Disclaimer

This publication sets forth detailed recommended procedures for using Stryker devices and instruments. It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to performing your first surgery. All non-sterile devices must be cleaned and sterilized before use.

Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly / disassembly instructions. Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See package insert (Instructions for Use) (V15125 and V15114) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks including the finite lifetime of the device with the patient when necessary.
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Introduction

The ReMotion Total Wrist System 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 are designed to 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.
Indications & Contraindications

Indications
The ReMotion Total Wrist System is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osteo-arthritis, or post-traumatic arthritis.

Please see package insert for Warnings, Precautions, Adverse Effects, and other essential product information.

Contraindications
Bone, musculature, tendons, or adjacent soft tissue compromised by disease, infection, or prior implantation, which cannot provide adequate support or fixation for the prosthesis.
• Known sensitivity to materials used in this device
• Skeletal Immaturity
Operative Technique

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 (Fig. 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 (Fig. 1B).

After exposure, a synovectomy of the extensor tendons is performed as required (Fig. 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 (Fig. 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.
Carpal Resection

Assemble the Lunate Tab and mount the Assembly onto the PGT Guide (Fig. 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 (Fig. 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 (Fig. 2C).

Note: Radiopaque marker within PGT guide handle must be parallel to the radius on the A/P and Lateral.
Operative Technique

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 preoperative 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 (Fig. 2D).

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 (Fig. 2E).

Generally, 1mm to 2mm 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.
Operative Technique

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 2mm increments (Fig. 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 (Fig. 3B).

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

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

Place the 2mm threaded guide pin into the distal radius and advance 4cm to 5cm 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 (Fig. 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 (Fig. 3F).

The cannulated PGT Radial Counterbore Drill is used to create a pilot hole for broaching (Fig. 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 (Fig. 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. Burrning may be needed in the radial styloid region to prevent ulnar migration of the broach during impaction (Fig. 3I).
Operative Technique

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 (Fig. 3J).
Operative Technique

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 (Fig. 4A).

Drill a 2.0mm 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 (Fig. 4B).

Trial reduction is accomplished using the Carpal Template by cropping the K-Wire with the Wire Cutters (Fig. 4C) and placing the Carpal Ball Trial over the Carpal Template (Fig. 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 ulnar) must be corrected to allow carpal alignment with the distal radius. Soft tissue release of volar/ulnar capsule may be required.
Operative Technique

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

After removal of the Trial & K-Wire, place the Carpal Reamer central over the K-Wire insertion point. The reamer is marked with 3 lines which correspond to the carpal component sizes; small, medium and large by using the Carpal Reamer to the appropriate size will assist in preparing the capitate for broaching.

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 (Fig. 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 (Fig. 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 2 K-Wires and the center stem of the Trial in the capitate (Fig. 4H).

Once proper positioning is achieved, remove the K-Wire 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.

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 (Fig. 4I). Replacing the Carpal Ball Trial on to the Carpal Trial and articulate the Total Wrist for stability (Fig. 4J).

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

**Implant Placement**

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

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

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

**Note:**

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

The polyethylene carpal ball is now placed onto the distal component and snapped into place using the carpal ball impactor (Fig. 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 or palmar laxity or instability.
Operative Technique

Closure
Assess range of motion through radioulnar 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 2.0mm or 3.0mm 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 (Fig. 6A, 6B).

Follow Up
After wound closure, the wrist may be immobilized in extension of 25-30° and neutral radioulnar deviation with plaster support. The surgical drain may be removed at 24-48 hours, and at this time a short arm cast may be applied with inclusion of the base of the thumb.

The cast may be worn for 2 weeks. At that time (2 weeks), sutures may be removed and physiotherapy of the wrist with assisted range of motion started.

Continued support splinting for up to 6 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 may 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)¹. 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, 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 9kg is discouraged related to the adverse mechanical effect of weight lifting on the wrist.

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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