Patient Information

Motec®

Wrist Joint
Arthrodesis 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 Arthrodesis System provides three different salvage options that limit unnecessary implant removal by taking advantage of pre-existing stable and osseointegrated[1] implants from the Motec® Wrist Joint Prosthesis. The existing (E) and additional (A) components are outlined below.

Option 1

Double Taper (straight or angled)

(E) Metacarpal Threaded Implant
(A) Double Taper OR
(A) Angled Double Taper
(E) Radius Threaded Implant

Option 2

Metacarpal Taper & Radius Connector

(E) Metacarpal Threaded Implant
(A) Metacarpal Taper
(A) Long Lock Screw
(A) Distal Lock Screw
(A) Proximal Lock Screw
(A) Radius Connector
(E) Radius Threaded Implant

Option 3

Metacarpal Nail & Radius Connector

(A) Metacarpal Nail
(A) Cortical Screws ø 2.7 mm
(A) Long Lock Screw
(A) Distal Lock Screw
(A) Proximal Lock Screw
(A) Radius Connector
(E) Radius Threaded Implant

All implants are made of blasted titanium alloy (Ti6Al4V) and are MRI compatible, i.e. they do not interfere with magnetic resonance imaging procedures.

Specific information about each component used in the wrist arthrodesis 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.

[1] Osseointegration: Intimate contact of bone tissue with the surface of a titanium implant.

Manufacturer:

Swemac Innovation AB
Cobolgatan 1
SE-583 35 Linköping
Sweden

+46 13 37 40 30
info@swemac.com
www.swemac.com

Introduction

You are reading this booklet, because your Motec® Wrist Joint Prosthesis has failed. As disappointing as this experience may be for you, the good news is that you do not have to get used to constant pain or instability of the wrist. The Motec® Wrist Joint Arthrodesis System was developed to enable easy conversion of a Motec® Wrist Joint Prosthesis with poor clinical outcome to a total wrist arthrodesis. What you will sacrifice is some mobility of your wrist joint, but the bone fusion achieved by this salvage procedure should provide pain relief.

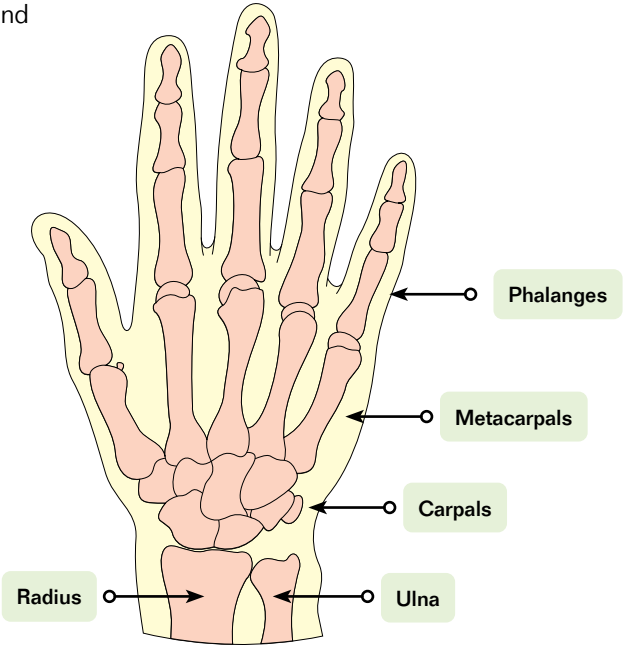
There are many sources of information that will help you, prior to surgery, to have informed consent discussions with your physician on the decision regarding the salvage procedure for conversion of your wrist joint prosthesis to an arthrodesis device. This patient information booklet will help you to understand:

- the anatomy of the wrist;
- which components of your current prosthesis will stay and what 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 Arthrodesis

The Motec® Wrist Joint Arthrodesis System is suitable in several cases and offers three different options depending on your implant situation. No matter in which configuration, the system requires a stable and osseointegrated radius component. The implants are only intended for initial fixation. The desired long term stability of the wrist is achieved by bone fusion. The fusion (also called arthrodesis) eliminates pain by making bones grow together into one solid bone. The wrist joint fusion involves the radius in the forearm and the carpal bones of the wrist. Supported by the initial fixation achieved by the implants, all of these bones will grow together into one long bone. Since the ulna of the forearm is not affected by the bone fusion, forearm rotation remains unrestricted. However, you must be very clear on the fact that the arthrodesis will not allow you to bend your wrist anymore. Together with your surgeon, you will evaluate whether the benefit of regaining a strong grip and a pain-free wrist will outweigh the loss of some motion.

Preparation for Surgery

When your artificial wrist joint prosthesis has failed, your surgeon may recommend a wrist fusion. You and your surgeon should make the decision to proceed with salvage 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. 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 arthrodesis 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.

Surgical Procedure

As previously mentioned in the implant identification section, the Motec® Wrist Joint Arthrodesis System is modular and offers various options for a straight or slightly angled bone fusion. Your surgeon will select the implant configuration which is most suitable for you. 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. The radius threaded implant of your existing prosthesis remains in the bone, provided it is stable and osseointegrated, but the articulating components (metacarpal head and radius cup) will be removed and replaced. Depending on the salvage option chosen, the metacarpal threaded implant can also stay in the bone or will be removed and replaced by a metacarpal nail.

The surgeon will remove any remaining cartilage and sclerotic bone between the carpal bones and the distal radius. The spongious bone surfaces provide optimal conditions for fusion of the wrist. The surgeon will use trials to determine the appropriate sizes of the components connecting the radius implant and the metacarpal implant and also decide which angle of extension or flexion (straight or with the hand bent slightly up or down) is best suited for your needs. It may be necessary to make a small incision on the radial side for easier insertion of the proximal lock screw, unless the double taper option was chosen. When all implants are in place and properly locked, the wrist cavity is filled with bone graft to get maximum stability and optimal conditions for fusion. Bone graft may be harvested from your iliac crest (which involves another small incision over your pelvis) or from the end of your radius. Finally, the joint capsule is closed, the tendons are placed back in their proper position and, if deemed necessary, a subcutaneous drainage 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 for 2 weeks. If used, the plastic tube that drains blood from the wrist 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. If there is any problem with upper extremity motion, you will receive hand therapy.

6 weeks post-op

After 6 weeks the cast is removed and radiographs are taken to check the progress of bony fusion. You may then start with limited weight bearing and gradually increase the weight. Free weight-bearing is allowed when radiographs confirm complete bony fusion.

Complications

On your way to recovery, you should make progress and feel less pain in the wrist. 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 wrist arthrodesis surgery are

- Infection
- Nerve and blood vessel injury
- Nonunion of the bones

Infection

You may be given prophylactic antibiotics as premedication before surgery, but infection following bone fusion surgery can still occur and may require more antibiotics or even surgery to drain the infection.

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.

Nonunion of the bones

If the bones do not fuse as planned and the nonunion continues to cause pain, you may need another operation to add more bone graft. In that case, your wrist will most likely be completely immobilized for fusion to occur.

Adverse Event Reporting

It is quite normal that you will feel some discomfort after surgery and that even gentle exercises will cause moderate pain. You should contact your doctor immediately in the case of any undue pain or 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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Manufacturer

Swemac Innovation AB

CE 0413

Cobolgatan 1 • SE-583 35 Linköping • Sweden

+46 13 37 40 30 • info@swemac.com • www.swemac.com

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