Diaphyseal implant
surgical technique
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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

Femoral stem
ø12-18mm cementless
ø11-17mm cemented

Extension piece

Connecting for Diaphyseal implant

Diaphyseal implant cemented
ø15, 17, 19 mm
Diaphyseal implant

assembling options
(length in mm)

Remark: The MUTARS® Diaphyseal implant was developed to bridge diaphyseal bone defects of the femoral bone. For the part which is closer to the diaphyseal part with the shorter stem of 100 mm length is recommended. It is available only in cemented version in diameters of 15, 17 and 19mm. For the part which is farer from the joint the cemented and cementless femoral stems should be used.

<table>
<thead>
<tr>
<th>reconstruction length *</th>
<th>Diaphyseal implantat</th>
<th>connecting part</th>
<th>Extension piece</th>
<th>screw</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>-</td>
<td>100</td>
<td>-</td>
<td>25</td>
</tr>
<tr>
<td>120</td>
<td>-</td>
<td>120</td>
<td>-</td>
<td>45</td>
</tr>
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<td>-</td>
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<td>-</td>
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<td>-</td>
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<td>120</td>
<td>100</td>
<td>145</td>
</tr>
<tr>
<td>240</td>
<td>-</td>
<td>120</td>
<td>80 + 40</td>
<td>165</td>
</tr>
<tr>
<td>260</td>
<td>-</td>
<td>120</td>
<td>80 + 60</td>
<td>185</td>
</tr>
<tr>
<td>280</td>
<td>-</td>
<td>120</td>
<td>100 + 60</td>
<td>205</td>
</tr>
<tr>
<td>300</td>
<td>-</td>
<td>120</td>
<td>100 + 80</td>
<td>225</td>
</tr>
</tbody>
</table>

*The reconstruction length includes both collars on the stems.

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.
Resection of the tumor
Start with the resection of the tumor. Please measure the length of the resected bone. The minimum resection is 100 mm.

Preparation of the medullary cavities
Prepare the proximal (fig. 1a) and the distal (fig. 1b) femoral medullary cavities with the MUTARS® medullary cavity reamer.

Cementless fixation of the stem.
Ream the femoral medullary cavity preferably up to a depth of 130mm with a flexible reamer 1.5 mm smaller than the preoperatively chosen femoral stem (fig. 2).

Cemented fixation
Ream the femoral medullary cavity preferably up to a depth of 130mm with a flexible reamer 2 mm larger than the preoperatively chosen femoral stem (fig. 2).

Remark
In case flexible reamers are not part of the inventory of the hospital flexible reamers can be provided on special demand.
Rasping of the femoral cavity

Mark the anterior aspect of the femoral bone to meet the correct antecurvature of the femur (fig. 3).

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

Assemble the femoral rasp of the appropriate size (table 1), the sleeve and the slide hammer. Lock the rasp on the slide impactor by using the engineers’ wrench (fig. 4a).

<table>
<thead>
<tr>
<th>Stem size</th>
<th>Rasp size</th>
</tr>
</thead>
<tbody>
<tr>
<td>12mm</td>
<td>12mm</td>
</tr>
<tr>
<td>13mm</td>
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<td>14mm</td>
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<td>15mm</td>
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<tr>
<td>16mm</td>
<td>16mm</td>
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<tr>
<td>17mm</td>
<td>17mm</td>
</tr>
<tr>
<td>18mm</td>
<td>18mm</td>
</tr>
</tbody>
</table>

**table 1**

Optional technique for the use of cemented stems
If you want to prepare for a cemented stem with the femoral rasp, please use the rasp which is 2 mm larger than the preoperatively chosen cemented femoral stem (fig. 4b). That will provide a cement mantle of 1mm thickness (table 2). Use the 18mm rasp to prepare for the 17mm stem.

<table>
<thead>
<tr>
<th>Stem size</th>
<th>Rasp size</th>
</tr>
</thead>
<tbody>
<tr>
<td>11mm</td>
<td>13mm</td>
</tr>
<tr>
<td>13mm</td>
<td>15mm</td>
</tr>
<tr>
<td>15mm</td>
<td>17mm</td>
</tr>
<tr>
<td>17mm</td>
<td>18mm</td>
</tr>
</tbody>
</table>

**table 2**

Remark
It is recommended to clean the rasp from bone chips during the rasping. Leave the femoral rasp in the bone for the trialing.
Preparation for the Diaphyseal implant

As the Diaphyseal implant for the distal part of the femur is only available in cemented version the intramedullary cavity is reamed with a flexible reamer which is 2 mm larger than the preoperatively chosen implant (fig. 5).

That will provide a cement mantle of 1mm thickness (table 3).

<table>
<thead>
<tr>
<th>Implant size</th>
<th>Reamer size</th>
</tr>
</thead>
<tbody>
<tr>
<td>15mm</td>
<td>17mm</td>
</tr>
<tr>
<td>17mm</td>
<td>19mm</td>
</tr>
<tr>
<td>19mm</td>
<td>21mm</td>
</tr>
</tbody>
</table>

Trial assembly

Please check the correct length and position of the implants by inserting the Diaphyseal implant (without cement), the connecting module and combine it with the femoral rasp (fig. 6).

Remark

For the cemented procedure femoral rasps are usually not available. Please insert the cemented stems (without cement) for trialing purposes.

Use additional extension pieces to enlarge the prosthesis if necessary. Consider the assembling options on page 1 of this brochure. Please resect more bone if necessary.
Implantation of the femoral stem

Impact the MUTARS® femoral stem (fig. 21).
Insert the stem of the same size as the rasp if a cementless stem is used.
To prevent fractures of the cortical bone it is helpful to fix a bone forceps around the femoral bone during impaction.

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

Remove all instruments during the cement hardening to prevent bending moments.
Implantation of the Diaphyseal implant

Please use an intramedullary plug before inserting bone cement.

Choose the Diaphyseal implant with a stem diameter which is 2 mm smaller than the previously used reamer or rasp.

Mount the connecting part on the Diaphyseal implant and use the hand piece of the MUTARS® extractor device to impact (fig. 8).

Remark
It is recommended to insert additional bone locking screws to enhance rotational stability of the implant.

figure 8
Combining of the implant components

Mount the connecting module to the femoral stem. If necessary add the extension piece.

Insert the bar screw of the appropriated length (see page 1) and lock it with the socket wrench (fig. 9).

Perform a trial assembling and, if necessary, readjust the rotation, of the implant by unlocking the screw and turning the clock mechanism (adjustable by 5° steps).

If the correct position is found, lock the connecting screw by using the swing wrench and the engineers’ wrench to counter (fig. 10).
**Final implant locking**

Connect the Diaphyseal implant and the connecting part with the two locking screws.

Use the swing wrench to lock the screws (fig. 11).
MUTARS® Diaphyseal implant

IMPLANTS

MUTARS® Diaphyseal implant incl. 2 locking screws
mat.: implavit®; CoCrMo casting alloy according to DIN ISO 5832/4
5730-1015  15 mm
5730-1017  17 mm
5730-1019  19 mm

MUTARS® connecting part for Diaphyseal implant
mat.: implatan®, TiAl6V4 according to DIN ISO 5832/3
5730-1100  100 mm
5730-1120  120 mm

MUTARS® extension piece
mat.: implatan®, TiAl6V4 according to DIN ISO 5832/3
5772-2504  40 mm
5772-2506  60 mm
5772-2508  80 mm
MUTARS® bar screw
mat.: implatan®; TiAl₆V₄ 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
5792-1020 M10x205 mm
5792-1022 M10x225 mm

MUTARS® femoral stem cemented
mat.: implavit®; CoCrMo casting alloy according to DIN ISO 5832/4
5760-0011 11 mm
5760-0013 13 mm
5760-0015 15 mm
5760-0017 17 mm

MUTARS® femoral stem cementless
mat.: implatan®; TiAl₆V₄ according to DIN ISO 5832/3 with HA coating
5760-0012 12 mm
5760-0013 13 mm
5760-0014 14 mm
5760-0015 15 mm
5760-0016 16 mm
5760-0018 18 mm
5760-0018 18 mm
MUTARS® Diaphyseal implant

INSTRUMENTS

MUTARS® basic instrument tray cementless
7999-5710

MUTARS® extractor device
7220-0000

MUTARS® socket wrench
7420-0000

MUTARS® medullary cavity reamer
7760-05001

MUTARS® engineers' wrench SW 24
7490-0000

MUTARS® universal impactor
7210-0000

MUTARS® impact and extract sleeve
7230-0000

MUTARS® swing wrench
7411-0000

MUTARS® slide hammer
7220-0001

MUTARS® rasp for femoral stem
7760-2512  12 mm
7760-2513  13 mm
7760-2514  14 mm
7760-2515  15 mm
7760-2516  16 mm
7760-2517  17 mm
7760-2518  18 mm

handle for intramedullary plug
7512-4001
The MUTARS® surgical technique:

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.

**Contraindications**

3. other insufficient muscular conditions which lead to insufficient support of the joint.
4. total replacement of the femoral bone

In those cases (described above) the use of the MUTARS® lock PEEK-Optima® is strictly recommended. Contraindications which generally exclude the joint replacement and indicate alternative methods (i.e. knee arthrodesis) are not influenced by the described special indications.

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.

**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 synovitis.
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 arthrodesis, 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 - 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 medullary canal. 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 electophytic 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 sterile 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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