# HipAlign®

Surgical Technique Manual Total Hip Arthroplasty Posterior Approach





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# **General Operation**

### **Types of Beeps:**

- Short beep: Acknowledgment that button was pressed.
- Long beep: Input was not accepted, or there was a fault.
- Double beep: Unit completed registration or calibration step successfully.



**A** Warnings

### NAVIGATION UNIT / REFERENCE SENSOR:

Laser aperture may be open or closed with the shutter

**Up and Down** Toggles between different options or adjusts numerical input

*NOTE:* Holding Left and Up buttons simultaneously powers unit off



Risk of communication errors increases if multiple OrthAlign Plus® systems are used in close proximity.

- If navigation unit is dropped on floor, it must be discarded. If reference sensor is dropped on floor, it must be returned to manufacturer for verification of function and calibration.
- Probe scale and lens of reference sensor must be kept clean for reliable operation. Note that lens of reference sensor is on its underside.
- Avoid impacting jig and electronics. Verify position of jig and electronics after impacting and before checking angles.

#### LASER MODULE/OTHER INSTRUMENTS:

- Inspect laser module prior to use. Do not use laser module if it appears damaged or moisture is present under the lens.
- If laser module fails to function after initial registration, abandon leg length and offset measurement feature.
- The laser module is a Class 2 laser product, maximum output: <1mW, emitted wavelength: 635nm, duration > 0.25 seconds (continuous), beam divergence: 10 degrees, per IEC 60825-1: 2014-05. This information can be found etched onto the back surface of the laser module.
- Do not stare into beam. Eye damage could result.
- Take care when using laser to avoid possible dazzle, flash-blindedness or after-image effects.
- Use of controls of adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.
- Use the movable shutter on the front of the laser module to expose the lens for use, and cover the lens to stop projection of the laser beam.
- Once the battery is installed, the laser is always on and the shutter must be closed to stop projection of the laser beam.
- The strong magnetic fields near a neodymium magnet can affect pacemakers, ICDs and other implanted medical devices. Keep the laser module, vertical laser target, adapter socket driver and any other instruments with magnets at least six inches away from any such heart device.

#### SURGICAL TECHNIQUE:

- Utilize standard surgical practice in joint reduction (for joint stability and soft tissue laxity).
- Take care to avoid damage to nervous and vascular structures when using registration probe to register landmarks or when mounting jig.
- Do not impact or hammer system components except where components are designated as impactor devices. Acetabular shell impactor may be impacted.
- Abort the use of the navigation feature if the landmarks cannot be identified or registered.
- Remove all pins, screws, and other instruments prior to closing wound. Do not implant any system components.



DO NOT STARE INTO BEAM CLASS 2 LASER

<1mW, 635nm IEC 60825-1:2014-05

# Pre-Op

**Patient Positioning** 



- Patient must be placed in the lateral decubitus position.
- When positioning patient prior to surgery, take care to align the anterior pelvic landmarks (both ASIS's and pubic tubercle) in a vertical plane parallel to the long edge of the operating table. Ensure that pelvis is securely held by an appropriate positioning device such as a peg board or vise-type patient positioner.

WARNING: Correct patient positioning is essential for accurate navigation. The system calculates cup angles and changes in leg length and joint offset based on the assumption that the pelvis is accurately positioned during table registration.

### **Opening and Powering on the Navigation Unit**



1. Open navigation unit package.



2. Pass sterile inner blister package into operative field.



3. Peel back cover to expose navigation unit and sensor battery.



4. Remove navigation unit and sensor and laser batteries from blister pack.



5. Press center button to power on navigation unit.

# **Back-Table Set Up**



#### Select Joint

Use center button to select Hip.



#### Select Approach

Use center button to select approach.



#### **STEP 1: Install Sensor Battery**

Insert battery into reference sensor and close cover.

*TIP:* Reference sensor LED will slowly flash yellow to indicate battery has been inserted correctly. LED will momentarily flash green and navigation unit will move to next screen when reference sensor is found.





#### **STEP 2: Confirm Sensor ID**

Press center button if displayed number matches the one marked on reference sensor being used. Otherwise, press left button to let navigation unit find another reference sensor. Repeat until correct reference sensor serial number is displayed.



#### **STEP 3: Attach to Pelvic Jig**

Slide the navigation unit onto jig toward lever. Navigation unit should be firmly secured in place on the jig. Attach reference sensor to coupler at other end of the pelvic jig as shown.

NOTE: Navigation unit must be secure on the pelvic jig before proceeding.





# **Calibration Steps**

### TIPS FOR CALIBRATION STEPS:

- Navigation unit must be maintained in steady position, or calibration will not be accepted. A red hand will flash on screen if unit is not steady.
- Level circle must be green, but ball does not need to be in exact center of circle.
- Do not move to next position too quickly. Wait for double beep, then place in next position as shown on screen.
- Displayed numbers are the percent errors from the nominal jig angles on each axis, and should be 4.0 or less.
- If navigation unit does not proceed to next screen after several seconds, check that navigation unit and reference sensor are correctly attached to the bracket and press left button three times to repeat from first calibration step (Step 4).





#### STEP 4:

Angle unit away from you so that pelvic jig rests on table with navigation unit screen facing up.





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#### STEP 5:

Angle unit toward you so that reference sensor rests on table with navigation unit screen facing you.





#### STEP 6:

Rest navigation unit on left side on table.





#### **STEP 7:**

Angle unit away from you so that pelvic jig rests on table with navigation unit screen facing up.





#### STEP 8:

Attach reference sensor to coupler on probe. Verify that numbers are displayed on the screen by sliding the probe to different positions.

# **Prepare Instruments**

- Remove required instruments from tray, and prepare them for use.
- Select appropriate shell adapter. See "Shell Adapter Options" table below.
- Note: The Probe Calibration Jig is not required for this procedure.



WARNING: Only shells with an apex hole matching one of the sizes listed can be attached to impactor.

# **Attach Laser to Pelvic Base**



**Step 9: Attach Laser** Close shutter on the laser module. Insert battery and close cover.



Attach laser to the posterior side of the bracket at a selected angle. The laser can be angled downward to project more proximal or angled straight to project more distally. Ensure the laser module is securely attached and does not rotate or pivot on the bracket.

*NOTE:* The laser remains on as long as the battery is installed. The laser beam is shown/hidden through the movement of a shutter.



Closed Shutter Angled Down Angled Straight

WARNING: Do not shine laser beam into eyes.

# **Pre-Op Selections**



Step 10: Select Hip

Select operative hip.



(Radiographic Anteversion)

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Input:

### **Step 12: Input Abduction**

Input target cup abduction angle. This is the Radiographic Inclination angle defined as the coronal plane projection of the angle between the acetabular axis and the longitudinal axis of the body.

### **Step 13: Input Anteversion**

Input target cup anteversion angle. This is the Radiographic Anteversion angle defined as the angle between the acetabular axis and the coronal plane.

# **Securing Base**

### **Securing Pelvic Base**

Placement of the fixation pins in the iliac crest should be vertical to optimize orientation of the instrumentation.





For the first pin, make a stab incision over the ipsilateral iliac crest, directly superior to the greater trochanter. Insert a 4.0mm threaded fixation pin vertically using a wire driver.



Make a second stab incision, and insert the second fixation pin in the iliac crest 2cm anterior parallel to the first pin. You may use the pelvic base as a guide for spacing between the pins.



Slide the Pelvic Base over both pins to the level of the skin, and use the 3.5mm Hex Driver to tighten the two bottom screws to secure Base.

### WARNING:

- The base must be attached prior to dislocating the hip to ensure correct patient positioning and navigation accuracy.
- *Take care to avoid plunging through the medial wall of the iliac wing.*
- Verify that pelvic base is securely mounted to the bone.
- Take care to minimize divergence of pins, as excessive bending can damage pins.
- Ensure pins are aligned in the tracks within the pelvic base and the base is clamped on the cylindrical part of the pins.

# **Attaching Sensors and Registration of Landmarks**

### **Attaching Sensors**

Attach pelvic bracket and probe to pelvic base.





*TIP*: Attach reference sensor to probe by aligning arrows on sensor and probe.



*TIP*: Attach pelvic bracket, with navigation unit attached, to coupler on pelvic base while pushing on pelvic bracket lever.



*TIP:* Attach probe assembly to pelvic base by aligning arrows on probe and base.

## **Aligning Jig**



- Place the leg on the operative side in a neutral • abduction, flexion and rotation using a roll if necessary.
- Place the thigh plate on the lateral distal thigh and secure using Coban<sup>™</sup> by wrapping around thigh on either side of plate.
- Mark the boundary of the plate on the skin.
- Place the vertical target on the plate •
- Open shutter on laser. .
- Align pelvic bracket so the laser beam projects crosshairs on the vertical target mounted on the distal thigh and remove vertical target.

NOTE: Ensure laser lens is clear. Close laser shutter when not in use.

### WARNING:

- Discontinue use of laser if crosshair pattern is obscured.
- Discontinue use if unable to verify thigh plate is aligned with original marking on skin or if unable to return it to original position.

### **Adjusting the Registration Jig**

TIP: To adjust the laser alignment on the leg, loosen pelvic base locking screw, and adjust angle of pelvic bracket.

### Locking the Registration Jig



- Use the 3.5mm hex driver to lock screw tightly to secure jig in this position for remainder of procedure.
  - Close the shutter on the laser module.









### How to Register Landmarks



TIP: Hold probe close to the tip to maximize accuracy of point.



TIP: When pressing buttons, support back of navigation unit to avoid flexing jig. If registration is not accepted, keep probe tip stationary and gently squeeze center button.

### **INCORRECT:**



# Registrations



igittal plane of pelvis is le

#### **Register Home**

Place tip of probe into hole of the pelvic base and press center button.

#### Register Table

- Position operating table horizontally.
- Verify the sagittal plane of pelvis is level.
- Move probe, with reference sensor attached, to align parallel long axis of body with the tip pointing towards the feet.
- Press the center button to register.

### WARNING:

- Correct patient positioning is essential for accurate navigation. The system calculates cup angles based on the assumption that the pelvis is accurately positioned during table registration.
- Table registration must be completed prior to dislocating hip, as torque applied during dislocation can move pelvis away from the correct initial alignment.
- Pelvic Base cannot be moved after this point.
- Pelvic Bracket angle to the base cannot be adjusted after this point.
- If fixation pins become loose, navigation must be aborted, since table registration is no longer valid.

### **Registering Femur**

- Make the standard incision and identify a point along greater trochanter to insert a registration marker for femoral registration. Insert femur registration marker.
- Open laser shutter, place the vertical target on the thigh plate and align the leg so that the laser projects onto the lower part of the target.
- Trace the crosshair pattern with a marking pen.
- While laser projection is aligned with laser marking, hold the probe tip in the center hole of the marker and press the center button to register the femur.
- Close shutter on the laser and remove vertical laser target. *TIPS*:
- 1. When marking the vertical target and registering the femur registration marker, position the thigh in neutral flexion, abduction and rotation.
- 2. Stack legs vertically atop each other in a stable position which will be easy to return to prior to registration.



Register Femur

Position Femur

rt Tack





#### WARNING:

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- If laser module moves, leg length must be aborted since leg alignment cannot be replicated.
- Discontinue use if unable to verify thigh plate is aligned with original marking on skin or if unable to return it to original position.

#### **Prepare Acetabulum**

*NOTE:* Once registration is complete, proceed to dislocate the hip, resect the femoral head, and prepare the acetabulum as per the implant manufacturer's technique.



# **Options Menu**



# **Prepare Impactor and Shell**

Select the appropriate adapter as listed on page 7 of this surgical technique.



- Snap the adapter into the impactor.
- Thread the adapter into the acetabular shell.
- The release lever can be used to release the adapter from the impactor.

#### Offset Impactor:

- Snap the adapter into the impactor.
- Thread the adapter into the acetabular shell.
- Pull on the finger grip shown to release the adapter from the impactor.
- Following full seating of the shell, remove the impactor from the implant adapter.
- Use the socket driver to remove the adapter from the implant.

#### NOTE:

- Align the screw holes of shell as desired; Adapter can be assembled in multiple angles relative to the impactor.
- Vertical orientation of the Reference Sensor post is not required for accuracy; it is recommended for ease of use when transferring the Reference Sensor to the impactor for navigation.
- *If none of available adapters fits on selected implant, impactor cannot be navigated.*

WARNING: Prior to impacting, verify shell is fully seated on shoulder of impactor and that threads do not protrude beyond outer face of shell.



# Set / Check Cup Angle

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#### **Step C1: Dock Sensor**

- Remove probe assembly from bracket.
- Remove reference sensor from probe.
  - Dock reference sensor on the jig by attaching it to the coupler on the jig (as shown on the display).



#### **Step C2: Set Cup Angle**

- Hold hip stable until green light appears.
- There are 30 seconds of live navigation
- Remove reference sensor from jig by pushing lever and attach to impactor.
- If sensor is moved too quickly, an error message will appear and Step C1 must be repeated.





#### *NOTE:* The blue bar on right indicates remaining time.

- Align impactor at desired cup angle. Aligning crosshairs in center of bull's eye will set cup angle at inclination and anteversion angles entered earlier.
- Angles displayed are calculated according to their radiographic definitions.

NOTE: The navigation unit proceeds to the next step if:

- 30 second timer expires
- center button is pressed
- reference sensor detects an impact strong enough to disrupt navigation



### **Step C3: Cup Angle**

Inclination and anteversion cup angles are now displayed statically.

#### NOTE:

- Once reference sensor is attached to impactor, navigation unit displays abduction and anteversion angles based on the Table reference frame.
- The OrthAlign Plus® System does not navigate or control shell impaction depth or insertion point. Please refer to implant manufacturer's technique guide for guidance.

#### WARNING:

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- Check cup angle after impacting as cup angle will change during impaction. Not checking cup angle will reduce accuracy.
- Verify position of reference sensor and navigation unit after impacting before checking angles.
- Visually confirm shell angles before proceeding.

# **Check Leg Length**



### Attach Sensors Step F5: Attach Sensors

Attach probe with reference sensor to jig

### nur Step F5A: Position Femur

- Position the magnetic vertical target on the distal thigh
- Open shutter on laser
  - Re-align leg so that the laser projection aligns with the marking on the vertical target.

NOTE: Ensure laser lens is clear.

WARNING:

- Discontinue use of laser if crosshair pattern is obscured.
- Discontinue use if unable to verify thigh plate is aligned with original marking on skin or if unable to return it to original position.

### **Step F6: Register Femur**

- Hold the probe tip in the center hole of the screw and press the center button to register the femur.
- Remove vertical laser target.



### **Step F9: Register Femur**

- Leg Length and offset are displayed.
- Close the shutter on the laser.

# **Verify Homepoint**



### Step V1: Attach Sensors

• Attach probe and probe mount to bracket. Attach bracket to pelvic base.

### **Step V2: Verify Homepoint**

- Place tip of probe into hole of Pelvic Base.
- Press center button to register Homepoint.

### **Step V3: Homepoint Accuracy**

• View change in Homepoint which is change in probe tip position between original Homepoint and current Homepoint registrations.

*NOTE:* The number displayed may not be zero due to mechanical play and reference sensor noise. If displayed number is greater than 3mm, it is suggested to verify all reference sensor attachments and jig connections are correct and secure before repeating. Repeat registrations if accuracy or previous registrations is in question.



Register Femur

# **Repeat Registrations**



- Repeating registrations will result in a loss of all previous registrations.
- Determine if pelvic base has moved, and select 'Yes' or 'No' to continue repeating registrations

# **End Procedure**



- Ending procedure will result in a loss of all previous registrations, and will return you to Step 10 (Pre-Op Selections).
- Remove pelvic base and pins prior to closure.

# **Shut Down and Disposal**

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#### NAVIGATION UNIT MUST BE POWERED OFF AND DISCARDED

Prior to disposal, power off navigation unit by pressing left and up arrow buttons until unit is turned off. Additionally, remove unit from pelvic bracket by pushing down on top lever.

*NOTE:* The unit will power off after 90 minutes without a button being pressed.





#### DO NOT DISCARD THE REFERENCE SENSOR or LASER MODULE

Batteries must be removed from reference sensor and laser module and discarded. Do not reuse batteries.

Return reference sensor and laser module to instrument tray.

# **Instruments with Part Numbers**

Part Number	Part Description	Quantity
403105	Hex Driver - 3.5MM, Teardrop	1
403258	Probe Calibration Jig - Tripod	1
403370	Laser Module	1
403305	Registration Probe	1
403306	Pelvic Base, Anterior	1
403307	Pelvic Bracket Assembly, Short	1
403338	Straight Cup Impactor	1
405001 or 403087-06	Reference Sensor 5 Hip (RS5H)	1
403317-110	Threaded Fixation Pin, 4.0mm x 110mm with 3.2mm Proximal End	3
403376	Thigh Plate, Slotted	1
403377	Vertical Target, Magnet	1
Additional Instru	ments	
403402	Femur Registration Marker, 3.5mm Hex Head	
403108	Screw, 4.5mm dia x 20mm, 3.5mm Hex Head	
403339	Impactor Adapter, DPY	
403342	Impactor Adapter, S/B	
403341	Impactor Adapter, S&N	
403343	Impactor Adapter, ZIM	
403340	Impactor Adapter, DJO	
403344	Impactor Adapter, MPO	
Optional Instrum	ents	
403309	Offset Cup Impactor	
403347	Adapter Socket Driver	

# **Instrument Tray Configuration for Sterilization**

Position Instruments in Instrument Tray as shown below for sterilization. Refer to the Instructions for Use for details on cleaning and sterilization parameters.



# Troubleshooting



All previous registrations will be lost. Press left button to return to Step M1. Press center button to proceed with Repeat Registrations or End Procedure.



Check that battery is correctly positioned in reference sensor. Battery may need to be replaced.

Check that no concurrent OrthAlign or KneeAlign cases are being conducted. There is a risk of communication interference between electronic units if multiple cases are conducted in close proximity.



Reference sensor does not report that it has started navigation.



Place reference sensor in docked position on jig. Refer to image on navigation unit for guidance.



Move probe, with reference sensor attached, to align parallel with sagittal plane. Adjust registration jig to align navigation unit closer to coronal plane.



No reference sensor motion is detected for registration.



Keep reference sensor in docked position until traffic light turns green.



The probe point is not in correct Home position. Repeat this step with probe tip situated in notch at the base of jig.



eposition pelvis back to starting position.

# Troubleshooting (cont.)



Reference Sensor's internal temperature exceeds limit of 70°C. Wait for sensor to cool down, then continue.



Confirm that all connections are secure.



Choose 'Yes' or 'No' depending on whether pelvic base or femur tack has moved during surgery. If 'Yes' is selected, leg length and offset measurements will be disabled.



Repeat current step. If error persists, reference sensor battery may need to be replaced.



Remove reference sensor and clean probe markings, clean reference sensor window located on bottom side and re-attach reference sensor. If problem persists, restart reference sensor by removing and replacing reference sensor battery.



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.



Replace reference sensor battery.



Remove femur tack and screws from the wound prior to closure.

Software Error	
Press and hold left and up buttons to turn unit off	
Then restart	

A software error has occurred. Power unit off and on again only one time. If System fault reoccurs after re-starting, power unit off and replace it. Contact OrthAlign and return unit for further analysis.

# **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 OrthAlign Plus® System, please contact us at 949.715.2424 or info@orthalign.com



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