Patient Information

Motec® Wrist Prosthesis

Swemac

Disclaimer

This material is for informational purposes only. It does not replace the advice or counsel of a physician or health care professional. In case of any questions you may have, do not hesitate to consult with your physician.

Contents

Introduction

The Motec® Wrist Prosthesis is an implant that replaces the wrist joint with the aims of reducing pain and restoring wrist function. This patient information booklet is designed to supplement information from your surgeon and will help you to understand:

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

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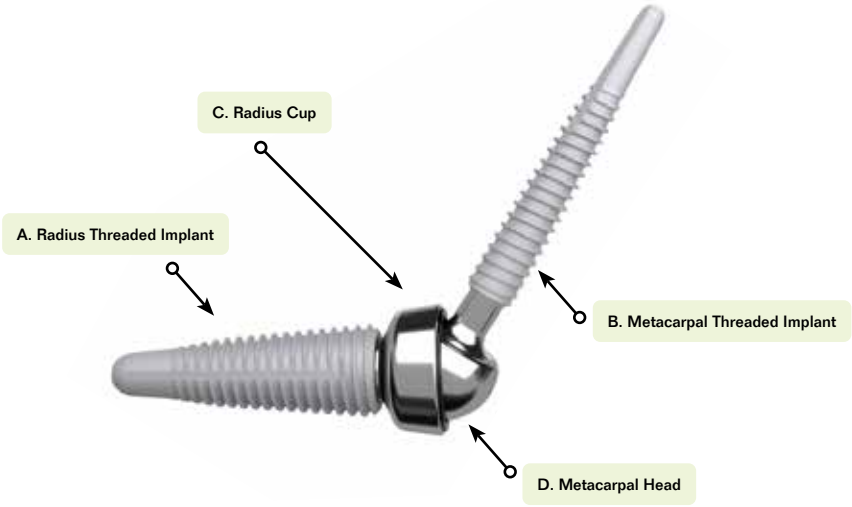
Implant Identification Information

The Motec Wrist Prosthesis consist of four components:



The Radius Threaded Implant (A) and the Metacarpal Threaded Implant (B) are made from titanium alloy (Ti6Al4V) and are used to achieve fixation in the Radius (one of the bones in your forearm) and in the metacarpal bone of your middle finger (one of the bones in your hand). The implants have a resorbable calcium phosphate coating (BONIT®) to help them to integrate with your bone. The articulation between the fixation components consists of the Radius Cup (C) and the Metacarpal Head (D). The Metacarpal Head is made of metal (cobalt chrome, CoCrMo). The Radius Cup is available in different materials; either metal (CoCrMo) or metal with a plasic insert (carbon fiber reinforced PEEK or PE). Each component is available in different sizes to give the surgeon options in terms of choosing the best fit.

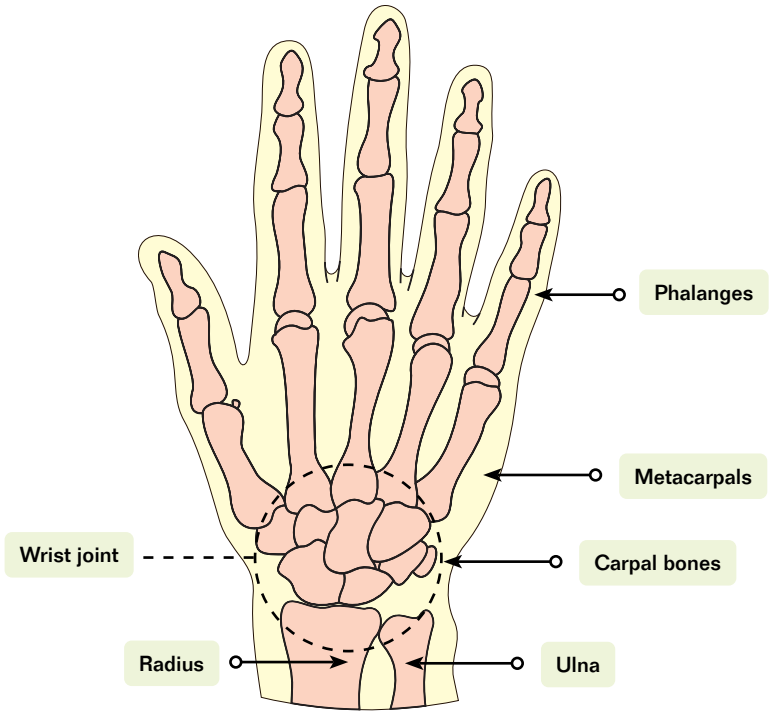
Specific information about each component used in your surgery (description, material, size, item number, lot number, manufacturing date, manufacturer) will be provided in the shape of patient record labels affixed to your Patient Implant Card (PIC) which you will receive after the surgery.

Anatomy

The anatomy of the wrist joint is complex and comprises numerous bones, articular cartilage, ligaments, tendons, nerves and blood vessels.

The wrist is made up of eight separate small bones (carpal bones) in two rows which connect the two forearm bones (radius and ulna) 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 forearm bones (radius and ulna).

Articular cartilage is the white, shiny, rubbery material that covers the bone surfaces in most joints. Articular cartilage has a smooth surface which helps the wrist to move and protects the bone surfaces from friction. Damage to the articular cartilage eventually leads to arthritis.



Rationale for Wrist Joint Replacement

The Motec Wrist Prosthesis is intended to replace the wrist joint in skeletally mature patients with pain, malalignment or instability due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or Kienböck's disease. You should be aware that the implant will not fully replicate a healthy anatomical joint but may help you to maintain your wrist function. The implant can remain in your wrist for the rest of your life if it is beneficial for you.

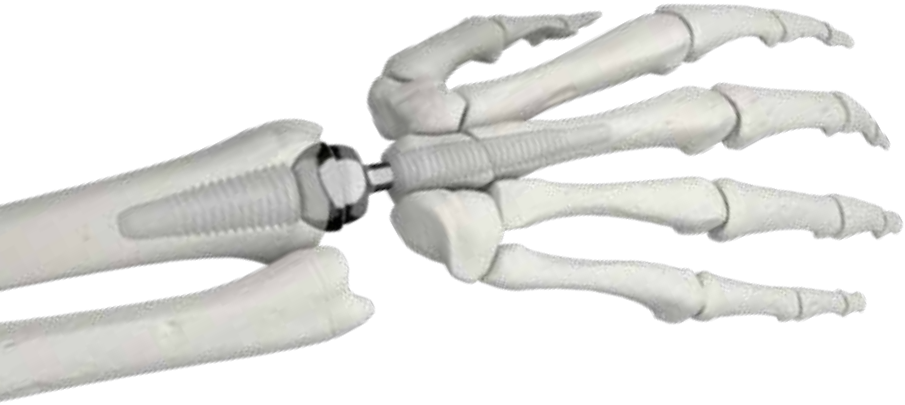
The Motec Wrist Prosthesis cannot always be implanted, the physician's education, training and professional judgment must be relied upon to choose the most appropriate surgical procedure for you.

Preparation for Surgery

Your medical team will instruct you how to prepare for surgery. The advice may vary depending on the type of anesthesia recommended for you and may include restrictions on eating and drinking prior to the surgery.

Surgical Procedure

As previously mentioned in the implant identification section, the Motec Wrist Prosthesis consists of four components. The radial side 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 components 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 and the tendons are placed back in their proper positions before the skin is stitched together.

After Surgery

The implantation will affect your mobility, your ability to carry loads and your general living circumstances. Your surgeon will choose the most appropriate postoperative care specifically for you and advise you about the use, limitations and possible complications. It is important that you follow the postoperative care instructions or there is a risk that the implant might fail.

Possible Complications

The replacement of a joint with a prosthesis is associated with certain risks. As in any surgery, infection, local inflammation and damages to nerves, bones, tendons or blood vessels may occur.

There is a risk of implants failing to fixate in the bone or loosening of implants that initially fixed well with the bone.

Excessive force to the prosthesis from e.g. falling on the hand, may cause damage to the implant.

The materials used in the prosthesis are all common in implants. Patients may still on rare occasions have an allergic response to the implanted materials.

Elevated blood levels of cobalt and chromium ions may occur due to wear of the metal components of the prosthesis. Wear-particles from the implanted materials may lead to local or systemic adverse effects.

Surgical interventions may be needed to treat the above-mentioned complications. This may involve re-operations to exchange implant components, adjustments to bone or soft tissue in the wrist or removal of the prosthesis. If the Motec Wrist Prosthesis must be removed, other treatment options include the conversion into a fused/stiff wrist.

MRI Safety Information

The Motec Wrist Prosthesis has not been tested for magnetic resonance imaging (MRI) scanning safety. You must inform your healthcare provider that you have an implant before having an MRI scan. They will evaluate any potential risks. You may also show them your Patient Implant Card.

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. You should also contact your doctor if you have any falls or accidents potentially affecting the wrist, even if the surgical area did not appear to be harmed at the time. Your doctor must report any serious incident that occurs in relation to the device to Swemac (as the manufacturer). Your doctor will evaluate the situation and take care of the adverse event reporting.

Swemac

Motec Wrist System

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