Swemac

The Motec Wrist System
Summary of Safety and Clinical Performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the Motec Wrist System. The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

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Information intended for healthcare professionals

Following this information there is a summary intended for patients in Annex B.

1 Device identification and general information

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<tr><td>SSCP, Document ID:</td><td>SSCP-P270-EN</td></tr>
<tr><td>Document revision date:</td><td>2026-01-26</td></tr>
<tr><td>Device family, trade name:</td><td>Motec Wrist System</td></tr>
<tr><td>Included configurations of devices:</td><td>
Motec Wrist Prosthesis
1 pc Radius Threaded Implant
1 pc Metacarpal III Threaded Implant
1 pc Radius Cup (available in CoCrMo, CFR-PEEK and UHMWPE)
1 pc Metacarpal Head
<table>
<tr><th>Radius Cup in CoCrMo</th><th>Radius Cup in CFR-PEEK</th><th>Radius Cup in UHMWPE</th></tr>
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Motec Wrist Arthrodesis
1 pc Radius Threaded Implant
1 pc Metacarpal III Threaded Implant
1 pc Double Taper (straight or angled)
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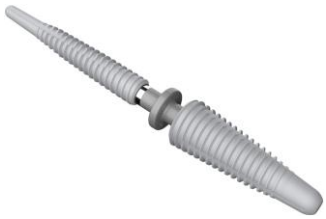
<tr><td>  </td><td>  </td></tr>
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7340111700012Q8: Metacarpal Head, Radius Cup
7340111700013QA: Double Taper</td></tr>
<tr><td>EMDN:</td><td>P09030401: Radius Threaded Implant, Radius Cup
P090303: Metacarpal III Threaded Implant, Metacarpal Head
P090399: Double Taper</td></tr>
<tr><td>MDA/MDN/MDS/MDT codes:</td><td>MDA: Not applicable
MDN: 1102
MDS: 1005
MDT: 2001, 2002, 2006, 2008, 2011</td></tr>
<tr><td>Class of the device:</td><td>Class III</td></tr>
<tr><td>Manufacturer:</td><td>Swemac Innovation AB
Cobolgatan 1, SE-583 30 Linköping, Sweden
SRN: SE-MF-000000727</td></tr>
<tr><td>Year when the first certificate (CE) was</td><td>Radius and Metacarpal III Threaded Implants, Radius Cup and Metacarpal Head in CoCrMo: 2006
CFR-PEEK Radius Cup: 2013</td></tr>
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issued covering the device:	UHMWPE Radius Cup: 2020 Double Taper: 2017
Authorised representative:	Not applicable
Notified body:	Intertek Medical Notified Body AB SIN: NB2862

2 Intended use of the device

2.1 Intended purpose

The Motec Wrist System is intended to replace the wrist joint. The arthrodesis solution is intended to be used as a salvage procedure for a failed prosthesis. The device is intended for professional use only.

2.1.1 Radius Threaded Implant

The Radius Threaded Implant is intended to contribute to the intended use by means of fixation in the radius.

2.1.2 Metacarpal III Threaded Implant

The Metacarpal III Threaded Implant is intended to contribute to the intended use by means of fixation in the third metacarpal or in the radius.

2.1.3 Radius Cup

The Radius Cup is intended to contribute to the intended use by means of proximal articulation surface of the ball-and-socket joint.

2.1.4 Metacarpal Head

The Metacarpal Head is intended to contribute to the intended use by means of distal articulation surface of the ball-and-socket joint.

2.1.5 Straight Double Taper & Angled Double Taper

The Double Taper is intended to contribute to the intended use by means of interconnection between the threaded implants in a case of arthrodesis.

The intended clinical benefits of the Motec Wrist Prosthesis are to provide wrist pain relief whilst improving wrist motion and function. For the Motec wrist arthrodesis the clinical benefit is an easy conversion from prosthesis to arthrodesis by taking advantage of pre-existing stable and osseointegrated fixation components.

2.2 Indications

The Motec Wrist System is indicated for wrist joint replacement in skeletally mature individuals 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. The Motec Wrist Arthrodesis is only indicated if there is a need for conversion after a failed Motec Wrist Prosthesis.

2.3 Contraindications

- Any active or suspected latent infection, sepsis or 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.
- Open fractures or infections in the joint.
- Use of the prosthesis in patients where soft tissue reconstruction cannot provide adequate stability to the wrist.
- Use of the prosthesis in cases with fixed malposition of the wrist or marked wrist muscle imbalance.
- Other physical, mental, medical or surgical conditions that would preclude the potential benefit of surgery.

3 Device description

3.1 General description of the device

The Motec Wrist System consists of a total wrist joint prosthesis (Motec Wrist Prosthesis) and a salvage arthrodesis solution for fusion of the wrist (Motec Wrist Arthrodesis). The Motec Wrist Prosthesis is available in three different articulation materials: CoCrMo, carbon fiber-reinforced polyetherether ketone (CFR-PEEK) and ultra-high molecular weight polyethylene (UHMWPE). The Motec Wrist Arthrodesis is available in a straight and an angled version. The Motec Wrist System configurations are illustrated in Table 1. All devices in the Motec Wrist System are for single use and delivered sterile. The method of sterilization is by exposure to gamma irradiation.

Table 1: Device configurations of the Motec Wrist System.

<table>
<tr><td colspan="3">Motec Wrist Prosthesis
1 pc Radius Threaded Implant
1 pc Metacarpal III Threaded Implant
1 pc Radius Cup (available in CoCrMo, CFR-PEEK and UHMWPE)
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1 pc Double Taper (straight or angled)</td></tr>
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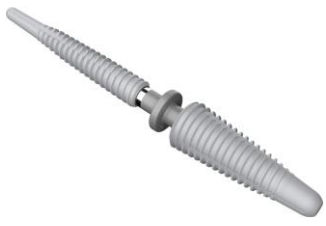
<tr><td colspan="2">  </td><td>  </td></tr>
</table>

3.1.1 Motec Wrist Prosthesis

The Motec Wrist Prosthesis fixation is achieved with Threaded Implants in the radius and in the fused capitate and third metacarpal (Fig. 1). To promote osseointegration, the surfaces of the implants are blasted with Al_2O_3 to achieve a specific roughness. In addition, the Threaded Implants are coated with BONIT®, a resorbable calcium phosphate. The Radius Threaded Implant is available in four standard lengths. Six additional lengths are available on special request to accommodate larger anatomies and revision cases

where the bone cavity is enlarged. The Metacarpal III Threaded Implant is available in two diameters and six lengths (of each diameter).

The articulation of the prosthesis consists of a spherical head and cup design. The distal part of the articulation is the Ø15 mm Metacarpal Head in CoCrMo with three different neck lengths. The proximal part of the articulation is the Ø15 mm Radius Cup, available in CoCrMo as well as in CoCrMo with a CFR-PEEK or UHMWPE insert. The spherical head and cup articulation of the prosthesis is designed to allow a wide range of motion in all directions and thereby also preserving the Dart Thrower's Motion that is important for daily activity and the experience of a functional wrist. The spherical design was also chosen to prevent rotational forces transferred into the Threaded Implants.

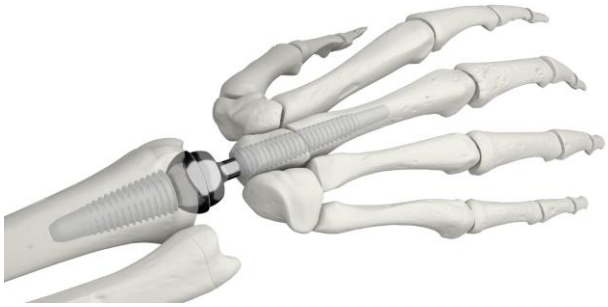


Figure 1: Implanted Motec Wrist Prosthesis.

3.1.2 Motec Wrist Arthrodesis

The Motec Wrist Arthrodesis is a salvage solution to be used for wrist fusion in the event of a failed Motec Wrist Prosthesis. The Double Taper device is a solid peg in titanium alloy connecting the Radius Threaded Implant and the Metacarpal III Threaded Implant. The Double Taper is tapped into place in the already osseointegrated implants to provide initial fixation of the wrist bones until bony fusion occurs. The complete fusion of the wrist is required for long-term stability.

The Double Taper is available in four different lengths and in a straight version and an angled version (15°) to allow the wrist to be fused in a position tailored to the patient's preference.

Figure 2: Implanted Motec Wrist Arthrodesis.

3.2 Previous versions of the device

The Motec Wrist Prosthesis was CE-marked in 2006 under the name Gibbon. In 2007, the prosthesis changed name to Motec Wrist Joint Prosthesis. The devices CE-marked in 2006 were the Threaded Implants and the Metacarpal Head and Radius Cup in CoCrMo. The Metacarpal Head and Radius Cup were initially only available in Ø18 mm. However, a smaller Head and Cup of Ø15 mm was introduced shortly after the first devices to fit smaller anatomies. The Ø15 mm articulation has been the primary option for most surgeons and the Ø18 mm components have been phased out. The first CE-marked Threaded Implants included in the system are still on the market without major changes.

To respond to requests from the market for additional articulation materials, the Radius Cup with a CFR-PEEK insert was introduced in 2013, followed by the UHMWPE Cup in 2020. The Metacarpal Head, size "Short" is associated with increased risks of impingement and wear-related complications. The risks are considered acceptable where other neck sizes cannot be fitted due to anatomical restrictions. However, with gained experience in the surgical technique to avoid the use of a short neck size, this device is being phased out.

The straight Double Taper used in Motec Wrist Arthrodesis was CE-marked in 2017 and the angled version followed in 2019. No further changes have been made to these devices.

3.3 Accessories

There are no accessories to be used with the Motec Wrist System.

3.4 Other devices to be used in combination with the device

The Motec Wrist System is supplied with a specific set of surgical instruments intended to be used for implantation and extraction of the Motec Wrist System implants.

4 Risks and warnings

4.1 Residual risks and side-effects

Risks related to the Motec Wrist System are managed through a continuous and systematic approach according to the EN ISO 14971:2020. All residual risks and side-effects related to the Motec Wrist System are presented in Table 2. Measures have been implemented to, as far as possible, reduce the risks and the occurrence of side-effects and the benefit of the device have been concluded to outweigh the residual risks.

Table 2: Residual risks and side-effects related to the Motec Wrist System and their estimated or observed frequencies.

Motec Wrist Prosthesis	
Residual risks and side-effects	**Frequency**
Surgical procedure The implantation of a wrist prosthesis can lead to complications involving disturbed tendon and nerve functions. These may be device or procedure-related where a suboptimal placement of the device or damage to tissues during the surgical procedure may increase the risk of complications. Complications may also be related to the underlying medical condition where tendons and ligaments are affected by inflammatory processes. Complications that may occur after the implantation includes tenosynovitis, tendon adhesion and tendon rupture as well as nerve-related problems such as carpal tunnel syndrome and complex	Data on frequency of complications that are specifically related to the surgical procedure is currently not available. However, clinical studies have shown that the overall complication rate after having a Motec Wrist Prosthesis is in line with those observed for similar wrist prostheses on the market.

regional pain syndrome. Re-operation may be required to treat these complications.	
Infection Deep infections at the implant site can appear months to years after implantation of a device. Sometimes the infection can be traced to other sites, such as tooth infections, skin infections, or other bacteraemia. This risk is related to implantable devices in general, not specifically to the device properties of the Motec Wrist components.	In a clinical study of 171 Motec patients with an average time in follow-up of 6 years, 2% (two patients) had a re-operation due to an infection. In another study of 56 Motec patients followed for an average of eight years, 4% (two patients) had a reoperation to treat infections.
Wear-particles Particles released from the wear of the materials in the prosthesis may cause adverse local effects such as synovitis and/or loosening of the Threaded Implants with re-operation or potentially fusion of the wrist as a consequence. Metal ions of cobalt, chromium and titanium may spread systemically, with the potential of causing elevated blood levels and systemic adverse effects. The risks related to wear-particles increase if using the Metacarpal Head with the short neck size due to the higher probability of a prosthesis-prosthesis impingement. The short neck size is being phased out but may still be available for use in certain regions. The Instructions for Use advice for a restrictive use of the short neck size.	Clinical studies have shown that the overall revision and re-operation rate after having a Motec Wrist Prosthesis is in line with those observed for similar wrist prostheses on the market. There is no exact frequency established as to how many of these complications that are wear-particle-related. In a clinical study of 113 implanted metal-on-metal Motec prostheses and 58 metal-on-PEEK Motec prostheses, there were no difference in complication or revision rates, indicating that both materials were equally safe. Two clinical studies of 56 and 20 patients have investigated blood levels of cobalt and chromium after implantation of Motec metal-on-metal articulations. During normal use of a well-functioning prosthesis, a slight elevation of both cobalt and chromium was observed, peaking after 6 months. The increase was deemed safe in terms of risks for systemic adverse effects. Higher levels of cobalt and chromium have been observed in cases where an impingement situation occurred after use of the short neck size of the metacarpal head. In these worst-case scenarios, a sufficient safety margin was still observed in systemic metal ion blood levels compared to those associated with systemic side-effects in e.g. failing total hip prostheses.
Implant breakage There is a risk for breakage of prosthesis components if the implanted wrist is exposed to excessive force by for example patients falling and landing on the wrist.	Implant breakage is a rare event. In over 6500 sold Motec Wrist Prostheses, two incidents of implant breakages have been reported from users.
Loosening of Threaded Implants Threaded Implants may become loose due to failed osseointegration, wear-induced osteolysis or from instabilities caused by for example failure to achieve a fusion between the capitate and the third metacarpal bone. Loose implants may require re-operation.	In three independent clinical studies following a total of 273 Motec patients for more than five years, the observed rate of implant loosening was 0-10%.
Wrist stiffness Post-operative wrist stiffness may occur as a consequence of implanting too large prosthesis components for the space available in the wrist. Revision surgery of implanted components may be indicated to treat wrist stiffness.	There is currently no frequency established for this complication. However, the overall revision rate of Motec is in line with those observed for similar wrist prostheses on the market.
Revision/removal procedure The strong osseointegration of the Motec Threaded Implants are intended to promote long-term stability of the prosthesis. In case osseointegrated implants need to be exchanged or removed, there is	There is currently no frequency established of complications related to the removal of osseointegrated implants.

a risk for complications, including fractures to the bones and removal of bone stock. It is not deemed possible to reduce this risk further while still maintaining optimal functionality for the primary purpose of the device. The Motec arthrodesis salvage solution (Double Taper) is designed to reduce the need for removal of osseointegrated implants for conversion to a fused wrist.	
Motec Wrist Arthrodesis	
Residual risks and side-effects	**Frequency**
Failed fusion Failure to achieve wrist fusion can be caused by insufficient bone grafting or insufficient preparation of the bones to be fused as well as from too early post-operative wrist mobilisation or excessive patient activity during the post-operative phase. A failure to achieve fusion may lead to implant breakage and the need for a reoperation.	Although the number of cases systematically investigated is still limited, fusion has been observed in all cases using the Motec Double Taper. There have been no reports of breakage of the Double Taper after >300 sold devices.
Malposition of the fused wrist Too early mobilisation or failure to firmly seat the Angled Double Taper in the Threaded Implants may allow the Double Taper to rotate during bone fusion which may result in malposition of the fused wrist. A reoperation may be required to adjust the position of the wrist.	In around 200 sold devices, the rotation of the Angled Double Taper has been reported from users in four cases.

4.2 Warnings and precautions

4.2.1 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 the 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 height, 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 technique brochure).
- Improper implantation and/or positioning of the device can increase the risk of loosening or migration and may lead to clinical failure.
- Do not re-use the implants. Previous stress may have created imperfections, which can lead to 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 must not be re-sharpened. This is especially important for instruments with a measuring function.
- Insufficient quantity or quality of bone/soft tissue may increase the risk of loosening or migration.
- Do not re-sterilise sterile packed implants because this could lead to surface damages.

- Handle implants gently and keep the implant surface clean. Foreign material on the articulation surface might cause surface damage and implant failure.
- 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.
- Failure to firmly engage the tapers of the Angled Double Taper into the Threaded Implants, or mobilising too early, can lead to unintentional rotation of the Angled Double Taper and fusion to occur in an undesirable wrist position.

The implants in the Motec Wrist System have not been evaluated for safety in the MRI environment. They have not been tested for heating or unwanted movement in the MRI environment. The safety of the Motec Wrist System in the MRI environment is unknown. Performing an MRI examination on a person who has this medical device may result in an injury or device malfunction.

4.2.2 Precautions

- Ensure that all components needed for the surgery are available in the surgical theatre.
- Inspection of implants should be done prior to surgery to determine if implants have been contaminated or damaged during transport or storage. Discard all damaged or mishandled implants.
- Handle instruments with care. Instruments should be examined for wear or damage prior to surgery. For details see Swemac Inspection Instructions.
- The Motec Wrist System is not compatible with implants from other manufacturer's systems.

4.2.3 Post-operative care instructions

Postoperative care is important. The physician's education, training and professional judgment must be relied upon to choose the most appropriate postoperative regime. 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 his/her mobility and general living circumstances. For this reason, each patient needs individual instructions on correct behaviour after implantation.
- The patient must be informed to report unusual changes in the surgical area as well as any 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.

4.2.4 Field safety of the device

All field actions that have been taken to prevent or reduce the risk of serious incidents related to the Motec Wrist System are listed in Table 3.

Table 3: Field safety actions taken in relation to the Motec Wrist System

Field Safety Notice	***Issuing date***	***Impacted regions***
Incidents related to wear-particle-induced inflammation when using the Metacarpal Head with a short neck size resulted in information to users of the risk and the instruction to apply a restrictive use of the short neck size. Instructions for Use and the Surgical Technique were updated with this information.	2018	All
Batch-related re-call of the Radius PE Cup manufactured before October 2021 due to an error in the manufacturing procedure. This error led to risks related to the fastening of the PE cup insert in the metal cup.	Nov 2023	Individual hospitals depending on batches used in EEA, UK, Switzerland and Australia.
A new warning was added in the Instructions for Use and in the Surgical Technique to inform users of risks related to the rotation of the Angled Double Taper during fusion of the wrist.	Mar 2024	All

5 Summary of clinical evaluation and post-market clinical follow-up

The conformity of the Motec Wrist System to the Medical Device Regulation (MDR, EU 2017/745) was assessed and endorsed by the Notified Body based on clinical data from the actual devices. No equivalence to other devices has been claimed.

5.1 Clinical data on the safety and performance of the Motec Wrist Prosthesis

The clinical evidence for the safety and performance of the Motec Wrist Prosthesis is based primarily on four post-market clinical studies.

One study reported the outcome of 56 Norwegian patients, 8 years (range 5-11) after implantation of a Motec Wrist Prosthesis (Reigstad 2017a). The patients were 40 men and 16 women, all non-rheumatoid with a mean age of 52 years. The results showed that pain scores were reduced, and range of motion in the wrist were increased also eight years after the primary surgery. During follow-up, 8 patients had revision surgery where 4 could keep their wrist prosthesis after exchange of components and 4 had to be fused. The reasons for revision surgery were loosening of the Threaded Implant (n=4), inflammation (n=2), pain (n=1) and fixed malposition of the wrist (n=1). The study also reported that patients on average had normal blood levels of chromium (0.6 µg/L) and cobalt (0.8 µg/L), with the reference range for both metals being < 1µg/L[1]. The maximum metal level observed in blood for any individual was 1.6 µg/L chrome and 3.2 µg/L cobalt.

The Motec Wrist Prosthesis was studied in a second cohort of 23 non-rheumatoid patients operated in the United Kingdom (Giwa 2018). This study reported the results after follow-up of on average 4 years (range 2-5.5) and supported the previous results from Reigstad *et al.*, that patient-reported outcomes and range of motion improves after having a Motec Wrist Prosthesis. Three patients out of the total 23 in the study had revision surgery due to loosening of the Threaded Implant (n=1) and persistent pain (n=2). Two of them were converted into an arthrodesis.

The clinical outcome of the Motec Wrist Prosthesis was compared to a similar total wrist arthroplasty (ReMotion, Stryker) in a randomized controlled trial in Norway (Holm-Glad 2022). Forty patients were included in the trial and randomized 1:1 to the two arthroplasties and followed-up at 6, 12 and 24 months. Motec and ReMotion demonstrated similar outcomes in terms of significant reductions in postoperative pain and improved patient-reported function. The Motec group demonstrated a significant improvement in

[1] Reference ranges from The Mayo Clinic Laboratories: https://www.mayocliniclabs.com/

wrist range of motion compared to pre-operative observations. This was not the case for ReMotion. There were also highly similar complication rates in the two groups with 6 re-operations in each group whereof 2 and 3 were revisions of prosthesis components in the ReMotion and Motec groups, respectively. In the Motec group, the revisions were caused by synovitis while the ReMotions had loosenings of the implants.

Complications were investigated in a retrospective study on 171 patients with an implanted Motec prosthesis that had an average time in follow-up of 5.8 years. There were 113 implanted metal-on-metal prostheses and 58 metal-on-PEEK. The implant survival in this study was 92% and the most common complication leading to revision was distal loosening of implants. There was no difference in revision or complication rates between the metal and the PEEK articulation materials (Redfern 2024).

All published clinical studies have investigated the outcome of the metal-on-metal (CoCrMo-CoCrMo) or the metal-on-PEEK articulation of the Motec Wrist Prosthesis. The clinical evidence for the UHMWPE cup is so far based on real-world data from smaller sets of patients with a maximum of 4 years in follow-up (un-published data). The UHMWPE material show similar outcomes as for the other cup materials in short-term follow-up.

5.2 Clinical data on the safety and performance of the Motec Wrist Arthrodesis

Since the Motec Wrist Arthrodesis utilises osseointegrated Threaded Implants already in place after an implanted Motec Wrist Prosthesis, the clinical evidence for safety and performance of the Motec Wrist Arthrodesis largely relies on the evidence presented above for the Prosthesis.

In addition, the Double Taper has been validated using cadaver bone and clinical case reports of successful fusions (unpublished). There is also three published cases using a similar custom-made peg (Reigstad 2017b) .

5.3 Overall clinical performance and safety

It can be concluded that the intended clinical benefits, performance, and safety of the Motec Wrist System have support in clinical data. It has been shown that the Prosthesis can be used for reduction of wrist pain and for a maintained wrist function. Complication frequencies of the Motec Wrist Prosthesis are in line with other wrist prostheses available on the market. Further, it has been demonstrated that the Motec Wrist Arthrodesis can be used as a salvage solution for a failed Motec Wrist Prosthesis.

The Motec Wrist Prosthesis is intended to be used for ten years but all devices included in the Motec Wrist System can remain in the body life-long in case that is beneficial for the patient. Currently, clinical evidence supports a functional wrist prosthesis after 10 years although there are expected complications that might reduce the lifetime of the device. Biological evaluation of the materials used in the Motec Wrist System, supports that the devices can remain in the body life-long.

5.4 Plans for future post-market clinical follow-up

Clinical studies are ongoing for a systematic follow-up of the long-term safety and performance of the most recent UHMWPE Radius Cup.

6 Possible diagnostic or therapeutic alternatives

Osteoarthritis, rheumatoid arthritis, traumatic arthritis as well as Kienböck's disease are all treated using nonoperative strategies such as pharmaceuticals and splints. If these strategies are inefficient to relieve pain, surgery may be considered. Surgical approaches include denervation, partial or complete fusion and proximal row carpectomy. In later stages of the disease, wrist joint arthroplasty or wrist fusion is considered. The choice of therapy is based on several factors such as symptoms, conditions of the joints in the wrist as well as patient lifestyle and preference.

In general, wrist fusion and wrist arthroplasties have been considered the last resort after other surgical treatments. Wrist fusions have been considered the gold standard treatment since it is usually reliable in relieving pain. However, as clinical results of wrist arthroplasties have improved, this method is used more frequently. A wrist arthroplasty has the advantage of preserving wrist motion while also relieving pain. On the other hand, some clinical studies have shown higher complication frequencies and re-operation rates compared to a wrist fusion.

7 Suggested profile and training for users

The Motec Wrist System is intended for professional use only. The intended users of the device are professional orthopaedic surgeons, hand surgeons and assistant surgical staff. Swemac requires all surgeons to complete a training session held by Swemac or its partners prior to use of the Motec Wrist System.

8 Reference to harmonised standards and common specification applied

See Annex A for a full list of harmonised standards applied to the Motec Wrist System. No common specifications were identified as applicable to the device.

9 Revision history

Doc. ID	Revision date	PSUR and CER versions from which the SSCP info is sourced	Description of main changes	Date submitted to Notified Body	Revision validated by the Notified Body
SSCP-P270-EN	20230928	PSUR 2022 – Motec Wrist Joint Systems, P125_P145_TF_10.3, Rev02. Clinical evaluation report, P270_TF_08.1 Rev03.	First version	29 Sep 2023	x Yes Validation language: English □ No (only administrative corrections of the SSCP)
SSCP-P270-EN	20251210	PSUR 2024 – Motec Wrist Joint Systems, P125_P145_TF_10.3, Rev01. Clinical evaluation report, P270_TF_08.1 Rev05.	Updated information in line with MDR approved technical documentation.	10 Dec 2025	x Yes Validation language: English □ No (only administrative corrections of the SSCP)
SSCP-P270-EN	20260126	PSUR 2024 – Motec Wrist Joint Systems, P125_P145_TF_10.3, Rev01. Clinical evaluation report, P270_TF_08.1 Rev05.	Administrative corrections	26 Jan 2026	□ Yes. Validation language: English x No (only administrative corrections of the SSCP)

10 References

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4. Redfern JAI, Mehta N, Farnebo S, McGuire D, Solomons M, Thomas Thorvaldson K, et al. Complication rates and modes of short and medium-term failure in Motec total wrist arthroplasty: an international cohort study. J Hand Surg Eur Vol. 2024;49(1):27-33.
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Annex A – Applied harmonised standards

Document ID	Document name
EN ISO 13485:2016 + A11:2021	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 14971:2019 + A11:2021	Medical devices — Application of risk management to medical devices (ISO 14971:2019)
EN ISO 15223-1:2021	Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 10993-1:2009 + AC:2010	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 11137-1:2015 + A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
EN ISO 11137-2:2015 + A1:2023	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
EN ISO 11607-1:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
EN ISO 11607-2:2020 + A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)
EN 556-1:2024	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 14602:2011	Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010)
EN ISO 14630:2012	Non-active surgical implants - General requirements (ISO 14630:2012)
EN ISO 16061:2009	Instrumentation for use in association with non-active surgical implants - General requirements (ISO 16061:2008 Corrected version 2009-03-15)

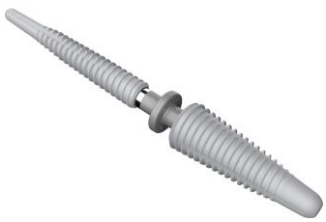
Annex B - Information for patients
Summary of Safety and Clinical Performance

Revision date: 26 Jan 2026

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information provided below is intended for patients or lay persons. A more extensive summary prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare provider in case you have questions about your medical condition or about having a device implanted in your particular situation. This SSCP is not intended to replace the information in your implant card or the advice and instructions you have received from healthcare providers.

1 General information

<table>
<tr><td>Device family:</td><td colspan="3">Motec Wrist System</td></tr>
<tr><td rowspan="5">Included configurations of devices:</td><td colspan="3">Motec Wrist Prosthesis
1 pc Radius Threaded Implant
1 pc Metacarpal III Threaded Implant
1 pc Radius Cup (available in CoCrMo, CRF-PEEK and UHMWPE)
1 pc Metacarpal Head</td></tr>
<tr><td>Radius Cup in CoCrMo</td><td>Radius Cup in CFR-PEEK</td><td>Radius Cup in UHMWPE</td></tr>
<tr><td>  </td><td>  </td><td>  </td></tr>
<tr><td colspan="3">Motec Wrist Arthrodesis
1 pc Radius Threaded Implant
1 pc Metacarpal III Threaded Implant
1 pc Double Taper (straight or angled)</td></tr>
<tr><td>Double Taper, straight</td><td colspan="2">Double Taper, angled</td></tr>
<tr><td>  </td><td colspan="2">  </td></tr>
<tr><td>Basic UDI-DI:</td><td colspan="3">7340111700014QC: Radius and Metacarpal III Threaded Implants
7340111700012Q8: Metacarpal Head, Radius Cup
7340111700013QA: Double Taper</td></tr>
<tr><td>Manufacturer:</td><td colspan="3">Swemac Innovation AB
Cobolgatan 1, SE-583 30 Linköping, Sweden
SRN: SE-MF-000000727</td></tr>
<tr><td>Year for first CE-marking:</td><td colspan="3">Radius and Metacarpal III Threaded Implants, Radius Cup and Metacarpal Head in CoCrMo: 2006
CFR-PEEK Radius Cup: 2013
UHMWPE Radius Cup: 2020
Double Taper: 2017</td></tr>
</table>

2 Intended use of the device

2.1 Intended purpose

The Motec Wrist System is intended to replace the wrist joint in adults with wrist pain or a dysfunctional wrist due to arthritis or Kienböck's disease. The arthrodesis solution is intended to be used for fusion of the wrist bones in case of a failed prosthesis.

The intended clinical benefits of the Motec Wrist Prosthesis are to provide wrist pain relief whilst improving wrist motion and function. For the Motec Wrist Arthrodesis the clinical benefit is an easy conversion from prosthesis to arthrodesis by taking advantage of pre-existing bone screws.

2.2 Contraindications

- Suspected or actual infection or local inflammation in the area requiring surgery.
- Sensitivity to the material in the implants.
- Interactions with other devices already implanted in the same area.
- Reduced blood supply, damaged skin or nerve function in the area requiring surgery.
- Weakened bone that cannot provide adequate support for the implant.
- The patient is unwilling or unable to follow healthcare provider advice on post-operative care and safe activities.
- Open fractures or infections in the joint.
- Use of the prosthesis in patients where surrounding tissue cannot provide adequate stability to the wrist.
- Use of the prosthesis in cases with fixed malposition of the wrist or wrist muscle imbalance.
- The implant must not be used if the patient has other physical, mental, medical or surgical conditions that would rule out the potential benefit of surgery.

3 Device description

The Motec Wrist System consists of a total wrist joint prosthesis (Motec Wrist Prosthesis) and an arthrodesis solution (Motec Wrist Arthrodesis) for fusion of the wrist bones if the prosthesis fails. All devices in the Motec Wrist System are sterilized during manufacturing.

3.1 Treatment principles

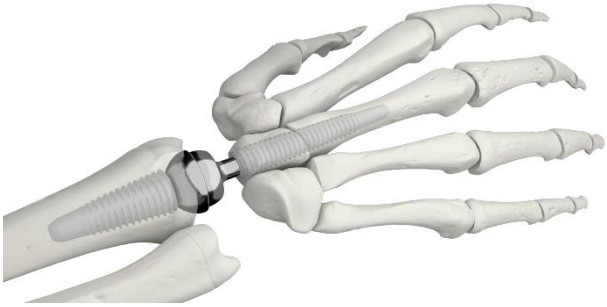
The Motec Wrist Prosthesis is implanted in the radius bone in the forearm and in the middle bone in the hand by screws (Fig. 1A). The screws are made from a titanium alloy with a rough surface covered by calcium phosphate to promote ingrowth in the bones. The artificial joint is made from a spherical head and a cup. The head is seated in the screw in the middle bone in the hand and the cup is seated in the screw in the radius bone. The head can rotate inside the cup in any direction, mimicking a natural motion of the wrist. The head and cup are made in metal (CoCrMo) and the cup are available in two optional plastic material inserts, carbon-reinforced polyetherether ketone (CFR-PEEK) or ultra-high molecular weight polyethylene (UHMWPE).

If the prosthesis fails, the head and cup of the prosthesis can be removed and replaced by the Motec Wrist Arthrodesis device. The arthrodesis device is a solid peg in titanium alloy called a Double Taper. The Double Taper connects the two bone screws and stabilizes the wrist while the bones heal into a stiff, immobile

wrist (Fig 1B). The Double Taper is available in a straight version and in a version with 15° angle to allow the wrist to be fused in a position tailored to the patient's preference.

All devices in the Motec Wrist System are intended to remain in the wrist for life.

A



B

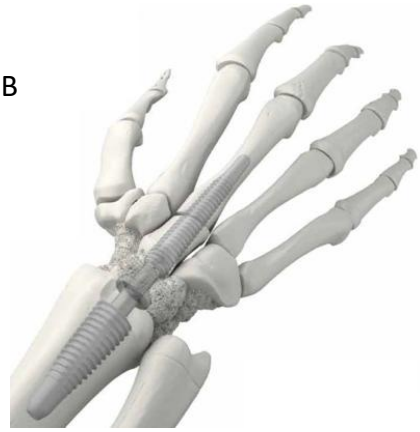


Figure 1: Implanted Motec Wrist Prosthesis (A) and Motec Wrist Arthrodesis (B).

4 Risks and side-effects

Please contact your healthcare provider if you think you are experiencing side effects from the implants, or if you are worried about risks. This information is not intended to replace any consultation with your healthcare professional.

The implants are continuously assessed regarding risks and reported side effects. Every means of preventing risks and side effects has been considered and applied as far as possible. However, implants can still have unwanted risks and side effects; see Table 1.

Table 1: Risks and side-effects from treatment with the Motec Wrist System.

Motec Wrist Prosthesis	
Risks and side effects	**Frequency**
Surgical procedure The implantation of a wrist prosthesis can lead to complications involving disturbed tendon and nerve functions. However, these complications can also be related to the underlying wrist arthritis condition. Complications that may occur after the implantation can include inflammation of the tendons, tendon adhesion and tendon rupture as well as nerve-related problems such as carpal tunnel syndrome and persisting pain. Re-operation may be required to treat these complications.	The frequency of complications related to the surgical procedure is currently not established. However, clinical studies have shown that the overall complication rate after having a Motec Wrist Prosthesis is similar to those observed for other wrist prostheses on the market.
Infection Infections at the implant site can appear months to years after implantation. Sometimes the infection can be traced to other sites, such as tooth infections, skin infections, or other bacteraemia. This risk is related to implantable devices in general, not specifically to the device properties of the Motec Wrist components.	In a clinical study of 171 Motec patients with an average time in follow-up of 6 years, 2% (two patients) had a re-operation due to an infection. In another study of 56 Motec patients followed for an average of eight years, 4% (two patients) had a reoperation to treat infections.
Wear-particles Particles released from the wear of the materials in the prosthesis may cause local inflammation in the wrist and/or loosening of the bone screws that may require additional surgery or potentially fusion of the wrist as a consequence.	Clinical studies have shown that the overall re-operation rate after having a Motec Wrist Prosthesis is in line with those observed for similar wrist prostheses on the market. There is no exact

Metal ions of cobalt, chromium and titanium may spread systemically, with the potential of causing elevated blood levels and systemic side-effects.	frequency established as to how many of these complications that are wear-particle-related. In a clinical study of 113 implanted metal cup prostheses and 58 PEEK (plastic) cup Motec prostheses, there were no difference in complication or surgical revision rates, indicating that both materials were equally safe. Clinical studies have shown that blood levels of cobalt and chromium are slightly elevated after implantation of the prosthesis when using the metal cup with a metal head. However, these studies did not report any metal blood levels that would be of concern for systemic toxicity. In rare cases, where the cup and head of the prosthesis did not function as intended, higher levels of metals have been observed in blood. However, also in these cases, the observed blood metal levels had a sufficient safety margin to blood levels that would be of concern for systemic side-effects.
Implant breakage There is a risk of breakage of the prosthesis components if the wrist is exposed to excessive force by for example patients falling and landing on the wrist.	Implant breakage is a rare event. In over 6500 sold Motec Wrist Prostheses, two incidents of implant breakages have been reported from users.
Loosening of bone screws Bone screws may become loose due to failure of the implant to integrate with the bone, wear-particles from the prosthesis or from instabilities caused by for example failure to achieve a fusion between the capitate and the third metacarpal bone. Loose bone screws may require re-operation.	Loosening of the bone screws have been investigated in clinical studies that report a frequency of 0-10%.
Wrist stiffness Post-operative wrist stiffness may occur as a consequence of implanting too large prosthesis components for the space available in the wrist. Revision surgery may be indicated to treat wrist stiffness.	There is currently no frequency established for this complication. However, the overall surgical revision rate of Motec is in line with those observed for similar wrist prostheses on the market.
Removal of implants Motec bone screws are intentionally designed to form a strong integration with the bones in the hand and wrist to provide stability for the prosthesis over many years. If the integrated bone screws would need to be replaced or removed, this firm bone integration confers a risk for complications, including fractures and removal of bone stock in the implanted bones. It is not deemed possible to reduce this risk further while still maintaining optimal functionality for the primary purpose of the device. The Motec arthrodesis solution (Double Taper) is designed to reduce the need for removal of integrated bone screws if there is a need for conversion of the prosthesis into to a fused wrist.	There is currently no frequency established of complications related to the removal of integrated bone screws.
Motec Wrist Arthrodesis – for wrist fusion after a failed Motec prosthesis	
Residual risks and side-effects	**Frequency**
Failed wrist fusion The procedure to fuse bones in the wrist can fail due to reasons related to the surgical procedure as well from too early post-operative wrist mobilisation or excessive patient activity during the post-operative phase. A failure to achieve wrist fusion may lead to implant breakage and the need for a reoperation.	Although the number of investigated patients is still limited, successful wrist fusion has been observed in all cases using the Motec arthrodesis device (Double Taper).

	There have been no reports of breakage of the Motec arthrodesis device (Double Taper) after >300 sold devices.
Malposition of the fused wrist Too early post-operative mobilisation of the wrist or failure to fixate the device during surgery may allow the angled arthrodesis device to rotate while the wrist is healing. This may result in an unintentional position of the fused wrist. In such cases, a reoperation may be required to adjust the position of the wrist.	In around 200 sold angled arthrodesis devices, the rotation of the device and an unintended position of the wrist have been reported from users in four cases.

4.1 Warnings and precautions

4.1.1 Warnings

The implants have not been tested for magnetic resonance imaging (MRI) scanning safety. To avoid the risk of injury or implant malfunction, patients with any Motec Wrist System implant must inform their healthcare provider about the implant and show them their implant card before having any MRI scan.

4.1.2 Post-operative care

Patients must be given individualised instructions from their healthcare provider concerning rehabilitation, care and follow-up. It is important for patients to follow the instructions provided. The patients should also be warned that the prosthesis cannot fully replicate a healthy anatomical joint.

4.1.3 Field safety of the device

All field actions that have been taken to prevent or reduce the risk of serious incidents related to the Motec Wrist System are listed in Table 3.

Table 3: Field safety actions taken in relation to the Motec Wrist System

Field Safety Notice	***Issuing date***	***Impacted regions***
Incidents related to wear-particle-induced inflammation when using the Metacarpal Head with a short neck size resulted in information to surgeons and health care providers of the risk and the instruction to apply a restrictive use of the short neck size.	2018	All
Certain manufactured batches of the Motec prosthesis with the PE (plastic) insert of the cup had to be re-called from the market due to an error in the manufacturing procedure. This error led to a risk for the PE insert of the cup not being properly seated in the outer metal shell of the cup.	Nov 2023	Individual hospitals depending on batches used in EEA, UK, Switzerland and Australia.
A new warning was added in the Instructions for Use and in the Surgical Technique to inform surgeons of risks related to the rotation of the angled Motec arthrodesis device that can lead to the fusion of the wrist in an unintended position.	Mar 2024	All

5 Summary of clinical evaluation and follow-up

The Motec Wrist Prosthesis has been used since 2006 and based on number of sold devices, around 6500 surgeries have been performed with the prosthesis world-wide. The Motec Wrist Arthrodesis device has been available since 2017 and is a more rarely implanted device since it is only intended to be used if the prosthesis fails. More than 300 surgeries have been performed using the arthrodesis device.

The clinical evidence for the safety and performance of the prosthesis mainly relies on four different clinical studies involving in total 270 patients. One of the studies followed patients for 8 years (range 5-11) and the other three studies followed patients for an average of 2, 4 and 5.8 years, respectively.

The clinical studies consistently show that on average, patients with a Motec Wrist Prosthesis have reduced pain and improved wrist mobility and function after surgery and the effects last for 8 years. However, complications were seen in all studies and the study with the longest follow up shows that it is expected that 86% of patients have an intact Motec Wrist Prosthesis ten years after surgery. The remaining 14% of patients had to exchange components of the prosthesis or had surgeries to fuse their wrist using an arthrodesis.

Clinical studies are ongoing for a systematic follow-up of the long-term safety and performance of the PE Radius Cup that was introduced on the market in 2020.

6 Alternative treatment options

When considering alternative treatments, you are recommended to contact your healthcare provider, who will be able to take your particular situation into account in giving you the best advice.

Arthritis of the wrist as well as Kienböck's disease are treated using nonoperative strategies such as pharmaceuticals and splints. If these strategies are inefficient to relieve pain, surgery may be considered. Surgical approaches include denervation, partial or complete fusion of wrist bones, resection of bones, implantation of a wrist joint prosthesis or fusion of the affected bones into a stiff wrist (arthrodesis). The choice of therapy is based on several factors such as symptoms, conditions of the joints and bones in the wrist as well as patient lifestyle and preference.

In general, wrist fusion and wrist joint prosthesis have been considered the last resort after other surgical treatments. Wrist fusions have been considered the gold standard treatment since it is usually reliable in relieving pain. However, as clinical results of wrist joint prostheses have improved, this method is used more frequently. A prosthesis has the advantage of preserving wrist motion while also relieving pain. On the other hand, some clinical studies have shown higher complication frequencies and re-operation rates compared to a wrist fusion.