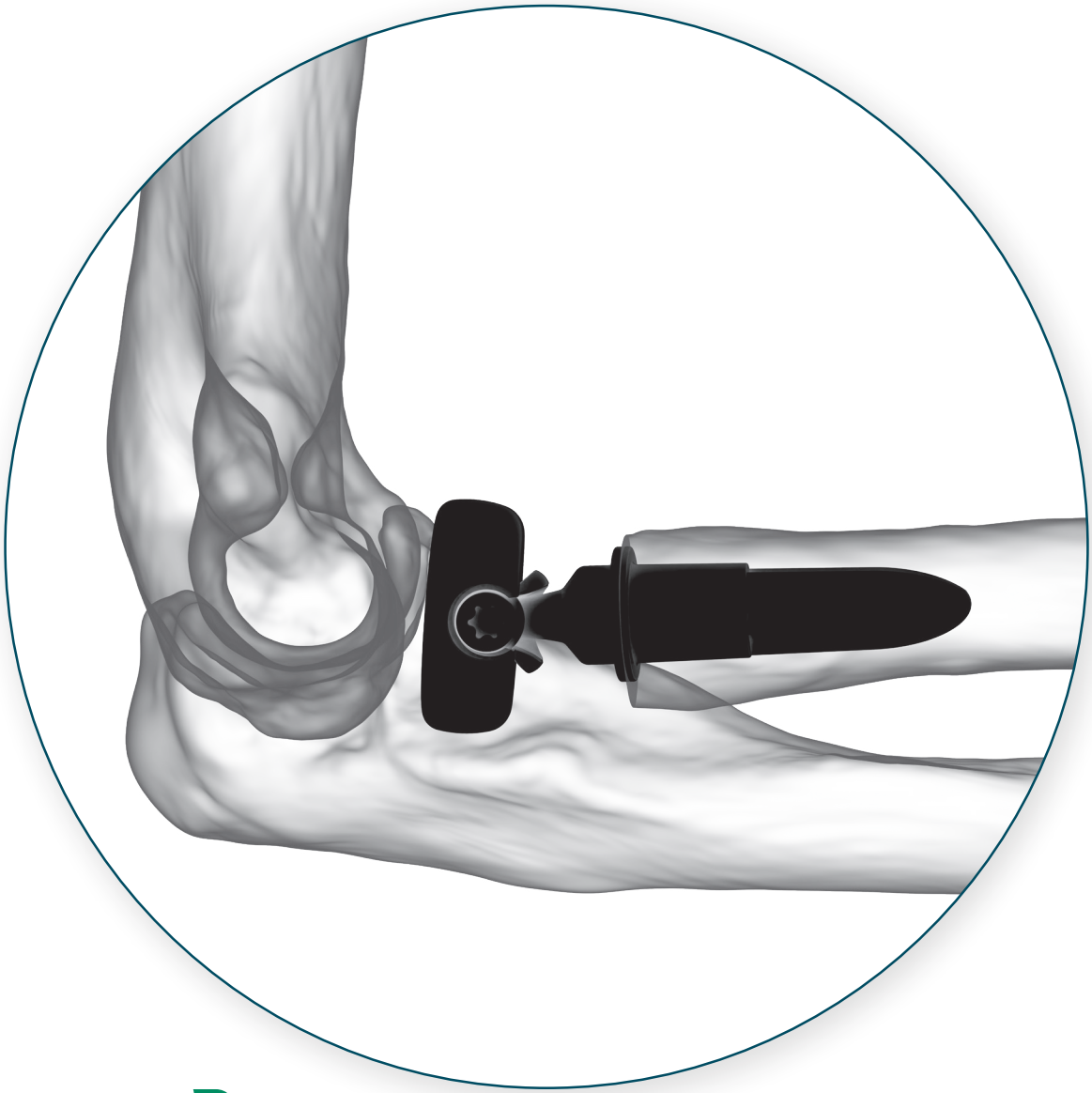
SURGICAL TECHNIQUE GUIDE

ALIGN®

radial head system



skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY

As described by:
Jorge L. Orbay, M.D.
Miami Hand & Upper Extremity Institute

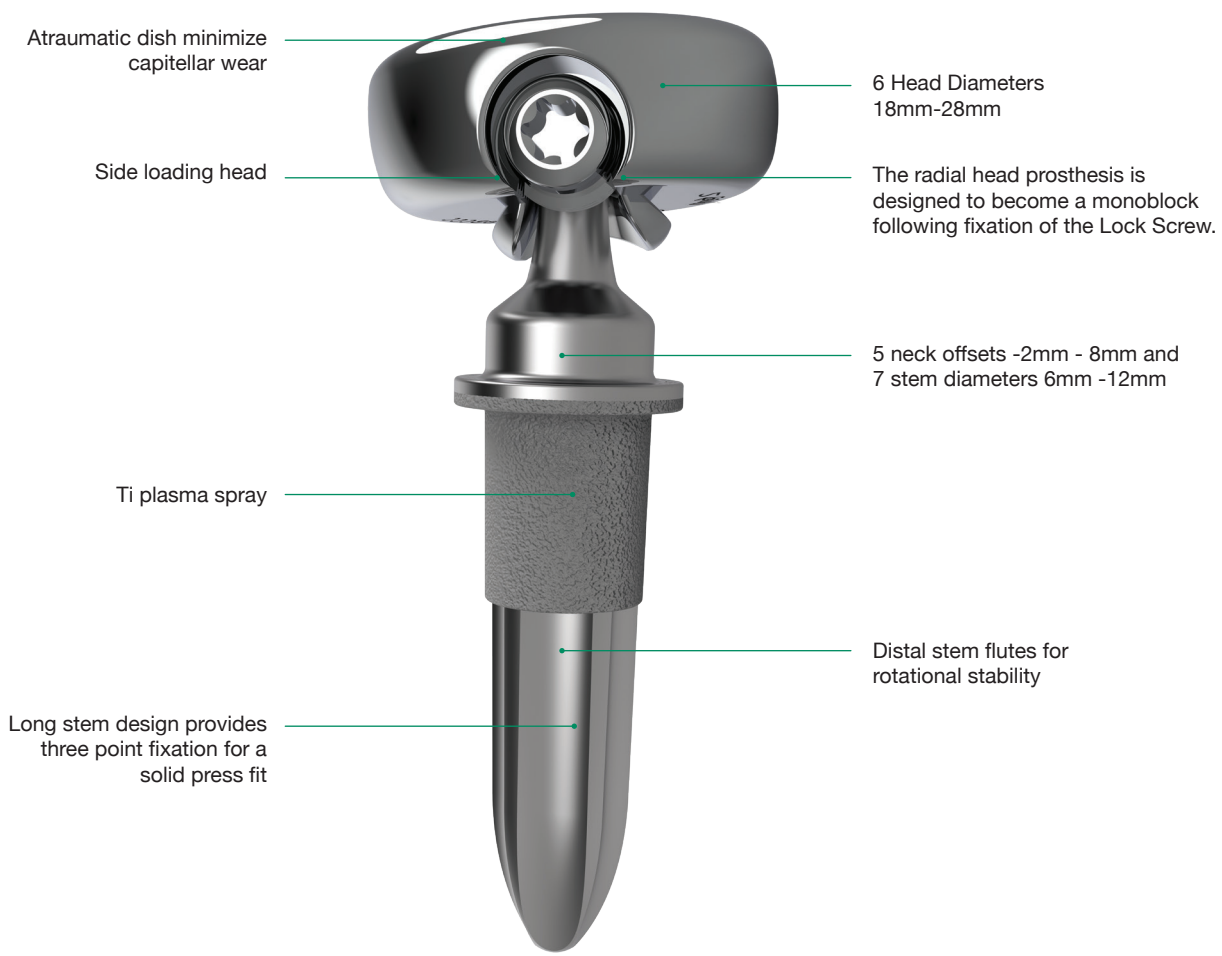
ALIGN®
radial head system

Indications for Use

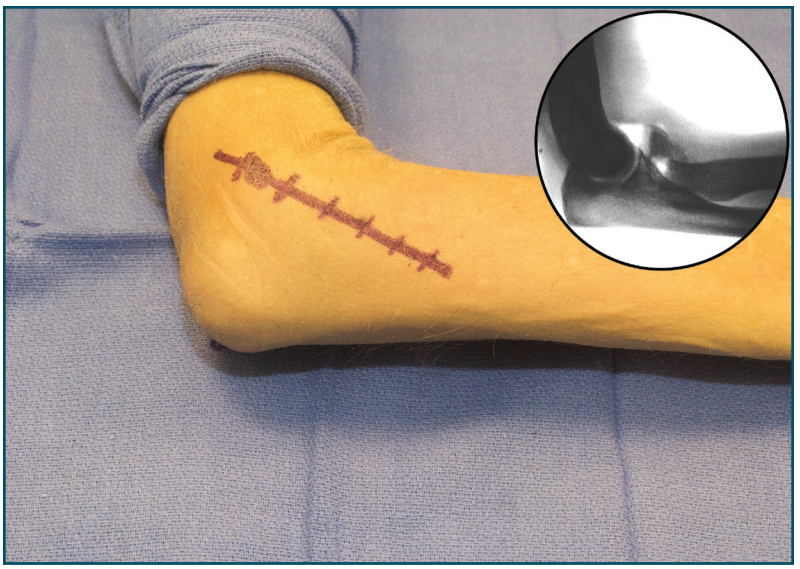
The ALIGN® Radial Head System and accessories are designed specifically for:

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



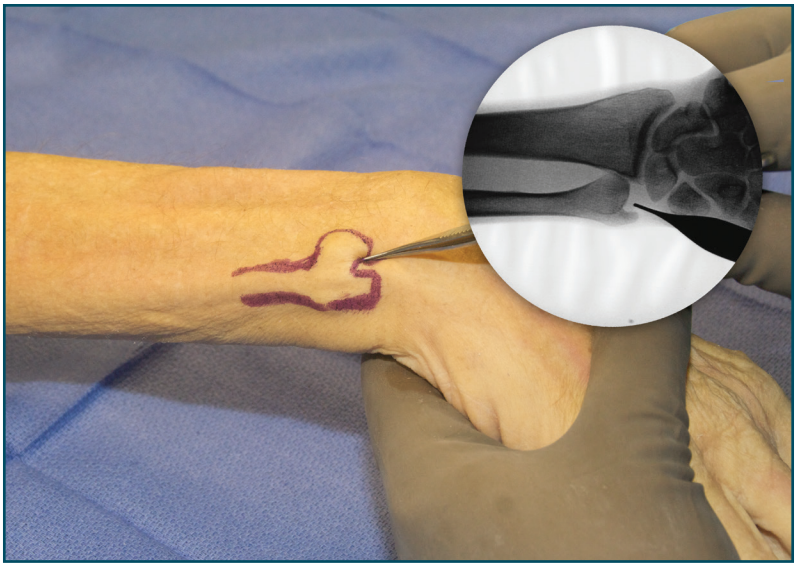
1 ELBOW LANDMARKS



With the elbow flexed 90 degrees, palpate and mark the lateral epicondyle.

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.

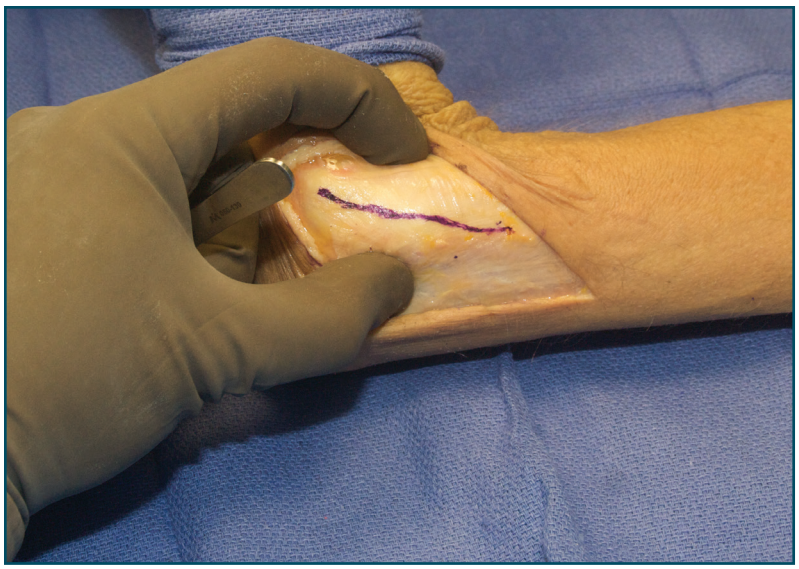
Palpate and mark the ulnar styloid, ulnar head and the direction of the shaft.

Note:
Use fluoroscopic imaging to verify proper landmark placement.

SUPERFICIAL EXPOSURE 3

Make your incision.

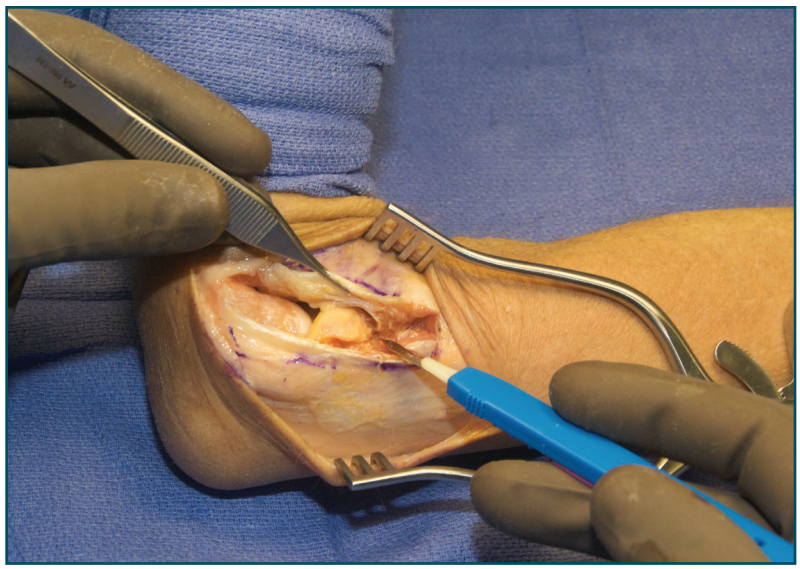
Make a longitudinal fascial incision over the center of the capitellum for the Kaplan approach.



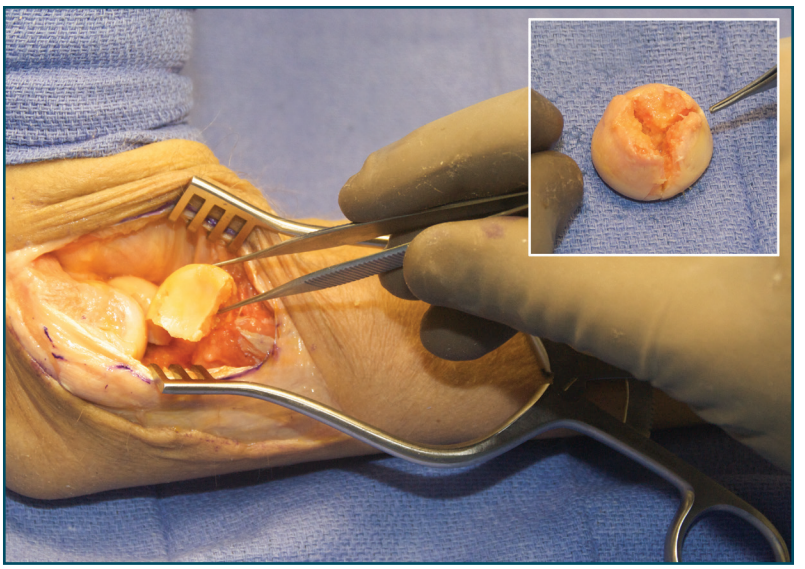
DEEP EXPOSURE 4

Open the joint and gain access to the radial head.

Limit distal dissection to protect the radial nerve.

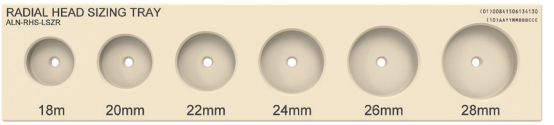


5 HEAD SIZING



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

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

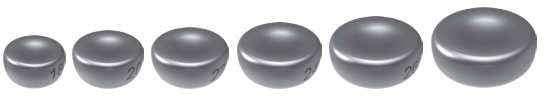


ALN-RHS-LSZR: ALIGN, Large Sizer, Radial Head Implant

6 TRIAL HEAD SELECTION



Select the Trial Head that corresponds to the native head.



ALN-RHT-XXX: ALIGN, Trial, Radial Head, XXmm

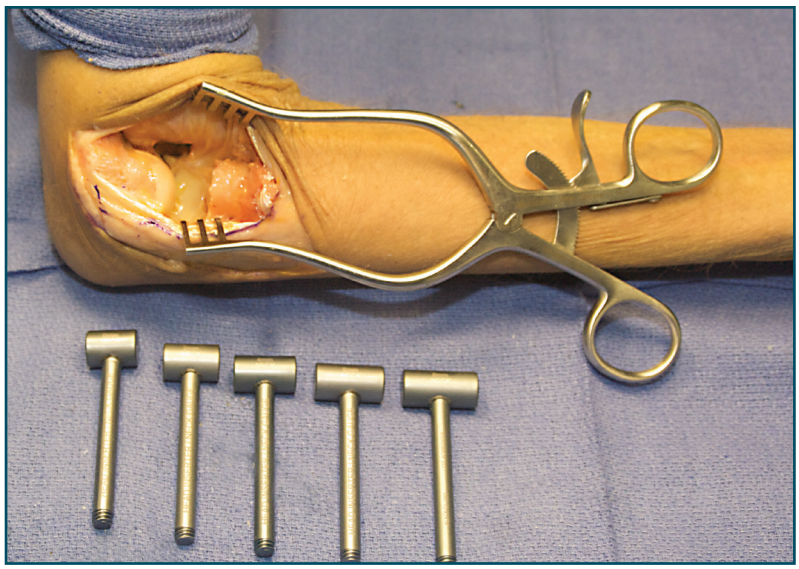
PROVISIONAL NECK SIZING

7

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

Neck Sizing Options:
-2 Offset - 13mm
0 Offset - 15mm
2 Offset - 17mm
4 Offset - 19mm
8 Offset - 23mm

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

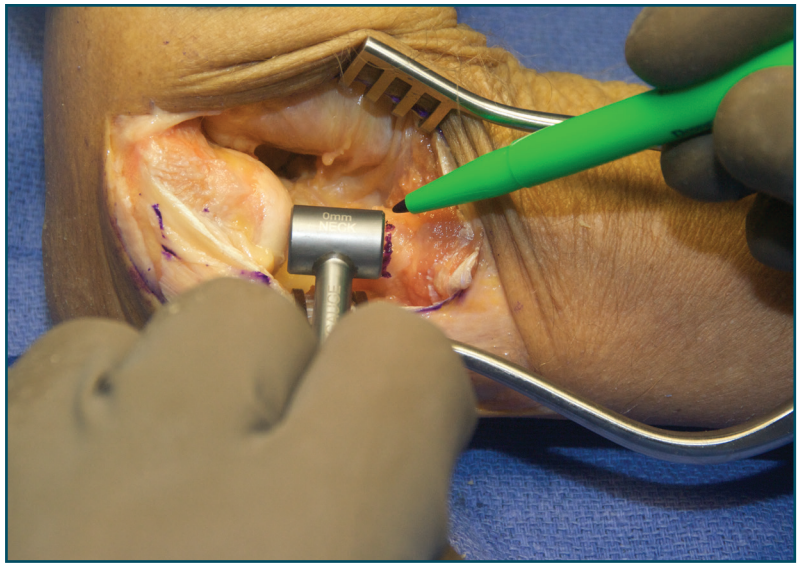


INITIAL NECK SIZING

8

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

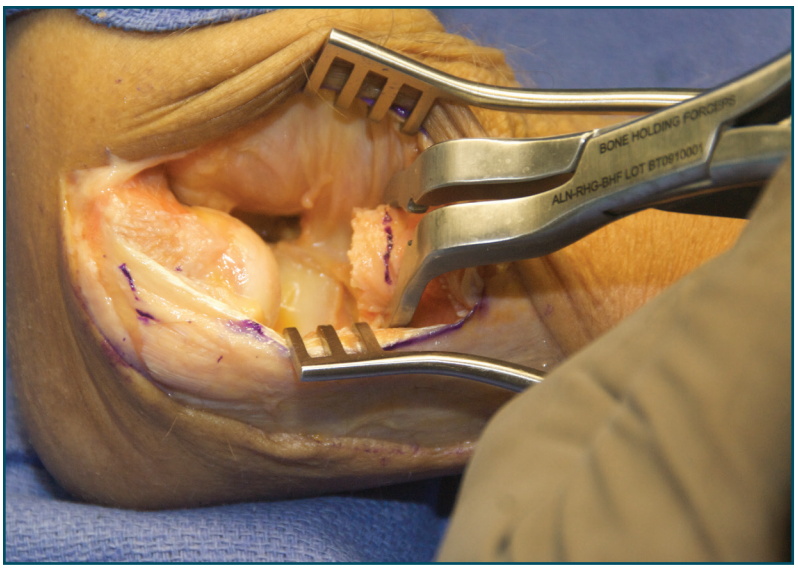
Mark the radial neck just distal to the Neck Sizing Gauge.





ALN-NGI-XXX: LIGN, Neck Gauge & Head Inserter, XXmm

9 ATTACHING BONE FORCEPS

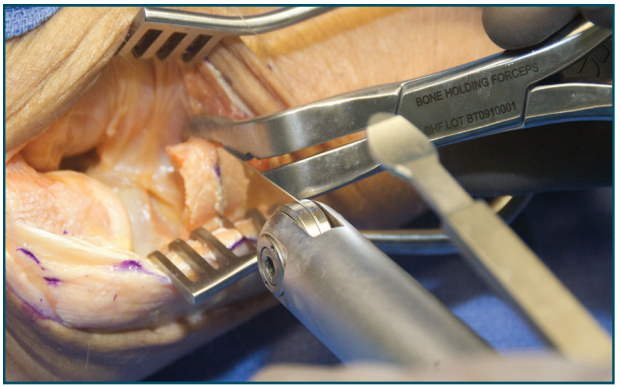


Secure the Bone Holding Forceps just distal to the marked radial neck.



ALN-RHG-BHF: ALIGN, Bone Holding Forceps

10 RESECTION



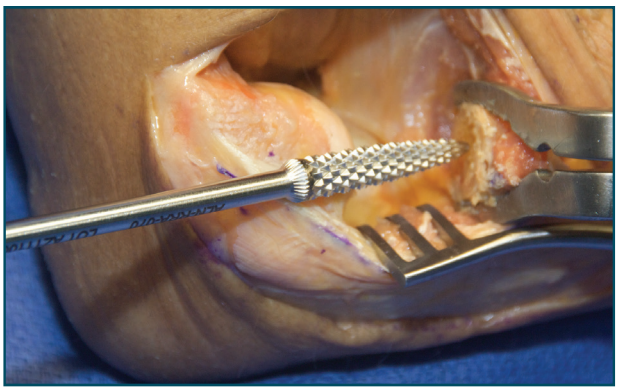


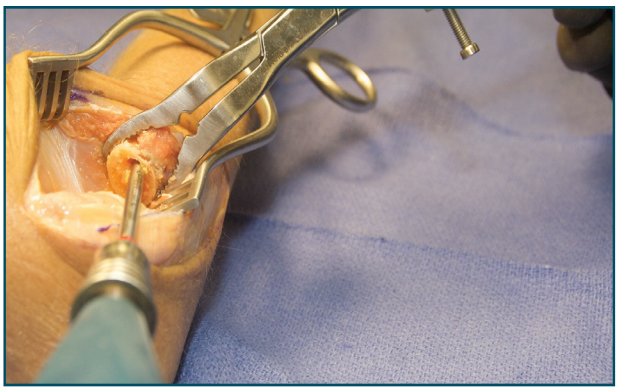
Lift the radius with the Bone Holding Forceps, then make the radial neck cut.

Note:
The maximum defect that can be corrected is 23mm.

Caution:
Protect the radial nerve.

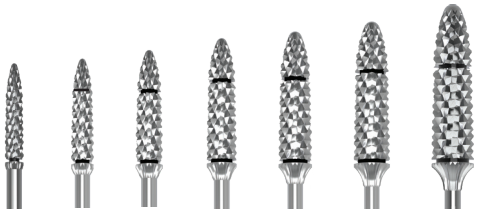
OPENING RADIAL CANAL 11





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.



ALN-RRA-XXX: ALIGN, Radial Rasp, Stem XX.0mm

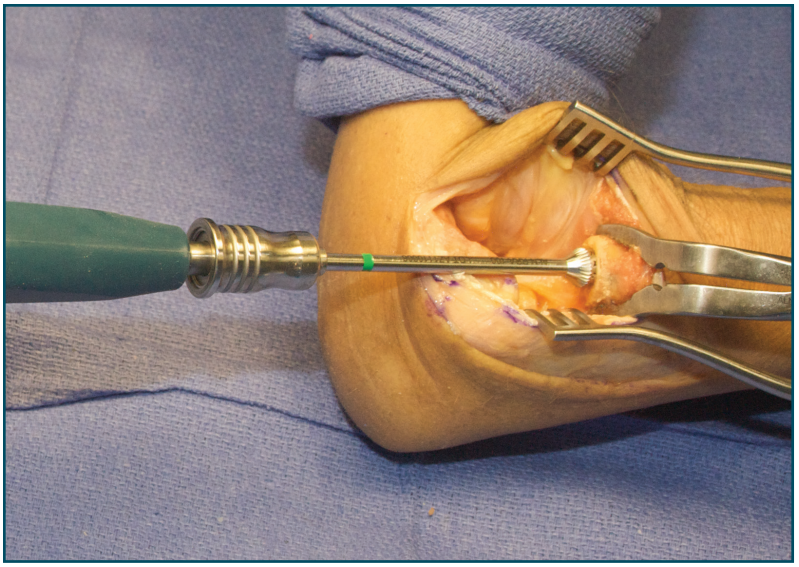
CANAL PREPARATION 12

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.

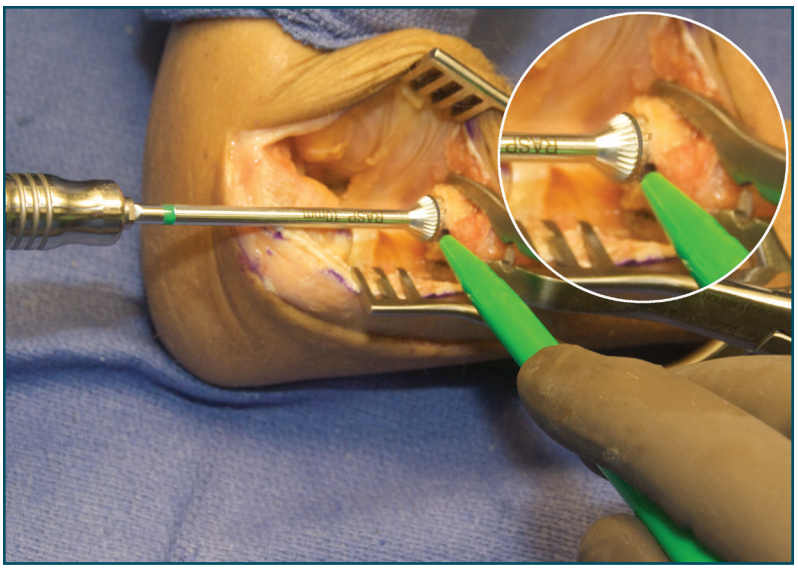
Note:
Do not use rasps under power.





ALN-RRA-XXX: ALIGN, Radial Rasp, Stem XX.0mm

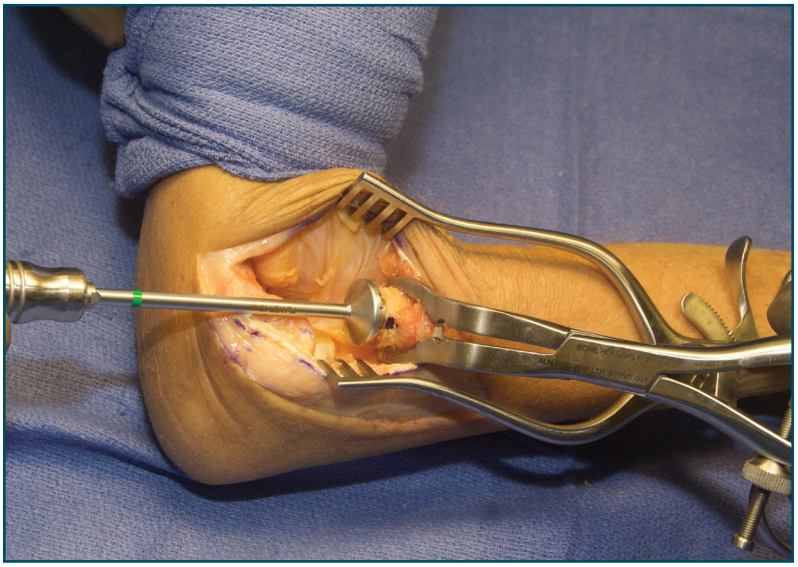
13 IDENTIFY PLANING LINE



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.

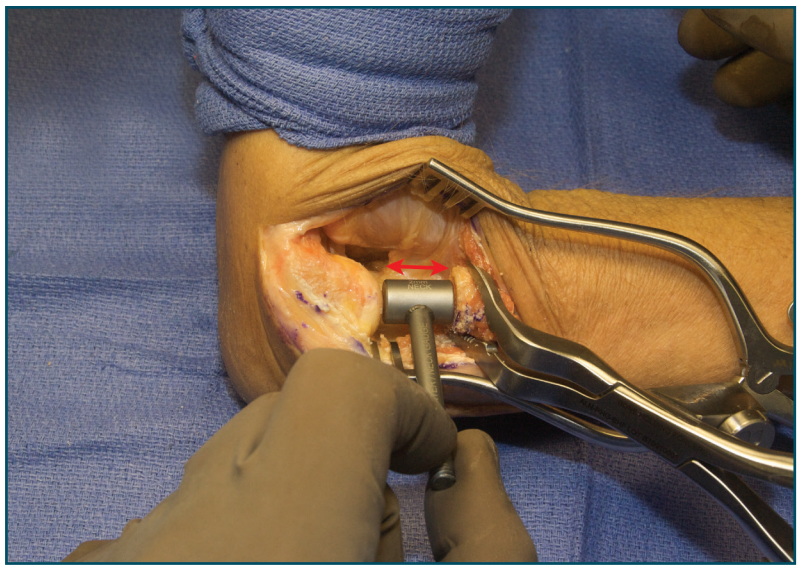


ALN-RPL-UNI ALIGN, Radial Planer, Stem, Universal

FINAL NECK SIZING 15

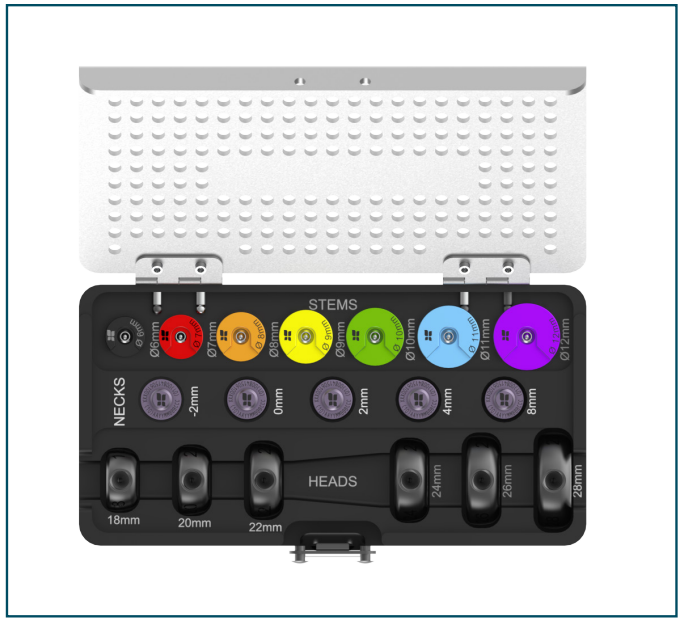
With the forearm pronated, confirm the final radial neck length using the Neck Sizing Gauges.

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



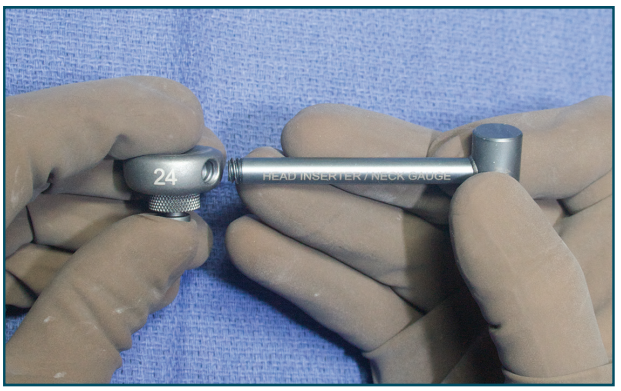
TRIAL STEM SELECTION 16

Select the Trial Stem that corresponds to the final Rasp/Planer used and insert it into the prepared canal.



17 TRIAL HEAD & NECK ASSEMBLY

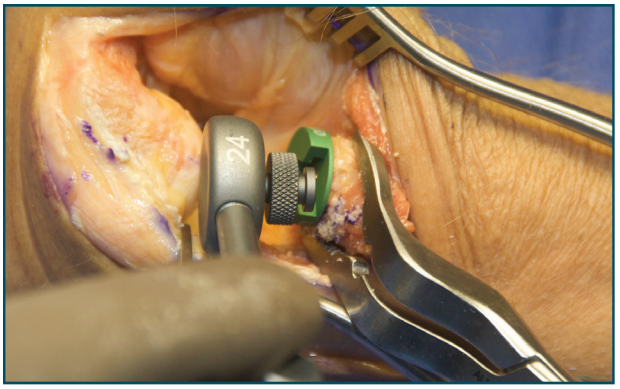


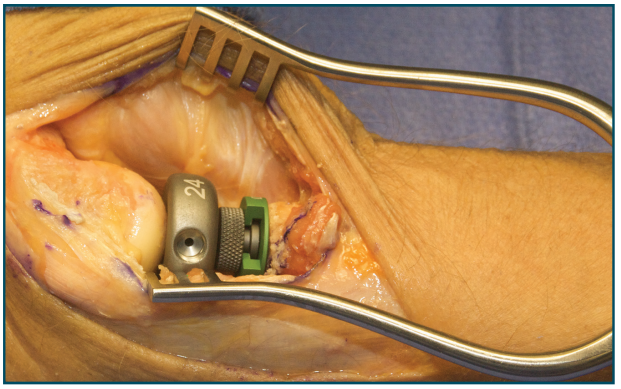


Assemble the Trial Head and Neck by threading the two components together.

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.

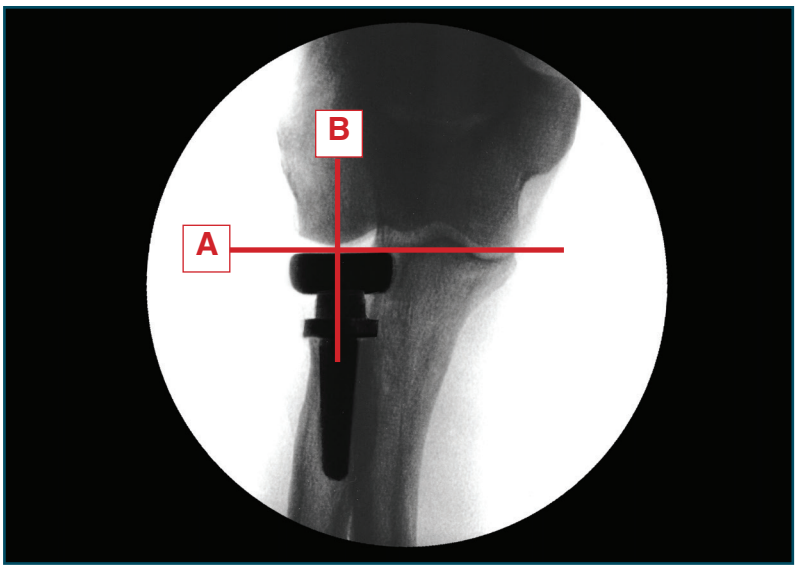
Note:
Ensure that the joint has not been over-stuffed.

FLUOROSCOPIC CONFIRMATION 19

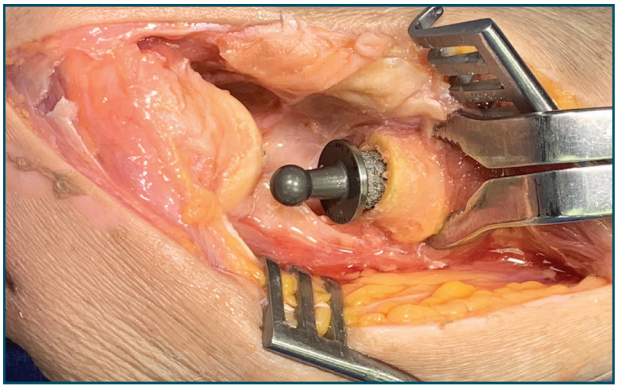
Confirm a proper fit using fluoroscopy, then remove the trial components.

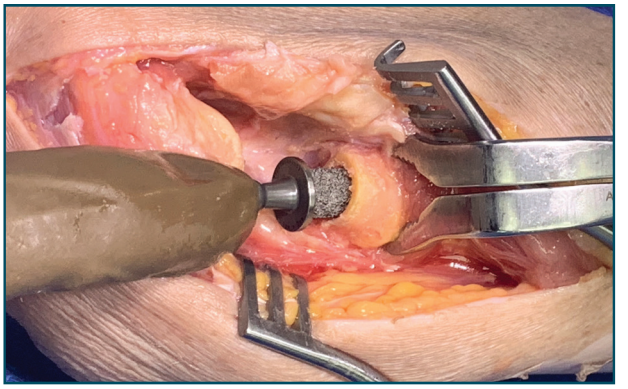
A. In a true A/P view of the proximal forearm in supination, confirm that the height of the radial head trial is at or distal to the corner formed by the lesser and greater sigmoid notches.

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



PROSTHETIC STEM INSERTION 20

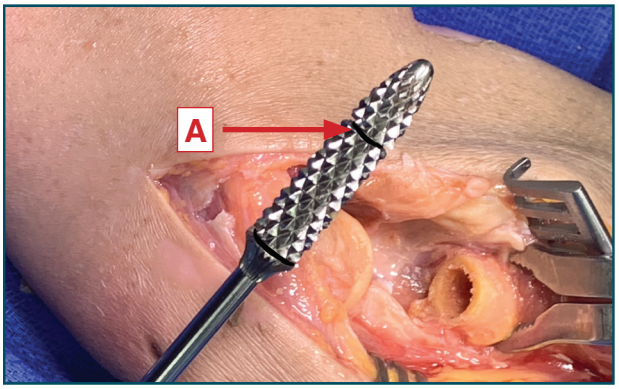


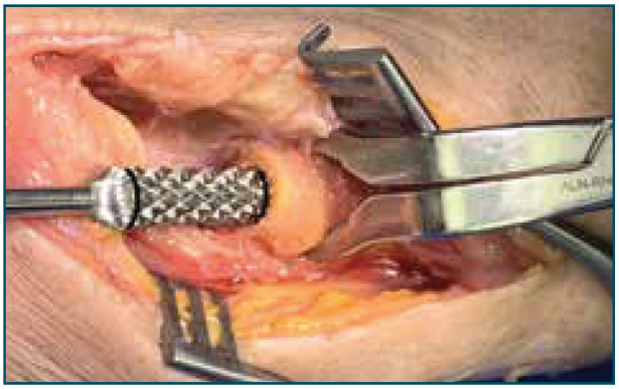


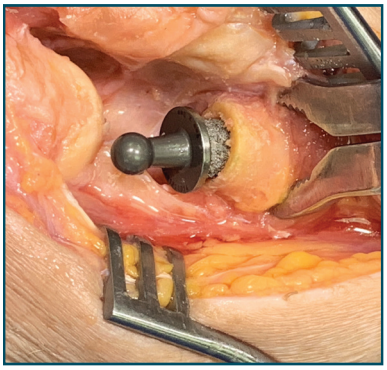
With the forearm in pronation, use the Bone Holding Forceps to lift the radius out of the wound, then insert the Radial Stem implant into the canal.

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)





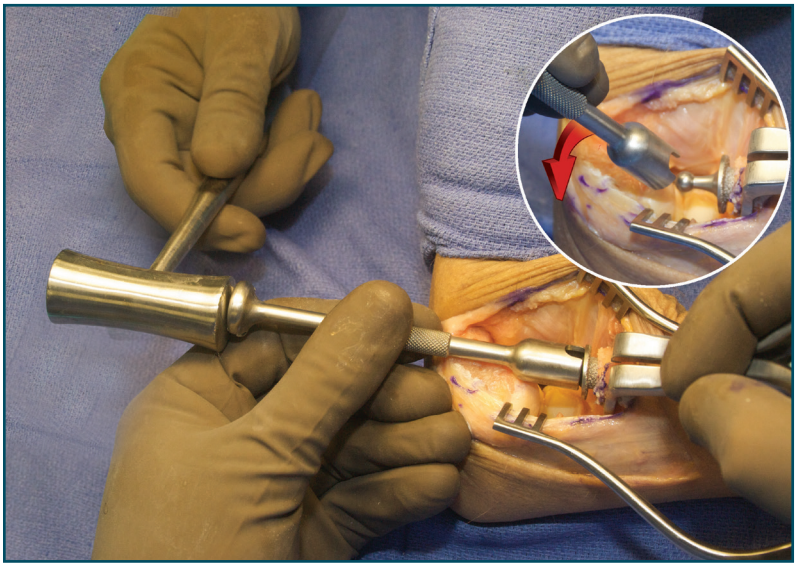


A. Distal Depth Mark

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.



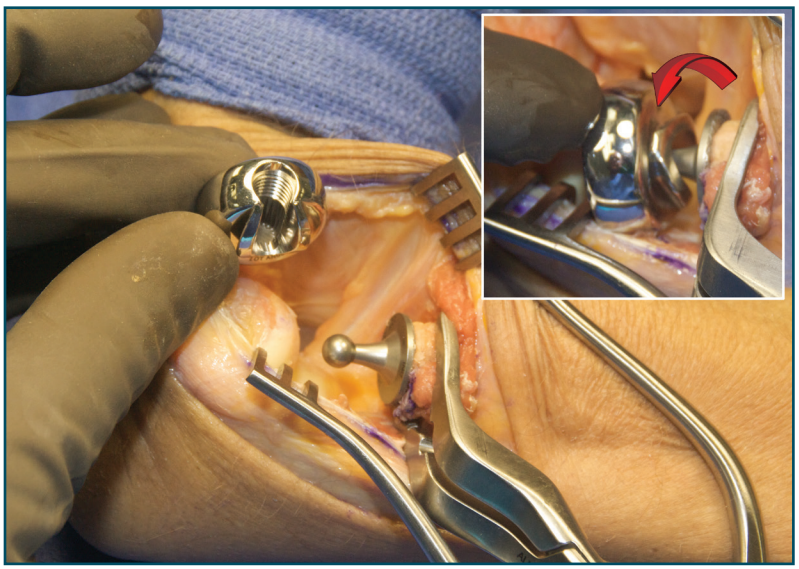
ALN-RST-IMP: ALIGN, Stem Impactor

PROSTHETIC HEAD LOADING 22

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.

Optional: The Radial Head Implant can be loaded using the side load Head Alignment Tool.
Engage the two tines of the Head Alignment Tool onto the Radial Head grooves.

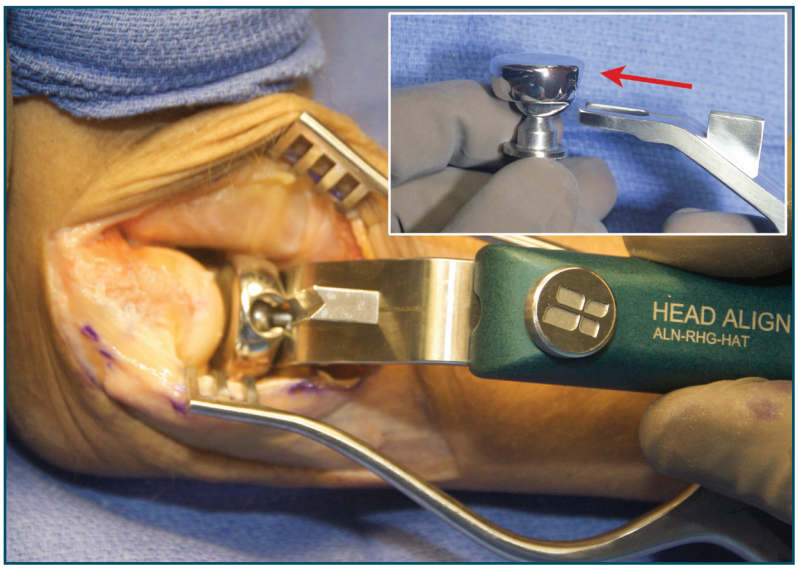


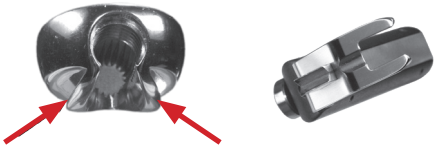
HEAD ALIGNMENT TOOL ENGAGEMENT 23

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.

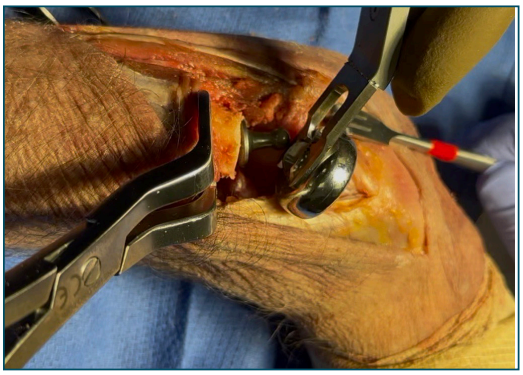
Note:
The Head Alignment Tool is used to control the position of the Radial Head.





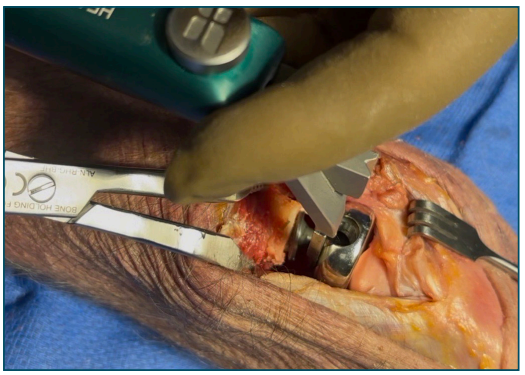
ALN-RHG-HAT: ALIGN, Head Alignment Tool, Radial Head Guide
ALN-RHG-HAT1
ALN-RHG-HATSL

23 HEAD ALIGNMENT TOOL ENGAGEMENT

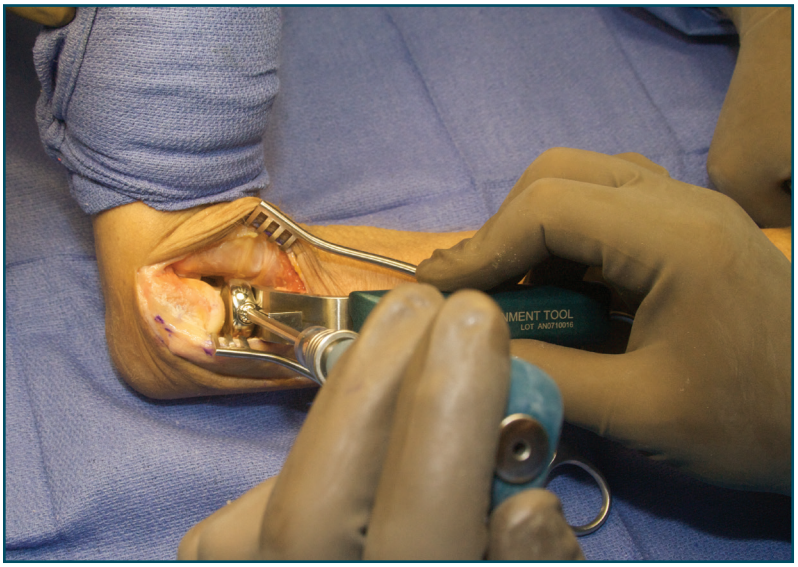


Optional: With the Head Alignment Tool handle held posteriorly, slide the tine cutout slot over the stem ball and pull to engage the head with the ball.





24 LOCK SCREW INSERTION



Loosely thread the Lock Screw into the Radial Head.

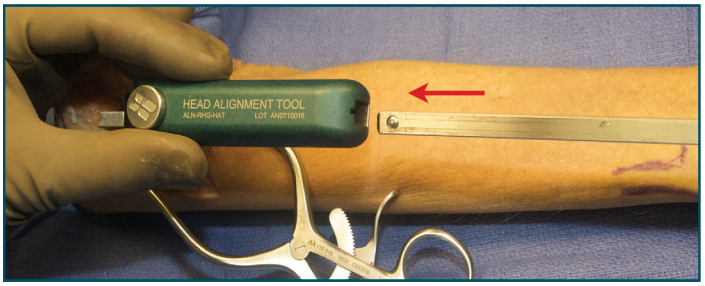


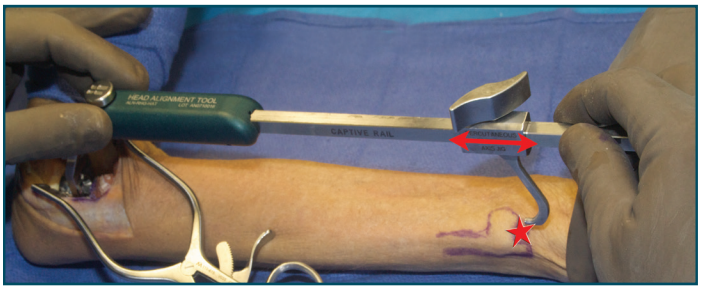
HNDL-UQC-FXD: Handle, Universal QC, Fixed

FOREARM GUIDE ASSEMBLY 25

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.







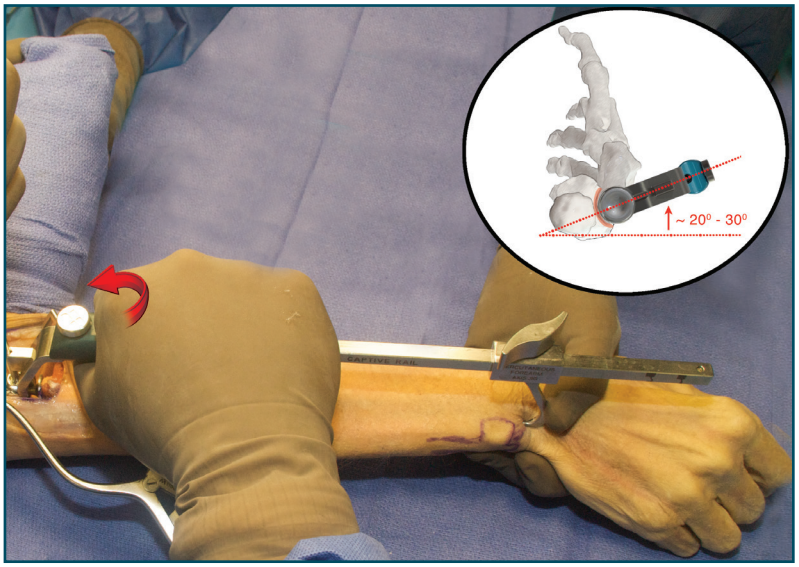
ALN-RHG-CRL: Captive Rail & Axis Jig, Radial Head Guide

INITIAL IMPLANT LOCKING 26

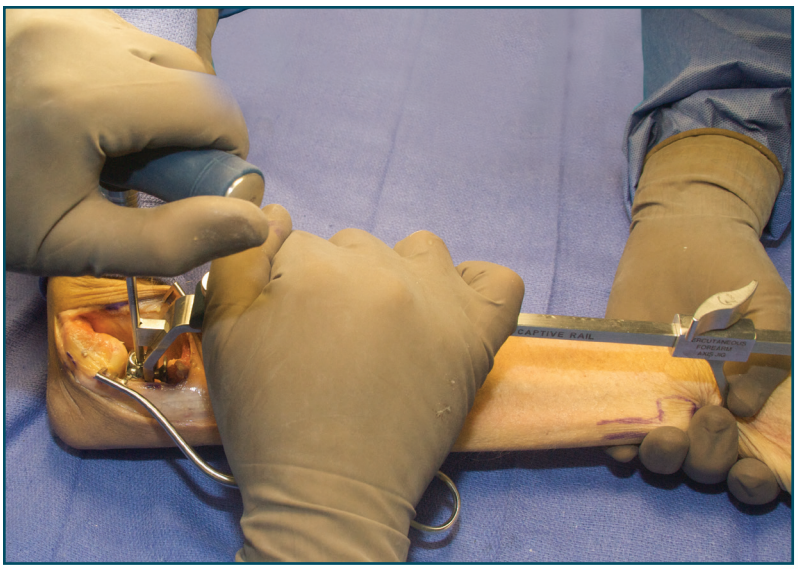
Pronate the Head Alignment Tool ~20 - 30 degrees from the neutral forearm position, then tighten the Lock Screw while providing counter-torque.

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

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



27 FINAL IMPLANT LOCKING



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

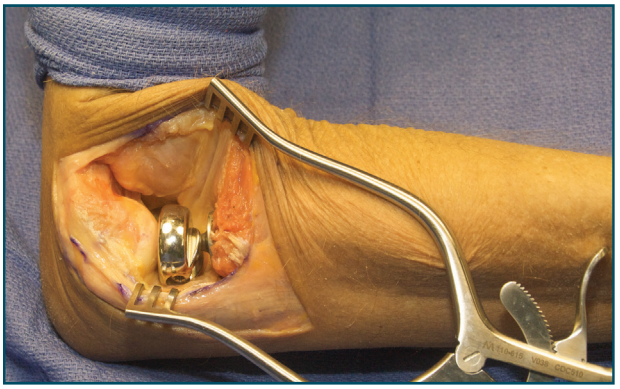
If desired, additional torque can be gained using the Universal Driver Handle.

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

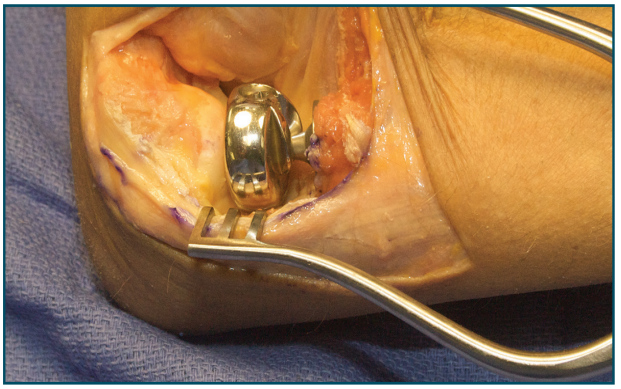


ALN-RHA-TQH: ALIGN, Torque Handle, Radial Head

28 IMPLANT VALIDATION



Supination

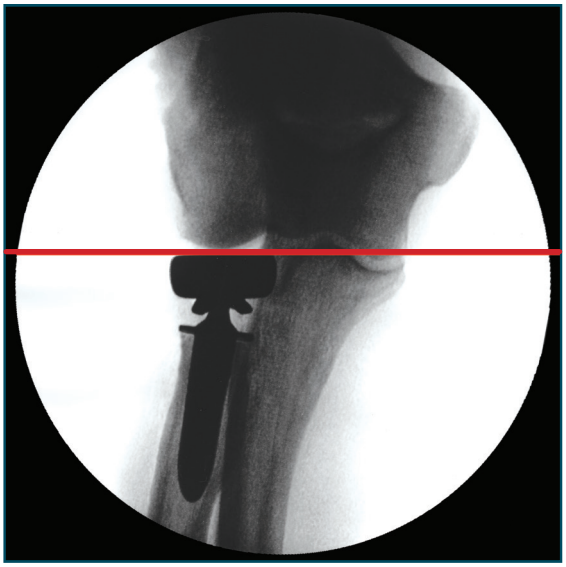


Pronation

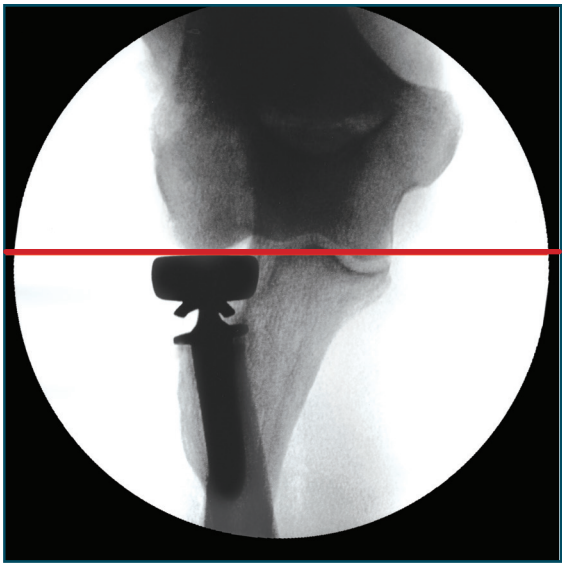
Remove the Forearm Axis Guide assembly.

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

FLUOROSCOPIC CONFIRMATION 29



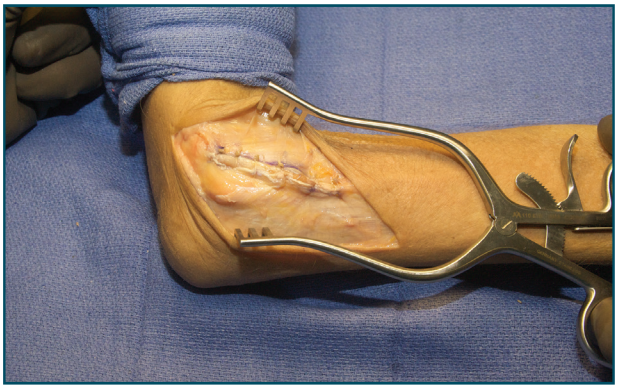
Supination



Pronation

Confirm final implant alignment using fluoroscopic imaging.

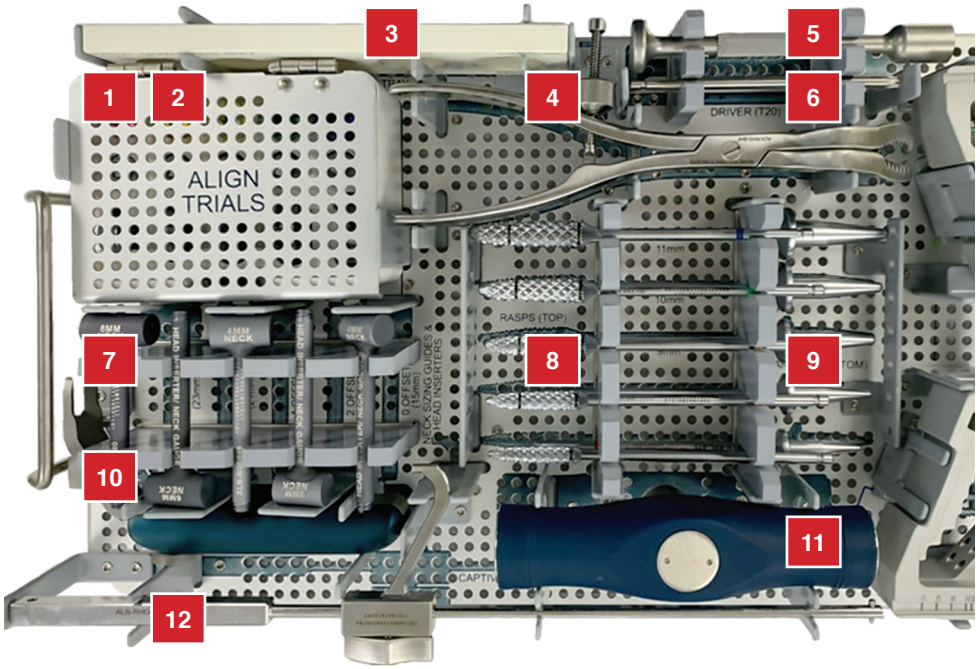
WOUND CLOSURE 30





Repair soft tissues as needed, then close the incision.

INSTRUMENT TRAY (Standard Configuration)



Loc #	Catalog #	Description
1	ALN-RHT-180	ALIGN, Trial, Radial Head, 18mm
	ALN-RHT-200	ALIGN, Trial, Radial Head, 20mm
	ALN-RHT-220	ALIGN, Trial, Radial Head, 22mm
	ALN-RHT-240	ALIGN, Trial, Radial Head, 24mm
	ALN-RHT-260	ALIGN, Trial, Radial Head, 26mm
	ALN-RHT-280	ALIGN, Trial, Radial Head, 28mm
2	ALN-RNT-0M2	ALIGN, Trial, Radial Neck, -2.0mm
	ALN-RNT-000	ALIGN, Trial, Radial Neck, 0.0mm
	ALN-RNT-020	ALIGN, Trial, Radial Neck, 2.0mm
	ALN-RNT-040	ALIGN, Trial, Radial Neck, 4.0mm
	ALN-RNT-080	ALIGN, Trial, Radial Neck, 8.0mm
3	ALN-STL-060	ALIGN, Long Trial, Radial Stem, 6.0mm
	ALN-STL-070	ALIGN, Long Trial, Radial Stem, 7.0mm
	ALN-STL-080	ALIGN, Long Trial, Radial Stem, 8.0mm
	ALN-STL-090	ALIGN, Long Trial, Radial Stem, 9.0mm
	ALN-STL-100	ALIGN, Long Trial, Radial Stem, 10.0mm
	ALN-STL-110	ALIGN, Long Trial, Radial Stem, 11.0mm
	ALN-STL-120	ALIGN, Long Trial, Radial Stem, 12.0mm
	ALN-RHS-SZR	ALIGN, Sizer, Radial Head Implant
4	ALN-RHG-BHF	ALIGN, Bone Holding Forceps
5	ALN-RST-IMP	ALIGN, Stem Impactor

Loc #	Catalog #	Description
6	DRVR-UQC-T20	Universal Driver QC, T-20
7	ALN-NGI-0M2	ALIGN, Neck Gauge & Head Inserter, -2mm
	ALN-NGI-000	ALIGN, Neck Gauge & Head Inserter, 0mm
	ALN-NGI-020	ALIGN, Neck Gauge & Head Inserter, 2mm
	ALN-NGI-040	ALIGN, Neck Gauge & Head Inserter, 4mm
	ALN-NGI-080	ALIGN, Neck Gauge & Head Inserter, 8mm
8	ALN-RRA-060	ALIGN, Radial Rasp, Stem 6.0mm
	ALN-RRA-070	ALIGN, Radial Rasp, Stem 7.0mm
	ALN-RRA-080	ALIGN, Radial Rasp, Stem 8.0mm
	ALN-RRA-090	ALIGN, Radial Rasp, Stem 9.0mm
	ALN-RRA-100	ALIGN, Radial Rasp, Stem 10.0mm
	ALN-RRA-110	ALIGN, Radial Rasp, Stem 11.0mm
	ALN-RRA-120	ALIGN, Radial Rasp, Stem 12.0mm
9	ALN-RPL-UNI	ALIGN, Radial Planer, Stem, Universal
10	ALN-RHG-HAT	ALIGN, Head Alignment Tool, Radial Head Guide
11	ALN-RHA-TQH	ALIGN, Torque Handle, Radial Head
12	ALN-RHG-CRL	Captive Rail & Axis Jig, Radial Head Guide
	HNDL-UQC-FXD	Handle, Universal QC, Fixed *

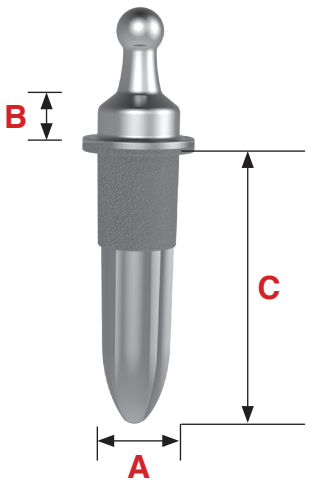
* Not pictured

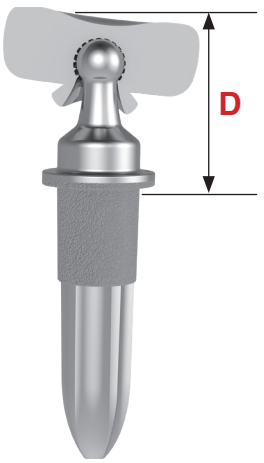
ALIGN® RADIAL HEAD & LOCK SCREW



CATALOG#	RADIAL HEADS (CoCr)
ALN-RHI-180	Ø 18mm
ALN-RHI-200	Ø 20mm
ALN-RHI-220	Ø 22mm
ALN-RHI-240	Ø 24mm
ALN-RHI-260	Ø 26mm
ALN-RHI-280	Ø 28mm

ALIGN® RADIAL STEM



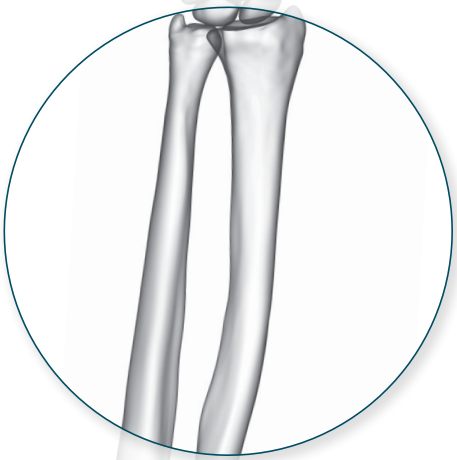


CATALOG#	RADIAL STEMS (Ti)			
	A	B	C	D
ALN-RST-06M2	6mm	-2mm	29mm	13mm
ALN-RST-0600	6mm	0mm	29mm	15mm
ALN-RST-0602	6mm	2mm	29mm	17mm
ALN-RST-0604	6mm	4mm	29mm	19mm
ALN-RST-0608	6mm	8mm	29mm	23mm
ALN-RST-07M2	7mm	-2mm	29mm	13mm
ALN-RST-0700	7mm	0mm	29mm	15mm
ALN-RST-0702	7mm	2mm	29mm	17mm
ALN-RST-0704	7mm	4mm	29mm	19mm
ALN-RST-0708	7mm	8mm	29mm	23mm
ALN-RST-08M2	8mm	-2mm	30mm	13mm
ALN-RST-0800	8mm	0mm	30mm	15mm
ALN-RST-0802	8mm	4mm	30mm	17mm
ALN-RST-0804	8mm	4mm	30mm	19mm
ALN-RST-0808	8mm	8mm	30mm	23mm
ALN-RST-09M2	9mm	-2mm	33mm	13mm
ALN-RST-0900	9mm	0mm	33mm	15mm
ALN-RST-0902	9mm	2mm	33mm	17mm
ALN-RST-0904	9mm	4mm	33mm	19mm
ALN-RST-0908	9mm	8mm	33mm	23mm
ALN-RST-10M2	10mm	-2mm	35mm	13mm
ALN-RST-1000	10mm	0mm	35mm	15mm
ALN-RST-1002	10mm	2mm	35mm	17mm
ALN-RST-1004	10mm	4mm	35mm	19mm
ALN-RST-1008	10mm	8mm	35mm	23mm
ALN-RST-11M2	11mm	-2mm	37mm	13mm
ALN-RST-1100	11mm	0mm	37mm	15mm
ALN-RST-1102	11mm	2mm	37mm	17mm
ALN-RST-1104	11mm	4mm	37mm	19mm
ALN-RST-1108	11mm	8mm	37mm	23mm
ALN-RST-12M2	12mm	-2mm	42mm	13mm
ALN-RST-1200	12mm	0mm	42mm	15mm
ALN-RST-1202	12mm	2mm	42mm	17mm
ALN-RST-1204	12mm	4mm	42mm	19mm
ALN-RST-1208	12mm	8mm	42mm	23mm

skeletal dynamics®

UNDERSTANDING THE UPPER EXTREMITY







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