SURGICAL TECHNIQUE GUIDE

ALIGN®
radial head system

As described by:
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**Indications for Use**

The ALIGN Radial Head System and accessories are designed specifically for:

Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radio-humeral and/or proximal radioulnar joint with:

- Joint destruction and/or subluxation
- Resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty
- The system is intended for press-fit use
1 ELBOW LANDMARKS

With the elbow flexed 90 degrees, palpate and mark the lateral epi-condyle.

Make an 8 -10cm line through the marked point.

2 DISTAL ULNA LANDMARKS

To identify the axis of forearm rotation, pronate the hand and flex the wrist.

Palpate and mark the ulnar styloid, ulnar head and the direction of the shaft.

Note: Use fluoroscopic imaging to verify proper landmark placement.
SUPERFICIAL EXPOSURE

Make your incision.

Make a longitudinal fascial incision over the center of the capitellum for the Kaplan approach.

DEEP EXPOSURE

Open the joint and gain access to the radial head.

Limit distal dissection to protect the radial nerve.
5 HEAD SIZING

Remove the radial head fragments; assemble and measure them using the Radial Head Sizing Tray.

Note: If between radial head sizes, select the smaller.

6 TRIAL HEAD SELECTION

Select the Trial Head that corresponds to the native head.
With the forearm pronated, select the radial neck length using the Neck Sizing Gauges.

**Neck Sizing Options:**
- 0 Offset - 15mm
- 2 Offset - 17mm
- 4 Offset - 19mm
- 6 Offset - 21mm
- 8 Offset - 23mm

**Note:**
If between two lengths, always select the shortest sizing option.

Use the Neck Sizing Gauge to select the level of the desired radial cut.

Mark the radial neck just distal to the Neck Sizing Gauge.
ATTACHING BONE FORCEPS

Secure the Bone Holding Forceps just distal to the marked radial neck.

Lift the radius with the Bone Holding Forceps, then make the radial neck cut.

**CAUTION:**
Protect the radial nerve.

**Note:**
The maximum defect that can be corrected is 23mm.
Starting with the smallest Rasp, position the hand in pronation and insert the Rasp past the tuberosity in the direction of the radial styloid.

**Note:**
*This will establish the trajectory for all subsequent Rasps.*

Fully insert each of the rasps up to the proximal depth mark using an oscillating motion.

Continue sequential rasping until cortical bone is encountered. Note the size of the final rasp used.

While final rasp is still fully inserted, maintain positive pressure and perform counter clockwise rotation prior to removing.

**Note:**
*Do not use rasps under power.*
**13 IDENTIFY PLANING LINE**

If the radial cut is not coplanar with the proximal depth mark of the rasp, planing may be required for proper seating of the prosthesis.

With the final rasp fully seated, mark the highest point on the radius to identify the area to be planed.

**14 NECK PLANING**

Prepare the resected end of the radius using the Planer.
FINAL NECK SIZING

With the forearm pronated, confirm the final radial neck length using the Neck Sizing Gauges.

Note:
If between two lengths, always select the shortest sizing option.

TRIAL STEM SELECTION

Select the Trial Stem that corresponds to the final Rasp/Planer used and insert it into the prepared canal.
17 TRIAL HEAD & NECK ASSEMBLY

Assemble the Trial Head and Neck by threading the two components together.

Thread the handle of the Neck Sizing Gauge into the Trial Head to facilitate loading onto the Trial Stem.

18 TRIAL VALIDATION

Assemble the Trial Head and Neck into the Trial Stem.

Reduce the joint and assess the sizing of the trial components by manipulating the elbow through its full range of motion.

Note:
Ensure that the joint has not been over-stuffed.
Confirm a proper fit using fluoroscopy, then remove the trial components.

A. In a true A/P view of the proximal forearm in supination, confirm that the height of the radial head trial is at or distal to the corner formed by the lesser and greater sigmoid notches.

B. Also, confirm proper radial head diameter by assuring that the appex of the capitellum is centered over the radial head.

PROSTHETIC STEM INSERTION

With the forearm in pronation, use the Bone Holding Forceps to lift the radius out of the wound, then insert the Radial Stem implant into the canal.

If the Radial Stem cannot be inserted by hand to a depth covering more than half of the TPS coated area, remove the stem and see optional step 20 on the following page.
20 PROSTHETIC STEM INSERTION (Optional)

Use the next larger sized Rasp and insert it up to the distal depth mark (A) to slightly enlarge the proximal portion of the intramedullary canal in a counter clockwise motion.

Reinsert the stem to confirm adequate insertion depth (at least half of the TPS coated section).

21 PROSTHETIC STEM IMPACTOR

Insert the Stem Impactor laterally, then lower the handle until in-line with the stem.

Impact the stem until the collar seats flush against the radius.

Note:
The notch on the Stem Impactor facilitates loading.
Side load the Radial Head implant onto the stem, then rotate it until the threads are positioned laterally.

**Note:**
*Each Radial Head implant is packaged with its respective Lock Screw.*

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**HEAD ALIGNMENT TOOL ENGAGEMENT**

Remove the Bone Holding Forceps and secure the Head Alignment Tool to the Radial Head.

The two tines of the Head Alignment Tool should engage the grooves of the Radial Head.

**Note:**
The Head Alignment Tool is used to control the position of the Radial Head.
Loosely thread the Lock Screw into the Radial Head.

Keeping the Head Alignment Tool connected to the Radial Head, slide the rail of the Forearm Axis Jig into the handle until it snaps securely.

With the elbow flexed and the forearm in neutral, adjust and lock the distal end of the Forearm Axis Jig to the marked fovea of the ulna.
Pronate the Head Alignment Tool ~20 - 30 degrees from the neutral forearm position, then tighten the Lock Screw while providing counter-torque.

**Warning:**
The Head Alignment Tool must be used when tightening the Lock Screw to provide the necessary counter-torque.

**Note:**
*Positioning the Head Alignment Tool in 20 - 30 degrees of pronation ensures the Lock Screw is at the center of the “safe zone”.*

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Use the torque indicating T-Handle Driver to ensure the minimal torque has been achieved.

If desired, additional torque can be gained using the Universal Driver Handle.

**Warning:**
The Head Alignment Tool must be used when tightening the Lock Screw to provide the necessary counter-torque.
IMPLANT VALIDATION

Remove the Forearm Axis Guide assembly.

Manipulate the elbow through its full range of motion to confirm final implant alignment.

Supination    Pronation

FLUOROSCOPIC CONFIRMATION

Confirm final implant alignment using fluoroscopic imaging.

Supination    Pronation
Repair soft tissues as needed, then close the incision.
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