

Wrist Joint Prosthesis System



Motec[®] Wrist Joint Prosthesis

The Motec[®] Wrist Joint Prosthesis has been designed with the objective to provide a strong, stable, mobile and pain free wrist while minimizing the risk of luxation, loosening and osteolysis.

The overall clinical results achieved with the Motec Wrist Joint Prosthesis are very promising. In the end of 2016, more than 1.000 surgeries have been performed. The longest follow-up time is +15 years. Recent studies indicate a survival rate of approximately 80% at 10 years follow up for OA-patients. (Ref. 1,5,11)

Fixation is achieved by threaded implants made of titanium alloy, blasted and coated with Bonit[®], which promotes osseointegration between the titanium oxide and the bone.

The articulation is modular and can be configured depending on surgeon and patient preference, either with CoCrMo articulation on CoCrMo or CoCrMo articulation on carbon fiber reinforced PEEK Motis[™].

Each component is available in different sizes, to allow firm seating and close replication of the patient's normal range of motion.

The Motec Wrist Joint Prosthesis is a product with world wide patent protection.

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 such as four corner fusion, proximal row carpectomy, or arthrodesis. (Ref. 2)

Features and benefits

The Motec Wrist Joint Prosthesis has the following features and benefits:

- Modular design
- State-of-the-art articulation
- Preserves soft tissue and ligament structures
- Improved short term fixation
- Optimized long term fixation through osseointegration
- Compatible wrist arthrodesis solution
- Fast and straightforward operative procedure
- Preserves the DRU joint

Modular design

The Motec Wrist Joint Prosthesis is completely modular in its design to give the surgeon maximum flexibility in matching the anatomy of the patient.

- The primary fixation in bone is achieved by threaded implants which are available in different sizes.
- The head component is available with several different neck lengths to enable fine tuning of the joint tension.
- The cup component is available in different materials depending on surgeon and patient preference.
 See page 6-7 for details.
- In case of failure of the prosthesis due to loosening of the Metacarpal Threaded Implant, continuing pain or abnormal soft tissue balance, the fully compatible Motec Wrist Joint Arthrodesis solution is available as a salvage procedure. See page 14 for details.

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The Radius Threaded Implant

is available in different sizes to allow matching of the radius anatomy.

Large Radius Threaded Implants, for salvage procedures or in cases with a very large radius, are not included in the standard Motec Wrist Prosthesis System

but can be ordered on request.

The Radius Cup is available in CFR-PEEK as well as in CoCrMo.

Metacarpal Threaded Implant

The Metacarpal Head Implant is available in two diameters and in

to adjust the tension of the joint.

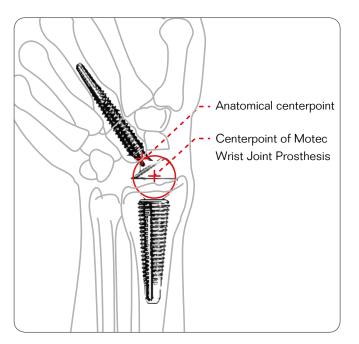
different neck lengths allowing the surgeon

is available in different sizes to match different anatomies.



Ball-and-socket design

- Allows 136°–160° range of motion (ROM). The articulation componets are available in different sizes and the ROM is depending on the choosen size.
- Increased stability, especially in patients with poor soft tissue.
- The ball and socket articulation prevents loosening of the osseointegrated implants by preventing transfer of rotational forces.
- Can resist forces that cause luxation
- Note that the Metacarpal Head with short neck should be reserved for previously failed PRC:s or other similar conditions, where the presented space in the wrist is tight and there is no other realistic alternative.



Center point of the Motec Wrist Joint Prosthesis

Closely replicates the anatomical center of rotation

The anatomical center point of rotation, in both radial-ulnar deviation and flexion-extension is located in the proximal part of the head of the capitate, near the lunate.

The Motec Wrist Joint Prosthesis places the center of rotation very close to the anatomical center point which is not the case for egg formed prosthesis. (Ref. 3)

... rotation occurs about a fixed axis located within the head of the capitate, and the location of each axis is not changed by the position of the hand in either plane.

Youm Y, McMurthy RY, Flatt AE, Gillespie TE.

An experimental study of radial-ulnar deviation and flexion-extension. J Bone Joint Surg Am. 1978 Jun;60(4):423-31

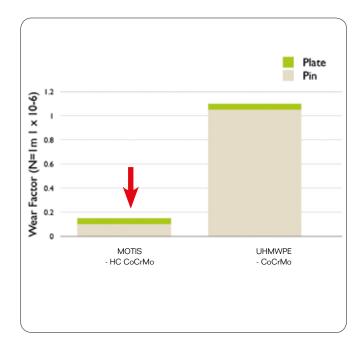
State-of-the-art articulation

Metal on carbon fiber reinforced PEEK

The Motec Wrist Joint Prosthesis also offers an articulation option where the Metacarpal Head is made from CoCrMo, and the Radius Cup is made from carbon fiber reinforced polyetheretherketone (PEEK Motis[™]). PEEK Motis has been specifically developed for bearing applications against hard counterfaces, such as CoCrMo.

Benefits of carbon fiber reinforced PEEK

- Exceptional wear performance supported by research and published data. (Ref. 4,13,14,15,16)
- Extensive testing to ISO 10993 standards demonstrates biocompatibility and biostability for use in long term implant applications
- The thin components allows preservation of bone
- An alternative to metal-on-metal combinations, which eliminates metal ion concerns
- Demonstrated resistance to gamma sterilization (does not become brittle over time like polyethylene)



Pin-on-plate screening of polymer against hard counterface combinations.

Source: Invibio Biomaterial Solutions



Motis[™] is a trademark of Invibio Biomaterial Solutions.

CFR-PEEK represents an alternative load-bearing material because of its superior mechanical and chemical behaviour without any increased biological activity of the wear particles, compared with a standard load-bearing material.

Utzschneider S, Becker F, Grupp TM, Sievers B, Paulus A, Gottschalk O, Jansson V.

Inflammatory response against different carbon fiber-reinforced PEEK wear particles compared with UHMWPE in vivo. Acta Biomater. 2010 Nov;6(11):4296-304





Weartest has been performed for both MoM (metal on Metal) and MoP (Metal on Plastic) at test laboratory in Sweden and Germany.

Metal on metal

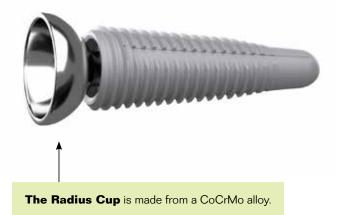
The articulation components have been optimized for biocompatibility and minimized wear rate, to reduce the risk of osteolysis typically associated with polyethylene and conventional metal-on-metal bearings.

The Motec Wrist Joint Prosthesis offers an articulation option where the Metacarpal Head is made of cobalt chromium molybdenum alloy (CoCrMo) and the Radius Cup is made of CoCrMo.

Benefits of metal on metal

- The thin components allows preservation of bone
- Demonstrated resistance to gamma sterilization (does not become brittle over time like polyethylene)
- Metal ions released in blood have been monitored in Motec patients at two independent hospitals. The mean follow up time is 4.6 years. The data shows that the mean amount of cobalt and chromium in blood was 0.7 µg/l. According to MHRA guidelines, the levels of metal ions released in the blood should not exceed 7ug/L for metal-on-metal hip prosthesis. (Ref. 19)





Limited bone resection

• Saves joint space

The ball-and-socket components are less bulky than conventional polyethylene on metal components.

• Compatible arthrodesis

The limited bone resection ensures that a secondary arthrodesis procedure can be performed. This procedure can also be further simplified by the Motec Wrist Arthrodesis device, which utilizes the existing threaded implants for fixation whenever possible. (See page 14 for details)



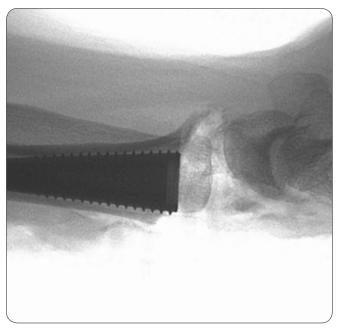
Preserves soft tissue and ligament structures

• Maintained joint stability

Most of the soft tissue and ligament structures between the radius, ulna and the carpal bones are preserved, maintaining the natural stability of the wrist. The distal radio-ulnar joint is unaffected by the presence of the wrist prosthesis. The peripheral rim of the distal radius is preserved, along with its important ligamentous and soft tissue attachments.



Improved short term fixation



The threads of the conical Radius Threaded Implant engage into the cortical bone, volarly and dorsally, preventing the implant from sinking. Immediate primary fixation in cortical bone Immediate primary fixation is achieved by threaded implants. The design of the threaded implants has been optimized for maximum bone purchase.

• Cementless fixation

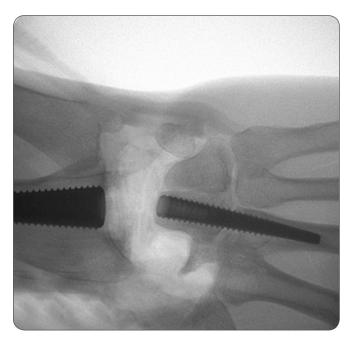
The cementless fixation of the components simplifies the surgical procedure and eliminates potential cement related complications.

• Promoting bone formation

The conical shape distributes the forces evenly into the cancellous and cortical bone, thereby promoting bone formation.

Prevents fractures

The non-threaded distal 1/3 of the threaded implants prevents fractures by being non-threaded, especially at the isthmus in the third metacarpal. The rounded tip of the threaded implants reduces stress concentration.

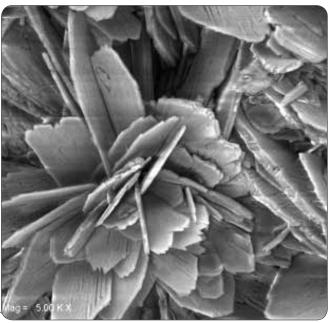


The threads of the conical Metacarpal Threaded Implant engage into the cancelleous and cortical bone of the capitate and the third metacarpal, ensuring a stable fixation. Fusion of the midcarpal bones is only needed between the capitate and the third metacarpal.

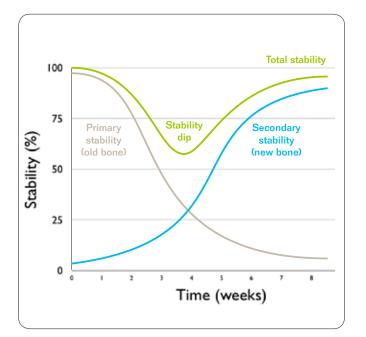
Optimized long term fixation and osseointegration

- Optimal blasting of titanium alloy implants improves long term fixation and osseointegration (Ref. 7,17). The titanium surface is blasted with extra pure Al2O3 using a specific technique and to a specific roughness value to maximize the bone ingrowth.
- The titanium alloy threaded implants are coated with Bonit[®], a resorbable calcium phosphate combination with proven osteoconductive properties, improving long term fixation.



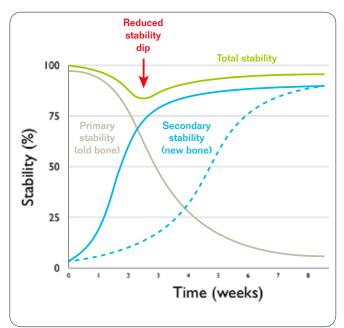


The implants are coated with a Bonit layer of 20-30 $\mu m.$



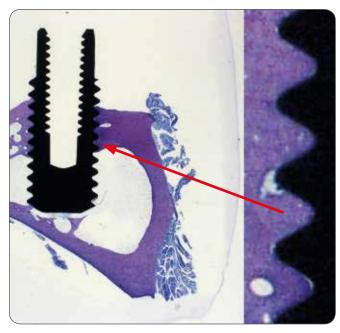
Without Bonit

Without Bonit there would be a significant reduction in stability 2-5 weeks postoperatively. This dip coincides with the release of the plaster, thereby increasing the risk of loosening.



With Bonit

Bonit promotes early formation of new bone, thereby reducing the risk of loosening. (Ref. 8,9,10)



In vivo biomechanical comparison of Bonit versus Hydroxyapatite

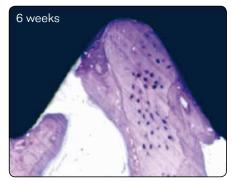
Titanium screws coated with Bonit and screws coated with hydroxyapatite (HA) were implanted in the proximal tibia of a rabbit, for the purpose of comparing the increase of fixation over time.

The fixation of the Bonit coated screws increased significantly over time (6 to 12 to 52 weeks) whereas the screws coated with HA showed no increase in fixation after 6 weeks.

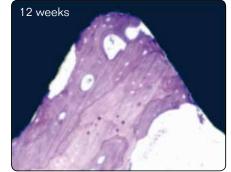
After 52 weeks, the Bonit layer was fully resorbed (Ref. 8).

Implant in black and bone in purple.

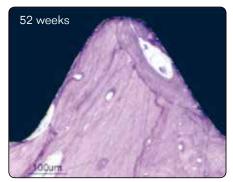
Bonit



The Bonit layer is partly resorbed.

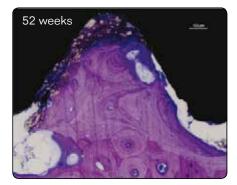


The Bonit layer is no longer visible.



The Bonit layer is fully resorbed. Osseointegration has taken place between the titanium oxide layer and bone.

HA coating



In contrast to the fully resorbable Bonit, the HA-layer and particles are loosening from the titanium surface. Giant cell, macrophages are visible.

Problems with long term fixation using HA coating on implants have also been shown in a thesis by M. Røkkum (Ref. 10).

Case



Articulation with CoCrMo on CoCrMo.



Articulation with CoCrMo on carbon fiber reinforced PEEK.

Five- to 10-Year Prospective Follow-Up of Wrist Arthroplasty in 56 Nonrheumatoid Patients

Reigstad O, Holm-Glad T, Bolstad B, Grimsgaard C, Thorkildsen R, Røkkum M.

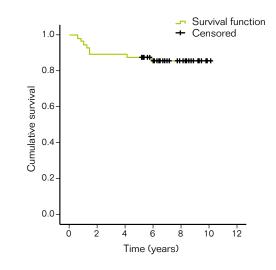
J Hand Surg Am. 2017

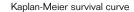
Abstract

Fifty-seven (40 male) patients with end-stage arthritis changes received an uncemented ball-and-socket total wrist arthroplasty (Motec Wrist). Function was evaluated before surgery and at yearly follow-ups. Visual analog scale at rest and activity, quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH), active range of motion (AROM), and grip-strength were recorded. Standardized radiographs were taken to assess osteolysis, loosening, and subsidence.

Fifty-six patients were followed for a mean of 8 years (SD, 2 years). Eight wrists were reoperated with arthrodesis (4) or a new arthroplasty (4) owing to distal component loosening (3), infection (2), pain/fixed malposition (2), or proximal and distal component loosening (1). One radiocarpal dislocation was reduced closed and remained stable. Improved QuickDASH score and visual analog scale pain score both at rest and during activity were found at the last follow-up, as well as increased AROM (97 vs 126) and grip strength (21 kg vs 24 kg). The radiological follow-up demonstrated loosening in 2 wrists. Thirty-five patients were working at surgery (17 manual labor) and 27 (11 manual labor) at follow-up. The 10-year Kaplan-Meyer survival of the implants was 86% for revision any cause, 2 additional arthroplasties are loose (but not revised), giving a survival rate of 82% if these are revised prior to 10 years of observation.

An uncemented total wrist arthroplasty can provide long-lasting unrestricted hand function in young and active patients.





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Fully compatible salvage procedure

Motec Wrist Joint Arthrodesis

The Motec Wrist Joint Arthrodesis has been developed as a part of the Motec Wrist Joint Prosthesis family to enable conversion of the prosthesis to a total wrist fusion, if the need should arise. (Ref. 12)

The Motec Wrist Joint Arthrodesis implant is intended to be used as a salvage procedure for the Motec Wrist System, using the pre-existing prosthesis implants. Removal of bone during primary procedures, bony erosion, and bone loss during implant extraction will otherwise decrease the bone stock that is available for arthrodesis.

The intramedullary Motec Wrist Arthrodesis System has been developed to overcome the problem of soft tissue irritation in wrist fusions and thereby minimize the need for unnecessary implant removal.



Post op; 4,3 years. Motec Wrist Joint Arthrodesis, Straight Double Taper.

The Motec Wrist Joint Arthrodesis offers three different options

The Motec Wrist Joint Arthrodesis is suitable in several cases. When the Metacarpal Threaded Implant is loose, the first option is always to insert a new, longer Metacarpal Threaded Implant, if prosthesis still is the optimal choice for the patient.

> Depending on the patient and the implant situation, three different options of Motec Wrist Joint Arthrodesis are available. The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment.

Conversion of a failed total wrist arthroplasty to arthrodesis can be difficult. A custom made titanium alloy peg was constructed to enable arthrodesis with the original arthroplasty components in situ. Two out of three patients were especially challenging cases with little bone available. Bony union was achieved in 2 to 3 months. The peg simplified a difficult revision situation and gave good, predictable results at follow-up.



Reigstad O, Røkkum M.

Conversion of Total Wrist Arthroplasty to Arthrodesis with a Custom-Made Peg J Wrist Surg 2014;3:211–215

Double Taper

Requirements: Fixed Radius Threaded Implant and fixed Metacarpal Threaded Implant.

 Fixation of the Radius Threaded Impant and Metacarpal Threaded Implant but failure of the Motec Wrist Prosthesis for other problems such as continuing pain or abnormal soft tissue balance.

Metacarpal Taper & Radius Connector

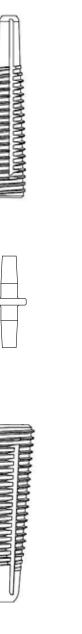
Requirements: Fixed Radius Threaded Implant and fixed Metacarpal Threaded Implant.

 Fixation of the Radius Threaded Impant and Metacarpal Threaded Implant but failure of the Motec Wrist Prosthesis for other problems such as continuing pain or abnormal soft tissue balance.

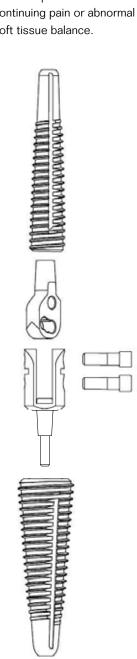
Metacarpal Nail & Radius Connector

Requirements: Fixed Radius Threaded Implant.

 If the Metacarpal Threaded Implant is loose or otherwise unsuitable.

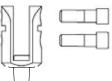


See separate sales borchure "Motec Wrist Joint Arthrodesis System" for details.



See separate sales borchure "Motec Wrist Joint Arthrodesis System" for details.







See separate sales borchure "Motec Wrist Joint Arthrodesis System" for details.

Product information

- Needed for CFR-PEEK articulation
- Needed for CoCrMo articulation

Implants			
Radius Cup CoCrMo Ø15 mm	40-1015S	•	
Radius Cup CoCrMo Ø18 mm (optional)	40-1018S	•	
Radius Cup CFR-PEEK Ø15 mm	40-1915S	٠	
Metacarpal Head Ø15 mm Short Neck (optional)	40-1115S	• •	
Metacarpal Head Ø18 mm Short Neck (optional)	40-1118S	•	
Metacarpal Head Ø15 mm Medium Neck	40-1715S	• •	
Metacarpal Head Ø18 mm Medium Neck (optional)	40-1718S	•	
Metacarpal Head Ø15 mm Long Neck	40-1215S	• •	
Metacarpal Head Ø18 mm Long Neck (optional)	40-1218S	•	
Metacarpal Head Ø15 mm Extra Long Neck	40-1315S	••	
Radius Threaded Implant length 32 mm	40-1332S	• •	
Radius Threaded Implant length 38 mm	40-1338S	••	
Radius Threaded Implant length 44 mm	40-1344S	• •	
Radius Threaded Implant length 50 mm	40-1350S	• •	
Radius Threaded Implant length 56-80 mm (optional)			
Metacarpal Threaded Implant length 45 mm Large	40-1445S	• •	
Metacarpal Threaded Implant length 50 mm Large	40-1450S	• •	
Metacarpal Threaded Implant length 55 mm Large	40-1455S	• •	
Metacarpal Threaded Implant length 60 mm Large	40-1460S	••	

Metacarpal Threaded Implant length 65 mm Large (optional)	40-1465S	
Metacarpal Threaded Implant length 70 mm Large (optional)	40-1470S	
Metacarpal Threaded Implant length 45 mm Small	40-1475S	
Metacarpal Threaded Implant length 50 mm Small	40-1480S	
Metacarpal Threaded Implant length 55 mm Small	40-1485S	
Metacarpal Threaded Implant length 60 mm Small	40-1490S	
Metacarpal Threaded Implant length 65 mm Small (optional)	40-1495S	
Metacarpal Threaded Implant length 70 mm Small (optional)	40-1400S	
Trials		

Trial – Radius Cup Ø15 mm	40-1522	•	
Trial – Radius Cup Ø18 mm (optional)	40-1521	•	
Trial – Radius Cup Ø15 mm For CFR-PEEK Cup	40-1541	٠	215
Trial – Metacarpal Head Ø15 mm Short Neck (optional)	40-1529	• •	
Trial – Metacarpal Head Ø18 mm Short Neck (optional)	40-1527	•	
Trial – Metacarpal Head Ø15 mm Medium Neck	40-1524	• •	I
Trial – Metacarpal Head Ø18 mm Medium Neck (optional)	40-1523	•	
Trial – Metacarpal Head Ø15 mm Long Neck	40-1528	• •	
Trial – Metacarpal Head Ø18 mm Long Neck (optional)	40-1526	•	
Trial – Metacarpal Head Ø15 mm Extra Long Neck	40-1602	••	

Instruments			
Hohmann Retractor	40-1503		
Bits 3,5 mm HEX with Quick-Lock	40-1513	• •	
Impactor	40-1516	••	
Guide Wire T-handle	40-1518	• •	•
Cup Remover	40-1519	••	
Cannulated Drill for Radius 32-50 mm	40-1546		
Cannulated Drill for Metacarpal III 45-70 mm Large	40-1551		
Cannulated Drill for Metacarpal III 45-70 mm Small	40-1552		
Guide Wire with sharp tip Ø2 mm	40-1561	• •	
Guide Wire with round tip Ø2 mm	40-1563	••	
Radius Spherical Drill Ø18 mm (optional)	40-1566	•	
Radius Spherical Drill Ø15 mm	40-1567	••	
Handle Tri-Lobe with Quick-Lock	45-2585	••	
Handle Tri-Lobe with Ratchet (optional)	40-2593	••	
Adapter, from AO male to Tri-Lobe female (optional)	40-5000	••	
Hammer	52-2211	••	
Awl	62-3070	• •	
Tray and lid	40-1600	• •	

IFU

For the latest version of this Instruction For Use. Please visit: http://download.swemac.com/Motec-Wrist-Joint-Prosthesis

Swemac develops and promotes innovative solutions for fracture treatment and joint replacement. We create outstanding value for our clients and their patients by being a very competent and reliable partner.



Motec Wrist Joint Prosthesis

Manufacturer

€€ 0413

Swemac Innovation AB Cobolgatan 1 · SE-583 35 Linköping · Sweden

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



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