

Modular Wrist Arthroplasty System Surgical Technique



Real change *starts* here[™]



Indications for use

The KinematX Total Wrist Arthroplasty System is indicated for the replacement of wrist joints disabled by pain, deformity, and/or limited motion caused by:

- 1. Non-inflammatory degenerative wrist disease of the radiocarpal joint, including osteoarthritis, post-traumatic arthritis, and Kienböck disease
- 2. Revision where other devices or treatments have failed
- 3. Scapholunate Advanced Collapse (SLAC)
- 4. Rheumatoid Arthritis

The device is intended to be implanted with bone cement.





Customer Service: 888.499.0079

www.extremitymedical.com



Implants



4.75mm Locking Screws



Instruments



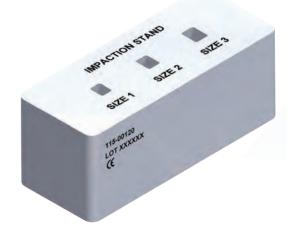


Ratcheting Handle

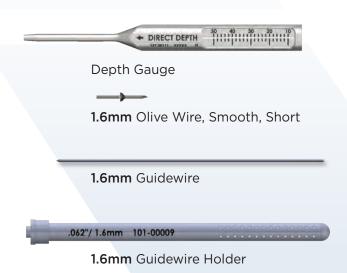
Slap Hammer







Impaction Stand













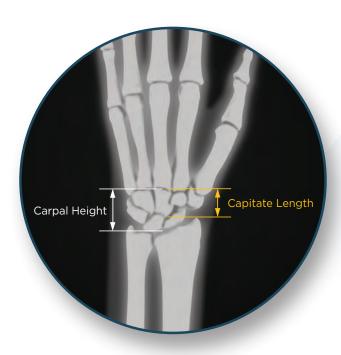
Pre-operative Case Planning and Review

The following technique guide (starting at Step 1 on page 7) illustrates the operative steps for a total wrist arthroplasty with the KinematX Total Wrist System for a patient with osteoarthritis.

It is recommended to use radiographs and pre-operative planning for cases that may demonstrate increased soft tissue tension.

These may include:

- Previous PRC
- Previous 4-corner fusion
- Inflammatory arthritis with subluxation and bone loss
- Severe SLAC wrist arthritis with collapse
- SCAC (CPPD) wrist arthritis with erosion into radius
- Kienböck disease with lunate collapse
- Anatomically small wrists



Pre-operative Planning

The following guidelines are useful for the evaluation of patient anatomy relative to technique and implant size. Also provided are suggestions for release procedures that may be beneficial for patients with excessive soft tissue tension. Technique and implant choice are left up to the surgeon's discretion.

Pre-operative measurements

- <u>Capitate Length</u> the minimal length needed to utilize the KinematX prosthesis is 19mm.
- <u>Carpal Height</u> measurement from the 3rd CMC joint space to the radial articular surface along the axis of the 3rd metacarpal:
 - 31mm or less indicates substantial soft tissue tension and likely will require one or more of the release procedures listed on the next page.
 - A 36mm height indicates the implant will fit without excessive soft tissue tension.

Releases and other procedure options for consideration for patients with increased soft tissue tension

Distally-based capsular flap

When operating on a patient with suspected soft tissue tension, a distally-based capsular flap is advised. This allows trimming or removal of the dorsal radial rim as needed for radial component recession (see below), and lengthening of dorsal capsule by interposition of a retinacular flap.

Raise a wide retinacular flap:

- **a.** Protect all branches of the dorsal radial sensory nerve by elevating them in the skin flap.
- **b.** Extend the division of the retinaculum over the extensor pollicis longus to the level of the index CMC joint or beyond.

- c. Incise the retinaculum transversely over the fourth dorsal compartment as distal as possible, provided there is good retinacular tissue. In a similar fashion, incise the retinaculum transversely far proximal to the wrist joint, and raise the flap to the ulnar side.
- d. Release the fifth dorsal compartment tendon from proximal to distal, with careful preservation of the retinaculum and EDM.
- e. The retinacular flap may be split transversely at the time of closure and the distal segment passed deep to the tendons to lengthen or replace portions of the capsular flap as needed.

Elevate the capsular flap from proximal to distal:

- **a**. Divide posterior interosseous nerve 2cm proximal to joint line.
- **b.** Incise capsule along radial rim beginning near the radial styloid and along the radial rim above the scaphoid to Lister's tubercle.
- **c.** Proceed ulnarwards, preserving 1-2mm of dorsal radiocarpal ligament on the radius and the dorsal radioulnar ligament.
- d. Make longitudinal incisions in the capsule immediately below 2nd and 5th dorsal compartments to the level of the CMC joints.
- e. Raise capsulo-ligamentous flap to the level of the CMC joints by dividing ligamentous insertions on the proximal and distal carpal rows.

Carpal Cap component considerations for increased soft tissue tension

When possible, make the +2mm capitate cut to gain additional soft tissue length. Perform preoperative templating prior to the case to ensure adequate room for the 12 or 15mm carpal post of the Baseplate is available with the +2mm cut.

Perform trial reduction with the standard radial trial once the Carpal Cap component is implanted. If there is excessive laxity, increase the radial tray size as necessary (+2, +4, +6).

If there is excessive tension with the standard radial trial, you can gain length by the following stepwise recommendations:

- a. 360-degree capsular release
- b. Radial component recession
- c. Sub-capitate recession

360-degree capsular release

(may be done stepwise to gauge adequacy of release)

- a. Release the retinaculum in a subperiosteal fashion from the Lister tubercle, beneath the second and first dorsal compartments to the radial styloid.
- **b.** Release the first dorsal compartment subsheath to the styloid
- **c.** Carefully preserve and dissect deep to the first dorsal compartment tendons and release the brachioradialis tendon from the radius.
- **d.** Flex the wrist to expose the palmar capsule, and translate the carpus palmarwards with an elevator or a small Bennett retractor.
- e. Continue to release around the tip of the radial styloid and the volar rim of the radius, staying tangential to the volar cortex of the radius.
- f. Excise the radial styloid if arthritic.
- g. Release the entire volar ligament complex and capsule from the volar rim as a sleeve of tissue.
- **h.** Continue the release as needed by releasing the pronator quadratus with a periosteal elevator.
- i. If needed, release the ulnolunate and ulnotriquetral ligaments from the palmar radioulnar ligament.

Radial component recession is ideal for patients with ulnar negative wrists. This decreases the likelihood of ulnar impingement.

- **a.** Place guidewire at desired entry point and trajectory as determined by preoperative templating. Remove wire and mark entry hole.
- **b.** Use the Radial Cartilage Removal Tool to deepen the radial concavity as needed.
- c. Excise the radial styloid as needed.
- **d.** Deep erosions of the scaphoid into the radius in SCAC may require considerable deepening.
- e. If soft cancellous bone or large subcondral cysts are exposed, be sure to secure the radial component with cement.
- f. When desired depth is reached, make a preliminary oblique cut with a micro-sagittal saw to preserve the sigmoid notch with a 3-4mm safety zone and preserve the dorsal/palmar radioulnar ligaments. See diagram.

- g. Remove the remaining dorsal and palmar lips of the radius with a sagittal saw, leaving the sigmoid notch and radioulnar ligaments intact.
- **h.** Continue with broaching and radial component implantation.

Sub-capitate recession

- a. Release capsule beneath trapezoid, trapezium, capitate and hamate with a blade or periosteal elevator.
- **b.** Special care should be taken about hamate hook due to proximity of ulnar nerve.
- **c.** An unlimited distal capsular release is not possible or advisable.

Step 1. Exposure

Utilizing a dorsal approach to the carpus, create a longitudinal incision approximately 5-7cm long in line with the third metacarpal beginning at the base of the third metacarpal.

Extensor Retinaculum

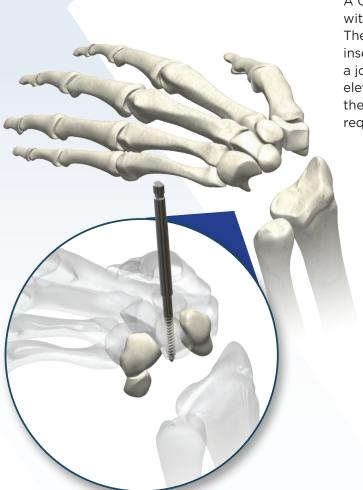
Incise and reflect a portion of the extensor retinaculum over the third and fourth dorsal compartments but leave the proximal 1-2cm of the retinaculum intact. Reflect the extensor tendons radially and ulnarwards to expose the wrist capsule. The approach allows preservation of the posterior interosseous innervation of the wrist at the surgeon's discretion.

Radiocarpal Exposure

Create a proximally-based rectangular dorsal capsular longitudinal flap by incising the capsule transversely at the CMC joints and along its most radial and ulnar margins. Raise the capsular flap from distal to proximal to expose the distal carpal row and midcarpal joint. Using a 7mm osteotome, raise a 1-2mm thick dorsal wafer of the triquetrum in continuity with the capsule in order to preserve the attachments of the dorsal radiocarpal and dorsal intercarpal ligaments.

Proximal Row Carpectomy

Remove the scaphoid, lunate, and remainder of the triquetrum, taking care to preserve the capitate head and volar wrist ligaments. A Carpal Extractor instrument is provided with the system to assist with this process. The Carpal Extractor instrument can be inserted into each of these bones and act as a joy-stick to apply traction while employing elevators as the surgeon carefully divides the capsular and ligamentous attachments required for carpal extraction.



Step 2. Radius Preparation: Denude the Articular Cartilage

The KinematX Total Wrist does not require any resection of the radius and thus preserves the length and inclination of the radius. Prepare the radius by removing the articular cartilage in the standard fashion with curettes. The system does provide a Radial Cartilage Removal Tool which can be a helpful instrument for the removal of the radial articular cartilage. If desired, attach this tool to power and use in a sweeping motion (radial to ulnar and dorsal to volar). Take care to create a smooth elliptical surface while preserving the subchondral bone along the dorsal and volar extrinsic capsular ligaments.

Ensure the entire surface of the radius including the dorsal and ulnar rim of bone of the articular surface is prepared.

Note: The Radial Cartilage Removal Tool is compatible with Stryker TPS and Command II, and Conmed HALL power-saws.

Step 3. Radial Guidewire Position/Placement

Utilizing fluoroscopy, insert the 1.6mm guidewire down the center of the radial canal approximately half of its length (~75mm). The typical guidewire starting point should be located below Lister's tubercle in the dorsal/ulnar quadrant of the scaphoid fossa. Confirm that the guidewire is centered in the radial canal on both the AP and lateral views.

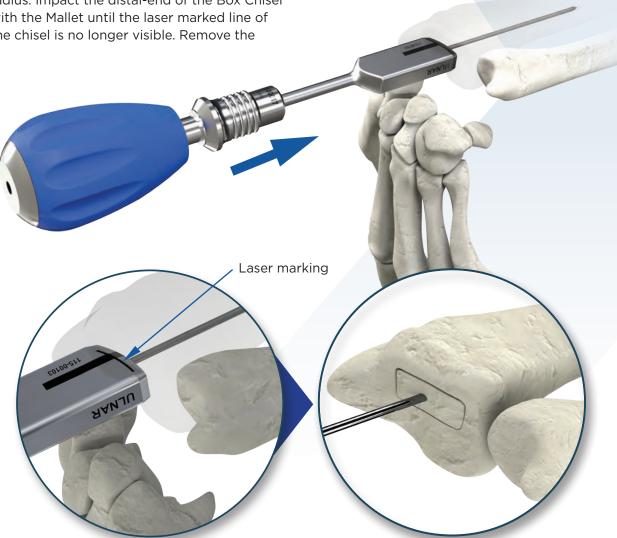
Step 4. Preparation for Broaching

As a preparatory step for broaching for the Radial Stem implant, the Cannulated Box Chisel is used to score the subchondral bone of the radius.

Slide the Cannulated Box Chisel over the 1.6mm Guidewire and down to subchondral bone of the radius. Note the ulnar/radial orientation of the chisel. The Box Chisel should be roughly parallel to the volar cortex of the radius. Impact the distal-end of the Box Chisel with the Mallet until the laser marked line of the chisel is no longer visible. Remove the

interior portion of the "scored" rectangle shaped bone using a burr (1-2mm), small osteotomes, and/or rongeurs.

Note: If utilizing a burr, run the burr around the edges created by the Box Chisel to remove the cortical bone. The remaining bone can remain in situ for impaction grafting when the Radial Broaches are used in the next step.



Step 5. Radial Broaching

It is recommended to sequentially broach the radial canal. Attach the Size 1 Radial Broach to the Broach Handle by inserting the threaded shaft from the handle into the female thread in the Radial Broach while tightening the thread engagement by turning the knob at the top of the broach handle in the clockwise direction.

Note: line up the black laser marking on the Broach Handle to the line on the broach.



Advance the Radial Broach over the guidewire

taking care to orient the Broach Handle so that

the ulnar and radial markings on the Broach

Step 6. Radial Trialing for Capitate Cut Assessment

Place the Radial Trial (size STD) into the broached radius. Gently reduce the capitate onto the bearing surface of the Radial Trial. Assess and verify the implant size for fit and wrist range of motion. This trialing will assist in determining the choice of the cut with the Carpal Resection Guide in the next step.

If insufficient laxity is present with the STD size trial, additional soft tissue release should be considered, and the +2 position of the Carpal Resection Guide should used to resect the capitate.





Step 7. Carpal Bone Preparation

Place a 1.6mm Guidewire into the capitate stopping short of the CMC joint. Use preoperative templates to identify the ideal starting point and trajectory of the guide wire so that it aligns parallel to the coronal and sagittal plane central axes of the third metacarpal. From the ideal starting point, insert the guide wire to closely align parallel to these axes in both planes, while being central in the capitate. Stop short of the 3rd CMC joint.

Place the Cannulated Depth Gauge over to measure this wire. This measurement will help determine the best option for carpal resection with the Carpal Resection Guide. Typically, the standard cut (STD) on the guide represents the standard anatomic alignment. The surgeon has the option to excise +2mm if the STD trial demonstrates excess tension when articulating with the native capitate as demonstrated in the previous Radial Trial step.

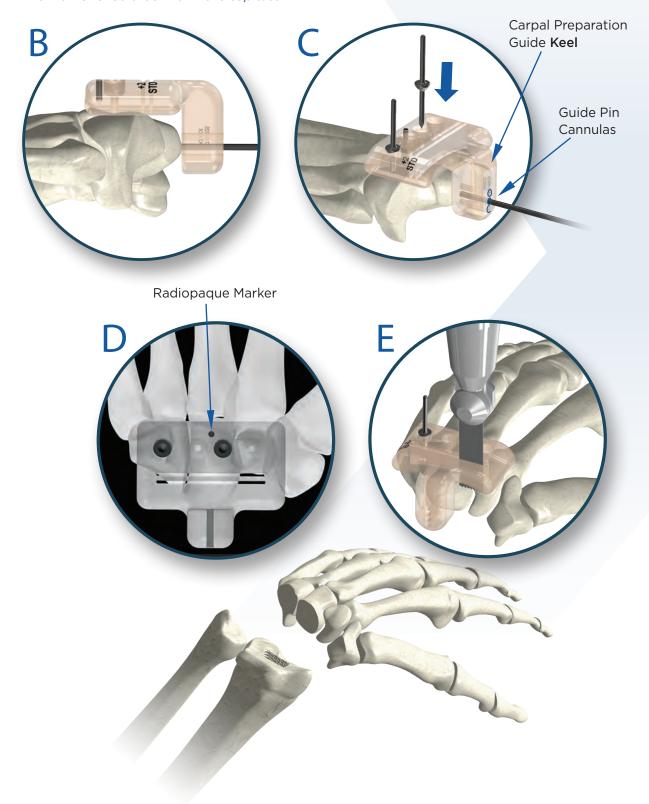
Capitate wire measurement / Baseplate selection guidelines:

- 19mm is the minimal measurement of the capitate required to fit the 12mm Baseplate with the standard (STD) cut on the Carpal Resection Guide
- 22m is the minimal measurement of the capitate required to fit the 15mm Baseplate with the standard cut on the Carpal Resection Guide

Place the Carpal Resection Guide over this Guidewire taking care to advance it so that it is contact with the capitate. The keel of the Carpal Resection Guide has several hole options. Dock the Carpal Resection Guide with the top-most hole on the keel that allows for an unrestricted abutment of keel to the capitate. Pin the Carpal Resection Guide dorsally with two Olive Wires. Resect the proximal aspect of the capitate and hamate.



Note: The Carpal Resection Guide has a radiopaque marker at the distal end of the guide. The marker should be within the capitate.



Step 8. Carpal Bone Preparation

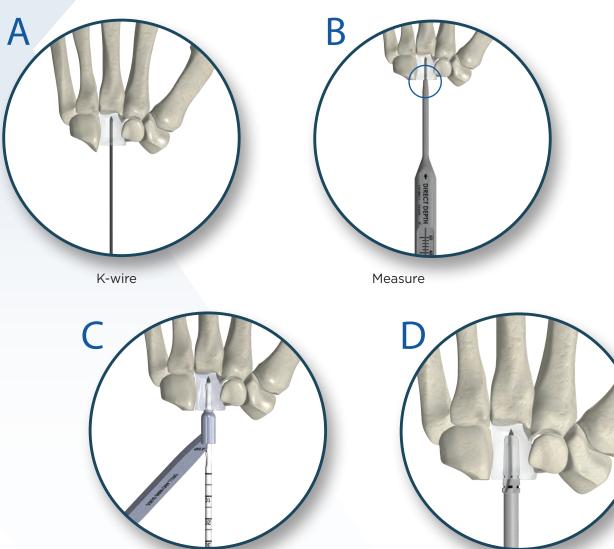
Using the previous wire hole, place a 1.6mm guidewire in the center of the capitate taking care not to violate the third metatarsal/capitate joint. The Carpal Preparation Guide can be used to reinsert the wire orthogonal to the prepared capitate. Confirm wire placement using fluoroscopy.

Measure the guidewire with the cannulated depth gauge (direct depth) to determine the appropriate sized Stem for the Baseplate.

Drill

Drill with the 3.0mm Drill, and then ream over the wire with the Reamer to prepare for the stem of the baseplate. Note, the first line on the Reamer is for the 12mm stem and the second line is for 15mm. Advance the Reamer until the laser marking is below the end of the resected capitate. This will ensure enough space has been created to fully seat the stem of the Baseplate. Carefully and completely remove bone within the reamed space to allow for full seating of the Baseplate.

Ream



Step 9. Baseplate Insertion

The 2nd CMC joints should be prepared for a fusion prior to placing the Baseplate. For cementing the Baseplate, it is recommended to prepare the holes for the screws prior to injecting the bone cement.

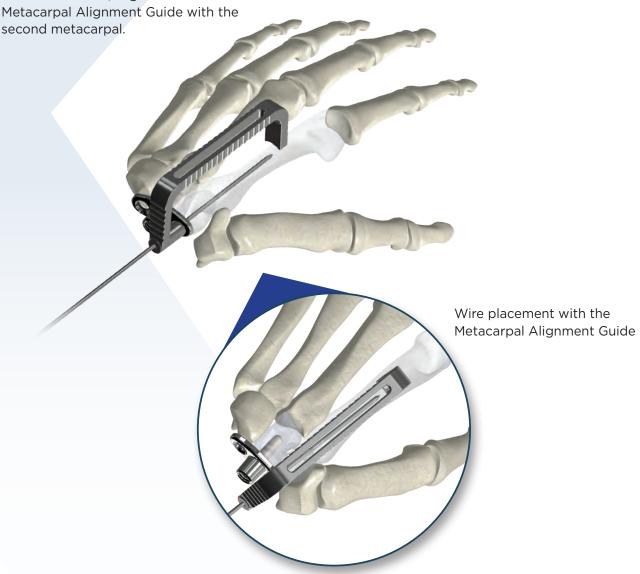
Orient the Baseplate ensuring that the Dorsal side (curved side) is aligned dorsally. Insert the Baseplate by pressing the stem into the capitate and the plate against the distally resected carpus using the T20 Star driver. The driver can be impacted to fully seat the plate.



Step 10. Carpal Plate Fixation

Two Locking Screws will be placed in the Baseplate—the first past the 2nd CMC joint into the Metacarpal, and the other into the Hamate.

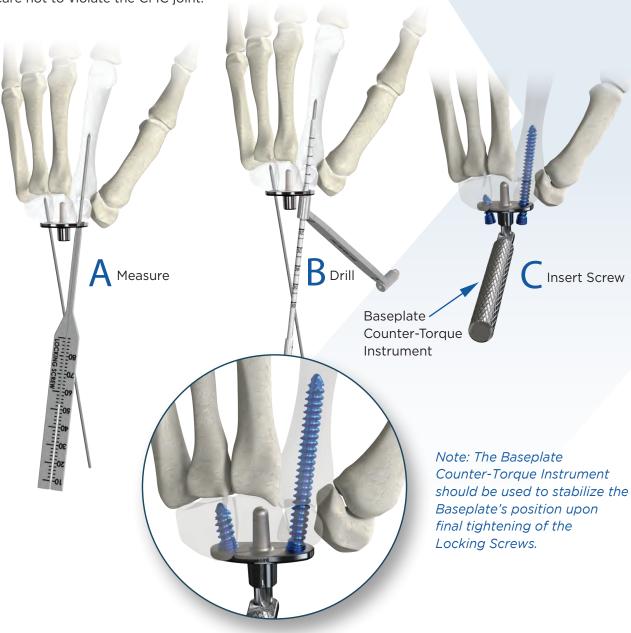
Advance a 1.6mm guidewire through the trapezoid into the center of the index metacarpal adjacent to the isthmus. To assist with the placement of this wire, align the distal end of the Metacarpal Alignment Guide with the



Step 10. Carpal Plate Fixation (continued)

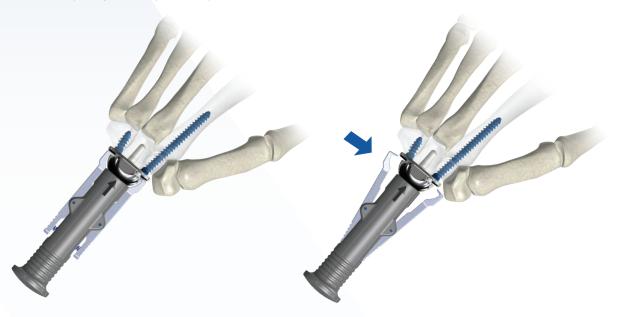
Measure the wire with the cannulated depth gauge (locking screw side) to determine the appropriate screw length. Drill over the wire with a 3.0mm Cannulated Drill to prepare for screw insertion. Repeat with the same wire placement and drilling steps on the ulnar side into the hamate. Utilize fluoroscopy to take care not to violate the CMC joint.

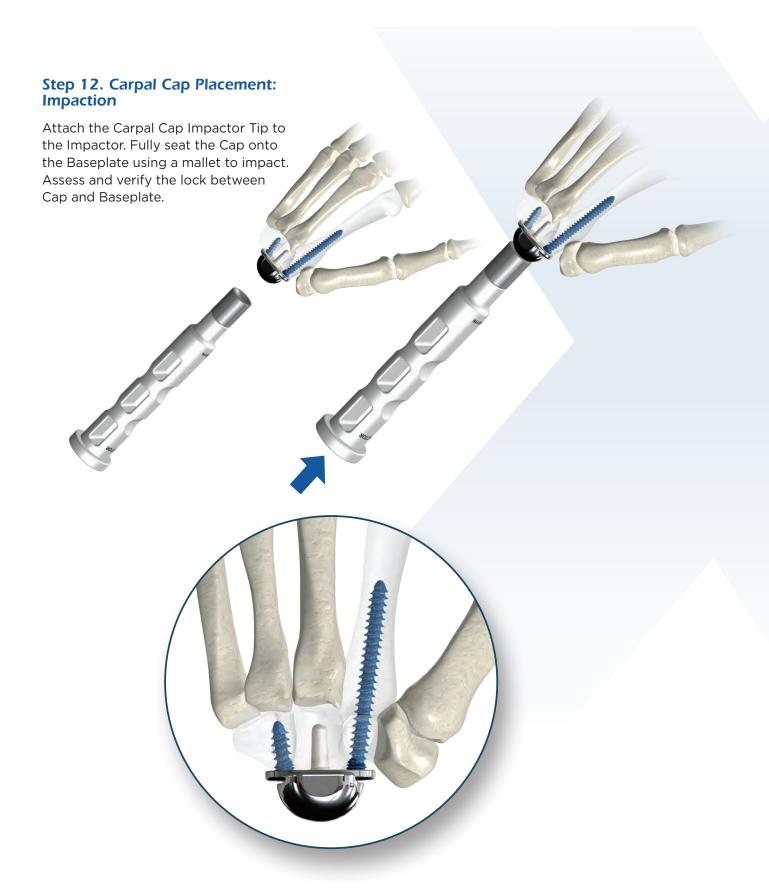
Remove the Baseplate and inject cement into the prepared holes. Reinsert the Baseplate and insert the Locking Screws with the T20 Star Driver. It is recommended to place both screws prior to final tightening.





Place the Cap onto the taper and squeeze the tabs on the sides of the Cap Holder to release the Cap as you tamp it into place.

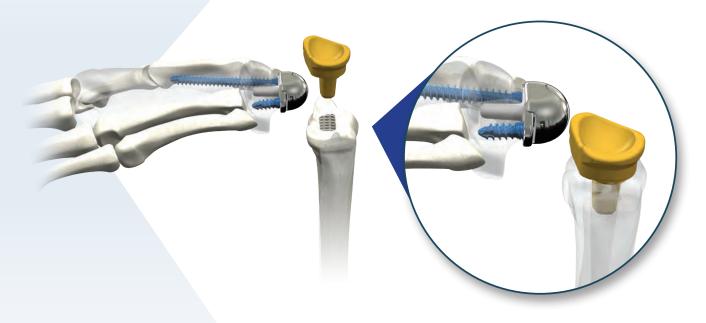




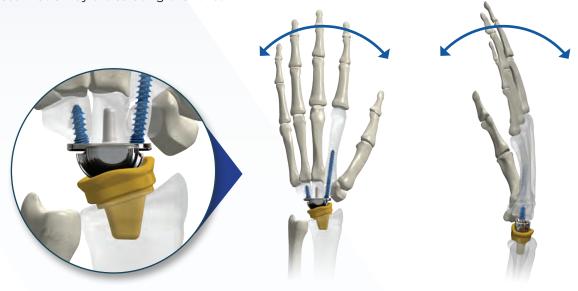
Step 13. Tray Assembly

Confirm the Radial size by placing the Radial Trial size determined in the earlier trial step into the radial canal. Gently reduce the Carpal Cap with the surface of the Radial Trial. Assess and verify fit and wrist range of motion.

If the joint has too much laxity, switch-out the Radial Trial to one of the larger sizes and reassess for fit and ROM. Select the Radial Tray Assembly and Stem Implants that corresponds to this trial.



Range of Motion: After radial trial insertion, verify ROM and assess motion by articulating the wrist.



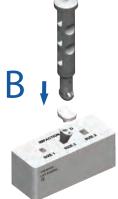
Step 14. Radial Implant Assembly and Placement

Option 1 - Back Table Assembly

Load the selected Radial Stem (size determined by the initial broaching step) into the corresponding pocket of the Impaction Stand. Align the taper and position the Stem with their mating features on the selected Radial Tray Assembly.

Attach the Radial Impactor Tip to the Impactor. Impact the Radial Tray Assembly with the Impactor and Mallet until it is fully seated onto the Stem. Assess and verify the lock between the Radial Tray Assembly and Stem.







Place the assembled KinematX Implant into the broached radius. Impact the assembly until the stems flange makes contact with the subchondral surface.

Option 2 - In Situ Assembly

Load the selected Radial Stem (size determined by the initial broaching step) onto the Radial Stem Inserter.

Place the Radial Stem into the broached radius. Seat it approximately 50% into the radius. Dissemble the Radial Stem from the Inserter. Align the taper and position the Stem

with their mating features on the selected Radial Tray Assembly. Attach the Radial Impactor Tip to the Impactor.

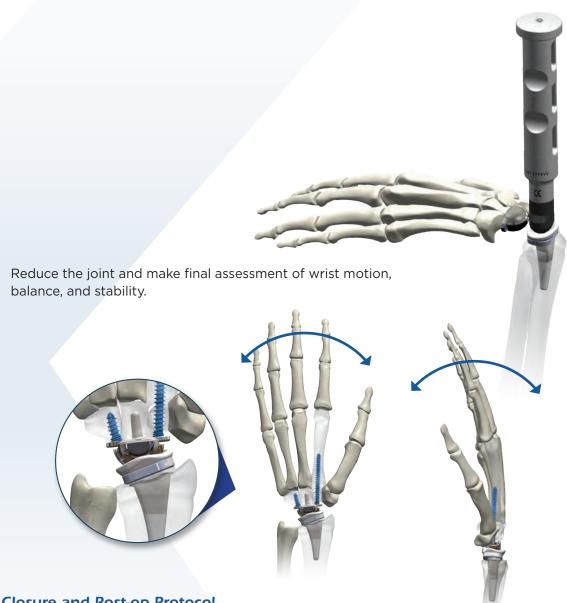
Impact the Radial Tray Assembly with the Impactor and Mallet until it is fully seated onto the Stem and the assembly the stems flange makes contact with the subchondral surface.











Closure and Post-op Protocol Recommendations

After thorough irrigation, re-approximate the proximally-based capsular flap to the rim of capsular tissue on the ulnar, distal and radial aspects of the carpus, using a running or interrupted 3-0 nonabsorbable suture. Replace the tendons in their bed, and close the retinaculum as needed with a running or interrupted 2-0 absorbable suture. The surgeon may transpose the EPL out of the retinaculum at their discretion. The skin is closed routinely, and the wrist immobilized in a short arm splint with the digits and thumb free for 7-10 days. The patient is encouraged to perform supination and pronation exercises as well as digital

exercises during the immediate postoperative period. Further immobilization should be directed by the surgeon as indicated by the stability of the prosthesis at surgery. In most cases, it is advisable to begin range of motion exercises in all planes, including circumduction and dart-throwing motion immediately following removal of the postoperative splint. A resting orthosis is helpful for comfort and the patient should be advised to avoid weight bearing, resistance loading, strengthening or athletic activity for at least six weeks postoperatively. Gradual return to activities should be permitted as strength and flexibility permit.

The KinematX Total Wrist Arthroplasty System is a modular system which allows for the combination of its components. Below is a summary of the compatible combinations of these components.



Screw Compatibility

All locking screws provided in the system are compatible with all baseplates.

Baseplate and Cap Compatibility Matrix	
Standard Baseplate, 12mm Stem	Carpal Cap
Standard Baseplate, 15mm Stem	(one size)

Radial Assembly and Cap Compatibility Matrix

Radial Tray Assembly, (L or R) Std	
Radial Tray Assembly, (L or R) +2mm	Carpal Cap (one size)
Radial Tray Assembly, (L or R) +4mm	(Offer size)
Radial Tray Assembly, (L or R) +6mm	



Radial Stem and Radial Tray Assembly Compatibility Matrix

Radial Stem Size 1	
Radial Stem Size 2	All Radial Tray Assembly Sizes (L or R), Std, +2mm, +4mm, +6mm
Radial Stem Size 3	

KinematX Implant Removal Instructions

Proximal Components

Disassemble the Radial Assembly from the stem by wedging a straight osteotome between the two components on the dorsal side. Remove the Radial Assembly. Attach the Stem Extractor to the Stem, and impact the underside of the Stem Extractor's impaction cap to back the Stem out of the radius. The Slap Hammer may also be attached to the impaction cap to remove the Stem.



Distal Components

Separate the Cap from the Baseplate by wedging a straight osteotome between the Cap and the Baseplate. After removing the Cap, utilize the T20 Star driver to remove the Locking Screws in a counter-clockwise fashion.

A Slap Hammer can be attached to the thread inside the baseplate to facilitate removal of the baseplate from the capitate bone.

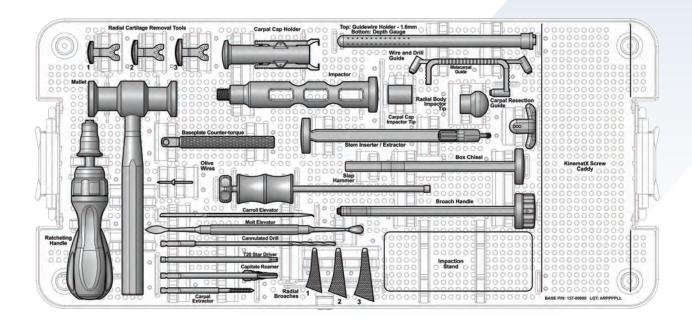
KinematX Total Wrist System Implants and Instruments

Implants (Sterile Packed)

Part #	Description
115-11000-S	Radial Stem - Size 1; Sterile Packed
115-21000-S	Radial Stem - Size 2; Sterile Packed
115-31000-S	Radial Stem - Size 3; Sterile Packed
137-30001-S	Radial Tray Assembly - LEFT, STD; Sterile Packed
137-30002-S	Radial Tray Assembly - RIGHT, STD; Sterile Packed
137-30201-S	Radial Tray Assembly - LEFT, +2; Sterile Packed
137-30202-S	Radial Tray Assembly - RIGHT, +2; Sterile Packed
137-30401-S	Radial Tray Assembly - LEFT, +4; Sterile Packed
137-30402-S	Radial Tray Assembly - RIGHT, +4; Sterile Packed
137-30601-S	Radial Tray Assembly - LEFT, +6; Sterile Packed
137-30602-S	Radial Tray Assembly - RIGHT, +6; Sterile Packed
137-50012-S	Standard Baseplate, 12mm Stem; Sterile Packed
137-50015-S	Standard Baseplate, 15mm Stem; Sterile Packed
137-31000-S	Carpal Cap; Sterile Packed

Screws

Part #	Description
137-47515	4.75mm Locking Screw x 15
137-47520	4.75mm Locking Screw x 20
137-47525	4.75mm Locking Screw x 25
137-47530	4.75mm Locking Screw x 30
137-47535	4.75mm Locking Screw x 35
137-47540	4.75mm Locking Screw x 40
137-47545	4.75mm Locking Screw x 45
137-47550	4.75mm Locking Screw x 50



Reusable Instruments

	istraments	
Part #	Description	
137-00015	Carpal Extractor	
137-00020	Carpal Cap Holder	
137-00025	Carpal Resection Guide	
137-00110	Baseplate Counter-Torque	
137-00111	KinematX Depth Gauge	
137-00115	Broach Handle	
137-00116	Impactor	
137-00117	Radial Impactor Tip	
137-00118	Carpal Cap Impactor Tip	
137-01600	Metacarpal Alignment Guide	
137-01630	Wire and Drill Guide	
137-03001	Radial Trial- LEFT, STD	
137-03002	Radial Trial - RIGHT, STD	
137-03201	Radial Trial - LEFT, +2	
137-03202	Radial Trial - RIGHT, +2	
137-03401	Radial Trial - LEFT, +4	
137-03402	Radial Trial - RIGHT, +4	
137-03601	Radial Trial - LEFT, +6	
137-03602	Radial Trial - RIGHT, +6	
148-00010	T20 Star Driver	
148-02039	Ratcheting Handle	
GS-43.3680	Carroll Elevator	
GS-43.3700	Molt #9 Elevator	
101-00009	Guidewire Holder - 1.6mm	
102-00017	Palm Handle	
102-00022	Slap Hammer	
115-00003	Mallet	
115-00112	Stem Inserter / Extractor	
115-00120	Impaction Stand	

Disposable Instruments

Part #	Description
101-00006	Trocar Guide Wire Dia = 1.6mm **
115-00103	Radial Box Chisel
118-00006	Post Reamer
118-02030	Cannulated Drill
137-00006	Radial Cartilage Removal Tool
137-00010	Capitate Reamer
137-01001	Radial Broach Size 1
137-01002	Radial Broach Size 2
137-01003	Radial Broach Size 3
144-61111	Olive Wire 1.6mm, Smooth, Short

(Stored w/in holder)**

NOTES:	

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Deliveringa smarter approach for total wrist **Period.**

Real change *starts* here[™]



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