



TruMatch®
PERSONALIZED SOLUTIONS

PIN GUIDE SYSTEM

TRUMATCH® Personalized Solutions
Surgical Technique with ATTUNE™ Knee
INTUITION™ Instruments



PIN GUIDE SURGICAL TECHNIQUE

The following steps are an addendum to the ATTUNE™ Knee INTUITION™ Instruments Surgical Technique (Cat. No. 0612-09-512).

This surgical technique provides instructions on how to incorporate the use of the TRUMATCH® Solutions Femoral and Tibial Pin Guides into the broader ATTUNE Knee INTUITION Surgical Technique. The surgeon must be familiar with the proper use of the appropriate instruments that are necessary to complete the operation following the use of the TRUMATCH Solutions Femoral and Tibial Pin Guides.

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

Note: Pin Guides are only cleared for use with ATTUNE Knee and SIGMA Fixed Bearing Total Knee Implants.

DePuy Synthes
A Johnson & Johnson Company

TruMatch
Personalized Solutions

Use with Attune Instrumentation:

- Distal Cutting Block
- 4-In-1 Cutting Block
- Tibial Cutting Block

Patient Information:

Patient Name: [Redacted]
DOB: 04-08-1963
Gender: Male
Reference Case #: 1502889
Pin Guide Special Consideration: 16-012-2013

Case Information:

Implant Type: [Redacted]
Implant System: [Redacted]
Primary Concern: [Redacted]
Clinical Concerns: [Redacted]
Surgeon Reference: [Redacted]
Social Anam. Reference: [Redacted]
Posterior Tibial Slope: [Redacted]

Pin Guide:

Shape: [Redacted]
Offset: [Redacted]
C/P: [Redacted]
Anterior Slope: [Redacted]
T from the Columbian Axis: [Redacted]
Medial Taper Slope: [Redacted]
L2 from Base of High Plateau: [Redacted]

Notes/Comments:

This section contains communications between the surgeon and designer.

Proposal Version: 1

CONFIDENTIAL

BASIC TRUMATCH® SOLUTIONS PIN GUIDE SURGICAL STEPS

ATTUNE™ Knee System steps shown.

Tibial Preparation



Step 1: Insert Drill Guides and twist clockwise to tighten



Step 2A: Tibial Guide placement



Step 2B: Tibial Guide alignment



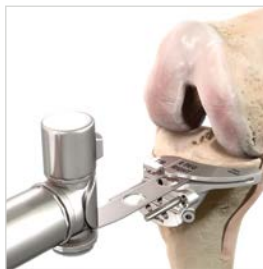
Step 3: Use of Uprod Extension. Verification of Varus/Valgus and lateral alignment



Step 4: Placement of Anterior Pins.



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

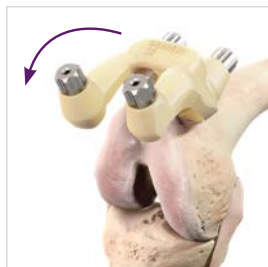


Step 6: Proximal tibial resection using ATTUNE Knee Tibial Cutting Block

Femoral Preparation



Step 1: Insert Drill Guides and twist clockwise to tighten



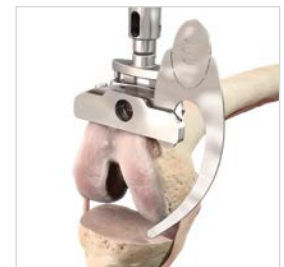
Step 2: Femoral Guide placement



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



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



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



Step 6: Distal femoral resection



Step 7: Use of Fixed Reference Guide to position the 4-in-1 Cutting Block



Step 8: Use of Angel Wing to verify anterior resection



Step 9: Fixation of 4-in-1 Cutting 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 1).

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 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 2).

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 shipped separately from the TRUMATCH 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 3A). Do not grasp the Uprod or the area on which the metal Drill Guides are located. (Figure 3B).

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

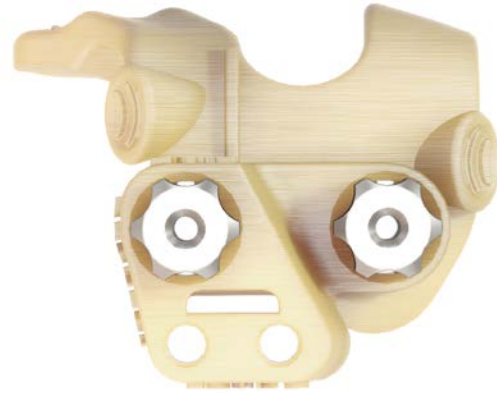


Figure 1

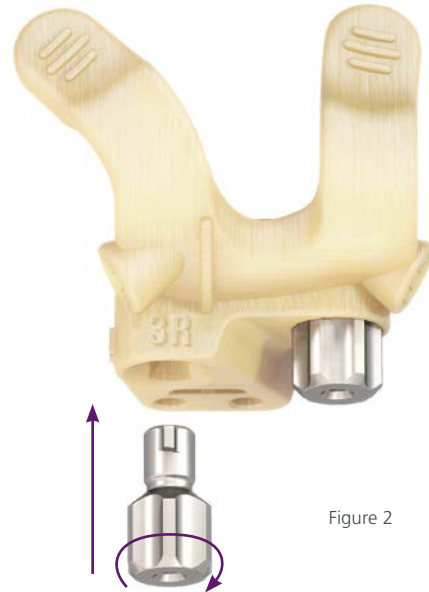


Figure 2



Figure 3A

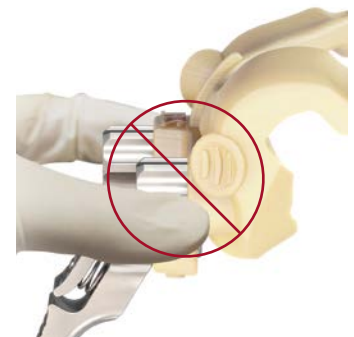


Figure 3B

With the knee flexed at 90 degrees, place the Tibial Resection Guide and Uprod Assembly onto the proximal anterior medial aspect of the tibia and both 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 4).

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 5). The Rod is designed to be parallel to the mechanical axis of the tibia regardless of the planned tibial slope, when viewed laterally.

Note: The position of the line in the Patient's Proposal is intended to reference the medial one-third of the tibial tubercle and not the middle of the tibial crest (Figure 4).

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 ATTUNE Threaded Headless Pins (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111), first through the lateral and then the medial, Drill Guide pin holes (Figure 6).

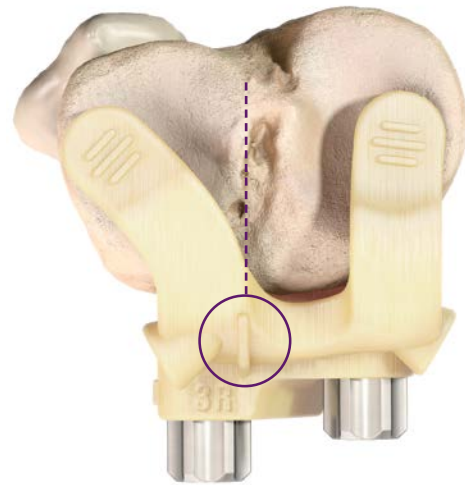
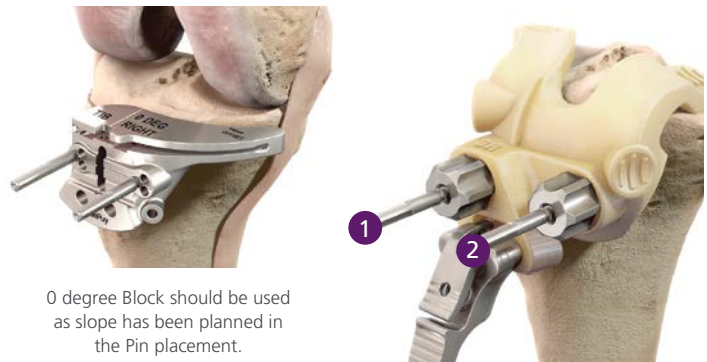


Figure 4



Figure 5



0 degree Block should be used as slope has been planned in the Pin placement.

Figure 6

PROXIMAL TIBIAL RESECTION

After drilling the two Anterior Pins, the TRUMATCH Solutions Drill Guides are removed by twisting in a counterclockwise direction, while leaving the two Anterior Pins in place (Figure 7). Remove the Tibial Pin Guide by moving it up and pulling it away from the Anterior Fixation Pins.

Slide the appropriate L/R 0 degree ATTUNE Proximal Tibial Cutting Block over the Anterior Fixation Pins through the "0" mm holes (Figure 8). 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 ATTUNE Tibial Cutting Block and make sure bone cuts are clean and void of any under-cut 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 ATTUNE Knee INTUITION Instruments Surgical Technique.



Figure 7



Figure 8

DISTAL FEMORAL RESECTION

The Femoral Pin Guide (in addition to the product packaging label) will have patient specific identifiers: Patient Name, Lot No., Size and Patient Anatomy (R/L). Verify the accuracy of these identifiers prior to opening the sterile package (Figure 9).

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

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 10).

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

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

Note: Soft tissue impingement may cause difficulty in seating the Femoral Pin Guide on the femur and could impact the overall alignment of the Guide. It 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 9



Figure 10

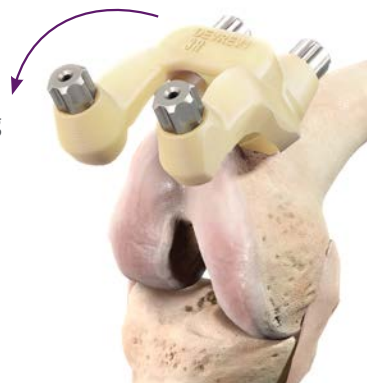


Figure 11A

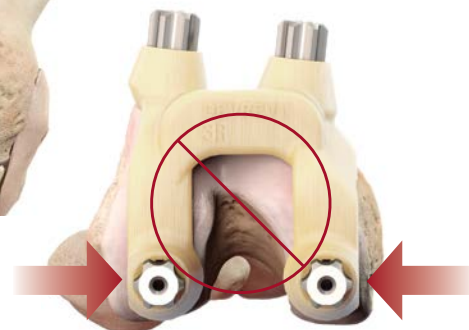


Figure 11B

DISTAL FEMORAL RESECTION

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 due to cartilage loss. Next drill two Anterior Pins and two Distal Pins through the appropriate Drill Guides (Figure 12).

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

The anterior holes will be used to place the ATTUNE 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 4-in-1 Cutting 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 are reusable after sterilization. A minimum of four (4) Drill Guides should be on hand for a case. They are shipped separately from the TRUMATCH Solutions Pin Guides.

Attach the ATTUNE Impaction Handle (P/N 2544-01-017) to the ATTUNE Anterior Reference Guide (P/N 2004-20-927) and position the Guide's spikes through the "0" mm holes in the ATTUNE Distal Femoral Resection Block (Figure 13). Using the Handle, place the ATTUNE Anterior Reference Guide spikes now located through the ATTUNE Distal Femoral Resection Block into the anterior holes.

Note: The ATTUNE 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.

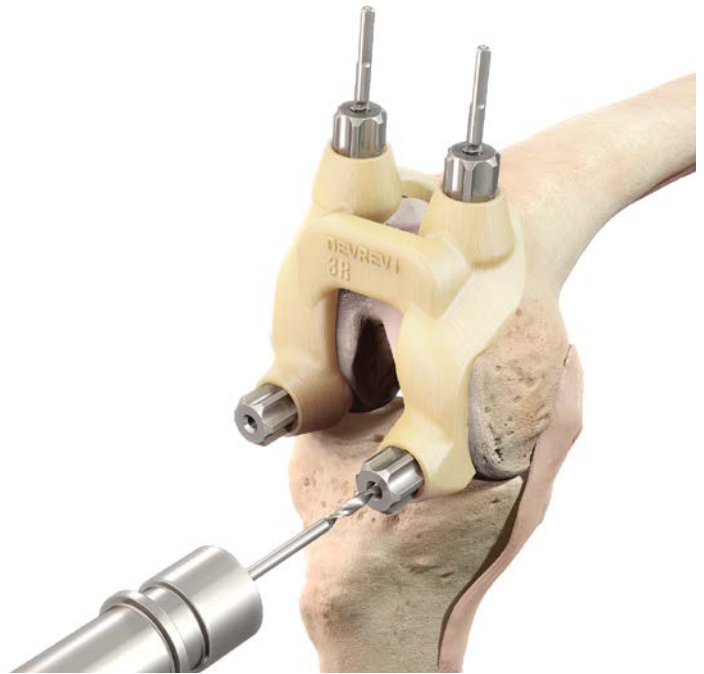


Figure 12



Figure 13

Evaluate the distal cut using the Reference Guide or Angel Wing (Figure 14A). If needed, the Block may be shifted 2 mm proximally or distally by selecting one of the appropriate offset holes adjacent to the "0" mm hole.

For additional stability during the cut, an optional third Fixation Pin can be placed through the Cutting Block in either the lower medial or lateral holes. Perform the distal femoral resection using a 1.19 mm Whale Tail Saw Blade (Figure 14B).

Remove the Distal Femoral Cutting Block and confirm the bone cuts are clean and without any under-cut bone fragments.

Note: In order to address gap assessment and ligament tension, it may be necessary to re-cut 2 or 4 mm of additional bone from the distal femur or the proximal tibia. The ATTUNE Spacer Block and Alignment Rod are useful in assessing leg alignment and gap balance.

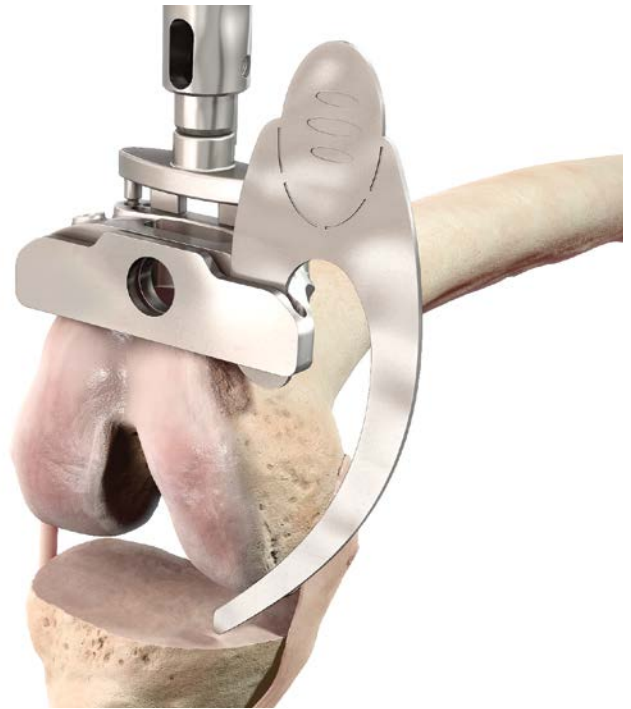


Figure 14A

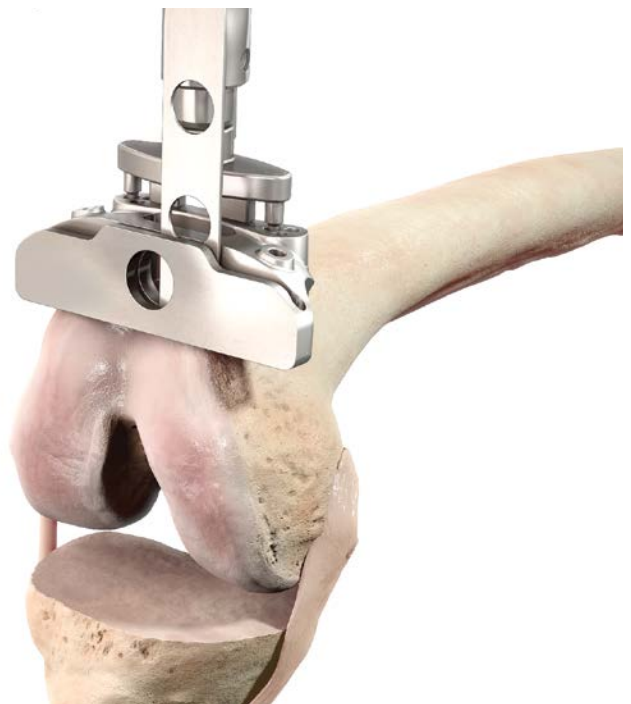


Figure 14B

FEMORAL PREPARATION: AVP AND CHAMFER CUTS

Attach the ATTUNE Impaction Handle (P/N 2544-01-017) to the ATTUNE 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 ATTUNE Femoral Fixed Reference 4-in-1 Cutting Block without the Posterior Saw Capture (Figure 15). Insert the construct spikes into the previously drilled holes located on the distal femoral bone cut.

Note: The ATTUNE 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 16). 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 notes section on page 11 for additional detail).

Secure the Block's location by inserting Threaded Headed Pins (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111) into the convergent pin holes on the medial and lateral aspect of the 4-in-1 Cutting Block. Remove the Handle/Fixed Reference Guide Assembly and perform the femoral resections (Figure 17). After performing all cuts, remove the Pins and Cutting Guide, making sure bone cuts are clean and void of any under-cut bone fragments. 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.

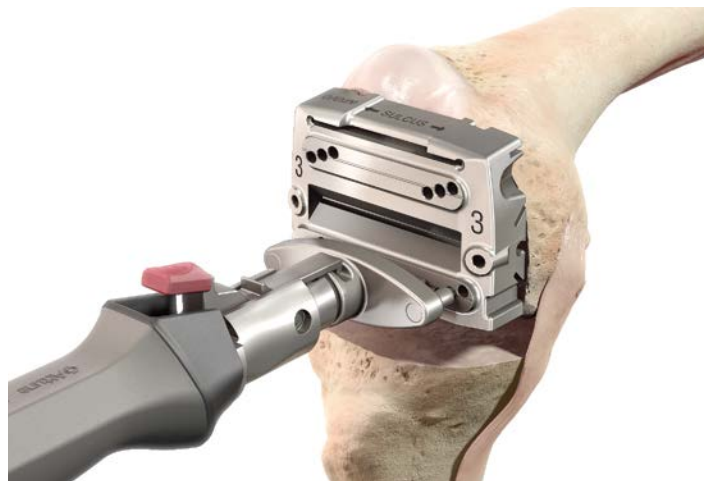


Figure 15

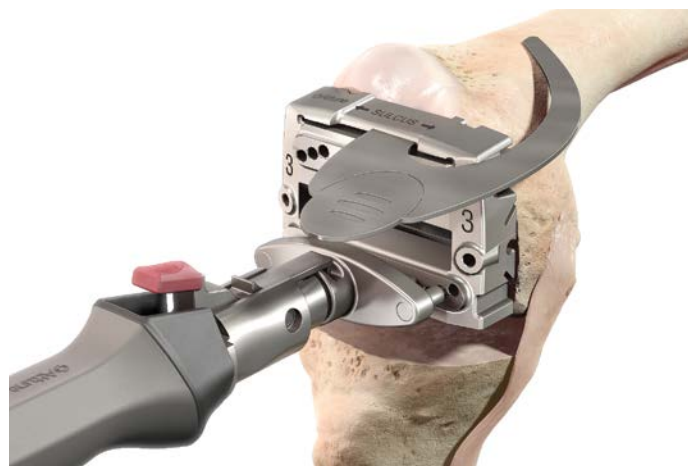


Figure 16

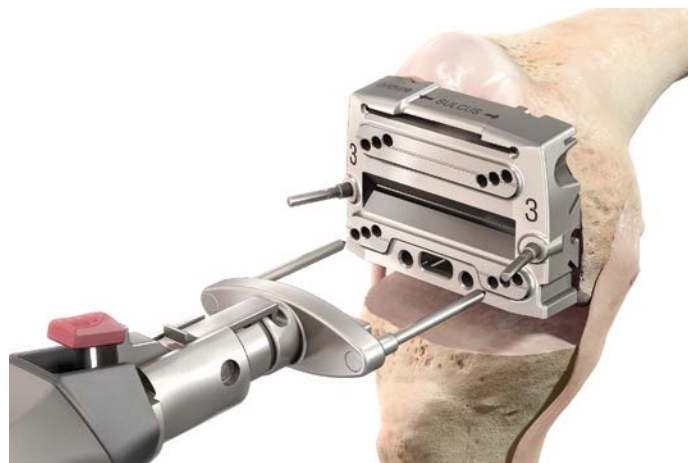


Figure 17

Note: If the ATTUNE 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 ATTUNE Femoral 4-in-1 Cutting 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 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 Block can be inserted over the posterior 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 anterior placed Pins with the smaller Block when downsizing. The anterior femoral resection will remain unchanged and additional posterior femoral condylar bone will be taken.

SURGICAL TIPS AND PEARLS

PRE-OPERATIVE CONSIDERATIONS

Order Submission

Evaluate the M/L Joint Space Loss by utilizing weight-bearing knee joint radiographs and provide the values with the order submission. These values are an important part of the algorithm used to determine the cartilage offset for proper positioning of the guides. For ease of assessment, it is sufficient to use “0”, “50” or “100” % joint space loss when estimating the affected side. The optional Order Form (Figure 18) can be utilized to collect all the necessary information required to submit the TRUMATCH Solutions order online.

Patient Proposal

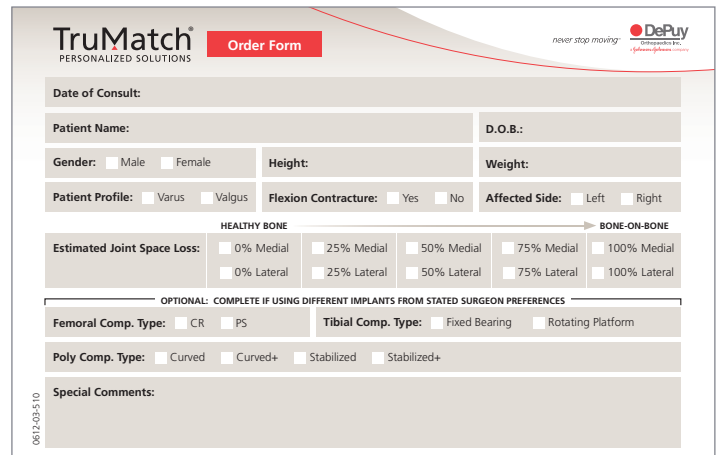
- Review the entire document in detail prior to the surgery.
- Review the Notes/Comments section for important information from the TRUMATCH Solutions Design Team regarding the design of the Guides.
- Print in Color! All Notes/Comments will be shown in red.
- For intra-operative reference, display the wall chart summary page (Figure 19) at an easy to read location in the OR, such as the light box or back wall.

Intra-operative Check-List

Review the Wall Chart Summary (last page), which contains implant sizing bone resection information and the tibial guide orientation line.

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.



The image shows a digital 'TruMatch Order Form' for personalized solutions. It includes fields for 'Date of Consult', 'Patient Name', 'D.O.B.', 'Gender' (Male/Female), 'Height', 'Weight', 'Patient Profile' (Varus/Valgus), 'Flexion Contracture' (Yes/No), and 'Affected Side' (Left/Right). A section for 'Estimated Joint Space Loss' allows selection of percentages (0%, 25%, 50%, 75%, 100%) for both Medial and Lateral sides, with a scale from 'HEALTHY BONE' to 'BONE-ON-BONE'. An 'OPTIONAL' section for different implants includes 'Femoral Comp. Type' (CR, PS), 'Tibial Comp. Type' (Fixed Bearing, Rotating Platform), and 'Poly Comp. Type' (Curved, Curved+, Stabilized, Stabilized+). A 'Special Comments' field is at the bottom. The DePuy logo and 'never stop moving' slogan are in the top right.

Figure 18

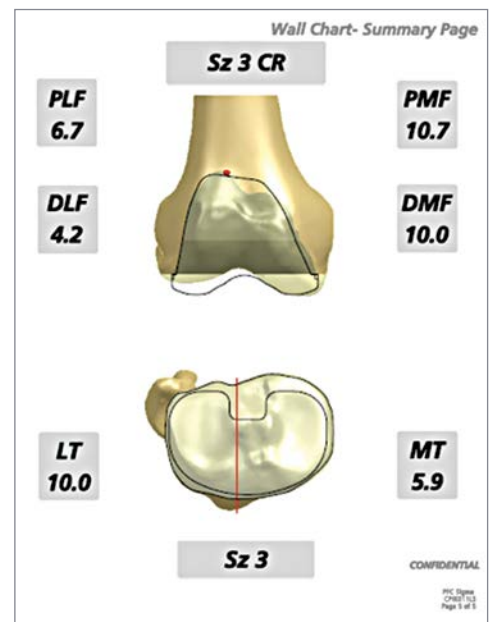


Figure 19

INTRA-OPERATIVE CONSIDERATIONS

Fixation Pins and Saw Blades

- a. The ATTUNE Threaded Headless Sterile Pins (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111), 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.
- b. For efficient resection of large bones, select the longest Saw blade possible, with a 12.7 mm (0.5 in) wide x 1.19 mm (.05 in) thick dimensions.

Femoral Resection Guide

- a. The Femoral Guide's primary reference surface is the anterior cortex of the femur (Figure 20). The most upper portion of the Guide should clear the anterior femoral flange and sit flush on the cortical surface. It may be necessary to remove the thin soft tissue to expose the underlying bone.
- b. Distally, a gap may be seen between the Guide and the femoral condyles. If the Guide is securely positioned anteriorly, do not force the Guide's arms to sit flush on the femoral condyles.



Figure 20

If the Femoral Pin Guide does not fit, verify the following:

1. Was the tissue in the anterior surface of the femur removed and is the proximal portion of the Guide sitting on bone?
2. Did the upper Guide portion clear the anterior femoral flange and is it sitting on the anterior cortex?
3. Is the incision preventing the placement of the Guide on the bone? The incision must be large enough to provide a clear view of the Guide fit to bone.

SURGICAL TIPS AND PEARLS

INTRA-OPERATIVE CONSIDERATIONS

Tibial Resection Guide

- a. The Tibial Guide's primary reference surface is the anterior/medial aspect of the tibia. This area, roughly triangular in shape, matches the Guide's largest surface contact area (Figure 21). When positioning the Guide, apply most of the pressure (~75%) against the anterior aspect of the tibia. It may be necessary to remove the thin soft tissue to expose the underlying bone.
- b. If the Guide is securely positioned anteriorly, do not force the Guide's arms to sit flush on the tibial plateau. While applying force anteriorly, apply light downward force (~25%) on the Guide's proximal arms to hold the Guide stable while drilling the Anterior Pins.

If the Tibial Guide does not fit, verify the following:

1. Is the incision preventing placement of the Guide on the bone? The incision must provide a clear view of the Guide fit on the bone.
2. Check for interference of the lateral aspect of the Guide with the patellar ligament.
3. Confirm that both of the Guide's proximal arms are not impinging by tissue close to the tibial spine.
4. Check the Patient Proposal; was the Joint Space Loss reported to be 100% for either of the condyles and the actual patient has little to no joint space loss? If so, scrape the condyle where full joint loss was requested.



Figure 21

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.

Exclusion Criteria:

The following conditions are not compatible with TRUMATCH Personalized Solutions:

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

Limited Warranty and Disclaimer: DePuy Synthes Joint Reconstruction products 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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