Motec®

Wrist Joint Prosthesis System

Swemac

Motec®

Wrist Joint Prosthesis

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

The overall clinical results achieved with the Motec Wrist Joint Prosthesis are very promising. As of December 2019, it is estimated that over 1800 arthroplasties have been implanted. The longest follow-up time is +15 years. Recent studies indicate a survival rate of approximately 80% at 10 years follow up for non-rheumatoid patients. [1, 2, 3, 4]

Fixation is achieved by threaded implants made of titanium alloy. The surface is blasted and coated with Bonit®, a resorbable calcium phosphate coating 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.

Each component is available in different sizes to allow firm seating and replicate the patients normal range of motion as closely as possible.

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

Indications

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

Features and benefits

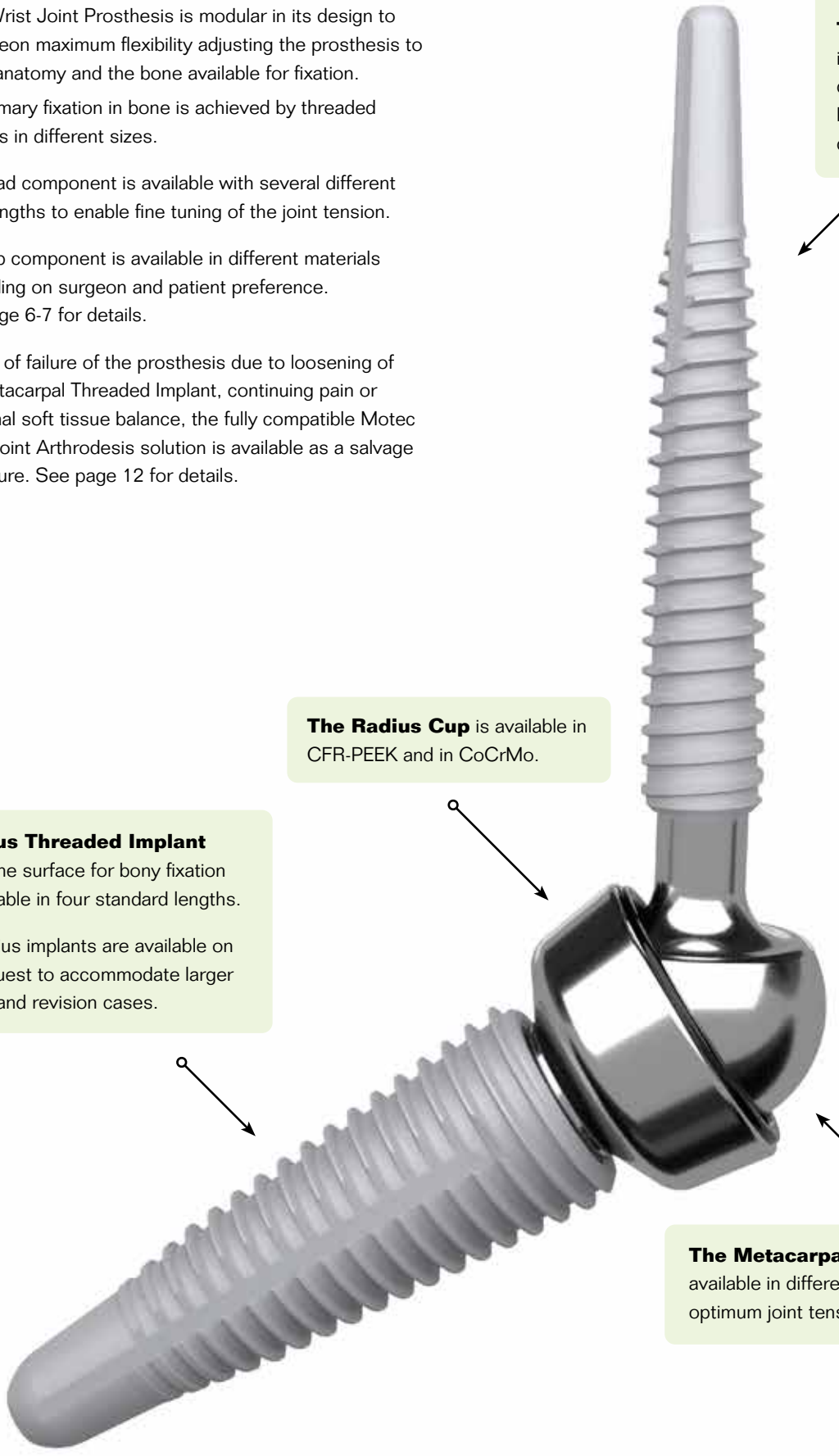
The Motec Wrist Joint Prosthesis has the following features and benefits:

- Modular design
- Minimized risk of luxation
- Preserves soft tissue and the DRU joint
- Low risk for osteolysis
- State-of-the-art articulation
- Optimized osseointegration and long term fixation
- Optimized short term fixation
- Straightforward operative procedure
- Allows Dart Thrower´s Motion
- Compatible wrist arthrodesis solution

Modular design

The Motec Wrist Joint Prosthesis is modular in its design to give the surgeon maximum flexibility adjusting the prosthesis to the patients anatomy and the bone available for fixation.

- The primary fixation in bone is achieved by threaded implants 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 12 for details.



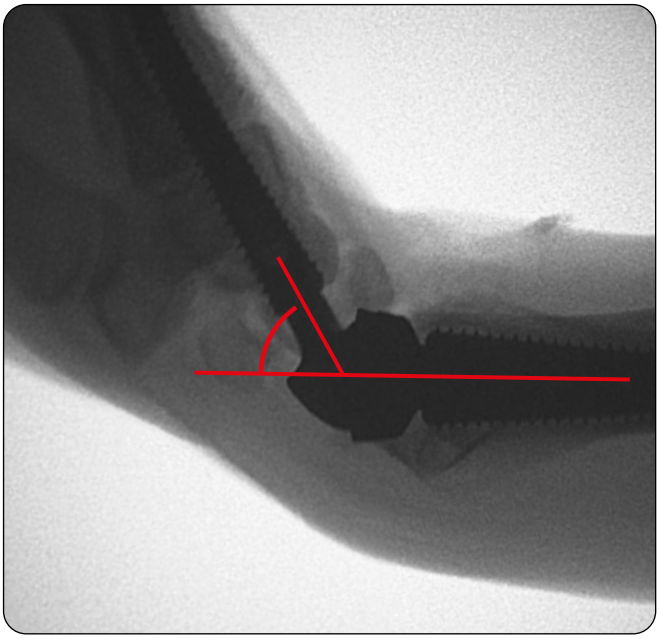
The Metacarpal Threaded Implant is available in two diameters and six lengths to match different anatomies.

The Radius Cup is available in CFR-PEEK and in CoCrMo.

The Radius Threaded Implant increases the surface for bony fixation and is available in four standard lengths.

Larger Radius implants are available on special request to accommodate larger anatomies and revision cases.

The Metacarpal Head implant is available in different neck lengths to allow optimum joint tension to be achieved.

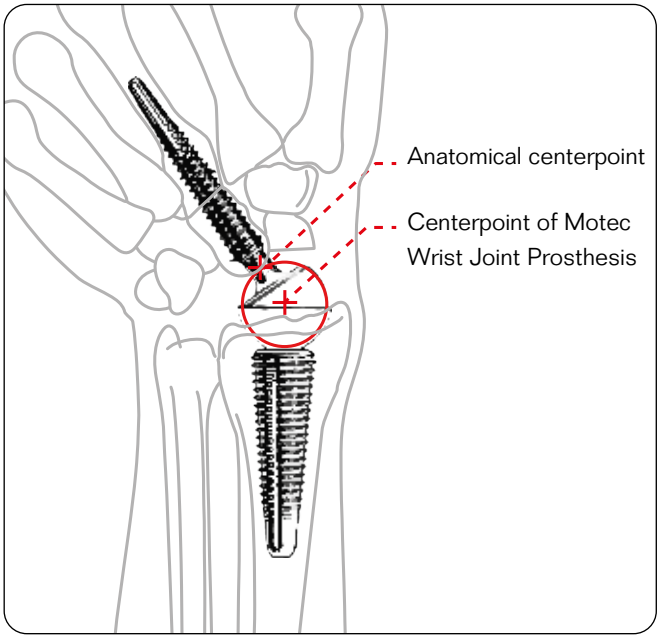


Ball-and-socket design

- Allows up to 80° theoretical range of motion (ROM) in all directions. The articulation components are available in different sizes and the ROM is dependent on the chosen size.
- Provides optimal stability and reduces the risk of luxation.
- The ball and socket articulation prevents transfer of rotational forces, thereby reducing the risk of loosening of the osseointegrated implants.
- Allows Dart Thrower's Motion (see page 11 for details).

Preserves soft tissue and the DRU joint

- **Joint stability**
  Much of the soft tissue and ligament structures can be preserved during the surgery. The DRUJ meanwhile is unaffected along with the volar soft tissue structures. This, together with the inherent stability of the implants, secures optimal articulation conditions.



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. [6]

> *... 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

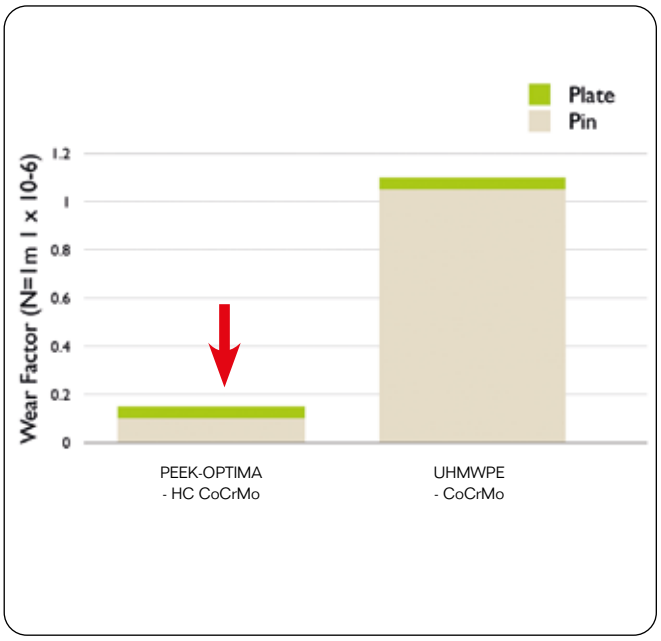
State-of-the-art articulation

Metal on carbon fiber reinforced PEEK

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

Benefits of carbon fiber reinforced PEEK

- Excellent wear performance supported by research and clinical data. [7, 8, 9, 10, 11]
- Biocompatible in accordance to ISO 10993.
- Small components allows preservation of bone and optimal tension adjustments.
- Optimal sterilization qualities (resistant to gamma sterilization and does not become brittle over time).



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

Source: Invibio Biomaterial Solutions

PEEK OPTIMA™ Wear Performance Polymer 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

Laboratory wear test demonstrated very low wear rates.

Metal on metal

The Motec Wrist Joint Prosthesis also offers an articulation option where both the Metacarpal Head and the Radius Cup are made from CoCrMo. This metal on metal articulation has been optimized for biocompatibility, minimal wear and reduced risk of osteolysis and loosening.

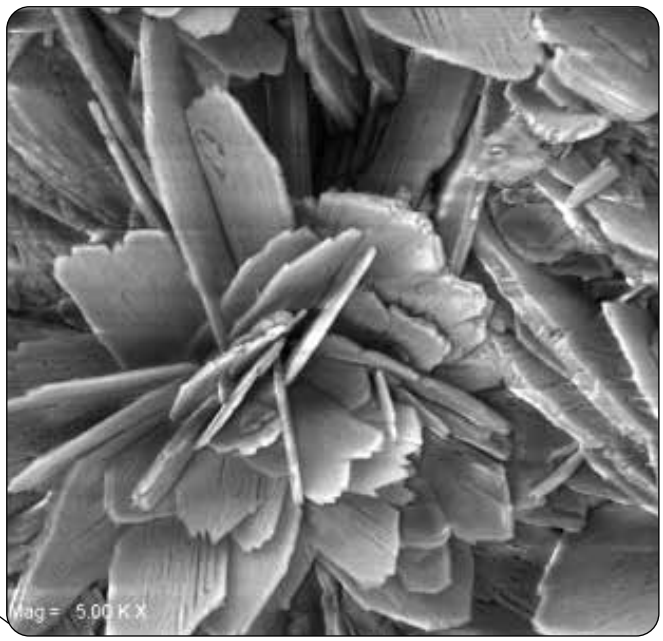
Benefits of metal on metal

- The small components allows preservation of bone
- Demonstrates resistance to gamma sterilization (does not become brittle over time like standard polyethylene)
- The problem with high wear, as seen in hip arthroplasty metal on metal solutions, has not been identified with the use of Motec Wrist Prosthesis. Metal ions in blood have been monitored in patients and the measured levels of chrome and cobalt were 0.7 µg/l. This is far below the guideline levels for the hip prostheses. (According to the MHRA guidelines the levels of metal ions released in the blood should not exceed 7ug/L for metal-on-metal hip prosthesis [12, 13]).

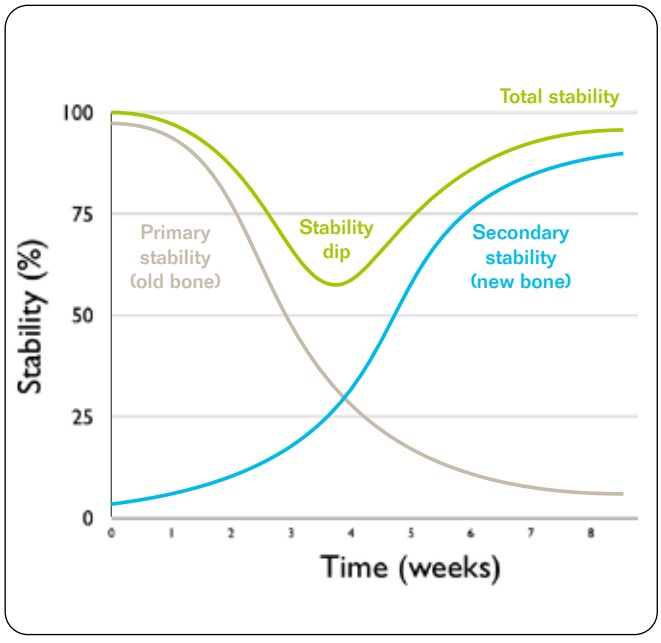
The Radius Head and Cup in highly polished, wear resistant CoCrMo. The Cup has a smooth rim to minimise impingement wear.

Optimized osseointegration and long term fixation

- Optimal blasting of titanium alloy implants improves long term fixation and osseointegration [14, 15]. The surfaces of the threaded implants are blasted with extra pure Al2O3 to achieve a specific roughness to maximise bone ingrowth.
- The titanium alloy threaded implants are coated with Bonit, a resorbable calcium phosphate combination with proven osteoconductive properties, to improve long term fixation.

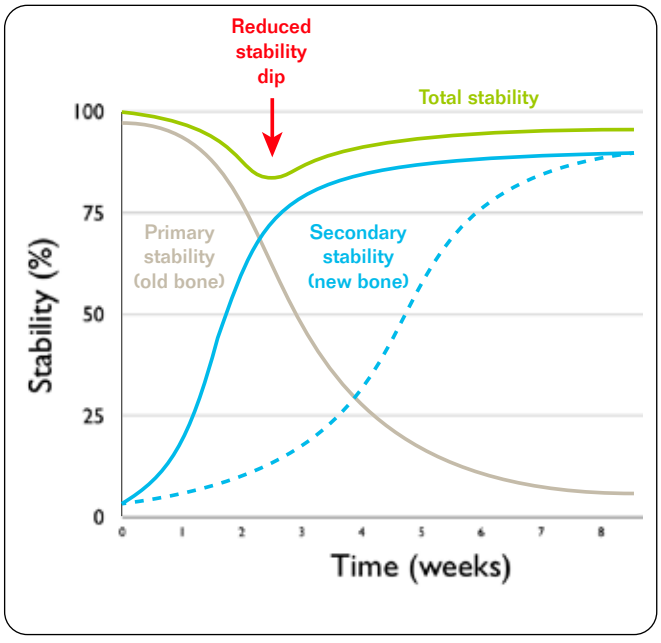


The implants are coated with a Bonit layer of 20-30 µm.



Without Bonit

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

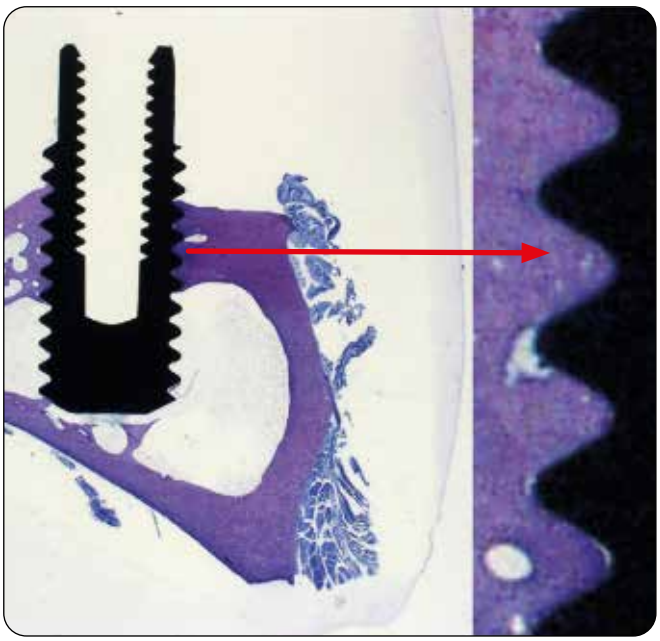


With Bonit

Bonit promotes early formation of new bone, thereby reducing the risk of loosening. [16, 17] (*)

Bonit® is a registered trademark of DOT GmbH.

(*) This is a principal theoretical model of the accelerating healing process and stability dip. No specific datapoint is scientifically proven.



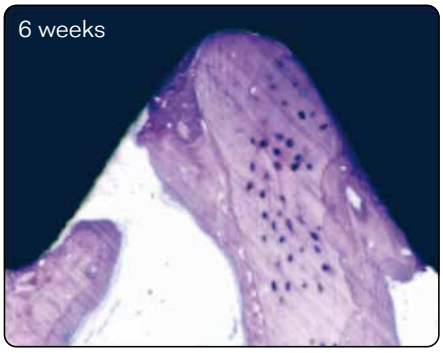
Implant in black and bone in purple. The Bonit layer is too thin to be visible.

In vivo biomechanical studies of Bonit

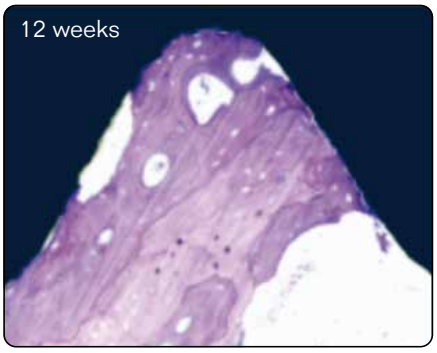
Animal studies and clinical trials have proven the impressive efficacy of Bonit coating. Accelerated implant healing, increased bone formation and improved mechanical implant anchoring have been observed, especially in the early post-implant phases. This means that the load bearing properties of the implant are robust at an early stage.

The Bonit coating is completly resorbed in a controlled way (approximately 6 to 12 weeks following implantation) and is simultaneously replaced by bone.

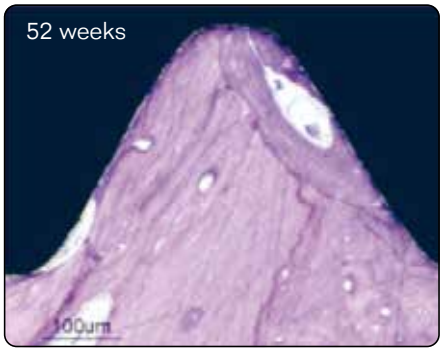
Osseointegration of titanium oxide coated with Bonit - Timeline



The Bonit layer (too thin to be visible in the photo) is partly resorbed and the osseointegration have started.



The Bonit layer is fully resorbed and the bone will keep growing around the implant.

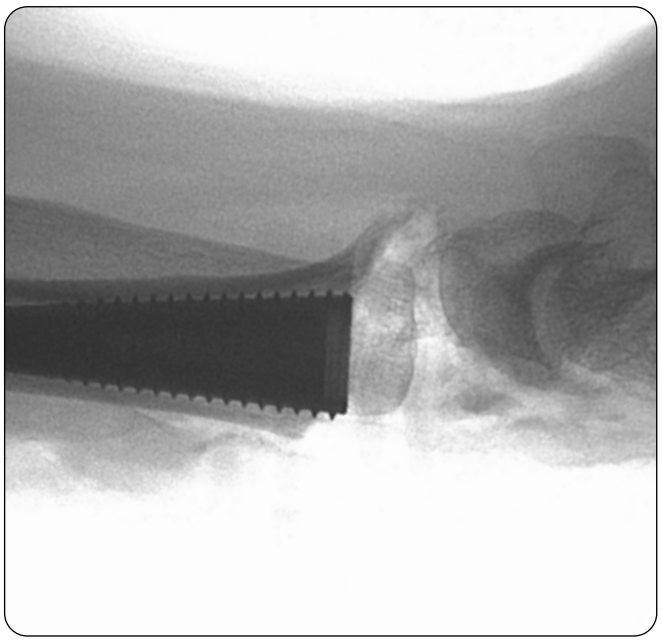


Osseointegration has taken place between the titanium oxide layer and bone.

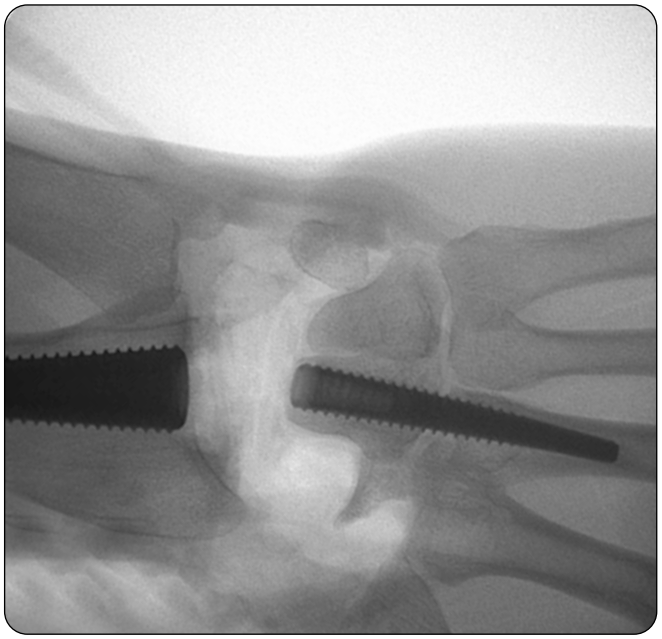
Features and benefits

- Outstanding biocompatibility
- Thin coating
- Microcrystalline structure, large open surface
- High solubility and controlled resorption area
- 100% coverage of porous surfaces and complex implant geometries
- No particle shedding or flaking

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.



The threads of the conical Metacarpal Threaded Implant engage into the cancelleous and cortical bone of the capitate and the third metacarpal. Fusion of the third CMC joint ensures a stable fixation.

- **Cementless fixation**
  The cementless fixation of the components simplifies the surgical procedure and eliminates potential cement related complications.
- **Immediate primary fixation**
  Immediate primary fixation is achieved by threaded implants. The design of the threaded implants has been optimized for maximum bone purchase.
- **Promoting bone formation**
  The conical shape distributes the forces evenly into the cancellous and cortical bone, thereby promoting osseointegration.
- **Fracture prevention**
  The non-threaded distal third of the metacarpal implant reduces stress concentration, especially in the metacarpal isthmus, thereby reducing the risk of fracture.

Dart Thrower's Motion

Introduction

A Biomechanical study was performed at Flinders University, Adelaide Australia, by Associate Professor John Costi and Professor Gregory Bain, with 10 matched specimens (5 left, 5 right) to determine the Dart Thrower's Motion with the Motec Wrist Joint Prosthesis [1]. The intact normal wrist specimens were mounted in the Hexapod robot [2] and the wrist range of motion and biomechanical behavior were evaluated in six degrees of freedom. Assessments were repeated following insertion of the Motec Wrist Joint Prosthesis.

Wrist mounted in Hexapod robot

Background

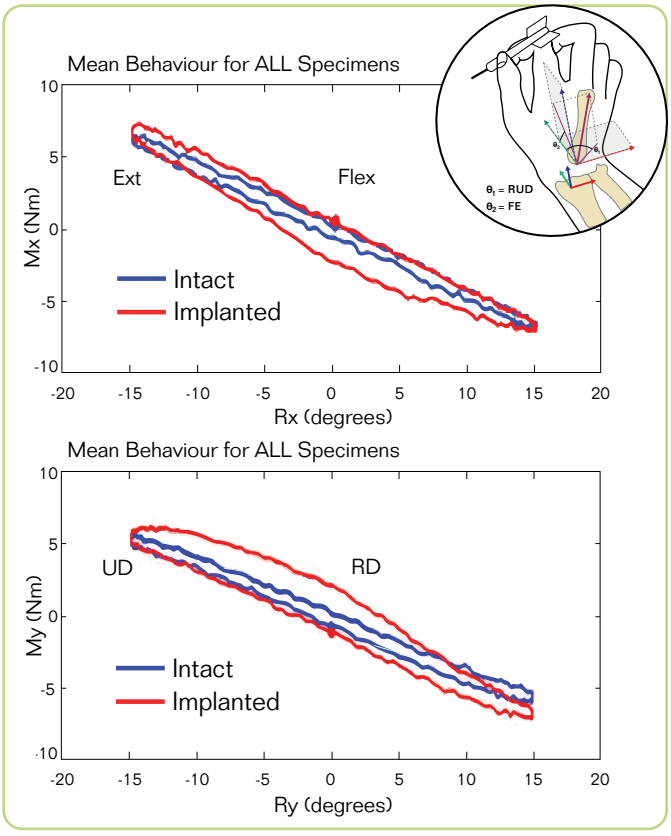
Dart Thrower's Motion (DTM) has been identified as an important motion to perform normal daily activities [3]. The 3rd generation wrist arthroplasties with an anatomical articulation of the radiocarpal joint are not really designed to reproduce the dart throwers motion. The Motec Wrist Joint Prosthesis is a new generation prosthesis with a spherical articulation which allows mobilization in any direction, including the dart thrower's motion.

Conclusion

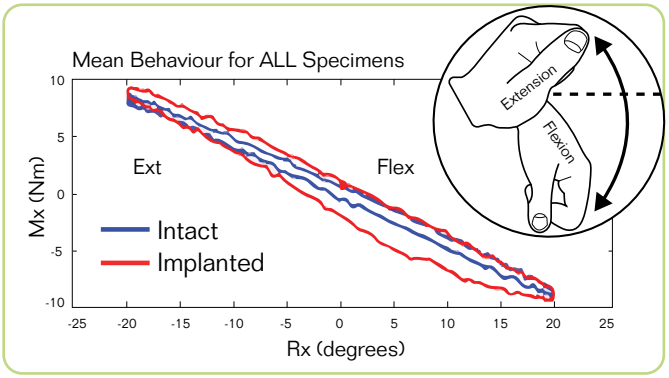
Within the range of motion tested, Motec Prosthesis:

- Allows Dart Throwing Motion [1].
- Allows flexion / extension [1].
- Allows radial / ulnar deviation [1].
- The constrained ball and socket joint creates a fixed center of rotation. Surgical technique should aim to closely recreate the normal center of rotation [1].

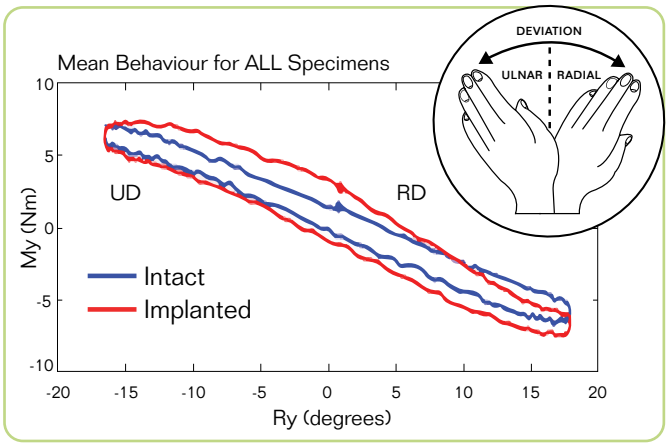
Dart Throwers: Component of Motion



Flexion-extension: Load vs Displacement behaviour



Radial-ulnar Deviation: Load vs Displacement behaviour



[1] Costi, J., and Bain, G. Biomechanical Assessment of the Motec Wrist Joint Prosthesis, Report ID: 101218-BIL, 2018."

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[3] Scott W. Wolfe et al. The Dart-Throwing Motion of the Wrist: Is it Unique to Humans? J Hand Surg Am, 2006.

Compatible salvage procedure

Motec Wrist Joint Arthrodesis

The Motec Wrist Joint Arthrodesis System has been developed to enable easy conversion of the Motec Wrist Joint Prosthesis to a total wrist arthrodesis [19].

The system provides salvage options that limit unnecessary implant removal by taking advantage of pre-existing stable and osseointegrated implants from the Motec Wrist Joint Prosthesis. This preserves the bone available for arthrodesis by minimising bone loss which would otherwise occur during removal of well-fixed implants. The intramedullary system has been developed to reduce soft tissue irritation from hardware and the associated need for secondary implant removal.

The Motec Wrist Joint Arthrodesis System is a patented product with worldwide protection.

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

The different techniques of Motec Wrist Joint Arthrodesis

The Motec Wrist Joint Arthrodesis System is suitable in several cases and has three different options available depending on the patient and implant situation. The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment.

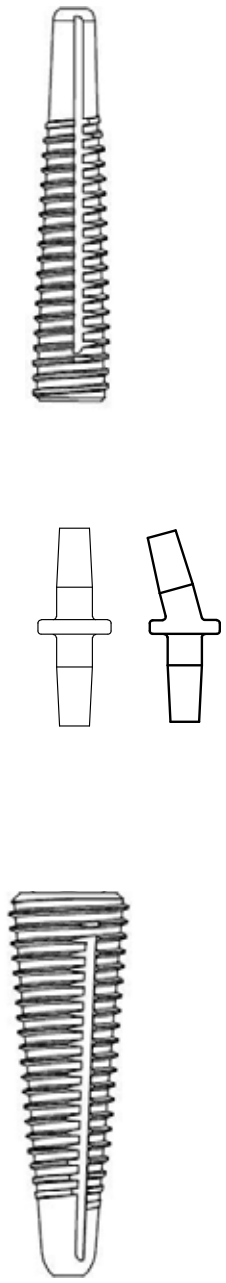
"Conversion of a failed total wrist arthroplasty to arthrodesis can be difficult. A custom made titanium alloy peg was constructed to enable arthrodesis with the original arthroplasty components in situ. Two out of three patients were especially challenging cases with little bone available. Bony union 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

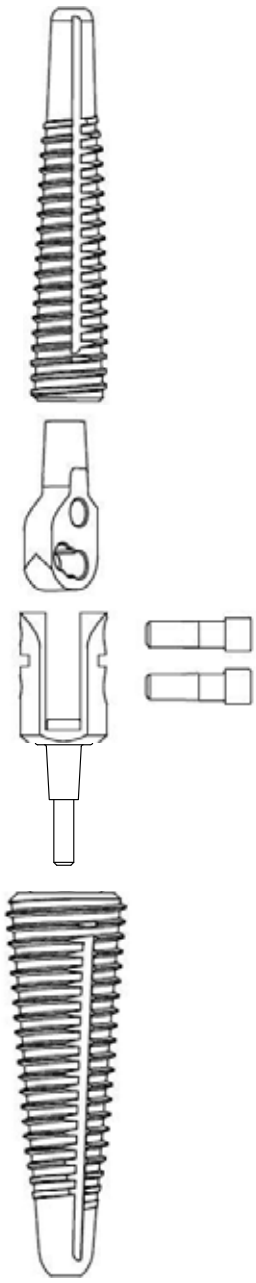
Double Taper
(Straight & Angled)

Indications: Stable and osseointegrated radius and metacarpal components, failure of articulation (for example pain, soft tissue imbalance or wear problems).



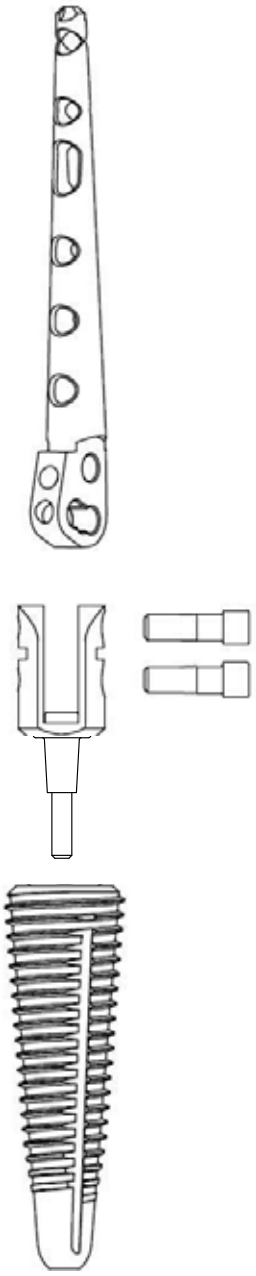
Metacarpal Taper & Radius Connector

Indications: Stable and osseointegrated radius and metacarpal components, failure of articulation (for example pain, soft tissue imbalance or wear problems).



Metacarpal Nail & Radius Connector

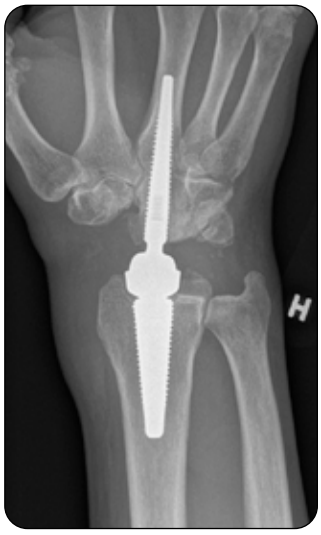
Indications: Stable and osseointegrated radius component, failure of articulation and/or the Metacarpal Threaded Implant (for example pain, soft tissue imbalance or wear problems).



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

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.

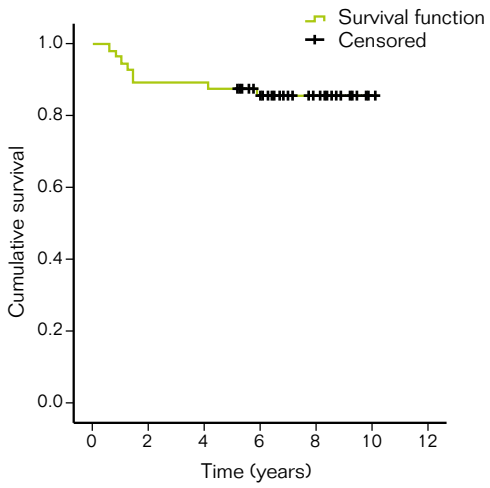
J Hand Surg Am. 2017. Oct;42(10):788-796.

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.



Kaplan-Meier survival curve

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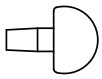
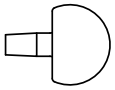
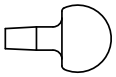
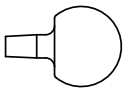
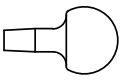
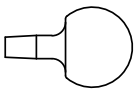
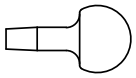
Product information

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

Implants

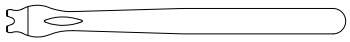
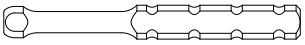
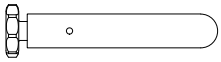
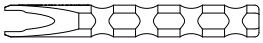
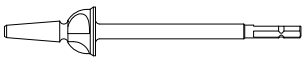
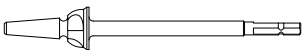
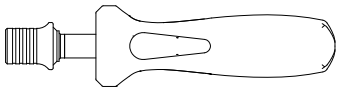
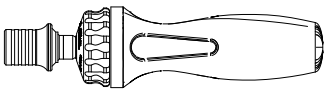
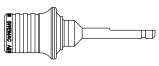
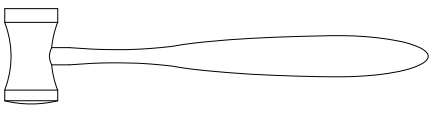
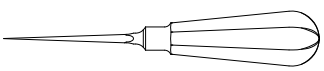
Radius Cup | CoCrMo | Ø15 mm	40-1015S	●	
Radius Cup | CoCrMo | Ø18 mm	40-1018S	●	
Radius Cup | CFR-PEEK | Ø15 mm	40-1915S	●	
Metacarpal Head | Ø15 mm | Short Neck	40-1115S	● ●	
Metacarpal Head | Ø18 mm | Short Neck	40-1118S	●	
Metacarpal Head | Ø15 mm | Medium Neck	40-1715S	● ●	
Metacarpal Head | Ø18 mm | Medium Neck	40-1718S	●	
Metacarpal Head | Ø15 mm | Long Neck	40-1215S	● ●	
Metacarpal Head | Ø18 mm | Long Neck	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	● ●	
Metacarpal III Threaded Implant | length 45 mm | Large	40-1445S	● ●	
Metacarpal III Threaded Implant | length 50 mm | Large	40-1450S	● ●	
Metacarpal III Threaded Implant | length 55 mm | Large	40-1455S	● ●	
Metacarpal III Threaded Implant | length 60 mm | Large	40-1460S	● ●	

Metacarpal III Threaded Implant | length 65 mm | Large	40-1465S	●	●
Metacarpal III Threaded Implant | length 70 mm | Large	40-1470S	●	●
Metacarpal III Threaded Implant | length 45 mm | Small	40-1475S	●	●
Metacarpal III Threaded Implant | length 50 mm | Small	40-1480S	●	●
Metacarpal III Threaded Implant | length 55 mm | Small	40-1485S	●	●
Metacarpal III Threaded Implant | length 60 mm | Small	40-1490S	●	●
Metacarpal III Threaded Implant | length 65 mm | Small	40-1495S	●	●
Metacarpal III Threaded Implant | length 70 mm | Small	40-1400S	●	●

Trials

Trial – Radius Cup | Ø15 mm	40-1522	●	
Trial – Radius Cup | Ø18 mm	40-1521	●	
Trial – Radius Cup | Ø15 mm | For CFR-PEEK Cup	40-1541		●
Trial – Metacarpal Head | Ø15 mm | Short Neck	40-1529	●	●
Trial – Metacarpal Head | Ø18 mm | Short Neck	40-1527	●	
Trial – Metacarpal Head | Ø15 mm | Medium Neck	40-1524	●	●
Trial – Metacarpal Head | Ø18 mm | Medium Neck	40-1523	●	
Trial – Metacarpal Head | Ø15 mm | Long Neck	40-1528	●	●
Trial – Metacarpal Head | Ø18 mm | Long Neck	40-1526	●	
Trial – Metacarpal Head | Ø15 mm | Extra Long Neck	40-1602	●	●

Instruments

Hohmann Capitate 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	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

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