BEZNOSKA

We bring back joy to movement

Total replacement of trapeziometacapral joint – type T

Primary Implants

ARTHROPLASTY

Introduction

Total replacement of trapeziometacarpal joint, type T, was designed using latest findings and experience with this type of implants. It allows a simple and perfect fixation of the implant at minimal bone resection.

Optimization of dimensions of the joint replacement's surface ensures maximum scope of mobility, while retaining good functional stability. Finish of the articular and anchoring surfaces minimizes effects of wearing and ensures very good integration of the components with bone tissue.

Assortment of the stem and cup sizes covers evenly whole range of necessary sizes, so that– in combination various lengths and angles of the necks – practically all situations as may occur in primary implantation of joint replacements an adequate solution can be found.

A broad range of instruments facilitates exact positioning of the implant and its perfect fitting. Design is conceived so that the surgeon is able, by following simple, exactly defined, and contingent steps, to solve virtually all common problems.

Purpose of this publication is to be used as a handbook of instructions for each concrete implant and instrument. Its concise contents focus on the process of implanting a specific type of endoprosthesis, on the assumption that the surgeon and other personnel are thoroughly acquainted with general rules applicable to trapeziometacarpal joint replacement.

Aim of this publication is to help surgeons and theater nurses to orientate themselves quickly and use the individual elements of the set of instruments properly, in order to attain optimal results and, last but not the least, to avoid unnecessary damaging and depreciation of the instruments or the implant. It is not, by any means, a study book of surgical techniques.

General Information

Elements of total endoprosthesis may be combined nearly without limitations .... e.g., any of stems can be used with any of necks. The only limitation is requirement of matching of diameters of the articular surfaces of cup and head – e.g.: for neck with a diameter of 7 mm, solely a cup with articular surface's diameter of 7 mm could be used.

The implant (total replacement set) must contain the following elements:

- Stem (metacarpal component)
- Neck (with head)
- Cup (trapezial component)

Fig. 1 - Total replacement of trapeziometacapral joint – type T

TMCJ - Stem, cementless – type T/I

Metacarpal component is designed as symme-trical component, i.e., identical both for left and right hand, and it is available in 4 sizes. It is made of an alloy, Ti6Al4V, as per ISO 5832-3 Standards.

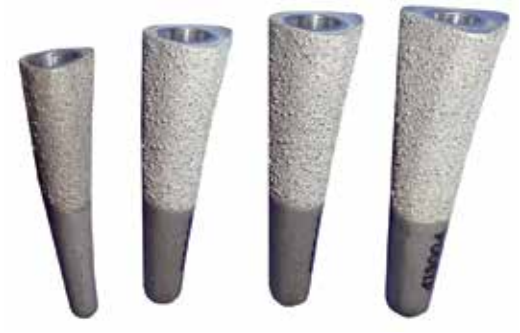


Fig. 2 - TMCJ - Stem - range of 4 dimensions

TMCJ – TEP Neck – Type T/I and Type T/II

Component is designed as 2 basic types (for non-cemented cup with the articular surface's diameter of 7 mm, or cemented cup articular surface's diameter of 5 mm), and in several variants: (a) straight (the axis of anchoring part and the axis of neck and head are identical) or (b) valgus (axis of anchoring part and the axis of neck and head forming an angle of 15°). Moreover, both types and all variants are delivered in four lengths – see Fig. 2. TEP neck is made of an alloy, CoCrMo, as per ISO 5832-12 Standards. The surface of implant is brushed, head is polished, and head's articular surface, in type T/I, is coated with a layer of DLC.

Fig. 3 - Straight variant

Fig. 4 - Valgus variant

TMCJ – TEP Cup – Type T/I and Type T/II

Component is designed in 2 basic types (cementless cup with articular surface's diameter of 7 mm (type T/I) or cemented cup with articular surface's diameter of 5 mm (type T/II)). The non-cemented cup is made of an alloy, CoCrMo, as per ISO 5832-12 Standards. Cup's outer diameter is 9 and 10 mm, respectively, and its surface coated with a layer of porous Ti. Inner articular surface is coated with a layer of DLC. The cemented cup is made of UHMWPE as per ISO 5834-2 Standards. Cup's outer diameter is 10mm.

Fig. 5 - TMCJ – Cementless cup outer

Fig. 6 - TMCJ – Cementless cup inner

Fig. 7 - TMCJ – Cemented cup

Introduction

This is a description of a standard recommended surgical process that begins with metacarpal incision. However, the modularity of instrumentation makes it easily possible to start the process with resection of trapezium, at surgeon's discretion. The following steps of operation's individual phases remain unchanged.

Approach

Instruments make it possible to implant the joint replacement comfortably using any of standard surgical approaches used for implanting TMC joints without requiring any substantial change in surgical procedures normally used at given workplace. Standard approach is dorsal approach, for it makes use of all of advantageous features of the instruments. (Fig. 1).

Process is not influenced by use of a tourni-quet to stop blood flow.

With dorsal approach, we access joint in interval between extensor pollicis brevis and abductor pollicis longus, while securing terminal branch of ramus superficialis n. radialis. Upon resecting casing's lobed tissue dorsally, we expose the base of first metacarpus (M1). (Fig. 2).

Fig. 1 - Recommended hand position

Fig. 2 - Access to the base of first metacarpal

1. Resecting the base of the first metacarpal (M1)
The following steps prepare medullary canal for the TEP stem. Firstly, open the bone marrow canal (see Fig. 3) a reamer drill of 2÷3 mm in diameter may be used). Thereupon we assemble resection block's holder and the resection block properly, and induce the assembled set into the open canal (see Fig. 4a). After determining the resection level, we secure set using one or two fixation wires (Ø1.2 mm) that we induce through the holes in resection block (see Fig. 4b and 4c). Thereupon we remove resection block's holder and, using oscillation saw, we resect base M1 (see Fig. 5). When resection is done, we carefully remove resection block, too, including the fixation wires.

We always try to make resection as small as possible.

Fig. 3 - Access to the base of metacarpal

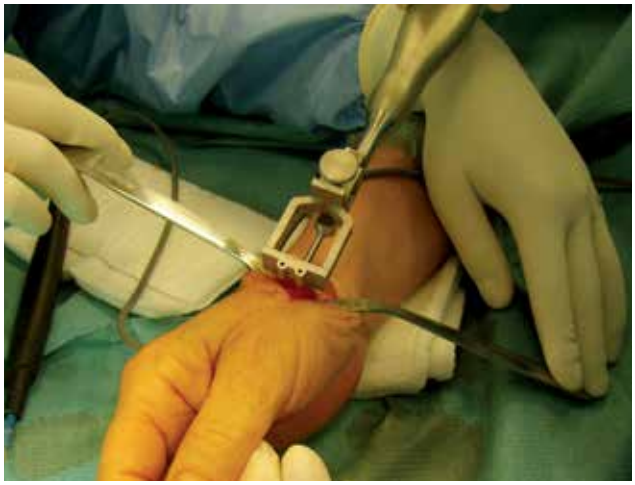


Fig. 4a - Resection block implemetation

Fig. 4b - Fixation wires implementation

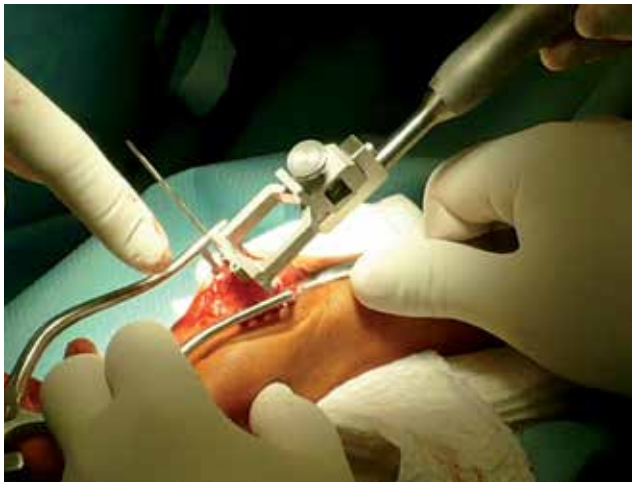


Fig. 4c - Secured resection block

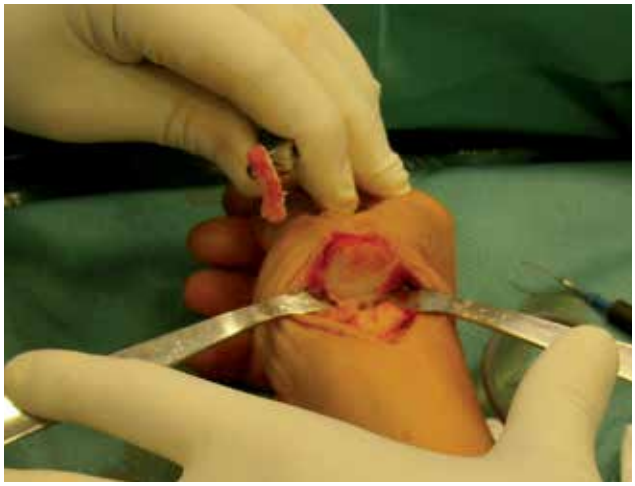


Fig. 5 - Resection base M1

2. Preparing medullary canal for TEP stem

Next, we prepare medullary canal for TEP stem. During pre-operation planning we could merely estimate probable size, but it is only after preparing bone marrow cavity that we are able to determine size correctly. Using the rasps, from the smallest to the largest, we work on medullary canal gradually until intimate contact of the rasp's larger surface with the cortical bone is reached (see Fig. 6a). Simultaneously, we keep checking the depth of rasp's penetration – the upper end of rasp indicates depth of the implant's position (see Fig. 6b). After completion of processing pulp cavity prepare trial stem with size last used rasp with insertion instrument and implement it to pulp cavity (see Fig. 7a and 7b).

If pulp cavity was correctly prepared, upper surface is implemented to trial stem at the same time with resection plane (see Fig. 7c).
During rasping and implementation of trial stem triangular shape of pulp cavity of first metacarpal must be respected - marking volar side of rasp and stem (see Fig. 8).
For inducing the rasp, we may use a small hammer, but utmost care must be taken to avoid damaging the metacarpus (esp. by cracking) or the soft tissue around it.

Fig. 7a,b - Trial stem and insertion instrument compilation and implementation

Fig. 6a - Medullary canals rasping below stem

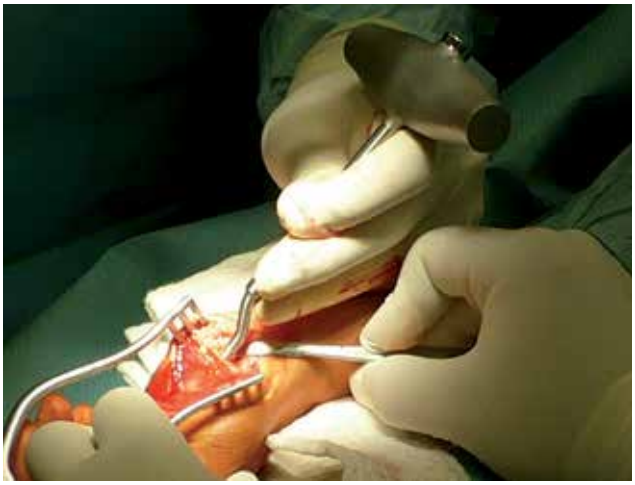


Fig. 6b - Completion of rasping. Correctly implemented rasps.

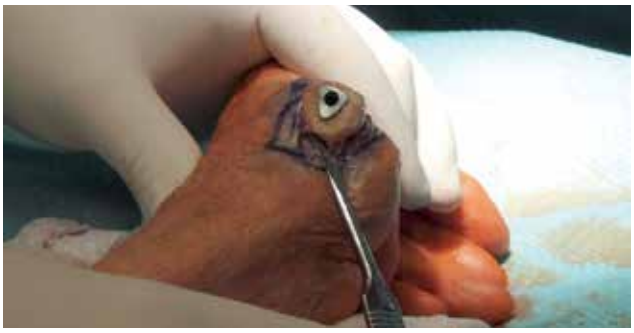


Fig. 7c - Implemented trial stem

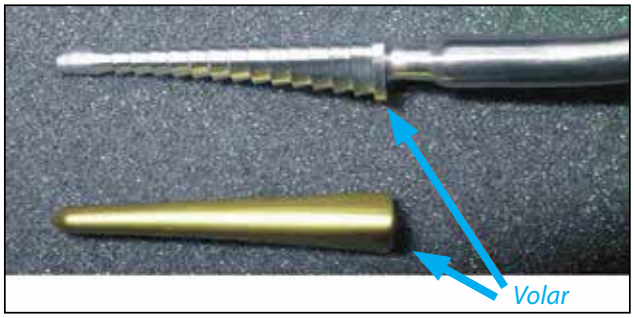


Fig. 8 - Rasp and trial stem volar side

3. Preparing the trapezium

Firstly, using an oscillation saw, we resect the trapezium. Purpose of the resection is to remove all residue cartilage and sclerotic bone, as they do not ensure good support for the cup. Resection should be as small as possible, bearing in mind however, that the bone must cover the entire external surface of the cup induced subsequently. Level of resection on trapezium should be parallel with base M1 of the first MCP joint (see Fig. 9a).

Preferably, it is possible to use an oscillating saw (see Fig. 9b).

Before we modify the trapezium, we have to process articulated surfaces by osteophytes resection (see Fig. 9c). It is advisable, if the rest of subchondral bone will stay on the articulated surface.

Obr. 9c - Completed trapezium resection

4. Place the matrix

Place the matrix with guide wire (see Fig. 10a and 10b) on the resected facet and screw guide wire through hole into the trapezium (Ø1.2 mm). (see Fig. 11). Pointed guide wire and the matrix form part of set of instruments.

Fig. 10a - Template with guide sleeve

Fig. 9a - Articulated trapezium surface

Fig. 9b - Trapezium resection by oscillation saw

Fig. 10b - Template with guide sleeve and guide wire Ø1.2 mm

Exact positioning of matrix (i.e., in the center of resected facet) is very important for correct positioning the cup and its proper fixation in the trapezium. After introduction of the wire is therefore advantageous to adjust upper surfaces of trapezium with flush reamer.

5. Milling the medullary canal for cup

Next we cut the medullary canal for cup. This is done with a rotary cutter of the relevant diameter – on principle, we use the guide wire for inducing the cutter. We always begin with 8 mm cutter. Cutter may be fitted in the reamer drill (see Fig. 12a). or handled manually using the "T" handle (see Fig. 12b).

Medullary canal's finishing is always done by careful manual milling to ensure its perfect shape and surface finish, as it is crucial for joint's primary stability and time necessary for secondary fixation of the cup (see Fig. 13).

Fig. 11 - Implemented guide wire Ø1.2 mm

Fig. 12a - Milling medullary canal for cup

Fig. 13 -Complete medullary canal with imple ment guide wire Ø1.2 mm

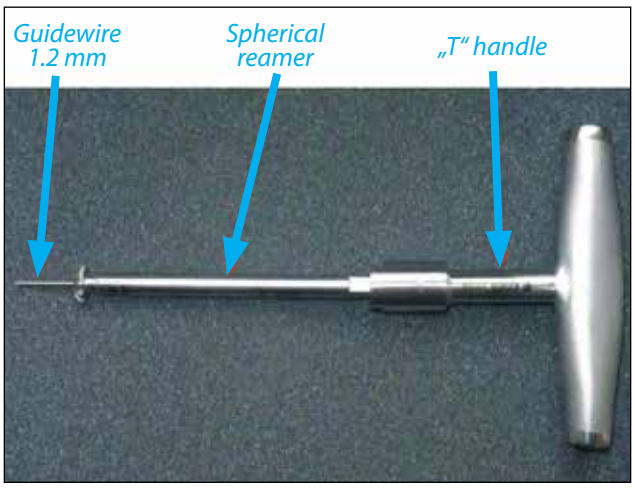


Fig. 12b - Set for handmade milling bed

The medullary canal's shape and dimensions are checked with aid of 9 and 10 mm matrixes (see Fig. 14a and 14b). Only when we plan to use cementless cup keep the wire implement in cup after compilation of medullary canal.

The matrixes may be used for preliminary functionality testing during the first trial fitting in the trial assembly using a trial stem, trial neck, and trial "cup" (matrix). However, no guide wire may be induced in the trapezium during this trial.

6. Trial Fitting of Joint

After finishing the medullary canal in metacarpus and trapezium, we are ready to check position of components and functionality of the joint.

In essence, there are two kinds of trial fitting:

a) The first kind presumes the use of a complete assembly of trial components (trial stem, trial neck and matrix of the cup). In this case we induce the trial stem first. Then we take from the cassette of instruments a stem of the same size as was the size of rasp used last, where upon using guide wire screwed into threading inside the stem (see Fig. 7) we insert assembly into the metacarpal medullary canal. Depth of the insertion should be identical to the position of rasp of corresponding size. Next we insert the trial neck into the hole in stem, whereby we make sure to have selected the correct size of neck and the correct angle variant: straight or valgus. Lastly, we induce the matrix of cup of a previously tried-out diameter (9 or 10 mm) (see Fig. 15).

In this phase we can test the stability of head (its retention in the cup) and also, to a certain degree, the scope of joint's mobility.
Depending on the result, we can change the length of neck (available are four lengths – 10, 12, 14, 16 mm) as well as the angle of neck's axis (straight or valgus of 15°.

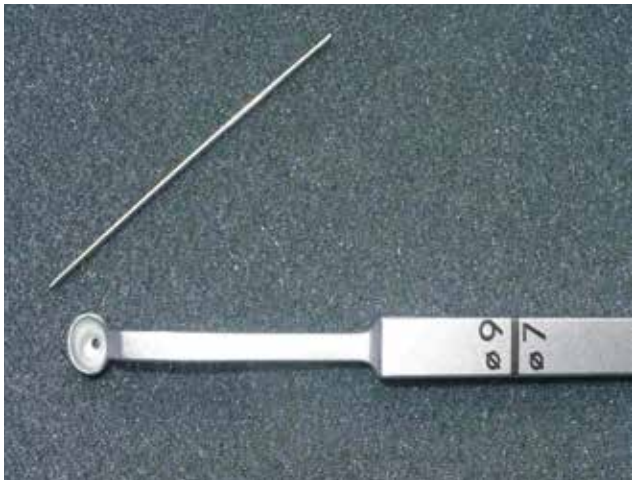


Fig. 14a - Cup size template with guide wire Ø1.2 mm

Fig. 14b - Implemented cup size template with guide wire Ø1.2 mm

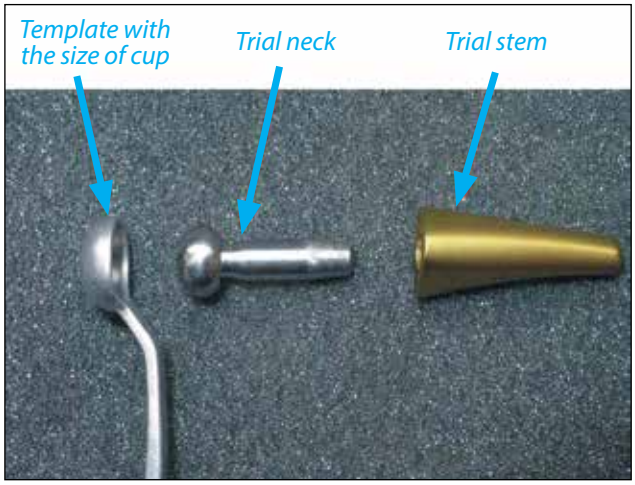


Fig. 15 - Trial set TEP with cup template

Provided that trial fitting proves joint's stability and functionality as satisfactory, we may proceed to the last step – inducement of the definitive implant.

b) Second kind of trial fitting involves use of definitive components (stem and cup complemented with a trial neck. In this case, the sequence of steps is reversed, i.e., the insertion of components starts with the cup. Advantage of this mode of procedure is the use of a guide wire of a diameter of 1.2 mm for centering the cup. For this purpose, the guide wire has to remain inserted at the bottom of trapezium. During implantation proper, we place the cup on wire carefully (see Fig. 16a) and push it into the prepared medullary canal.

Then we push to the cup by direct or curved insertion instrument (see Fig. 16b). We have to remember the diameter of the spherical surface when we are selecting insertion instrument. For cementless cup it is neccessary to use the insertion instrument (direct or curved) with spherical surface with diameter of 7 mm.

This phase is very important for success of the operation - good post-surgery stability of cup can only be ensured if it is inserted with an overlap and all three pins around its circumference are jammed firmly into the trapezium.

On picture 17 is implemented cup with guide wire and then after his removal.

Fig. 16a - Cup with guide wire ø 1.2 mm

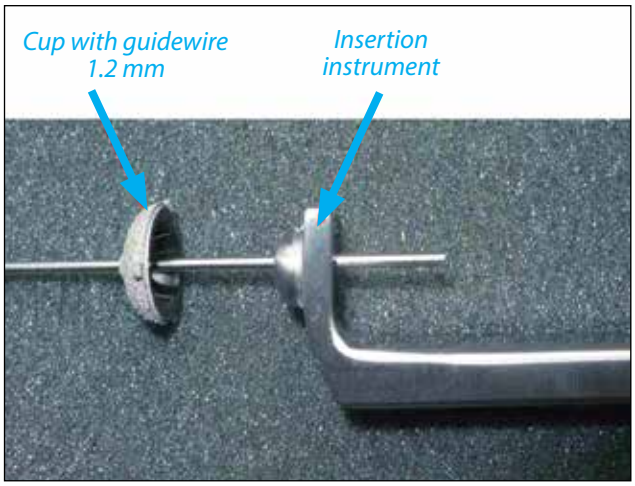


Fig. 16b - Cup set with guidewire and insertion instrument

Fig. 17 - Implemented cementless cup

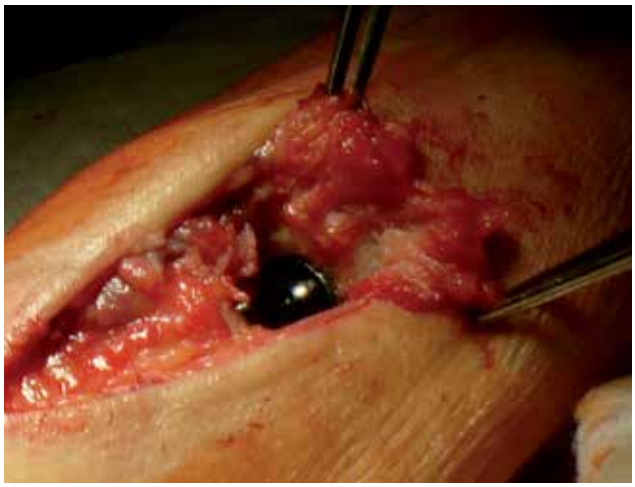


Fig. 18 - Implemented cementless cup – Detail

Cup implemetation is completed with implementation plug of guide hole. For safe insertion to cup, the plug is delivered in sterile packaging with cup and already firmly connected with guide wire with diameter of 1 mm. Plug is carefully inserted to hole in cup in order to not damage articulated surface.
After plug insertion guide wire is pulled out from plug hole in way that firstly hold the plug with insertion instrument by cup and then rip out the wire (mostly is possible to do with hand but in caution is possible to do with pliers).

When we are using cemented cup, firstly we have to modify the medullary canal for better connection of bone cement with bone by drilling three to four holes with diameter of about 1,5÷2 mm and 1÷2 mm to depth, then we have to perfectly desiccate the medullary canal and apply coherent layer of cement on medullary canal. We will use insertion instrument for cup implementation again, but this time with spherical surface with diameter of 5 mm.

Next step is insertion of the definitive stem. For this purpose, we take insertion driver from cassette of instruments, screw it onto the implant's threading and insert assembly into the metacarpal medullary canal. When handling the implant, we proceed with utmost care, making sure to fit driver's chamfer onto the stem's upper facet perfectly (see Fig. 19).
The depth of stem's insertion has to be identical to the depth of rasp. If there is too much resistance, therefore danger of breaking the metacarpus apart, we recommend working medullary canal a little more with rasp or waiting for pressure to subside.

If screwed connection comes loose, it might damage threading and cause problems with removal of insertion tool.

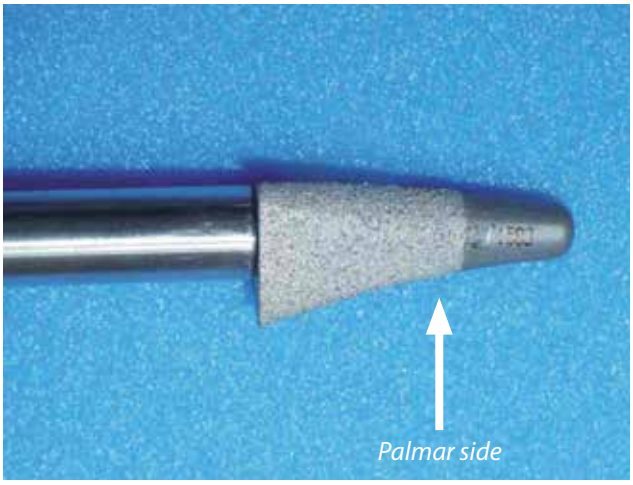


Fig. 19 - Set of stem and insertion instrument

Finally, we insert the trial neck and check joint's functionality and stability. Provided that the TEP properties are satisfactory, we unwrap definitive neck and replace the trial neck. For manipulation with implant and with trial neck use holding pliers or extractor (see Fig. 20 and 21).

Neck with stem connection is ensured with self-locking cone and during removing trial neck or implant from stem it is appropriate to use an extractor. If we used more power during neck implementation or repeatedly inserted joint it is probable that neck will relatively well hold in stem. If we try to remove neck by force, implemented stem can be riped out from medullary canal.
To avoid similar undesirable situation, adjustable extractor with distraction member is in set of instruments. Method of can be seen on Fig. 21.

Picture 22 shows complete set of implant.

7. Final Steps

Operation ends with reconstruction of joint's casing (capsule), closing of surgical incision layer by layer, and application of a bandage.

Pictures from MUDr. Trtík's operations were used for this manual.

Fig. 20 - Correct way of holding neck

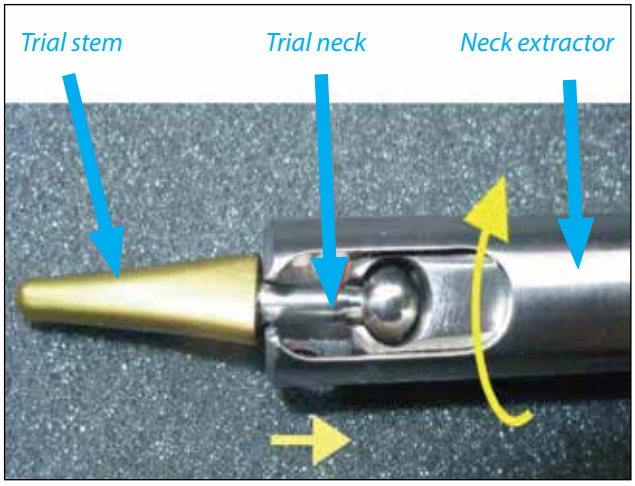
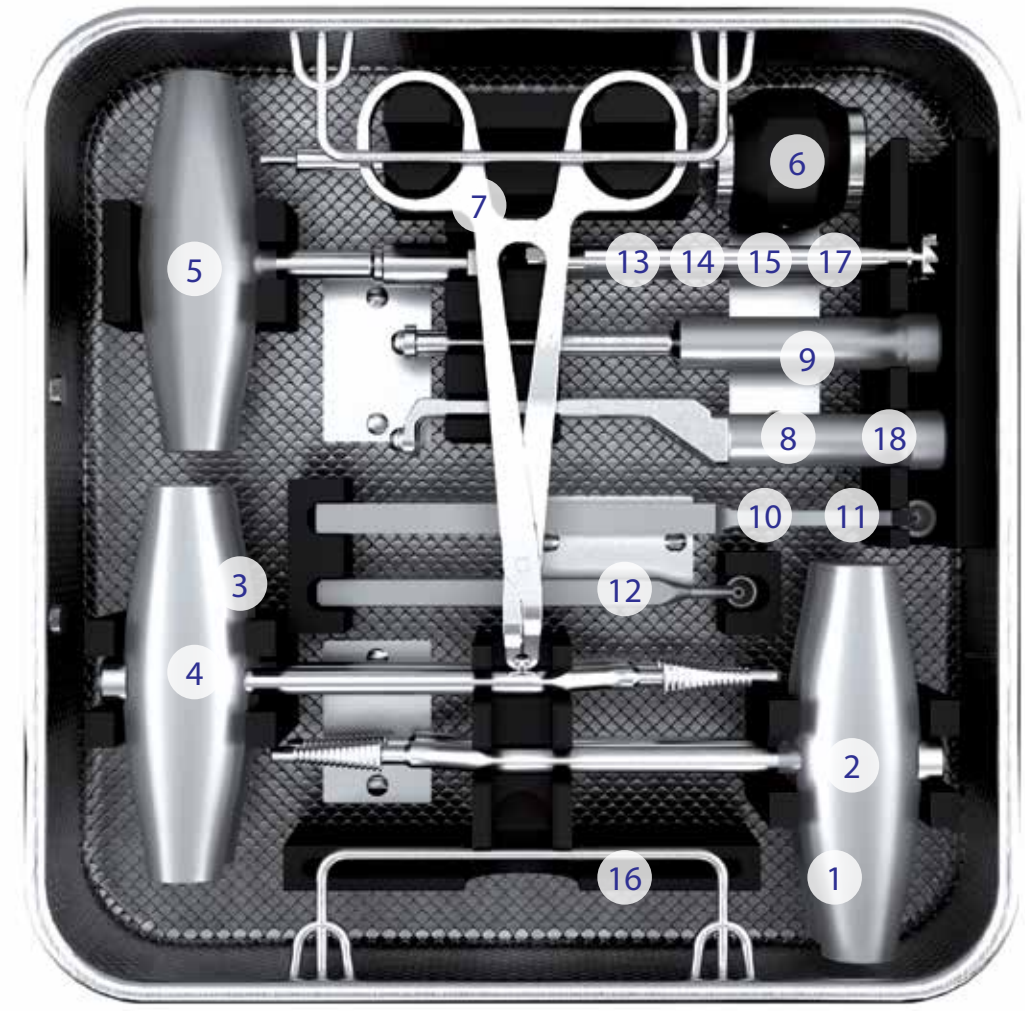


Fig. 21 - Procedure of using adjustable extractor

Fig. 22 - Complete set of implant

Instruments set

The instruments set (Ordering number 400015) are suitable for hadling during operation, transportation, sterilization and storage as well.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Set of instruments for Total replacement of trapeziometacarpal joint – type T **L AY - O U T – T R AY I.**			
	Denomination	**Qty**	**Order number**
	Tray 1, instruments TMCJ		400016
1	Rasp 1	1	400415
2	Rasp 2	1	400416
3	Rasp 3	1	400417
4	Rasp 4	1	400418
5	„T“ inserting instrument	1	400408
6	Extractor boot shaft	1	400401
7	Gripping pliers	1	400437
8	Curved loader 7	1	400405
9	Direct loader 7	1	400406
10	Template 9	1	400402
11	Template 10	1	400403
12	Gauge 9mm	1	400431
13	Cutter 8	1	400411
14	Cutter 9	1	400412
15	Cutter 10	1	400413
16	Guide wire	5	400435
17	Alignment cutter	1	400409
18	Curved loader 5	1	400404


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Set of instruments for Total replacement of trapeziometacarpal joint – type T **L A Y - O U T – T R A Y II.**			
	Denomination	**Qty**	**Order number**
	Tray 2, instruments TMCJ		400017
19	Block resection holder	1	400421
20	Perforators	1	400442
21	Raspatorium	1	400441
22	Elevatorium	1	400440
23	Neck extractor hard	1	400444
24	Neck extractor adjustable	1	400430
25	Head inserting instrument I 7 mm	1	400425
26	Head inserting instrument II 5 mm	1	400426
27	Block resection	1	400423
28	TMCJ - Trial stem - size 1	1	400301
29	TMCJ - Trial stem - size 2	1	400302
30	TMCJ - Trial stem - size 3	1	400303
31	TMCJ - Trial stem - size 4	1	400304
32	TMCJ - Trial neck straight 7/12	1	400311
33	TMCJ - Trial neck straight 7/14	1	400312
34	TMCJ - Trial neck straight 7/16	1	400313
35	TMCJ - Trial neck straight 7/18	1	400314
36	TMCJ - Trial neck valgus 15° 7/12	1	400321
37	TMCJ - Trial neck valgus 15° 7/14	1	400322
38	TMCJ - Trial neck valgus 15° 7/16	1	400323
39	TMCJ - Trial neck valgus 15° 7/18	1	400324
40	TMCJ - Trial neck straight 5/12	1	400351
41	TMCJ - Trial neck straight 5/14	1	400352
42	TMCJ - Trial neck straight 5/16	1	400353
43	TMCJ - Trial neck straight 5/18	1	400354
44	TMCJ - Trial neck valgus 15° 5/12	1	400361
45	TMCJ - Trial neck valgus 15° 5/12	1	400362
46	TMCJ - Trial neck valgus 15° 5/12	1	400363
47	TMCJ - Trial neck valgus 15° 5/12	1	400364

Content of cassettes is only informative and could be changed up to implemented innovative changes.

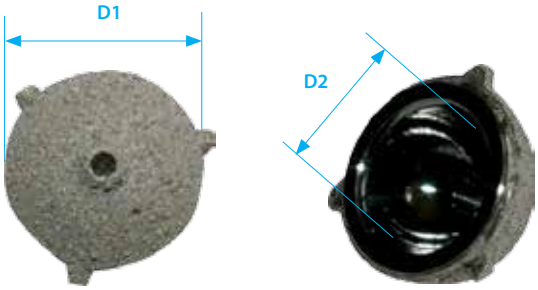
Stem cementless – type T

Material: Wrought titanium 6Al-4V alloy (ISO 5832-3)

Size	Dimensions L [mm]	Dimensions D [mm]	Order No.
1	26	7	413001
2	27	8	413002
3	29	9	413003
4	30	10	413004

Cup cementless – typ T/I

Material: Wrought Co-Cr-Mo alloy (ISO 5832-12) + DLC

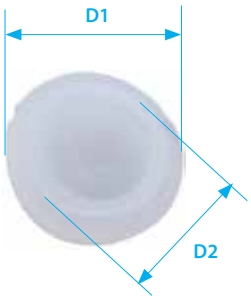


Dimensions D1 [mm]	Dimensions D2 [mm]	Order No.
9	7	413161
10		413162

Cup cemented – type T/II

Material: Ultra-high molecular weight polyethylen (ISO 5834-2)

Dimensions D1 [mm]	Dimensions D2 [mm]	Order No.
10	5	413082



Neck TEP – type T/I

Material: Wrought Co-Cr-Mo alloy (ISO 5832-12) + DLC

Variant	Dimensions L [mm]	Dimensions D [mm]	Order No.
Straight	12	7	413112
	14		413113
	16		413114
	18		413115
Valgus 15°	12	7	413122
	14		413123
	16		413124
	18		413125

Neck TEP – typ T/II

Material: Wrought Co-Cr-Mo alloy (ISO 5832-12)

Variant	Dimensions L [mm]	Dimensions D [mm]	Order No.
Straight	12	5	413072
	14		413073
	16		413074
	18		413075
Valgus 15°	12	5	413077
	14		413078
	16		413079
	18		413080

BEZNOSKA

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Certificate No. 2004-OSL-AQ-0013

This is to certify that the Management System of:

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has been found to conform to the standard:

ISO 13485:2012

This Certificate is valid for the following product or service ranges:

Design and development, production and sales of implantable medical devices and instruments.

Initial Certification date: 23 November 2003

This Certificate is valid until: 23 November 2015

The audit has been performed under the supervision of: Evangelos Tavandis, *Lead Auditor*

Place and date: Høvik, 13. November 2012

for the Accredited Unit: DET NORSKE VERITAS CERTIFICATION AS, NORWAY

Eugenie Winger Husebye, *Management Representative*

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 24539-2008-CE-NOR 2.0

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This is to certify that the Quality Management System of

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for design, development, production and final product inspection/testing of

Orthopaedics and Traumatology Implants

has been assessed with respect to
the conformity assessment procedure described in Article 11.1.a and Annex II (Module H1)
of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date: Høvik, 24 May 2013

This Certificate is valid until: **11 April 2018**

For DET NORSKE VERITAS CERTIFICATION AS NORWAY

Eugenie Winger Husebye, *Certification Manager*

CE

Notified Body No.: 0434

Aud Loken Eikli, *Technical Reviewer*

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

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