**Motec CMC Prosthesis - Instructions For Use**

**English**

**IFU-P126-EN-20130318**

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**FURTHER INFORMATION:**

This Instruction For Use leaflet is only provided in English. Other languages of this leaflet and the recommended surgical techniques as well as detailed instructions for cleaning, sterilization and re-sterilization can be downloaded in PDF format from the Swemac website http://www.swemac.com/ifu/IFU-P126/. Printed documentation can be provided free of charge upon request. Delivery time is max 7 days.

**DESCRIPTION:**

The Motec CMC prosthesis is a cementless, single use, ball-and-socket, modular total prosthesis intended to replace the joint between the proximal end of the first metacarpal bone and the trapezium. Fixation is achieved by titanium alloy (Ti6Al4V) threaded implants, coated with Bonit. The articulation is modular and can be configured depending on surgeon and patient preference, either with CoCrMo on CoCrMo or CoCrMo on carbon fiber reinforced PEEK. The system also features a cemented UHMWPE salvage cup. The device is for professional use only.

**COMPATIBILITY:**

The implants are safe for the patient undergoing an MR procedure, but depending on the implant materials, image artifacts may occur.

**INDICATIONS:**

The system is indicated in cases of pain, instability or reduced motion of the basal thumb joint caused by rheumatoid arthritis, primary osteoarthritis and secondary arthritis. The patient must be at least 15 years of age.

**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.
- Severe osteoporosis, insufficient quantity or quality of bone/soft tissue.
- 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 fracture or infection in the joint.
- Irreparable tendon or ligamentous apparatus.

**WARNINGS:**

- Do not use the device without reading the surgical manual, which has been provided to the clinic separately.
- The device must only be used by a professional surgeon who is thoroughly familiar with 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 in to consideration the length, body weight, anatomy and functional demands of the patient. Implants which consist of several components must only be used in the prescribed combination (see surgical manual).
- Improper positioning of the device may lead to clinical failure.
- Do not re-use implants, since previous stresses may have created import decompressions, 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.
- Do not use this prosthesis in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, an artificial joint 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 or handle the implants using metal instruments. Implant components should be handled only with instruments provided by Swemac. Incorrect handling can cause surface damage and lead to premature wear or failed osseointegration.
- Make sure not to penetrate the STT joint when inserting the guide wire.
- Make sure to perform the drilling in one single motion.

**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 storage.
- Handle instruments with care. 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 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.
- Material sensitivity, histological or allergic reaction resulting from implantation of a foreign material may occur.
- Abscess of the prosthesis surface and the development of osteolysis due to a foreign body reaction.
- Material sensitivity reactions in patients following implantation have rarely been reported, however their significance await further clinical evaluation.
- Surgical intervention maybe required to treat adverse effects. This may involve exchange of a screw, removal of a prosthesis and conservative treatment.

**POSTOPERATIVE CARE INSTRUCTIONS:**

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 he/she 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 behaviour after implantation.
- The device is not designed to immediately withstand the stress of weight bearing, load bearing or excessive activity.
- 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.
- The patient should be warned that the device cannot fully replicate a healthy anatomical joint.

**CLEANING AND DISINFECTION:**

The instruments should be disassembled before cleaning. Cleaning shall be performed in accordance with ISO 15883. Cannulated instruments must be visually inspected after cleaning.

**STERILIZATION AND RE-STERILIZATION:**

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. The instruments shall be sterilized and re-sterilized by using a validated sterilization process in accordance with ISO 17665.

Do not re-sterilize the implants because this could lead to surface damages.

The following sterilization parameters are recommended:

<table>
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<tr>
<th>Temperature</th>
<th>Time</th>
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<td>134°C for min. 3 minutes*</td>
<td>121°C for min. 15 minutes*</td>
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* Holding time. These times do not include air removal or penetration.

**STORAGE INSTRUCTIONS:**

Store in a cool dry place and keep away from direct sunlight.

**SYMBOLS USED ON THIS PRODUCT:**

- ![Sterilized using irradiation](image)
- ![Do not use if package is damaged](image)
- ![Consult instruction for use](image)
- ![Caution](image)
- ![Non-sterile](image)

**CAUTION:** Federal law (USA) restricts this device to sale by or on order of a licensed physician or hospital.