WristMotion® Total Wrist Arthroplasty System
Instructions for Use

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Description

The Arthrosurface Total Wrist Arthroplasty (TWA) System is a modular joint restoration system that consists of both a radial implant assembly and carpal implant assembly. The radial implant assembly is comprised of a metallic stemmed tray component and Ultra-High-Molecular-Weight-Polyethylene (UHMWPE) articular component. The carpal implant assembly consists of a taper post component, a carpal plate, an articular component and two auxiliary bone screw components, all of which are metallic. The system is designed to replace the radiocarpal joint (distal radius and proximal row of carpal bones) and is intended to alleviate pain while restoring functionality and mobility of the joint.

Materials

Radial Stem Component:	Titanium Alloy (Ti-6Al-4V)
Surface Coating	Titanium (CP Ti)
Radial Insert Component:	Medical Grade UHMWPE)
Carpal Taper Post Component:	Titanium Alloy (Ti-6Al-4V)
Carpal Plate Component:	Cobalt-Chrome Alloy (Co-Cr-Mo)
Surface Coating	Titanium (CP Ti)
Carpal Articular Component:	Cobalt-Chrome Alloy (Co-Cr-Mo)
Bone Screws- Implantable:	Titanium Alloy (Ti-6Al-4V)

Indications for Use

The Arthrosurface Total Wrist Arthroplasty System is indicated for replacement of the painful wrist joint due to rheumatoid arthritis, oseto-arthritis, or post-traumatic arthritis.

The device is a single-use implant intended to be used with bone cement.

Patient Population

Patient Selection Factors to be Considered Include:

- Need to obtain pain relief and improve function.
- Patient age as a potential for early-age-revision of total joint arthroplasty or arthrodesis.
- Patient's overall well-being, including the ability and willingness to follow pre- and post-operative treatment regimen.
- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.

Contraindications

Absolute contraindications include:

1. Significant bone demineralization or inadequate bone stock.
2. Inadequate skin, musculotendinous or neurovascular system status.
3. Infection, sepsis and osteomyelitis (acute or chronic).
4. Patients that have a known sensitivity to cobalt-chrome and/or titanium alloys or UHMWPE polymers typically used in prosthetic devices.

Relative contraindications include:

1. Uncooperative patient or patient incapable of following pre-operative and post-operative instructions.
2. Osteoporosis.
3. Metabolic disorders which may impair the formation or healing of bone.
4. Infections at remote sites which may spread to the implant site.
5. Rapid joint destruction or bone resorption visible on roentgenogram.
6. Chronic instability or deficient soft tissues and other support structures.

7. Vascular or muscular insufficiency.
8. Absent or insufficient wrist extensor tendons.

Warnings

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

When placing implant, carefully trim articular cartilage debris around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the taper post and articular component, carefully clean taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post-operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

All surgical implants are subjected to repeated stresses that can result in failure. The use of an implant should be avoided if excessive loading cannot be prevented at or near the implant site. No other metallic or non-metallic implantable devices are to be used in conjunction with Arthrosurface Inc.'s Total Wrist Arthroplasty System at the implant site. Doing so may compromise implant performance and patient safety.

These implants have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating or migration in the MR environment. Scanning a patient who has this device may result in patient injury.

Precautions

Arthrosurface implants are intended to be fitted and installed with the appropriate Arthrosurface instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement, which could result in implant failure or poor clinical outcome. The instruments should be regularly inspected for any signs of wear or damage.

Surgeon or Physician should discuss general risks and potential complications associated with this and any surgical procedure with the patient prior to patient consent.

Possible Adverse Effects and Complications

1. Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
2. Infection or allergic reaction.
3. Loosening, migration or loss of fixation of implant.
4. Fretting and crevice corrosion can occur at the interface between implant components.
5. Fatigue fracture of the implants as a result of bone resorption around the implant components.
6. Wear and damage to the implant articulating surfaces.
7. Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
8. Intraoperative or postoperative bone fracture.
9. Post-operative pain or incomplete resolution of pre-operative symptoms.
10. Incomplete range of motion or joint tension due to improper selection or position of components.
11. Transient nerve palsy.
12. Embolism.

Sterility

The implants and single-use disposable instruments are provided STERILE. Metallic implant components are

sterilized by exposure to gamma radiation. Non-metallic implant components are sterilized by gas plasma sterilization. All other single-use disposable instruments are sterilized by exposure to gamma radiation. Do not re-sterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date. Do not reuse implants or single-use disposable instruments. Reuse of these devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device(s).

Caution

United States Federal Law restricts this device to sale by or on the order of a physician.

Surgical Procedure

All surgeons are required to evaluate the appropriateness of the described surgical technique based on personal experience and medical training. It is the surgeon's responsibility to obtain the necessary training and become familiar with the procedure before the use of this system.

A basic outline of the procedure is provided herein, and is as follows:

EXPOSURE

1. Begin with a dorsal longitudinal incision over the wrist, in line with the 3rd metacarpal, extending proximally from its midshaft to approximately 6cm proximal to the wrist joint.
2. The skin and subcutaneous tissue are elevated together off the extensor retinaculum, with care to protect the branches of the superficial radial nerve and the dorsal cutaneous ulnar nerve.
3. The EDQ extensor compartment is opened and the entire retinaculum is elevated radially to the septum between the 1st and 2nd extensor compartments. Each septum is divided carefully to avoid creating rents in the retinaculum, especially at Lister's tubercle.
4. An extensor tenosynovectomy is performed if needed, and the tendons are inspected. The ECRB must be intact or repairable (preferably the ECRL is also functionally). Quarter inch Penrose tubing is used to retract the extensor tendons, with the EDQ and EDC tendons pulled ulnarly and the EPL, ECRB, ECRL pulled radially.
5. The dorsal wrist capsule is raised as a broad distally-based rectangular flap off the distal radius to the level of the mid capitate. The radial side of the flap is made in the floor of the 2nd extensor compartment and ulnar side extends from the radius to the triquetrum.
6. The 1st extensor compartment is elevated subperiosteally from the distal 1cm of the radial styloid. The remaining dorsal wrist capsule is elevated ulnarly from the triquetrum.

7. The wrist is fully flexed to expose the joint. If necessary, a synovectomy is performed. If the distal ulnar is to be resected, a separate capsulotomy is made proximal to the triangular fibrocartilage complex (TFCC).
8. Excise the lunate, triquetrum and the proximal pole of the scaphoid after bisecting the scaphoid obliquely at its waist.
9. Take care to avoid injury to palmar wrist ligaments, TFCC, capitate and pisiform.

CARPAL PREPARATION

10. With the **Carpal Drill Guide**, locate the capitate's long axis, normal to the proximal articular surface. Once in position, the **Carpal Dill Guide** is also used to determine the size of the carpal implant components. Place the **Carpal Guide Pin** into a cannulated power drill and advance it into the bone through the **Carpal Drill Guide**, making sure that it is central to the articular surface. Verify that the **Carpal Drill Guide** is seated on the capitate, creating a normal axis to the proximal articular surface.
11. Place the **Capral Twist Drill** into a cannulated power drill and advance it into the bone over the **Carpal Guide Pin**. Drive until the proximal shoulder of the **Carpal Twist Drill** is flush with the articular surface. Use lavage during the drilling to prevent possible tissue damage from heat effects. Should the **Carpal Guide Pin** loosen, use the **Carpal Twist Drill** to re-center the **Carpal Guide Pin** in the pilot hole and advance into the bone.
12. Using the **Carpal Tap**, tap the pilot hole until the etched depth mark is flush with the articular surface. Insert bone cement into pilot hole.
13. Using the **Carpal Hex Driver**, drive the **Taper Post** over the **Carpal Guide Pin** until the etched depth mark on the **Carpal Hex Driver** is flush with capitate's articular surface.
14. Choose the appropriate **Carpal Reamer** based on the implant size determined with **Carpal Drill Guide**. Place the **Carpal Reamer** into a cannulate power drill

and advance it over the **Carpal Guide Pin** until it contacts the top surface of the **Taper Post**. Use lavage during the reaming to prevent possible tissue damage from heating effects. Make sure not to bend the **Carpal Guide Pin** during reaming, as it may result in implant misalignment.

15. Place the **Carpal DF Reamer** into the taper of the **Taper Post.** The **Carpal DF Reamer** should be oriented such that dorsal ream is at the 12 o'clock position, removing the dorsal aspect of the capitate. Using a cannulated power drill, advance the **Carpal DF Reamer** to the stop depth and remove the guide.
16. Choose the appropriate **Carpal Cutting Jig** based on the implant size determined with the **Carpal Drill Guide**. Place the **Carpal Cutting Jig** into the taper of the **Taper Post.** Pin the **Carpal Cutting Jig** to the carpus using two **Tack Pins** and a cannulated power drill. Using a sagittal saw, remove the proximal aspect of the hamate and scaphoid by placing the blade flush with the jig while cutting. Once the bones are resected, remove the **Tack Pins** and **Carpal Cutting Jig**.

RADIAL PREPARATION

17. With the system's **Radial Drill Guides**, determine which component size achieves the desired radial coverage. Once the desired size and position is selected, confirm that the aimer feature of the **Radial Drill Guide** is positioned to clear the TFCC.
18. Place the **Radial Guide Pin** into a cannulated power drill and advance it into the bone through the **Radial Drill Guide**. Verify that the **Radial Drill Guide** is fully seated on the radius. Using fluoroscopy, ensure that the **Radial Guide Pin** is centered in the radius' intramedullary canal in the palmar/dorsal plane. Accurate pin placement is necessary for proper implant fit.
19. Place the **Radial Starter Drill** into a cannulated power drill and advance it into the bone over the **Radial Guide Pin**. Drive until the proximal shoulder of the **Radial Starter Drill** is flush with the articular surface

of the radius. Use lavage during the drilling to prevent possible tissue damage from heat effects. Remove the **Radial Starter Drill** and **Radial Guide Pin**.

20. Place the **Radial V Guide** into the drilled socket and rotationally position the guide. Secure the position of the **Radial V Guide** by drilling the two **Tack Pins** through the guide's interfacing holes with a cannulated power drill.
21. Place the **Radial Core Drill** into a cannulated power drill and advance it into the bone through the guide hole of the **Radial V Guide,** until the marked depth line is flush to the **Radial V Guide's** shoulder. Repeat this process using the other drill guide hole in the **Radial V Guide.** Remove the **Tack Pins** and the **Radial V Guide.**
22. Thread the **Radial Depth Guide** onto the **Radial Inserter** and place the **Radial Depth Guide** into the drilled socket. Advance the assembly until the depth indicator of the **Radial Inserter** is flush with the articular surface. If necessary, a mallet can be used to impact the assembly to desired depth. Remove the **Radial Inserter.**
23. Place a **Tack Pin** into a cannulated power drill and advance it into the bone through the pin hole of the **Radial Depth Guide** until the laser line on the pin is flush with the guide.
24. Place the **Radial Surface Reamer** into a cannulated power drill and advance it into the bone over the **Tack Pin**. Drive until the depth stop feature of the **Radial Surface Reamer** contacts the **Radial Depth Guide.** Use lavage during the reaming to prevent possible tissue damage from heat effects. Remove the **Tack Pin** and **Radial Depth Guide.**

TRIALING AND IMPLANTATION

25. Position the appropriate **Radial Stem Component** using the **Radial Stem Inserter.** Impact the assembly until the bone contacting surface of the tray is flush with the reamed bone. Remove the **Radial Stem Inserter**.

26. Select the appropriate thickness **Radial Poly Sizing Trial and** the appropriate size of the **Carpal Articular Sizing Trial** that provides the best radio/ulnar coverage of the carpus. Evaluate implant position, range of motion and joint tension.
27. Clean the taper of the **Taper Post** with the **Taper Cleaner** and remove any debris from the surrounding implant bed. Align the taper features of the **Carpal Plate** and the **Taper Post** and ensure the correct implant rotational orientation before joining the two components with the slight taps from the **Carpal Impactor**.
28. Position the **Bone Screw Guide** into the radial hole of the **Carpal Plate** and insert the **Bone Screw Drill** into the base of the 2nd metacarpal with a cannulated power drill. Confirm position using fluoroscopy and remove the **Bone Screw Guide.**
29. Insert the **Bone Screw Depth Guide** over the **Bone Screw Drill** to determine the length of the radial **Bone Screw** and remove the components.
30. Using the **Bone Screwdriver** and the appropriate **Bone Screw,** begin to drive the **Bone Screw** into the 2nd metacarpal through the threaded radial hole of the **Carpal Plate,** do not fully tighten.
31. Position the **Bone Screw Guide** into the ulnar hole of the **Carpal Plate** and insert the **Bone Screw Drill** into the hamate using a cannulated power drill. Manually extend the 4th and 5th metacarpal and continue until the **Bone Screw Drill** reaches the distal cortex of the hamate. The **Bone Screw Drill** should not penetrate to the 4th CMC joint. Confirm position using fluoroscopy and remove the **Bone Screw Guide.**
32. Using the **Bone Screw Depth Guide**, determine the length of the ulnar **Bone Screw** and using the **Bone Screwdriver,** begin to drive the ulnar **Bone Screw,** do not fully tighten.
33. Alternately advance both **Bone Screws** until they are tightened. Take care to not overtighten screws.

34. Clean the taper of the **Carpal Plate** and remove any debris from the **Carpal Plate** and **Bone Screws**. Alight the taper feature of the desired **Carpal Articular Component** and ensure that the **Carpal Articular Component** is evenly seated around the **Carpal Plate.** Use a slight tap from the **Carpal Impactor** to seat the **Carpal Articular Component** and progressivity tap the until the components are firmly seated.
35. Reposition and final evaluation of the appropriate thickness **Radial Poly Sizing Trial**
36. Select and position the appropriate **Radial Articular Component** and impact using the **Radial Impactor** to join snap feature.
37. Evaluate implant position, range of motion and joint tension.

CLOSURE

38. Perform an intercarpal fusion of the remaining carpal bones to stabilize the carpus. Inter carpal articular surfaces are to be removed using a curette or burr with care to not damage any of the implant components. Cancellous chips from previously resected bone are packing into the interspaces.
39. The dorsal capsule is reattached to the distal margin of the radius using the previously places sutures. The medial and later aspects of the capsule are also closed.
40. If the capsule is insufficient for closure with the wrist flexed 30°, the extensor retinaculum is divided in line with its fibers and one half is placed under the tendons to lengthen the capsule. The entire implant must be covered to achieve proper stability and function and to avoid extensor tendon irritation. The remaining extensor retinaculum is repaired over the EDC tendons to prevent bowstringing, however, the EPL, ECRB and ECRL are typically left superficial to the retinaculum. A suction drain may be placed, and the skin is closed. A bulky gauze dressing and a short arm plaster splint are applied.

Manufacturer

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STERILE | H_2O_2

Gas Plasma Hydrogen Peroxide

STERILE | R

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