CUTTING GUIDE SYSTEM

with the SIGMA® High Performance Instruments System

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 instruction on how to incorporate the TRUMATCH™ femoral alignment/distal and tibial alignment/proximal resection guides into the broader SIGMA HP Instruments Fixed Reference Surgical Technique. As such, the surgeon must be familiar with the proper use of the SIGMA HP Instruments, as these are required in steps prior to, and following, the utilisation of the TRUMATCH femoral and tibial resection guides.

The surgeon must also carefully review the customised TRUMATCH Patient Proposal prior to proceeding with the surgical procedure. The Patient Proposal is available through the web-based, password protected, TRUMATCH Personalised Solutions portal.

The Patient Proposal contains in-depth information utilised in the design of the customised guides including, as necessary, requests that are listed in the Notes/Comments section about resection of impinging osteophytes for proper block placement and fit.
BASIC TRUMATCH SOLUTIONS SURGICAL STEPS

Femoral Preparation

Step 1: Femoral block positioning

Step 2: Placement of anterior pins

Step 3: Drill and placement of distal pins

Step 4: Distal femoral resection

Step 5: Use of the fixed reference to position the 4-in-1, chamfer block

Step 6: Use of the angelwing to verify anterior resection

Step 7: Placement of chamfer block pins and removal of the fixed reference guide

Tibial Preparation

Step 1: Tibial block placement aided by customised patient proposal

Step 2: Placement of two anterior pins

Step 3: VV verification with alignment adapter and rod

Step 4: Placement of divergent locking pin

Step 5: Tibial plateau resection
DISTAL FEMORAL RESECTION

These are custom-made devices. The femoral alignment/distal resection guide (including the guide packaging) is supplied with patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (right/left). Please verify the accuracy of these identifiers prior to use (Figure 1).

Place the femoral alignment/distal resection guide onto the distal aspect of the femur while in flexion of approximately 90 degrees (Figure 2). Due to the large amount of contact area between the guide and the bone, it may be easier to position the guide by seating the anterior aspect of the guide on the anterior cortex first (Figure 2) and then toggle the device posteriorly. Avoid using excessive force to seat the guide, as it is not needed.

Note: It may be necessary to clear extraneous tissue along the anterior cortex as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualisation of the proper seating may be possible if the guide is viewed from a sagittal viewpoint. See the Surgical Tips and Pearls section for further information.

Once the optimum position is found for the femoral alignment/distal resection guide, check that it allows no toggling or rocking. It is not uncommon to see a 2 to 3 mm gap around the periphery of the guide due to cartilage loss.

When placement is optimised, secure the femoral alignment/distal resection guide by inserting one threaded 3.25 mm pin through the anterior medial hole (Figure 3). After the medial pin is secured, place another pin through the lateral pin hole (Figure 3).
After the femoral alignment/distal resection guide is secured, drill the two distal holes with a 3.25 mm drill bit. Pins placed in these holes set the femoral rotation and match the A/P chamfer block from the standard instrument set (Figure 4).

Prior to cutting, the pins may be removed. However, it is recommended to perform the distal femoral resection by leaving one distal pin in the block while resecting the opposite side of the femur.

Perform the distal femoral resection with a 1.19 mm blade (Figure 5).

Remove the femoral alignment/distal resection guide. Make sure the bone cuts are clean and cleared of any under-cut bone fragments.

Note: In order to adjust ligament tension, it may be necessary to recut the distal aspect of the femur or the proximal aspect of the tibia to achieve proper balance. In these instances, the anterior location of the pins are compatible with the regular HP Instruments distal femoral cutting or tibial resection guides. Both guides can be used to cut either 2 or 4 mm of additional bone. These guides fit over pins placed in the previously drilled guide pin locations.
FEMORAL PREPARATION - A/P AND CHAMFER CUTS

Attach the Universal Handle to the Fixed Reference Guide and position the guide’s spikes on the 0 mm pin holes of the SiGMA Fixed Reference A/P chamfer block (Figure 6). Once the handle/guide/block assembly is put together, insert the guide’s spikes into the existing holes located on the distal femoral bone cut.

Note: The TRUMATCH femoral block is designed to position the pin holes posteriorly while maintaining the desired “anterior down” or “posterior up” fixed reference selection. Be aware that the SIGMA RP-F and standard SIGMA A/P and chamfer cutting blocks look very similar. Care should be taken not to confuse the blocks as this will result in under or over resection of the posterior condyles.

Confirm the anterior cut placement with the reference guide, or angelwing (Figure 7). If desired, the block may be shifted 2 mm anteriorly or posteriorly by selecting one of the offset holes around the “0” hole. When downsizing, using the smaller A/P chamfer block and the most anterior pin holes will take 2 mm more bone anteriorly and 2 mm less bone posteriorly.

Secure the location of the block by inserting headed threaded pins into the convergent pin holes on the medial and lateral aspect of the A/P chamfer block. Once completed, remove the handle/fixed reference guide assembly and perform the femoral chamfer cuts in the regular manner (Figure 8).
PROXIMAL TIBIAL RESECTION

These are custom-made devices. The tibial alignment/proximal resection guide (including the guide packaging) is supplied with patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (right/left). Please verify the accuracy of these identifiers prior to use (Figure 9).

Place the tibial alignment/distal resection guide onto the proximal aspect of the tibia while in flexion of approximately 90 degrees. Avoid using excessive force to seat the guide, as it is not needed. To assist in the M/L positioning of the tibial resection guide, the last page of the Patient Proposal document contains a top view of the tibial surface. As shown in the Proposal’s customised view, align the line on top of the tibial resection guide with the one displayed on the tibial bone (figure 10).

Note: It may be necessary to clear extraneous tissue along the anterior aspect of the tibia as this may cause the guide to not seat properly. Be careful to avoid any soft tissue impingement, as this will impact the overall alignment of the resection guide. Better visualisation of the proper seating may be possible if the guide is viewed from a sagittal viewpoint.

To position the guide, it is helpful to apply approximately 25% pressure to the proximal aspect and 75% pressure to the anterior aspect of the guide. This will aid in seating the guide to arrive at the appropriate resection level. Once the optimum position is found for the tibial alignment/proximal resection guide, check that it allows little to no toggling or rocking.

When placement is optimised, secure the resection guide by inserting one non-headed threaded 3.25 mm pin through the medial hole. After the medial pin is secured, place another pin through the lateral pin hole (Figure 11).
After selecting the proper right/left orientation of the Alignment Verification Adapter (rod holes to be lateral) insert one of the two HP Alignment Rods. Then, insert the adapter’s blade into the resection guide’s saw slot (Figure 12).

Confirm the Varus/Valgus (V/V) position of the guide by verifying that the rod distally lies along, or parallel to, the patient’s tibial crest. If the V/V alignment is not acceptable, check for proper seating, soft tissue impingement or proper M/L orientation of the resection guide. If necessary, remove the fixation pins and reposition the resection guide following the steps previously described. See Surgical Tips and Pearls section for further information.

Once the V/V alignment of the resection guide is satisfactory, insert an additional pin in the distal hole. This hole will place the pin in a divergent path to add stability (Figure 13).

Note: Optionally, the tibial resection guide can be V/V aligned and fixed by a) positioning it M/L, as described, aided by the image in the Patient Proposal; b) inserting only the medial fixation pin; c) using the alignment adapter/rod assembly, verify the V/V alignment of the guide d) manually holding the guide and inserting the remaining two fixation pins.

Perform the proximal tibial resection with a 1.19 mm blade (Figure 14).

After removing all fixation pins and the tibial resection guide, make sure bone cuts are clean and cleared of any under-cut bone fragments.

Note: If additional tibial resection or tibial slope is desired, replace the two proximal fixation pins and use the appropriate SIGMA HP Instrument's tibial resection guide.

Proceed with the remaining steps for proximal tibial preparation as outlined by the SIGMA HP Instruments Surgical Technique.
Order Form
a. Take careful consideration when estimating the M/L "Joint Space Loss" by using weight bearing knee joint radiographs and providing it with the order submission. This value is an important part of the algorithm used to design the cartilage offset for proper positioning of the blocks.

Patient Proposal
a. Review this in detail prior to the surgery.

b. Review the Notes/Comments section for information from the TRUMATCH Solutions design team regarding the design of the blocks and/or requests for removal of osteophytes.

c. Print in Colour! A request for resection of osteophytes will be shown in red on the appropriate bone(s) (Figure 15).

d. For intraoperative reference, display at an easy to read area in the OR, such as the light box or back wall.

e. Review the Intraoperative check-list (last page), which contains bone resection information and tibial block orientation view (Figure 16).
Fixation Pins
a. The SIGMA HP threaded, headless and sterile pins (9505-02-302), combined with the HP driver (9505-02-071), are recommended for firmly securing the blocks, especially for the tibial block when used on soft bone.

Femoral Resection Block
a. The femoral block’s primary reference surface is the anterior cortex of the femur (Figure 17). The uppermost portion of the block should clear the anterior femoral flange and sit flush on the bone cortex. It may be necessary to remove the thin soft tissue to expose the underlying bone. When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the femur.

b. Distally, a gap may be seen between the block and the femoral condyles (Figure 17). If the block is securely positioned anteriorly, do not force the block’s arms to sit flush on the femoral condyles. While applying anterior force apply light force (~25%) distal-to-proximal, to stabilise the block. Secure it by inserting the anterior fixation pins.

c. After performing the distal femoral resection and removing the block, examine the posterior aspect of the block’s arms. If it appears to be damaged by the saw blade, that respective condyle cut is likely to be undercut and out of plan. The block should be repositioned and the cut repeated (Figure 18).

If the femoral block 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 block sitting on bone?

2. Did the block upper portion clear the anterior femoral flange and is it sitting on the bone cortex?

3. Is the incision preventing placement of the block on the bone? The incision must provide a clear view of the block fit to bone.

4. Check the Patient Proposal, does it require removal of osteophytes? These are highlighted in red.
Tibial Resection Block

a. The tibial block’s primary reference surface is the anterior/medial aspect of the tibia. This area, roughly triangular in shape, matches the block’s largest surface contact area located below the saw slot (Figure 19). When positioning the block, apply most of the pressure (~75%) against the anterior aspect of the tibia. It may be necessary to remove the thin soft tissue, and/or non-osseous osteophytes, to expose the underlying bone (Figure 20).

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

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

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

2. Check that the lateral aspect of the block is not sitting on the patellar tendon.

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

4. Check the Patient Proposal, does it require removal of osteophytes? These are highlighted in red.

5. Check the Patient Proposal, was the “Joint Space Loss” reported to be 100% for either of the condyles, although the actual patient has little to no joint space loss? If so, scrape the condyle where full joint loss was requested.
The TRUMATCH Personalised Solutions system is currently targeted for patients with osteoarthritis who:

1) Meet the criteria for primary fixed and mobile bearing total knee replacement performed with a measured resection technique.
2) Have mild bone deformities and/or angular deformities less than 15 degrees of fixed varus, valgus, or flexion.

Some previous implants are acceptable, including hip implants, ankle implants, and soft tissue anchors. Contralateral knee replacement is acceptable as long as the contralateral knee is flexed away (not within the same medial/lateral axis) from the knee of interest during the CT scan. Please refer to the TRUMATCH CT Centre User Guide for more information.

**Contraindication Criteria**

The following conditions are not compatible with TRUMATCH Personalised Solutions:

- Previous knee replacement of the same knee.
- Femoral nails and bone plates that extend into the knee, or within 8 cm from the joint line.
- Any metal device that will cause scatter in the CT through the knee.
- Angular deformities greater than 15 degrees of fixed varus, valgus, flexion, or tibial slope exceeding 15 degrees.
- Moderate to severe bony deformities, Charcot knees, or patients with severe patella tendon calcification that may prevent patella eversion.

The patient-specific components of TRUMATCH are custom-made medical devices within the EU Council Directive 93/42/EEC. Standard products reference in this surgical technique are **CE** marked.