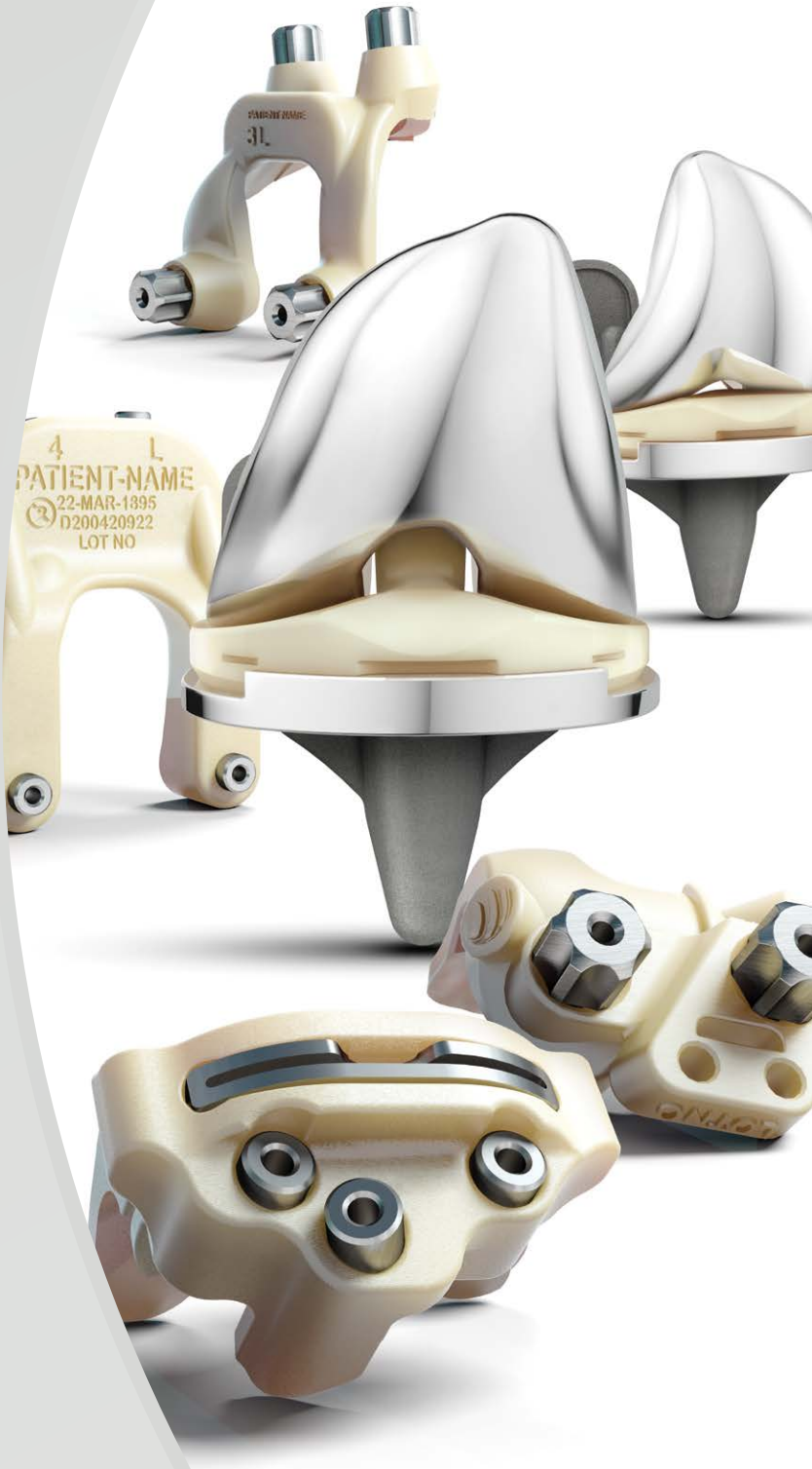
Attune® Knee System | TruMatch® PERSONALIZED SOLUTIONS



RESECTION GUIDE & PIN GUIDE SYSTEMS

TRUMATCH® Personalized Solutions Surgical Technique with INTUITION™ Instruments

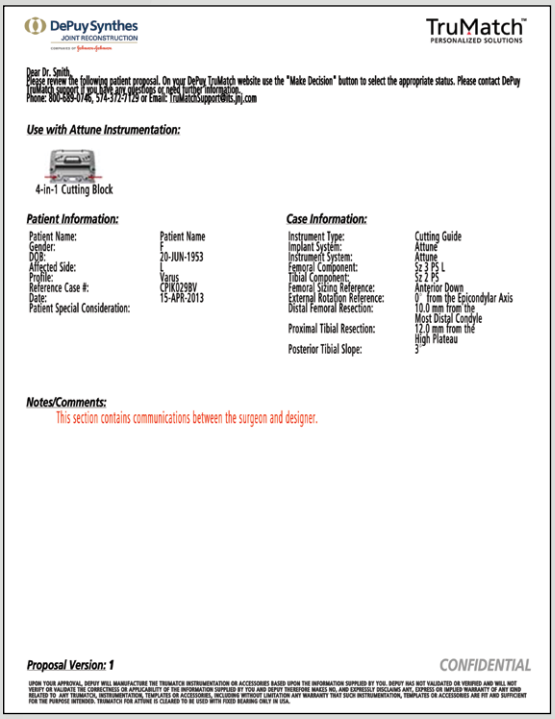
DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

RESECTION GUIDE & PIN GUIDE SURGICAL TECHNIQUES

The following steps are an addendum to the INTUITION™ Instruments Surgical Technique, The TRUMATCH® Personalized Solutions Surgical Technique with ATTUNE® Knee System INTUITION SOLO™ INSTRUMENTS and The ATTUNE® Knee System Femur First Patient Specific Alignment Surgical Technique.

This surgical technique provides instruction on how to incorporate the TRUMATCH® Personalized Solutions Femoral and Tibial Resection Guides, Pin Guides and Hybrid (Femoral Resection Guide & Tibial Pin Guide) Kits into the broader INTUITION Instruments Surgical Technique. The surgeon must be familiar with the proper use of the INTUITION Instruments, because the INTUITION Instruments are required in the 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 survey for potential anatomical changes since the case was submitted and created and 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.trumatchsolutions.com. The Patient Proposal contains in-depth information utilized in the design of the patient-specific guides including, as necessary, surgeon requested plan modifications that are listed in the Notes/Comments section.


DePuy Synthes
JOINT RECONSTRUCTION
TruMatch™
PERSONALIZED SOLUTIONS

Dear Dr. Smith,
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: 800-689-0748, 574-372-7129 or Email: TruMatchSupport@its.jnj.com

Use with Attune Instrumentation:

4-in-1 Cutting Block

Patient Information:

Patient Name:	Patient Name
Gender:	F
DOB:	20-JUN-1953
Affected Side:	L
Profile:	Varus
Reference Case #:	CPK0298V
Date:	15-APR-2013
Patient Special Consideration:	

Case Information:

Instrument Type:	Cutting Guide
Implant System:	Attune
Instrument System:	Attune
Femoral Component:	Sz 3 PS L
Tibial Component:	Sz 2 PS
Femoral Sizing Reference:	Anterior Down
External Rotation Reference:	0° from the Epicondylar Axis
Distal Femoral Resection:	10.0 mm from the Most Distal Condyle
Proximal Tibial Resection:	12.0 mm from the High Plateau
Posterior Tibial Slope:	3

Notes/Comments:
This section contains communications between the surgeon and designer.

Proposal Version: 1
CONFIDENTIAL

UPON YOUR APPROVAL, DEPUY WILL MANUFACTURE THE TRUMATCH INSTRUMENTATION OR ACCESSORIES BASED UPON THE INFORMATION SUPPLIED BY YOU. DEPUY HAS NOT VALIDATED OR VERIFIED AND WILL NOT VERIFY OR VALIDATE THE CORRECTNESS OR APPLICABILITY OF THE INFORMATION SUPPLIED BY YOU AND DEPUY THEREFORE MAKES NO, AND EXPRESSLY DISCLAIMS ANY, EXPRESS OR IMPLIED WARRANTY OF ANY KIND RELATED TO ANY TRUMATCH, INSTRUMENTATION, TEMPLATES OR ACCESSORIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY THAT SUCH INSTRUMENTATION, TEMPLATES OR ACCESSORIES ARE FIT AND SUFFICIENT FOR THE PURPOSE INTENDED. TRUMATCH FOR ATTUNE IS CLEARED TO BE USED WITH FIXED BEARING ONLY IN USA.

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 INTUITION Instrumentation.

Reusable instruments compatible with the TRUMATCH Personalized Solutions Surgical Technique

Resection Guide

Product Code	Product Name	Femoral	Tibial
2000-42-074	Distal Fixed Reference Guide	●	
2000-42-062	Alignment Verification Adapter		●
9505-01-207	HP Alignment Rod		●

Pin Guide

Product Code	Product Name	Femoral	Tibial
2004-20-927	Anterior Fixed Reference Guide	●	
2000-42-074	Distal Fixed Reference Guide	●	
9505-01-228	EM Tibial Jig Uprod		●
2004-20-923	Rod Extension		●
2004-20-925	Drill Guides	●	●

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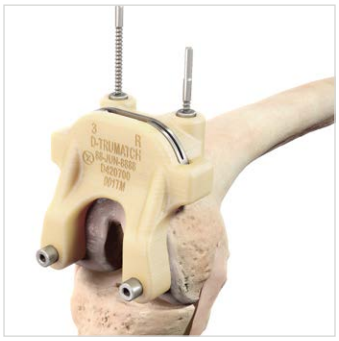
RESECTION GUIDE

RESECTION GUIDE SURGICAL STEPS

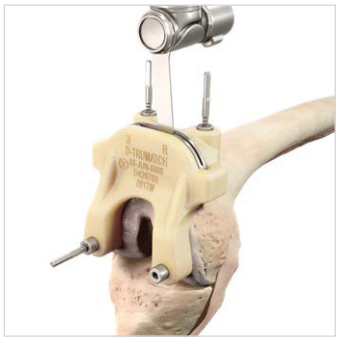
Femoral Preparation

Step 1: Femoral Resection Guide positioning

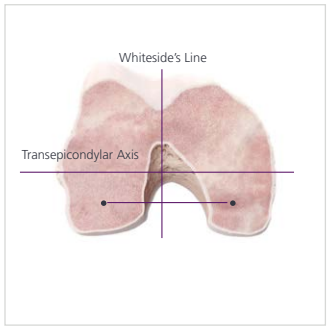


Step 2: Drill and placement of Anterior Pins

Step 3: Drill and placement of Distal Pins

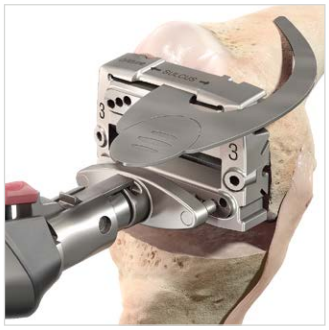


Step 4: Replace first Distal Pin; remove second Distal Pin and finish resection



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

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



Step 7: Use of Angel Wing to verify 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 Middle (oblique), Lateral and Medial Pins

Step 3: Varus/Valgus and slope verification with Alignment Adapter and Rod. Rod should always be placed to the lateral side of the knee

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 "Att" for ATTUNE® Knee and should only be used with ATTUNE Knee INTUITION Instrumentation. Please verify the accuracy of these identifiers prior to use (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.

Note: It is recommended to clear extraneous tissue along the anterior cortex to avoid improper seating of the Guide. Avoid any soft tissue impingement, as this will impact the overall alignment of the Resection Guide. 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 arms 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 1

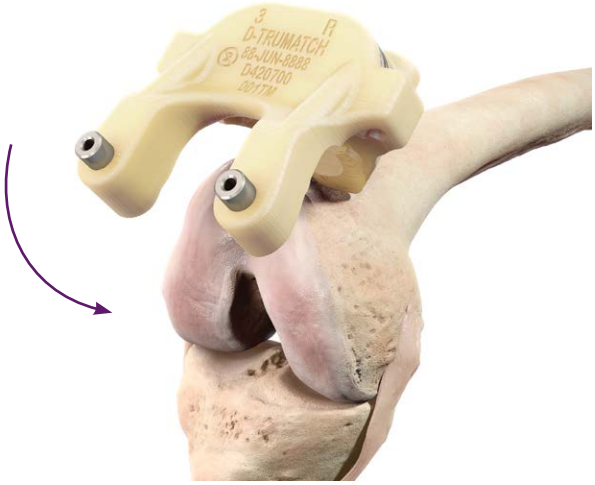


Figure 2

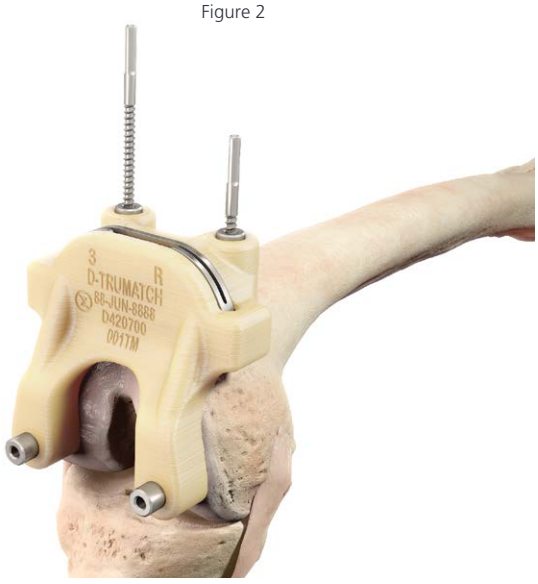


Figure 3

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 INTUITION A/P Chamfer Block (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 femur for improved stability.

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 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 locations of the Pins are compatible with the standard INTUITION 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.

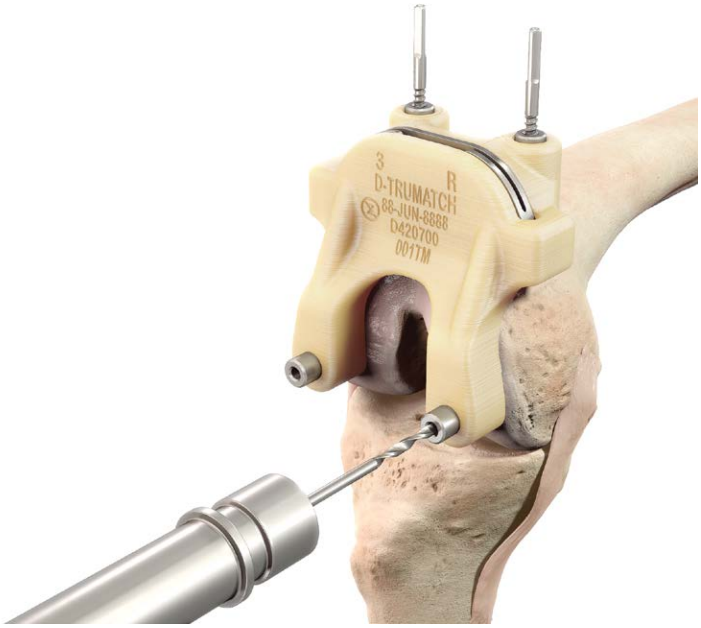


Figure 4

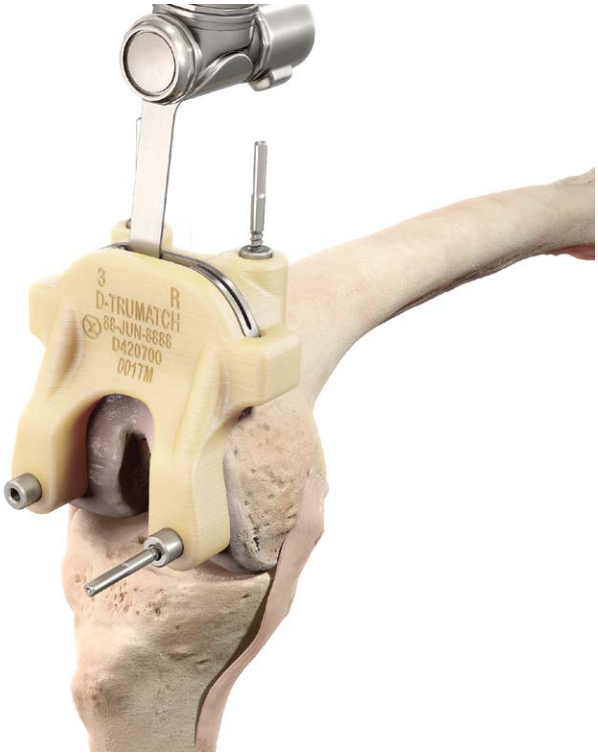


Figure 5

FEMORAL PREPARATION: A/P AND CHAMFER CUTS

Attach the INTUITION Impaction Handle (P/N 2544-01-017) to the INTUITION Fixed Reference Guide (P/N 2000-42-074) and position the Guide's spikes through the 0 mm pin holes of the INTUITION Fixed Reference A/P Chamfer Block without the Posterior Saw Capture (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.

Note: The TRUMATCH Personalized Solutions Femoral Resection Guide is designed to place the pin holes posteriorly while maintaining the desired "anterior down" or "posterior up" fixed reference selection.

Note: The INTUITION Anterior Reference Guide (P/N 2004-20-927) and Fixed Reference Guide (P/N 2000-42-074) are not included in the INTUITION 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 A/P Chamfer Block may be shifted 1.5 mm anteriorly or posteriorly by selecting the appropriate offset holes. When downsizing, using the smaller A/P Chamfer Block will remove 3 mm more bone anteriorly. For additional details on downsizing refer to the INTUITION Instrument 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). If the use of the Posterior Saw Capture is desired, it may be inserted after removing the Handle/Fixed Reference Guide Assembly and prior to performing the additional femoral finishing cuts.

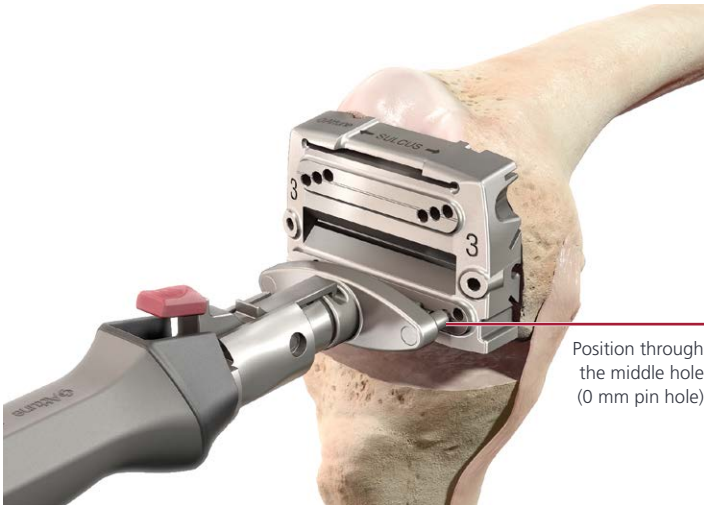


Figure 6

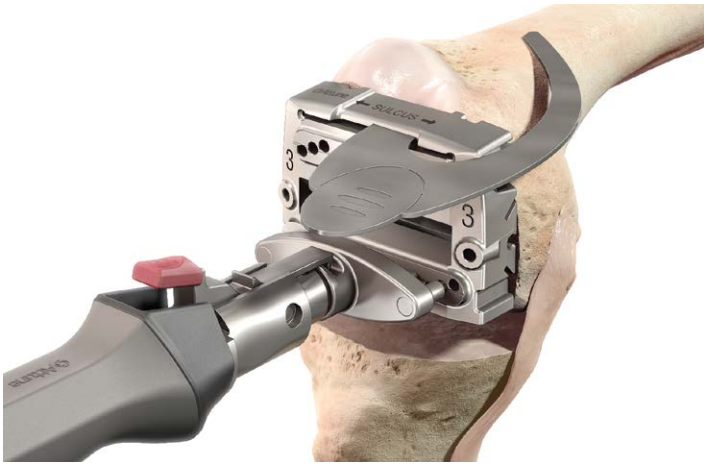


Figure 7

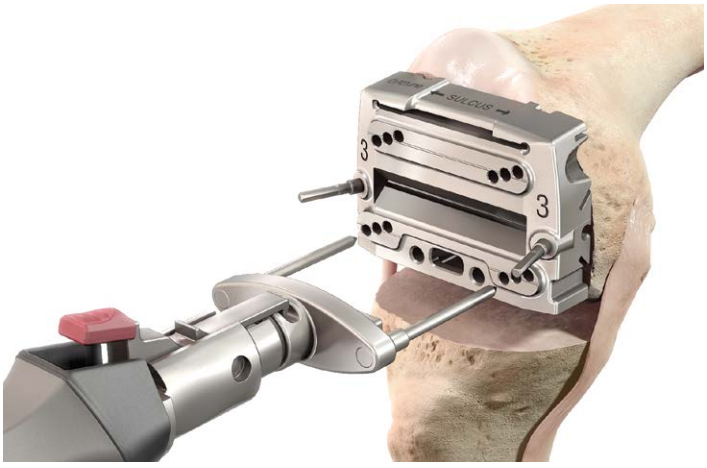


Figure 8

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 "Att" for ATTUNE Knee and should only be used with ATTUNE Knee INTUITION Instrumentation. Please verify the accuracy of these identifiers prior to use (Figure 9).

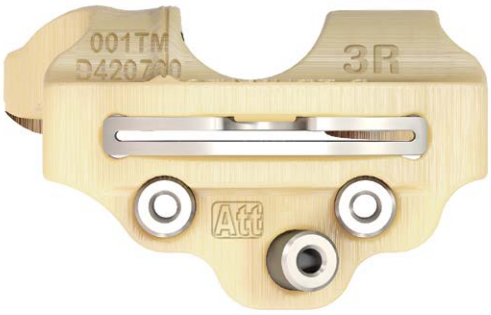


Figure 9

With the knee flexed to approximately 90 degrees, place the Tibial Resection Guide onto the proximal aspect of the tibia. Avoid using excessive force to seat the Guide. To assist in the M/L positioning of the Tibial Resection Guide, reference the last page of the Patient Proposal document showing the 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 red line displayed on the proposal tibial bone (Figure 10).

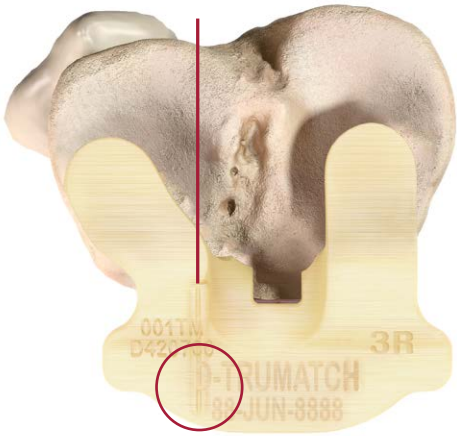


Figure 10

Note: It is recommended to clear extraneous tissue along the anterior/medial aspect of the tibia to avoid improper seating of the Guide. Avoid any 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 25 percent pressure to the proximal aspect and 75 percent pressure to the anterior 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 a 3.15 mm diameter Non-Headed Pin through the center oblique hole ❶, followed by the pinning of the lateral hole ❷ (Figure 11).

Figure 11

Insert the HP Alignment Rod (P/N 950501207) 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 INTUITION Anterior Reference Guide (P/N 2004-20-927) and Fixed Reference Guide (P/N 2000-42-074) are not included in the INTUITION Instrument Sets. 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. In the case of Patient Specific Alignment, the Rod will instead be offset from this orientation by the angular value shown on the Patient Proposal. 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, replace the two proximal Fixation Pins and utilize the appropriate (L/R) INTUITION Instrument 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 INTUITION Instruments Surgical Technique.

Figure 12

Figure 13

PRE-OPERATIVE CONSIDERATIONS

Patient Proposal

a. Review in detail prior to the surgery.

b. Review the Notes/Comments section for information from the TRUMATCH Personalized Solutions Design Team regarding the design of the Guides.

c. Print in Color! Some Notes/Comments will be shown in red.

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

e. Review the Wall Chart – Summary (last page), which contains bone resection information and Tibial Guide orientation view (Figure 14).

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 revisited.

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.

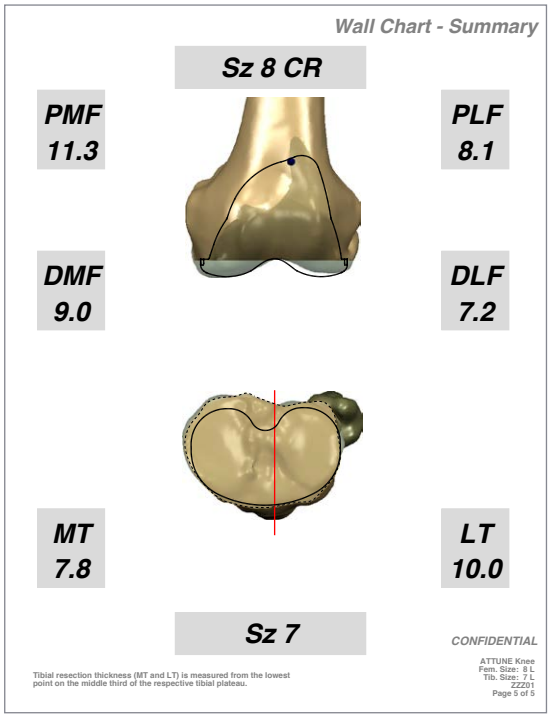


Figure 14

INTRA-OPERATIVE CONSIDERATIONS

Fixation Pins

a. 3.15 mm diameter Threaded, Non-Headed Pins, 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.

b. Perform the resection with a 1.19 mm Whale Tail Saw Blade.

Femoral Resection Guide

a. The Femoral Resection Guide's primary reference surface is the anterior cortex of the femur (Figure 15-a). The uppermost 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. When positioning the Guide, apply most of the pressure (~75%) against the anterior aspect of the femur.

b. Distally, the guide should be in contact with the distal femoral condyles, although a slight gap may exist along the periphery (Figure 15-b). 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, also apply light force (~25%) distal-to-proximal, to stabilize the Guide. Secure it by inserting the Anterior Fixation Pins (3.15 mm diameter 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).

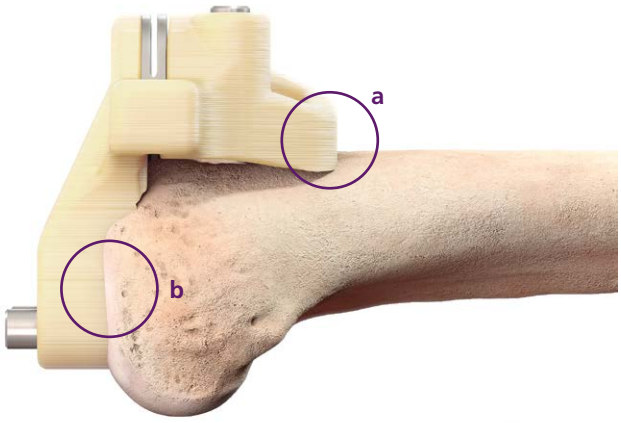


Figure 15

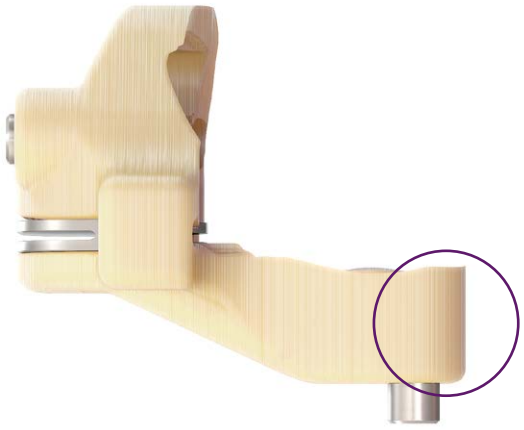


Figure 16

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 upper portion clear the anterior femoral flange and is it positioned 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.

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 located below the saw slot (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 the Guide by inserting the Anterior Fixation Pins in the following order: middle/oblique, lateral and medial.

Figure 17

If the Proximal 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.

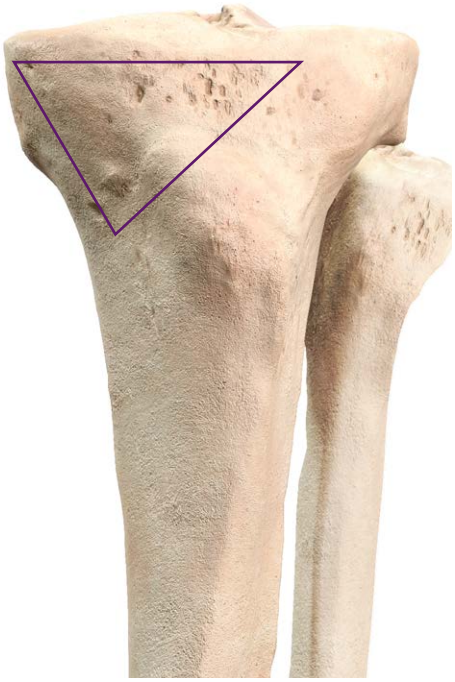
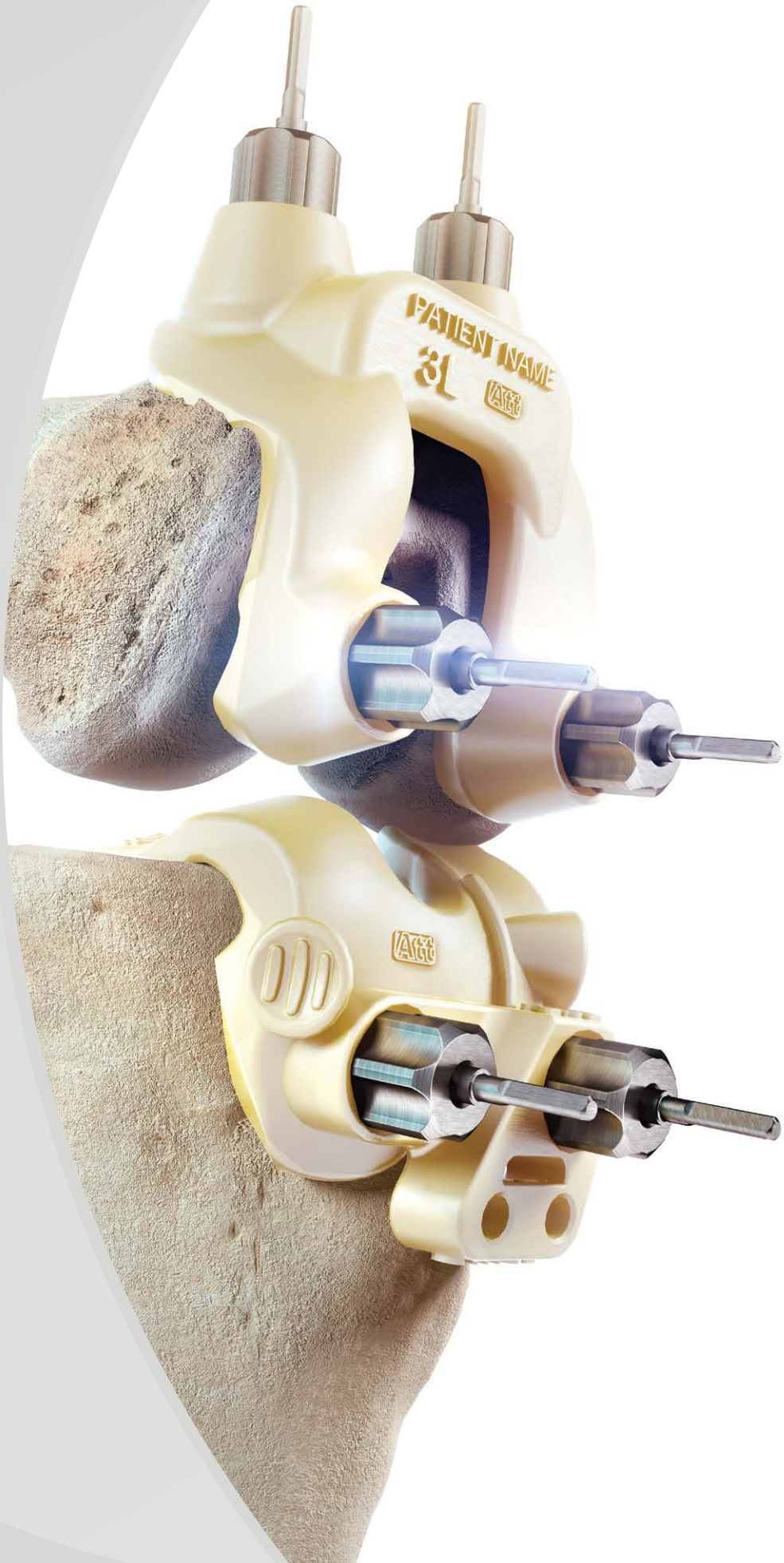


Figure 18

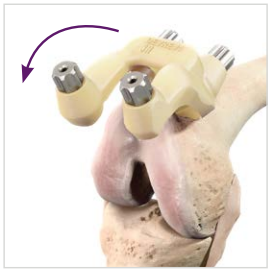
PIN GUIDE



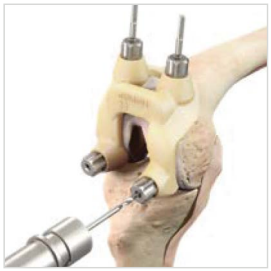
PIN GUIDE SURGICAL STEPS

Femoral Preparation

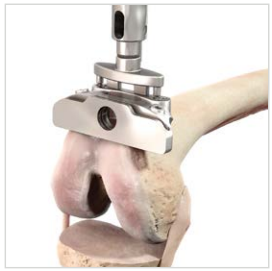
Step 1: Insert Drill Guides and twist clockwise to tighten



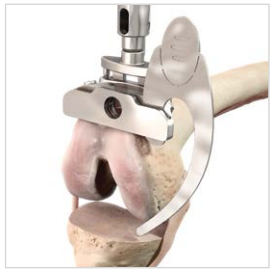
Step 2: Femoral Pin Guide positioning



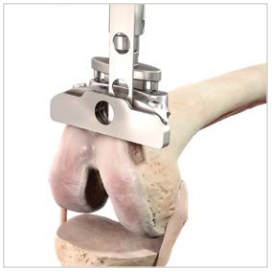
Step 3: Drill anterior and distal pin holes and remove Femoral Pin Guide



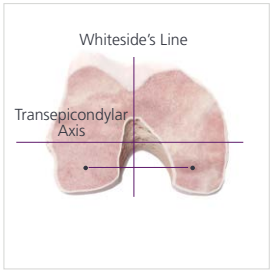
Step 4: Position the Distal Femoral Cutting Block with Anterior Reference Guide



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

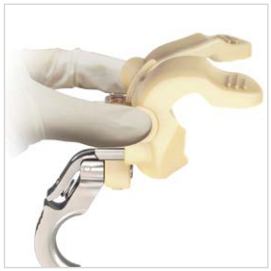
Step 8: Use of Fixed Reference Guide to position the A/P Chamfer Block

Step 9: Use of Angel Wing to verify anterior resection

Step 10: Fixation of A/P Chamfer Block to complete femoral resection

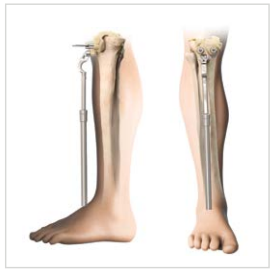
Tibial Preparation

Step 1: Insert Drill Guides and twist clockwise to tighten

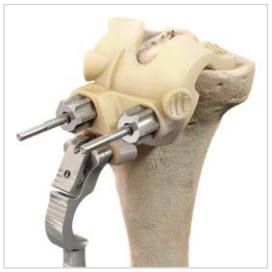


Step 2A: Tibial Pin Guide positioning

Step 2B: Tibial Pin Guide alignment



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



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

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

Step 6: Proximal tibial resection using INTUITION Tibial Cutting Block

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 19).

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

Prior to use, insert the TRUMATCH Personalized 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 20).

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 21A). Avoid using excessive force to seat the Guide. Care should be taken to avoid squeezing the Guide and causing the legs to deform while Pins are being placed (Figure 21B).

The majority of the finger pressure should be applied on the anterior aspect of the Guide while applying light 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 positioning of the Guide. Visualization for proper seating may be enhanced when the guide is observed from a sagittal or side view.

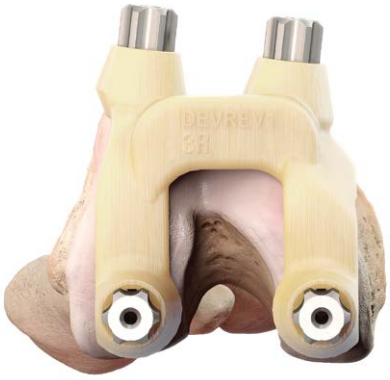


Figure 19

Figure 20

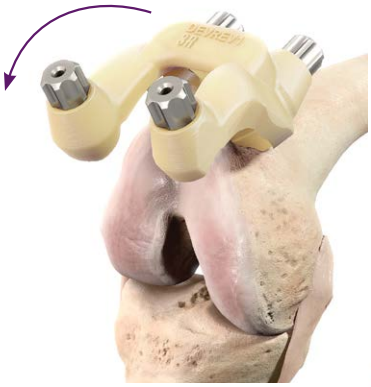


Figure 21A

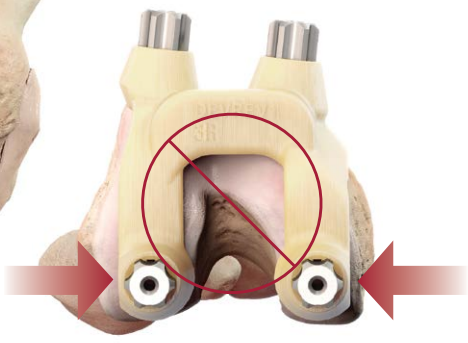


Figure 21B

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 22).

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

The anterior holes will be used to place the INTUITION 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 ATTUNE 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 Personalized 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 Personalized Solutions Pin Guides.

Attach the INTUITION Impaction Handle (P/N 2544-01-017) to the INTUITION Anterior Reference Guide (P/N 2004-20-927) and position the Guide's spikes through the "0" mm holes in the INTUITION Distal Femoral Cutting Block (Figure 23). Using the Handle, place the INTUITION Anterior Reference Guide spikes now located through the INTUITION Distal Femoral Resection Block into the anterior holes.

Note: The INTUITION Anterior Reference Guide (P/N 2004-20-927) and INTUITION Fixed Reference Guide (P/N 2000-42-074) are not included in the INTUITION Instrument Sets. These will need to be ordered separately.

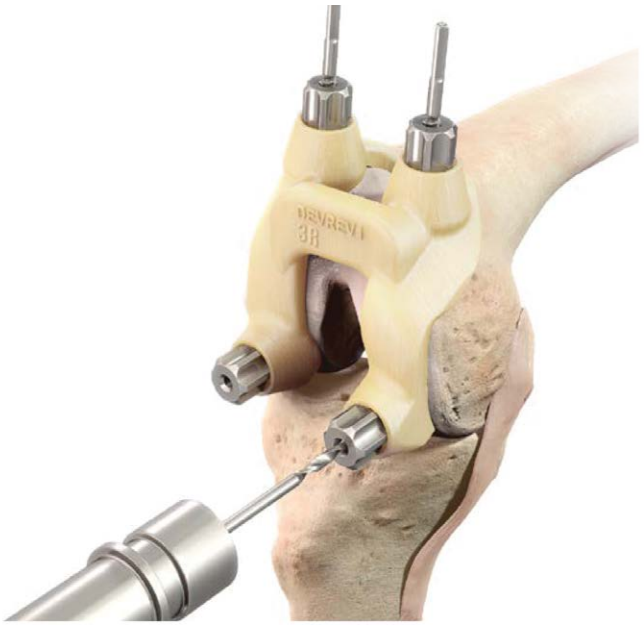


Figure 22

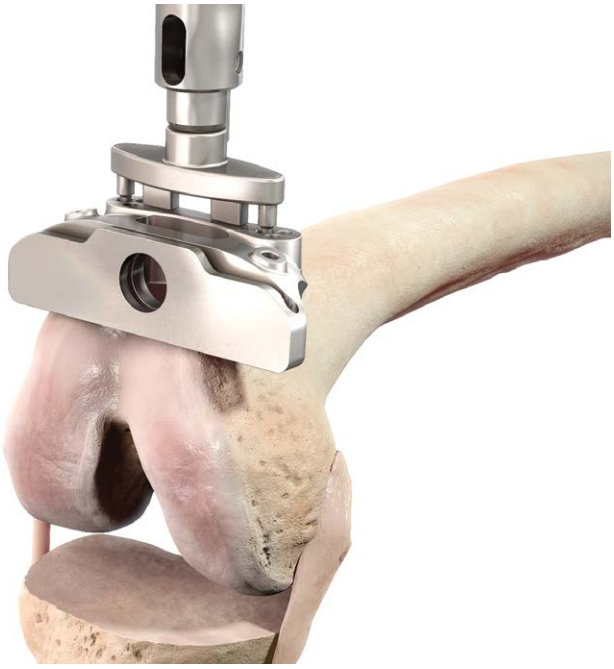


Figure 23

Evaluate the distal cut using the Reference Guide or Angel Wing (Figure 24A). 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 Whale Tail Saw Blade (Figure 24B).

Remove the 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 recut 2 mm of additional bone from the distal femur or the proximal tibia. The INTUITION Spacer Block and Alignment Rod are useful in assessing leg alignment and gap balance.

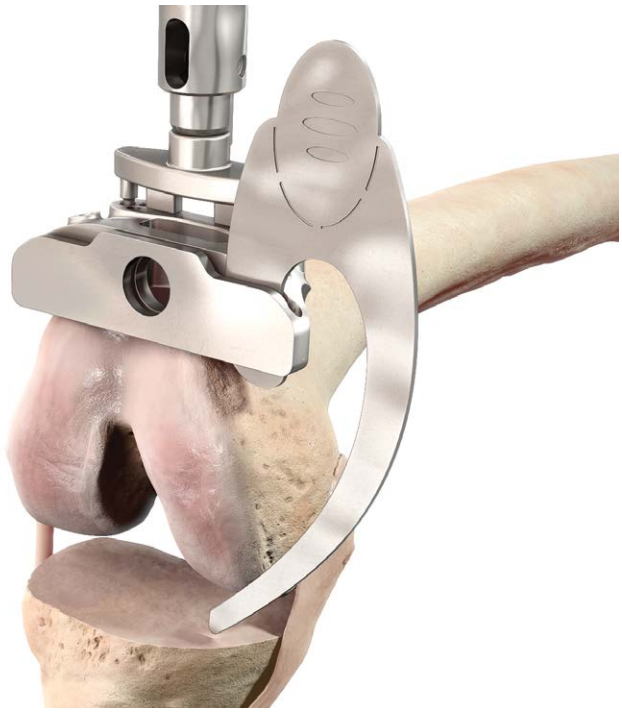


Figure 24A

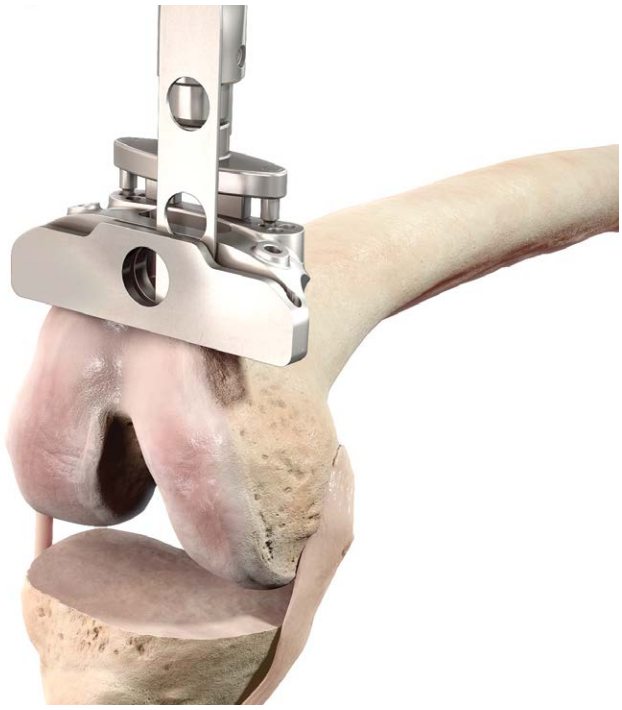


Figure 24B

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 25).

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

Prior to use, insert the TRUMATCH Personalized Solutions Drill Guides (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 26).

Note: The TRUMATCH Personalized 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 Personalized Solutions Pin Guides.

For optimal handling and placement stability of the Tibial Pin Guide, first insert the HP Extramedullary (EM) 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. Then, grasp the Guide using the medial and lateral finger pads (Figure 27A). Do not grasp the Uprod or the area on which the metal Drill Guides are located (Figure 27B).

Note: The INTUITION Instrument Set does not include the HP EM Tibial Uprod and Rod Extension. These will need to be ordered separately or taken from an existing SIGMA® HP Instrument Set.

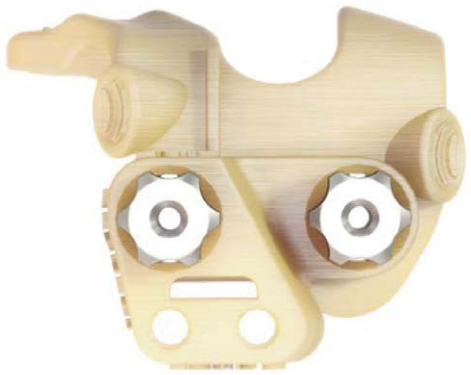


Figure 25

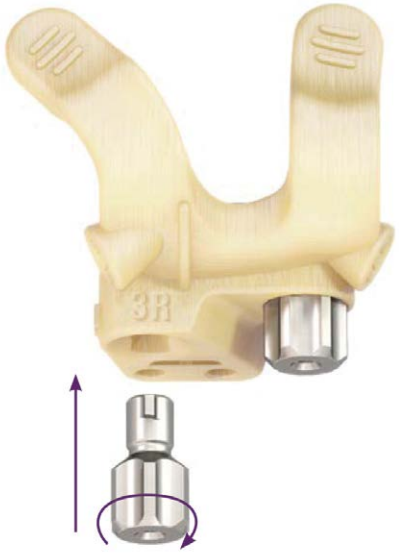


Figure 26

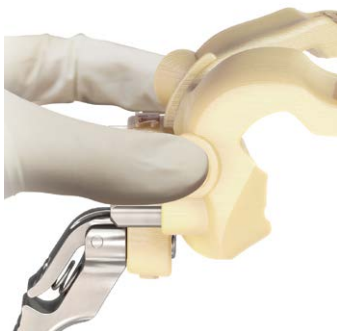


Figure 27A

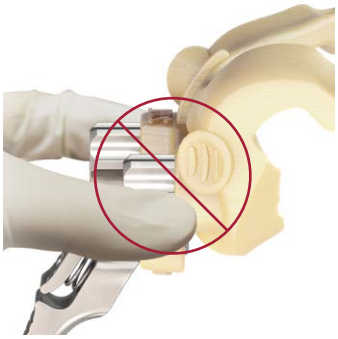


Figure 27B

With the knee flexed at 90 degrees, place the Tibial Pin Guide and 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 28).

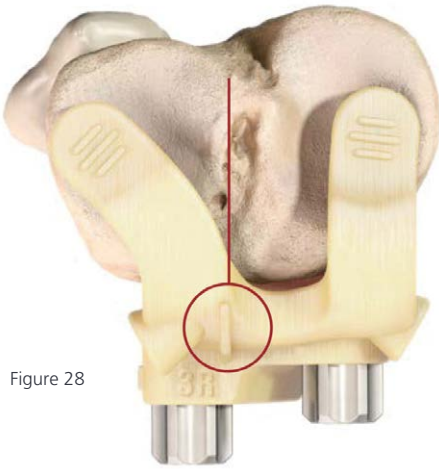


Figure 28

The planned Varus/Valgus (V/V) alignment can be confirmed by verifying the alignment of the Rod to the patient's tibial crest and center of the ankle (Figure 29). In the case of Patient Specific alignment, the Rod will instead be offset from this orientation by the angualr value shown on the Patient Proposal. 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 INTUITION Tibial Cutting Block is positioned over the drill pins and secured to the tibia. The EM Tibial Jig Uprod (P/N 9505-01-228) and Rod Extension (P/N 2004-20-923) should be attached and positioned down toward the ankle. The INTUITION Alignment Handle (P/N 2544-01-011) should be connected to the INTUITION 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.

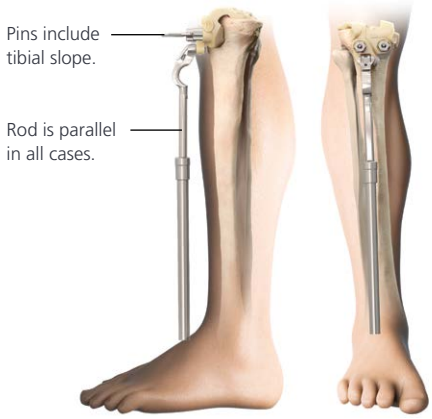


Figure 29

Note: The position of the line in the Patient's Proposal is intended to reference the medial one-third of the tibial tubercle and not the middle of the tibial crest (Figure 28).

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.

Once the Tibia Pin Guide and Uprod Assembly is in the desired position, hold it in place, and secure it to the bone by inserting two 3.15 mm diameter Threaded Non-Headed Pins, first through the lateral 1 and then the medial 2, Drill Guide pin holes (Figure 30).

After drilling the two Anterior Pins, the TRUMATCH Personalized Solutions Drill Guides are removed by twisting in a counterclockwise direction, while leaving the two Anterior Pins in place (Figure 31). Remove the Tibial Pin Guide by moving it up and pulling it away from the Anterior Fixation Pins.

Slide the appropriate L/R/Symmetric INTUITION Proximal Tibial Cutting Block over the Anterior Fixation Pins through the "0" mm holes (Figure 32). If desired, confirm the cut orientation with an 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 INTUITION 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.

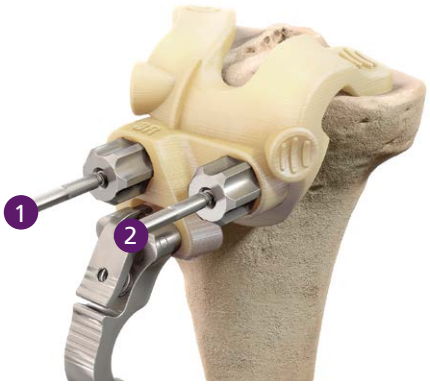


Figure 30

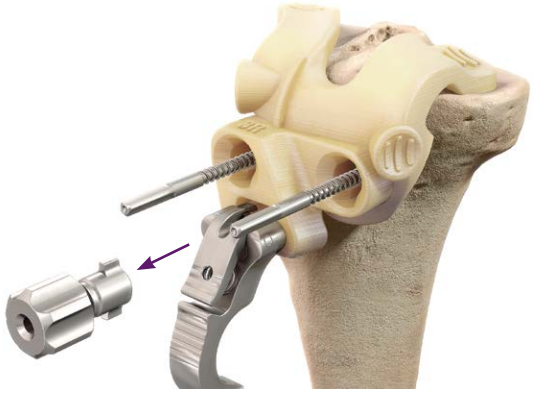


Figure 31

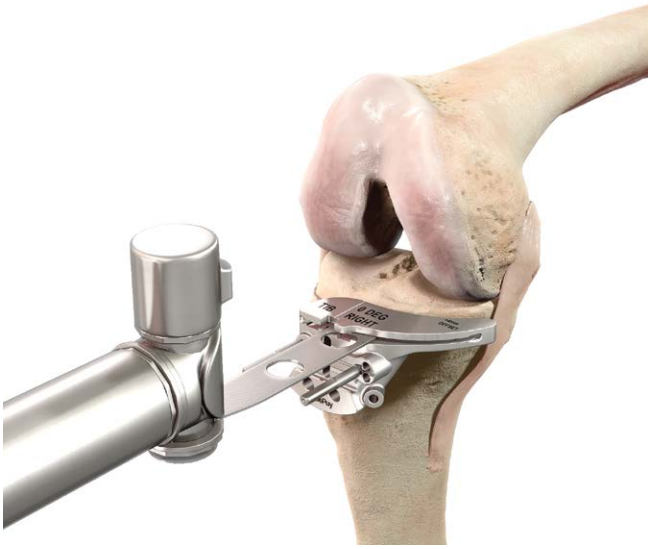


Figure 32

FEMORAL PREPARATION: A/P AND CHAMFER CUTS

Attach the INTUITION Impaction Handle (P/N 2544-01-017) to the INTUITION Fixed Reference Guide (P/N 2000-42-074) and position the Guide's spikes through the "0" mm holes located at the bottom of the INTUITION A/P Chamfer Block without the Posterior Saw Capture (Figure 33). Insert the construct spikes into the previously drilled holes located on the distal femoral bone cut.

Note: The INTUITION Anterior Reference Guide (P/N 2004-20-927) and Fixed Reference Guide (P/N 2000-42-074) are not included in the INTUITION 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 1.5 mm anteriorly or posteriorly by selecting the appropriate offset holes adjacent to the "0" mm hole. (See "Femoral Preparation: A/P Chamfer Cuts" on page 8 for additional detail).

Secure the Block's location by inserting Threaded Headed Pins (INTUITION Single-Use Pin Pack; P/N 2544-00-111) 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). If the use of the Posterior Saw Capture is desired, it may be inserted after removing the Handle/Fixed Reference Guide Assembly and prior to performing the additional femoral finishing cuts. 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.

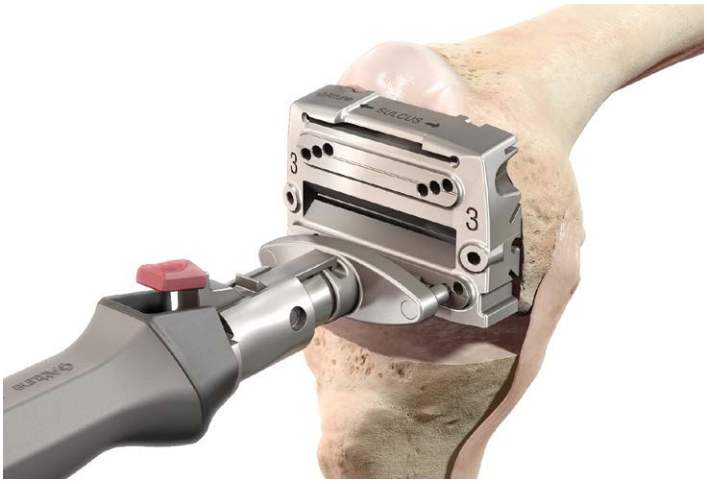


Figure 33

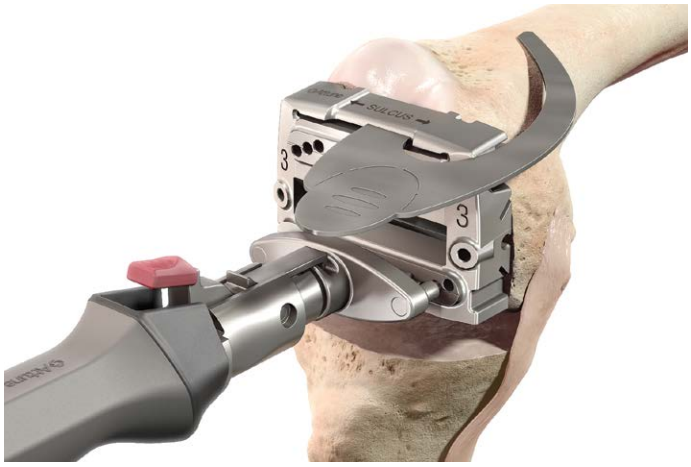


Figure 34

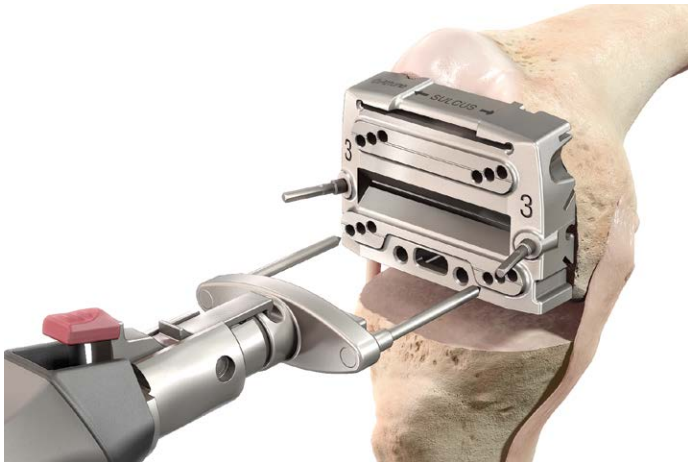


Figure 35

Note: **If the INTUITION Fixed Reference Guide (P/N 2000-42-074) is unavailable, two Fixation Pins can be inserted in the previously drilled distal femoral holes and used to set the location of the INTUITION A/P Chamfer Block. The TRUMATCH Personalized 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 1.5 mm more bone anterior or 1.5 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. The posterior femoral resection will remain unchanged and additional anterior femoral bone will be taken. In order to address an anterior-down preference and the ability to downsize the component, drill two Fixation Pins through the anterior "0" mm holes with the planned Femoral Block. Remove the Femoral Block and use these anteriorly placed Pins with the smaller Block when downsizing. The anterior femoral resection will remain unchanged and additional posterior femoral condylar bone will be taken.**

PRE-OPERATIVE CONSIDERATIONS

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 Personalized 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 implant sizing bone resection information and the tibial Guide orientation line.

f. 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 revisited.

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.

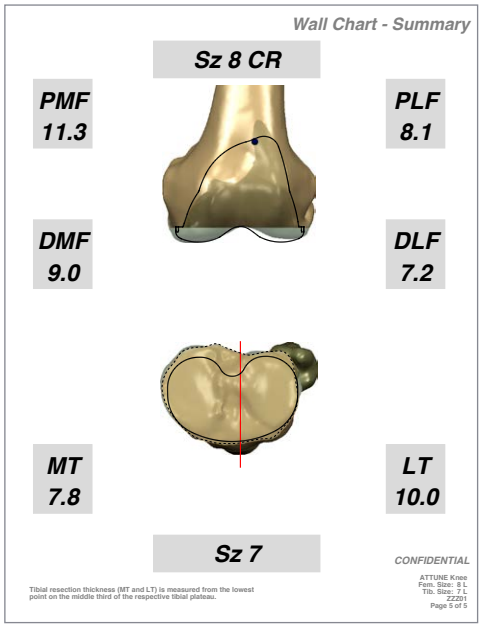


Figure 36

INTRA-OPERATIVE CONSIDERATIONS

Fixation Pins

a. The INTUITION Threaded Non-Headed Pins, combined with the HP Driver (P/N 9505-02-071), are recommended for firmly securing the Guides, especially for the Tibial Guide 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 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 accommodate the Guide.

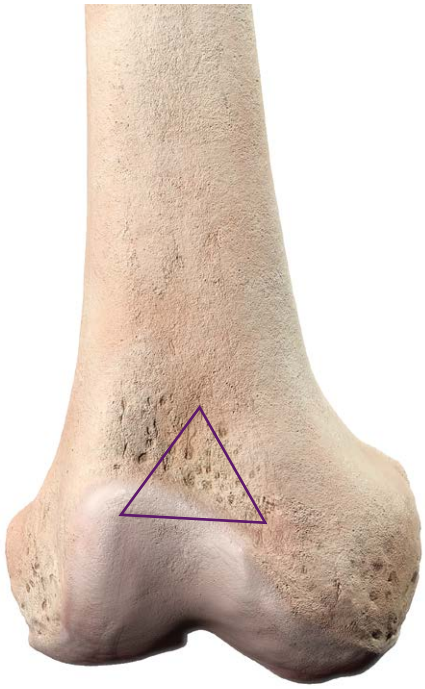


Figure 37

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 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 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.

DePuy Synthes

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