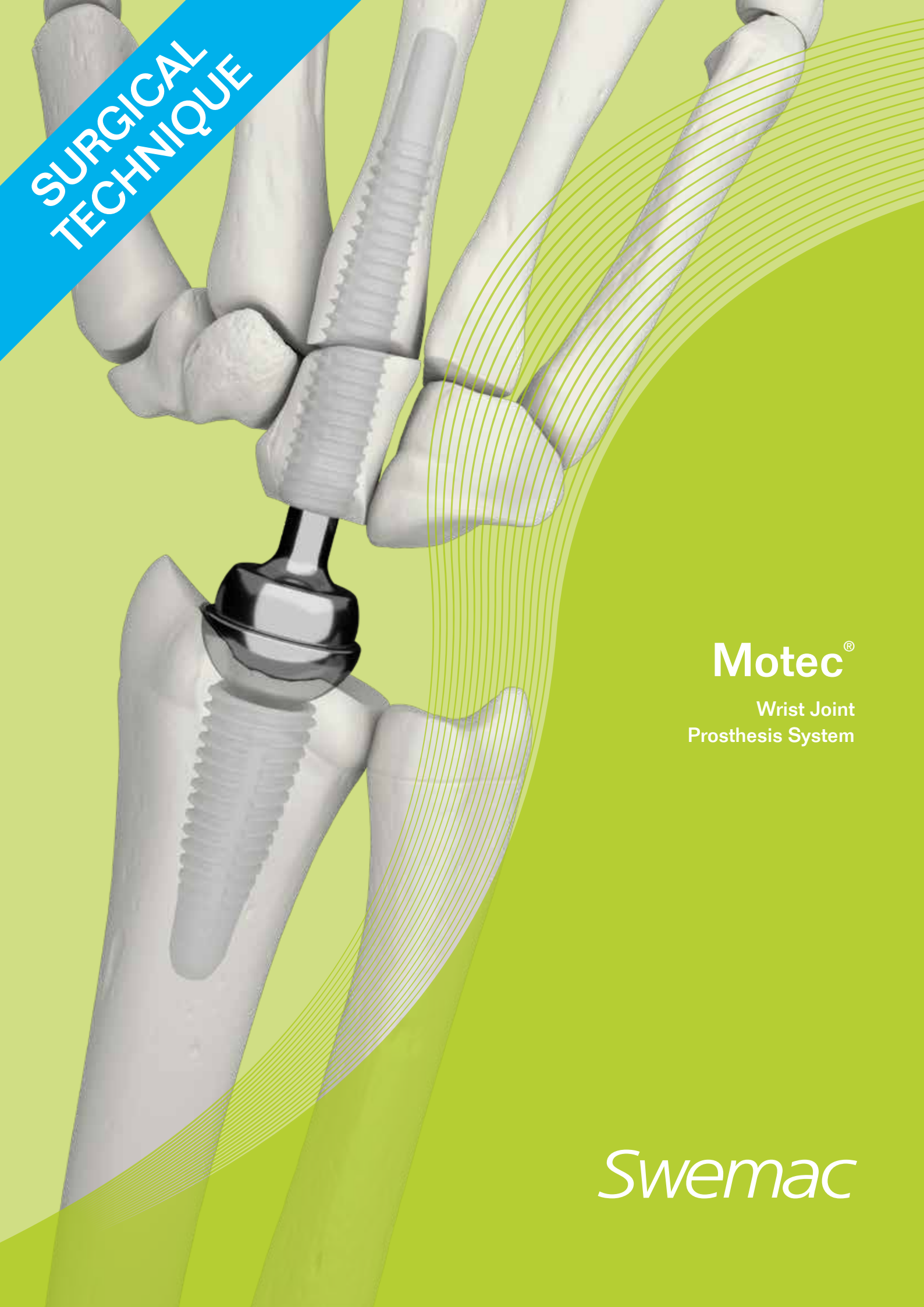
SURGICAL TECHNIQUE



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.

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.

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

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.

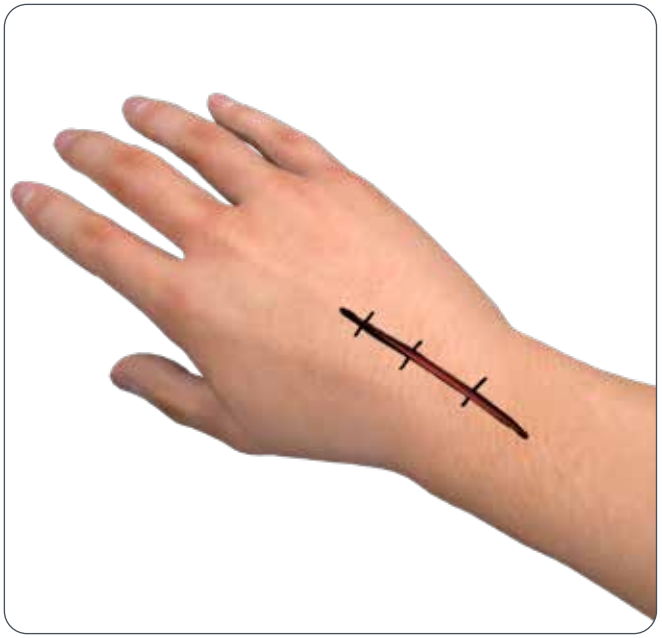
Contraindications

The physician's education, training and professional judgement must be relied upon to choose the most appropriate device and treatment. Conditions presenting an increased risk of failure include:

- Any active or suspected latent infection, sepsis or marked local inflammation in or around the surgical area.
- Material sensitivity, documented or suspected.
- Physical interference with other implants during implantation or use.
- Compromised vascularity, inadequate skin or neurovascular status.
- Compromised bone stock that cannot provide adequate support and/or fixation of the device due to disease, infection or prior implantation.
- Patients who are unwilling or incapable of following post-operative care instructions.
- Other physical, medical or surgical conditions that would preclude the potential benefit of surgery.
- Previous open fractures or infections in the joint.
- Irreparable nerve, tendon or ligament apparatus.

Surgical technique

1. Make incision



A 60 mm dorsal incision is made and the extensor retinaculum is exposed.

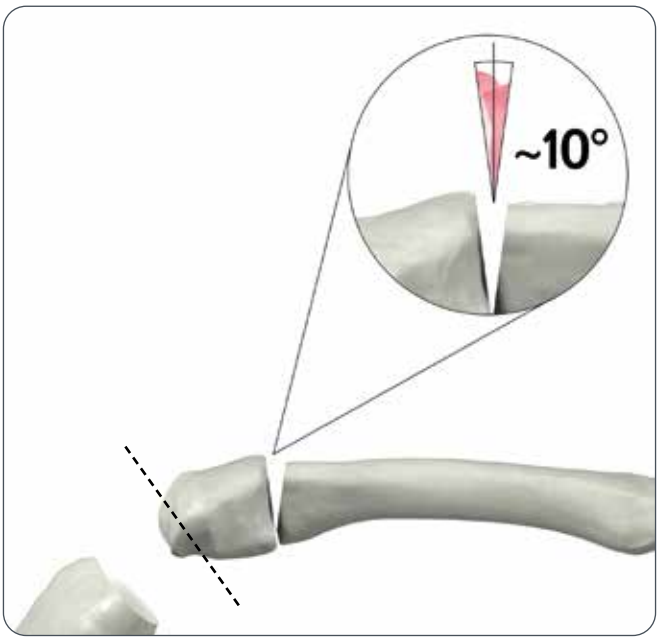
The extensor retinaculum is split at the Lister's tubercle. The two radial wrist extensors and the long thumb extensor are held radially and the finger extensors ulnarly. The capsule is fully exposed.

There is an alternative surgical approach, called the "Proximal Flap Procedure", described by M.D. Greg Packer. A step-by-step description of this approach can be obtained from Swemac separately (P125-28-2-20130118).

2. Bone resection

A proximal row carpectomy (PRC) is performed by removing the triquetrum, the lunate and the scaphoid. Preserve the resected bones on a sterile tissue to allow collection of bone chips if needed.

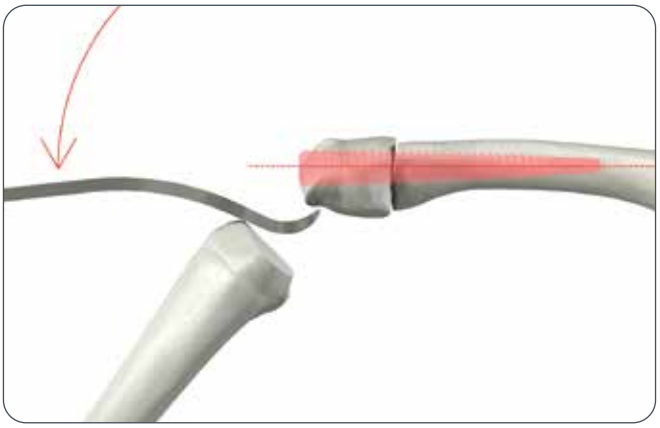
3. Preparation of the capitate and the third metacarpal



To facilitate fusion of the two bones, all subchondral sclerosis and cartilage must be removed, using either an oscillating saw or a Gouge forceps. The normal CMC3 joint has a volar angle of approximately 10 degrees. To allow the capitate to be aligned with the third metacarpal, a 10 degree wedge of bone should be resected. Make sure to avoid damaging the volar ligaments.

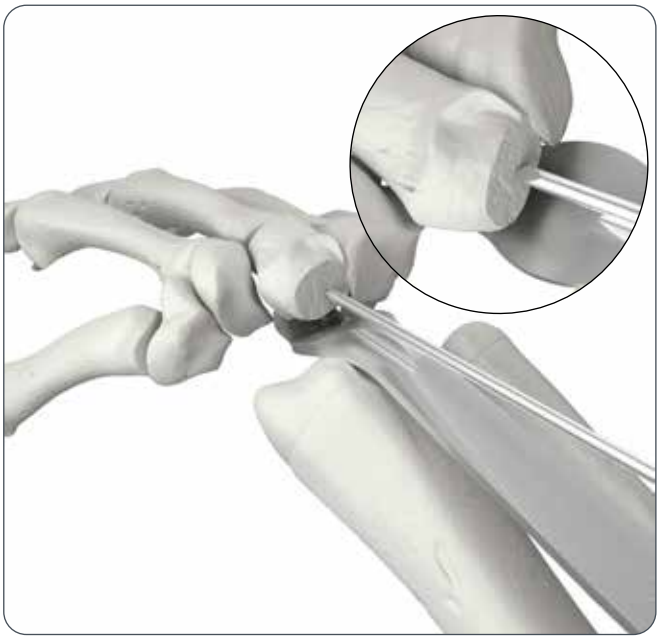
Use an oscillating saw to make a vertical cut and remove 1-2 mm of the capitate pole. This will increase the space in the joint and make it easier to place the Guide Wire correctly (see surgical step 4).

Note: When using the oscillating saw, it is important to keep the saw blade cold by spraying sterile water on it.

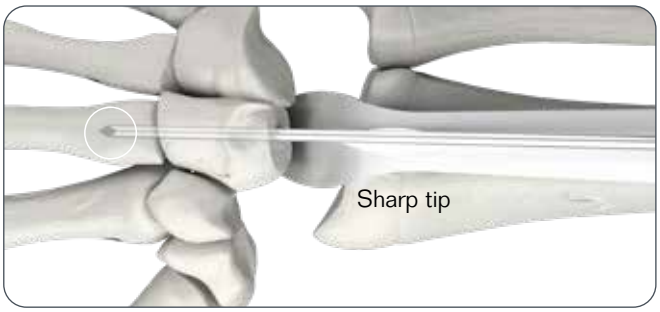


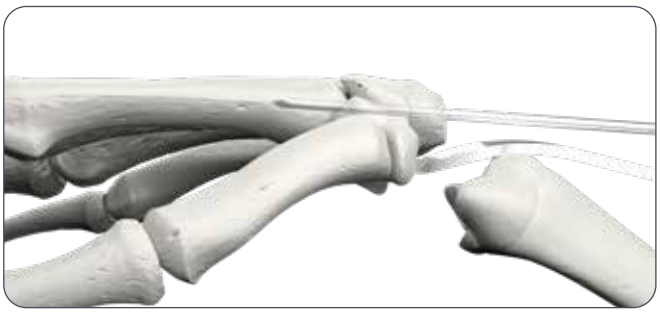
The wrist is angled volarly and the Hohmann Retractor is placed beneath the capitate to lift it up. This will close the gap between the capitate and the third metacarpal. The capitate should be fully aligned with the third metacarpal when the above procedure is completed.

4. Guide Wire insertion



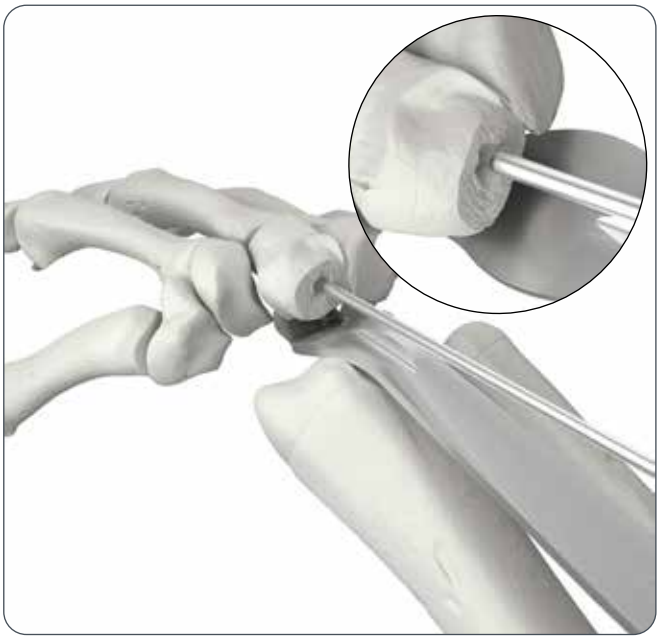
A sharp tip Guide Wire is used to create a central canal through the capitate and about 10-20 mm into the intramedullary canal of the third metacarpal bone. When inserting the Guide Wire, or the Awl, make sure to penetrate the capitate pole in the center or even better; slightly volar. If going too dorsal, there is a risk that the capitate will crack during drilling. If the canal through the capitate needs to be adjusted, this is best achieved using an Awl.



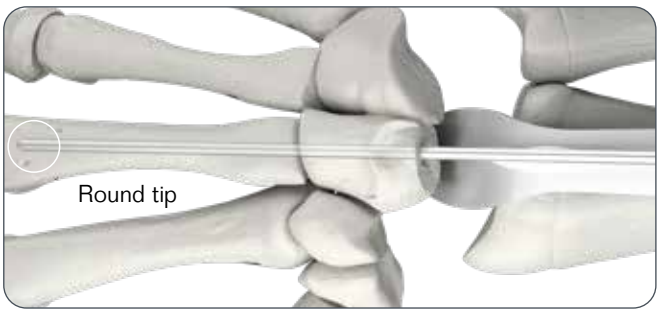


To ensure proper orientation of the Guide Wire, it is important to have a true A/P and lateral view.

Note: The surgeon can use his thumb to put pressure on the CMC-3 joint. This will align the capitate and the third metacarpal.

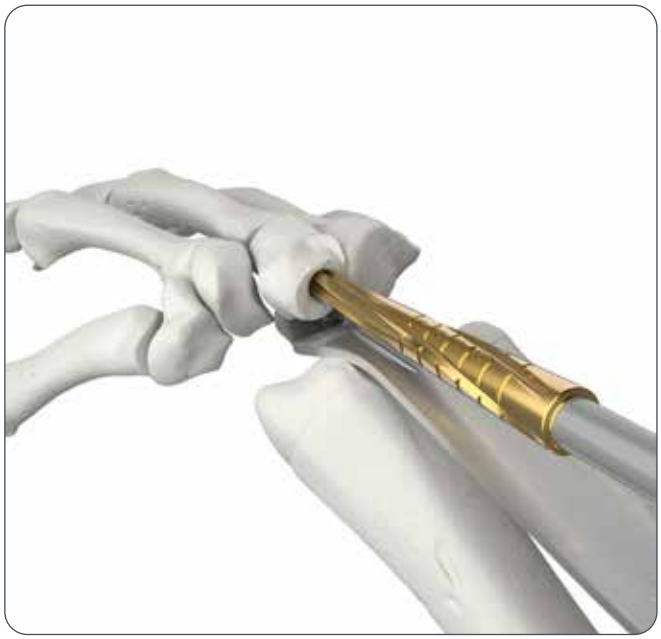


The sharp tip Guide Wire is then removed and a round tip Guide Wire is mounted in the Guide Wire T-handle or inserted by power. It is introduced through the capitate and into the intramedullary canal of the third metacarpal. The Guide Wire should be advanced all the way to the distal subchondral bone. The advantage of using a round tip Guide Wire is that it will not penetrate the cortical wall of the third metacarpal.

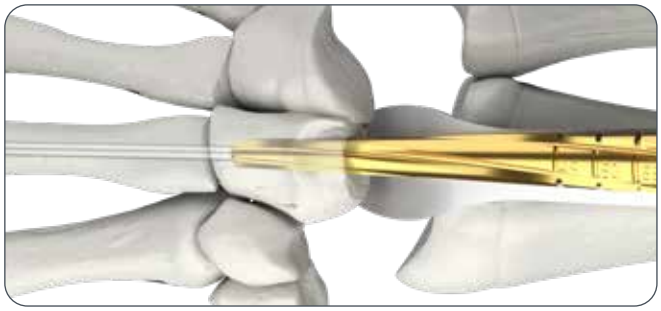


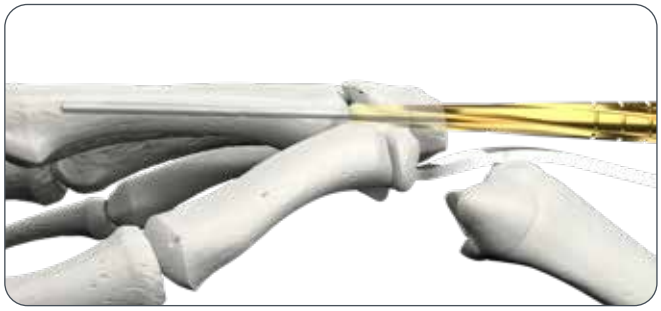
The guide wire is introduced down to the end of the intramedullary canal.

5. Drilling of the capitate and the third metacarpal



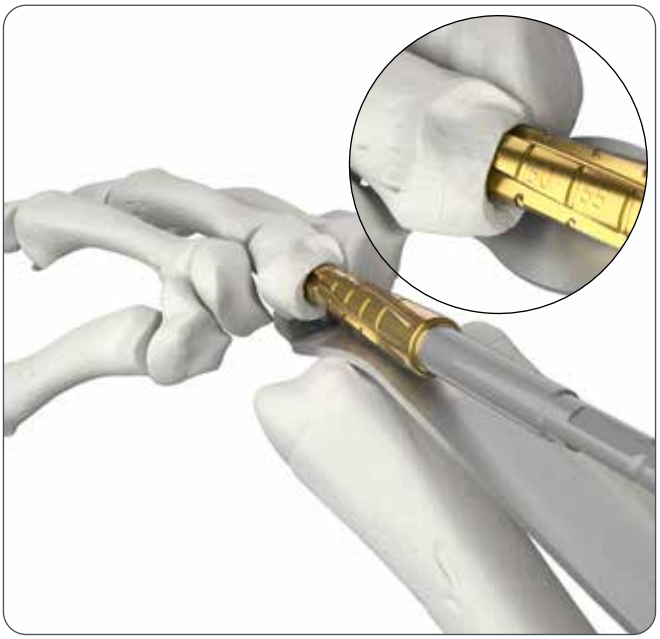
Start by drilling with the small diameter Cannulated Metacarpal Drill. The drill is introduced over the Guide Wire and advanced at reamer speed.
Keep the drill cold by spraying sterile water on it. It is usually easy to drill through the capitate but the hard bone in the third metacarpal can be difficult to open up. The drill must be cleaned several times. It is recommended to drill further than the isthmus.



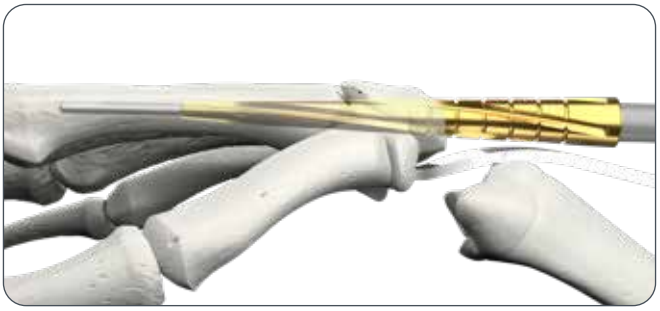


To ensure proper orientation of the drill, it is important to have a true A/P and lateral view.

6. Measuring the drill depth

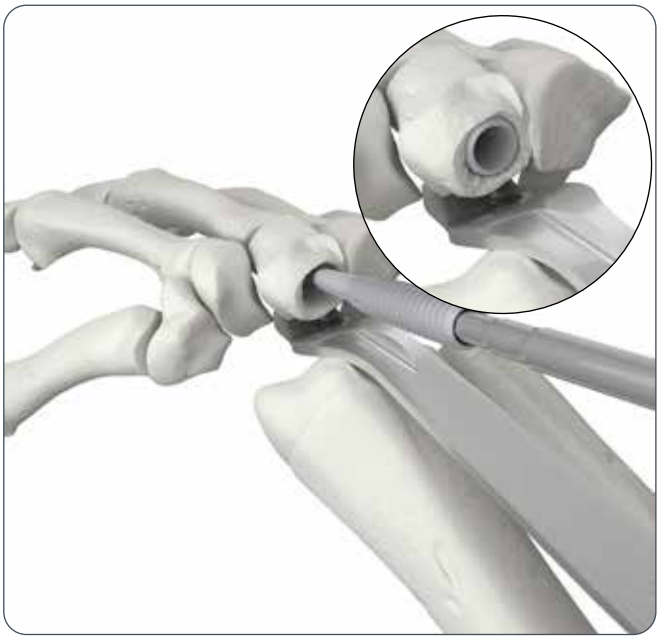


Drill depth can be taken directly from the cutting flutes of the Cannulated Metacarpal Drill. Make sure that the slot that indicates which length of the Metacarpal Threaded Implant to choose, is flush to the bone or inside the capitate. If no cortical resistance is felt during drilling of the third metacarpal, the drill should be exchanged to the large diameter drill. Push forward to eliminate any gap between the capitate and the third metacarpal when measuring.



It is important that the threads of the implant engage into the cancellous and cortical bone of the third metacarpal, ensuring stable fixation. Always try to pass the isthmus. The Cannulated Metacarpal Drill and the Guide Wire are then removed.

7. Introducing the Metacarpal Threaded Implant



The Metacarpal Threaded Implant should always be implanted at this stage. This will minimize any possible damage to the bone during preparation of the radius.

Note: Make sure all subchondral sclerosis and cartilage between the capitate and the third metacarpal is removed before introducing the Metacarpal Threaded Implant.

When introducing the Metacarpal Threaded Implant, it is important to push the implant forward, closing the gap between the capitate and the third metacarpal. Avoid touching the implant surface. Use a sterile cloth to avoid contact with the patient's skin and avoid touching the implant with surgical gloves. Use the screwdriver to pick up the implant from the sterile packaging.

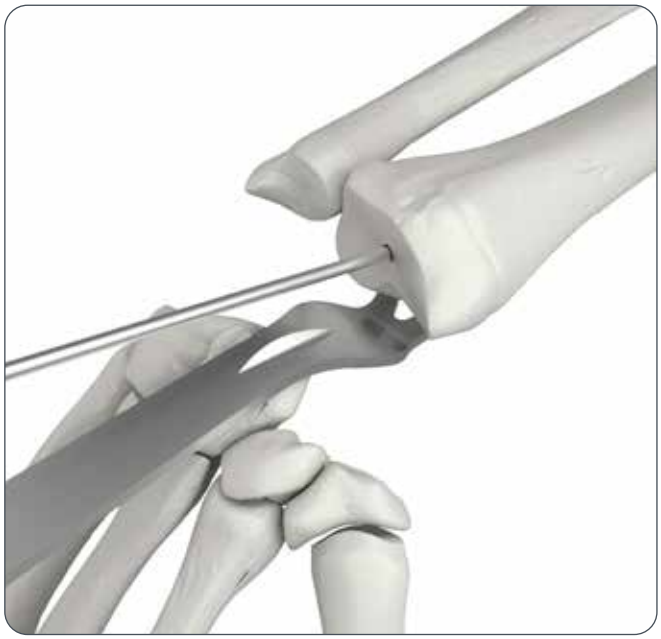
Note: Countersink the Metacarpal Threaded Implant to accomplish more joint space in order to insert a longer neck. The implant shall be flush to the bone or inside the capitate bone.

8. Preparation of the radius

The Awl is introduced under image intensification through the joint surface of the radius. It should be placed central in the A/P view and slightly volar in the lateral view.

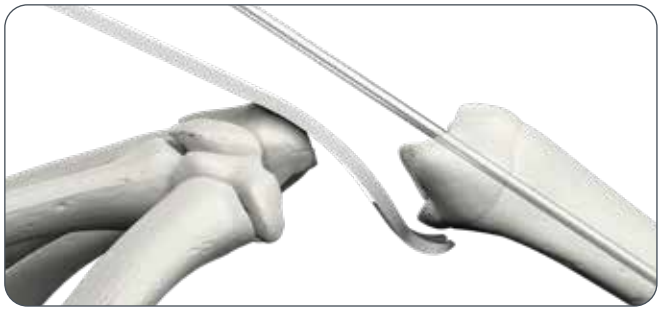
Note: If the radius is deformed or the bone channel is too narrow, it is possible to use the metacarpal drill with the corresponding Metacarpal Threaded Implant.

9. Guide Wire insertion



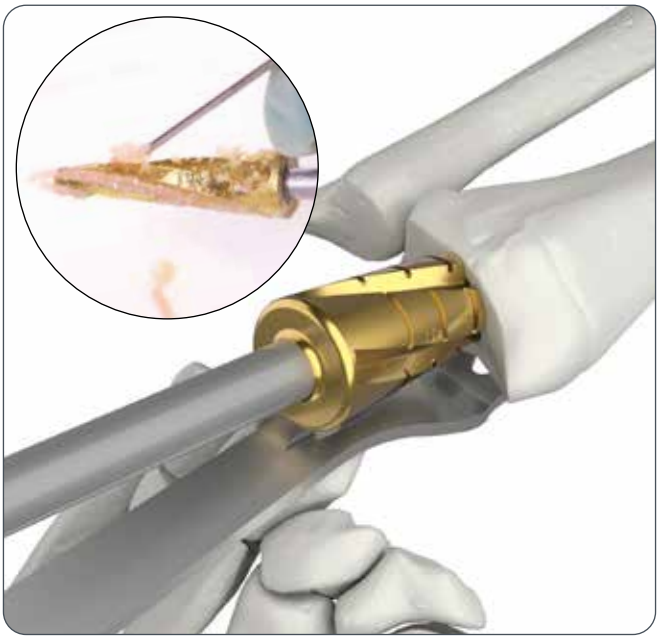
The Hohmann Retractor is placed beneath the edge of the volar ridge to lift the radius. This will facilitate the insertion of the Guide Wire and protect the capitate from the power drill.

The Guide Wire is introduced through the hole made by the Awl in the joint surface of the radius.



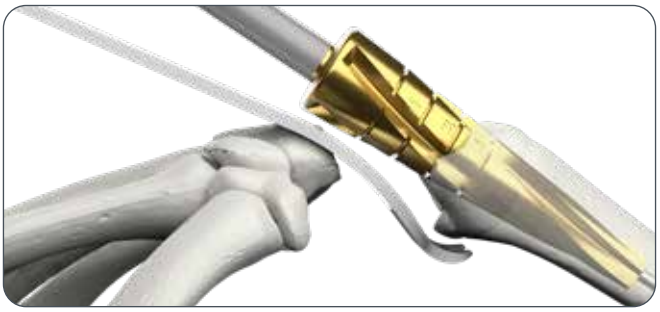
The orientation of the guide wire is checked under image intensification in both A/P view and lateral view.

10. Drilling of the radius



The Cannulated Radius Drill is introduced over the Guide Wire and drilling is carried out at reamer speed. Gather the bone chips that are collected in the cutting flutes of the drill on a sterile cloth. These will be used in surgical step 18, to ensure a successful fusion between the capitate and the third metacarpal.

If the radius is deformed or the intramedullary canal is very narrow, it is possible to use the Metacarpal Threaded Implant in the radius. In such a case, use one of the Cannulated Metacarpal Drills.



To ensure proper orientation of the drill it is important to check the position under image intensification during drilling. Continue drilling until cortical resistance is felt.

11. Reaming of the radius

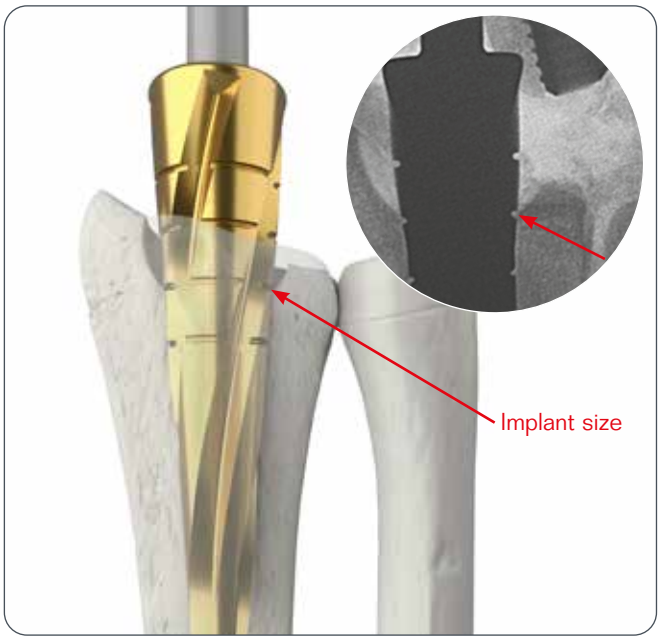
It is necessary to ream a cavity for the Radius Cup in the radius. Always start with the Radius Spherical Drill Ø15 mm.

The appropriate Radius Cup size (15 mm or 18 mm) is selected based on the height of the distal radius. The edge of the cup (15 mm or 18 mm) should not rise above the dorsal radius.

The Driver Handle and the appropriate Radius Spherical Drill are used to ream the cavity for the cup. The Reamer has a mechanical stop that prevents over-reaming.

Note! The Radius CFR-PEEK Cup is only available in Ø15 mm.

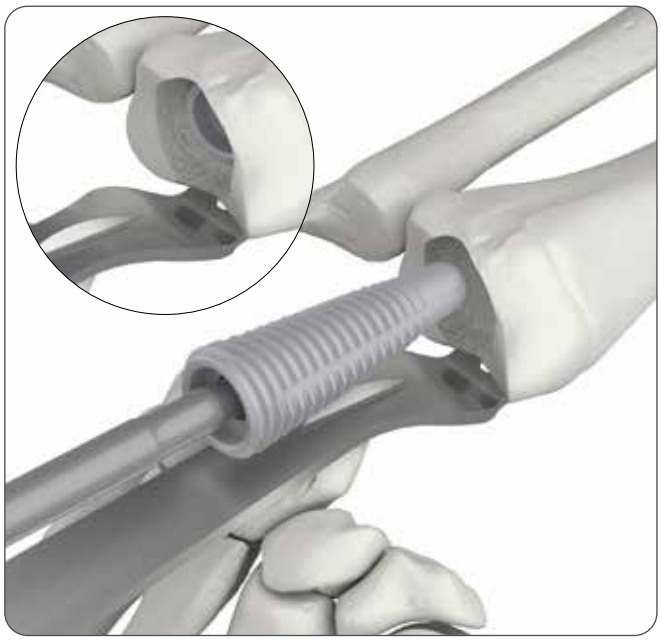
12. Determining the correct Radius Threaded Implant size



After reaming with the spherical drill, reinsert the cannulated drill to measure the size of the Radius Threaded Implant. The correct size will be indicated by the drill slot that is level with the bottom of the depression left by the speherical drill. If in between sizes, advance the cannulated drill until the next slot is flush with the bottom of the depression.

Note! A step-by-step description of the surgical technique regarding the optional large Radius Threaded Implants can be obtained from Swemac separately (P125-28-2-optional)

13. Insertion of the Radius Threaded Implant



Avoid touching the implant surface. Use a sterile cloth to avoid contact with the patient's skin and avoid touching the implant with surgical gloves. Use the screwdriver to pick up the implant from the sterile packaging. Clean the joint cavity with saline to remove small bone chips.

14. Insertion of the trials

The Radius Cup Trial is inserted in the Radius Threaded Implant. Ensure that the cup can be firmly seated in the Radius Threaded Implant without impingement against the edge of the cavity created by the cup reamer. Do not use the Impactor on the trial.

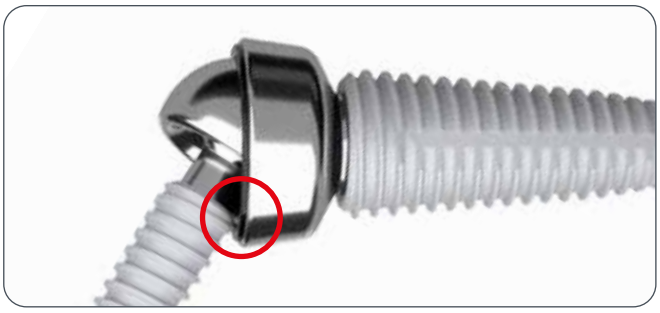
Note! The Ø15 mm Cups shall only be used in combination with a Ø15 mm Head. It is prohibited to combine the Ø15 mm and Ø18 mm articulation components.

To determine the correct size of the Metacarpal Head component, start by inserting the Metacarpal Head Trial with long neck. Increase or decrease the Trial size until the right tension has been achieved.

When pulling the fingers, the Metacarpal Head Trial should only just lift from the bottom of the cup. If a larger size feels too tight, or if one size smaller feels too loose, it is possible to slightly adjust the Metacarpal Threaded Implant further into the bone. Keep in mind that tension will increase when closing the capsule.

Note! The Metacarpal Head with short neck should be used with caution due to the risk of impingement between the Radius Cup (Metal or PEEK) and the Metacarpal Threaded Implant. Please see step 15. for more details.

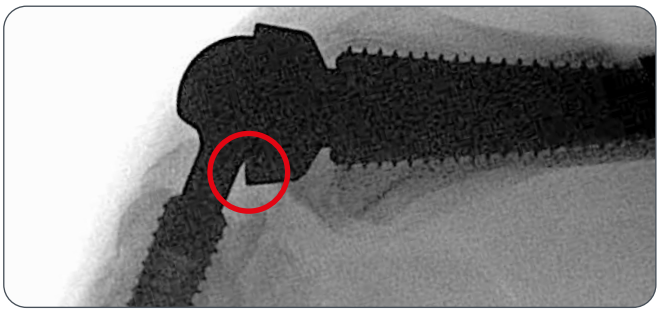
15. Use of the Metacarpal Head with short neck



The Metacarpal Head with short neck should be used with caution due to the risk of impingement between the Radius Cup (Metal or PEEK) and the Metacarpal Threaded Implant (see images above and below). This impingement might result in excessive wear which should be avoided.

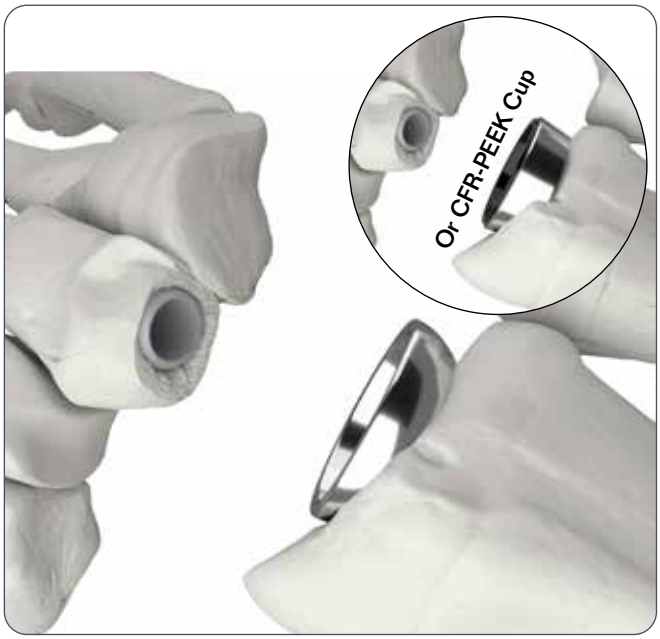
The Metacarpal Head with short neck should therefore only be reserved for special cases where a longer neck is not suitable. Such cases may include failed PRCs or other conditions where the space in the joint is restricted.

If the short neck is utilized then care must be taken to ensure that the tension of the patient's soft tissue is sufficient to restrict excessive ROM which will increase the risk of impingement.

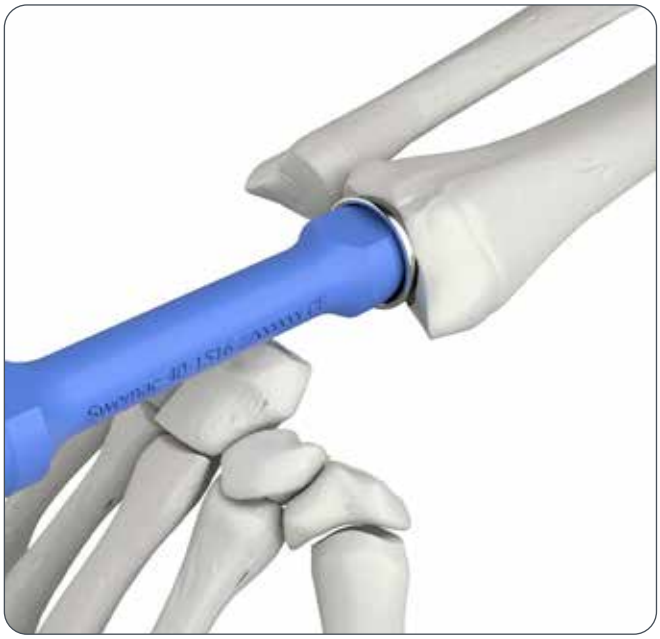


Note! The best tip to increase the space in the joint is to adjust the Metacarpal Threaded Implant further into the bone.

16. Insertion of the Radius Cup



Before introducing the Radius Cup, make sure that the internal taper of the Radius Threaded Implant is clean. The Radius Cup is then inserted into the Radius Threaded Implant.



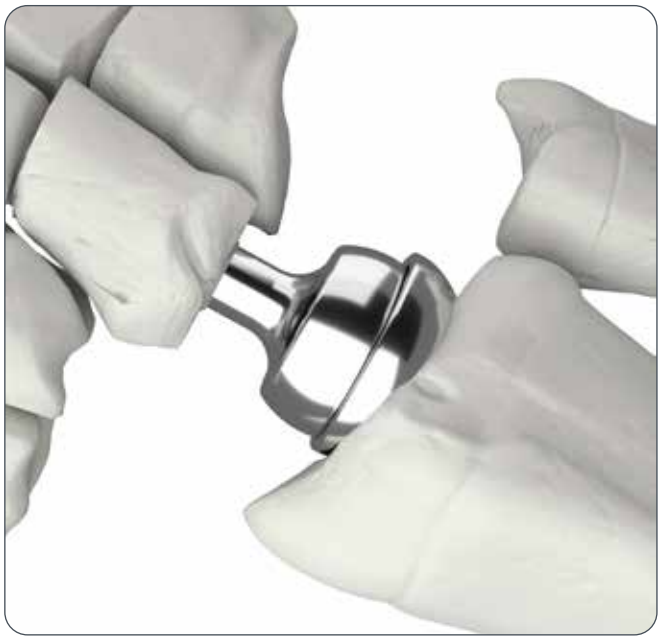
Tap the Impactor to ensure firm seating of the Radius Cup. Tap the Impactor once for the best attachment between the rough surfaces of the Radius Cup and the Radius Threaded Implant.

Note! Make sure that the taper of the Radius Cup is firmly seated in the Radius Threaded Implant. There should be a 1-2 mm gap between the cup and the bone.

17. Insertion of the Metacarpal Head

Before introducing the chosen Metacarpal Head, make sure that the internal Morse taper of the Metacarpal Threaded Implant is clean. The Metacarpal Head is then inserted into the Metacarpal Threaded Implant. Tap the Impactor once to ensure firm seating.

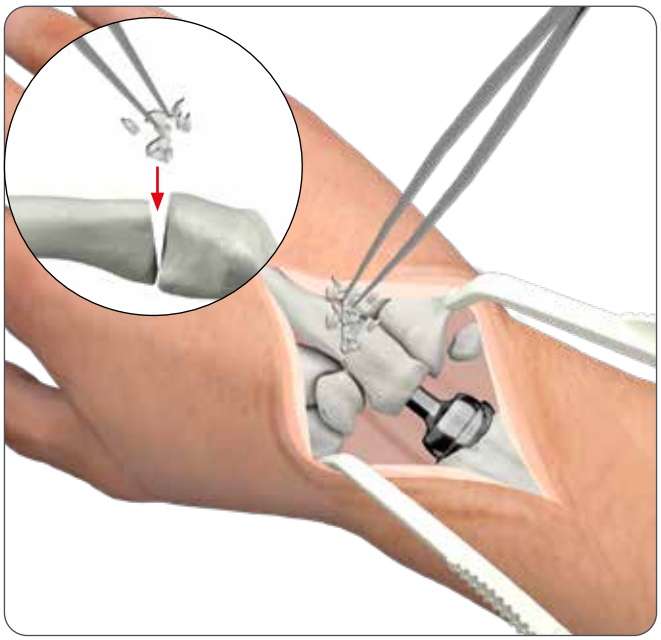
Note: Do not use excessive force when impacting the Metacarpal Head, this might strip the threads of the Metacarpal Threaded Implant.



Reduce the joint and evaluate stability and range of motion under image intensification.

Note! It is mechanically possible to reverse the prosthesis, placing the Metacarpal Head in the Radius Implant. This has however not been investigated and can not be recommended.

18. Packing the gap between capitate and third metacarpal

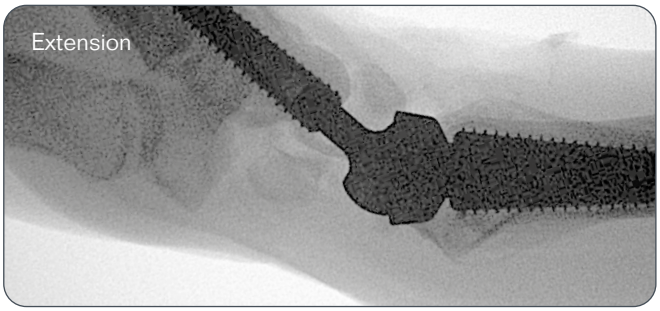


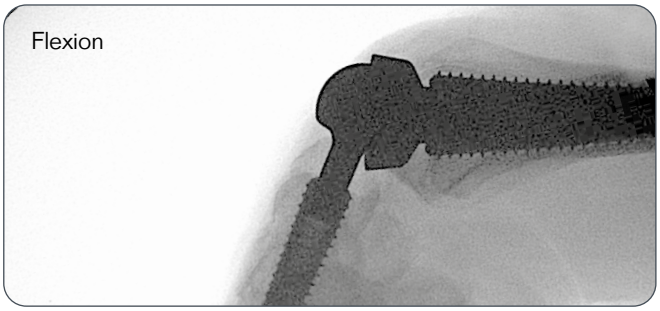
Successful fusion of the capitate and the third metacarpal is absolutely crucial for the long term fixation of the Metacarpal Threaded Implant. To ensure successful fusion, pack the gap using the bone chips that were gathered during drilling of the radius. If necessary, collect additional bone chips from the resected bones from the PRC.

If the capitate cracked

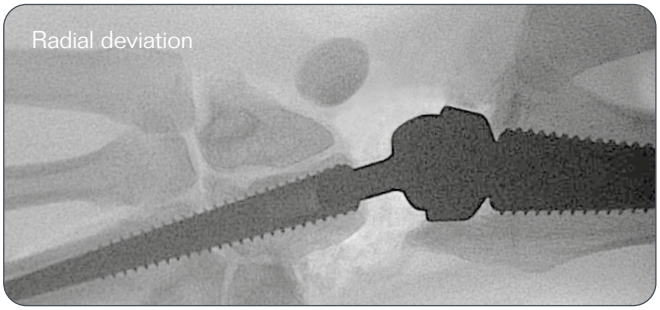
If a crack occurred in the capitate during the procedure, pack the crack with bone chips and increase the cast period by about two weeks.

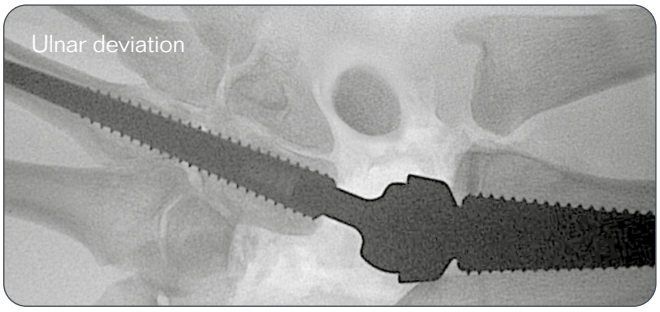
19. Final reduction





The joint is reduced and stability and range of motion is evaluated under image intensification. Haemostasis is obtained after releasing the tourniquet.





In this case there were no signs of bone impingement during final reduction.

20. In case of bone impingement

If the range of motion in radial deviation is limited because of bone impingement, the tip of the radial styloid can be removed.

When resecting the radial styloid, use a periostal elevator to gently loosen the soft tissue. This will help preserve the stability of the wrist.

21. Closure

The dorsal capsule is closed carefully. The extensor retinaculum is sutured back and a subcutaneous drainage is introduced before the incision is closed.

Postoperative care

Postoperative care is extremely important. The physician's education, training and professional judgment must be relied upon to choose the most appropriate postoperative care specified for the patients need.

Note: The following postoperative regime has been recommended by Dr. O. Reigstad, Rikshospitalet, Hand and Microsurgery Section, Orthopaedic Department N-0027 Oslo, Norway.

0-6 weeks: A short arm cast allowing free forearm rotation and finger function is recommended for 6 weeks (a plaster slab is used for the first 2 weeks). Depending on the surgeons judgement, additional weeks might be prefered. Start early hand therapy during the hospital stay, with finger, forearm, elbow and shoulder motion.

At approximately 2 weeks the slab and sutures are removed and a circular cast applied for additional 4 weeks. If there is any problem with upper extremity motion the patient shall receive hand therapy.

6 weeks: The cast is removed (and radiographs to evaluate bone fusion are taken). Start with limited weight bearing and gradually increase the weight. Free weight-bearing is allowed when radiographs confirm bone fusion.

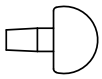
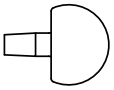
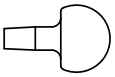
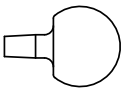
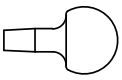
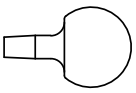
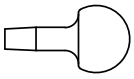
6 months: Radiographs are taken and ROM/grip strength/ VAS pain is recorded. If the patient have a slow progression, the hand therapist is involved.

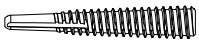
The patient is further followed at 1 year and yearly thereafter with radiographs and recording of ROM/grip strength/VAS pain. The improvement halts between the 2 and 3 year. Further follow up according to the doctors preference, but should include a 5 and 10 year appointment.

Product information

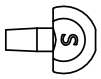
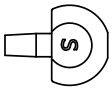
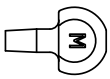
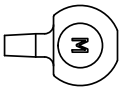
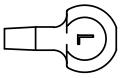
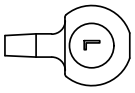
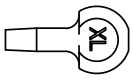
- Needed for CFR-PEEK articulation
- Needed for CoCrMo articulation

Implants

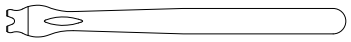
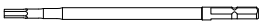
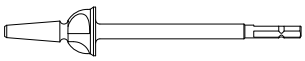
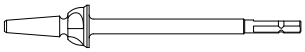
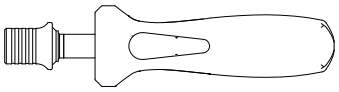
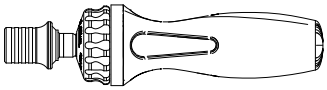
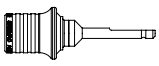
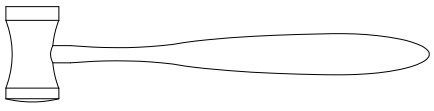
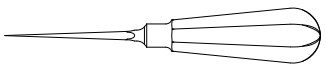
Radius Cup | CoCrMo | Ø15 mm	40-1015S	●	
Radius Cup | CoCrMo | Ø18 mm	40-1018S	●	
Radius Cup | CFR-PEEK | Ø15 mm	40-1915S	●	
Metacarpal Head | Ø15 mm | Short Neck	40-1115S	● ●	
Metacarpal Head | Ø18 mm | Short Neck	40-1118S	●	
Metacarpal Head | Ø15 mm | Medium Neck	40-1715S	● ●	
Metacarpal Head | Ø18 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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