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## WristMotion™ Wrist Hemiarthroplasty System Instructions for Use

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### Description

The Arthrosurface WristMotion™ Wrist Hemiarthroplasty System consists of a contoured capitate articular implant designed to articulate with the natural radius bone, a taper post and set of instruments used for implant site preparation and delivery. The capitate articular components are manufactured using implant grade cobalt chrome alloy and is offered in two diameters, and four articular radii. The taper post is manufactured using implant grade titanium alloy and is offered in one fixed size designed to work with all capitate articular implants.

### Materials

Carpal Articular Component: Cobalt-Chrome Alloy (Co-Cr-Mo)  
Surface Coating: Titanium (CP Ti)  
Taper Post Component: Titanium Alloy (Ti-6Al-4V)

### Indications for Use

The Arthrosurface Wrist Hemiarthroplasty System is indicated for use as a partial replacement of wrist joint(s) disabled by pain, deformity and/or limited motion caused by:

- Non-inflammatory degenerative joint disease including osteoarthritis, traumatic arthritis and avascular necrosis.
- Rheumatoid arthritis.
- Revision where other devices or treatments have failed.
- Scapholunate Advanced Collapse (SLAC) and other functional deformities.
- Trauma, including fractures of the carpal bones.

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

## **Patient Population**

### *Patient Selection Factors to be Considered Include:*

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.
- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

## **Contraindications**

### *Absolute contraindications include:*

- Significant bone demineralization or inadequate bone stock.
- Inadequate skin, musculotendinous or neurovascular system status.
- Infection, sepsis and osteomyelitis.
- Patients that have a known sensitivity to cobalt-chrome and/or titanium alloys typically used in prosthetic devices.

### *Relative contraindications include:*

- Uncooperative patient or patient incapable of following pre-operative and post-operative instructions.
- Osteoporosis.
- Metabolic disorders which may impair the formation or healing of bone.
- Infections at remote sites which may spread to the implant site.
- Rapid joint destruction or bone resection visible on roentgenogram.
- Chronic instability or deficient soft tissues and other support structures.
- Vascular or muscular insufficiency.
- Absent or insufficient wrist extensor tendons.

## **Warnings and Precautions**

- 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.

- 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.
- Arthroscopic implants are intended to be fitted and installed with the appropriate Arthroscopic 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 Arthroscopic WristMotion™ Wrist Hemiarthroplasty System instrument sets should be regularly inspected for any signs of wear or damage.
- Do not reuse implants. Reuse of single use devices can increase the risk of patient infection and can compromise service life and other performance attributes of the device.
- 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 Arthroscopic Inc.'s WristMotion™ Wrist Hemiarthroplasty System at the implant site. Doing so may compromise implant performance and patient safety.
- This system has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

**Possible Adverse Effects and Complications**

- Loosening, migration or loss of fixation of implant.
- Infection, both deep or superficial, or allergic reaction.
- 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 from similar materials. Some types of

wear debris have been associated with osteolysis and implant loosening.

- Embolism.
- Tissue reactions such as macrophage and foreign body reaction at or near implant site.
- Fretting or crevice corrosion can occur at the interface of articular component and taper post component.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Intraoperative or postoperative bone fracture.
- Post-operative pain or incomplete resolution of pre-operative symptoms.

#### **Sterility**

The Arthrosurface WristMotion™ Wrist Hemiarthroplasty implant components are provided STERILE. All implant components are sterilized by exposure to gamma irradiation. Do not resterilize. Do not use components if packaging is opened or damaged. Do not use components if beyond expiration date. For Single Use Only.

#### **Caution**

Federal Law (USA) 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:

1. Begin with a dorsal longitudinal approach through the third compartment. Transpose the extensor pollicis longus tendon and reflect the retinaculum over the second and fourth dorsal compartment. Enter the radiocarpal joint through a dorsal ligament sparing incision.
2. Inspect the lunate fossa and head of the capitate for degenerative changes.
3. Preserve the radioscapocapitate ligament.
4. Perform a proximal row carpectomy removing the scaphoid, lunate and the triquetrum.

5. Take care to avoid injury to palmar wrist ligaments, TFCC, capitate and pisiform.
6. Using the **Coronal Radius Template** and the **Sagittal Radius Template** determine the appropriate curvatures of the articular surfaces of the distal radius. This combination corresponds with a prescribed capitate articular implant curvature. Use the decision matrix below to determine the indicated curvature. Note: the **12 mm Articular Component** is only available with a sagittal curvature of 17 mm.



Coronal		Sagittal	
Radius Curvature (Measured)	Capitate Curvature (Indicated)	Radius Curvature (Measured)	Capitate Curvature (Indicated)
If 34 mm Measured	Use 22 mm	If 18 mm Measured	Use 17 mm
If 56 mm Measured	Use 35 mm	If 25 mm Measured	Use 23 mm

7. With the **Drill Guide**, locate the capitate's axis normal to the articular surface. Use the **Drill Guide** to determine which capitate articular component diameter matches the surface diameter. Place **1.5 mm Guide Pin** into a cannulated power drill. Advance the **1.5 mm Guide Pin** into the bone making sure that is central to the articular surface. It is important to verify that the **Drill Guide** is seated on the surface such that all 4 points of contact are established on the articular surface. A normal axis and correct diameter measurement are necessary for proper implant fit.



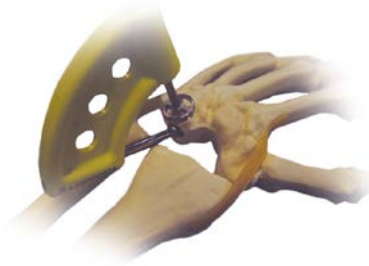
8. Place cannulated **Drill** over **1.5 mm Guide Pin** and drive until the proximal shoulder of the **Drill** is flush to the articular surface. (Use lavage during drilling to prevent possible tissue damage from heat effects.) Should the **1.5 mm Guide Pin** loosen, use the **Drill** to re-center the **1.5 mm Guide Pin** in the pilot hole and advance into bone.
9. Tap hole to etched depth mark on **Tap**. Insert bone cement into pilot hole.
10. Place the **Hex Driver** over the **Taper Post** and advance the **Taper Post** until the line on the **Hex Driver** is flush with the articular surface.



11. Choose the appropriate **Capitate Reamer** based on the diameter measured by the **Drill Guide** in Step 7. Drive **Capitate Reamer** over **1.5 mm Guide Pin** until it contacts the top surface on the **Taper Post** (Use lavage during drilling to prevent possible tissue damage from heating effects). Make sure not to bend the **1.5 mm Guide Pin** during drilling as it may result in **Articular Component** misalignment.



12. Place the **Dorsal Reamer Guide** into the taper of the **Taper Post**. The **Dorsal Reamer Guide** should be oriented such that the dorsal ream is at the 12 o'clock position. Using a cannulated power drill, advance the **Dorsal Reamer** to the stop depth. Once the **Dorsal Reamer** has advanced to the handle, immediately remove the power drill **Dorsal Reamer Guide**.



13. Clean taper in **Taper Post** with **Taper Cleaner** and remove any debris from the surrounding implant bed.

14. Place the **Sizing Trial** that matches the chosen **Articular Component** at the reamed implant site. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed.
15. Before placing the **Articular Component** on the **Suction Holder** make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Suction Holder**. Align the **Articular Component** with the appropriate offsets. Insert into the taper of **Taper Post**.
16. Use a slight tap on the **Impactor** to seat **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.





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