About OrthAlign, Inc.

OrthAlign is committed to providing surgeons with user-friendly, cost-effective, surgical navigation products for precise alignment.

For more information about the KneeAlign® 2 System, please contact us at 866.582.0879 or info@orthalign.com.
This technique guide describes the proper use of the KneeAlign® 2 System. This system is not compatible with its previous generation, the KneeAlign® System and the two systems should not be used in the same operating environment. Any reference below to the “navigation unit” or “sensor” refers to the KneeAlign® 2 unit and Reference Sensor 2 system components.

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SET UP

**Attach Bracket**
- Attach navigation unit to mounting bracket by sliding unit in the direction indicated by arrow on bracket. Attach sensor to coupler at other end of mounting bracket as shown.
- Press center button when completed.

⚠️ If navigation unit is dropped on floor, it must be discarded. If sensor is dropped on floor, it must be returned to manufacturer for verification of function and calibration.

**Hold Horizontally**
*Calibration Step 1:*
Rest navigation unit horizontally on level surface with screen facing upwards and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Verify Calibration**
*Calibration Step 3:*
Rest navigation unit in angled position on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Hold Vertically**
*Calibration Step 2:*
Rest navigation unit vertically on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Set up**
- Attach Bracket
  - Attach navigation unit to mounting bracket by sliding unit in the direction indicated by arrow on bracket. Attach sensor to coupler at other end of mounting bracket as shown.
  - Press center button when completed.

⚠️ If navigation unit is dropped on floor, it must be discarded. If sensor is dropped on floor, it must be returned to manufacturer for verification of function and calibration.

**Hold Horizontally**
*Calibration Step 1:*
Rest navigation unit horizontally on level surface with screen facing upwards and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

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*Calibration Step 3:*
Rest navigation unit in angled position on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Hold Vertically**
*Calibration Step 2:*
Rest navigation unit vertically on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Set up**
- Attach Bracket
  - Attach navigation unit to mounting bracket by sliding unit in the direction indicated by arrow on bracket. Attach sensor to coupler at other end of mounting bracket as shown.
  - Press center button when completed.

⚠️ If navigation unit is dropped on floor, it must be discarded. If sensor is dropped on floor, it must be returned to manufacturer for verification of function and calibration.

**Hold Horizontally**
*Calibration Step 1:*
Rest navigation unit horizontally on level surface with screen facing upwards and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Verify Calibration**
*Calibration Step 3:*
Rest navigation unit in angled position on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.

**Hold Vertically**
*Calibration Step 2:*
Rest navigation unit vertically on level surface and hold steady with ball in circle. Navigation unit will beep twice and automatically proceed to next screen.
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SET UP

Assemble Tibial Jig
- Assemble tibial jig as follows:
  - Set fixation arm on proximal end of tibial jig to “Left” or “Right” for leg being operated on.
  - Ensure that varus/valgus and posterior slope levers of tibial jig are locked.
  - Attach midline probe (a) to proximal end of tibial jig.
  - Attach shin spacer (b) to tibial jig.
  - Attach ankle tube (c) to distal end of tibial jig and lock in place.
  - Attach malleolar probe (d) to ankle tube.
  - Press center button on navigation unit when completed.

TIP: Fixation arm is spring-loaded and may be adjusted by pulling arm away from jig, then rotating.
TIP: Shin spacer may already be attached.
TIP: Squeeze button on ankle tube and insert malleolar probe through slot until it reaches limit of its travel. Use curved malleolar probe to extend range for extremely long or short tibias.

Assemble Femoral Jig
- Once assembled, ensure microblock is in neutral position by adjusting varus/valgus and flexion/extension screws with ball driver.
- Press center button when completed.

TIP: Plate and bracket of microblock should be approximately parallel to each other when viewed from front and side.

Assemble Femoral Jig (cont.)

- Push guide rod in direction indicated by arrow labeled “Lock” until it stops.
- Fully extend slider to its maximum setting in order to position guide rod against gold latch. Ensure gold latch is unlocked.
- Lock guide rod by sliding gold latch into position.
- Slide femoral cutting block onto guide rod in direction indicated by arrow on cutting block labeled “Assemble” until it locks into place.

Tips and Tricks:
- Set up
- Assemble tibial Jig
- Ensure fixation arm is spring-loaded and may be adjusted by pulling arm away from jig, then rotating.
- Ensure that varus/valgus and posterior slope levers of tibial jig are locked.
- Attach midline probe (a) to proximal end of tibial jig.
- Attach shin spacer (b) to tibial jig.
- Attach ankle tube (c) to distal end of tibial jig and lock in place.
- Attach malleolar probe (d) to ankle tube.
- Press center button on navigation unit when completed.

TIP: Fixation arm is spring-loaded and may be adjusted by pulling arm away from jig, then rotating.
TIP: Shin spacer may already be attached.
TIP: Squeeze button on ankle tube and insert malleolar probe through slot until it reaches limit of its travel. Use curved malleolar probe to extend range for extremely long or short tibias.
Femur

Secure on Femur

- Expose knee.
- Place knee in flexion and seat microblock on femur in approximately neutral varus/valgus and flexion/extension position.
- Insert headed pin in center hole of microblock slider and drive it into most distal point of sulcus of trochlea, directing it toward center of femoral head.
  
  **TIP:** A typical IM drill placement approximates this point. Do not bias medially or laterally.
- Rotate microblock to approximately line up with Whiteside's line.
- Slide microblock in anterior/posterior direction as necessary to achieve three-point contact to femur. Pin medial and lateral feet of instrument against condyles, using headed pins provided in instrument tray.
- Press center button when completed.

**Tip:** Hardened, stainless steel headed pins provided in instrument tray should be used.

**Tip:** Do not impact or hammer system components.

TIP: Verify that there is approximately 10 mm of clearance between femoral cutting block and anterior condyles.

FEMUR

Input A/P Offset

- Read anterior/posterior offset position of center pin on microblock slider scale.
- Enter offset value into navigation unit by pressing right button until correct number is displayed on bottom right corner of screen.
- Press center button when completed.

**Tip:** If displayed value exceeds desired offset, continue to press right button to cycle back to desired value.

**Tip:** If “TIB” is selected, proceed to Tibia resection steps on page 12.

**Tip:** If “FEM” is selected, proceed to Femur resection steps on page 7.

**Tip:** If displayed value exceeds desired offset, continue to press right button to cycle back to desired value.

Step 1

Insert pin at knee center toward hip.

Step 2

Read A/P Offset.

Step 3

Whiteside’s line.

Step 4

Read A/P Offset.

Step 5

Select Bone

- Press button to select tibia or femur.

**Tip:** If “TIB” is selected, proceed to Tibia resection steps on page 12.

**Tip:** If “FEM” is selected, proceed to Femur resection steps on page 7.

Step 6

Select Knee

- Press button to select “L” (Left) or “R” (Right) for leg being operated on.

**Tip:** If displayed value exceeds desired offset, continue to press right button to cycle back to desired value.

Select Bone

- Press button to select tibia or femur.

**Tip:** If “TIB” is selected, proceed to Tibia resection steps on page 12.

**Tip:** If “FEM” is selected, proceed to Femur resection steps on page 7.

**Tip:** If displayed value exceeds desired offset, continue to press right button to cycle back to desired value.

Step 9

Femur

Secure on Femur

- Expose knee.
- Place knee in flexion and seat microblock on femur in approximately neutral varus/valgus and flexion/extension position.
- Insert headed pin in center hole of microblock slider and drive it into most distal point of sulcus of trochlea, directing it toward center of femoral head.

**TIP:** A typical IM drill placement approximates this point. Do not bias medially or laterally.

- Rotate microblock to approximately line up with Whiteside’s line.
- Slide microblock in anterior/posterior direction as necessary to achieve three-point contact to femur. Pin medial and lateral feet of instrument against condyles, using headed pins provided in instrument tray.
- Press center button when completed.

**Tip:** Hardened, stainless steel headed pins provided in instrument tray should be used.

**Tip:** Do not impact or hammer system components.

TIP: Verify that there is approximately 10 mm of clearance between femoral cutting block and anterior condyles.

Step 10

Select Bone

- Press button to select tibia or femur.

**Tip:** If “TIB” is selected, proceed to Tibia resection steps on page 12.

**Tip:** If “FEM” is selected, proceed to Femur resection steps on page 7.

Set up

Select Knee

- Press button to select “L” (Left) or “R” (Right) for leg being operated on.

Input A/P Offset

- Read anterior/posterior offset position of center pin on microblock slider scale.
- Enter offset value into navigation unit by pressing right button until correct number is displayed on bottom right corner of screen.
- Press center button when completed.

**Tip:** If displayed value exceeds desired offset, continue to press right button to cycle back to desired value.

**Tip:** If “TIB” is selected, proceed to Tibia resection steps on page 12.

**Tip:** If “FEM” is selected, proceed to Femur resection steps on page 7.
Step 3: Attach Sensors
- Attach navigation unit and sensor to microblock.
  - Align ball in center of rectangular box on side of screen by changing angle of femur until box turns green.
  - Tip: Navigation unit on mounting bracket should be attached to coupler adjacent to white dot on microblock. Sensor should be attached to coupler adjacent to black dot on microblock.
  - Tip: If sensor is not attached correctly, box on the side of screen will not appear and screen will read “Mount Sensor Here.” Once navigation unit and sensor are attached, do not adjust varus/valgus or flexion/extension screws of microblock until after completing hip point registration (Femur-Step 4).

Step 4: Maneuver Leg
- Hold femur stationary until green light appears on navigation unit screen and unit starts to beep continuously. As soon as navigation unit starts beeping, maneuver femur rapidly as follows while keeping the pelvis stationary:
  - First, move knee in medial-lateral arc by internally and/or externally rotating hip while keeping heel on table, and maintaining knee in flexion.
  - Next, move knee in sagittal plane by flexing and extending hip.

Tips for Maneuver:
- Maneuver must be completed before beeping stops and as rapidly as possible.
- Tip: Maneuver leg using two hands, grasping behind knee and ankle. Do not hold navigation unit or femoral jig. Rotate knee between 10° and 45° subtended during registration maneuver.
- For accurate results, it is important that hip is kept stationary during registration. Knee must be returned to start position (within ± 2 cm and ± 5° rotation).
- Tip: Following maneuver completion, during hip point calculation, navigation unit screen will provide user with feedback on speed of maneuver in medial-lateral (M/L) and anterior-posterior (A/P) planes. Green bars displayed for a given plane indicate that speed of the maneuver is sufficient in that plane. Red bars displayed for a given plane indicate that speed in that plane is insufficient.
- Tip: In the event maneuver is too slow in a given plane, or otherwise insufficient, navigation unit screen will provide instructions to repeat maneuver.
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FEMUR

Set Resection Plane

- Set desired varus/valgus and flexion/extension angles using ball driver to adjust microblock navigation screws.
- Press center button when completed.

**Tip:** Navigation unit must be oriented within its operating range in order for unit to display resection angles.

**Tip:** Varus/valgus and flexion/extension angles are measured relative to mechanical axis of femur.

Do not attempt to adjust cutting block orientation by applying force to jig. Angles must be adjusted using ball driver to adjust screws prior to pinning the cutting block.

Applying excessive torque to adjustment screws at limit of travel will cause damage to microblock.

If bone interferes with cutting block while setting resection angle, microblock has been pinned in too much flexion. Two alternatives may be considered:

1. Use sagittal saw to trim interfering bone to provide additional travel for cutting block. Care should be taken not to remove too much bone, which could cause notching or interfere with subsequent sizing.
2. Unpin microblock and re-pin closer to neutral flexion angle, repeating Femur–Steps 1-4.

**Set Resection Depth** (cont.)

- Resection depth is indicated by scale on anterior face of guide rod, viewed at top of distal guide. Shoulders on guide rod stops distal guide at 9 mm resection depth. Resection depth can be increased in 1 mm increments by squeezing pushbutton and pulling distal guide up.

Resection depth measurement should be set according to implant manufacturer’s recommendations.

Resection depth scale is relative to position of distal guide. Ensure that distal guide paddles remain flush on highest point of condyle being referenced.

**Tip:** When pinning the cutting block, take care to avoid applying excessive force that could alter intended varus/valgus and flexion/extension angles.

To prevent potential interference of oblique pin with microblock pins, do not insert oblique pin until microblock has been removed. Use angle wing stylus to verify resection level prior to resection.

**Tip:** If more bone needs to be resected, move cutting block proximally on parallel pins (+2 mm, +4 mm). Required saw blade thickness is 1.27 mm (or 0.050 in).

If distal guide contacts condyle before the desired depth setting is reached, microblock has been pinned in too much extension. Unpin microblock and re-pin closer to neutral flexion angle, repeating Femur–Steps 1-4.

Set Resection Depth

- Remove navigation unit/bracket assembly, and sensor from microblock.
- Attach distal guide to microblock guide rod by squeezing pushbutton (b), and slide distal guide to desired resection depth (c).
- Press gold latch on side of microblock to unlock guide rod/cutting block assembly from its maximum anterior position. Position distal guide paddles flush against condyles, and slide cutting block posteriorly to contact femur.
- Pin distal femoral cutting block to anterior femur using most proximal holes using headless pins provided in instrument tray.
- Remove pins from microblock by pulling in distal direction, while securely holding cutting block in place. Fix cutting block with oblique pin if desired.
- Resect distal femur.
- Press center button when completed.

Finished Femur

- Use of navigation unit for distal femoral resection is finished.

**Tip:** Press center button to continue if additional use is appropriate in this procedure.
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TIBIA

Step 1

Attach Sensors

- Remove navigation unit and sensor from mounting bracket and attach to tibial jig.
- Press center button when completed.

Tip: Attach sensor so that it is on lateral side of tibial jig (opposite fixation arm) during procedure.

Step 2

Secure on Tibia (cont.)

- Midline probe should not be impacted into tibial plateau.
- During pinning, ensure that midline probe is not pulling away from main tibial jig body. If it has, push probe down to reset.
- After pinning, fixation arm should be inspected to verify it has not pulled away from main tibial jig body and that it is seated fully within notch in jig body. If fixation arm has disengaged from jig body, push jig towards tibia to fully reseat fixation arm in jig body.

Tip: Hardened, stainless steel pins provided in instrument tray should be used for pinning KneeAlign® 2 instrumentation.

Tip: If jig appears in extension relative to tibia, remove shin spacer. This may be the case for very obese legs.

Step 3

Match Probe Offsets

- Confirm tip of midline probe is placed just posterior to insertion of ACL.
- Read number on midline probe where arrow indicates.
- Release PS and V/V levers to allow jig to move freely.
- Set matching number on malleolar probe by pushing button on ankle tube and sliding malleolar probe to desired position.
- Press center button when completed.

Step 2

Secure on Tibia

- Pull malleolar probe to maximum anterior position in order to avoid interference during placement of jig.
- Place tibial jig on anterior tibia, aligning etched line on fixation arm of jig with medial third of tibial tubercle.
- Position tip of midline probe just posterior to insertion of Anterior Cruciate Ligament (ACL).
- Secure fixation arm to tibia with at least two headed pins provided in instrument tray.
- Secure mid-tibia v-rest of tibial jig with calf strap.
- Press center button when completed.

Step 2

Secure on Tibia

- Pull malleolar probe to maximum anterior position in order to avoid interference during placement of jig.
- Place tibial jig on anterior tibia, aligning etched line on fixation arm of jig with medial third of tibial tubercle.
- Position tip of midline probe just posterior to insertion of Anterior Cruciate Ligament (ACL).
- Secure fixation arm to tibia with at least two headed pins provided in instrument tray.
- Secure mid-tibia v-rest of tibial jig with calf strap.
- Press center button when completed.
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TIBIA

Register Lateral Malleolus
- Palpate lateral malleolus and place cup of malleolar probe on its apex.
- Press center button to register lateral malleolus.

**TIP:** Extend jig distally if necessary, by releasing ankle tube latch.

In event that leg is positioned at orientation outside of range of KneeAlign® 2 system, box at top center of screen will turn orange. Change position of leg until black ball is within square box and box has turned green.

**TIP:** A double beep will sound on registration.
- Navigation unit must be maintained in steady position or red hand will flash on screen.
- Ankle tube should be locked during registration.

Set Resection Plane
- Retract malleolar probe to maximum anterior position.
- Move distal end of tibial jig to obtain desired varus/valgus and posterior slope angles and lock in place with side levers.

**TIP:** Malleolar probe may be adjusted to assist in setting posterior slope angle.
- Do not use malleolar probe to set posterior slope angle if posterior slope lever is locked.
- After locking levers, do not move jig relative to the tibia. Pushing or pulling locked bars of the jig may introduce errors in navigation accuracy.

KneeAlign® 2 System does not display measurement values when oriented outside of its operating range. Change position of leg until black ball is within rectangular box and box has turned green.

Register Medial Malleolus
- Palpate medial malleolus and place cup of malleolar probe on its apex. Press center button on navigation unit to register medial malleolus.

**TIP:** A double beep will sound upon registration.

- After registration, do not move base of jig relative to tibia. Keep fixation arm and v-rest in their attached positions. Pushing or pulling fixed base of jig may introduce errors in navigation accuracy.

- Press center button on KneeAlign® 2 when this step is completed and remove midline probe by pulling straight up.
**Set Resection Depth**
- Insert tibial cutting block and rotate it into position against tibia. Attach resection stylus to tibial cutting block.
- Push release plate of tibial jig up to adjust height of the tibial cutting block (locking mechanism on cutting block is in 1 mm increments). Once tibial cutting block is at desired position, pin in place with headless pins provided in instrument tray using distal pin holes.
- Resect tibia.
- Press center button when completed.

**TIP:**
- While setting resection depth, stylus end should not be pressed into tibial plateau.
- Resection depth measurement should be set according to implant manufacturer’s recommendations.
- If additional support is required, place oblique pin through tibial cutting block.
- If additional resection is required, move cutting block down on pins (2 mm). Tibial jig will need to be removed to facilitate this.
- Required saw blade thickness is 1.27 mm (or 0.050 in). Verify resected tibia with drop rod.

**DISPOSAL**
- To power off navigation unit, press and hold down left and right buttons simultaneously.
- Navigation unit must be powered off and discarded.
- Battery must be removed from sensor and discarded.
- Sensor, calf strap, and pins must NOT be discarded. These items should be returned to their designated locations in the instrument tray.

**Prior to disposal, power off navigation unit by pressing left and right buttons for 2 seconds.**
**Troubleshooting**

### Setup

- **Sensor Not Attached Correctly to Femoral Jig.**
  - Reattach sensor as shown in Screen F3.

- **Calibration Step During Setup Invalid Due to Incorrect Attachment of Sensor.**
  - Reattach sensor correctly and repeat validation steps.

### Femur Maneuver

- **Sensor Not Attached Correctly to Femoral Jig.**
  - Reattach sensor as shown in Screen F3.

- **Hip Point Registration Maneuver Performed Too Slowly in Either, or Both Anterior/Posterior (A/P) or Medial-Lateral (M/L) Planes.**
  - Press center button to repeat maneuver at higher speed sufficient to obtain green color bars for both A/P and M/L speeds.

- **Sensor Medial-Lateral Position on Tibial Jig Was Changed During Registration Process.**
  - Attach sensor to lateral side of tibial jig and restart tibial navigation Step 3 (Register Lateral Malleolus).

- **Hip Point Registration Maneuver Not Finished Prior to End of Navigation Unit Beeping Stream.**
  - Press center button to repeat maneuver, finishing maneuver and returning knee to starting position prior to end of unit beeping stream.

- **Knee Was Not Returned to Starting Position at End of Maneuver.**
  - Press center button to repeat maneuver, returning knee to within ± 2 cm and ± 5° rotation of starting position prior to end of unit beeping stream.

### Tibia

- **Sensor Medial-Lateral Position on Tibial Jig Was Changed During Registration Process.**
  - Attach sensor to lateral side of tibial jig and restart tibial navigation Step 3 (Register Lateral Malleolus).

- **Sensor Signal is Lost.**
  - Remove and reattach sensor battery to re-establish connection.

### System

- **There is a Major System Fault and Navigation Unit Must Be Turned Off and Replaced.**
  - Please recover faulty unit and return to manufacturer for analysis.
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INSTRUMENT SPECIFICATIONS

ORDERING INFORMATION

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<tr>
<th>Product Description</th>
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<tr>
<td>KneeAlign® 2 Navigation Unit</td>
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<td>KneeAlign® 2 Instrument Set Replacement Parts</td>
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<td>KneeAlign® 2 Tibial Jig Body</td>
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Note: For cleaning and sterilization instructions, please refer to the Instructions for Use.