

TruMatch®  
PERSONALIZED SOLUTIONS

**SIGMA**®  
HIGH PERFORMANCE  
INSTRUMENTS

# TRUMATCH® Personalized Solutions

with SIGMA® High Performance Instruments

## Resection Guide & Pin Guide Systems



# Resection Guide & Pin Guide Surgical Techniques

The following steps are an addendum to the SIGMA® High Performance (HP) Instruments, Fixed Reference Surgical Technique.

This surgical technique provides instruction on how to incorporate the TRUMATCH® Solutions Femoral and Tibial Resection Guides, Pin Guides and Hybrid (Femoral Resection Guide & Tibial Pin Guide) Kits 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 utilization of the TRUMATCH Personalized Solutions Femoral and Tibial Resection Guides, Pin Guides and Hybrid Kits.

It is strongly recommended that the surgeon carefully review the TRUMATCH Personalized Solutions Patient Proposal prior to proceeding with the surgical procedure. The Patient Proposal is available through the web-based, password protected, TRUMATCH Personalized Solutions portal ([www.depuysynthes.com/trumatch](http://www.depuysynthes.com/trumatch)).

The Patient Proposal contains in-depth information utilized in the design of the patient-specific guides including, as necessary, requests that are listed in the Notes/Comments section.

**Note: The TRUMATCH Personalized Solutions Resection and Pin guides are provided sterile. If sterility becomes compromised, discard the guide and complete the surgery with the SIGMA HP Instrumentation.**

## Reusable instruments compatible with the TRUMATCH Personalized Solutions Surgical Technique

### Resection Guide

Product Code	Product Name	Femoral	Tibial
2004-20-920	Distal Fixed Reference Guide	●	
2000-42-062	Alignment Verification Adapter		●
9505-01-207	HP Alignment Rod		●

### Pin Guide

Product Code	Product Name	Femoral	Tibial
2004-20-926	Anterior Fixed Reference Guide	●	
2004-20-920	Distal Fixed Reference Guide	●	
9505-01-228	EM Tibial Jig Uprod		●
2004-20-925	Drill Guides	●	●



**DePuy Synthes**  
JOINT RECONSTRUCTION



**TruMatch**  
PERSONALIZED SOLUTIONS

Dear Dr. Surgeon,  
Please review the following patient proposal. On your DePuy TruMatch website use the "Make Decision" button to select the appropriate status. Please contact DePuy TruMatch support if you have any questions or need further information.  
Phone: 800-889-0746, 514-372-7129 or Email: [TruMatchSupport@depuy.com](mailto:TruMatchSupport@depuy.com)

**Use with HP Instrumentation:**



4-in-1 Cutting Block

<b>Patient Information:</b>	<b>Case Information:</b>	
Patient Name: Example Patient	Instrument Type: Cutting Guide	
Gender: M	Implant System: PFC Sigma	
DOB: 01-Jan-9999	Instrument Style: HP	
Affected Side: R	Femoral Component: Sz 6 CR R	
Profile: Varus	Tibial Component: Sz 5 CR	
Reference Case #: CPK9999X	Femoral Sizing Reference: Anterior Down	
Date: 01-JAN-9999	External Rotation Reference: 3° from Posterior Condyles	
Patient Special Consideration:	Distal Femoral Resection: 12.0 mm from the Most Distal Condyle	
	Proximal Tibial Resection: 10.0 mm from the High Plateau	
	Posterior Tibial Slope: 7°	

**Notes/Comments:**

Distal femur resection thickness increased by 1.0mm to accommodate the additional 1.0mm thickness of the Sigma size 6 femoral implant (size 1.5 to 5 = 9mm, size 6 = 10mm).

**Proposal Version: 1**

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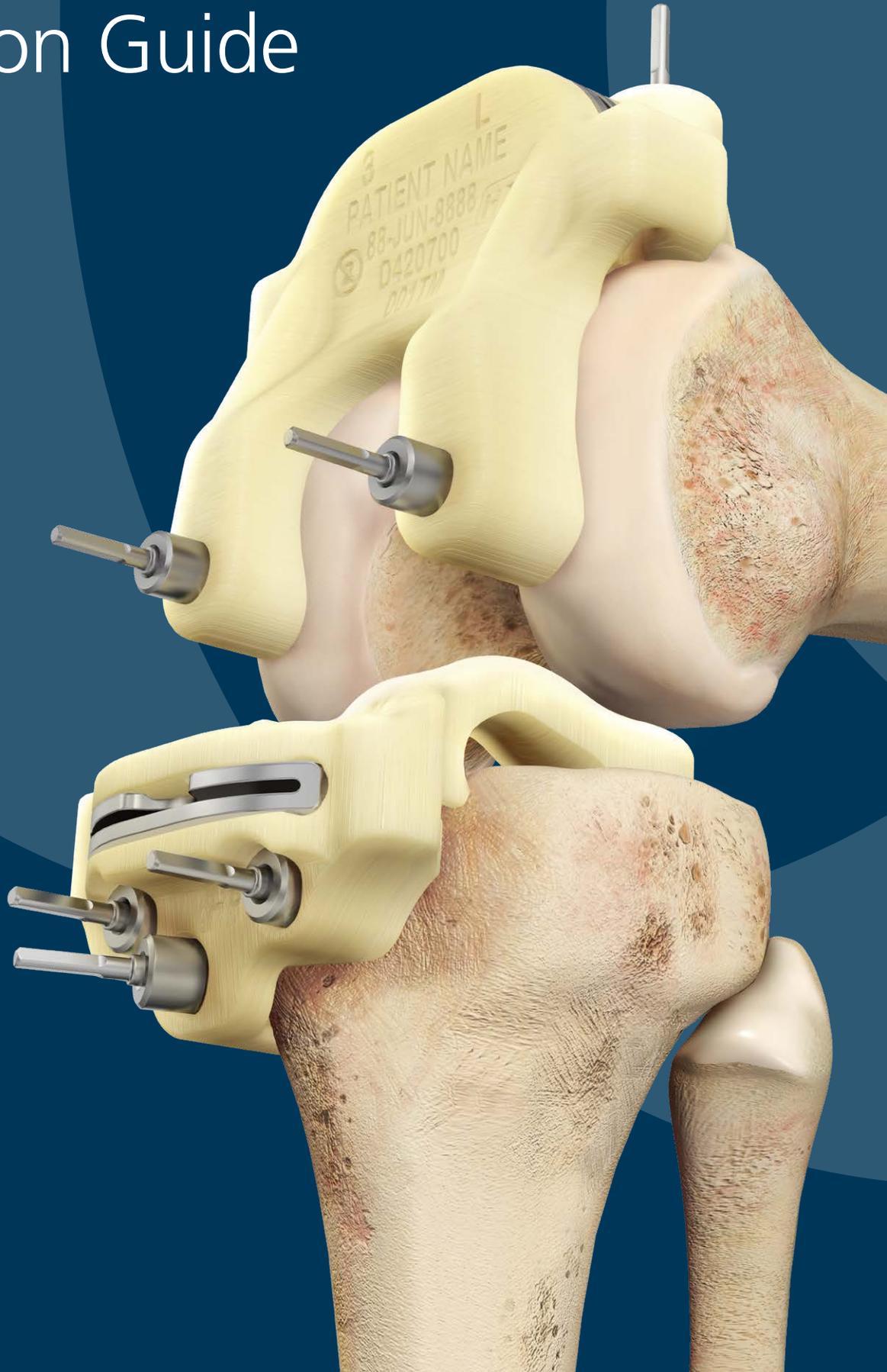
# Table of Contents

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<b>Resection Guide Technique</b>	Resection Guide Surgical Steps	5
	Distal Femoral Resection	6
	Femoral Preparation: A/P and Chamfer Cuts	8
	Proximal Tibial Resection	9
	Pre-operative Considerations	11
	Intra-operative Considerations	12
	<hr/>	
<b>Pin guide technique</b>	Pin Guide Surgical Steps	15
	Proximal Tibial Resection	16
	Distal Femoral Resection	19
	Femoral Preparation: A/P and Chamfer Cuts	22
	Pre-operative Considerations	24
	Intra-operative Considerations	25

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# Resection Guide



# Resection Guide Surgical Steps

## Femoral Preparation



**Step 1:** Femoral Resection Guide positioning



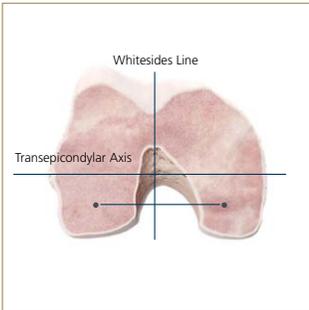
**Step 2:** Drill and placement of Anterior Pins



**Step 3:** Drill and placement of Distal Pins



**Step 4:** Distal femoral resection



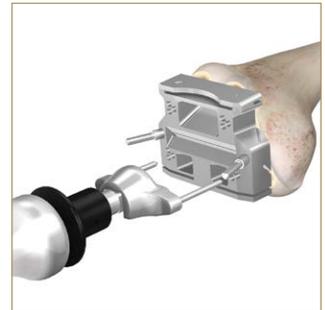
**Step 5:** Verify rotation of femoral component by marking Transepicondylar Axis and Whiteside's Line.



**Step 6:** Use of the Fixed Reference Block to position the A/P Chamfer Block

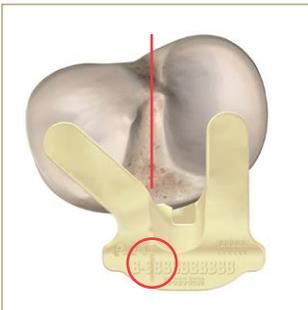


**Step 7:** Use of Angel Wing to evaluate anterior resection



**Step 8:** Placement of A/P Chamfer Block pins and removal of the Fixed Reference Guide

## Tibial Preparation



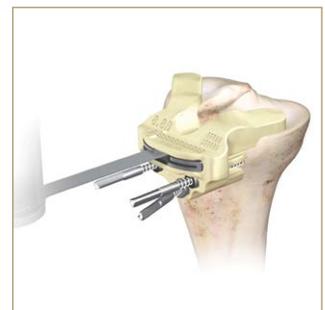
**Step 1:** Tibial Resection Guide positioning aided by Patient Proposal



**Step 2:** Placement of oblique, Lateral and Medial pins



**Step 3:** V/V verification with Alignment Adapter and Rod



**Step 4:** Tibial plateau resection

# Distal Femoral Resection

The Femoral Resection Guide (including packaging) will have patient specific identifiers: Patient Name, Patient Date of Birth (D.O.B.), Size and Patient Anatomy (R/L). The Resection Guide will also have the identifier "HP" for SIGMA Knee and should only be used with SIGMA Knee HP Instrumentation. Please verify the accuracy of these identifiers prior to use (Figure 1).



Figure 1

With the knee flexed to approximately 90 degrees, place the Femoral Resection Guide onto the distal aspect of the femur (Figure 2). Due to the large contact area between the Guide and bone, it is recommended that the Guide is positioned on the anterior cortex first (Figure 2) and then positioned posteriorly. Avoid using excessive force to seat the Guide.

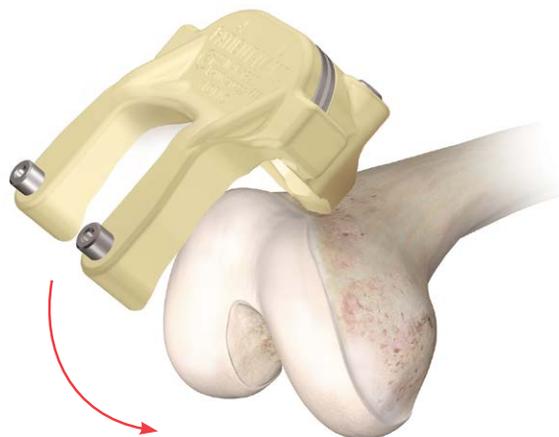


Figure 2

**Note:** It is recommended to clear extraneous tissue along the anterior cortex to avoid improper seating of the Guide from soft tissue impingement, as this will impact the overall alignment of the Resection Guide. Improved visualization from the sagittal or side viewpoint is helpful in assessing proper fit of the guide.

Once the correct position is found for the Femoral Resection Guide, there should be no toggling or rocking. It is not uncommon to see a 1 to 2 mm gap around the periphery of the Guide at the distal femoral condyles.

When satisfactory placement is achieved, secure the Femoral Resection Guide by inserting one 3.15 mm diameter Non-Headed Pin through the anterior medial hole (Figure 3). After the Medial Pin is secured, place another Pin through the lateral pin hole (Figure 3).



Figure 3

After the Femoral Resection Guide is secured, drill the two distal holes using the 3.15 mm diameter Non-Headed Pins. The Pins should always be drilled and not hammered in. These pin holes set the femoral component rotation and match the corresponding holes in the HP A/P Chamfer Block (Figure 4).

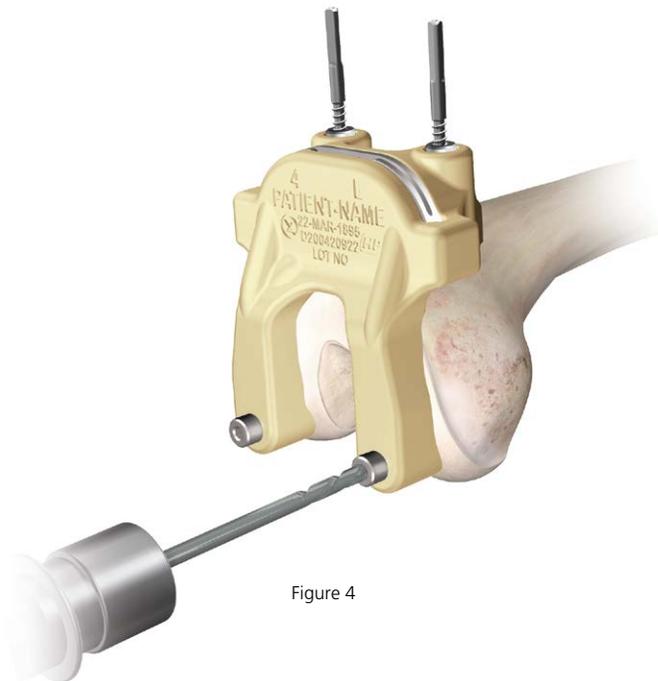


Figure 4

It is recommended to perform the distal femoral resection by leaving one Distal Drill Pin in the Guide while resecting the opposite side of the femoral condyle.

**! Caution:** Perform the distal femoral resection using a 1.19 mm Whale Tail Saw Blade (Figure 5).

Remove Femoral Resection Guide. Make sure bone cuts are clean and void of any undercut bone fragments.

**Note:** In order to adjust ligament tension, it may be necessary to re-cut 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 standard HP Instrument Distal Femoral or Tibial Cutting Blocks. Both Cutting Blocks can be used to cut 2 mm of additional bone. These Cutting Blocks slide over Pins placed in the previously drilled Guide Pin locations.



Figure 5

# Femoral Preparation: A/P and Chamfer Cuts

Attach the Universal Handle to the Fixed Reference Guide (Part Number (P/N) 2004-20-920) and position the Guide's spikes through the posterior 0 mm (marked with square) pin holes of the HP Fixed Reference A/P Chamfer (Figure 6). Once the Handle/Guide/Block is assembled, insert the Guide's spikes into the existing holes located on the distal femoral bone cut. Check to verify that the spikes of the Fixed Reference Guide are in the middle holes of the bottom hole cluster. It is possible to position the spike through the top hole and opposite bottom hole (vice-versa). This will result in an incorrect rotation placement of the A/P Chamfer Block.

**Note:** The TRUMATCH Solutions Femoral Resection Guide is designed to place the pin holes posteriorly while maintaining the desired “anterior-down” or “posterior-up” fixed reference selection. In addition, the SIGMA RP-F, SIGMA CR-150 and standard SIGMA A/P Chamfer Blocks look very similar. Care should be taken to use the appropriate block as this could result in under or over resection of the posterior condyles.

**Note:** The HP Anterior Reference Guide (P/N 2004-20-926) and Fixed Reference Guide (P/N 2004-20-920) are not included in the HP Instrument sets. These will need to be ordered separately.

Confirm the anterior cut placement with the Reference Guide, or Angel Wing (Figure 7). If desired, the block may be shifted 2 mm anteriorly or posteriorly by selecting the offset holes. When downsizing, using the smaller A/P Chamfer Block will remove more bone anteriorly. For additional details on downsizing refer to the SIGMA Knee HP Surgical Technique.

Secure the Block's location by inserting Threaded Headed Pins into the 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 anterior/posterior and chamfer cuts (Figure 8).

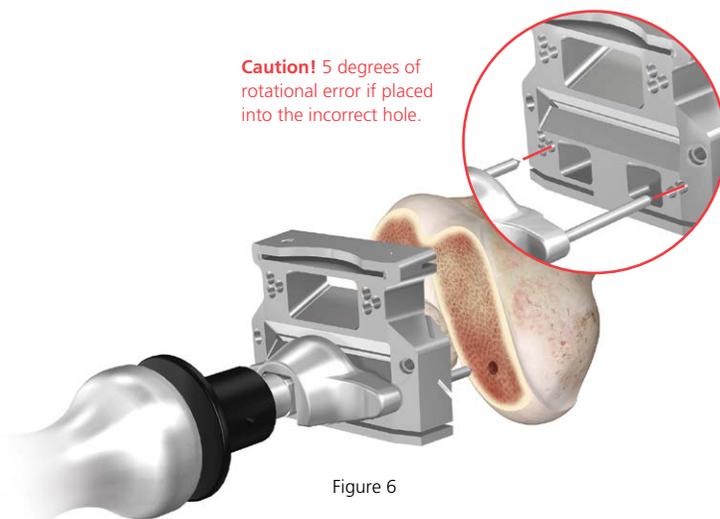


Figure 6

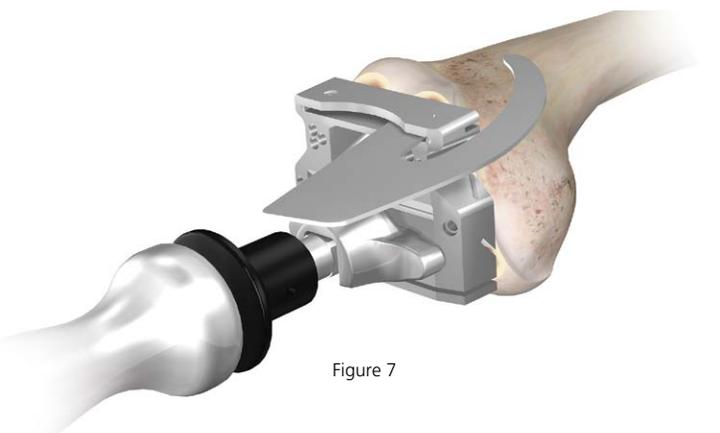


Figure 7

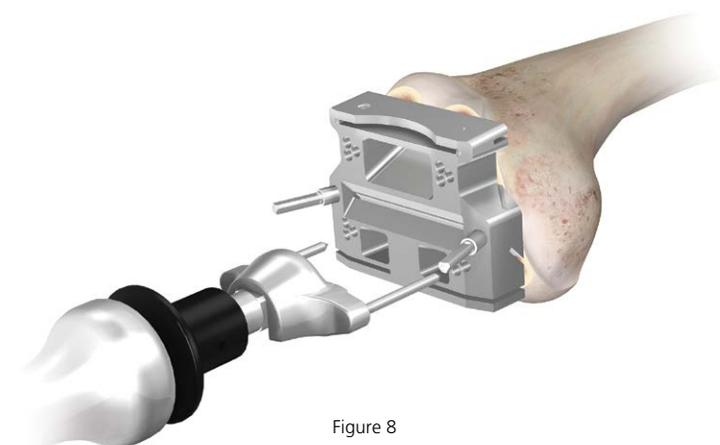


Figure 8

# Proximal Tibial Resection

The Tibial Resection Guide (including packaging) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). The Resection Guide will also have the identifier "HP" for SIGMA Knee and should only be used with SIGMA Knee HP Instrumentation. Please verify the accuracy of these identifiers prior to use (Figure 9).



Figure 9

With the knee flexed approximately 90 degrees, place the Tibial Resection Guide onto the proximal aspect of the tibia. 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 patient specific view, align the line on top of the Tibial Resection Guide with the line displayed on the proposal tibial bone (Figure 10).

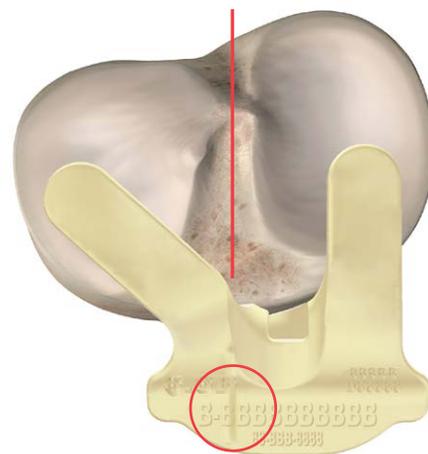


Figure 10

**Note:** It is recommended to clear extraneous tissue along the anterior/medial aspect of the tibia to avoid improper seating of the Guide from soft tissue impingement, as this will impact the overall alignment of the Resection Guide. Visualization from the sagittal or lateral viewpoint is helpful in assessing proper fit of the Guide.

To position the Guide, it is helpful to apply approximately 75 percent pressure to the anterior aspect and 25 percent pressure to the proximal aspect of the Guide. This will aid in seating the Guide at the appropriate resection level. Once the correct position is found for the Tibial Resection Guide, there should be no toggling or rocking.

When satisfactory placement is achieved, secure the Resection Guide by inserting one Non-Headed Threaded Pin through the middle hole. After the middle Pin is secured, place another Pin through the lateral pin hole and last through (Figure 11).



Figure 11

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Insert the HP Alignment Rod through the holes in the Alignment Verification Adapter (holes need to be oriented laterally). Next, insert the Adapter's blade into the Resection Guide's saw slot (Figure 12).

**Note:** The HP Anterior Reference Guide (P/N 2004-20-920) and the Fixed Reference Guide (P/N 2004-20-926) are not included in the HP Instruments set. These will need to be ordered separately.

Confirm the Varus/Valgus (V/V) alignment of the Guide by verifying that the Rod distally aligns with 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.

**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 middle Fixation Pin; c) utilizing 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.

**!** **Caution:** Perform the proximal tibial resection with a 1.19 mm Whale Tail Saw Blade (Figure 13).

After removing all Fixation Pins and the Tibial Resection Guide, make sure bone cuts are clean and void of any undercut bone fragments.

**Note:** If additional tibial resection is desired, place two proximal Fixation Pins and utilize the appropriate (L/R) HP Tibial Cutting Block.

**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 steps for proximal tibial preparation as outlined by the SIGMA HP Instruments Surgical Technique.

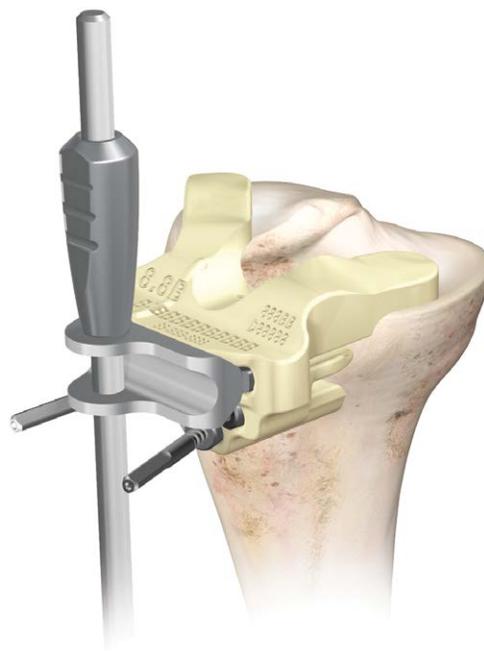


Figure 12



Figure 13

# Pre-operative Considerations

## Patient Proposal

- Review in detail prior to the surgery.
- Review the Notes/Comments section for information from the TRUMATCH Solutions Design Team regarding the design of the Guides.
- Print in Color! Some Notes/Comments will be shown in red.
- For intra-operative reference, display at an easy to read area in the OR, such as the light box or back wall.
- Review the Wall Chart – Summary (last page), which contains bone resection information and Tibial Guide orientation view (Figure 14).
- The bone resection information can be used to verify if bone cuts 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.

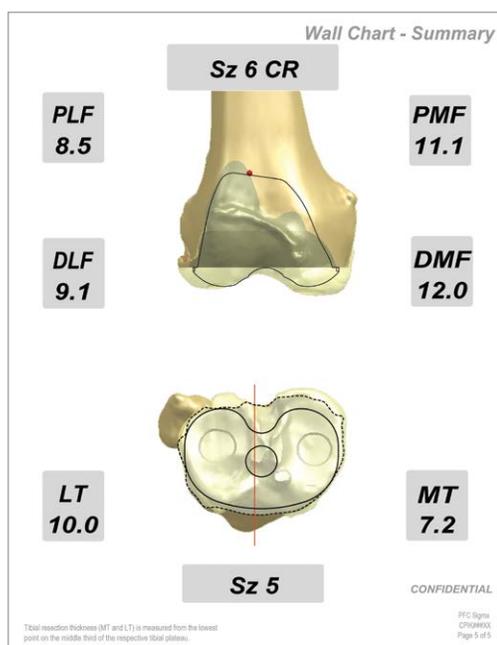


Figure 14

# Intra-operative CONSIDERATIONS

## Fixation Pins

- a. The HP Threaded, Non-Headed Sterile Pins (P/N 9505-02-302), combined with the HP Driver (P/N 9505-02-071), are recommended for firmly securing the Guides, especially for the Tibial Resection Guide when used on soft bone.

## Femoral Resection Guide

- a. The Femoral Resection Guide's primary reference surface is the anterior cortex of the femur (Figure 15a). The uppermost portion of the Guide should clear the anterior femoral flange and sit flush on the cortical surface. It is recommended to remove the anterior soft tissue to expose the underlying bone. When positioning the Guide, apply most of the pressure (~75%) against the anterior aspect of the femur.
- b. Distally, a small gap may be seen between the Guide and the femoral condyles (Figure 15b). If the Guide is securely positioned anteriorly, do not force the Guide's arms to sit flush on the femoral condyles. While applying anterior force apply light force (~25%) distal-to-proximal, to stabilize the Guide. Secure it by inserting the Anterior Fixation Pins.
- c. After performing the distal femoral resection and removing the Guide, examine the posterior aspect of the Guide's arms. If an arm appears to be damaged by the Saw Blade, that respective condyle cut was likely undercut and out of plan. The Guide should be repositioned and the cut repeated (Figure 16).

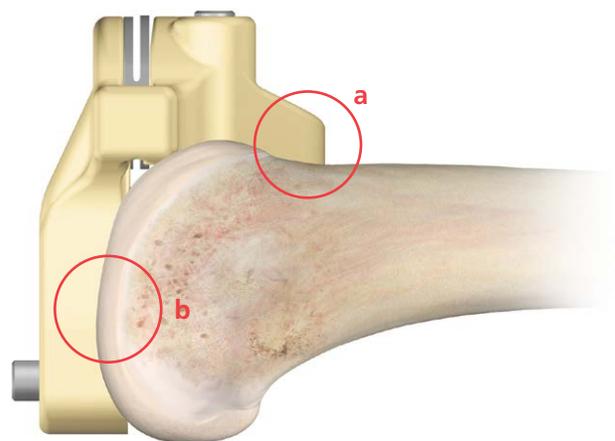


Figure 15

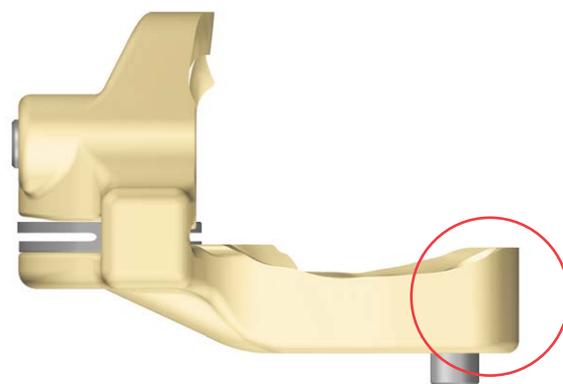


Figure 16

### **If the Femoral Resection 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 Guide's upper portion clear the anterior femoral flange and is it sitting on the anterior cortex?
3. Is the incision preventing placement of the Guide on the bone? The incision must be large enough to accommodate the Guide.

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## Tibial Resection Guide

- a. The Tibial Resection 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 17). 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 (Figure 18).
- b. While applying force anteriorly, apply light downward force (~25%) on the Guide's proximal arms to hold the Guide stable. Secure it by inserting the Anterior Fixation Pins in the following order: middle/oblique, lateral and medial.

### **If the Tibial Resection Guide does not fit, verify the following:**

1. Is the incision preventing placement of the Guide on the bone? The incision must be large enough to accommodate the Guide.
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 impinging tissue close to the tibial spine or the anterior rim of the tibial plateau.

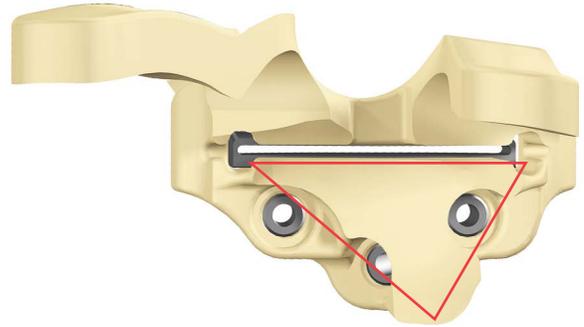


Figure 17

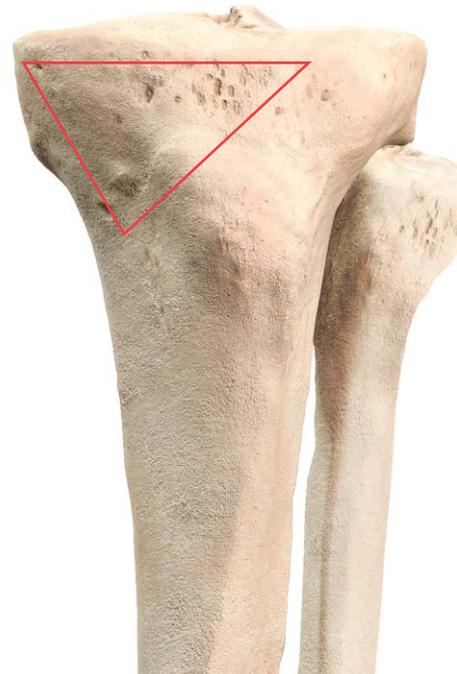


Figure 18

# Pin Guide



# Pin Guide Surgical Steps

## Tibial Preparation



**Step 1:** Insert Drill Guides and twist clockwise to tighten.



**Step 2A:** Tibial Pin Guide positioning



**Step 2B:** Tibial Pin Guide alignment



**Step 3:** Use of Uprod Extension. Verification of Varus/Valgus alignment



**Step 4:** Placement of Anterior Pins. Use of HP Uprod and Rod Extension



**Step 5:** Twist counterclockwise and remove Drill Guide and Tibial Pin Guides. Anterior Pins left in place



**Step 6:** Proximal tibial resection using HP Tibial Cutting Block

## Femoral Preparation



**Step 1:** Insert Drill Guides and twist clockwise to tighten



**Step 2:** Femoral Pin Guide positioning



**Step 3:** Drill anterior and distal pin holes, remove Drill Pins and Pin Guide



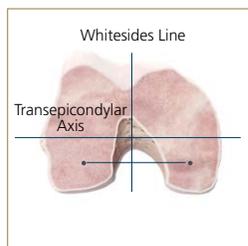
**Step 4:** Position the Distal Femoral Cutting Block with Anterior Reference Guide



**Step 5:** Use of Angel Wing to verify distal resection level



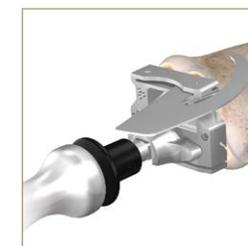
**Step 6:** Distal femoral resection



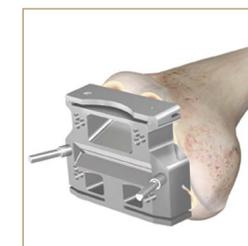
**Step 7:** Verify rotation of femoral component by marking Transepicondylar Axis and Whiteside's Line.



**Step 7:** Use of Fixed Reference Guide to position the A/P Chamfer Block



**Step 8:** Use of Angel Wing to verify anterior resection



**Step 9:** Fixation of A/P Chamfer Block to complete femoral resection

# 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 19).

**Note:** The size information was selected pre-operatively based on the Patient Proposal. Final implant sizing may change due to intra-operative assessment of implant fit and/or joint gap balance.



Figure 19

Prior to use, insert the TRUMATCH Solutions Drill Guides (Part Number (P/N) 2004-20-925) into the two anterior openings of the plastic Tibial Pin Guide by twisting in a clockwise direction until tightened (Figure 20).

**Note:** The TRUMATCH Solutions Drill Guides (P/N 2004-20-925) are reusable after sterilization. A minimum of four (4) Drill Guides should be on hand for a case. They are **ordered** separately from the TRUMATCH Solutions Pin Guides.



Figure 20

For optimal handling and placement stability of the Tibial Pin Guide, first insert the HP Extra Medullary Tibial Uprod (P/N 9505-01-228) into the anterior holes of the Tibial Pin Guide. Then slide the Rod Extension (P/N 2004-20-923) over the distal end of the Uprod. This will lengthen it to reach the patient's ankle. Grasp the Guide using the medial and lateral Finger Pads (Figure 21A). Do not grasp the Uprod or the area on which the metal Drill Guides are located. (Figure 21B).

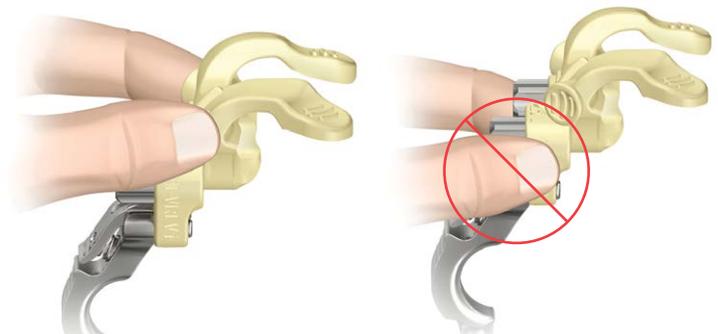


Figure 21A

Figure 21B

With the knee flexed at 90 degrees, place the Tibial Resection Guide with Uprod assembly onto the proximal anterior medial aspect of the tibia and both plateaus. 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 which contains a top view of the patient's tibial surface. It is recommended to visualize 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 22).

The planned Varus/Valgus (VV) alignment can be confirmed by verifying the alignment of the Rod to the patient's tibial crest and center of the ankle (Figure 23). The Rod is designed to be parallel to the mechanical axis of the tibia regardless of the planned tibial slope, when viewed laterally.

Tibial slope can be checked after the 0 degree Tibial Cutting Block is positioned over the Drill Pins and secured to the tibia. The EM Tibial Jig Uprod (P/N 9505-01-228) should be attached and positioned down toward the ankle. The HP Alignment Handle (P/N 9505-01-307) should be connected to the SIGMA Tibial Cutting Block in order to insert an Alignment Rod. Viewing from the lateral position, the tibial slope can be assessed using the Alignment Rod.

**Note:** The position of the line in the Patient Proposal is intended to reference the medial one-third of the tibial tubercle and not the middle of the tibial crest (Figure 22).

**Note:** It is recommended 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. Visualization in assessing proper fit observed from a sagittal or side view is helpful.

**Note:** To position the Guide, 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.



Figure 22

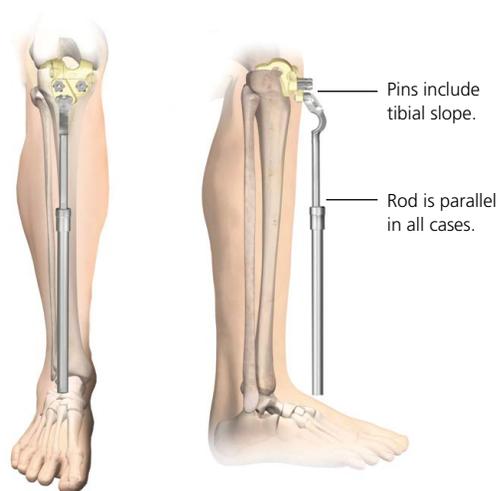


Figure 23

Once the Tibial Pin Guide and Uprod Assembly is in the desired position, hold it in place, and secure it to the bone by drilling two (3.15 mm diameter) Pins, first through the lateral and then the medial, Drill Guide pin holes (Figure 24).

After drilling the two Anterior Pins, the TRUMATCH Solutions Drill Guides are removed by twisting in a counter-clockwise direction, while leaving the two Anterior Pins in place (Figure 25). 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 26) If desired, confirm the cut orientation with the Angel Wing. If necessary, the Block may be shifted 2 mm proximally or distally by selecting the appropriate offset holes adjacent to the "0" mm hole. Perform the proximal resection with a 1.19 mm Whale Tail Saw Blade.

Remove the HP Tibial Cutting Block and make sure bone cuts are clean and void of any undercut bone fragments.

**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 trialing, as outlined by the INTUITION™ Instruments Surgical Technique.



Figure 24



Figure 25



Figure 26

# 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 27).

**Note:** The size information was selected pre-operatively based on the Patient Proposal. Final implant sizing may change due to intra-operative assessment of implant fit and/or joint gap balance.

Prior to use, insert the TRUMATCH Solutions Drill Guides (P/N 2004-20-925) into the two anterior and two distal openings of the plastic Femoral Pin Guide by twisting in a clockwise direction until tightened (Figure 28).

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 “arms” of the Guide over the distal femoral condyles (Figure 29A). Avoid using excessive force to seat the Guide. Care should be taken to avoid squeezing the Guide and causing the arms to deform while Pins are being placed (Figure 29B).

The majority of the finger pressure should be applied on the anterior aspect of the Guide while applying less pressure 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 is recommended to clear extraneous soft tissue from the anterior aspect of the femur to facilitate proper placement of the Guide. Visualization for proper seating may be enhanced when the Guide is observed from a sagittal or side view.



Figure 27



Figure 28



Figure 29A

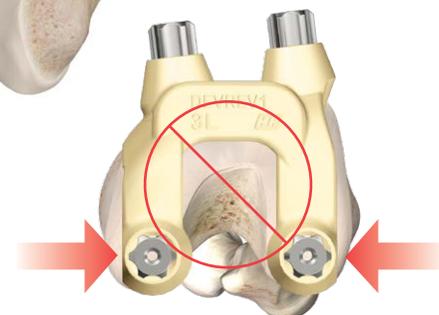


Figure 29B

Evaluate the lack of toggling or rocking of the Femoral Pin Guide to confirm the optimum placement of the Guide. It is not uncommon to see a 1 to 2 mm gap around the periphery of the Guide. Next, drill two 3.15 mm Non-Headed Pins anteriorly and two 3.15 mm Non-Headed Pins distally. (Figure 30).

**Note:** Pins should always be drilled and not hammered in.

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 HP A/P Chamfer Block.

Extract the two Anterior Pins and two Distal Pins and remove Femoral Pin Guide by flexing the Guide from posterior to anterior.

**Note:** The TRUMATCH Solutions Drill Guides (P/N 2004-20-925) are reusable after sterilization. A minimum of four (4) Drill Guides should be on hand for a case. They are ordered separately from the TRUMATCH Solutions Pin Guides.

Attach the H/P Universal Handle to the Anterior Reference Guide (P/N 2004-20-926) and position the Guide's spikes through the "0" mm holes, marked with a square, in the HP Distal Femoral Cutting Block (Figure 31). Using the handle, place the Anterior Reference Guide spikes located through the HP Distal Femoral Cutting Block into the anterior femoral holes.

**Note:** The Anterior Reference Guide (P/N 2004-20-926) and Fixed Reference Guide (P/N 2004-20-920) are not included in the HP Instrument Sets. These will need to be ordered separately.

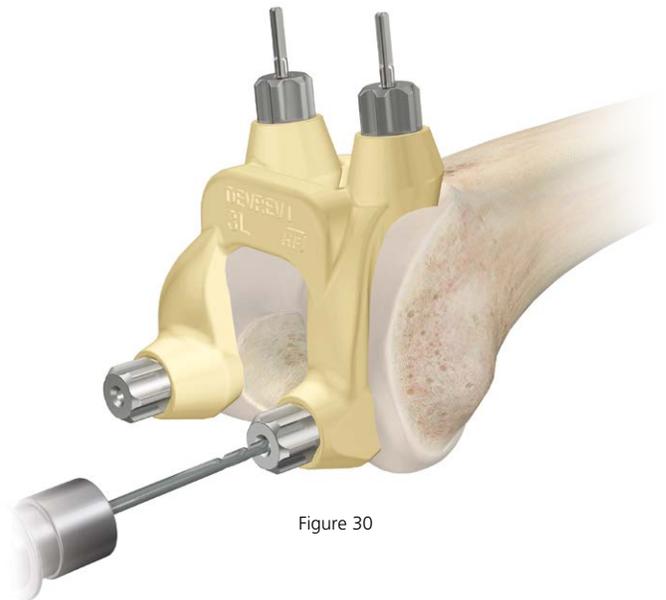


Figure 30

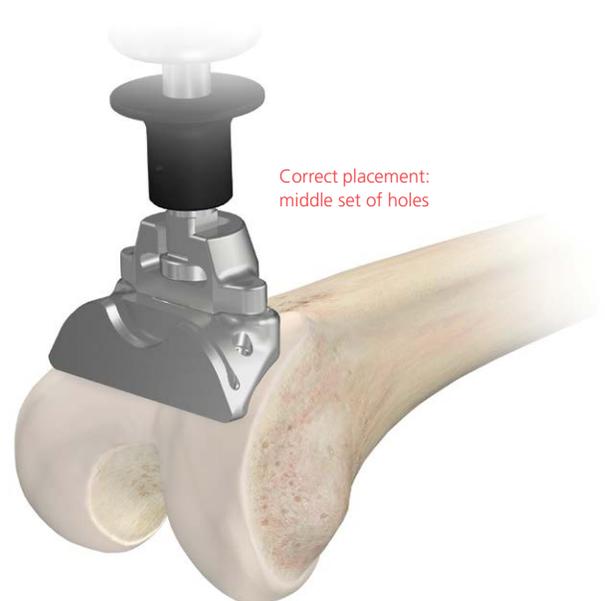


Figure 31

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Evaluate the distal cut using the Reference Guide or Angel Wing (Figure 32A). If needed, the Block may be shifted 2 mm proximally or distally by selecting 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 Whale Tail Saw Blade (Figure 32B).

Remove the HP Distal Femoral Cutting Block and confirm the bone cuts are clean and without any undercut bone fragments.

**Note:** In order to address gap assessment and ligament tension, it may be necessary to re-cut 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.

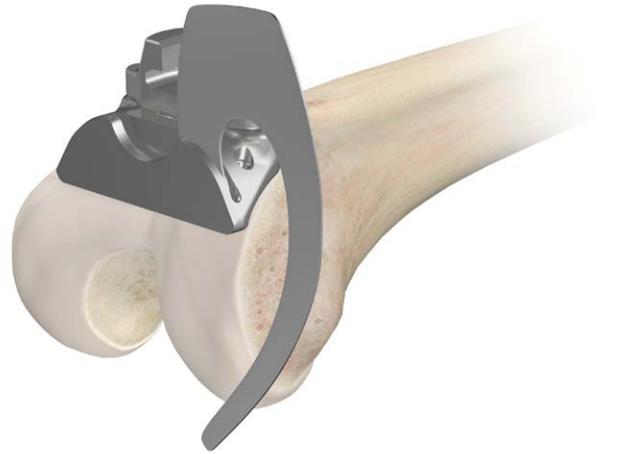


Figure 32A

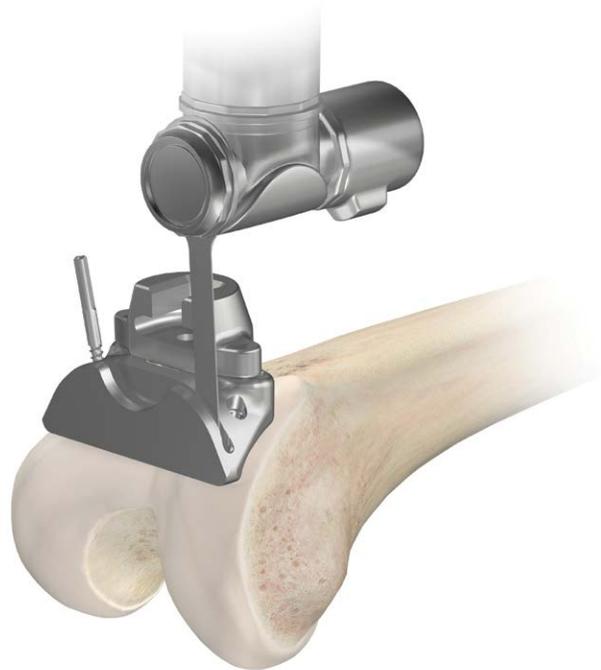


Figure 32B

# Femoral Preparation: A/P and Chamfer Cuts

Attach the HP Universal Handle to the Femoral 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 HP Fixed Reference A/P Chamfer Block (Figure 33). Insert the construct spikes into the previously drilled holes located on the distal femoral bone cut. Check to verify that the spikes of the Fixed Reference Guide are in the middle holes of the bottom hole cluster. It is possible to position the spike through the top hole and opposite bottom hole (vice-versa). This will result in an incorrect rotation placement of the Cutting Block.

**Note: The Anterior Reference Guide (P/N 2004-20-926) and Fixed Reference Guide (P/N 2004-20-920) are not included in the SIGMA HP Instrument Sets. These will need to be ordered separately.**

Evaluate the anterior cut with the Angel Wing (Figure 34). 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 "Femoral Preparation: A/P Chamfer Cuts" on page 8 for additional detail)

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 35). After performing all cuts, remove the Pins and A/P Chamfer Block, making sure bone cuts are clean and void of any undercut bone fragments.

**Caution!** 5 degrees of rotational error if placed into the incorrect hole.

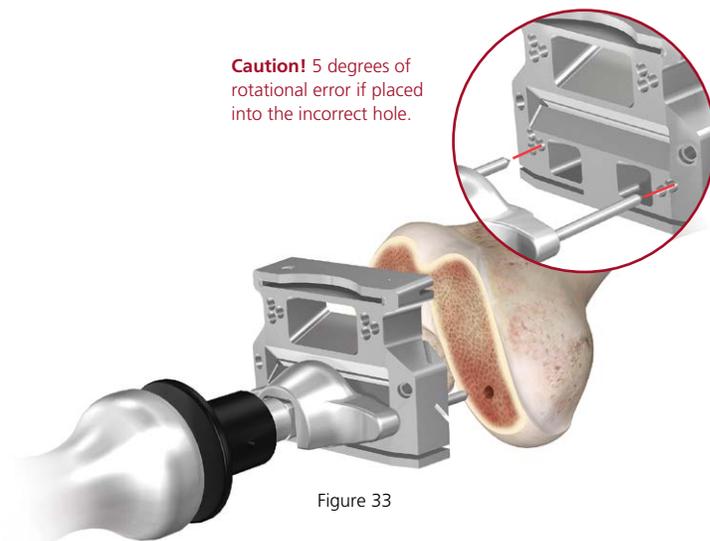


Figure 33

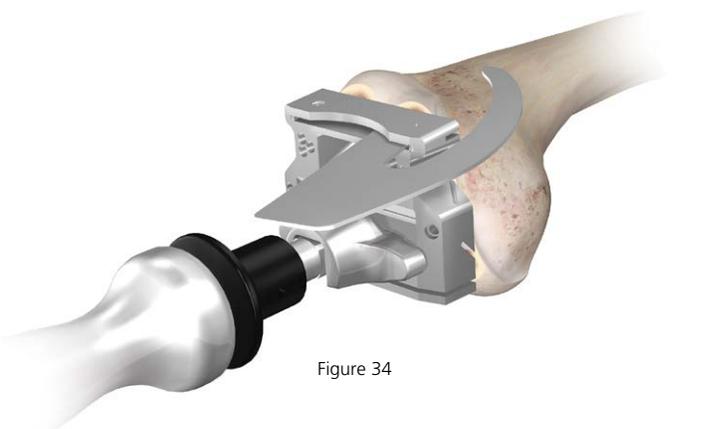


Figure 34

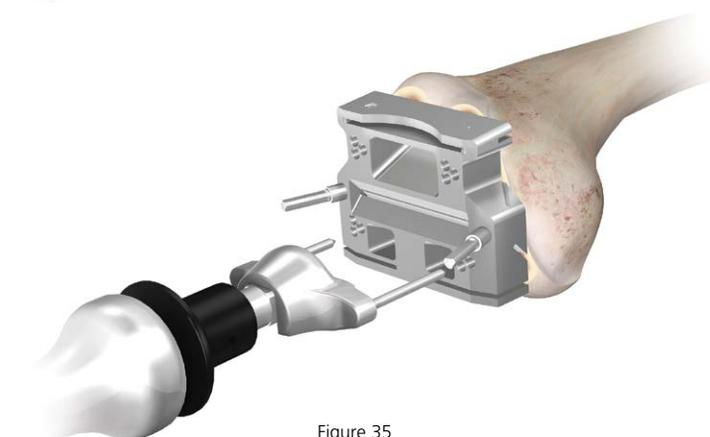


Figure 35

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**Note:** If the 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 A/P Chamfer Block. The TRUMATCH Solutions Femoral Pin Guide is designed to position the pin holes posteriorly on the femur which maintains the ability to move the A/P Chamfer Block to resect 2 mm more bone anterior or 2 mm more bone posterior with the *same size Block* regardless if 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 A/P Chamfer Block can be inserted over the posteriorly 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 A/P Chamfer Block and use these anteriorly 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.

In addition, regarding the SIGMA Knee System, the SIGMA RP-F Fixed Reference A/P Block, SIGMA CR150 Fixed Reference A/P Block and the standard SIGMA HP Fixed Reference A/P Chamfer Block look very similar. Care should be taken as using the incorrect Block could result in under or over resection of the posterior femoral condyles with use of the wrong Cutting Block.

# Pre-operative Considerations

## Patient Proposal

- a. Review in detail prior to the surgery.
- b. Review the Notes/Comments section for important information from the TRUMATCH Solutions Design Team regarding the design of the Guides.
- c. Print in Color! All Notes/Comments will be shown in red.
- d. For intra-operative reference, display the wall chart summary page (Figure 36) at an easy to read location in the OR, such as the light box or back wall.
- e. Review the Wall Chart Summary (Figure 36), which contains bone resection information and the Tibial Guide orientation line.
- f. The bone resection information can be used to verify if bone cuts 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.
- g. For clarity, the tibial resection thickness, shown for each condyle, is measured from the lowest point on the middle third of the respective condyle.

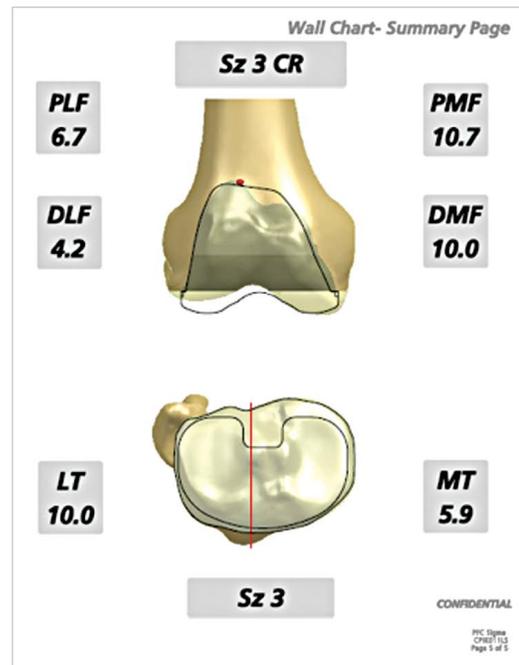


Figure 36

# Intra-operative Considerations

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## Fixation Pins

- a. The HP Threaded Non-Headed Pins (P/N 9505-02-302), combined with the HP driver (P/N 9505-02-071) are recommended for firmly securing the Guides, especially when used in soft bone.

## Femoral Pin Guide

- a. The Femoral Pin Guide's primary reference surface is the anterior cortex of the femur (Figure 37). The uppermost portion of the Guide should clear the anterior femoral flange and sit flush on the cortical surface. It is recommended 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 accommodate the Guide.



Figure 37

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## Tibial Pin Guide

- a. The Tibial Pin 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 38). When positioning the Guide, apply most of the pressure (~75%) against the anterior aspect of the tibia. It is recommended to remove the thin soft tissue to expose the underlying bone.
- b. 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 Pin Guide does not fit, verify the following:**

1. Is the incision preventing placement of the Guide on the bone? The incision must be large enough to accommodate the Guide.
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 impinging by tissue close to the tibial spine.



Figure 38



**Indications For Use:**

The TRUMATCH Patient Specific Instruments are intended to be used as patient-specific surgical instrumentation to assist in the positioning of a joint replacement component intra-operatively and in guiding the marking of bone before cutting.

The anatomical landmarks necessary for the creation of the TRUMATCH Patient Specific Instruments must be present and identifiable on CT.

The TRUMATCH Patient Specific Instruments are intended for use with SIGMA® Total Knee Implants and ATTUNE® Total Knee Implants and their cleared indications for use.

The TRUMATCH Patient Specific Instruments are intended for single use only.

**Contraindication:**

The following conditions are not compatible with TRUMATCH Personalized Solutions:

- Previous knee replacement of the same knee.

**Cautions:**

It can be difficult to attain usable CT images of patients with the listed conditions:

- 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 knee, or patients with severe patella tendon calcification that may prevent patella eversion.

For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

**Limited Warranty and Disclaimer:** Products from DePuy Synthes Products, Inc. are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

**WARNING:** In the USA, this product has labeling limitations. See package insert for complete information.

**CAUTION:** USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

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