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

Incision Length: MIS incisions are unlikely to provide sufficient access for use of ***PST System*** guides. A standard incision is essential to ensure accurate placement of the ***PST System*** guides.

Pre-operative Imaging Scan:
The initial step in the Lento ***PST 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 Lento ***PST System*** MRI web interface.
Pre-qualification of the imaging center by Lento is required prior to submitting scans for the ***PST 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 coil or the ability to remain motionless for the scan are not recommended for the ***PST System*** procedure.

The Lento *PST System*:
The ***PST 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' 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 Lento *PST System* 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	PST Instruments
1	Knee Exposure	Expose joint using standard approach. Allow enough exposure to allow seating of guide	NONE
2	Excise ACL	1. Excise the ACL	NONE
3	Femur Preparation	2. Place Femur Guide anteriorly on 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	Femur Guide

		4. Place angled anterior pin (stabilizer pin)	
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 tibia anterior 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 TKR	Return to standard TKR procedure	NONE

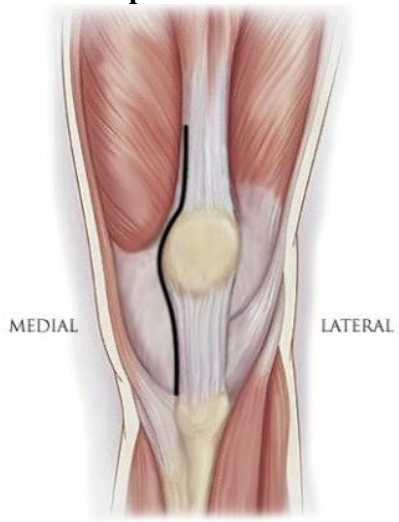
The Surgical Procedure:

Warning: If the Case ID markings do not match the patient and each other, **do not Use** the Lento ***PST System*** Guides for the surgery. **Use Standard Instruments**. Notify Lento 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 paraptellar 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.

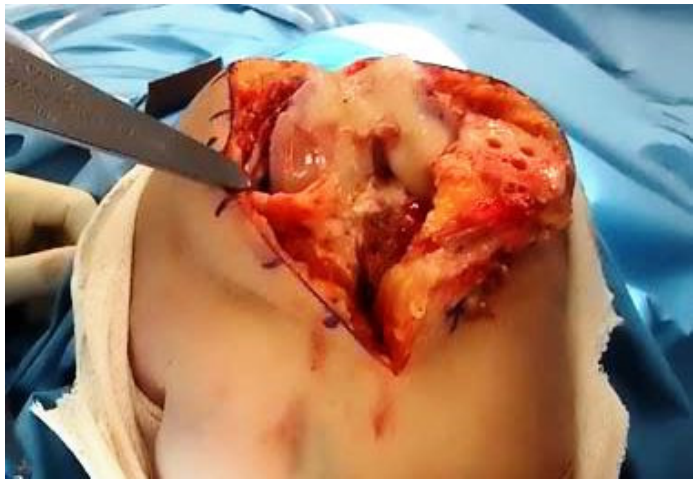
Parapatellar Incision



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 you normally 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. ***PST System*** guides are planned to affix in areas devoid of osteophytes. Their presence is generally not a detriment to proper fit of the guides.

Placing the Guides:

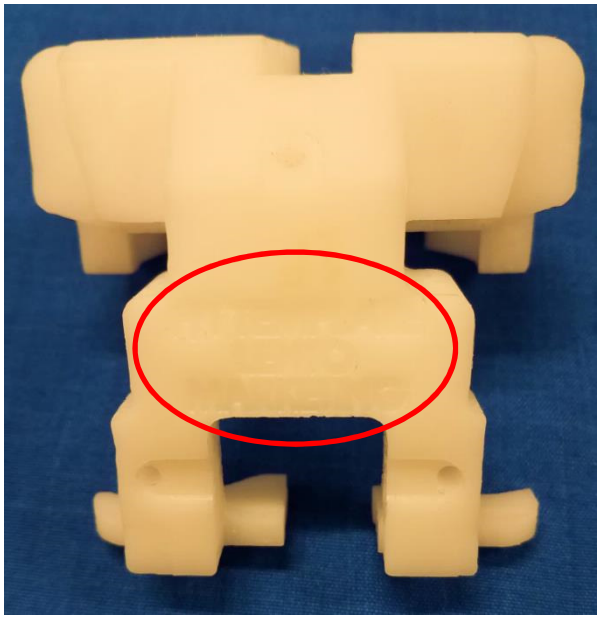
Place the guides sequentially beginning with the femur and finishing with the tibia. Whenever guides are placed, and before any bone cuts

are made, it is 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.

Examine the Femur Guide:

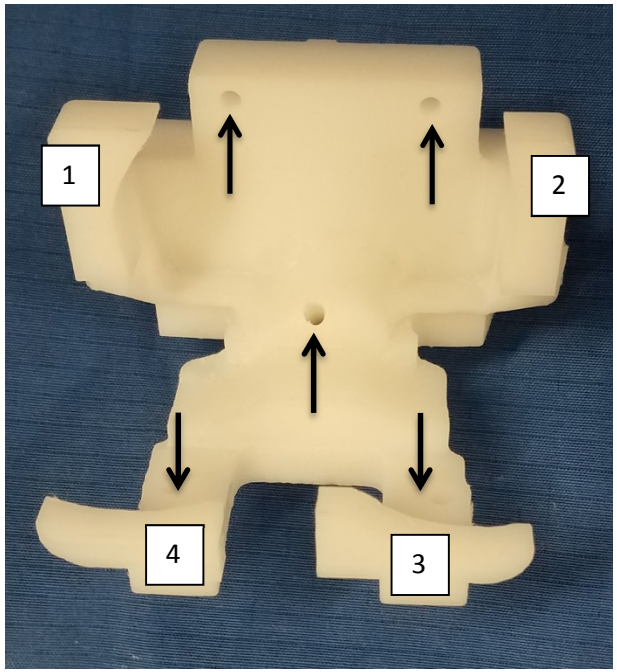
First, ascertain that you have received the correct guide. The face of the ***PST System*** guide contains the case identification information (red oval). Engraved here are the Guide Serial Number, Patient initial and ten alpha characters of the last name, DOB and knee descriptor.

AP View – Face



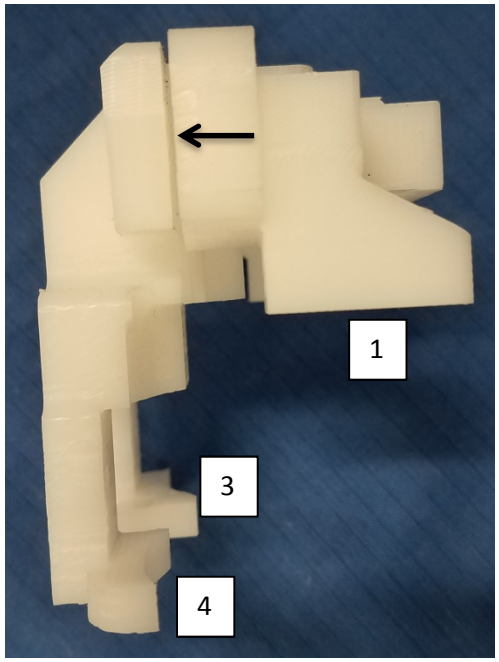
Next, examine the physical properties of the guide.

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 seven features carefully, they should be smooth and free of debris.

Medial - Lateral View

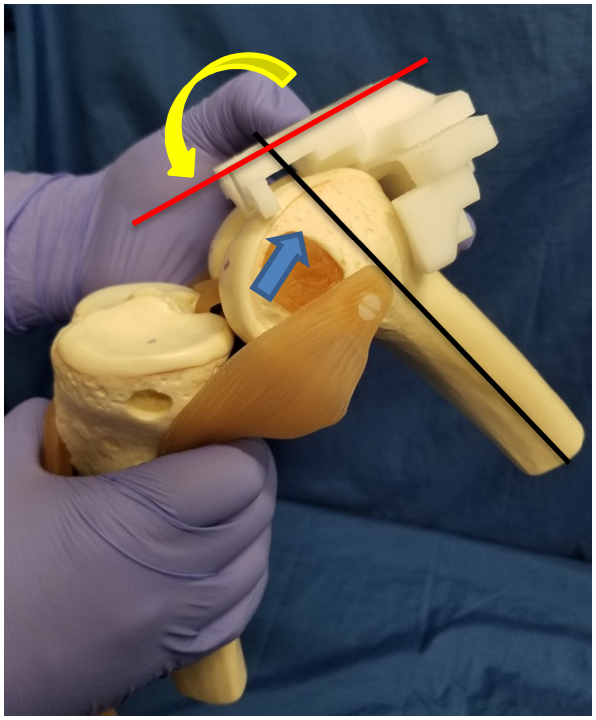


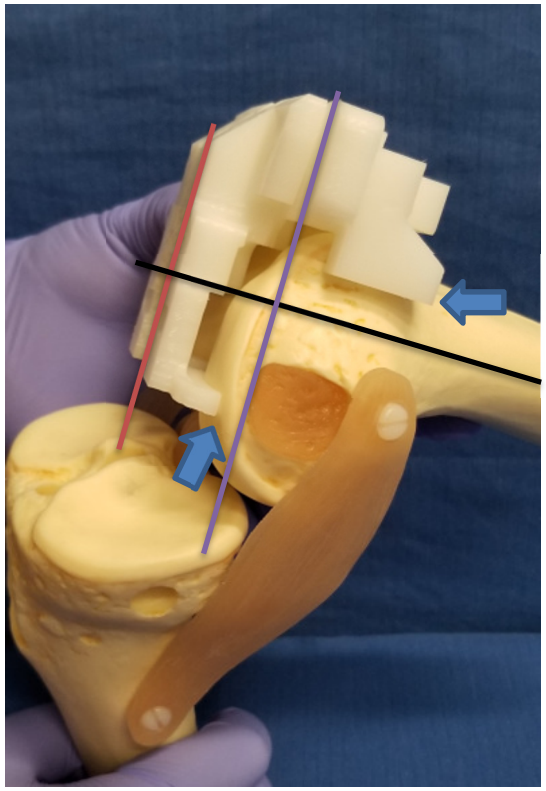
The lateral view above shows the cut slot indicated with a black arrow. Also depicted are the guide contact points. Also, note the contact points from the previous AP guide view. Guide contact point (2) is directly behind contact point (1). As explained previously, examine all surfaces and features carefully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

Placing the Femur Guide:

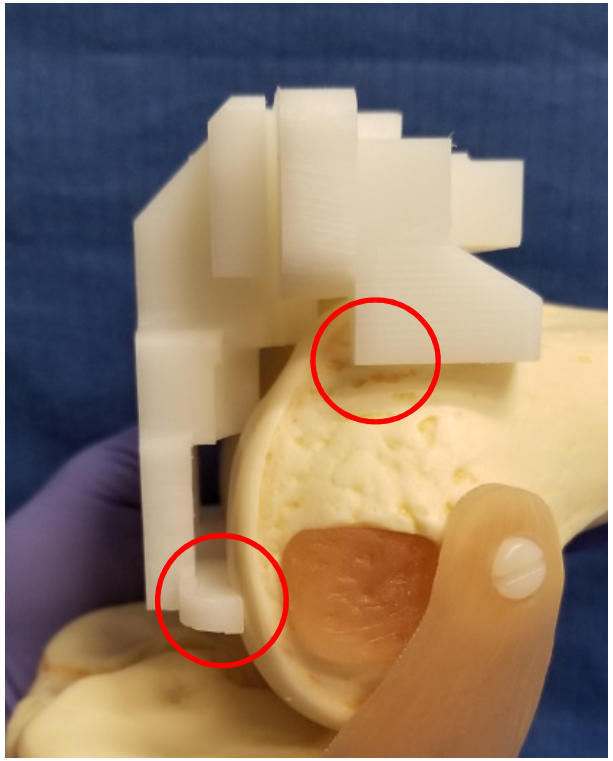
Initial placement of the femur guide is done by orienting the guide and the condyle contact feet slightly above the mid-point of the condylar curve to allow the superior feet to make initial contact slightly distal of the epicondylar area (blue arrow). The face of the guide (red line) should approximate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

The ***PST System*** 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.

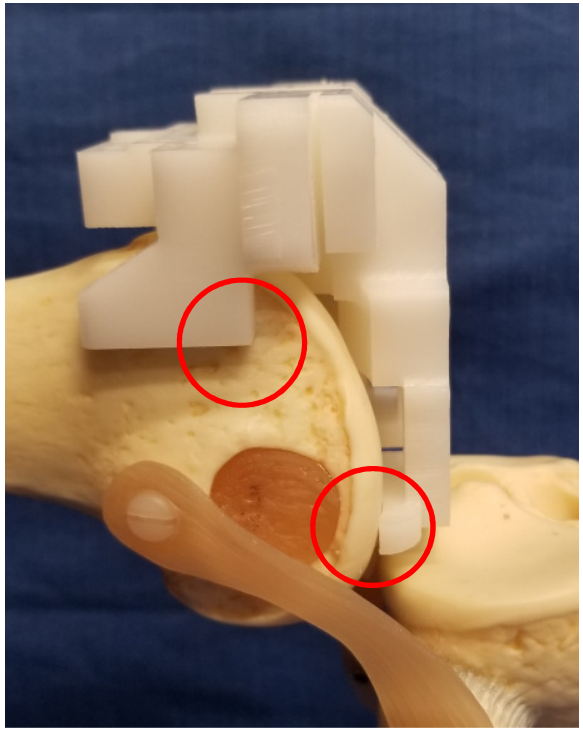




Once the guide is rotated posteriorly, the anterior and posterior feet of the guide make light contact with the anterior lateral and medial sides of the condyles and the distal condylar surfaces as shown (blue arrows). When properly positioned, the face of the guide (red line) will indicate the intended 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.



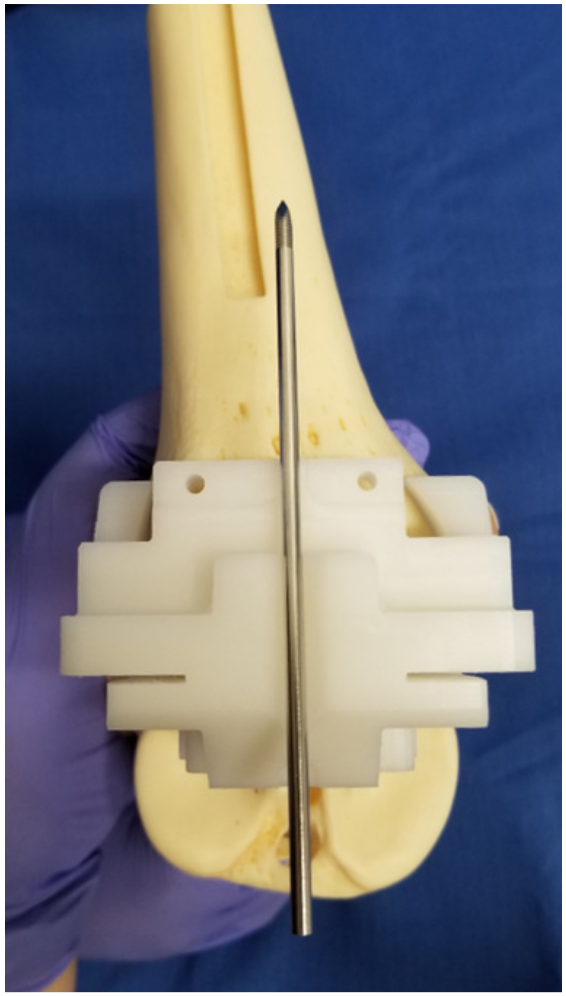
From medial side, verify position of medical guide contact points (red circles). Each contact point should lightly touch the surface of the tissue without using excessive force or excessive direct pressure. A small (less than 1.0 mm) gap may sometimes occur somewhere along the guide contact point surface.



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.

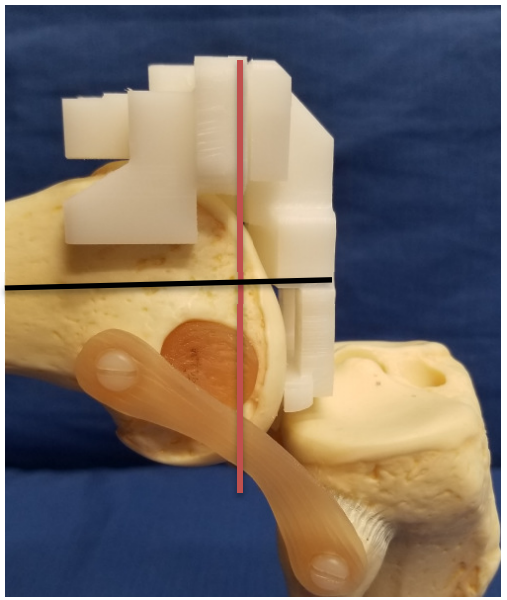
There are four tissue contact points (2 medial and 2 laterals) and one visual indicator (5th point). Verify the correct placement location of the guide before pinning or making any cuts.

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 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.