

# SURGICAL TECHNIQUE



**RE>MOTION** *PGT*<sup>TM</sup>  
TOTAL WRIST SYSTEM WITH PRECISE GUIDANCE TECHNOLOGY



**S*B*i**  
SMALL BONE INNOVATIONS

# RE-MOTION™ Total Wrist Implant System

## SURGICAL TECHNIQUE

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#### **Acknowledgement**

Small Bone Innovations, Inc. would like to acknowledge the co-designers of the RE-MOTION Total Wrist System; William P. Cooney III, MD, Mayo Clinic, Rochester Minnesota, and Amit Gupta, MD, University of Louisville, Louisville Kentucky. Dr. Cooney and Dr. Gupta are leaders in the field of total wrist arthroplasty. Both are dedicated to the advancement of small bone and joint surgery in order to provide better clinical outcomes for their patients.

## RE-MOTION™ Design Rationale

The RE-MOTION Total Wrist Implant is a prosthesis anatomically designed for minimal resection of the distal radius and carpal bones of the wrist. The implant is provided in left and right hand configurations with geometrically scaled sizes that approximate the anthropomorphic sizes of different radio-carpal joints. The prosthesis is composed of three primary articulating components; the radial, carpal ball, and carpal plate.

The radial component is designed much like a surface replacement arthroplasty (SRA) in that it seats against the scaphoid and lunate fossa and preserves the peripheral rim of the distal radius with its important ligamentous and soft tissue attachments. The configuration requires minimal resection of the distal radius and preserves the sigmoid notch and articulation with the head of the distal ulna.

The carpal plate component is a low profile design that minimizes the amount of bone resection and does not interfere with the normal function of the wrist extensor tendons. The carpal plate has a central stem for insertion into the capitate and accommodates two carpal screws for fixation to the scaphoid and hamate within the distal carpal row.

The carpal ball component acts as an intercalated segment that articulates with both the radial and carpal plate components. The primary articulation occurs with the radial component. This articulation is ellipsoidal and acts along two perpendicular axes of rotation, similar to a universal joint, which lie in coronal and sagittal planes where by permitting motions of flexion-extension and radio-ulnar deviation respectively. The convexity of the radial component's articular geometry resists ulno-volarly directed forces that can cause excessive wear and implant subluxation.

The secondary articulation of the carpal ball occurs with the carpal plate component. This articulation is rotational about an axis aligned with the longitudinal axis of the third metacarpal. This additional degree of freedom diverts rotational forces from the bone implant interface that can cause loosening and may lead to implant failure. The additional laxity also provides compensation for potential misalignment of the device due to advanced deformity caused by rheumatoid or degenerative arthritis.



## Precise Guidance Technology™ Design Rationale

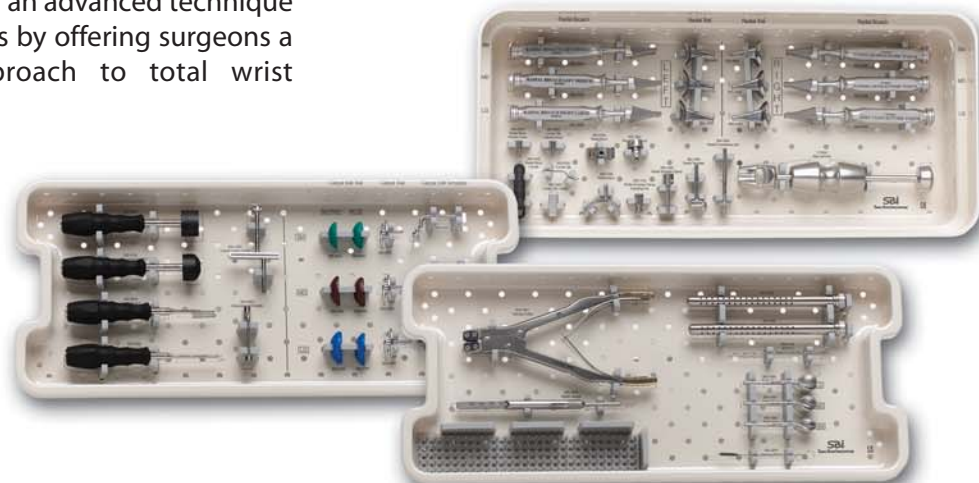
The wrist is one of the more complex joints in the human body. For this reason, it is one of the more difficult joints to reconstruct. Precise Guidance Technology (PGT™) Instrumentation was designed to produce consistent surgical outcomes by offering surgeons a predictable and reproducible approach to total wrist arthroplasty. PGT is an intuitive, step-by-step approach to wrist replacement that provides precise guidance when needed, while, leaving the freedom to adequately perform the procedure in the hands of the surgeon.

The RE-MOTION™ Total Wrist Implant has demonstrated years of successful clinical outcomes. This implant design utilizes the Surface Replacement concept, which requires minimal bone resection and preserves the soft tissue and ligamentous structures that provide natural stability to the wrist. The PGT instruments provide specifically designed outriggers and guides that orient from consistent anatomical landmarks, offering the surgeon control over preparation and implant placement.

PGT is a modular instrument system that originates with the placement of the PGT Guide. Once this guide is mounted successfully on the dorsum of the radius, the rest of the procedure is accomplished by attaching cutting guides and temples to the PGT Guide. Because these instruments use a common reference, the radial and carpal preparations remain in constant alignment.

Throughout the procedure, the surgeon is guided from one step to the next, mitigating the complications associated with treating complex disorders of the wrist. To obtain a successful outcome, it is important to assure proper orientation of the radial and carpal components and to preserve stabilizing structures. The PGT approach to total wrist arthroplasty eliminates the majority of these challenges.

The PGT Instrumentation coupled with an advanced technique produces consistent surgical outcomes by offering surgeons a predictable and reproducible approach to total wrist arthroplasty.



# Prosthesis Design

## Proximal Radial Component

The radial component is fabricated from cobalt chrome-molybdenum alloy. The intra-medullary stem is coated with commercially pure titanium plasma coating to promote osseointegration. The distal surface is contoured to approximate the volar tilt and ulnar inclination angles of the distal radius. The articular surface is precision machined and highly polished for articulation with the carpal ball component.

## Carpal Ball Component

The carpal ball component is fabricated from ultra-high molecular weight polyethylene (UHMWPE) material. The proximal articular surface is elliptical to maximize the surface contact with the radial component over a full range of flexion-extension and radio-ulnar deviation. The carpal ball is fastened to the carpal plate using a snap fit "ball and socket" configuration allowing for limited axial rotation to occur along the long axis of the third metacarpal. The distal articular surface of the carpal ball has two slotted openings that accommodate the carpal screws.

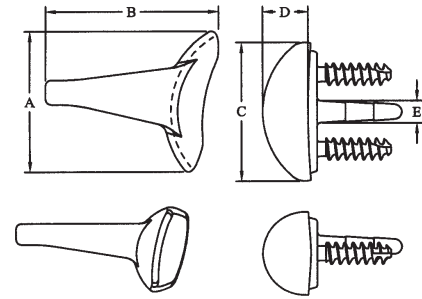
## Carpal Plate Component

The carpal plate component is fabricated from cobalt chrome-molybdenum alloy. The buttress surface and intramedullary stem are coated with commercially pure titanium plasma coating to promote osseointegration. The stem is dorsally offset from the carpal screw hole locations to accommodate the arch of the carpus. The articular surface and spherical ball are precision machined and highly polished to allow for articulation with the carpal ball component.

## Carpal Screw Component

The carpal screw component is fabricated from cobalt chrome-molybdenum alloy. The screws are provided in five (5) different lengths and have a cancellous thread form for optimum fixation with the carpal bones of the wrist. The spherical head allows for ideal screw angulation that is determined during the surgical procedure. The hex drive feature on the carpal screw component accepts a standard 2.5mm screw driver.

## Right Hand



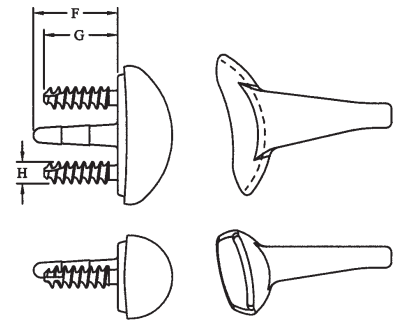
### Wrist Radial Component

		DIMENSIONS (mm)	
	SIZE	CAT NO	A B
RIGHT HAND	SMALL	WA/R-RS	29.2 36.0
	MEDIUM	WA/R-RM	31.4 38.9
	LARGE	WA/R-RL	34.1 42.3
LEFT HAND	SMALL	WA/R-LS	29.2 36.0
	MEDIUM	WA/R-LM	31.4 38.9
	LARGE	WA/R-LL	34.1 42.3

### Wrist Carpal Plate Component

		DIMENSIONS (mm)	
	SIZE	CAT NO	E F
	SMALL	WA/C-S	4.6 17.3
	MEDIUM	WA/C-M	5.0 18.7
	LARGE	WA/C-L	5.5 20.4

## Left Hand



### Wrist Carpal Ball Component

		DIMENSIONS (mm)	
	SIZE	CAT NO	C D
NEUTRAL	SMALL	WA/B-NS	28.9 9.3
	MEDIUM	WA/B-NM	31.2 10.1
	LARGE	WA/B-NL	33.9 11.1
PLUS	SMALL	WA/B-PS	28.9 10.3
	MEDIUM	WA/B-PM	31.2 11.1
	LARGE	WA/B-PL	33.9 12.1

### Wrist Carpal Screw Component

		DIMENSIONS (mm)	
	SIZE	CAT NO	G H
	15mm	WA/S-15	15 4.5
	18mm	WA/S-18	18 4.5
	22mm	WA/S-22	22 4.5
	26mm	WA/S-26	26 4.5
	30mm	WA/S-30	30 4.5

## Preoperative Assessment

Preoperative assessment consists of true A/P and Lateral x-rays of the wrist. The degree of carpal collapse and subluxation / dislocation of the carpus on the distal radius must be assessed for proper intra-operative planning.

A template overlay is used to determine the appropriate size wrist implant. Minimal resection of the distal radius should be combined with resection of the proximal carpal rows and proximal head of the capitate and hamate. With the template overlay, the distal component should provide insertion within the capitate, hamate and distal scaphoid. Avoid the central peg or radial and ulnar screws entering into the metacarpals or across the carpometacarpal joints.

From lateral x-rays (or wrist tomograms), volar subluxation of the carpus can be estimated and correction planned for by limited resection of the distal radius (to a perpendicular surface) and correct prosthetic alignment and placement.

In patients with excessive carpal bone resorption, the distal component fixation (screw fixation) may need to cross the carpo-metacarpal joints. A template overlaid on the wrist will assist in noting this variation in the surgical technique. Bone cement fixation or impaction grafting may be required to achieve firm distal implant fixation. In addition, bone grafting of the distal carpal row may be indicated to provide an "autofusion" for improved distal component fixation.

In patients with volar subluxation of the wrist, a resurfacing implant may be contra-indicated. Resection of the distal radius to provide sufficient carpal length for implant insertion may affect the principle of a resurfacing implant as soft tissue capsule constraints may be compromised. Wrist fusion may be preferred in patients with advanced synovitis of the wrist resulting in carpal subluxation, excessive ulnar translation and destruction of both proximal and distal carpal rows.



**Rheumatoid Diseased Wrist**

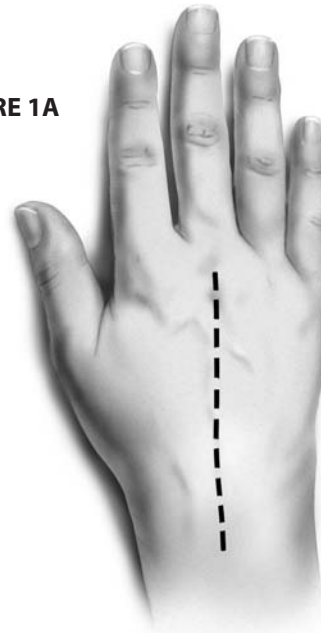
## SURGICAL PROCEDURE

**1 Exposure**  
A dorsal incision is made in line with the third metacarpal and centered directly over Lister's Tubercle. Skin flaps are elevated protected cutaneous nerves (**FIGURE 1A**).

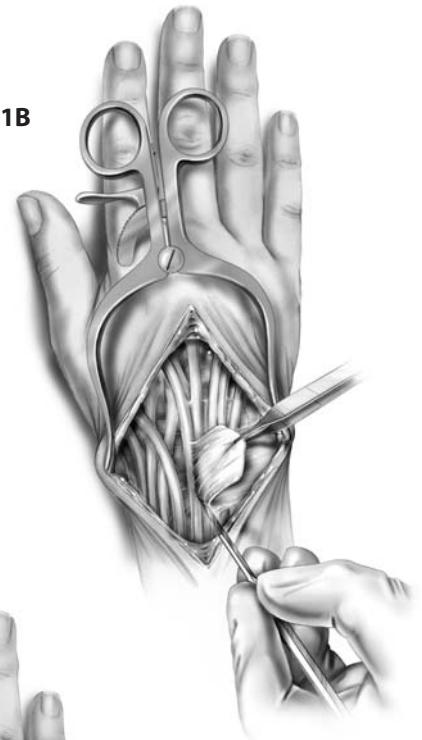
The extensor retinaculum is exposed and reflected from radial to ulna, from the first extensor compartment to the fifth or sixth extensor compartment. This reflection of the extensor retinaculum (rather than a central division) is recommended so that the distal 1/3 can be used to reinforce the dorsal joint capsule if necessary (**FIGURE 1B**).

After exposure, a synovectomy of the extensor tendons is performed as required (**FIGURE 1C**).

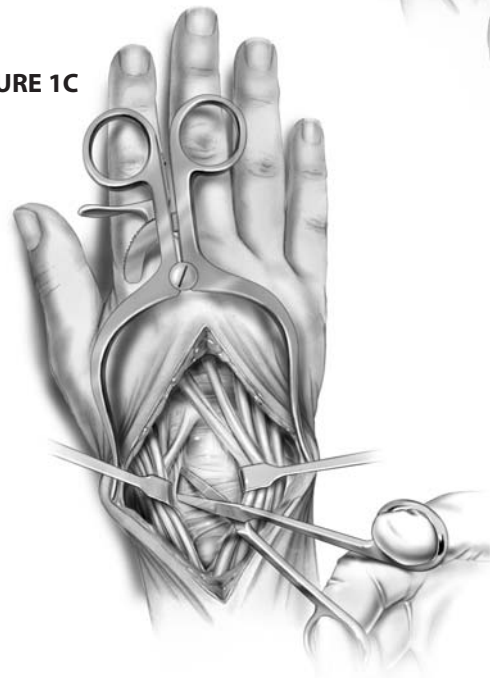
**FIGURE 1A**



**FIGURE 1B**



**FIGURE 1C**



A rectangular shaped wrist flap is reflected from proximal to distal to expose the proximal and distal carpal rows. The dorsal wrist flap should be divided close to the dorsal rim of the distal radius but with the proximal tissue preserved for capsule closure repair. (FIGURE 1D).

If insufficient capsule is anticipated, the extensor retinaculum should be preserved by a radial to ulnar reflection of the extensor retinaculum. The distal third of the retinaculum can then be used to augment the dorsal capsule repair.

If there is palmar subluxation of the carpus, or otherwise tight radio-carpal space, soft tissue release may be required to bring the carpus out to length. When complete release of the volar capsule is required to reduce the carpus, post-operative instability may occur. Surgeon judgment related to potential instability is required.

**Note:** A longitudinal incision is recommended. Preservation of the capsule on the dorsal rim of the distal radius is recommended.

## 2 Carpal Resection

Assemble the Lunate tab and mount the Assembly onto the PGT Guide (FIGURE 2A).

Place the wrist in flexion with slight distraction. Insert the Lunate Tab from dorsal to volar into the radio-carpal joint in an rolling method, for ease of insertion. Position the Lunate Tab against the lunate fossa (FIGURE 2B).

FIGURE 1D

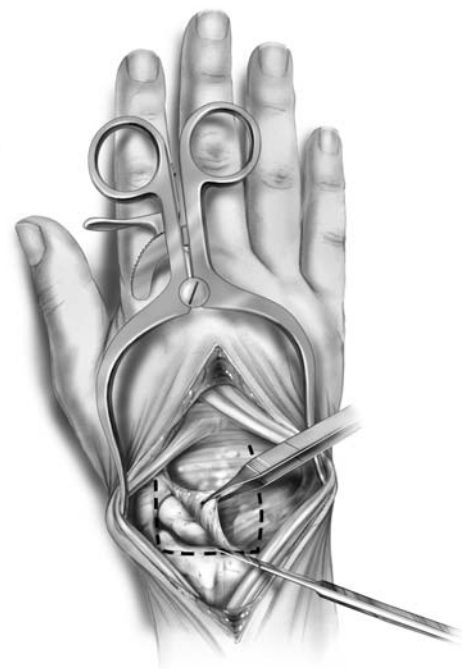


FIGURE 2A

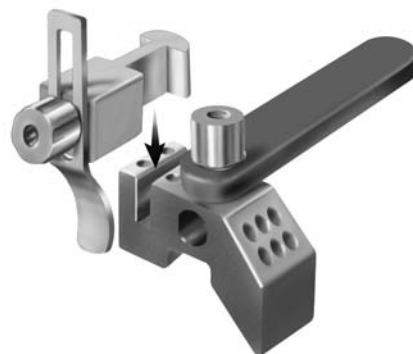
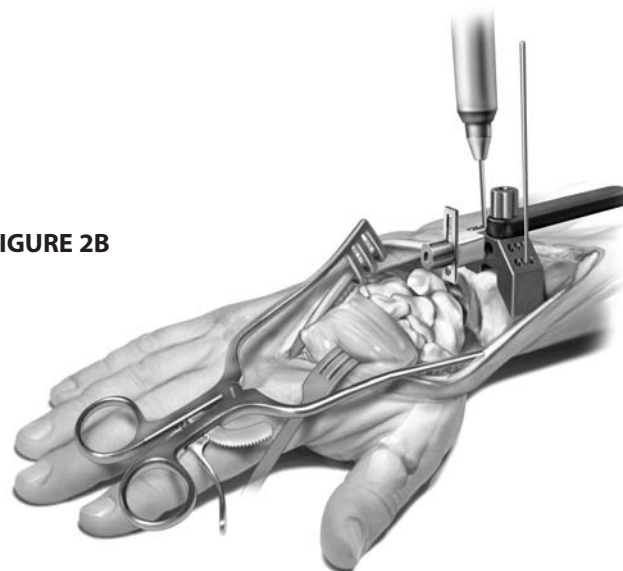
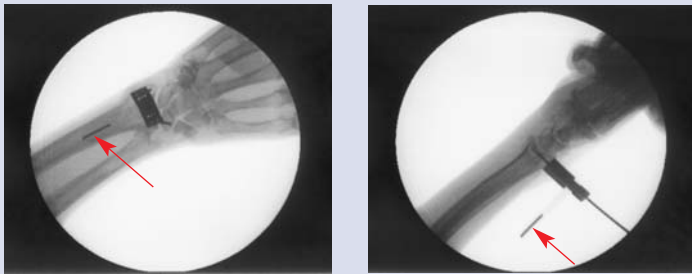


FIGURE 2B



Correct positioning of the PGT™ Guide is critical to the procedure. The PGT Guide should be located over Lister's tubercle and rest firmly on the dorsal surface of the distal radius. The distal end of the PGT Guide on the lateral x-ray should align with the articulating surface of the lunate fossa of the distal radius.

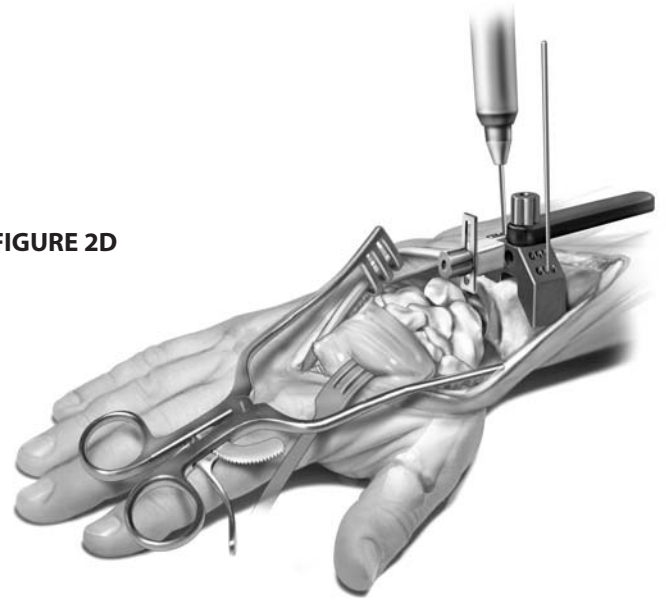
Secure the PGT Guide to the dorsal aspect of the distal radius with 2.0mm, non-threaded K-wires. Confirm position of the PGT Guide with x-ray imaging. A radiopaque rod runs down the middle of the PGT Guide Handle. This rod should appear parallel to the long axis of the radius on both, the A/P and Lateral x-rays. Once satisfactory positioning of the PGT Guide is achieved, remove the PGT Tab (**FIGURE 2D**).



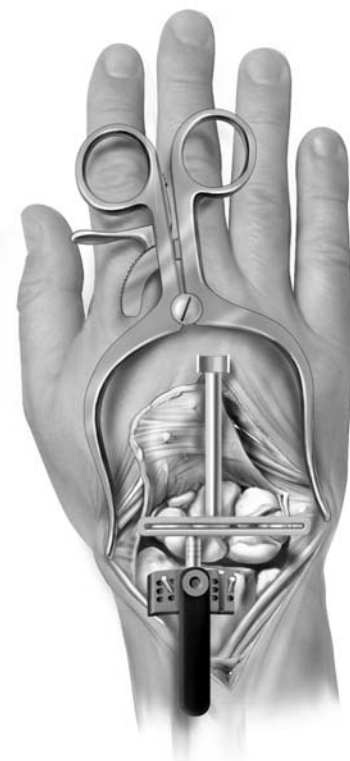
**Note:** Radiopaque marker within PGT guide handle must be parallel to the radius on the A/P and Lateral x-ray.

Insert the PGT Carpal Cutting Guide into the PGT Guide and tighten in place. The position of the Carpal Cutting Guide should be established based upon a pre-operative assessment using an x-ray template. The proximal shaft of the Carpal Cutting Guide is equipped with sizing graduation markers. These markers correspond to the small, medium, and large sized implants (**FIGURE 2E**).

**FIGURE 2D**



**FIGURE 2E**



Place the Carpal Cutting Guide across the wrist and align with the 3rd metacarpal. Typically, the lunate, triquetrum, proximal scaphoid, head of the capitate, and head of the hamate are resected. If the Carpal Cutting Guide is placed correctly, the cut should be perpendicular to the long axis of the forearm. Resect the carpal bones with an oscillating saw (**FIGURE 2F**).

Generally, 1 to 2 millimeters of the head of the capitate is resected. In patients with excessive carpal erosion or advanced DJD, a more distally based resection may be required. Generally, in these cases removal of all bone proximally is recommended, with preservation of the volar wrist capsule.

Once the carpal resection is complete, remove the Carpal Cutting Guide from the PGT Guide.

**Note:** It may be helpful, prior to resection, to use transverse K-wires to stabilize the distal scaphoid to the carpus.

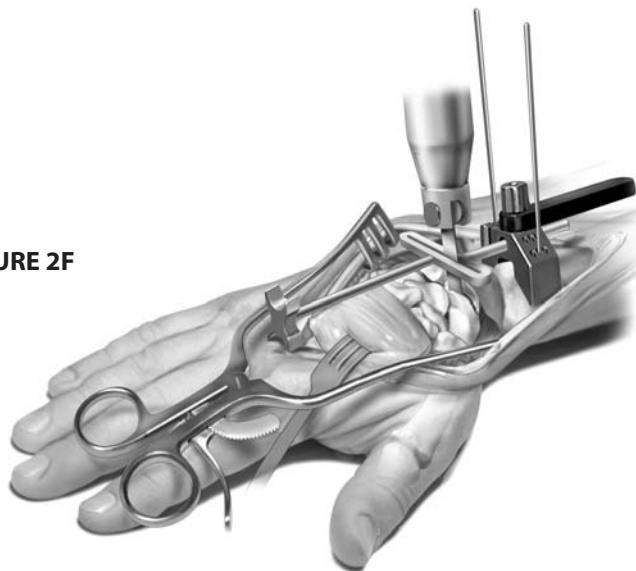
### 3 Radial Preparation

Insert the PGT Radial Resurfacing Guide into the PGT Guide. Tighten at the proper height to adequately contour the scaphoid and lunate fossae. The Resurfacing Guide is equipped with reference line markers to facilitate adjustment of the guide during burring. The reference lines are in two millimeter increments (**FIGURE 3A**).

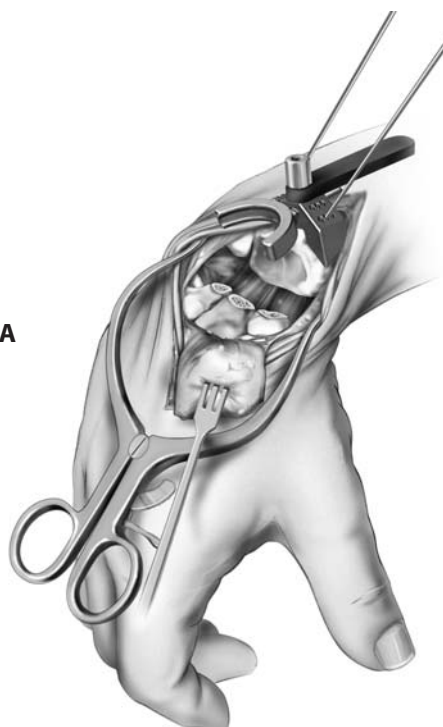
The lateral profile of the Burr should be centered about the distal radius. Tighten the set screw in the Burr Collar when adequate positioning is achieved. The PGT Radial Burr should remove excess bone on the radial styloid and central ridge between the scaphoid and lunate fossae. Care should be taken not to resect subchondral bone. A smooth surface that matches the contour of the radial prosthesis proximal surface should result. Remove the Radial Resurfacing Guide (**FIGURE 3B**).

**Note:** Surgeons may have better control of the burr if a pulling motion is used instead of a pushing motion.

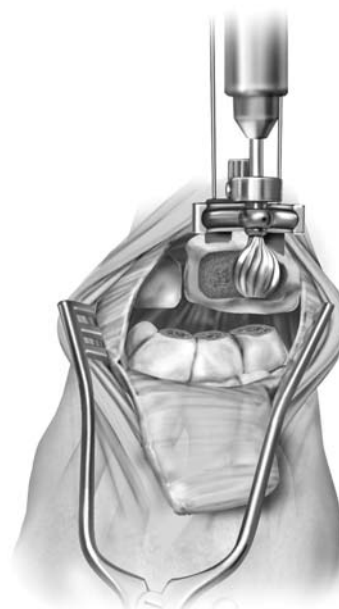
**FIGURE 2F**



**FIGURE 3A**

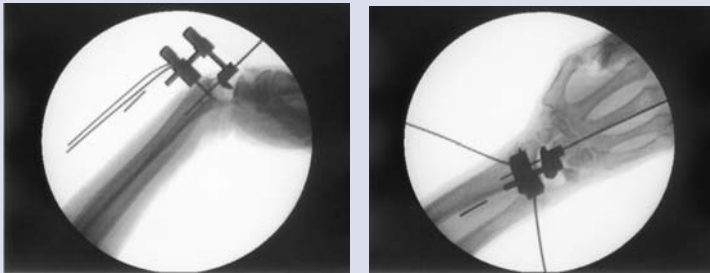


**FIGURE 3B**



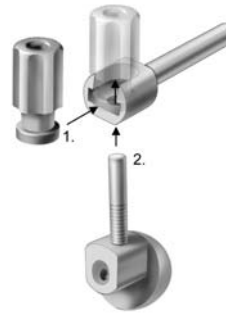
Insert the PGT Radial Pilot Template into the PGT Guide. (**FIGURE 3C**). The Radial Pilot Template should sit firmly against the prepared surface of the distal radius and 2 to 3 millimeters below the dorsal cortex of the radius. The Radial Pilot Template may be adjusted dorsal and palmar to achieve correct optimal alignment (**FIGURE 3D**).

Place the 2mm threaded guide pin into the distal radius and advance 4 to 5 centimeters until secure in the bone. The guide pin should be centered down the diaphysis of the distal radius. Confirm the position of the guide pin on A/P and Lateral x-ray (**FIGURE 3E**).

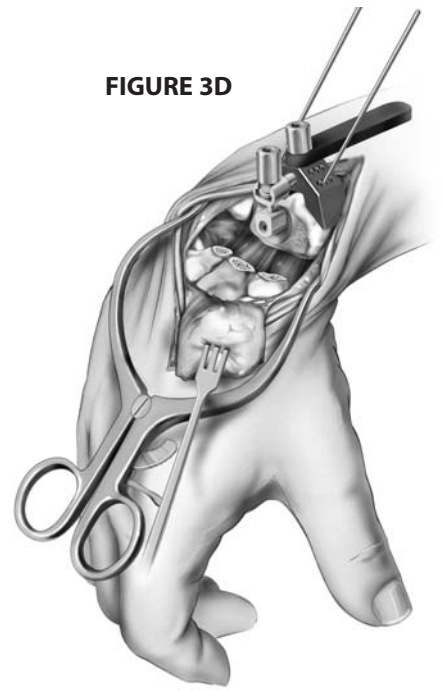


Once correct positioning of the guide pin is achieved, remove the Pilot Template distally by sliding it off the guide pin. Remove the PGT Guide by lifting it dorsally (**FIGURE 3F**).

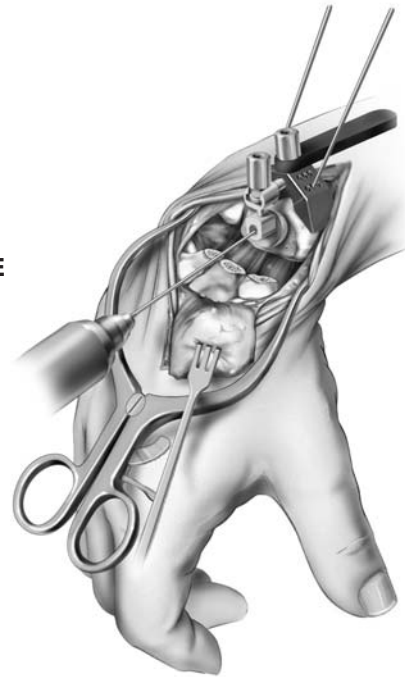
**FIGURE 3C**



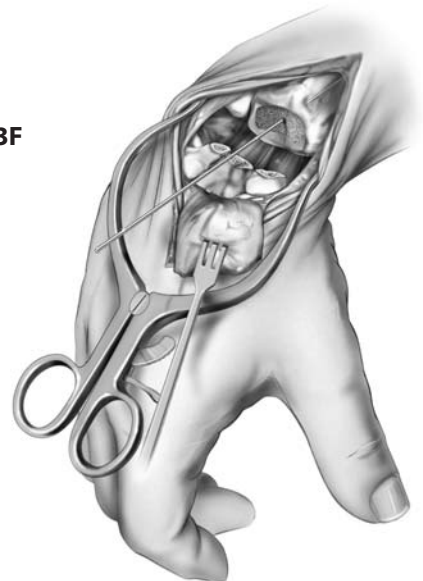
**FIGURE 3D**



**FIGURE 3E**

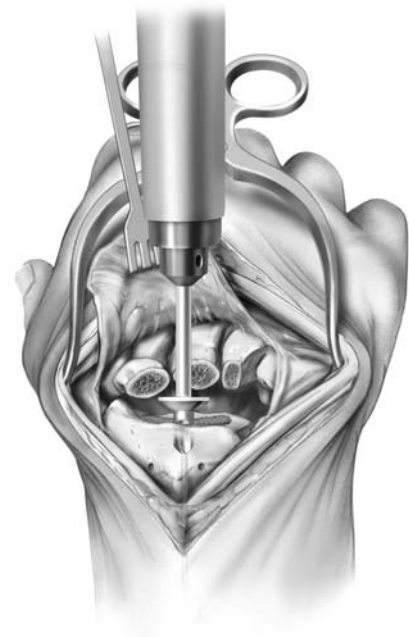


**FIGURE 3F**



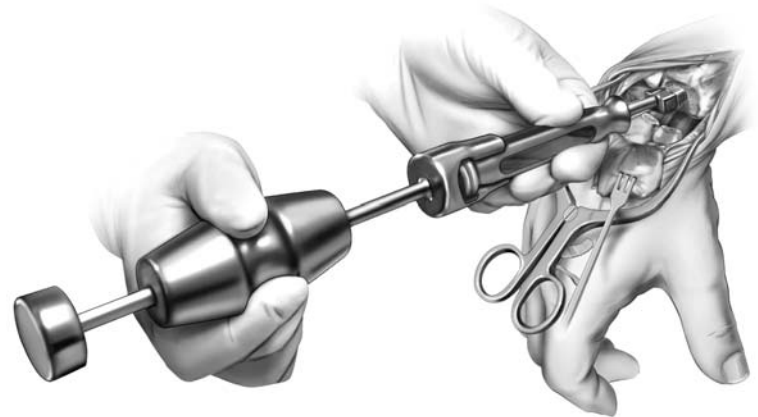
The cannulated PGT Radial Counterbore Drill is used to create a pilot hole for broaching (**FIGURE 3G**).

**FIGURE 3G**



Broach the distal radius over the guide pin. Based upon the preoperative assessment of the implant size, the distal radius is broached with increasing sized broaches to allow full seating of the radial component (**Figure 3H**).

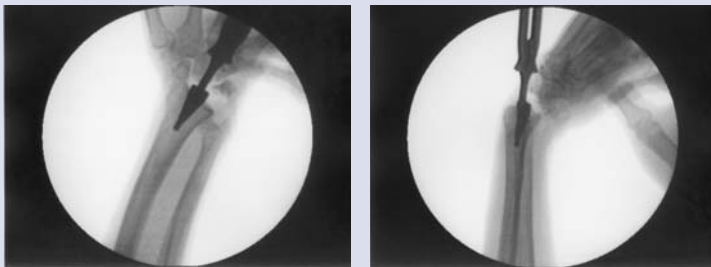
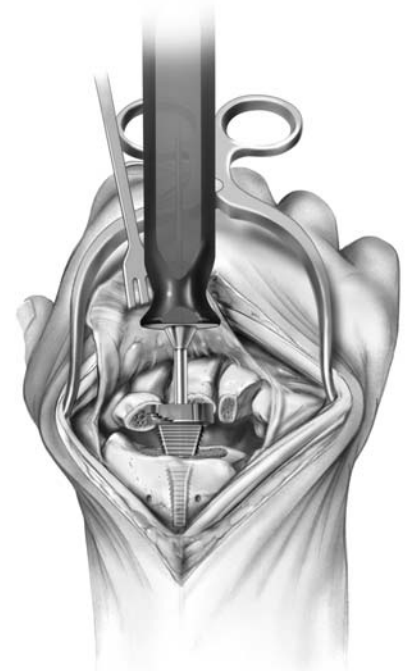
**FIGURE 3H**



**Note:** Take care not to over-broach or re-set the direction of the broach because a press-fit application of the radial component is the goal.

Care should be taken to make sure the angle of the broach is aligned with the long axis of the radius. The flat portion of the broach handle should always be parallel to the dorsum of the radius. The broach may need to be withdrawn to clean the teeth and clear the intramedullary cavity of debris. Burring may be needed in the radial styloid region to prevent ulnar migration of the broach during impaction (**FIGURE 3I**).

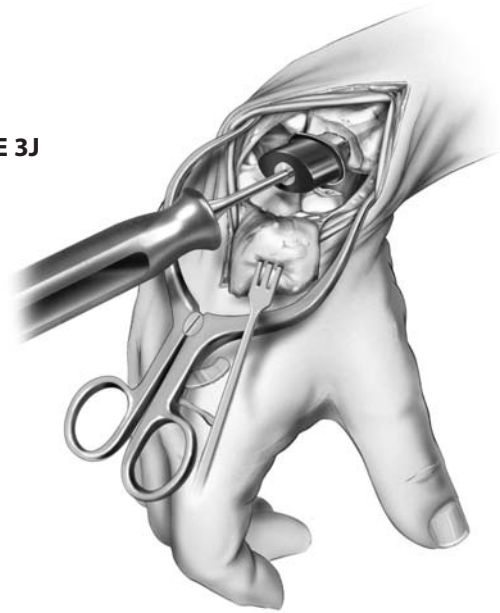
**FIGURE 3I**



Insert the radial trial into the prepared canal, and impact the trial until seated. Evaluate the fit of the component against the scaphoid and lunate fossae as well as the dorsal peripheral ridge. The implant should fit flush with or below the dorsal ridge of the distal radius. If the fit is satisfactory, remove the trial component by engaging the extraction holes with a towel clamp or equivalent instrument. If the trial is proud, further broaching or selective burring of the distal radius may be needed. However, subchondral bone should always be preserved (**FIGURE 3J**).



**FIGURE 3J**

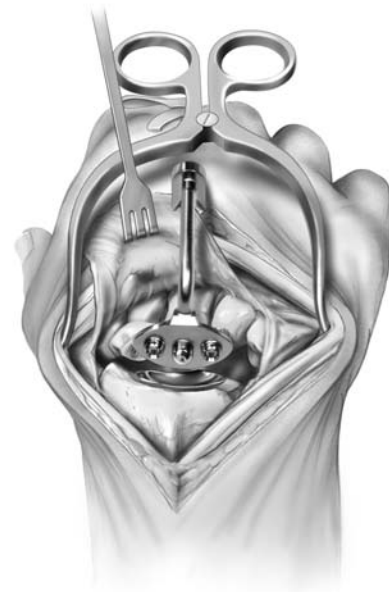


**4 Carpal Preparation**

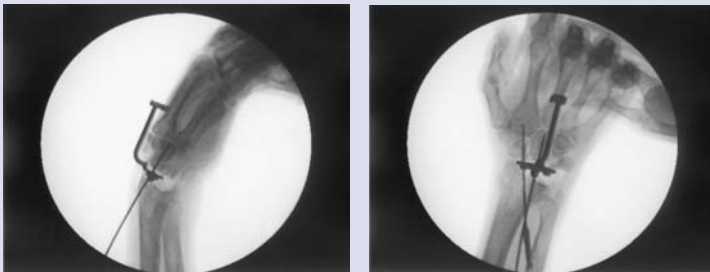
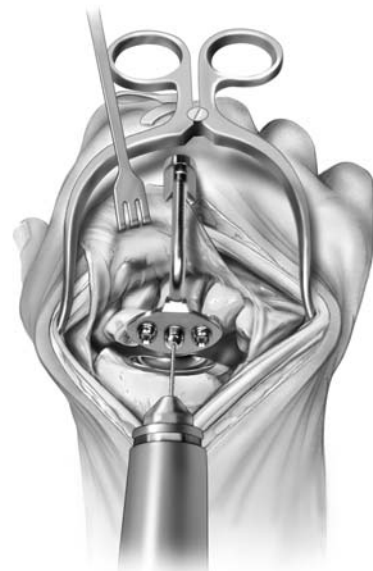
Position the PGT Carpal Template so it rests firmly on the dorsal aspect of the capitate and is aligned along the 3rd metacarpal. The dorsal aspect of the template should be flush with the dorsal surface of the capitate (**FIGURE 4A**).

Drill a 2.0 mm K-wire into the capitate. Advance the K-wire to the distal end of the capitate. Confirm the position of the K-wire with imaging (**FIGURE 4B**).

**FIGURE 4A**



**FIGURE 4B**



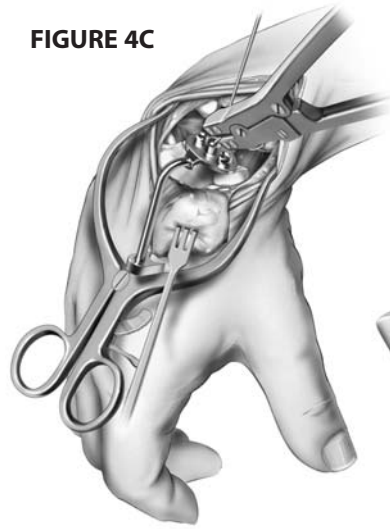
Trial reduction is accomplished using the Carpal Template by cropping the K-wire with the Wire Cutters (**FIGURE 4C**) and placing the Carpal Ball Trial over the Carpal Template (**FIGURE 4D**). Re-insert the Radial Trial and articulate with the Carpal Ball Trial. Judge wrist motion and stability and determine if further carpal bone resection is necessary. For over-resection, an extended carpal ball trial is available.

**Note:** Previous distal radius or carpal fracture may alter radio-carpal alignment. Correct mal-alignment with soft tissue release. Resection of radial styloid may be required but otherwise preserve subchondral bone. Carpal subluxation (volar and ulna) must be correct to allow carpal alignment with the distal radius. Soft tissue release of volar/ulnar capsule may be required.

Once proper positioning of the carpal implant is achieved, remove the Carpal Template and the K-wire (**FIGURE 4E**).

The Carpal Broach is used to widen the canal through the capitate. The broach has 3 lines which correspond with a small, medium and large size component. Insert the broach fully to the appropriate line (**FIGURE 4F**).

**FIGURE 4C**



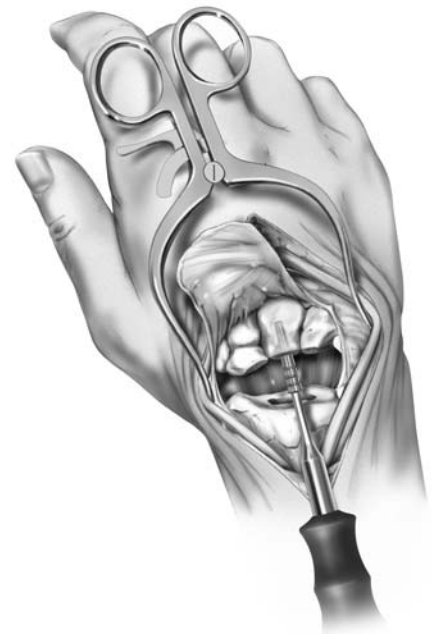
**FIGURE 4D**



**FIGURE 4E**

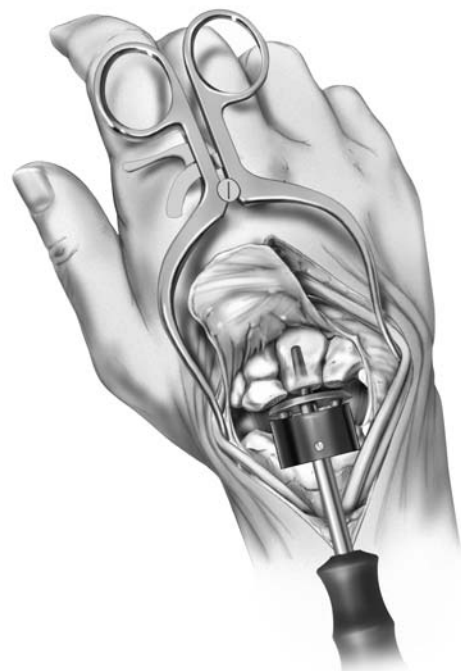


**FIGURE 4F**



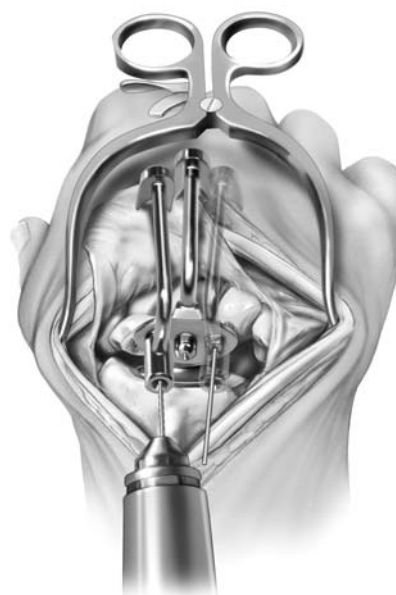
Insert the Carpal Trial by placing the center stem into the capitate. Use the impactor to push or gently tap the Trial completely into place. Use imaging to verify that the component is positioned correctly (**FIGURE 4G**).

**FIGURE 4G**



Prepare the screw pilot holes using the PGT Metacarpal Drill Guide. Align the Drill Guide on the radial button on the face of the Carpal Trial and over the 2nd metacarpal. Drill a K-wire through the Carpal Trial into the distal scaphoid, trapezoid on the radial side. Repeat the same procedure on the ulnar side. Align the Drill Guide on the ulna button on the face of the Carpal Trial and over the 4th metacarpal. Drill a K-wire through the length of the hamate. Use imaging to ensure proper preparation. A "W" should be visible on imaging between the two K-wires and the center stem of the Trial in the capitate (**FIGURE 4H**). Once proper positioning is achieved, remove the K-wires and drill into the K-wire holes using a 2mm drill bit in order to enlarge the holes enough to accept the 4.5mm bone screws.

**FIGURE 4H**

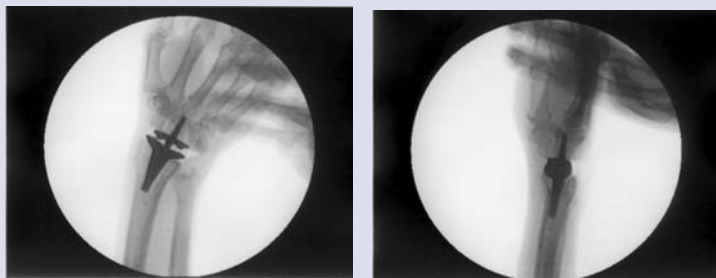


**Note:** Many surgeons prefer to cross the second carpometacarpal joint, but crossing the fourth carpometacarpal joint is not recommended.



Prior to implant placement, an additional trial reduction is recommended. If the radial trial was removed during carpal preparation, reinsert the Radial Trial into the prepared canal, and impact the trial until seated (**FIGURE 4I**). Replacing the Carpal Ball Trial on to the Carpal Trial and articulate the Total Wrist for stability (**FIGURE 4J**).

**Note:** Wrist range of motion should be tested to measure extension (40-50 degrees), flexion (30-35 degrees), and radial/ulnar deviation (40 degrees total). During trial reduction, no more than 2 to 3 millimeters of laxity should be present with dorsal-palmar displacement of the wrist. A Plus Carpal Ball, which provides 1 millimeter of additional thickness, can be used if necessary.



## 5 Implant Placement

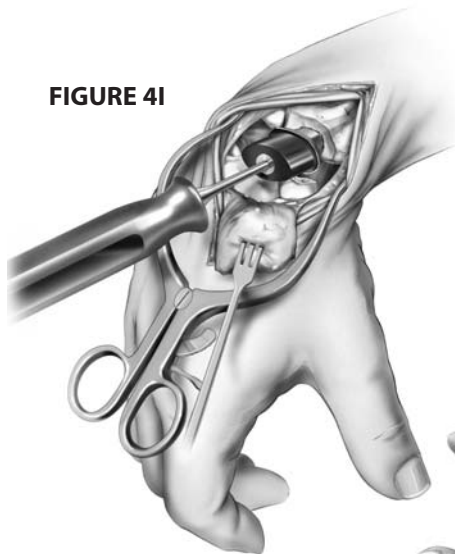
Insert the radial implant and press fit in place. Using the radial impactor, tap the implant until fully seated (**FIGURE 5A**).

**Note:** To determine implant fit, gentle traction on the radial component should be performed. If the radial component is loose, impaction grafting of cancellous bone is recommended. For osteoporotic patients, consider bone cement. Insert the radial component and tap firmly into place.

Insert carpal component and press fit. It is aligned with the centering hole in the capitate and pushed or tapped into place (**FIGURE 5B**).

Accurately measure the required radial and ulna screw lengths with a depth gauge.

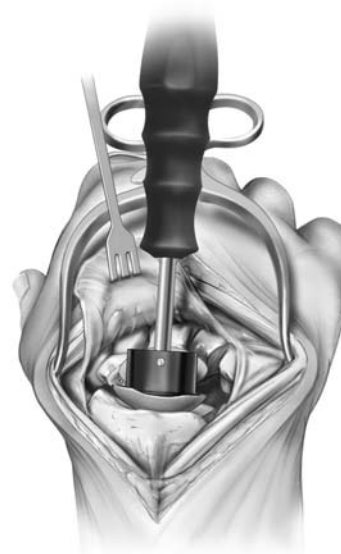
**FIGURE 4I**



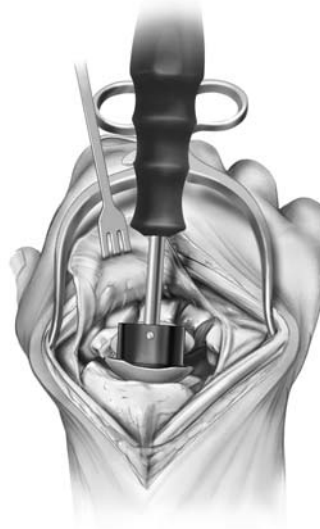
**FIGURE 4J**



**FIGURE 5A**



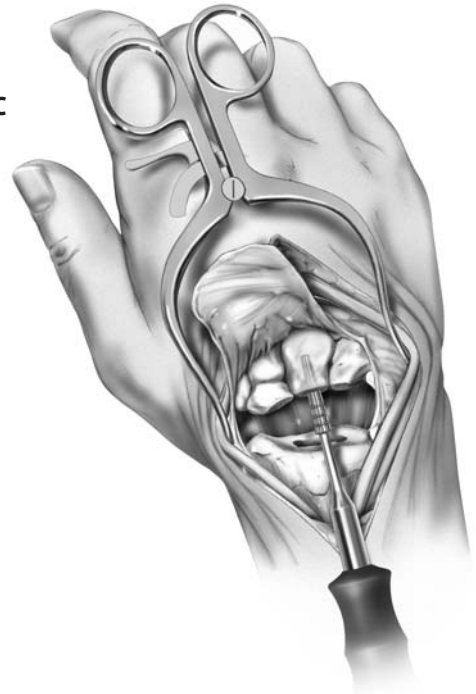
**FIGURE 5B**



The self tapping screws are inserted through the carpal plate and into the holes created by the 2mm drill bit with a 2.5 mm hex driver. Use imaging to determine that the screws are the correct length. The screws are then tightened into place (**FIGURE 5C**).

**Note:** The screws may cross the 2nd carpometacarpal joint but crossing the 4th carpometacarpal joint is not recommended.

**FIGURE 5C**



The polyethylene carpal ball is now placed onto the distal component and snapped into place using the carpal ball impactor (**FIGURE 5D**).

**Note:** Removal of the carpal ball may be necessary to adjust joint tension or laxity or to modify screw length. If the carpal ball needs to be removed, care must be taken to not damage the polished surface of the carpal component. This can be accomplished by drilling a small hole in the radial and ulnar tips of the polyethylene. Engage the holes with bone reduction forceps and pry in a radial or ulnar direction to disengage the snap fit assembly.

The total wrist joint is articulated and stability assessed. An extra length polyethylene ball may be indicated if there is residual dorsal-palmar laxity or instability.

**FIGURE 5D**



## 6 Closure

Assess range of motion through radio-ulnar deviation and flexion-extension of the wrist. If range of motion is satisfactory and there is good stability and no impingement, proceed with wound closure. Repair the dorsal capsule back to the soft tissue on the distal edge of the distal radius. If the capsule is thin at this area, reinforce the capsule with the distal half of the extensor retinaculum with non resorbable 2-0 or 3-0 sutures. Repair the proximal portion of the extensor retinaculum over the extensor tendons in the usual fashion, without including the extensor pollicis longus tendon which can be left extra-retinacular to prevent tendon irritation or rupture (FIGURES 6A & 6B).

## Follow Up

After wound closure, the wrist is immobilized in extension of 25-30° and neutral radioulnar deviation with plaster support. The surgical drain is removed at 24-48 hours, and at this time a short arm cast is applied with inclusion of the base of the thumb. The cast is worn for 2 weeks. At that time (2 weeks), sutures are removed and physiotherapy of the wrist with assisted range of motion started.

Continued support splinting for up to six weeks is recommended to allow for full bone ingrowth of the proximal and distal components. Cast or splint support for 8 weeks should be considered if there is osteoporotic or otherwise poor bone stock. Strengthening of the wrist can begin around 4-6 weeks with hand grippers and resisted weights. Resisted weights should not be used until a minimum of 8 weeks after surgery.

The range of motion goal is 40° of extension, flexion, and 40° total radioulnar deviation. Studies have shown that this range of motion is sufficient for 80% of activities of daily living (ADLs)<sup>1</sup>. In patients with "wet" synovitic-type rheumatoid arthritis, a longer period of cast immobilization prior to starting motion may be justified. Similarly, in post-traumatic arthritic conditions wherein stiffness of the wrist is a concern, earlier wrist motion may be justified.

Radiographic assessment of the total wrist should be at 6 weeks, 3 months, 6 months, and 1 year. Long-term assessment should be considered at 2 years, 5 and 10 years.

## Cautions

- Antibiotics are recommended pre-procedure for all patients requiring dental, urologic, colonoscopy, or other invasive body cavity procedures.
- Sports such as golf, tennis, and bowling are restricted. There is no clinical data to know the effect of sports activities on total wrist replacement patients.
- Similarly, use of the wrist in heavy duty work requiring heavy lifting over 20 pounds is discouraged related to the adverse mechanical effect of weight lifting on the wrist.

FIGURE 6A

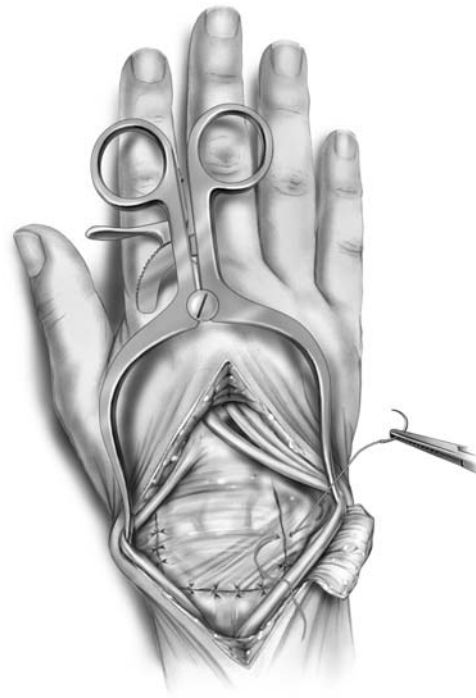


FIGURE 6B



## Technical Tips

1. Use imaging with each step of the procedure.
2. Proper placement of the PGT™ Guide is extremely important prior to proceeding with burring or broaching of distal radius.
3. Use of the Burr to smooth the distal radius articular surface can be helpful with radial prosthesis setting, but avoid removal of subchondral bone.
4. Avoid dorsal/palmar tilt of the distal radius.
5. Carpal component alignment with the capitate is key. Consider K-wire fixation and/or fusion of the distal carpal row to enhance distal component fixation.

Soft tissue capsule repair to distal radius is straight forward. If capsule is thin, use distal third of retinaculum to reinforce.

Proper surgical procedures and techniques are necessarily the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.

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## INDICATIONS

Recommended clinical situations for potential use of this device are as follows:

- Rheumatoid arthritis in which preservation of wrist motion is the goal. The total wrist replacement may be performed alone, or in association with resection of the distal ulna or distal ulna (uHead) prosthetic replacement.
- Degenerative arthritis (osteoarthritis) of the wrist. This is a less common type of wrist arthritis, but can occur across both the radial carpal and midcarpal joints.
- Post-traumatic arthritis of the wrist. This can result from failed treatment of scaphoid fractures, scapho lunate dissociation, Kienbock's Disease, or fracture-dislocations of the wrist. It may also follow intra-articular fractures of the distal radius. Total wrist replacement may also be indicated in failed intercarpal fusions and proximal row carpectomy.

The low profile of the RE-MOTION™ Total Wrist provides less bone resection than other total wrist replacements, providing the total wrist option for osteoarthritis and post-traumatic arthritis.

## CONTRAINDICATIONS

Clinical situations where the use of this device should be avoided are as follows:

- Previous infection of the wrist is an absolute contra-indication for prosthetic replacement.
- Wet (synovitis related) rheumatoid arthritis is a relative contra-indication since post operative wrist ligament laxity may lead to instability.
- Previous wrist fusion (partial or complete) and failed silicone implants are relative contra-indications unless wrist extensor tendon function can be restored and joint capsule ligament constraints re-established. There is little clinical experience with total wrist replacement with previous wrist fusion or previous prosthetic replacement (silicone or metal-poly).
- Carpal subluxation (if excessive) is also a contra-indication, especially if volar capsule release is required to restore carpal length in order to insert the prosthesis.

## WARNINGS

Strenuous loading, excessive mobility, and articular instability all may lead to accelerated wear and eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.

Notification in accordance with the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This product contains a chemical(s) known to the State of California to cause cancer, and/or birth defects and other reproductive toxicity.

## PRECAUTIONS

The implant is provided sterile in an undamaged package. If either the implant or the package appears damaged, expiration date has been exceeded, or if sterility is questioned for any reason, the implant should not be used. Do not re-sterilize. Meticulous preparation of the implant site and selection of the proper size implant increases the potential for a successful outcome. The implant should be removed from its sterile package only after the implant site has been prepared and properly sized. Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and articulating surfaces must not come in contact with hard or abrasive surfaces.

## PATIENT COUNSELING INFORMATION

In addition to the patient related information contained in the Warnings and Adverse Events sections, the following information should be conveyed to the patient:

While the expected life of total joint replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices, the components cannot be expected to withstand the activity level and loads of normal healthy bone for an unlimited period of time. Adverse effects may necessitate reoperation, revision, or fusion of the involved joint.

Please refer to implant package insert for additional product information including precautions and warnings.

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