

CarpoFit[®] trapeziometacarpal joint system

Surgical technique



CarpoFit®

trapeziometacarpal joint system

Surgical technique

The **CarpoFit®** trapeziometacarpal joint system was developed in cooperation with Prof. Dr. med. U. Joosten, orthopaedic surgeon from the Clinic for Traumatology Marienhospital Osnabrück (Germany).

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Note: The surgical technique described herein reflects the author's suggested treatment in straightforward interventions. Ultimately, however, the surgeon must decide which procedure is most appropriate and effective for the patient in question. The treatment described must be performed in accordance with the current state of the art. The instruments shown and described with the catalog number in the surgical technique refer to an example size. Further sizes and instrument variants can be found in the appendix to the surgical technique.

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System Overview

CarpoFit® is a cementless unconstrained trapeziometacarpal joint replacement system. The modular design of the prosthesis, which consists of three components, allows it to be adapted to the patient's individual anatomy.

Stems (metacarpal components)

The metacarpal stems are available in four sizes of 5 mm, 6 mm, 7 mm and 8 mm. The length of the stems grows with increasing size. The maximum diameter corresponds to the size specification (with the exception of the 5 mm stem, which has a diameter of 6 mm). The stems are made of **implatan®**, a forged titanium alloy, and are coated with a TCP (tricalcium phosphate) coating for improved bony integration. The stems are flattened on one side to follow the palmar curvature.

Joint components

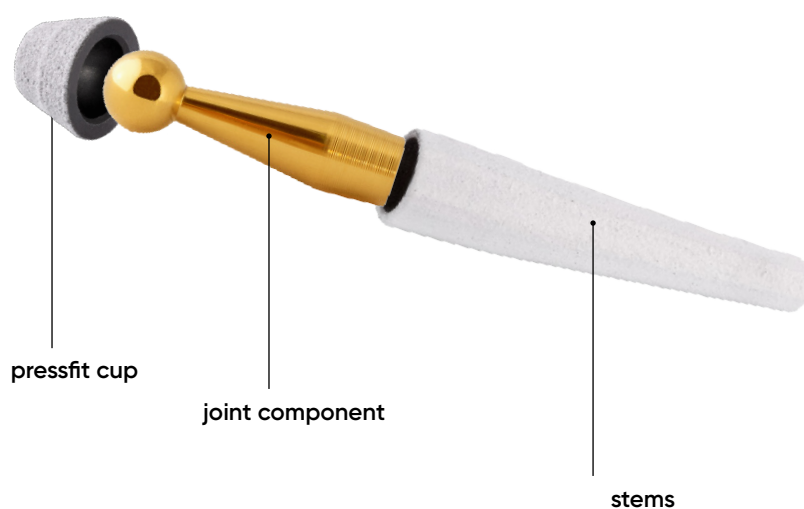
The joint components made of **implavit®** (CoCrMo alloy) are available in four neck lengths and can be freely combined with the metacarpal stems. In addition, all components are available with a TiNbN ceramic coating.

Pressfit Cup

The conical Pressfit cup enables a good primary stability. The cups have a small diameter (8 mm) so that they can also be placed well in the small os trapezium. The use of thin-walled polyethylene inserts is avoided. The bonefacing surface of the PressFit cup is coated with TCP for improved osseointegration.

The conical Pressfit cup is available as a PEEK-C component (carbon fiber-reinforced PEEK) and as a metal component* (**implavit®** CoCrMo alloy) with optional TiNbN coating. The dimensions and the coatings on the bonefacing surface are identical for all versions. The PEEK-C conical PressFit-cup prevents a metal-on-metal tribological pairing.

* The conical cup cementless (with and without TiNbN coating) is replaced by the Pressfit cup made of PEEK-C.



Preoperative planning

Preoperative planning and precise surgical techniques are mandatory to achieve optimal results. The instructions and the procedure given in the surgical technique for the system must be adhered to. Familiarity with the surgical technique recommended for this system and its careful application are essential to achieve the best possible outcome. Before surgery, the surgeon must conduct surgical planning in terms of the dimensions of the prosthetic model and positioning of the implant components in the bone.

Implant templates are made available for this purpose:

Digital templates: The templates are included in the databases of conventional planning tools. If the desired templates are not included in the software, please request them from the planning tool supplier.

Radiographic templates: Alternatively, radiographic templates of various scales are available, which can be obtained from your local sales partner upon request.

In addition, before surgery it must be ensured that:

- All necessary components are available. An adequate number of all necessary implant sizes should be available during surgery.
- All instruments necessary are present for surgery. Implants may only be used with the corresponding instrument set of implantcast GmbH. The only exception in this case are the instruments standardized for an operation.
- Correctly sized surgical instruments are used in the operation in order to prevent damage to the implant.

! Attention: Please note that the range of implants and instruments in loan sets may differ from the information in the catalog appendix to this surgical technique.

≡ Note: You can find more information in the final section of this surgical technique or in the instructions for use:

09300075E CarpoFit® TMC Prothesis



AP view

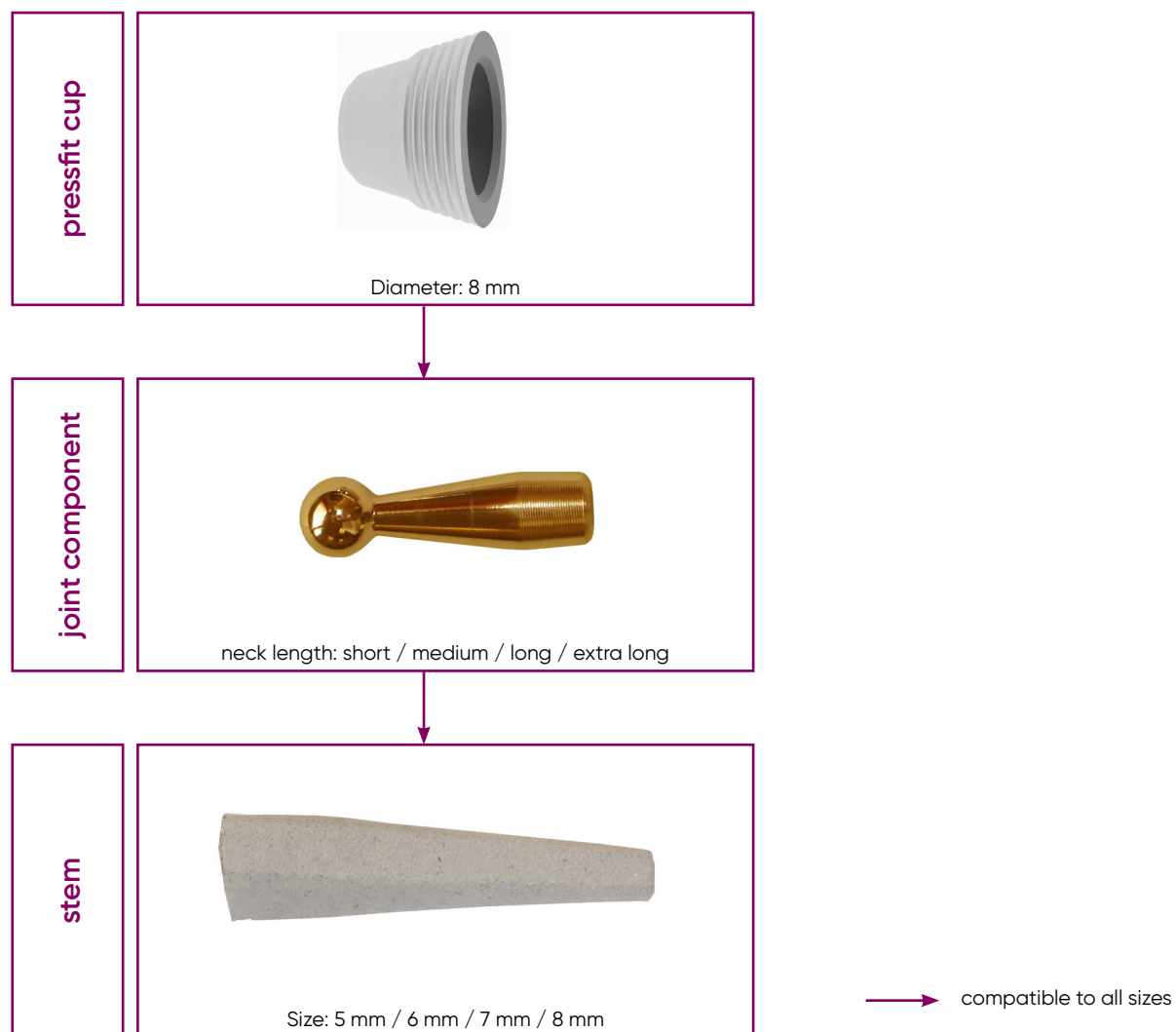


ML view

Compatibility

The joint components can be combined with the stems and pressfit cup regardless of size.

The combination of uncoated and coated joint components to the PEEK-C cup is allowed.



Surgical technique

Indication and surgical access

Symptomatic rhizarthrosis (primary and secondary) and rheumatoid arthritis are indications for the **CarpoFit®** prosthesis. The aim of treatment is to achieve freedom from pain and maintain strength, the greatest possible mobilization with complete circumduction and opposition while maintaining the length of the thumb.

The surgical approach is dorsolateral.

Select a straight skin incision in axis of the thumb (**Fig. 1** and **Fig. 2**). Open the capsule and incise the periosteum. Detach the muscle attachments of the interosseous muscles and the abductor pollicis longus (**Fig. 3**).



Fig. 1



Fig. 2



Fig. 3

Preparation of the os metacarpale I

Dislocate the base of the metacarpale I. Insert two Hohmann retractors and perform a thin resection of the metacarpal bone of about 2–3 mm. The resection needs to be perpendicular to the axis of the bone. Remove the resected bone (**Fig. 4**).



Note: Pay attention to protect the M. abductor pollicis longus.

Remove any osteophytes, especially volar and at the os trapezium.

Use two Hohman retractors to expose the joint.

Open the medullary canal with the awl¹⁾. Make sure to set the entry point correctly (**Fig. 5**).

Start with the smallest broach²⁾ (5 mm) to prepare the medullary canal (**Fig. 6**). Continue broaching with ascending broach sizes until the broach sits firmly.



Note: Ensure that the broaches are correctly aligned. They are flattened on one side according to the shaft geometry in order to follow the palmar curvature.

Once the hexagonal bone bed has been prepared, the stem component can be implanted. To do this, screw the stem onto the trial stem impactor³⁾.



Note: Optionally, the trial stems can be used at this stage. The trial stems are placed in the same way as the implants.

Insert the stem in the medullary canal of the os metacarpale I using gentle hammer strikes. The top of the stem should be flush with the resected surface (**Fig. 7**). The stem is anchored in the bone by pressfit.

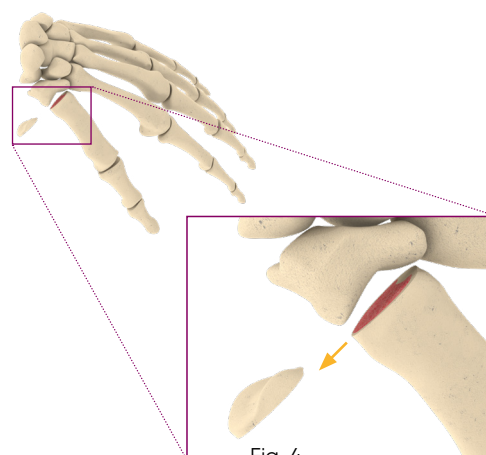


Fig. 4

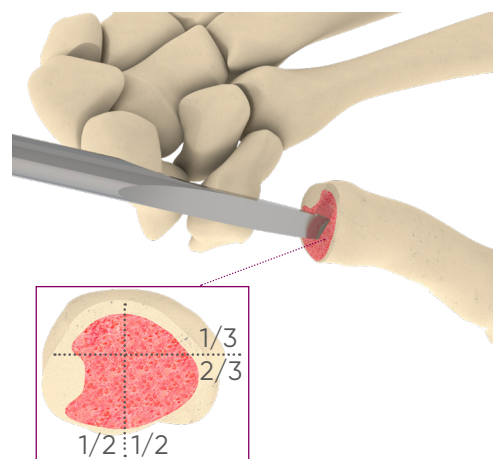


Fig. 5

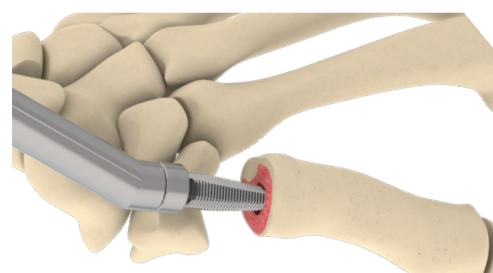


Fig. 6

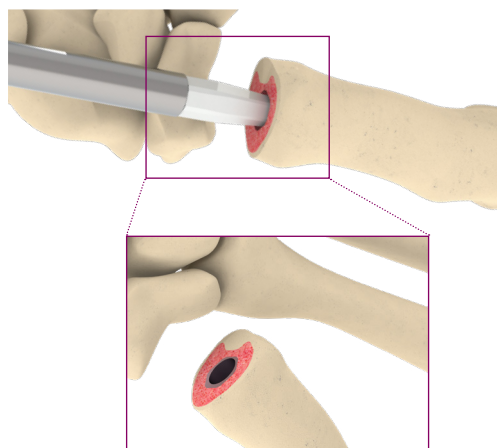


Fig. 7

¹⁾75120003: ic awl; ²⁾00510945: CarpoFit® monoblock broach; ³⁾00510901: CarpoFit® trial stem impactor

Preparation of the os trapezium

Expose the os trapezium. Use a Hohman retractor under the os trapezium and push the os metacarpale with the implanted stem ulnarly to obtain the best possible view on the os trapezium.

A centering guide¹⁾, is use to determine the correct, centered position for the guide wire (Fig. 8). The guide wire needs to sit in the center of the os trapezium and perpendicular to the proximal base of the trapezium bone.

Use the pin inserter²⁾ to place the guide wire³⁾ in the bone (Fig. 9).

 Note: Control the position of the guide wire using x-ray in two planes (Fig. 10). If the positioning is suboptimal, the guide wire must be repositioned.

 Attention: Particular caution is required in the case of a dysplastic os trapezium. The os trapezium must have a minimum thickness of 8 mm.

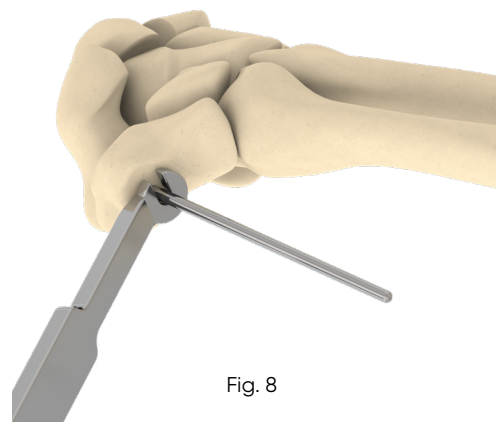


Fig. 8

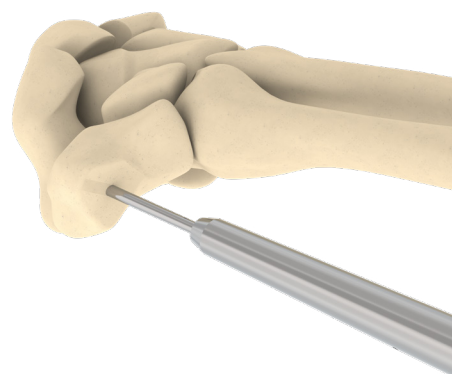


Fig. 9

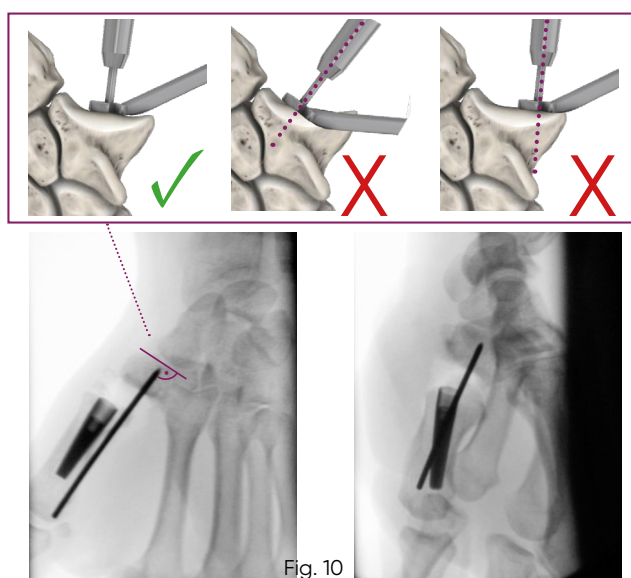


Fig. 10

¹⁾00510907: CarpoFit® centralizer; ²⁾00510903: CarpoFit® forceps for articulating; ³⁾00510918: guide wire

After confirming the central position of the guide wire, the cannulated reamer¹⁾ is used over the guide wire to prepare the bone (**Fig. 11**). The preparation is performed manually.



Note: Take care not to tilt the reamer in order to prepare the bone for an even pressfit of the cup.

The reamer is inserted until the reaming ring is flush with the surface of the trapezium bone.

Then remove the reamer and the guide wire.

Implantation of the pressfit cup

Continue with the implantation of the pressfit cup.

Place the pressfit cup using the cup introducer²⁾. First insert the cup into the clamping sleeve of the impactor by pushing in from the side (**A**). Then push the impactor rod towards the cup, to stabilize the assembly (**B**). While impacting, the sleeve will automatically release from the cup (**C**) (**Fig. 12**).

Make sure that the cup is completely seated (**Fig. 13**). If necessary use the non-coupled impactor³⁾ to enhance the cup impaction.

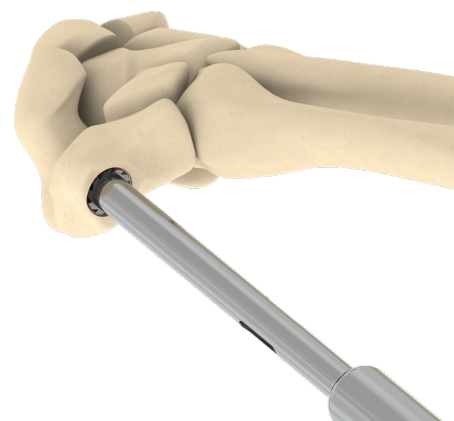


Fig. 11

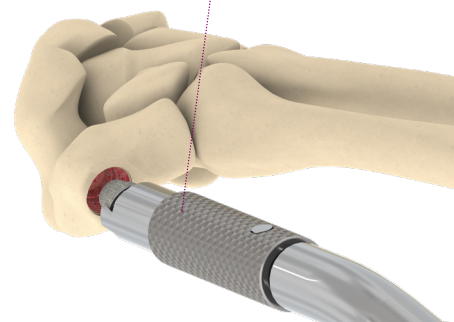
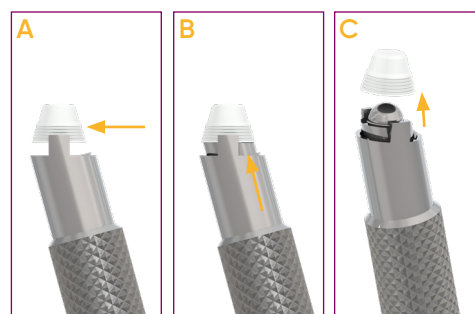


Fig. 12

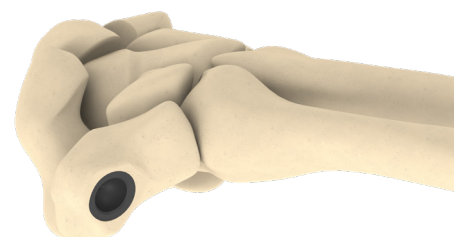


Fig. 13

¹⁾00510908: CarpoFit® trapezium reamer; ²⁾00510909: CarpoFit® cup introducer; ³⁾00510919: CarpoFit® cup inserter unconstrained

Determination of the neck length

Next, the soft tissue tension is checked and the correct neck length needs to be chosen.

First insert the smallest joint component¹⁾ „S“ and perform a trial reduction and stability test (**Fig. 14**).

Normally, there is no dislocation tendency with sufficient tissue tension, whereby full opposition capability is given. If there is a dislocation tendency, perform a trial reduction with a longer neck length.



Note: When selecting the neck length, excessive tension in the joint should be avoided.

If the trial reduction was performed with the trial stems, the final stem must be implanted first. The stem impactor²⁾ is used to remove the trial stem and implant the stem.

After successful trial reduction, the trial component is removed and the definitive implant with the previously selected neck length S, M, L or XL is inserted (**Fig. 15**). Use the joint component inserter³⁾ to tighten the morse taper connection between the stem and the joint component.

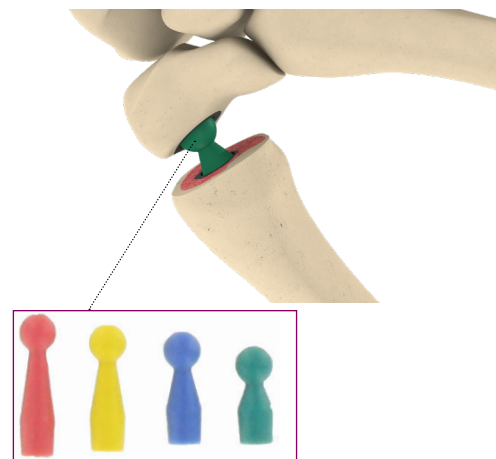


Fig. 14

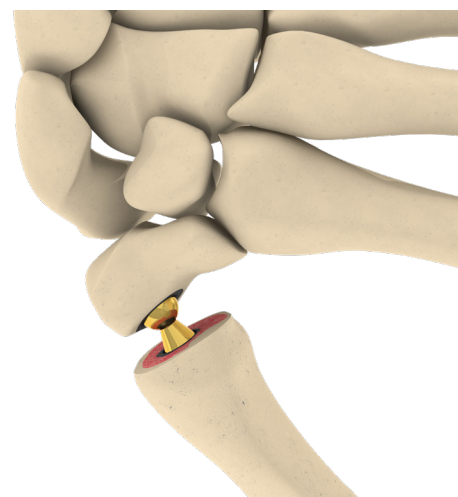


Fig. 15

¹⁾00510900: CarpoFit® trial joint component; ²⁾00510901: CarpoFit® trial stem impactor; ³⁾00510911: CarpoFit® joint component inserter

After reduction with the final joint component, the mobility and stability of the prosthesis is checked again (**Fig. 16** and **Fig. 17**) and a final x-ray check is performed (**Fig. 18**).

 **Note:** The cementless CarpoFit® cup made of PEEK-C with cpTi coating can not be displayed on x-ray images, as the main material is PEEK. Depending on the x-ray settings, the the cpTi and TCP coating may be visible as rim.

Follow-up treatment

- Immobilization in a cast for approx. 14 days
- after two weeks removal of cast and start of ergotherapy*, whereby active movements are permitted immediately
- intensive physical training is not recommended before end of the 6th postoperative week
- *** Specific physiotherapy is not necessary in every case and must always be assessed on an individual basis.**



Fig. 16



Fig. 17

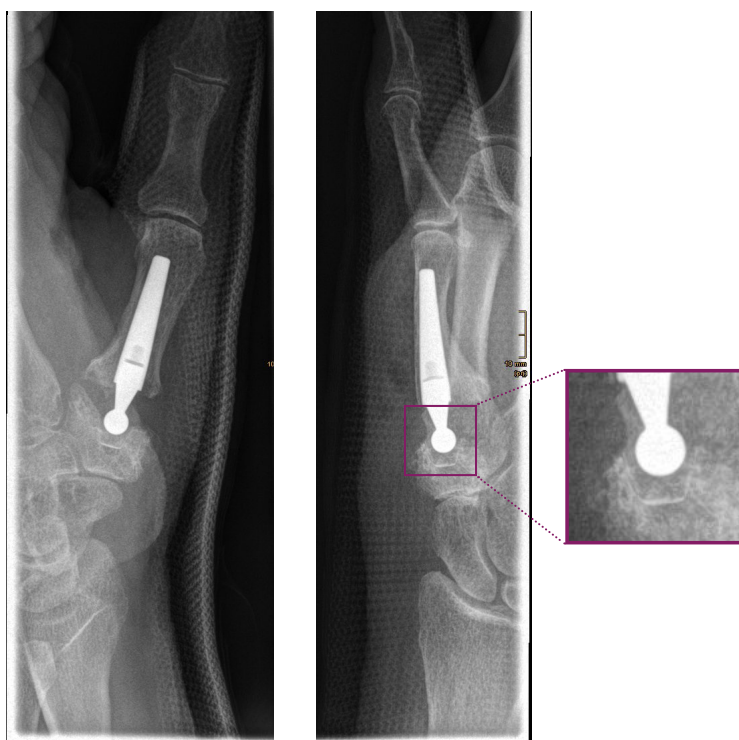


Fig. 18

Implants

CarpoFit® stem cementless

Material: implatan®; TiAl₆V₄ in accordance with ISO 5832-3

Coating: TCP-HA-coating acc. to ISO 13779-2

Article number	Size
00510205	5
00510206	6
00510207	7
00510208	8



CarpoFit® articular component

Material: implavit®; CoCrMo acc. to ISO 5832-12

Article number	Size	variant
00510100	short	
00510105	medium	
00510110	long	
00510115	extra long	
00510100N	short	TiNbN
00510105N	medium	TiNbN
00510110N	long	TiNbN
00510115N	extra long	TiNbN



CarpoFit® cup cementless PEEK-C

Material: PEEK-C

Coating: implaFix®; cpTi- and TCP-coating

Article number
00510021



CarpoFit® conical cup cementless

Material: implavit®; CoCrMo acc. to ISO 5832-12

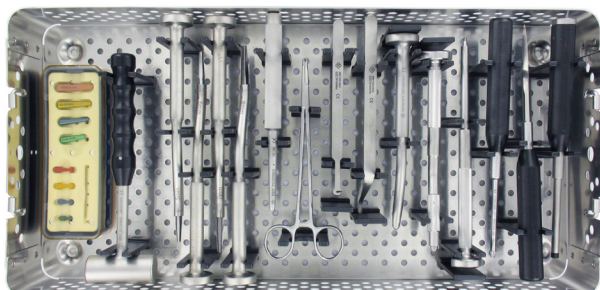
Article number	variant
00510020	
00510020N	TiNbN



Container

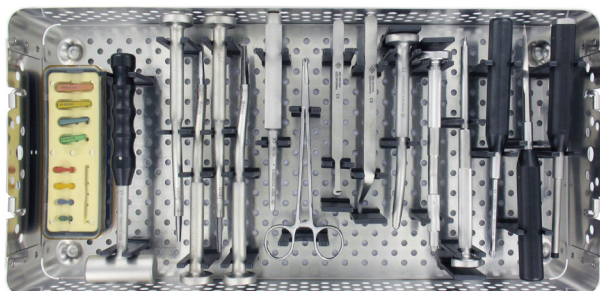
CarpoFit® – container

00519900



CarpoFit® container 1

00519901 *



* alternative to REF 00519900

Instruments

CarpoFit® – container

00519900

CarpoFit® trial joint component

Article number	Size
00510900	S
00510905	M
00510910	L
00510915	XL



CarpoFit® trial stem

Article number	Diameter
00510925	5
00510926	6
00510927	7
00510928	8



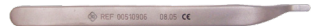
CarpoFit® trial stem impactor

00510901



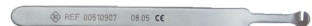
CarpoFit® hook

00510906



CarpoFit® centralizer

00510907



CarpoFit® trapezium reamer

00510908



CarpoFit® cup introducer

00510909



CarpoFit® joint component inserter

00510911



guide wire

Article number	Length	Diameter
00510918	50	1,8



ic hammer 350g

75120902



ic-pin inserter

Article number	Diameter
75120903	1,8



ic awl

75120003



CarpoFit® monoblock broach

Article number	Diameter
00510945	5
00510946	6
00510947	7
00510948	8



CarpoFit® cup inserter unconstrained

00510919



CarpoFit® forceps for articulating

00510903



CarpoFit® Container 1

00519901

CarpoFit® trial joint component

Article number	Size
00510900	S
00510905	M
00510910	L
00510915	XL



CarpoFit® trial stem

Article number	Diameter
00510925	5
00510926	6
00510927	7
00510928	8

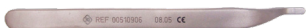




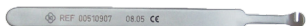
CarpoFit® trial stem impactor
00510901



CarpoFit® hook
00510906



CarpoFit® centralizer
00510907



CarpoFit® trapezium reamer
00510908



CarpoFit® cup introducer
00510909



CarpoFit® joint component inserter
00510911



guide wire

Article number	Length	Diameter
00510918	50	1,8



ic hammer 350g
75120902



ic-pin inserter

Article number	Diameter
75120903	1,8



ic awl
75120003



CarpoFit® monoblock broach

Article number	Diameter
00510945	5
00510946	6
00510947	7
00510948	8



CarpoFit® cup inserter unconstrained
00510919



Instructions for Use

Intended Use and Product Description

The **Carpofit®** Trapeziometacarpal Joint Replacement System is intended to replace the first metacarpal of the thumb trapeziometacarpal (TMC) joint.

The **Carpofit®** Conical Cup Cementless and **Carpofit®** Cup Cementless PEEK-C are cups intended to replace a partly-resected trapezium bone (os trapezium) of the wrist.

The **Carpofit®** Articular Component is a component connected to the **Carpofit®** stem and intended to articulate with the **Carpofit®** conical cup.

The **Carpofit®** Stem is a stem for cementless fixation intended to replace the first metacarpal bone.

Pre-operative Instructions

A pre-operative planning is mandatory for optimal results. Before surgery a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, x-ray templates are available:

Digital templates: Digital templates are included in the data base of the common planning systems. For missing templates, please contact the provider of the planning software and request for these templates.

Radiographic templates: Alternatively, radiographic templates are available in various scale factors, which can be obtained from your local representative.

The surgeon must ensure that:

- all needed components are available during surgery. An adequate number of all necessary implant components will be available during surgery.
- all instruments necessary will be present for surgery and that they match the implants being used. Only instruments designed for use with the implant system by implantcast GmbH should be used. An exception are exclusively the standardized instruments used during surgery.
- The correct sized instruments are used during surgery to prevent damage to the implants.

Operative Instructions

Before using, the implant should be checked to ensure that the product reference number, lot number and size correspond with the data on the labelling (REF, LOT and size).

Use appropriate aseptic technique when removing the implant from the packaging. The user is taking full responsibility for this. Implants should be implanted immediately after removal from the original packaging.

The surfaces of the implants are extremely sensitive. Implants should not be allowed to come into contact with objects that could damage the surfaces.

Before implantation, the implant should be visually inspected by the user for possible damage. Damaged implants must not be used.

The implant should not be modified in any way – modifications to the implant may lead to impairment of its function or early failure. The manufacturer assumes no liability for modified products. In case of changes or manipulation the regulatory responsibility is transferred to the person changing or manipulating the components. The manufacturer no longer guarantees the product.

In cementless applications, a firm fixation of the implant at the time of surgery is essential for the success of the implantation. The cementless components are seated in the bone by pressfit which

requires to perform precise surgery and the use of the instruments provided for this purpose.

Prior to wound closure, the surgical area including the articulation surfaces of the implant must be thoroughly cleaned to remove any foreign bodies such as bone splinters, bone cement residues and any remaining fragments of a previously revised component or instrument.

It is also recommended to take an intraoperative X-ray image and examine it for remaining particles and remove them before wound closure.

Post-operative Instructions

Post-operative patient care, patient instructions and warnings are of the utmost importance.

The use of an external support of the operated extremity for a limited period is recommended.

Active and passive movements of the operated extremity should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the operated extremity and stimulation of the healing process.

Regular monitoring of the position and condition of the prosthetic components and the surrounding bone is recommended.

Indications and Patient Target Group

The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising.

Danger of post-operative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants.

The provision of **Carpofit®** Trapeziometacarpal Prosthesis is generally indicated only in patients whose skeleton is fully grown. Before intervention, preoperative examinations should be performed. The examinations depend on the patient's medical history.

Under consideration of these conditions the **Carpofit®** Trapeziometacarpal Prosthesis applies to the following indications:

- Non-inflammatory degenerative joint disease including osteoarthritis (rhizarthrosis) and avascular necrosis,
- Rheumatoid arthritis.

Patients, that meet the indications given in this instruction for use and for whom the implantation of **Carpofit®** Trapeziometacarpal Prosthesis is a suitable therapy. The treating surgeon decides whether and which version of the implant is suitable for each patient. This decision depends on several factors, such as the patient's age and weight, bone quality, shape of the bone and deformation of the joint.

Contraindications

The longevity of an orthopaedic implant can be reduced by biological aspects, material characteristics and biomechanical factors. Therefore, a careful examination of the indications is recommended in overweight patients, in patients with very high joint loads due to high physical activity as well as in patients younger than 60 years.

Carpofit® Trapeziometacarpal Prosthesis is contraindicated in cases of:

- Allergy to one of the implant materials. (The label on the sec-



ondary packaging of the respective component indicates the materials used. It is strongly recommended to perform an allergy test.)

- Ongoing infections
- Physiological or anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis.
- undersized trapezium bone (the height of the trapezium should be greater than or equal to 8mm),
- Bone tumors in the implant fixation area
- Untreated vascular diseases which limit blood supply to the affected limb
- Metabolic disorders that may impair bone formation.
- In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony fixation should be considered.
- Arthritis of the scaphotrapezial joint

Risk Factors

The following risk factors may affect the success of the **CarpoFit®** Trapeziometacarpal Prosthesis:

- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Severe deformities which lead to an impairment of bone fixation or the exact positioning or the function of the implant
- Therapies that may affect bone quality
- Muscle insufficiency
- Neuromuscular disease of the affected limb
- Conditions that restrict the patient's ability or willingness to comply with medical instructions, especially during the healing process
- Obesity
- Nicotine and/or drug abuse
- Alcoholism
- Previous surgeries on the affected limb
- Diabetes
- Psoriasis



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