MUTARS®-Münster

implantcast

Total Humerus

surgical technique

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MUTARS® was developed in co-operation with
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MUTARS® has been in successful clinical use since 1992

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Nota Bene: The described surgical technique is the suggested treatment for the uncomplicated procedure. In the final analysis the preferred treatment is that which addresses the needs of the individual patient.

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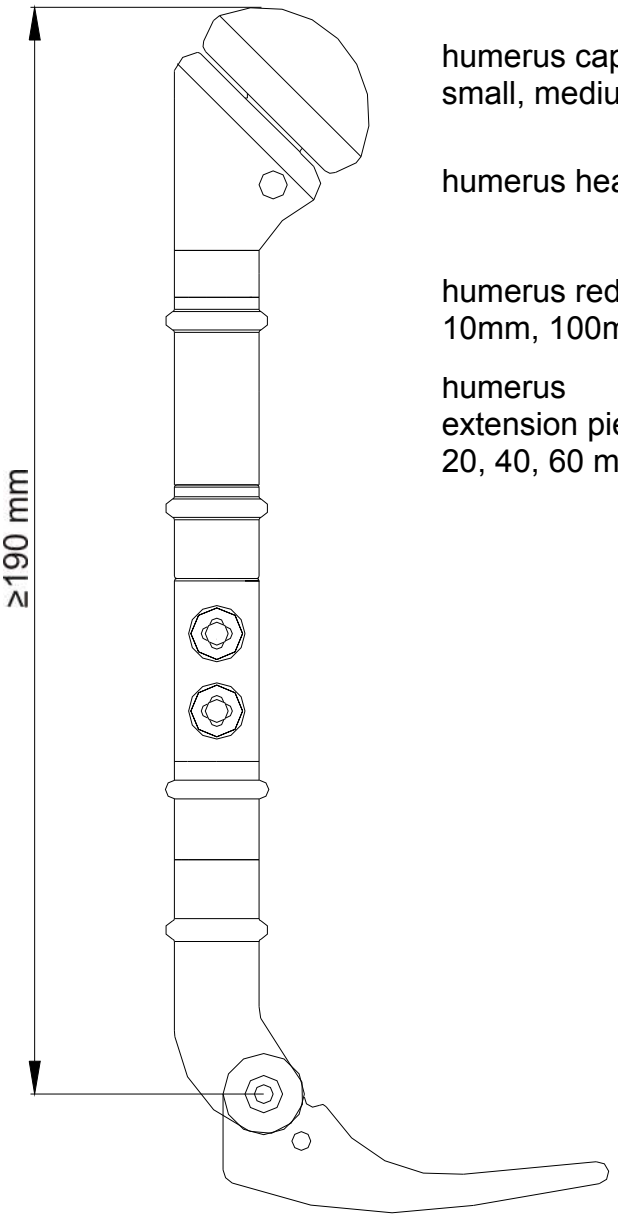
System Overview



humerus cap
small, medium, large

humerus head

humerus reducer
10mm, 100mm

humerus
extension piece
20, 40, 60 mm

ulna anchorage
cementless ($TiAl_6V_4$)
cemented (CoCrMo)

MUTARS® Total Humerus

assembling options

(length in mm)

The use of an 100mm reducer is recommended
for a reconstruction length over 300mm

	Humerus components					
reconstruction	head	reducer	extension piece	connecting part 80 mm	distal humerus	humerus screw
190	50	10		80	50	15+15+15
210	50	10	20	80	50	15+35+15
230	50	10	40	80	50	15+55+15
250	50	10	60	80	50	15+75+15
270	50	10	20+60	80	50	35+75+15
290	50	10	40+60	80	50	55+75+15
300	50	100	20	80	50	15+35+15
310	50	10	20+40+60	80	50	75+75+15
320	50	100	40	80	50	15+55+15

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.

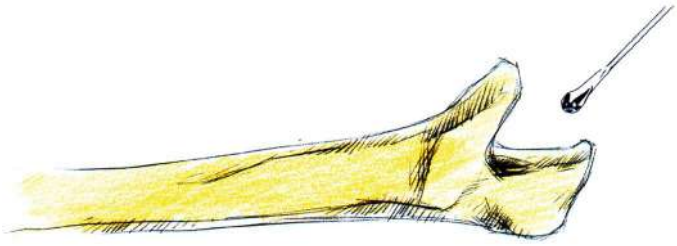


figure 1

Tumor resection

Measure the size of the resected amount of bone. Compare the length to the preoperative planning.

Remark
In the case that the radius head is free of tumor it needn't be resected.

The minimum bone resection is 60mm.

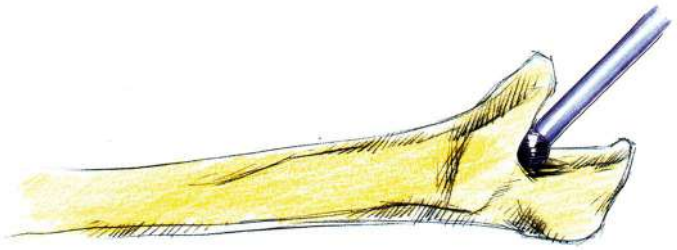


figure 2

Preparation of the proximal ulna

Open the medullary cavity.
Prepare the cavity with a sharp spoon (fig. 1) and the use of an air-drill (fig. 2).

To implant the ulna anchorage in the exact depth, the entry has to be extended ventral at the Proc. Coronoideus and dorsal.

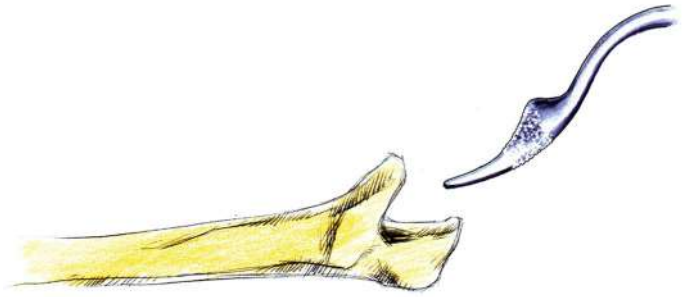


figure 3a

Rasp the medullary cavity with the MUTARS® rasp for ulna anchorage (fig. 3a and 3b).

Remark
Risk of the via falsa with cortical perforation. Control in 2 plains under x-ray is recommended.

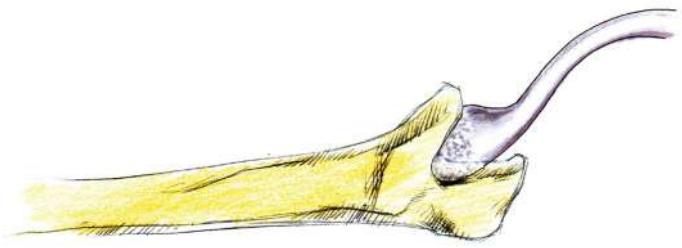


figure 3b

Implantation of the ulna anchorage

If a cemented implantation is planned, clean the ulnar cavity (fig. 4) and insert some cement.

Insert and impact the ulna anchorage cemented or cementless. Use either the straight or the cranked setting instrument for impaction (fig. 5).

Make again a concluding x-ray control in 2 plains.

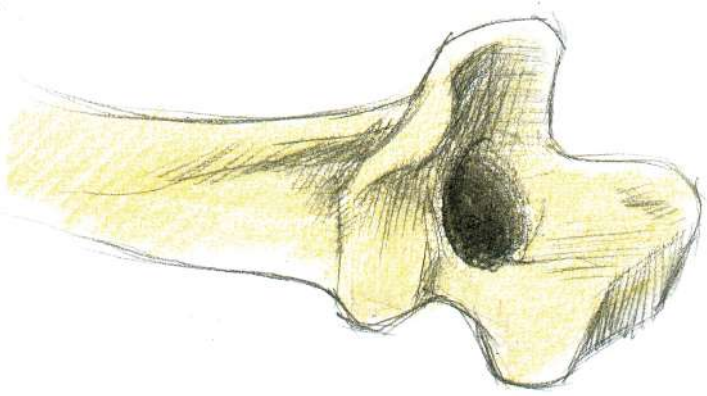


figure 4

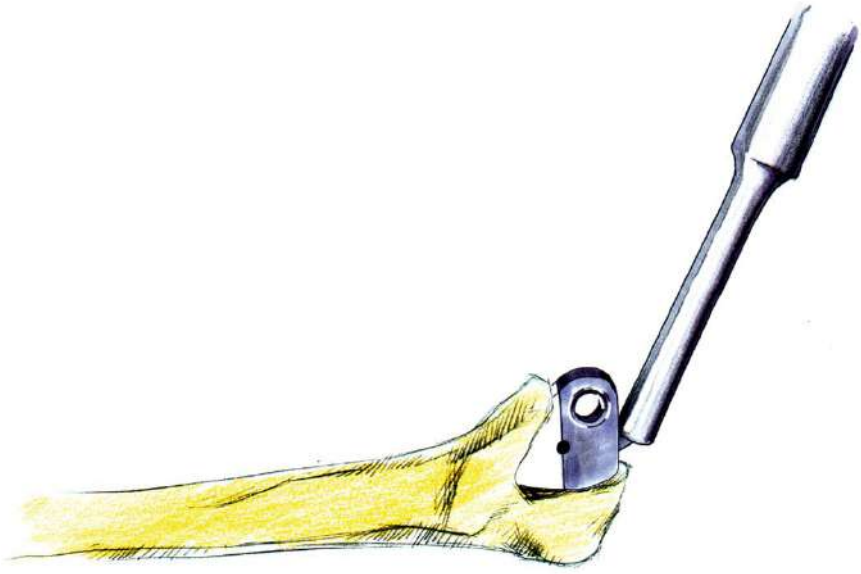


figure 5

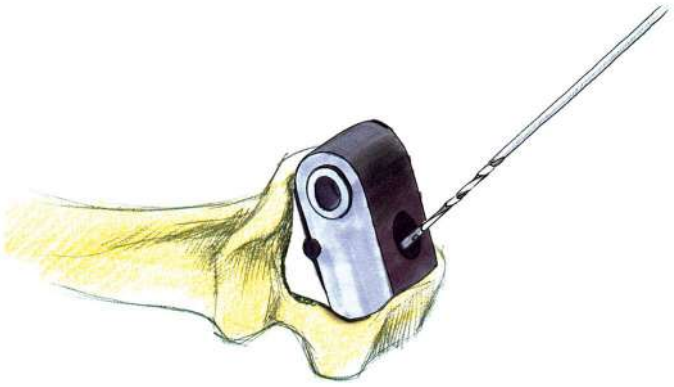


figure 6a

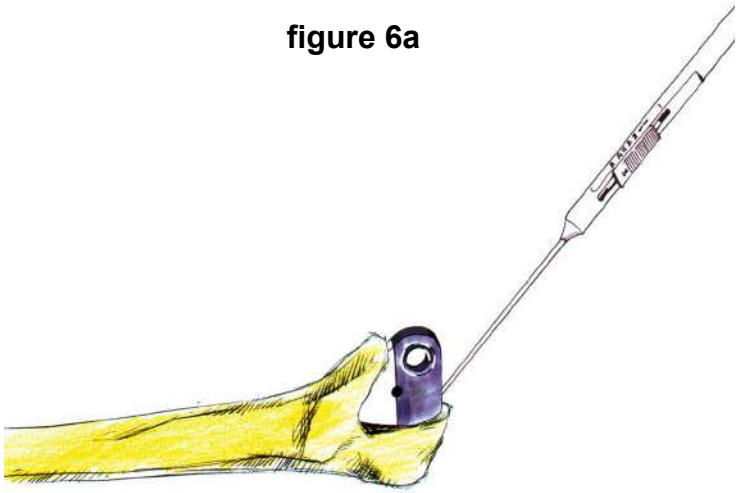


figure 6b

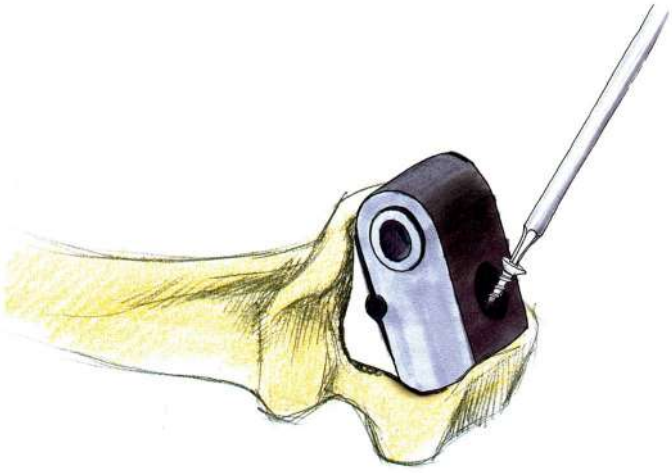


figure 6c

Screw fixation of the ulna anchorage

It is recommended to enhance the fixation of the ulna anchorage by adding a bone screw, both for the cementless and the **cemented** implantation.

Please follow the steps shown on the left. Drill with the 2mm drill (fig. 6a) measure the length of the 4 mm screw (fig. 6b) and insert the screw (fig. 6c).

Remark
The use of a cancellous screw is preferable, because a cortical screw can lead to a skin impigment.

Assembling of the humeral components

The modularity of the system allows the readjustment of the rotational alignment and the length after the trialing at several connectors.

Generally it is possible to build up the prosthetic body of the appropriated length by combining the long reducer (100mm) (fig. 7a) or by the use of the short reducer (10mm) in combination with the connecting part (fig. 7b).

Please see also the table of assembling options on page 2.

Remark
The use of a connection part is preferable, because in case of revision the disconnecting of the parts will be easier without opening of any of the both joints (fig. 8).

figure 7a

figure 7b

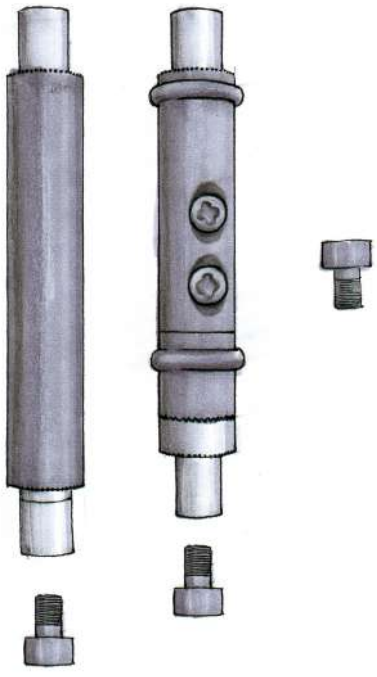


figure 8

Trial reduction with the humeral parts

It is recommended to combine all necessary humerus components before inserting them into the patient.

Please assemble first the distal humerus and the reducer and the connecting part distally (fig. 9).

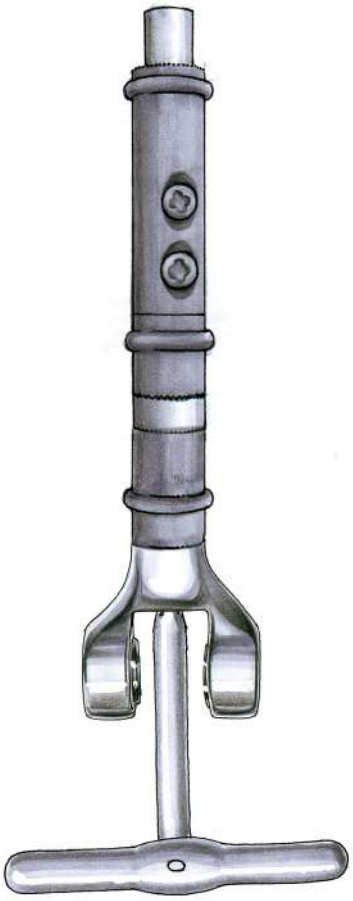


figure 9

Combine the distal humerus and the reducer with a 15mm screw (fig. 10a). Adjust the correct rotational position.

Lock the screw with the MUTARS® socket wrench small.

Secure the assembly by using the counter instrument (fig. 10c).

Lock the humerus safety screw in the same way (fig. 10b).

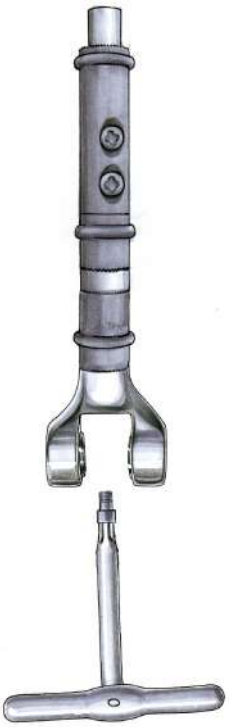


figure 10a

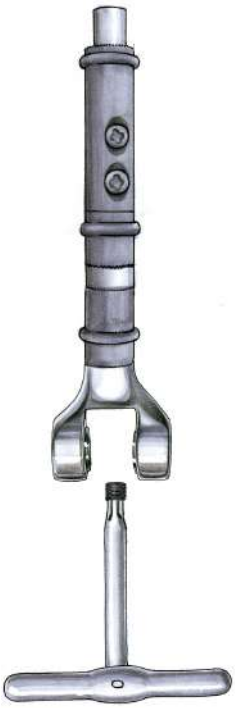


figure 10b

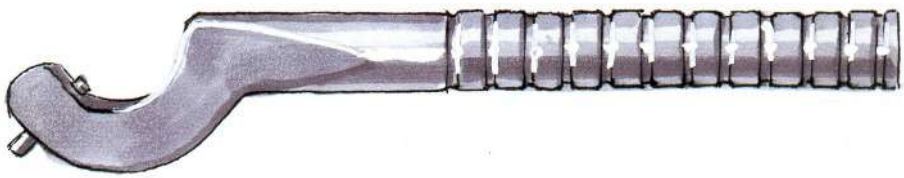


figure 10c

Insert the ulna stop by using the impactor (fig. 11) or a punch.

The ulna stop should be impacted completely.

Abbildung 11

Remark:
The elbow joint can be connected. Further adjustments of the rotation alignment can be performed by changing the proximal components.

Combine the ulna anchorage with the distal humerus components and insert the articulating axle (fig. 12).

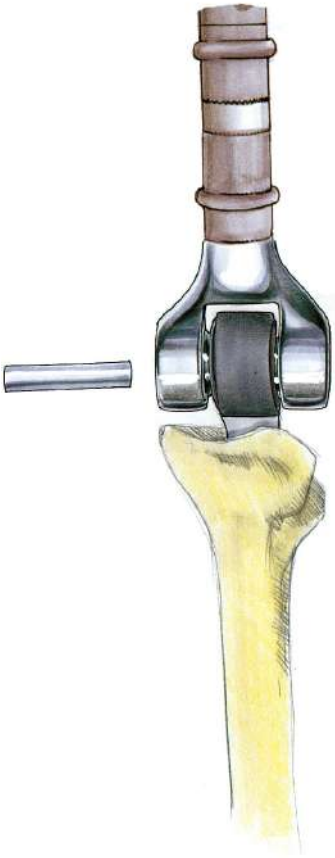


Abbildung 12

Abbildung 13a

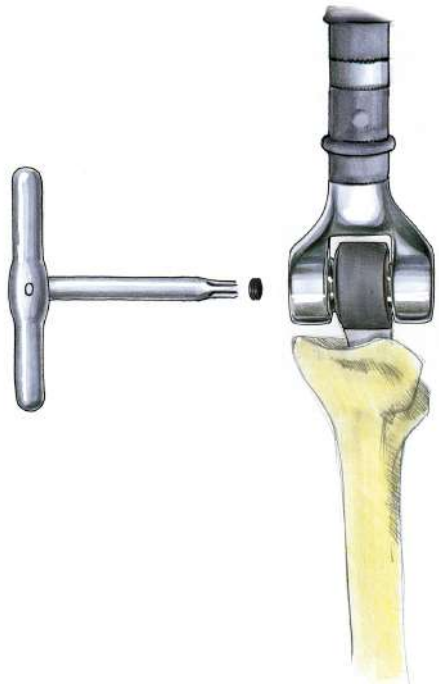


Abbildung 13b

Abbildung 13c

Locking of the joint mechanism

After inserting of the axle please close the distale humerus with the lock screw. (figb. 13a).

Use the socket wrench to tighten the locking screw (fig. 13b and 13c).

Trial reduction with trial components

Mount the humerus trial head and the possibly used trial extension pieces (possible enlargement from 20 to 200 mm; see table page2) onto the top of the connecting part. Insert the trial bar screw of the correct length and lock it with the socket wrench (fig. 14a).

Remark
If you perfrom the trial reduction by using the implant components (fig. 14b) don't insert the safety screw at that stage!

Abbildung 14a

Abbildung 14b

Put the humerus trial cap, which belongs to the size of the preoperative chosen humerus cap (small, medium or large) on the head (fig. 15).

Perform a trial reduction and control the muscle tension.

Remove the humerus trial cap, the humerus head and when sufficient stability is achieved.

Abbildung 15

Abbildung 16a

Abbildung 16b

Final implant assembly

Combine the proximal implant components on the connecting part. Insert the bar screw of the correct length length (see table on page 2), but do not tighten the screw completely at this stage (fig. 16a).

Put the chosen humerus cap on the humeral head (fig 16b). Perform stability tests and readjust the rotation if necessary.

Abbildung 17a

Abbildung 17b

If sufficient stability and the correct rotation is found please use the socket wrench small to tighten the screw. Use the counter instrument to secure the assembly (fig. 17a).

Lock the humerus safety screw in the same way (fig. 17b)

Abbildung 18

Screw the humerus cap of the correct diameter with the MUTARS® wrench for cap/counter instrument and secure it with the wrench for humerus (fig. 18).

The use of the attachment tube

Fasten the attachment tube. 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. 20a and fig. 20b).

Fix muscles and tendon tissues with sutures to the meshes of the tube (fig. 21a. and fig. 21b).

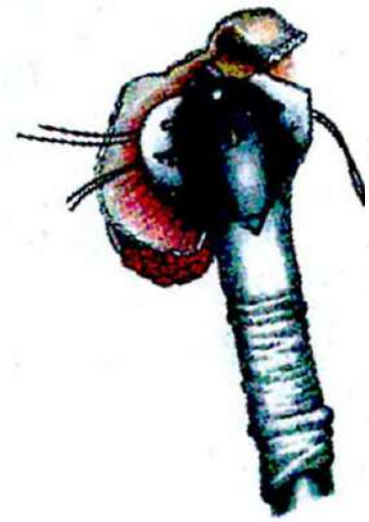


figure 20a

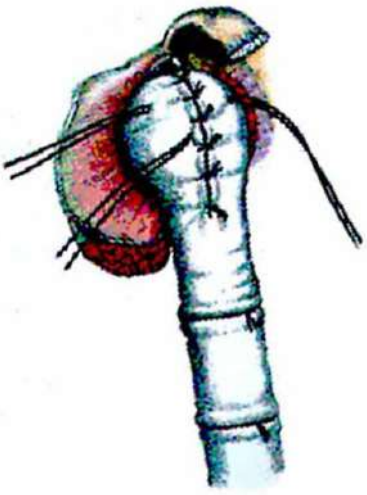


figure 20b

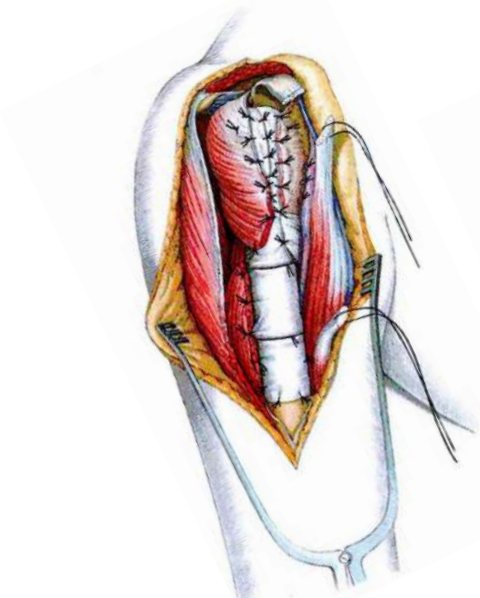


figure 21a

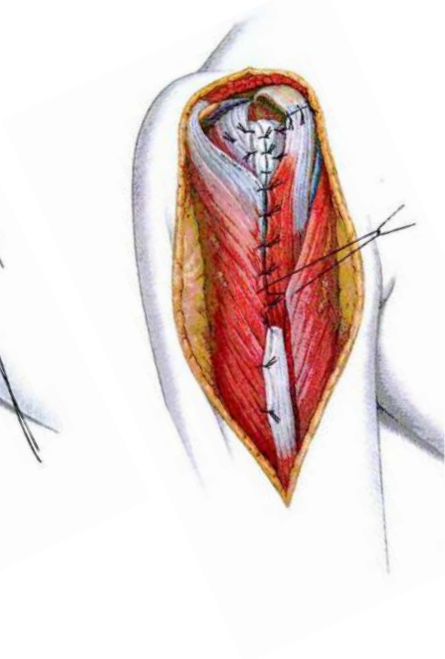


figure 21b

IMPLANTS

MUTARS® humerus cap
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3 with TiN-coating
5210-0000 small
5210-0005 medium
5210-0010 large

MUTARS® humerus head 50 mm
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5200-0000

MUTARS®humerus screw
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5230-0015 M8x15 mm
5230-0035 M8x35 mm
5230-0055 M8x55 mm
5230-0075 M8x75 mm
For a total humerus three screws are needed (see table page2)

MUTARS®humerus extension piece
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5220-0020 20 mm
5220-0040 40 mm
5220-0060 60 mm

MUTARS® humerus connecting part
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5221-0080 80 mm

IMPLANTS

MUTARS® humerus reducer
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5221-0000 10 mm
5221-0100 100 mm

MUTARS® distal humerus 50 mm incl. axle, safety screw and 2 lock screws humerus cap
mat.: implatan®; $TiAl_6V_4$ according to DIN ISO 5832/3
5250-0000

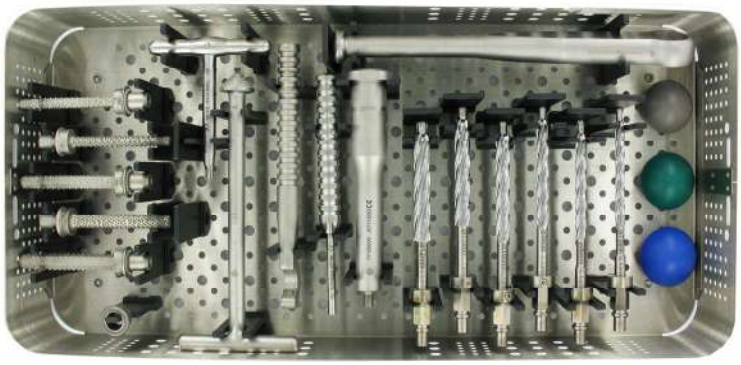
MUTARS® ulna stop
mat.: UHMWPE according to DIN ISO 5834/2
5250-1100

MUTARS® ulna anchorage cementless
mat.: implatan®; TiAl6V4 according to DIN ISO 5832/3 with cpTi and HA-coating
5250-1015 left
5250-1020 right

MUTARS® ulna anchorage cemented
mat.: implavit®; CoCrMo-casting alloy according to DIN ISO 5832/4
5250-1005 left
5250-1010 right

cancellous screw ∅ 4mm
Mat.: implatan®; $TiAl_6V_4$ acc. to DIN ISO 5832/3
5793-4026 26 mm
5793-4028 28 mm
5793-4030 30 mm
5793-4032 32 mm
5793-4034 34 mm

INSTRUMENTS



MUTARS® humerus instrument tray
7999-5200

MUTARS® instrument tray distal humerus
7999-5150

MUTARS® humerus trial component tray
7999-5202

INSTRUMENTS

MUTARS® extractor
7220-0000

MUTARS® socket wrench
7608-1010

MUTARS® cavity reamer
7760-0500

MUTARS® humeral drill

7630-0007	7 mm
7630-0008	8 mm
7630-0009	9 mm
7630-0010	10 mm
7630-0011	11 mm
7630-0012	12 mm

MUTARS® humeral rasp

7770-0709	9 mm
7770-0710	10 mm
7770-0711	11 mm
7770-0712	12 mm
7770-0713	13 mm

MUTARS® humerus impactor
7710-0000

MUTARS® humerus impact and extract sleeve
7721-0000

MUTARS® wrench for humerus
7420-0001

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

MUTARS® humerus trial cap
7710-1000 small
7710-1005 medium
7710-1010 large

MUTARS® rasp for ulna anchorage
left 7420-0006
right 7420-0007

MUTARS® instrument for ulna anchorage straight
7420-0013

MUTARS® instrument for ulna anchorage cranked
7420-0014

MUTARS® trial axle for distal humerus
7420-0015

depth measuring instrument small
0270-1015

drill 2 mm
7520-0000

hexagon head screw driver 2,5 mm
7608-1001

ball reamer 4 mm
7700-2604

INSTRUMENTS

MUTARS® humerus trial cap with taper
7710-1200 small
7710-1205 medium
7710-1210 large

MUTARS® humerus trial head
7710-1252

MUTARS® humerus trial extension piece
7710-0020 20 mm
7710-0040 40 mm
7710-0060 60 mm

MUTARS® humerus trial reducer
7710-2100 10 mm
7710-2101 100 mm

MUTARS® humerus trial connecting part 80 mm
7710-2180

MUTARS® humerus trial screw
7710-2315 M8x15 mm
7710-2335 M8x35 mm
7710-2355 M8x55 mm
7710-2375 M8x75 mm

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.

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 e

xtreme 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.

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