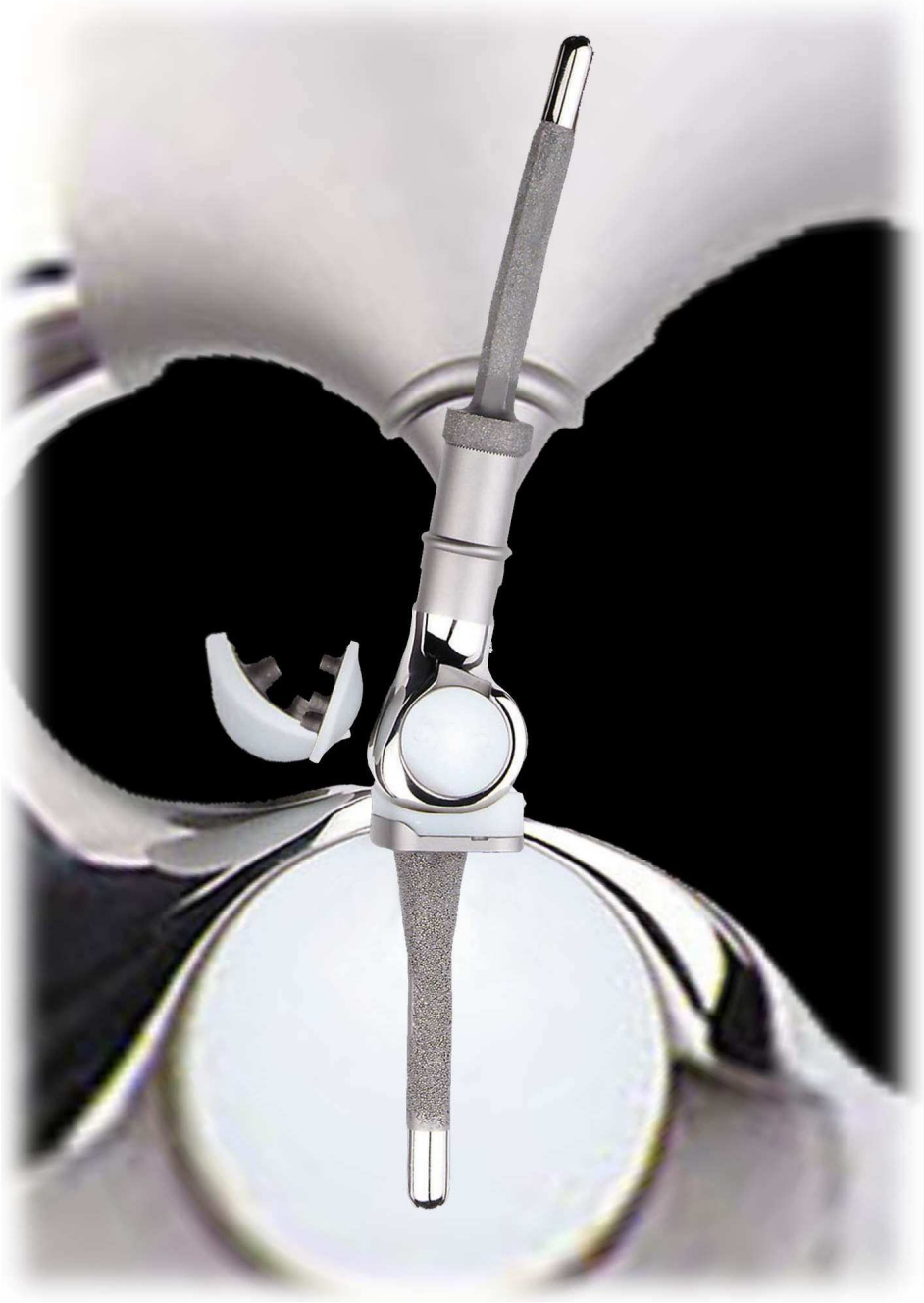
MUTARS®-Münster



implantcast

Distal Femur

MUTARS® Distal Femur

distal femur replacement
assembling options
(length in mm)

reconstruction	components			
	distal femur	connecting part 100 mm	extension piece	bar screw
100 mm	**90***			**25**
120 mm	110	-	-	45
140 mm	90*		40	65
160 mm	110	-	40	85
180 mm	110	-	60	105
200 mm	110	-	80	125
220 mm	110	100	-	45 + 25
240 mm	110	-	80 + 40	165
260 mm	110	100	40	65 + 45
280 mm	110	100	60	85 + 45
300 mm	110	100	80	105 + 45
320 mm	110	100	60 + 40	125 + 45

*A distal femur 90 mm is available on special request
(reconstruction length 100 mm)

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.

IMPLANTS

MUTARS® Distal Femur
incl. safety screw
mat.: implavit®;CoCrMo-casting alloy according to DIN ISO 5832/4

5720-0006	110 mm
5720-0011	110 mm
5720-0080	110 mm
5720-0085	110 mm
5720-0016	90 mm
5720-0021	90 mm
5720-0090	90 mm
5720-0095	90 mm

MUTARS® extension piece
mat.: implatan®;$TiAl_6V_4$ according to DIN ISO 5832/3

5772-2504	40 mm
5772-2506	60 mm

MUTARS® connecting part
mat.: implatan®;$TiAl_6V_4$ according to DIN ISO 5832/3

5730-0100	100 mm

IMPLANTS

MUTARS® bar screw
mat.: implatan®;$TiAl_6V_4$ according to DIN ISO 5832/3

5792-1002	M10x 25 mm
5792-1004	M10x 45 mm
5792-1006	M10x 65 mm
5792-1008	M10x 85 mm
5792-1010	M10x105 mm
5792-1012	M10x125 mm
5792-1014	M10x145 mm
5792-1016	M10x165 mm
5792-1018	M10x185 mm

MUTARS® femoral stem cementless
mat.: implatan®;$TiAl_6V_4$ according to DIN ISO 5832/3

5760-0510	10 mm
5760-0511	11 mm
5760-0512	12 mm
5760-0513	13 mm
5760-0514	14 mm
5760-0515	15 mm
5760-0516	16 mm
5760-0518	18 mm

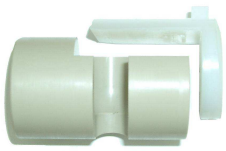
IMPLANTS

MUTARS® tibial joint cementless
mat.: implavit®;CoCrMo-casting alloy according to DIN ISO 5832/4

5750-4010	10 mm	extra small
5750-4012	12 mm	extra small
5750-4014	14 mm	extra small
5750-1010	10 mm	small
5750-1012	12 mm	small
5750-1014	14 mm	small

MUTARS® PE-inlay
mat.: UHMWPE according to DIN ISO 5834/2

5721-0002	for tibial joint small
5721-0013	for tibial joint X small



MUTARS® lock, 2-parts
mat.: PEEK®-Optima and UHMWPE according to DIN ISO 5834/2

5720-0910
5720-0905
5720-0920
5720-0915

IMPORTANT MEDICAL INFORMATION

Note

The MUTARS® system is a successful therapy, freeing e.g. tumor patients from pain and restricted mobility.

The system's main objectives are pain reduction and the restoration of physiological functions. Suitable patients should be selected according to the following conditions:

1) Patients disposing of adequate bone quality and with a bone structure that is likely to be preserved.

2) Patients, whose anatomic features allow for an adequate implant size for the prospective loading and degree of activity.

3) Patients who are willing and able to follow their physician's directions, especially with respect to the necessary total or partly stress reduction on the implant during the postoperative period. The largest possible stem size is to be selected from the MUTARS® system (especially for obese patients). Patients must be warned of the consequences of excessive weight-bearing, sport participation and any activity causing excessive strain or impingement on the implanted prosthesis.

Used materials

The MUTARS® implants consist of a cast CoCrMo-alloy (ISO 5832/4) or the titanium alloy TiAl6V4 (ISO 5832/3). The PE-components contain UHMW-PE (ISO 5834/2). Most of the instruments are made of acid-resistant stainless steel.

Indications

Adequate patient selection as well as a profound surgical analysis of the case are the basis of the whole surgical procedure. Careful preoperative planning and a precise surgical technique are necessary to obtain optimal results. In order to minimize the danger of postoperative complications different factors must be considered, i.e. the anatomical stress situation, the soft tissue basis and the planned component alignment. Generally, a prosthesis is only to be implanted in patients with fully-grown skeletons. To restore the anatomical function of the skeleton it may be necessary to repair and/or support/stabilize a traumatised or otherwise affected bone segment, to fuse it with other fragments or replace it by a prosthesis. The treatment of fractures, pseudarthrosis, arthrosis and similar diseases with the MUTARS® system can either be performed as an initial or a follow-up surgery, each with its corresponding surgical technique. The MUTARS® system is mainly implanted in cases of major bone defects, e.g. after bone tumor resections. The use of a modular prosthesis is often the consequence of a tumor resection. In the case of primary tumors it is necessary to perform an extensive resection (Enneking-method), extending into healthy tissue, in order to provide for an adequate surgical treatment of the disease. If this is not possible, other steps must be discussed, such as e.g. an amputation. The tumor system is not intended to support an intralesional/marginal and - with respect to the stage of the disease - in such cases unsuitable therapy.

In the case of bone metastases the indication depends on the entire patient status. Whenever a skeletal segment can take no more strain and stabilizing fusional steps of an osteosynthesis are not possible, the tumor implant system can restore the function of the segment within a short period of time. This increases the patient's life quality considerably. Nevertheless, this indication must be reconsidered in the case of a multiple invasion of the bone in which a remobilization of the patient cannot be expected. Other indications for a tumor prosthesis could be massive bone loss in cases of Morbus Gorham or due to an implant loosening. In cases of non-malign diseases as little bone material as possible should be resected. Here, the prosthesis serves as a spacer.

Contraindications

The main contraindications are bacterial infections, soft tissue defects due to irradiation, expected bone growth as well as - under certain conditions - better alternatives as e.g. a resection arthrodesis for infants and growing young persons or a temporary prosthesis. The major contraindication is when dimension and localization of the tumor make an extensive resection impossible. Other contraindications include:

1) Anatomical conditions which do not allow for or will not maintain sufficient bony support of the implant or which do not allow for an adequate implant size.

In general i.e.:

a) Insufficient blood supply caused by preceding surgeries or vessels affected by alcohol abuse etc.,

b) insufficient quantity and quality of bone material due to osteoporosis, adipositas etc.,

c) infections or other causes leading to reduced stability of the implant fixation.

2) Any mental or neurological conditions affecting the patient's will to follow restrictions in activity, especially during the post-operative healing process. These could be drug abuse, mental illness, senility and general neurological limitations.

3) Conditions leading to extreme stress on the implants, such as myopathies, multiple arthropathies etc.

Contraindications can be absolute or relative and must be carefully considered with respect to the whole patient status and the prognoses of possible alternative therapies such as e.g. a conservative treatment, an arthrodesis etc.

Possible adverse effects:

1) Device component loosening, distortion or fracture. Normally these effects are caused by one or several of the mentioned factors, listed above and below under contraindications and warnings.

2) Migration, subluxation and rotation of the implant, flexion contraction, reduced mobility, increased or decreased leg length, component loosening or bone wear and ligamentary laxity.

3) Fractures of the tibia, femur, patella and humerus.

4) Acute postoperative wound infection, severe sepsis and/or low-grade synoviitis.

5) Neuropathy

6) Cardiovascular disorders: wound-haematoma, thrombosis and embolism (e.g. venous thrombosis and pulmonary embolism)

7) Tissue reactions: phagocytal reactions, foreign body reactions and myositis ossificans. These reactions especially apply to male patients with hypotrophic arthrosis, preoperatively limited mobility and/or preceded myositis. The risk of a myositis ossificans is increased by preceding surgeries or acute infections.

8) Trochanteric pseudarthrosis: generally related to early stress and/or insufficient fixation in the case of a transtrochanteric surgical path.

Warning and Precautions

Implant loosening, bending, fissure and/or breakage and other complications can occur if the following instructions and warnings are not considered and followed

Preoperative:

1) In every surgery a sufficiently wide range of implant sizes must be present. The decision, whether cementation is to be performed or not, must be taken in advance. The preoperatively chosen implant, as well as the next bigger and smaller sizes must be prepared. Before insertion, the implant must be carefully checked to make sure that there is no damage or modification and that the correct size has been selected.

2) The implants are to be handled with care at all times, in order to avoid damage of the prepared implant surface. Cutting, bending or scratching of the component surfaces can considerably reduce their stability and resistancy against fatigue and wear. Even not directly visible defects can cause stress conditions within the implant, which can - because of the dynamic stress within the body - possibly lead to implant failure. If the preoperative observation shows that the modularity of the system can not fit the patient the use of a customised implant is necessary.

3) Allergies and other reactions to implanted materials should be considered, tested (if indicated) and excluded preoperatively, even if very uncommon.

4) The introducing instruments must correspond to the implant and must therefore belong to the MUTARS® system.

5) A description of the surgical technique is available from the manufacturer. In order to obtain best possible results the surgeon must be familiar with the recommended surgical techniques for this system and its proper use.

Intraoperative

1) Adequate and durable component support, obtained through cementation and/or bone material, as well as the correct selection of the component size are of vital importance.

2) Whenever a stem cementation is performed the entire stem must be cemented right up to the stem plate. During the process of cement hardening any repositioning of the implant components should be avoided.

3) After insertion of the stem, its plate must be flush against the resected bone. It is important to resect the bone plane, horizontal to the medullary canal.

4) For cementless tibia and femoral stems the use of our special MUTARS® rasps is mandatory.

5) Correct axial and rotational alignment of the implant is of major importance. Otherwise subluxation, dislocation and/or breakage of the prosthesis may occur. Special attention should be directed to cases with curved stems, since fixation might be achieved unplanned by a rotation of the implant during the insertion of the stem. In this case the implant-bone interface is insufficient.

6) In cases of congenital dysplastic coxarthropathy special care must be directed to the avoidance of a sciatic nerve paralysis. Moreover the fact must be considered that the medullary canal is often extremely narrow and straight, so that extremely small, straight femoral prostheses are necessary. Nevertheless the standard size should be applied whenever possible. Please consider that in these cases the original acetabulum is formed only rudimentarily and very narrow. Because of its anatomical biomechanical unreliability the acetabulum should not be used as implant bearing for the acetabulum component of the prosthesis.

7) From the technical point of view the performance of a revision surgery after preceding primary surgery is extremely demanding and critical. Common mistakes are: wrong surgical access, insufficient bone identification and mobilization, insufficient removal of ectophytic bone material or unprecise component positioning. Postoperative instability as well as extreme blood loss can be the consequences. Altogether longer operating times, increased blood loss and the risk of pulmonary embolism and wound haematoma must be taken into consideration in cases of revision surgery.

8) Conus surfaces must be thoroughly cleaned and dried before attaching the fitting component. Any unremoved particle can cause extreme friction and wear.

9) Implants whose conus has been attached to an endohead before should not be reused, since the conus interface has adapted itself to the former endohead. A new endohead would therefore not fit properly.

10) After bar screw tightening with the MUTARS® swing wrench and articulated MUTARS® engineers' wrench SW 24, the bar screw should be countered in order to obtain the necessary fixation.

11) To avoid damage of the threads the bar screws should always be tightened completely.

Postoperative

1) Postoperative patient care, detailed instructions and warnings by the physician are of major importance. To enhance the healing process an external support of the operated leg is recommended for a limited period of time.

2) Active and passive movement must be carried out with extreme caution.

3) Postoperative therapy should support the healing process and prevent the leg from being submitted to excessive stress.

4) Patients are to be reminded repeatedly of the necessity to reduce activity as recommended by their physician.

Special user information

Never reuse implants which have already been implanted or removed, even if they appear undamaged (danger of implant breakage due to internal material fatigue).

Packaging and labelling

Each of the MUTARS® implants and instruments is packaged separately. The packaging of the not steril products is suitable for steam and Ethyloxyd-sterilization. The MUTARS® PE-components are supplied sterile. They should only be accepted by hospitals and physicians if supplied in their original packaging and with an original label.

For reasons of safety, protection and identification all implants should always be kept in cool and dry environment in their unopened packagings.

Sterilization

The implants of the MUTARS® implant system have been sterilized by gamma-radiation (min. 25kGy) and are supplied in protective covers. Please always check the packages for perforation or other damage prior to surgery.

Resterilization of PE-components is not permitted.

For further information please refer to:

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Technical modifications are subject to change without notice.