

MUTARS[®]



implantcast



Humerus Inverse
Surgical Technique



Humerus Inverse Surgical Technique

MUTARS® was developed in co-operation with Univ.-Prof. Dr. W. Winkelmann (ex-director) and Univ.-Prof. Dr. G. Gosheger (director) Department of General Orthopaedics and Orthopaedic Oncology at the University Hospital of Münster, Germany. MUTARS® is in successful clinical use since 1992.

Table of Contents

Information About Silver and TiN Coating.....	2
Pre-Operative Planning	3
System Overview.....	4
Assembling Options.....	5
Surgical Technique	6
Implants.....	16
Instruments.....	18
Pre-operative, Intra-operative and Post-operative Instructions.....	22
Indications, Contraindication and Risk factors.....	23

Nota Bene: The herein described surgical technique shows the treatment suggested by the author in uncomplicated surgical procedures. However, it is ultimately the operating surgeon's decision, which approach is the most reasonable and effective for the respective patient.

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The Silver Coating

Infections represent the most severe complications of tumour arthroplastic treatments. Although local and systemic antibiotic treatments are considered, the scientific literature reports of infection rates from 5 to 35 percent [1]. Reasons for these high rates are, for example, the long surgery time, the large incisions and the immunosuppression due to chemo therapy and radio therapy as well as the increasing resistance of the bacteria against antibiotic drugs.

Silver, in particular free silver ions, is well known for its broad-spectrum antimicrobial activity. The silver coating has been shown to reduce bacterial colonization on the device surface.

Until now only non-articulating surfaces and surfaces without direct bony contact are coated with silver.

In the catalogue information of this surgical technique you can find the supplement *S indicating which MUTARS® components are available in a silver coated version. The eight digit REF number receives an addition after the last digit (e.g. 5220-0020S).

Important Intra-Operative Instructions for the Use of Silver-Coated Implants

It is not permitted to flush the wound with antiseptics that contain H₂O₂, Iodine or heavy metals (such as Betaisodona®) and acetic acid during surgery since this can lead to a subsequent loss of effectiveness of the silver coating due to their oxidative properties. Alternatively, solutions such as NaCl or Lavasept® and Prontosan® can be used. The additional use of antibiotic-containing bone cement can be an advantage particular in case of a septic revision.

The TiN Coating for Allergy Prophylaxis

All metallic implant components release ions to their environment over time. In some patients such ions can elicit allergic reactions. Nickel, cobalt and chromium, which are elements of the base material CoCrMo of the articulating implant components, are considered the most frequently allergy eliciting metals [2] The TiN-coating is biocompatible and acts like a barrier; the potential release of allergy eliciting ions of the base material is reduced to a minimum [3]. Also in clinical practice there have never been any evidence of allergic reactions with implants that have been TiN-coated showing an intact surface [5]. Therefore the TiN-coating on implant components is especially suitable for patients with sensitivity to nickel, chromium or cobalt [4][5].

Since almost all components of the MUTARS® tumour system consist of titanium alloy, this only concerns those components, which are made of a CoCrMo alloy. The REF-numbers of the TiN-coated implants have the suffix N after the last digit (e.g. 5720-0005N). Items which are available with Silver and TiN coating have the suffix SN after the last digit (e.g. 5720-0005SN).

***S:** Implants are available with Silver coating!

***N:** Implants are available with TiN coating!

***SN:** Implants are available with Silver and TiN coating!

[1] Gosheger et al. 2004. Silver-coated megaendoprostheses in a rabbit model – an analysis of the infection rate and toxicological side effects. *Biomaterials* 25, 5547-5556.

[2] Eben R et al. (2009) Implantatallergieregister - ein erster Erfahrungsbericht. *Orthopäde* 38: 557-562

[3] Wisbey et al. (1987) Application of PVD TiN coating to Co-Cr-Mo based surgical implants. *Biomaterials*, 11

[4] Prof. Thomas LMU München Final Report Effect of a TiNbN or TiN surface coating on cobaltchromium- molybdenum and stainless steel test specimens regarding the release of nickel, chromium and cobalt: evaluation via eluate analysis and in-vitro cytokine release from peripheral human blood cells, Data on file

[5] Baumann A. (2001) Keramische Beschichtungen in der KTEP Standardlösung für Allergiker. *JATROS Orthopädie & Rheumatologie* 6: 16-17

MUTARS® Humerus Inverse

Pre-Operative Planning

Pre-operative planning and precise surgical techniques are mandatory for optimal results. The instructions and the procedure given in the surgical technique to the system must be adhered to. Familiarity with the recommended surgical technique and its careful application is essential to achieve the best possible outcome.

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.



Picture shown: MUTARS® Humerus inverse implant in A/P view



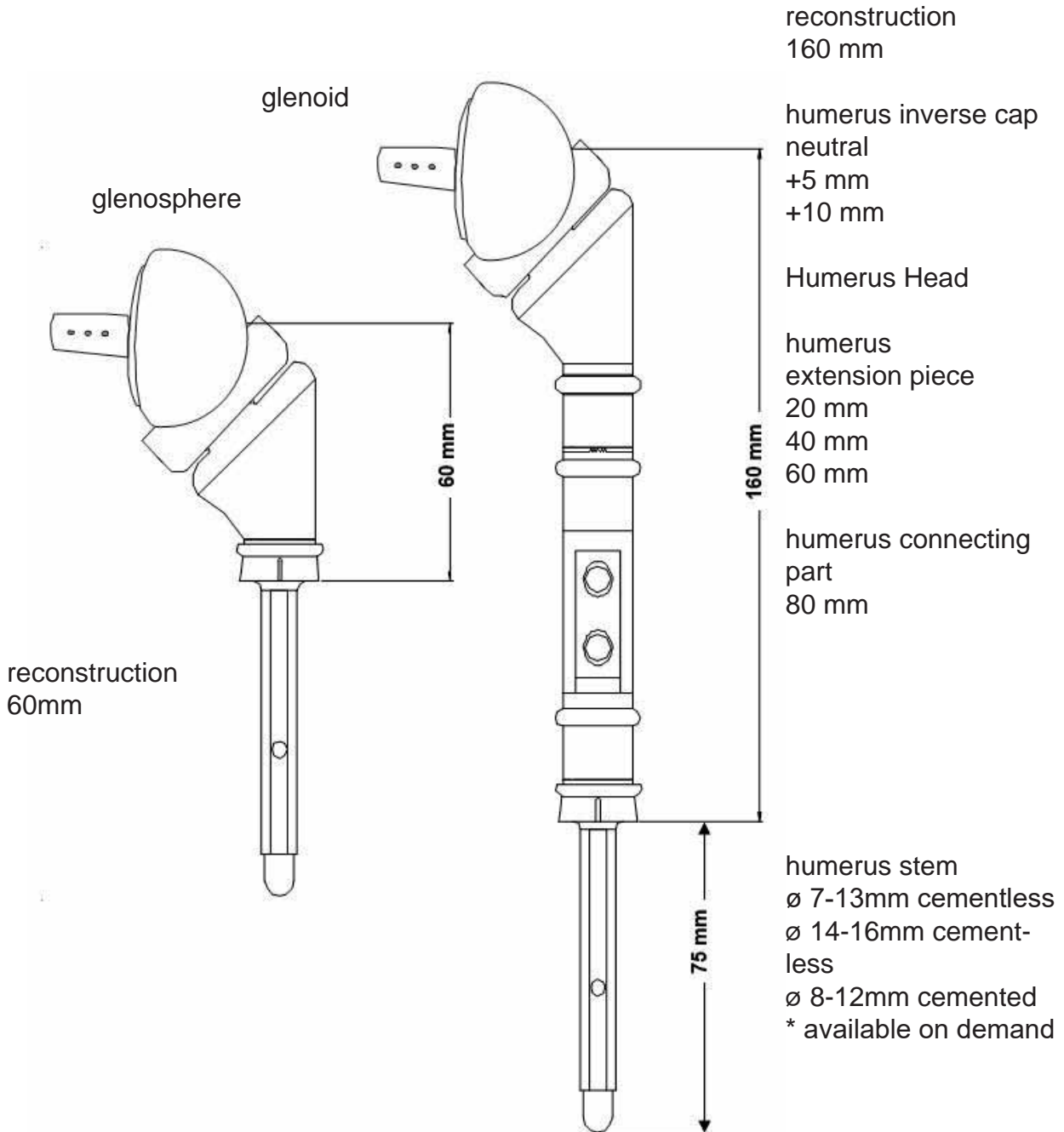
Picture shown: MUTARS® Humerus inverse implant in M/L view

For further information, please see the instructions for use for MUTARS® Tumor- and Revision System (Item number: 09300013GB) and p. 22, 23 of this surgical technique.



MUTARS® Humerus Inverse

System Overview





MUTARS® Humerus Inverse

Assembling Options

by using a MUTARS® humerus inverse cap (length in mm)

Components			
Reconstruction (mm)	Head (mm)	Extension piece / connecting part 80 mm (mm)	Screw (mm)
60	50	-	15
80	50	20	35
100	50	40	55
120	50	60	75
140	50	80	15 + 15
160	50	20 + 80	35 + 15
180	50	40 + 80	55 + 15
200	50	60 + 80	75 + 15
220	50	60 + 80 + 20	75 + 35
240	50	60 + 80 + 40	75 + 55
260	50	60 + 80 + 40 + 20	75 + 75

Note: Please notice that the amount of implants and instruments send with an individual shipment may differ from the information in the catalogue information of this brochure. Please make sure, during the preoperatively planning, that all necessary implants and instruments are available for the surgery.

Surgical Technique

Tumour Resection

Resect the tumour and measure the length of the explant and determine the length of the explant. The minimum bone resection is 60mm.

Preparation of the Glenoid

Place the glenoid drill guide and choose the correct position for the glenoid implant. Drill the central hole with the 3.2mm pin and leave in the pin (Fig. 1). Alternatively, the drill guide (Fig. 2) can be used. Drill approximately 2.5cm deep. Prevent from drilling too deeply as the drill has no stop.

In order to expose the subchondral bone, ream the glenoid bone with the glenoid reamer guided by the 3.2mm central pin. The reamer is guided by the central peg (Fig. 3 and Fig. 4).

Leave the pin inside the bone. The best fixation is achieved when the bleeding subchondral bone is reached (Fig. 5).

Note: The central peg hole is slightly smaller than the central peg of the implant. The central peg will lock by PressFit eventually.



Fig. 1



Fig. 2



Fig. 3



Fig. 4



Fig. 5

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Fig. 6



Fig. 7

Screw the humerus impactor to the glenoid implant. Make sure that the cranial marking is orientated correctly. Impact the implant with cautious beats into the bone until the glenoid lies completely flush on the reamed bone surface. Make sure that the "cranial" marking is properly placed (Fig. 6 and Fig. 7) and remove the impactor afterwards.

The drilling angle can be chosen freely between 0° and 15°.

Optional Surgical Technique



Fig. 8

In order to position the screws in 15° precisely, use the special glenoid drill guide correctly orientated, so the cranial and caudal position is found. Use the 2.0mm drill and the drill guide to pre-drill for the additional cancellous screws (Fig. 8).

The glenoid drill guide allows only to drill through the cranial and caudal hole in an angle of 15°. The pre-drilled threads in the glenoid implant allow only to position the cranial and caudal screws 15° angled.

Use the 2.0mm drill to predrill the screw holes for the additional fixation screws (Fig. 8).



Fig. 9

Measure the screw length with the depth guide (Fig. 9).



Insert the 4:2MM angle stable screws with the 2.5mm hexagon screwdriver until the screw head is fully flat with the surface of the metal glenoid implant (Fig. 10).



Fig. 10

Impaction of the Glenosphere

Seat the glenosphere to the glenoid implant. The lip of the glenosphere will lock onto the outer locking rim of the glenoid implant (Fig. 11).

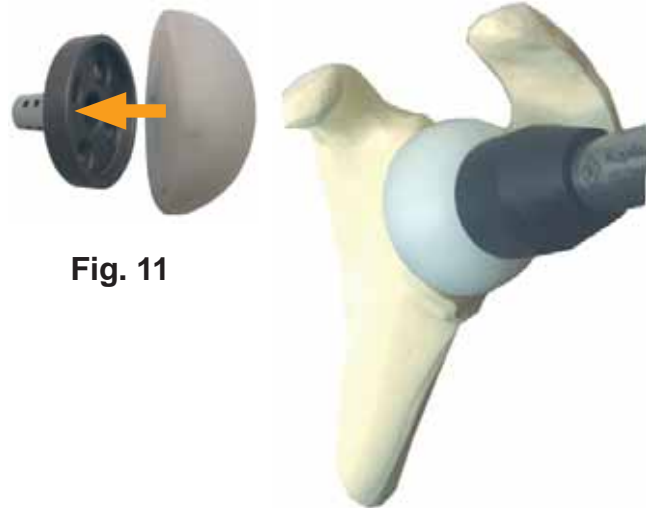


Fig. 11

Fig. 12

Enhance the locking by the use of the head impactor (Fig. 12).

Make sure that the glenosphere is fully seated onto the glenoid metal implant (Fig. 13).



Fig. 13



Fig. 14

Humeral Bone Preparation

Ream the medullary cavity with the medullary cavity reamer (Fig. 14).

Cementless Use

Drill the medullary cavity with a humerus drill 1 mm smaller than the size of the preoperatively chosen humerus stem (Fig. 15).

Make sure that at least 4cm of cortical bone contact is available.

Cemented Use

Drill the medullary cavity with a humerus drill 2 mm larger than the size of the preoperatively chosen humerus stem (Fig. 15).



Fig. 15



Rasping of the Humeral Cavity

Assemble the humeral rasp of the appropriated size (see tables below), the extractor device, the humerus impactor and the sleeve. Lock the rasp on the humerus impactor by using the counter wrench.

Remark: The use of a humeral rasp for a cemented stem is optional. Generally you can proceed with the trial assembly.

Use of Cementless Stems

Use the humeral rasp (Fig. 16), of the same size as the preoperatively chosen humerus stem (table 1).

Stem size	Rasp size
9 mm	9 mm
10 mm	10 mm
11 mm	11 mm
12 mm	12 mm
13 mm	13 mm

Table 1

Optional Technique for the Use of Cemented Stems

If you want to prepare for a cemented stem with the humeral rasp, please use the rasp which is 2 mm larger than the preoperatively chosen cemented humerus stem (Fig. 16).

That will provide a cement mantle of 1mm thickness (table 2).

Stem size	Rasp size
8 mm	10 mm
9 mm	11 mm
10 mm	12 mm
11 mm	13 mm
12 mm	14 mm

Table 2

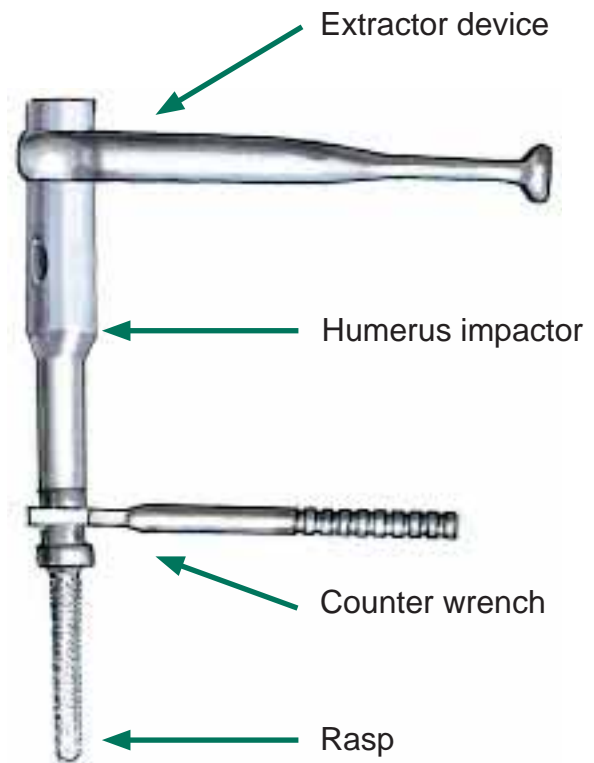


Fig. 16

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Fig. 17

Rasp the medullary cavity with the chosen humeral rasp (Fig. 17 and Fig. 18). A carefully use of the mallet is recommended.



Fig. 18

Remark: It is recommended to clean the rasp from bone chips during the rasping.
To prevent fractures of the cortical bone, it is helpful to fix a bone forceps around the humeral bone during rasping.

Leave the humeral rasp in the bone for the trialing.

Trial Reduction With the Trial Components

Mount the trial humerus head and the possibly used trial extension onto the top of the rasp (Fig. 19).

Please insert the trial screw of the appropriate length and tighten the screw with the socket wrench (Fig. 20).

Remark: Please, keep in mind that no humerus trial stems are available. If you have not opted for the rasping option when implanting cemented stems, the only way to trial will be with the original cemented stem without cementing it.



Fig. 19



Fig. 20

Put the inverse humerus trial cap inversely threaded titanium on the head (fig. 16). There are caps in sizes of neutral, +5 mm, +10 mm available.

Perform a trial reduction and control the muscle tension and the range of motion. In case of instability change the trial cap accordingly.

If a sufficient function is achieved please remove all trial components.



Fig. 21

MUTARS® Humerus Inverse

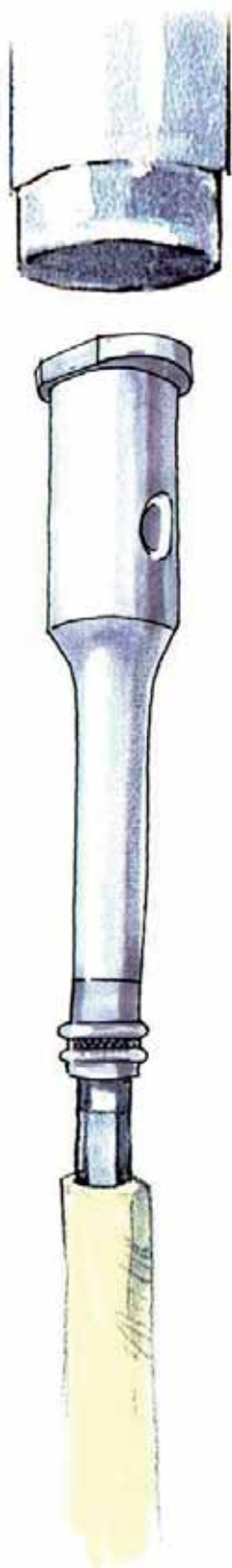


Fig. 22

Implantation of the Humeral Stem

Mount the humerus stem of the proper size, the impact sleeve on the impactor.

Fasten the connection using the counter instrument. Impact the humerus stem (Fig. 22).

When using the cementless stem, insert the stem of the same size as the previously used rasp.

Remark: To prevent fractures of the cortical bone, it is helpful to fix a bone forceps around the humeral bone during impactation.

It is possible to protect the humerus stem against rotation using a 3.5mm cortical screw.

If a cemented implantation is planned, insert the cement and use the cemented stem which is 2 mm smaller than the previously used drill or rasp.

Remove all instruments, especially during the cement hardening to prevent bending moments.

Final Assembly

Combine the proximal implant components on the humeral stem and lock the components in the correct rotational alignment. Fasten the screw of the bar screw of correct length (see „Assembling Options“ auf Seite 5). Use the socket wrench small and secure the composition with the counter instrument (Fig. 23). Lock the humerus safety screw in the same way (Fig. 24)

If a second trial reduction with the invers cap is planned, use the polymer humerus trial cap without a thread for trialing.

Remark: A second trial reduction may only be performed with the polymer humerus trial cap invers without a thread. A thread on a trial cap, would hamper the effect of the PE-safety plug, which secures a firm seat of the final cap.

Screw the humerus inverse cap of the correct size on the humeral head. Tighten the humerus inverse cap with the wrench for cap/counter instrument and secure it with the wrench for humerus (Fig. 26).

Reduce the shoulder joint and check the joint stability and the range of motion (fig. 20).



Fig. 23



Fig. 24



Fig. 25

Fig. 26



Fig. 27

MUTARS® Humerus Inverse



Fig. 28

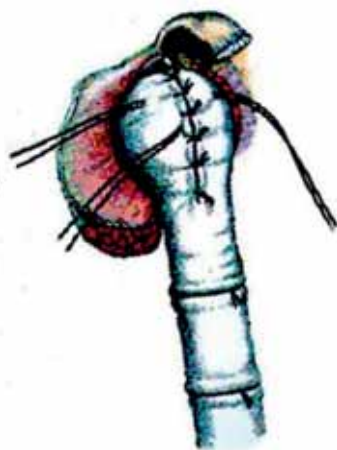


Fig. 29

The Use of the Attachment Tube

Fasten the attachment tube with 4 ethibond (thread size 2) or similar non-resorbable suture material to the remaining joint capsule / rotator cuff.

Fix the tube proximal first than distal. Pull the tube over the joint capsule and fix the tube to the capsule wall.

Afterwards tighten the tube and fix it over and under the pads of the MUTARS® components (Fig. 28 and Fig. 29).



Fig. 30

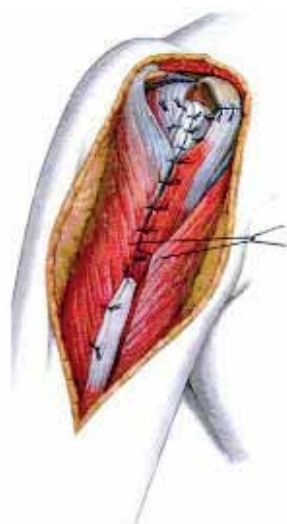


Fig. 31

Fix muscles and tendon tissues with sutures to the meshes of the tube (Fig. 30 and Fig. 31).



Implants

*S: Implants are available with Silver coating!

*N: Implants are available with TiN-coating!

*SN: Implants are available with Silver and TiN-coating!

MUTARS® humerus cap inverse

mat.: *iimplatan*®; $TiAl_6V_4$ acc. to ISO 5832-3
with TiN-coating

REF	size
5210-1000	0mm
5210-1005	+5mm
5210-1010	+10mm



MUTARS® humerus head *S

mat.: *implatan*®; $TiAl_6V_4$ acc. to ISO 5832-3
5200-0000



MUTARS® humerus screw

mat.: *implatan*®; $TiAl_6V_4$ acc. to ISO 5832-3

REF	size
5230-0015	M8x15 mm
5230-0035	M8x35 mm
5230-0055	M8x55 mm
5230-0075	M8x75 mm



MUTARS® humerus stem HA cementless

mat.: *implatan*®; $TiAl_6V_4$ acc. to ISO 5832-3 with
implaFix® HA; HA-coating acc. to ISO 13779-2

REF	size
5240-0808	8 mm
5240-0809	9 mm
5240-0810	10 mm
5240-0811	11 mm
5240-0812	12 mm
5240-0813	13 mm
5240-0814	14 mm*
5240-0815	15 mm*
5240-0816	16 mm*

*available on request.



MUTARS® humerus stem cemented *N

mat.: *implavit*®; CoCrMo acc. to ISO 5832-4

REF	size
5240-0408	8 mm
5240-0409	9 mm
5240-0410	10 mm
5240-0411	11 mm
5240-0412	12 mm

special stem sizes are available on request.



glenoid cementless size 3 round

mat.: pure titanium (*cpTi*) acc. to ISO 5832-2
with *implaFix*® HA; HA-coating acc. to ISO 13779-2
3800-4001



MUTARS® Humerus Inverse



MUTARS® glenosphere

mat.: UHMW-PE acc. to ISO 5834-2

	size
REF 5210-1002	40mm



cancellous screw size Ø 4.0mm

mat.: implatan®; TiAl₆V₄ acc. to ISO 5832-3

	size
REF 5793-4026	26mm
REF 5793-4028	28mm
REF 5793-4030	30mm
REF 5793-4032	32mm
REF 5793-4034	34mm



MUTARS® humerus extension piece *S

mat.: implatan®; TiAl₆V₄ acc. to ISO 5832-3

	size
REF 5220-0020	20 mm
REF 5220-0040	40 mm
REF 5220-0060	60 mm



MUTARS® humerus connecting part *S

mat.: implatan®; TiAl₆V₄ acc. to ISO 5832-3

	size
REF 5221-0080	80 mm



MUTARS® attachment tube

mat.: Polyethylene terephthalate (PET)

	size
REF 5900-0300	35 mm
REF 5900-0310	55 mm



cancellous screw angle stable 4.2mm

mat.: implatan®; TiAl₆V₄ acc. to ISO 5832-3

	size
REF 5794-4220	20mm
REF 5794-4222	22mm
REF 5794-4224	24mm
REF 5794-4226	26mm
REF 5794-4228	28mm
REF 5794-4230	30mm
REF 5794-4232	32mm
REF 5794-4234	34mm
REF 5794-4236	36mm
REF 5794-4238	38mm
REF 5794-4240	40mm

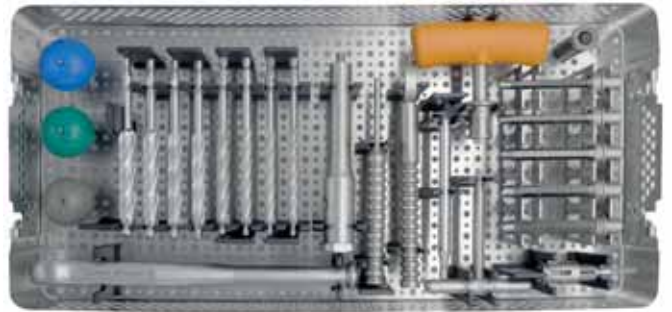


MUTARS® Humerus Inverse

Instruments

MUTARS® humerus container

7999-5200



MUTARS® humerus inverse container

7999-5201



MUTARS® humerus trial container

7999-5202



The implantcast GmbH instruments are supplied non-sterile and must be disinfected, cleaned, and sterilized before use.



MUTARS® Humerus Inverse

MUTARS® humerus container
7999-5200

MUTARS® extractor device
REF 7220-0000



MUTARS® socket wrench small
REF 7608-1010



MUTARS® humerus drill ic-connection

	size
REF 7630-0207	7 mm
REF 7630-0208	8 mm
REF 7630-0209	9 mm
REF 7630-0210	10 mm
REF 7630-0211	11 mm
REF 7630-0212	12 mm



MUTARS® medullary cavity reamer ic connection
REF 4220-0047



MUTARS® rasp for humerus stem

	size
REF 7770-0809	9 mm
REF 7770-0810	10 mm
REF 7770-0811	11 mm
REF 7770-0812	12 mm
REF 7770-0813	13 mm



MUTARS® humerus impactor
REF 7710-0000



MUTARS® humerus impact + extract sleeve
REF 7721-0000



MUTARS® wrench for cap/ counter instrument
REF 7710-0001



MUTARS® counter instrument Ø6mm
REF 7420-0001



MUTARS® humerus trial cap

	size
REF 7710-1000	small
REF 7710-1005	medium
REF 7710-1010	large



ic- T-handle Zimmer-Jakobs
REF 4223-0023



ic-adapter
REF 4223-0022





MUTARS® Humerus Inverse

MUTARS® humerus inverse container 7999-5201

MUTARS® humerus trial cap inverse

	size	
REF 7710-1301	0mm	
REF 7710-1305	+5mm	
REF 7710-1310	+10mm	

MUTARS® humerus trial cap invers threaded titanium

	size	
REF 7710-1301	0mm	
REF 7710-1305	+5mm	
REF 7710-1310	+10mm	

glenoid reamer 30mm



glenoid impactor



MUTARS® glenoid drill guide



screw driver 2.5mm



depth gauge small



glenoid drill guide



glenosphere impactor



drill A/O chuck 2.0mm



fixation pin 3.2 mm x 97 mm (2 pcs)



pin extractor

REF 4223-0007

or alternatively

ic-pin extractor

REF 7512-0800

pin inserter 3.2 mm



drill guide for glenoid cementless 12 mm



MUTARS® humerus trial container 7999-5202

MUTARS® humerus trial cap with thread

	size	
REF 7710-1200	small	
REF 7710-1205	medium	
REF 7710-1210	large	

MUTARS® humerus trial head



MUTARS® humerus trial extension piece

	size	
REF 7710-0020	20 mm	
REF 7710-0040	40 mm	
REF 7710-0060	60 mm	

MUTARS® humerus trial reducer

	size	
REF 7710-2100	10 mm	
REF 7710-2101	100 mm	

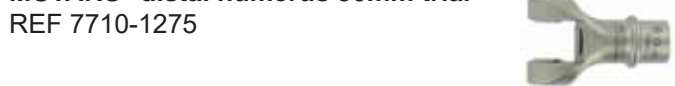
MUTARS® humerus trial connecting part

REF 7710-2180	80 mm	
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MUTARS® humerus trial screw

	size	
REF 7710-2315	M8x15 mm (x 2)	
REF 7710-2335	M8x35 mm	
REF 7710-2355	M8x55 mm	
REF 7710-2375	M8x75 mm (x 2)	

MUTARS® distal humerus 50mm trial





MUTARS[®] Humerus Inverse



Pre-operative Instructions

To ensure a life span of the implant that is as long as possible and to prevent any early implant failure the largest possible size of the MUTARS® stem should be selected, especially with patients who are overweight.

Please notice that the cementless femoral and tibial stems with the diameters of 10 mm and 11 mm have a weight limit of 60 kg and the cemented femoral and tibial stems with a diameter of 11 mm have a weight limit of 75 kg.

The surgeon should ensure that:

- 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.
- The correct sized instruments are used during surgery to prevent damage to the implants.

It should be noted that the cutting blocks and saw guides are precisely aligned to the saw blades offered by the implantcast GmbH so that only these combinations are approved. If there is a need to use other manufacturers saw blades, please request the implantcast GmbH whether a combination with the relevant product is possible.

The implantcast GmbH instruments are supplied non-sterile and must be disinfected, cleaned, and sterilized before use. Please refer to the cleaning statement RA_000_ISO17664 for the correct procedures. If the equipment is not treated before use, there is a risk of infection.

Intra-operative Instructions

Adequate and permanent support of the components by cement and/or bone and the selection of the correct component size are of ultimate importance.

In cemented application care should be taken that the stem is fully embedded till the level of the tray of the shaft. During setting of the cement care should be taken not to move the implant component.

It is important that the bone is resected straight and perpendicular to the intramedullary canal and that the tray of the component lies flush with the resected bone.

When applying cementless tibial- and femoral stems the use of MUTARS® broaches is mandatory.

Correct alignment in both axial and rotational direction is important. Incorrect alignment may lead to subluxation, dislocation and/or fracture of the component. Especially when using curved stems care should be taken not to rotate the implant upon impaction. This may lead to insufficient bone-implant contact.

In case of developmental hip dysplasia the sciatic nerve should be protected to prevent paralysis, the shape of the medullary canal which can be extremely narrow and/or straight may dictate the use of small straight femoral implants. However whenever possible a standard size should be implanted. The real acetabulum can be rudimentary, narrow and shallow. The false acetabulum should not be used to receive the acetabular component as this may lack anatomical and biomechanical reliability.

Revision of a failed primary arthroplasty may be technically demanding and relatively difficult. Complications may be problematic surgical approach, insufficient exposure and mobilisation of the joint, insufficient removal of ectopic bone or incorrect positioning of the components; this may result in postoperative instability and extreme blood loss. Longer surgical time, increased blood loss, risk of lung embolism and hematoma should be taken into consideration when planning a revision.

Screw connections should be countered after tightening with the MUTARS® engineers wrench and the MUTARS® swing wrench to provide the necessary connection. When using the MUTARS® instruments the screw connection should always be seated completely to prevent damage to the thread.

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 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, to stimulate healing is recommended.

Active and passive movements of the patient should be monitored.

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

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



MUTARS[®] Humerus Inverse

Indications

- 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 prostheses 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 history.
- To re-establish the full anatomical skeletal function it may be necessary to readjust any traumatized or diseased bone segment, attach it to present fragments or substitute in by implant components.
- Primary indication for the use of the MUTARS[®] - systems is after bone resection because of a tumour. In case of primary tumours an extensive resection, as described by Enneking, into the non-diseased area should be possible to ensure adequate surgical treatment of the disease. If this is not possible other treatment options, such as amputation should be considered. The application of the MUTARS[®] tumour system should not lead to intralaseal or marginal and therefore inadequate therapy.
- In case of bone metastasis the indication is related to the physical condition of the patient. If a resected part of the skeleton cannot take the normal anatomical loading and if simple osteosyntheses will not provide sufficient stability, the implantation of a tumour system may help to re-establish the function quickly and to improve the quality of life of the patient. In case of a multiple osseous affection the indication for the use of the MUTARS[®] system should be limited if a mobilisation of the patient cannot be expected.
- Further indications for the use of the MUTARS[®]- systems are massive bone loss such as in Morbus Gorham or for the revision arthroplasty and for the prosthetic treatment in case of fractures, pseudarthrosis and arthrosis. In benign diseases the resection of the bone should be limited and the prosthesis should be seen as a place holder only.
- The surgeon decides which version of prosthesis for the individual patient is used. This decision depends on several factors, such as the age and the patient's weight, bone quality, shape of the bone and deformation of the joint.

Contraindication

The longevity of an orthopaedic joint replacement device can be reduced by biological aspects, material characteristics and biomechanical factors. Patient selection and indication should be carefully monitored especially in patients who are overweight, patients with high physical activity levels and patients younger than 60 years of age.

An absolute contraindication is a known allergy to any of the implant materials used. The label on the secondary packaging of each component specifies the material used. Indication for testing, it is strongly recommended to perform an allergy test.

The TiNbN coating reduces the ion release from the CoCrMo alloy of the MOM coupling. The coating wears through in the articulating area. For this reason the treating physician should evaluate the risks and benefits in case of allergy patients.

Another absolute contraindication is infection.

The relative contraindications include:

- 1) 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.
 - Insufficient quantity and quality of bone stock, e.g. as a result of osteoporosis or osteomalacia
 - Vascular disease of the affected limb
- 2) Metabolic disorders that can affect a stable anchorage of the implant
- 3) Bone tumors in the implant fixation area
- 4) Neuromuscular diseases that can impair the affected limb
- 5) Lack of patient compliance
- 6) Mental or neurological conditions that affect the ability or willingness of patients to comply with medical instructions, especially during the healing phase
- 7) Obesity

Risk factors

The following risk factors may affect the success of joint replacement:

- Nicotine and/or drug abuse
- Alcoholism
- Muscle insufficiency
- Severe deformities, which lead to an impairment of the anchorage, the exact positioning or function of the implant
- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Therapies that may affect bone quality



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