PIN GUIDE SYSTEM

with the SIGMA® High Performance Instruments System

Surgical Technique
Pin Guide Surgical Technique

The following steps are an addendum to the SIGMA High Performance (HP) Instruments, Fixed Reference Surgical Technique (Cat. No. 9075-02-000).

This surgical technique provides instructions on how to incorporate the use of the TRUMATCH™ Femoral and Tibial pin guides into the broader SIGMA HP Instruments Fixed Reference Surgical Technique. The surgeon must be familiar with the proper use of the appropriate instruments that are necessary to complete the operation following the use of the TRUMATCH femoral and tibial pin guides.

It is strongly recommended that the surgeon carefully reviews the TRUMATCH Patient Proposal prior to proceeding with the surgical procedure. The Patient Proposal is available through the web-based, password protected, TRUMATCH Personalised Solutions Web Portal. The Patient Proposal contains in-depth information used in the design of the patient specific guides including, as necessary, case specific remarks that are listed in the Notes/Comments section.
TRUMATCH SOLUTIONS PIN GUIDE

Basic Surgical Steps

SIGMA Total Knee System steps shown.

Tibial Preparation

- **Step 1:** Insert drill guides
- **Step 2A:** Tibial guide placement
- **Step 2B:** Tibial guide alignment
- **Step 3:** Use of uprod extension. Verification of V/V alignment and slope
- **Step 4:** Placement of anterior pins. Use of HP uprod
- **Step 5:** Removal of drill guide and pin guide. Anterior pins left in place
- **Step 6:** Proximal tibial resection

Femoral Preparation

- **Step 1:** Insert drill guides
- **Step 2:** Femoral pin guide placement
- **Step 3:** Drill anterior and distal pin holes and remove pin guide
- **Step 4:** Position the distal femoral cutting block with anterior reference guide
- **Step 5:** Use of angelwing to verify distal resection level
- **Step 6:** Distal femoral resection
- **Step 7:** Use of fixed reference guide to position the 4-in-1 block
- **Step 8:** Use of angelwing to verify anterior resection
- **Step 9:** Fixation of 4-in-1 cutting block or HP femoral A/P chamfer block
PROXIMAL TIBIAL RESECTION

The tibial pin guide (in addition to the product packaging label) will have patient specific identifiers: patient name, lot no., size and patient anatomy (R/L). Verify the accuracy of these identifiers prior to opening the sterile package (Figure 1).

Note: The size information was selected preoperatively based on the Patient Proposal. Final implant sizing may change due to intraoperative assessment of implant fit and/or joint gap balance.

Prior to use, insert the TRUMATCH drill guides (P/N 200420925) into the two anterior openings of the plastic tibial pin guide by twisting in a clockwise direction until tightened (Figure 2).

For optimal handling and placement stability of the tibial pin guide, first insert the HP Extra Medullary Tibial Uprod (P/N 950501228) into the anterior holes of the tibial pin guide. Then slide the Rod Extension (P/N 200420923) over the distal end of the uprod. This will lengthen it to reach the patient’s ankle. Then, grasp the guide using the medial and lateral finger pads (Figure 3A). Do not grasp the uprod or the area on which the metal drill guides are located. (Figure 3B).
With the knee flexed at 90 degrees, place the tibial resection guide and uprod assembly onto the proximal anterior medial aspect of the tibia and both plateaux. Avoid using excessive force to seat the guide. Apply most of the force anterior to posterior while holding the guide as described.

To assist in the medial/lateral positioning of the tibial pin guide, refer to the last page of the Patient Proposal that contains a top view of the patient’s tibial surface. It is recommended to observe the red line shown in the Patient Proposal to the patient’s bone and to check alignment with the raised line on the lateral aspect of the tibial pin guide (Figure 4).

The planned Varus/Valgus (V/V) alignment can be confirmed by verifying the alignment of the rod to the patient’s tibial crest (Figure 5). The rod is designed to be parallel with the mechanical axis of the tibia regardless of the planned tibial slope, when viewed laterally.

Note: The position of the line in the Patient’s Proposal references the medial one-third of the tibial tubercle and not the middle of the tibial crest (Figure 4).

Note: It may be necessary to clear extraneous tissue along the anterior medial aspect of the tibia. Soft tissue impingement can impact the fit of the guide and overall alignment or slope. Vision for proper seating may be improved when the guide is observed from a sagittal or side view.

Note: To position the guide, it is helpful to apply most of the pressure to the anterior aspect and the remaining pressure to the proximal aspect of the guide. This will help assure proper seating of the guide at the appropriate resection level. The correct position is found when there is minimal or no toggling/rocking of the tibial pin guide.

Once the tibia pin guide and uprod assembly is in the desired position, while holding it in place, secure it to the bone by inserting two (recommended P/N 9505-02-302) pins, first through the lateral and then the medial, drill guide pin holes (Figure 6).
PROXIMAL TIBIAL RESECTION

After drilling the two anterior pins, the TRUMATCH drill guides are removed by twisting in a counter-clockwise direction, while leaving the two anterior pins in place (Figure 7). Remove the tibial pin guide by moving it up and pulling it away from the anterior fixation pins.

Slide the appropriate L/R 0 degree HP Proximal Tibial Cutting Block over the anterior fixation pins through the “0” mm holes marked with a square. (Figure 8) If desired, confirm the cut orientation with the angelwing. If necessary, the block may be shifted 2 mm proximally or distally by selecting one of the offset holes adjacent to the “0” mm hole. Perform the proximal resection with a 1.19 mm saw blade.

Remove the HP tibial cutting block and make sure bone cuts are clean and void of any under-cut bone fragments.

Note: If additional tibial resection or tibial slope is desired, remove the two anterior fixation pins and use the appropriate SIGMA HP Instrument Tibial resection guide.

Note: The arthritic disease process can cause adaptive bone changes that result in hard, sclerotic bone in the affected tibial condyle, thus making resection difficult. A solution is to start the tibial cut on the “least affected” or the side opposite to the more involved tibial condyle. This will provide an easier entry cut in the intended orientation and sets the path for the continued saw blade sweep through the hard, sclerotic bone of the involved plateau.

Proceed with the remaining surgical steps for distal femoral and proximal tibial preparation, and trialling, as outlined by the SIGMA HP Instruments Fixed Reference Surgical Technique.
DISTAL FEMORAL RESECTION

The femoral pin guide (in addition to the product packaging label) will have patient specific identifiers: patient name, lot no., size and patient anatomy (R/L). Verify the accuracy of these identifiers prior to opening the sterile package (Figure 9).

Note: The size information was selected preoperatively based on the Patient Proposal. Final implant sizing may change due to intraoperative assessment of implant fit and/or joint gap balance.

Prior to use, insert the TRUMATCH drill guides (P/N 200420925) into the two anterior and two distal openings of the plastic femoral pin guide by twisting in a clockwise direction until tightened (Figure 10).

With the knee flexed to at least 90 degrees, place the femoral pin guide over on the anterior aspect of the femur and position the “feet” of the guide over the distal femoral condyles (Figure 11A). Avoid using excessive force to seat the guide. Care should be taken to avoid squeezing the block and causing the legs to deform while pins are being placed (Figure 11B).

The majority of the finger pressure (~75%) should be applied on the anterior aspect of the guide while applying light pressure (~25%) over the distal aspect of the guide.

Note: Soft tissue impingement may cause difficulty in seating the femoral pin guide on the femur and could impact the overall alignment of the guide. It may be necessary to clear extraneous soft tissue from the anterior aspect of the femur to facilitate proper placement of the guide. Improved vision for proper seating may be enhanced when the guide is observed from a sagittal or side view.
DISTAL FEMORAL RESECTION

Evaluate the placement of the guide. The correct position is found when there is minimal or no toggling/rocking of the femoral pin guide. It is not uncommon to see a 1 to 2 mm gap around the periphery of the guide due to cartilage loss.

Insert two anterior pins and drill two distal holes using the appropriate drill guides (Figure 12).

The anterior holes will be used to place the HP distal femoral cutting block to perform the distal femoral cut. The distal holes set the femoral rotation and match the fixed reference pin placement of the SIGMA HP femoral A/P chamfer block.

Extract the two anterior and two femoral pins and remove femoral pin guide by flexing the guide from posterior to anterior.

Note: The TRUMATCH drill guides are reusable after sterilisation. A minimum of four (4) drill guides should be on hand for a case.

Attach the Universal Handle to the Anterior Fixed Reference Guide (P/N: 2004-20-926) and position the guide’s spikes through the “0” mm holes, marked with a square, in the SIGMA HP Distal Femoral Resection Block (Figure 13).
Evaluate the distal cut using the reference guide or angelwing (Figure 14A). If needed, the block may be shifted 2 mm proximally or distally by selecting one of the appropriate offset holes adjacent to the “0” mm hole.

For additional stability during the cut, an optional third, fixation pin can be placed through the cutting block in either the lower medial or lateral holes. Perform the distal femoral resection using a 1.19 mm thick saw blade (Figure 14B).

Remove the HP Distal Femoral cutting guide and confirm the bone cuts are clean and without any under-cut bone fragments.

Note: In order to address gap assessment and ligament tension, it may be necessary to re-cut 2 or 4 mm of additional bone from the distal femur or the proximal tibia. The HP spacer block and alignment rod are useful in assessing leg alignment and gap balance.
FEMORAL PREPARATION - A/P AND CHAMFER CUTS

Attach the Universal Handle to the Distal Fixed Reference Guide (P/N: 2004-20-920) and position the guide's spikes through the “0” mm holes marked with a square located at the bottom of the SIGMA Femoral Fixed Reference A/P chamfer block (Figure 15). Insert the construct spikes into the previously drilled holes located on the distal femoral bone cut.

![Figure 15](image15)

Evaluate the anterior cut with the angelwing (Figure 16). If desired, the block may be shifted 2 mm anteriorly or posteriorly by selecting the appropriate offset holes adjacent to the “0” mm hole marked with the square. (See notes section on page 11 for additional detail).

![Figure 16](image16)

Secure the block’s location by inserting threaded headed pins into the convergent pin holes on the medial and lateral aspect of the A/P chamfer block. Remove the handle/fixed reference guide assembly and perform the femoral resections (Figure 17). After performing all cuts, remove the pins and cutting guide, making sure bone cuts are clean and void of any under-cut bone fragments.

![Figure 17](image17)
Note: If the Distal Fixed Reference Guide (P/N: 2004-20-920) is unavailable, two fixation pins can be inserted in the previously drilled distal femoral holes and used to set the location of the HP Femoral A/P chamfer block. The TRUMATCH Femoral Pin guide is designed to position the pin holes posteriorly on the femur which maintains the ability to move the block to resect 2 mm more bone anterior or 2 mm more bone posterior with the same size block regardless of whether the surgeon preference is anterior-down or posterior-up. However, if it is necessary to downsize the femoral component, the pin placement references a posterior-up preference and the smaller femoral block can be inserted over the posterior placed pins. This will keep the posterior resection in the same plane and take additional anterior femoral bone. In order to address an anterior-down preference and the ability to downsize the component, drill two fixation pins through the “0” mm holes, marked with a square with the planned femoral block. Remove the femoral block and use these anterior placed pins with the smaller block when downsizing. This will keep the anterior femoral resection in the same plane and take additional posterior femoral condylar bone. Use caution regarding the SIGMA Knee System, the HP SIGMA RP-F, SIGMA CR-150 and the standard SIGMA Fixed Reference A/P and chamfer cutting blocks. These look very similar. Care should be taken to use the appropriate block. Use of an incorrect block could result in under or over resection of the posterior femoral condyles.
**Preoperative Considerations**

### Order Submission
Evaluate the M/L Joint Space Loss using weight-bearing knee joint radiographs and provide the values with the order submission. These values are an important part of the algorithm used to determine the cartilage offset for proper positioning of the guides. For ease of assessment, it is sufficient to select from “0”, “50” or “100” % of Joint Space Loss, for the affected side, without affecting the guide design accuracy. The optional Order Form (Figure 18) can be used to collect the information required to submit the TRUMATCH Solutions order online.

### Patient Proposal
- a. Review the entire document in detail prior to the surgery.
- b. Review the Notes/Comments section for important information from the TRUMATCH Design Team; regarding the design of the guides.
- c. Print in Colour! All Notes/Comments will be shown in red.
- d. For intraoperative reference, display the wall chart summary page (Figure 19) at an easy to read location in the OR; such as the light box or back wall.

### Intraoperative Check-List
Review the Wall Chart Summary (last page), that contains bone resection information and the tibial guide orientation line.

The bone resection information can be used to verify if bone cuts are within 2 mm of the planned values shown. In particular, the relationship between the medial and lateral cuts should be noted. If both cut measurements are proportionally similar (i.e. deviate by a similar amount), then the varus/valgus alignment is preserved. Otherwise, it is an indication that the guide placement and/or bone resection(s) should be re-visited.

For clarity, the tibial resection thickness, shown for each condyle, is measured from the lowest point on the middle third of the respective condyle.
Intraoperative Considerations

Fixation Pins and Saw Blades
a. The SIGMA HP Threaded Headless Sterile Pins (9505-02-302), combined with the HP driver (9505-02-071) are recommended for firmly securing the guides, especially for the tibial guide when used in soft bone.

b. For efficient resection of large bones, select the longest blade possible, such as 12.7 mm (0.5 in) wide x 1.19 mm (.05 in) thick.

Femoral Resection Guide
a. The femoral guide’s primary reference surface is the anterior cortex of the femur (Figure 20). The most upper portion of the guide should clear the anterior femoral flange and sit flush on the cortical surface. It may be necessary to remove the thin soft tissue to expose the underlying bone.

b. Distally, a gap may be seen between the guide and the femoral condyles. If the guide is securely positioned anteriorly, do not force the guide’s arms to sit flush on the femoral condyles.

If the femoral pin guide does not fit, verify the following:
1) Was the tissue in the anterior surface of the femur removed and is the proximal portion of the guide sitting on bone?

2) Did the upper guide portion clear the anterior femoral flange and is it sitting on the anterior cortex?

3) Is the incision preventing the placement of the guide on the bone? The incision must be large enough to provide a clear view of the guide fit to bone.
Intraoperative Considerations

Tibial Resection Guide

a. The tibial guide’s primary reference surface is the anterior/medial aspect of the tibia. This area, roughly triangular in shape, matches the guide’s largest surface contact area (Figure 21). When positioning the guide, apply most of the pressure (~75%) against the anterior aspect of the tibia. It may be necessary to remove the thin soft tissue to expose the underlying bone.

b. If the guide is securely positioned anteriorly, do not force the guide’s arms to sit flush on the tibial plateau. While applying force anteriorly, apply light downward force (~25%) on the guide’s proximal arms to hold the guide stable while drilling the anterior pins.

If the tibial guide does not fit, verify the following:

1) Is the incision preventing placement of the guide on the bone? The incision must provide a clear view of the guide fit on the bone.

2) Check for interference of the lateral aspect of the guide with the patellar ligament.

3) Confirm that both of the guide’s proximal arms are not impinged by tissue close to the tibial spine.

4) Check the Patient Proposal; was the Joint Space Loss reported to be 100% for either of the condyles and the actual patient has little to no joint space loss? If so, scrape the condyle where full joint loss was requested.
The patient-specific components of TRUMATCH are custom-made medical devices within the EU Council Directive 93/42/EEC. Standard products referenced in this surgical technique are CE marked.