



Patient Information

**Motec<sup>®</sup>**

Wrist Joint  
Prosthesis System

*Swemac*

# Disclaimer

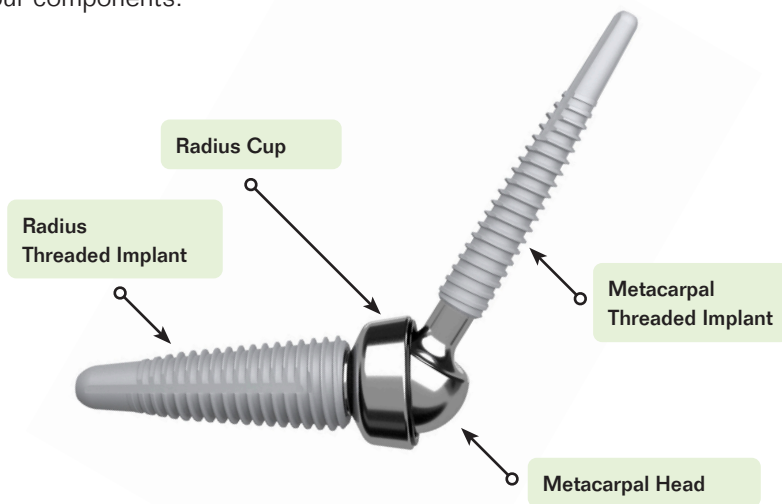
This material is for informational purposes only. It does not replace the advice or counsel of a doctor or health care professional. Swemac makes every effort to provide information that is accurate and presented in a plain language that should be easy to understand. In case of any questions you may have, do not hesitate to consult with your physician.

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# Implant Identification Information

The modular Motec® Wrist Joint Prosthesis consist of four components:



Fixation is achieved by threaded implants made of titanium alloy. The articulation is modular and can be configured depending on surgeon and your preference, either with CoCrMo articulation on CoCrMo (metal on metal) or CoCrMo articulation on carbon fiber reinforced PEEK (metal on plastic). Each component is available in different sizes to allow firm seating and replicate your normal range of motion as closely as possible.

Specific information about each component used in the wrist replacement surgery (description, material, size, item number, lot number, manufacturing date, manufacturer) will be provided in the shape of patient record labels affixed to your Patient Information Card (PIC) which you will receive after the surgery. You should always carry the PIC with you in your wallet or passport.

## Manufacturer:

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# Introduction

Are you experiencing wrist mobility issues or suffering from constant pain or instability of the wrist? You will probably have tried conventional treatment options such as wearing a wrist brace or splint, applying hot or cold compresses or taking anti-inflammatory or pain-relieving medications. If none of these measures helped to reduce wrist pain, you may be a candidate for wrist replacement surgery to effectively relieve the pain. In this surgical procedure the wrist joint is replaced with an artificial joint (prosthesis). When severe arthritis or failed previous surgery has destroyed the wrist joint, artificial wrist replacement surgery (wrist arthroplasty) can help restore wrist strength and motion for skeletally mature patients.

There are many sources of information that will help you, prior to surgery, to have informed consent discussions with your physician on the decision regarding the implantation of a wrist joint prosthesis. This patient information booklet will help you to understand

- the anatomy of the wrist;
- what parts of the wrist will be replaced;
- the type of medical device being considered for implantation;
- the medical conditions it is used for;
- what to expect before and after the operation;
- possible adverse events and malfunctions that may occur.

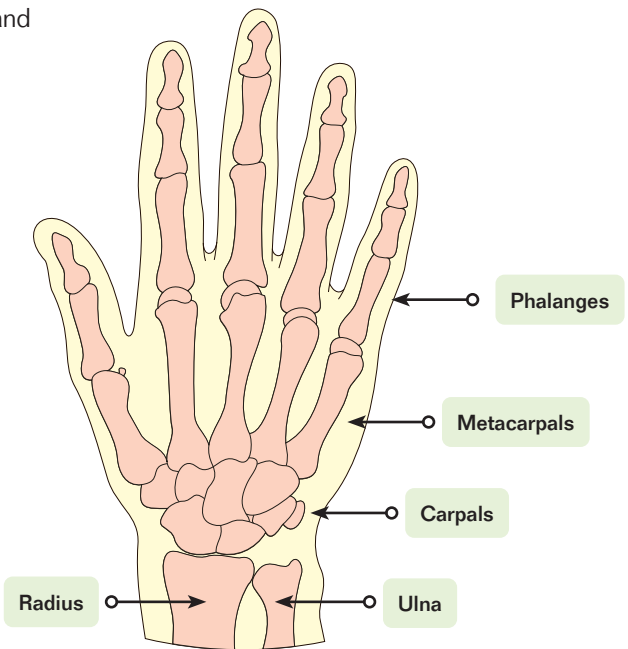
# Anatomy

The anatomy of the wrist joint is very complex. The wrist is composed of many small bones and joints, articular cartilage, ligaments and tendons, nerves and blood vessels. Together, these anatomical structures make the wrist extremely mobile to give our hands a full range of motion and also provide the strength for heavy gripping.

The wrist is made up of eight separate small bones (carpals) in two rows which connect the two bones (radius and ulna) of the forearm to the hand. The hand is composed of five long bones (metacarpals) within the palm which are attached to the bones in the fingers and thumb (phalanges).

Ligaments connect all the small bones to each other, and to the radius and ulna.

Articular cartilage is the white, shiny, rubbery material that covers the bone surfaces in most joints as shock absorber and smooth surface to make motion easier and protect the bone ends from friction when moving the joint. Damage to the articular cartilage eventually leads to arthritis.



## Rationale for Wrist Arthroplasty

The main goal of an artificial joint is to prevent the bones in an arthritic joint from rubbing against each other in cases with pain, malalignment or instability due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or Kienböck's disease.



# Preparation for Surgery

The medical conditions listed on the previous page may make it advisable to replace the painful and destroyed wrist joint with an artificial wrist joint. You and your surgeon should make the decision to proceed with surgery together. Once decided, a complete physical examination by your regular doctor will ensure that you are in the best possible condition to undergo surgery. Your surgeon may suggest a pre-operative physical therapist visit to record your current pain levels, your ability to do your activities, and the movement and strength of the affected wrist.

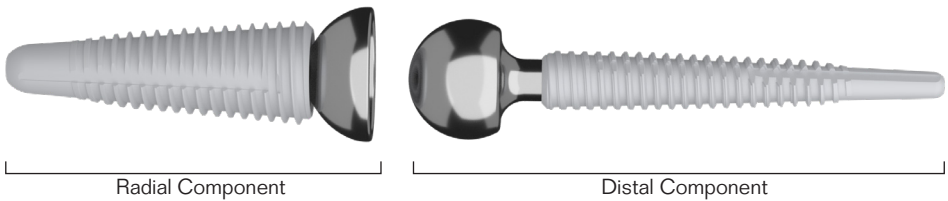
You will also meet the anesthetist before the operation. The type of anesthesia used will depend on the nature and duration of the procedure, your general medical condition, and your preference and those of your anesthetist and surgeon performing the procedure. Wrist replacement surgery can be done under general anesthesia or regional anesthesia. General anesthesia puts you to sleep, i.e. you are put into a state of unconsciousness for the duration of the operation. The anesthetist monitors your condition closely and constantly adjusts the level of anesthesia. Regional anesthesia paralyses only your arm, i.e. a nerve block numbs the part of the body where the surgeon operates and this avoids the need for general anesthesia. You may be awake or sedated.

On the day of your surgery, you will probably be admitted to the hospital early in the morning. You should not eat or drink anything after midnight the night before. Come prepared to stay in the hospital for at least one night.

# Surgical Procedure

As previously mentioned in the implant identification section, the prosthesis consists of four components.

The radial component is made up of two pieces: a threaded stem that will be implanted into the canal of the radius bone of your forearm and a metal cup with a plastic or metal surface which serves as a socket for the artificial wrist joint. The distal component replaces the small wrist bones and consists of a threaded stem that will be inserted in the third metacarpal bone (the metacarpal bone of the middle finger) and a spherical metal head which fits into the socket of the radial component. This ball-and-socket design allows movement of the wrist in all directions.



Following anesthesia, the surgeon will make a skin incision on the back of your wrist, move soft tissue structures out of the way and open the joint capsule. To make room for the artificial joint, the first row of carpal bones is removed and two other small bones are prepared for the implantation. After inserting the threaded implants, the surgeon will use trials to determine the appropriate sizes of the radius cup and the metacarpal head and then mount the selected implants into the stems. The fully assembled artificial joint is tested through its range of motion to make sure it moves correctly. Finally, the joint capsule is closed, the tendons are placed back in their proper positions and a subcutaneous drainage, if deemed necessary, is introduced before the skin is stitched together.



# After Surgery

Postoperative care is extremely important. Straight after surgery, your wrist will be put in a plaster slab and covered by a bulky bandage, which will keep the wrist in a natural position during healing. If used, the plastic tube that drains blood from the joint will be removed after one day. Keep your hand elevated above the level of your heart for several days to avoid swelling and throbbing. If necessary, medication will help to control any pain.

## Post-op

You will likely start early hand therapy during the hospital stay, with finger, forearm, elbow and shoulder motion. At about 2 weeks after surgery the slab and sutures will be removed and a circular short arm cast allowing free forearm rotation and finger function will be applied for another 4 weeks.

## 6 weeks post-op

After 6 weeks the cast is removed and radiographs are taken to evaluate that your implants are stable. You may then start with limited weight bearing and gradually increase the weight. Free weight-bearing is allowed when radiographs confirm implant stability. Recovery from wrist replacement surgery takes up to three months. Before your therapy sessions end, your physical or occupational therapist will teach you a number of ways to avoid future problems.

## 6 months post-op

After 6 months radiographs are taken to check your range of motion and grip strength and to assess your pain intensity. Further follow up at yearly intervals will continue for 2 or 3 years.



# Complications

On your way to recovery, you should make progress and enjoy the unrestricted motion of your wrist without pain. However, as with all major surgical procedures, complications can occur. It would go beyond the scope of this patient information guide to provide a complete list of all problems which may in rare cases occur during or after the operation. Some of the most common complications following artificial wrist replacement are

- Infection
- Loosening
- Nerve and blood vessel injury

## Infection

Infection following joint replacement surgery can occur while you are still in hospital, but may not show up for months after the operation. Infections are serious and can spread into the artificial joint from other infected areas, e.g. after dental or other surgical procedures. If an infection occurs that involves the implant, implant failure is likely and a second operation to remove the implant and fuse the wrist may become necessary.

## Loosening

The artificial joint can fail due to loosening of the metal components in the bone. You will feel pain caused by the loose joint prosthesis, and another operation will most likely be needed. Theoretically, the Motec® Wrist Joint Prosthesis does not have a finite life. It is designed to stay in the body for an unlimited period of time. However, artificial wrist joints tend to loosen earlier than other artificial joints.

## Intraoperative nerve or blood vessel injury

Nerves and blood vessels in the wrist joint are kept out of the way during surgery, but may still become injured during the procedure by retractors or other surgical instruments. The symptoms of such damage are usually temporary, but in rare cases the nerves and blood vessels can suffer permanent injury.



## Adverse Event Reporting

It is quite normal that you will feel some discomfort after surgery and that even gentle range of motion and strengthening exercises will cause moderate pain. You should contact your doctor immediately in the case of any undue pain, strange sounds coming from the prosthesis or any suspected malfunction, severe redness around the operation site or weeping from the wound. Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority. Your doctor will evaluate the suspected implant failure and take care of the adverse event reporting.

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