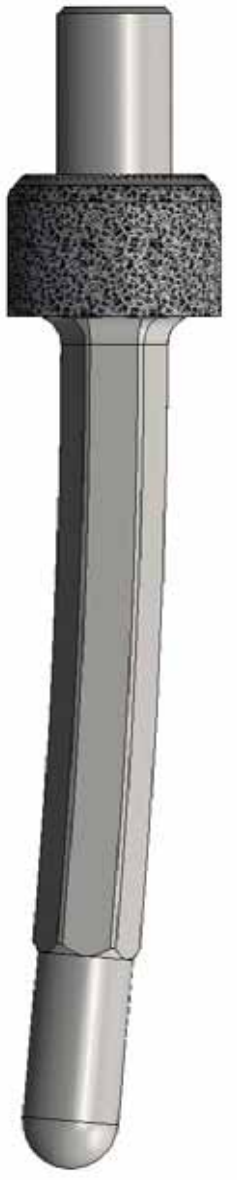
MUTARS®

implantcast



MUTARS® Modular Stem with EPORE® Collar

Surgical Technique

MUTARS®

MUTARS® Modular Stem with EPORE® Collar

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

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.

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 [1] 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 [2]. Also in clinical practice there have never been any evidence of allergic reactions with implants that have been TiN-coated showing an intact surface [4]. Therefore the TiN-coating on implant components is especially suitable for patients with sensitivity to nickel, chromium or cobalt [3][4].

Since almost all components of the MUTARS® tumour system consist of titanium alloy, this only concerns those components, which are made of a cast CoCrMo alloy. The REF-numbers of the TiN-coated implants have the suffix N after the last digit (e.g. 5902-1211N).

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

[1] Eben R et al. (2009) Implantatallergieregister - ein erster Erfahrungsbericht. Orthopäde 38: 557-562
[2] Wisbey et al. (1987) Application of PVD TiN coating to Co-Cr-Mo based surgical implants. Biomaterials, 11
[3] 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
[4] Baumann A. (2001) Keramische Beschichtungen in der KTEP Standardlösung für Allergiker. JATROS Orthopädie & Rheumatologie 6: 16-17

Pre-Operative Planning

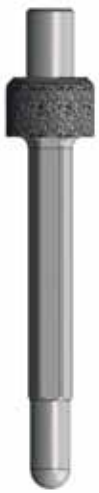
Pre-operative planning and precise surgical techniques are mandatory for optimal results. The instructions and the procedure given in the surgical technique to the system must be adhered to. Familiarity with the recommended surgical technique and its careful application is essential to achieve the best 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® modular stem with EPORE® collar curved in M/L view

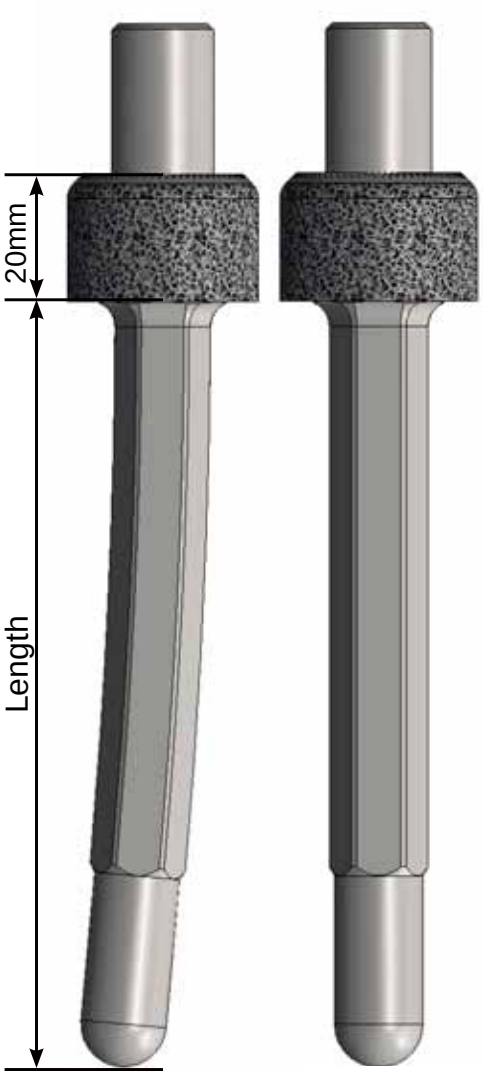


Picture shown: MUTARS® modular stem with EPORE® collar straight in M/L view

For further information, please see the instructions for use for MUTARS® Tumor- and Revision System (Item number: 09300013GB) and p. 24, 25 of this surgical technique.

System Overview

EPORE® HA collar
ø 24 mm - 36 mm round
ø 24/27 mm - 36/39 mm oval



EPORE® HA collar
ø 27 mm - 33 mm tibial

MUTARS® modular stems
cemented curved

ø 11 mm - 17 mm in 2 mm
increments

Lengths: 120, 160*, 200*
and 240 mm*

MUTARS® modular stems
cemented straight

ø 11 mm - 15 mm in 2 mm
increments

Length: 120 mm

* With interlocking holes.

Assembling Options

Proximal Femur				
Reconstruction (mm)	**Proximal Femur (mm)**	**Connecting Piece (mm)**	**Extension Piece (mm)**	**Screw**
90	50	-	-	25
110	70	-	-	45
130	50	-	40	65
150	50	-	60	85
170	50	-	80	105
190	50	100	-	25 + 25
210	70	100	-	25 + 45
230	50	100	40	65 + 25
250	50	100	60	85 + 25
270	50	100	80	105 + 25
290	50	100	40 + 60	125 + 25
310	70	100	40 + 60	145 + 25
330	50	100	60 + 80	165 + 25
350	70	100	60 + 80	185 + 25

Distal Femur				
Reconstruction (mm)	**Distal Femur (mm)**	**Connecting Piece (mm)**	**Extension Piece (mm)**	**Screw**
110	90	-	-	25
130	110	-	-	45
150	90	-	40	65
170	110	-	40	85
190	110	-	60	105
210	110	-	80	125
230	110	100	-	45 + 125
250	110	-	80 + 40	165
270	110	100	40	65 + 45
290	110	100	60	85 + 45
310	110	100	80	105 + 45
330	110	100	60 + 40	125 + 45

Proximal Tibia			
Reconstruction (mm)	**Connecting Piece (mm)**	**Extension Piece (mm)**	**Screw**
125	105	-	25
145	125	-	45
165	105	40	65
185	105	40	85
205	105	80	105
225	125	80	125
245	125	40 + 60	145

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

Perform the tumour resection (fig. 1).

Fig. 1

Bone Preparation

Subsequently, widen the femoral or tibial medullary cavity preferably with a flexible (for curved stems) or rigid (for straight stems) bone reamer until the diameter of the next available guiding rod for the resection reamer (fig. 2).

The curved stem is preferably used for femoral treatments, while straight stems are preferably used for the tibial bone.

Fig. 2

Connect the resection reamer with the guiding rod with the diameter that corresponds the last used medullary cavity reamer (fig. 3 and 4).

Fig. 3

Fig. 4

Fig. 5

Insert the guiding rod in the medullary cavity and ream the resection surface until the reamer lays flush on the surface (fig. 5).

Fig. 6

If you have chosen the optional surgical technique with reaming, widen the femoral medullary cavity preferably with a flexible reamer up until 0.5mm over the diameter of the preoperatively planned curved stem (fig. 6). When a straight stem is being used, widen the medullary cavity with a rigid reamer 0.5 wider than the planned straight stem.

If the preparation with rasps is not desired, widen the medullary cavity with either a flexible reamer (for curved stems) or a rigid reamer (for straight stems) 2mm larger than the diameter of the planned stem (fig. 6).

The minimal contact with the cortical bone should be no less than 2/3 of the stem length.

Fig. 7

Prepare the intramedullary cavity with the conical bone reamer (fig. 7).

Note: Reaming is optional when cemented stems are used.

For the preparation of a cemented stem, please use the rasp that has a diameter 2mm wider than the preoperatively planned stem. This allows for a cement mantle of 1mm.

Assemble the rasp of the proper size with the impaction sleeve and the MUTARS® slap hammer. Secure the connection with the engineers' wrench (fig. 8).

Fig. 8

In order to place the stem in the proper rotation to the antecurvation of the femoral bone, mark the anterior point of the femoral bone.

Also, in case of using the EPORE® HA collar tibial, mark the tibia anteriorly.

Make sure that the anterior marking on the bone is aligned with the marking on the rasp.

Rasp the intramedullary cavity with the rasp of the adequate size (fig. 9). It is advised to use the slap hammer carefully.

Fig. 9

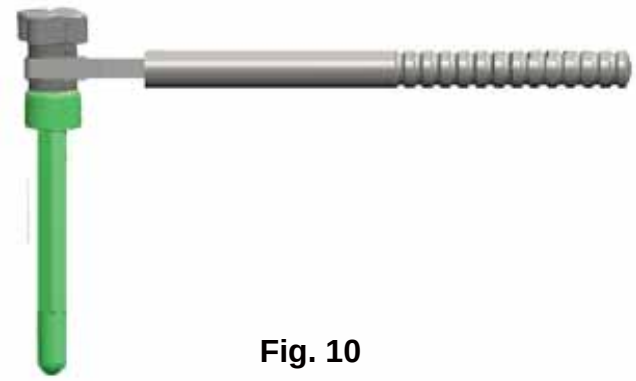


Fig. 10

Trialing with the MUTARS® Modular Stems with EPORE® Collars Trial Components

The trial reduction is performed with the trial stem, which has the same diameter as the prepared medullary cavity – the largest used reamer (in the surgical technique without rasps) or the largest used rasp (in the surgical technique with rasps).
Use the curved or straight trial stem in dependency of a planned curved or straight final stem, respectively. Connect the trial stem to the trial collar, which corresponds to the planned collar. Place the impact and extract sleeve on top of the trial collar. Secure the connection with the fixation screw for MUTARS® modular stems using the engineers' wrench for countering (fig. 10).
Ensure the correct alignment of the EPORE® HA trial collars tibial and the anterior marking of the trial stem, in case of using the EPORE® HA trial collars tibial.

Fig. 11

Insert the stem in the prepared medullary cavity (fig. 11). In case, the bone is marked anteriorly, make sure, that the anterior marking on the trial stem points anteriorly. Hereby, you ensure the correct allignment of the hexagonal cross section of the stem and the bone (surgical technique with rasping) and the correct orientation of the curvature (curved stem). Consequently, the EPORE® HA trial collar tibial is also correctly orientated (fig. 17).

Impact the stem carefully using the EcoFit® stem impactor (Fig. 12).

Fig. 12

Remove the fixation screw using the engineers' wrench as counter instrument, and the impact and extract sleeve (fig. 13).

Fig. 13

Note: Trialing with the rasps in not possible, as the collar height of the EPORE® collar (20mm) is higher than that of the MUTARS® stems (10mm).

Fig. 14

Assemble the remaining trial components of the chosen treatment on the MUTARS® modular trial stem with EPORE® HA collar trial. Fig. 14 shows an example of the proximal femur trial replacement.

Fig. 15

Perform the trial reposition (fig. 15).

Removal of trial components

Leave the EPORE® HA collar trial on the trial stem while removing the trial stem.

For removing the trial stem, connect both components to the impact and extract sleeve and the MUTARS® slide hammer.
Secure the connection of the four components using the engineers' wrench as counter instrument to prevent the trial stem from rotating in the bone (fig. 16).

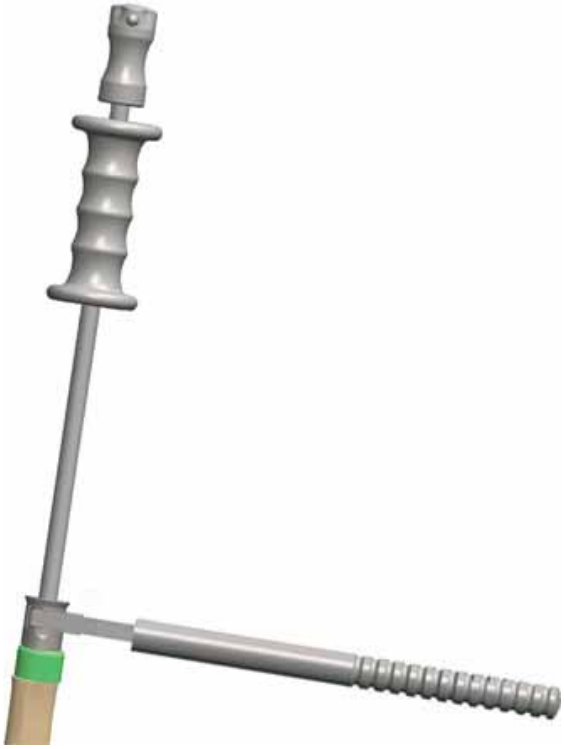


Fig. 16

Remove the trial stem and the EPORE® HA collar using the MUTARS® slide hammer (fig.17).

Fig. 17

Fig. 18

Implantation of the MUTARS® Modular Stem

Assemble the curved or straight stem of the proper size with the EPORE® HA collar. Place the impact and extract sleeve on top of the EPORE® collar. Secure the connection with the fixation screw for MUTARS® modular stems using the engineers' wrench as counter instrument (fig. 18).
Ensure the correct alignment of the EPORE® HA collars tibial and the anterior marking of the stem, in case of using the EPORE® HA collars tibial.

Note: The connection of collar and stem can be checked by turning both components in opposite directions. A clicking noise and a stepwise resistance should be heard and felt, respectively.

Fig. 19

Insert the stem in the prepared and previoulsy with bone cement filled medullary cavity. In case the tibia or femur was marked anteriorly before, make sure that the anterior marking on the femoral or tibial bone is aligned with the marking on the stem, so that the curvature of the stem (curved stem) and the hexagonal crosssectional shape of the stem and the bone is correctly alligned. Consequently, the EPORE® HA collar tibial is also correctly orientated (fig. 19).

Excess bone cement can be removed while inserting the stem.
The screw connection of stem, EPORE® HA collar, impact and extract sleeve and fixation screw must NOT be loosened while removing of bone cement.

Impact the stem carefully using the EcoFit® stem impactor (fig.20).

Fig. 20

Remove the fixation screw after the cement hardening in order to avoid the lifting up of the EPORE® collar due to the cement (fig. 21).

Note: Remove the safety screw only after cement hardening in order to avoid lifting up of the EPORE® HA collar, and therefore a potential penetration of cement into the teeth connection.

Fig. 21

Fig. 22

Remove the fixation screw using the engineers' wrench as counter instrument. Subsequently, remove the impact and extract sleeve (fig. 22).

Fig. 23

Proceed with the surgical technique of the chosen treatment. Fig. 23 shows the assembly of the proximal femoral replacement as an example.

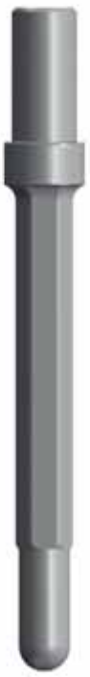
Implants

***N**: For anti-allergic treatment, TiN coated implants are available.

MUTARS® stem modular curved cemented *N
mat.: implavit®; CoCrMo acc. to ISO 5832-4

	Size
REF 5902-1211	ø11 / 120 mm
REF 5902-1213	ø13 / 120 mm
REF 5902-1215	ø15 / 120 mm
REF 5902-1217	ø17 / 120 mm
REF 5902-1611	ø11 / 160 mm *
REF 5902-1613	ø13 / 160 mm *
REF 5902-1615	ø15 / 160 mm *
REF 5902-1617	ø17 / 160 mm *
REF 5902-2011	ø11 / 200 mm *
REF 5902-2013	ø13 / 200 mm *
REF 5902-2015	ø15 / 200 mm *
REF 5902-2017	ø17 / 200 mm *
REF 5902-2411	ø11 / 240 mm *
REF 5902-2413	ø13 / 240 mm *
REF 5902-2415	ø15 / 240 mm *
REF 5902-2417	ø17 / 240 mm *

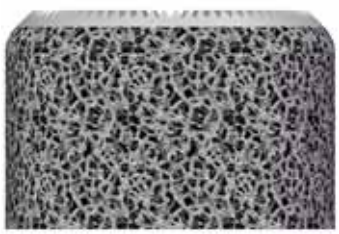
MUTARS® stem modular straight cemented *N
mat.: implavit®; CoCrMo acc. to ISO 5832-4



	Size
REF 5903-1211	ø11 / 120 mm
REF 5903-1213	ø13 / 120 mm
REF 5903-1215	ø15 / 120 mm

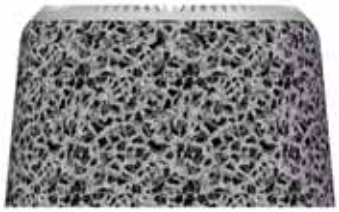
* with locking holes for Ø 4.5mm screws

MUTARS® Modular Stem with EPORE® Collar



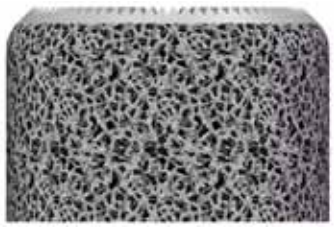
MUTARS® EPORE® HA collar 20 mm round
mat.: $TiAl_6V_4$ with EPORE® HA; TCP-coating

	Size
REF 5901-0024	ø 24
REF 5901-0027	ø 27
REF 5901-0030	ø 30
REF 5901-0033	ø 33
REF 5901-0036	ø 36



MUTARS® EPORE® HA collar 20 mm oval
mat.: $TiAl_6V_4$ with EPORE® HA; TCP-coating

	Size
REF 5901-2427	ø 24 / 27
REF 5901-2730	ø 27 / 30
REF 5901-3033	ø 30 / 33
REF 5901-3336	ø 33 / 36
REF 5901-3639	ø 36 / 39

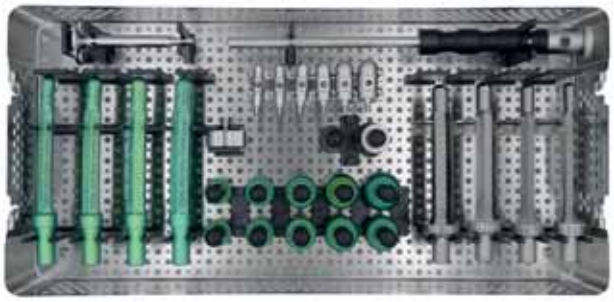


MUTARS® EPORE® HA collar 20 mm tibial
mat.: $TiAl_6V_4$ with EPORE® HA; TCP-coating

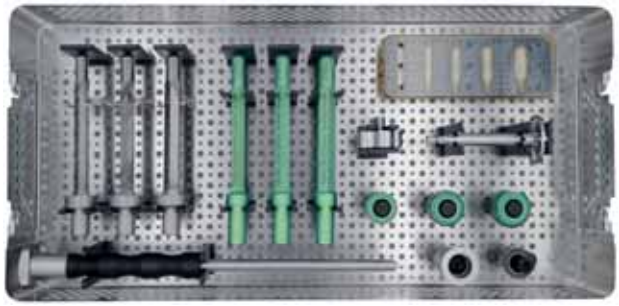
	Size
REF 5901-0127	ø 27
REF 5901-0130	ø 30
REF 5901-0133	ø 33

Instruments

7999-5761 MUTARS® modular stems with EPORE® collars container curved

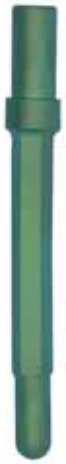


7999-5762 MUTARS® modular stems with EPORE® collars container straight



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

MUTARS® Modular Stem with EPORE® Collar



MUTARS® moduler stems with EPORE® collars container curved
7999-5761

MUTARS® trial stems modular curved cemented

	Size
REF 7764-1213	ø13 / 120 mm
REF 7764-1215	ø15 / 120 mm
REF 7764-1217	ø17 / 120 mm
REF 7764-1219	ø19 / 120 mm

MUTARS® EPORE® HA trial collars 20mm round

	Size
REF 7762-0024	ø 24 mm
REF 7762-0027	ø 27 mm
REF 7762-0030	ø 30 mm
REF 7762-0033	ø 33 mm
REF 7762-0036	ø 36 mm

MUTARS® EPORE® HA trial collars 20mm oval

	Size
REF 7762-2427	ø 24 / 27 mm
REF 7762-2730	ø 27 / 30 mm
REF 7762-3033	ø 30 / 33 mm
REF 7762-3336	ø 33 / 36 mm
REF 7762-3639	ø 36 / 39 mm

Resection reamer

REF 7765-0000

Guiding rod for the resection reamer

	Size
REF 7765-0008	ø8 mm
REF 7765-0010	ø10 mm
REF 7765-0012	ø12 mm
REF 7765-0014	ø14 mm
REF 7765-0016	ø16 mm
REF 7765-0018	ø18 mm

MUTARS® rasp for femoral stem

	Size
REF 7760-0113	ø 13 mm
REF 7760-0115	ø 15 mm
REF 7760-0117	ø 17 mm
REF 7760-0119	ø 19 mm

Fixation screw for MUTARS® modular stems

REF 7765-0003

EcoFit® stem impactor cross hole

REF 3039-0109

MUTARS® impact and extract sleeve

REF 7230-0000

MUTARS® Modular Stem with EPORE® Collar

MUTARS® moduler stems with EPORE® collars container straight
7999-5762

MUTARS® trial stems modular straight cemented

	Size
REF 7765-1213	ø13 / 120 mm
REF 7765-1215	ø15 / 120 mm
REF 7765-1217	ø17 / 120 mm

MUTARS® EPORE® HA trial collars 20mm tibial

	Größe
REF 7763-0027	ø 27 mm
REF 7763-0030	ø 30 mm
REF 7763-0033	ø 33 mm

Resection reamer
REF 7765-0000

Guiding rod for the resection reamer

	Size
REF 7765-0008	ø8 mm
REF 7765-0010	ø10 mm
REF 7765-0012	ø12 mm
REF 7765-0014	ø14 mm
REF 7765-0016	ø16 mm
REF 7765-0018	ø18 mm

MUTARS® rasp for tibial stem

	Size
REF 7750-0313	ø 13 mm
REF 7750-0315	ø 15 mm
REF 7750-0317	ø 17 mm

Fixation screw for MUTARS® modular stems

REF 7765-0003

EcoFit® stem impactor cross hole

REF 3039-0109

MUTARS® impact and extract sleeve

REF 7230-0000

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.

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 intralasional 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 attachment tube is used for the reattachment of soft tissues, ligaments and for the reconstruction of the capsule.
- 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

implantcast GmbH
Lüneburger Schanze 26
D-21614 Buxtehude
Germany
phone.: +49 4161 744-0
fax: +49 4161 744-200
e-mail: info@implantcast.de
internet: www.implantcast.de

CE 0482

Your local distributor:

MUTMSEKE-040320