RESECTION GUIDE SYSTEM

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

This surgical technique provides instruction on how to incorporate the TRUMATCH® Femoral Alignment/Distal and Tibial Alignment/Proximal Resection Guides into the broader ATTUNE Knee INTUITION Instruments Surgical Technique. The surgeon must be familiar with the proper use of the ATTUNE Knee INTUITION Instruments, because the INTUITION Instruments are required in the steps prior to, and following, the utilization of the TRUMATCH Solutions Femoral Alignment/Distal and Tibial Alignment/Proximal Resection 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.
BASIC TRUMATCH SOLUTIONS SURGICAL STEPS

Femoral Preparation

Step 1: Femoral Guide positioning

Step 2: Drill and placement of Anterior Pins

Step 3: Drill and placement of Distal Pins

Step 4: Remove one Distal Pin and begin distal femoral resection

Step 5: Replace first Distal Pin; remove second Distal Pin and finish resection

Step 6: Use of the ATTUNE Fixed Reference Guide to position the 4-in-1 Cutting Block

Step 7: Use of the Angel Wing to verify anterior resection

Step 8: Placement of 4-in-1 Cutting Block Pins and removal of the Fixed Reference Guide

Tibial Preparation

Step 1: Tibial Guide placement 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
The Femoral Alignment/Distal Resection Guide (including packaging) will have patient specific identifiers: Patient Name, Patient Date of Birth (D.O.B.), Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 1).

With the knee flexed to approximately 90 degrees, place the Femoral Alignment/Distal 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. See the Surgical Tips and Pearls section for further information.

Once the correct position is found for the Femoral Alignment/Distal 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 feet at the distal femoral condyles due to cartilage loss.

When satisfactory placement is achieved, secure the Femoral Alignment/Distal Resection Guide by inserting one ATTUNE Threaded Headless Pin (ATTUNE Knee INTUITION Single-Use Pin Pack; (Part Number (P/N) 2544-00-111) through the anterior medial hole (Figure 3). After the Medial Pin is secured, place another Pin through the lateral pin hole (Figure 3).
After the Femoral Alignment/Distal Resection Guide is secured, drill the two distal holes using the ATTUNE Threaded Headless Pins (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111). The ATTUNE Threaded Headless Pins should always be drilled and not hammered in. These pin holes set the femoral rotation and match the 4-in-1 Cutting Block from the ATTUNE Knee INTUITION Instruments set (Figure 4).

It is recommended to perform the distal femoral resection by leaving one Distal Pin in the Guide while resecting the opposite side of the femur for optimized stability.

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

Remove Femoral Alignment/Distal 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 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 ATTUNE Knee INTUITION Distal Femoral or Tibial Cutting Blocks. Both Cutting Blocks can be used to cut either 2 or 4 mm of additional bone. These Cutting Blocks slide over Pins placed in the previously drilled Guide Pin locations.
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 pin holes of the ATTUNE Knee INTUITION Fixed Reference 4-in-1 Cutting 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 Solutions Femoral Alignment/ Distal Resection Guide is designed to position the pin holes posteriorly while maintaining the desired “anterior down” or “posterior up” fixed reference selection.

**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.

Confirm the anterior cut placement with the Reference Guide, or Angel Wing (Figure 7). If desired, the Cutting Block may be shifted 1.5 mm anteriorly or posteriorly by selecting the appropriate offset holes around the “0” hole. When downsizing, using the smaller 4-in-1 Cutting Block will remove bone anteriorly with a posterior up preference plan. If the plan utilized an anterior down preference, the planned sized Cutting Block will need to have two Pins drilled in the “0” hole position in the anterior location of the Block. Remove the Cutting Block and slide the smaller 4-in-1 Cutting Block over the two anterior placed Drill Pins. This will remove posterior bone. For additional details on downsizing refer to the ATTUNE Knee INTUITION Instrument Surgical Technique 0612-09-512.

Secure the Block’s location by inserting Threaded Headed Pins into the convergent pin holes on the medial and lateral aspect of the 4-in-1 Cutting 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.
The Tibial Alignment/Proximal Resection Guide (including packaging) will have patient specific identifiers: Patient Name, Patient D.O.B., Size and Patient Anatomy (R/L). Please verify the accuracy of these identifiers prior to use (Figure 9).

With the knee flexed to approximately 90 degrees, place the Tibial Alignment/Proximal 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).

**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 Alignment/Proximal Resection Guide, there should be no toggling or rocking.

When satisfactory placement is achieved, secure the Resection Guide by inserting one ATTUNE Headless Threaded Pin (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111) through the center oblique hole, followed by the pinning of the lateral hole and medial hole last (Figure 11).
Take the Alignment Verification Adapter (P/N 2000-42-062) (holes need to be oriented laterally) and insert the HP Alignment Rod through the holes. Next, insert the Adapter’s blade into the Resection Guide’s saw slot (Figure 12).

**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.

Confirm the Varus/Valgus (V/V) position 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. See Surgical Tips and Pearls section for further information.

**Note:** Optionally, the Tibial Alignment/Proximal 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 Alignment/Proximal Resection Guide, make sure bone cuts are clean and void of any under-cut bone fragments.

**Note:** If additional tibial resection or tibial slope is desired, replace the two proximal Fixation Pins and utilize the appropriate (L/R) ATTUNE Knee INTUITION Instrument Tibial Resection Cutting Block.

Proceed with the remaining steps for proximal tibial preparation as outlined by the ATTUNE Knee INTUITION Instruments Surgical Technique.
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 design 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 14) can be utilized to collect all the necessary information required to submit the TRUMATCH Solutions order online.

Patient Proposal

a. Review in detail prior to the surgery.

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

c. Print in Color! All 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 15).

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Figure 14

Figure 15
Fixation Pins
a. The ATTUNE Knee INTUITION Threaded, Headless and 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 Alignment/Proximal Resection Guide when used on soft bone.

Femoral Alignment/Distal Resection Guide
a. The Femoral Alignment/Distal Resection Guide’s primary reference surface is the anterior cortex of the femur (Figure 16-a). The upper most 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, a small gap may be seen between the Guide and the femoral condyles (Figure 16-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 (ATTUNE Knee INTUITION Single-Use Pin Pack; P/N 2544-00-111).

c. After performing the distal femoral resection and removing the Guide, examine the posterior aspect of the Guide’s arms. If it appears to be damaged by the Saw Blade, that respective condyle cut was likely under cut and out of plan. The Guide should be repositioned and the cut repeated (Figure 17).

If the Femoral Alignment/Distal 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 Alignment/Proximal Resection Guide

a. The Tibial Alignment/Proximal 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 18). 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 19).

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.

If the Tibial Alignment/Proximal Resection 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 tissue close to the tibial spine or the anterior rim of the tibial plateau.

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.
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.