**DESCRIPTION:**
The Motec Wrist Prosthesis is a cementless, single use, ball-and-socket, modular and total prosthesis. It is designed to replace the wrist joint. The system consists of a head, a cup and 2 screws, one dorsal and one proximal. The screws are available in different sizes and are made of blasted Ti6Al4V (ISO 5832-3) provided with a bioreorbable Calcium Phosphate layer to improve the fixation to bone. The prosthesis has a metal-metal articulation with a spherical head and cup. The head and cup components are made of CoCrMo (ISO 5832-12) and connected to the screws in the capitate/metakarpal III and the radius, respectively, through a standard Morse-taper. The cup is also available in PEEK GIF.

The device is for professional use only.

**COMPATIBILITY:**
The device is compatible with Swemac Motec Wrist Arthrodesis. The implants are safe for the patient undergoing an MR procedure, but depending on the implant materials, images artifacts may occur.

**INDICATIONS:**
The Motec Wrist Prosthesis is indicated as replacement of the wrist joint in cases with pain, malalignment or instability due to rheumatoid arthritis, traumatic arthritis, osteoarthritis, Kienböck’s disease or carpal collapse. The system may also be indicated after failed wrist surgery like four corner fusion, proximal row carpectomy and the recommended surgical technique 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-0125. Printed documentation can be provided free of charge upon request. Delivery time is max 7 days.

**WARNINGS:**

- 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 fixation of the device due to disease, infection or prior implantation.
- Patients who are unwell 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.

**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.
- 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, neosis 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/fatigue 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 maybe 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 (PEEK or CoCrMo) and the Metacarpal Threaded Implant might occur. This might result in excess weight and pain.

**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.

**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 DISINFECTING:**
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:**
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:

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>134°C</td>
<td>for min. 3 minutes*</td>
</tr>
<tr>
<td>121°C</td>
<td>for min. 15 minutes*</td>
</tr>
</tbody>
</table>

* 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
- Do not use if package is damaged
- Do not reuse
- Consult instruction for use
- Caution
- Non-sterile
- Do not re-sterilize

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