Swemac

Motec Wrist Joint Prosthesis System - Instructions For Use

English
IFU-P125-EN-20200701

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CE 0413

FURTHER INFORMATION:
This Instruction For Use leaflet is only provided in English. Other languages of this leaflet, the recommended surgical technique and detailed instructions for cleaning, sterilization and re-sterilization can be downloaded in PDF format from the Swemac website http://download.swemac.com/Motec-Wrist-Joint-Prosthesis. Printed documentation can be provided free of charge upon request. Delivery time is maximum 7 days.

INTENDED USE:
The Motec Wrist Joint Prosthesis System is intended to be used as a wrist replacement.

Description:
The Motec Wrist Prosthesis is a cementless, single use, ball-and-socket, modular prosthesis. The system consists of two spherical articulation components and one distal- and one proximal threaded fixation implant. The fixation components are available in different sizes, made of Ti6Al4V (ISO 5832-3), blasted and coated with Bonit (bioresorbable calcium phosphate) for optimized osseointegration. The distal articulation component is made of CoCrMo (ISO 5832-12) and the proximal cup is available in both metal and plastic designs. The device is for professional use only.

Indications:
The Motec Wrist Prosthesis System is indicated for skeletally mature individuals as a replacement of the wrist joint in cases with pain, malalignment or instability due to osteoarthritis, traumatic arthritis (SLAC, SNAC, sequelae distal radius fracture), rheumatoid arthritis and Kienböck's disease. The prosthesis can be implanted after failed wrist surgery such as four corner fusion, proximal row carpectomy, or arthrodesis.

Contraindications:
The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection, sepsis or marked local inflammation in or around the surgical area.
- Material sensitivity, documented or suspected.
- Physical interference with other implants during implantation or use.
- Compromised vascularity, inadequate skin or neurovascular status.
- Compromised bone stock that cannot provide adequate support and/or fixation of the device due to disease, infection or prior implantation.
- Patients who are unwilling or incapable of following post-operative care instructions.
- Other physical, medical or surgical conditions that would preclude the potential benefit of surgery.
- Previous open fractures or infections in the joint.
- Irreparable nerve, tendon or ligament apparatus.

COMPATIBILITY:
The components included in this system have not been tested for safety, heating, or migration in an MRI environment. Similar products have been tested and evaluated in terms of how they may be safely used using MRI equipment. Prior to an MRI scan, a patient with a Swemac implant must always disclose the specific implant information to their physician. For details see *Swemac MRI Statement*.
The device is compatible with Swemac Motec Wrist Arthrodesis System.

WARNINGS:

- **Do not use the device without reading the surgical technique brochure, which has been provided to the user separately.**
- The device must only be used by a professional surgeon who is thoroughly familiar with indications and contraindications, the implant, the methods of application, instruments, and the recommended surgical technique of the device.
- The implant can be available in different sizes and versions. It is important to select the appropriate combination of implant components and sizes taking into consideration the length, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the described combination (see surgical manual).
- Improper insertion of the device during implantation can increase the risk of loosening or migration.
- Improper positioning of the device may lead to clinical failure.
- Do not reuse the implants, since previous stresses may have created imperfections, which can lead to a device failure.
- Do not touch sharp edges of instruments or implants.
- If either the product or package seems damaged, contaminated or if sterility is questioned for any reason, the product shall not be used.
- Do not re-use single use guide wires. Single use guide wires may be damaged or bent during surgical procedures. If a single use guide wire is re-used it may become lodged in a drill or reamer and unintentionally advanced into the body.
- Drills and reamers with measuring function must not be re-sharpened.
- Insufficient quantity or quality of bone/soft tissue may increase the risk of loosening or migration.
- Do not use this prosthesis in a joint where soft tissue reconstruction cannot provide adequate stability. An artificial joint also attains stabilization from the surrounding capsuloligamentous structures. If soft tissue reconstruction cannot provide adequate stabilization, the device may dislocate or loss of motion may occur.
- Do not re-sterilize the implants because this could lead to surface damages.
- Handle implants gently to avoid surface damage. Do not modify the implants. Implants should only be handled with instruments provided by Swemac. Incorrect handling can cause surface damage and lead to premature wear or failed osseointegration.
- Be restrictive in the use of Metacarpal Head Short neck because an impingement between the Radius Cup and the Metacarpal Threaded Implant might lead to excessive wear.

PRECAUTIONS:

- Ensure that all components needed for the operation are available in the surgical theatre.
- Inspection is recommended prior to surgery to determine if implants have been contaminated or damaged during transport or storage.
- Instruments should be examined for wear or damage prior to surgery.
- Avoid surface damage to the implant and discard all damaged or mishandled implants.
- After the procedure check the proper positioning of all implants using an image intensifier. Correct positioning of the implant parts is extremely important for the clinical outcome (see surgical manual).
- Do not use components from Swemac in combination with components from other manufacturer's system.

ADVERSE EFFECTS:

- Pain, discomfort, abnormal sensations, nerve damage, soft tissue damage, infections, necrosis of bone, bone resorption, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.
- Treatment failure such as fracture or loosening of the implant may occur due to excessive activity, prolonged loading upon the device, incomplete healing, delayed union, non-union or excessive force exerted on the implant during insertion.
- Implant migration and/or loosening may occur.
- Mal-union may occur.
- Shortening of the affected bone/fracture site.
- Metal sensitivity, histological or allergic reaction resulting from implantation of a foreign material may occur.
- Abrasion of the prosthesis surface and the development of osteolysis due to a foreign body reaction.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.
- Surgical intervention may be required to treat adverse effects. This may involve exchange of a screw, removal of a prosthesis or arthrodesis.
- Stiffness, tendinitis or transient neuritis.
- If Metacarpal Head Short neck is implanted, an impingement between the Radius Cup and the Metacarpal Threaded Implant might occur. This might result in excessive wear.

POSTOPERATIVE CARE INSTRUCTIONS:
Postoperative care is extremely important. The physician's education, training and professional judgment must be relied upon to choose the most appropriate postoperative care. The patient must be cautioned about the use, limitations and possible adverse effects of this implant. The patient must also be warned that the implant and/or treatment might fail if she/he neglects the postoperative care instructions.

- The implantation affects the patient's ability to carry loads and her/his mobility and general living circumstances. For this reason, each patient needs individual instructions on correct behavior after implantation.
- The implant is designed as a load sharing device and cannot withstand immediate weight bearing as a load bearing device.
- Explain the need to report unusual changes in the implantation area as well as falls or accidents even if the device or the surgical area did not appear to be harmed at the time. Serious incidents shall be reported to Swemac and the Competent Authority.
- The patient should be warned that the device cannot fully replicate a healthy anatomical joint.

STERILITY:
The implants are provided sterile. Sterile devices have been exposed to a minimum dose of 25.0 kGy gamma irradiation. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant shall not be used.

CLEANING AND DISINFECTION:
The washer/disinfector used for the automated cleaning process should have proven effectiveness in accordance with ISO 15883. Multi-component instruments should be disassembled before cleaning. For details see *Swemac reprocessing instructions*.

STERILIZATION AND RE-STERILIZATION:
The instruments shall be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17665. Sterile packaging shall be done in accordance to ISO 11607-1. Do not re-sterilize the implants because this could lead to surface damages.

The following sterilization parameters are recommended:	134°C for minimum 3 minutes*	132°C for minimum 4 minutes*
* Holding time. These times do not include air removal or penetration.		

STORAGE INSTRUCTIONS:
The package should not be exposed to direct sunlight, ionizing radiation, extreme temperatures or particulate contamination.

SYMBOLS USED ON THIS PRODUCT:

STERILE R	Sterilized using irradiation		Do not use if package is damaged
	Do not reuse		Caution
NON STERILE	Non-sterile	download.swemac.com	Consult instruction for use
	Do not re-sterilize		
	Keep away from sunlight	**RxOnly**	CAUTION: Federal law (USA) restricts this device to sale by or on order of a licensed physician or hospital.

Swemac

Motec Wrist Joint Prosthesis System – Patient Implant Card

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You have received the implant/implants stated on this Patient Implant Card.

Warnings, Precautions, Postoperative care instructions and possible Adverse effects are stated on the back side of this document.

http://www.swemac.com/PIC
For instructions on how to find additional implant information visit the website. You will need the **REF** number and **UDI** number from the attached Patient Record Labels to access the information.

Alternatively, contact our customer service:

Phone: +46 13374030
E-mail: PIC@swemac.com

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Patient Record Labels

Attach Patient Record Label from the used implant package

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