







Endo-Model Standard/ – M Knee System
with Segmental Bone Replacement Components
and MIRETO Instrument Set

Surgical Technique – Primary & Revision

CE 0482

Explanation of Pictograms			
	Manufacturer		Article number
	Material (number)		Product meets the applicable requirements, which are regulated in the EU harmonization legislation for the affixing of the CE marking.

Endo-Model Standard/ – M

Knee System with Segmental Bone Replacement Components
and MIRETO Instrument Set

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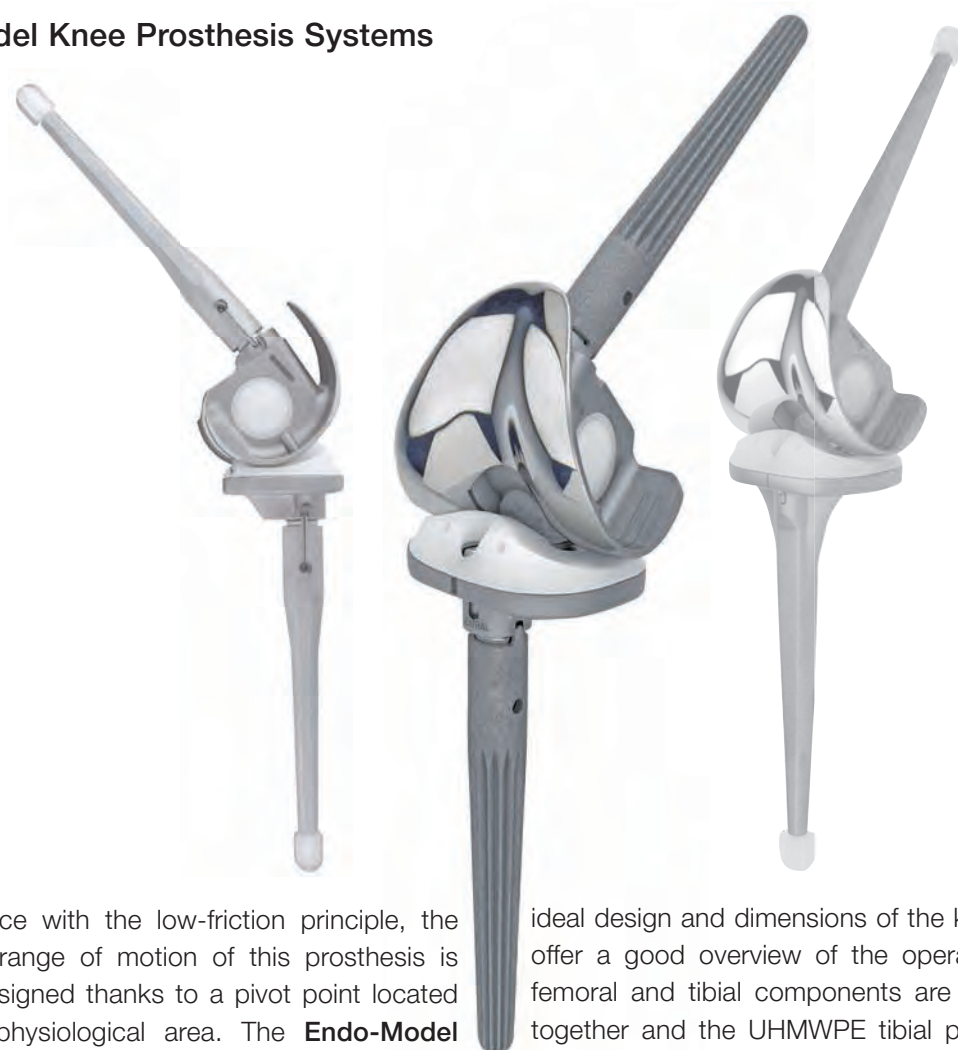
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Endo-Model Knee Prosthesis Systems



In accordance with the low-friction principle, the kinematical range of motion of this prosthesis is optimally designed thanks to a pivot point located within the physiological area. The **Endo-Model Standard/ – M** Rotational Knee Prosthesis enables flexion of the joint up to 142°. The joint kinematics also comprise physiological rotation which, given the special shape of the tibial contact surface, ensures elastic force transmission. The hinge knee prosthesis however permits flexion of the joint up to 142° without rotation.

With every step, and especially in the case of a fall, torsional stresses are transmitted to the prosthesis anchorage which impact negatively upon the lifespan of the anchorage. Constructively generated, elastic force transmission relieves stress at the prosthesis/bone cement and bone cement/bone interfaces. Because of the favorable dimensions of the **Endo-Model Standard/ – M** Knee Prosthesis, only minimal resection of 14 mm is necessary in the tibia-femur joint plane. The medium-sized intra-condylar component is only 30 mm wide. As a rule, there is thus less resection than with a primary total knee prosthesis. This is an advantageous factor with respect to subsequent revision surgery. The

ideal design and dimensions of the knee prosthesis offer a good overview of the operating field. The femoral and tibial components are simply pushed together and the UHMWPE tibial plateau is easily positioned using a special instrument. The two components are coupled by the plateau so as to prevent luxation and without reducing the range of motion or rotation. The hinge knee prosthesis is coupled by the axis mechanism.

Flexion and rotational movement of the rotational knee prosthesis are achieved by means of a cross joint. Hyperextension amounts to 2°. The compromise axis lies in the region of the physiological pivot point. Flexion up to 142° is possible. With standard knee replacement, advancement of the patella or of the patellar bearing surface is often seen. By moving the femoral component posteriorly relative to the tibial axis, physiological movement is also retained for the femoropatellar joint. This protects against progression of retropatellar arthrosis. Rotation of the prosthesis ends in extension by form closure, which ensures a secure standing position. Rotation increases continuously with greater flexion. This rotation is limited primarily by the capsular ligament apparatus. The shape of the surfaces which are in con-

Endo-Model Knee Prosthesis Systems

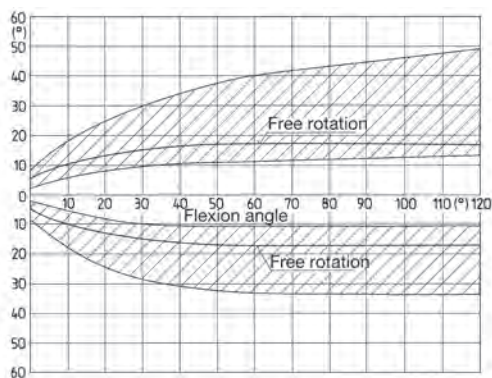
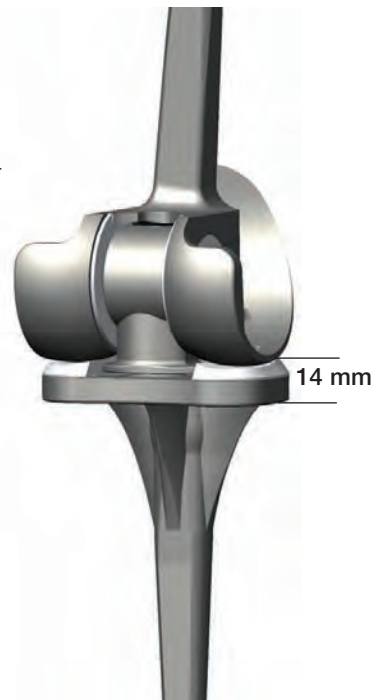
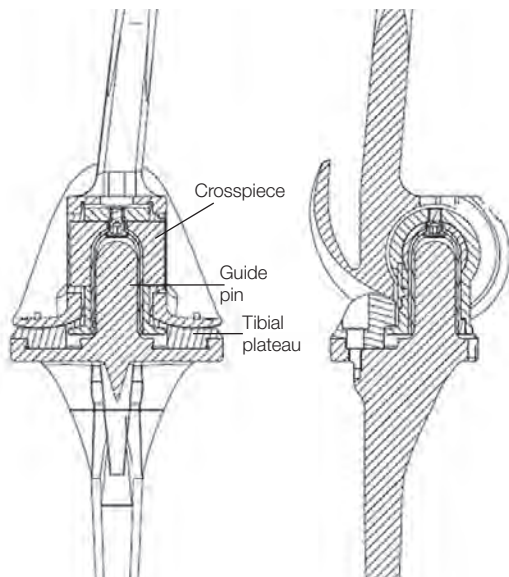
tact with each other means that further rotation is cushioned elastically by the body's weight bearing down on the joint. The femoral component of the **Endo-Model Standard/ – M** total knee prosthesis has a physiological valgus angle of 6°.

Both prosthesis components are broadly supported on their corresponding joint surfaces, such that the compressive strength of the cancellous bone vis-à-vis the femur and tibia is not exceeded. The majority of the femoral component (the box) is placed intracondylar and as such protected by the bone coverage, which in turn compensates the thin soft tissue cover in the knee joint partially. The sled runner-inspired shape of the femoral component is based on the anatomical conditions. The ventral depression provides a smooth transition to the bony patellar bearing surface.

The modular prosthesis stems are available for the **Endo-Model – M** both as a cemented version, without structuring, and with longitudinal ribs and microporous surface for cementless implantation. To achieve a central position within the medullary cavity, the tips of the cemented stems are fitted with star shaped UHMWPE centralizers. Direct contact of the metal stems with the inner wall of the bone is thereby prevented, and a gradual stress translation between metal and bone achieved. The stems are supplied in lengths of 50 mm up to 280 mm. For revision surgery of total knee prostheses, special femoral and tibial segments and spacers made of UHMWPE and Tilastan are available to reconstruct the condyles and the joint line as well as for tumor cases (segmental bone replacement). It must be noted here that these segments may only be used in combination with correspondingly longer stems.

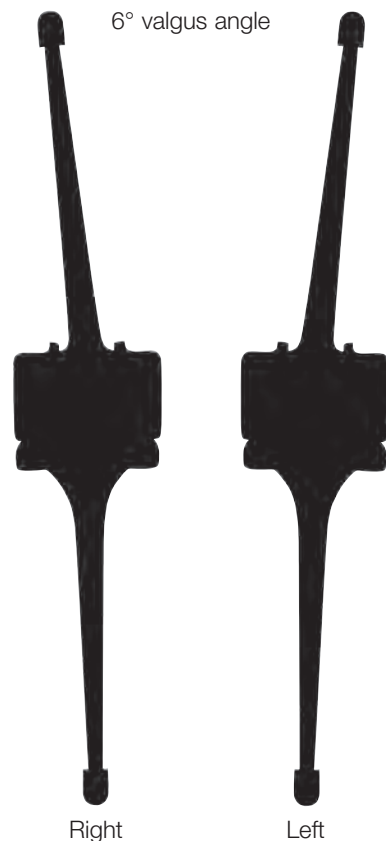
Endo-Model Knee Prosthesis Systems

In accordance with the low-friction principle, the kinematical range of motion of the rotational knee prosthesis is optimally designed thanks to a pivot point located within the physiological area. Flexion and rotational movement of the rotational knee prosthesis are achieved by means of a cross joint.



The extent of free rotation as a function of flexion and the constructively generated smooth cushioned slowed down rotation range are shown by the hatched area.

Engelbrecht, E.: Die Rotationsendoprothese des Kniegelenks (Rotational prosthesis for the knee joint), Springer-Verlag 1984, ISBN: 978-3-642-69819-4 (print), 978-3-642-69818-7 (online)

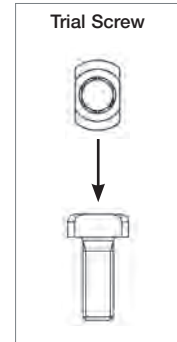


Endo-Model Knee Prosthesis Systems

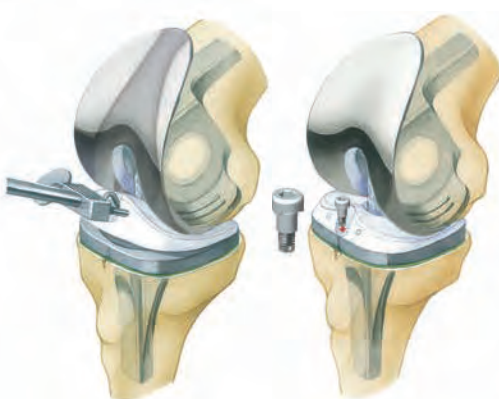
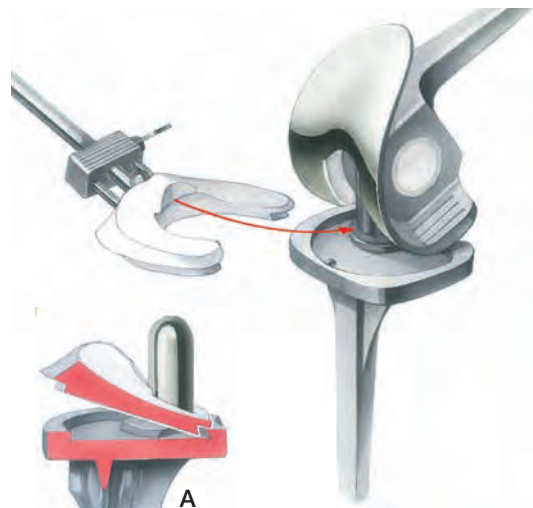
Assembly: Plateau with anti-luxation device



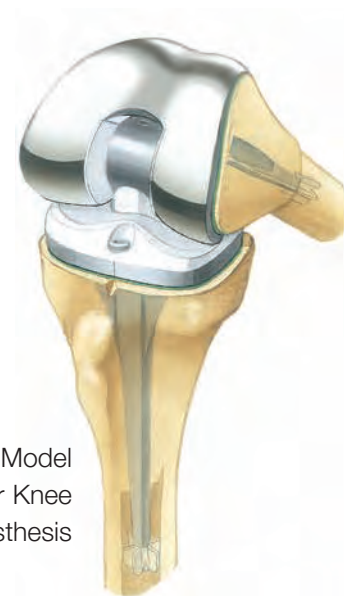
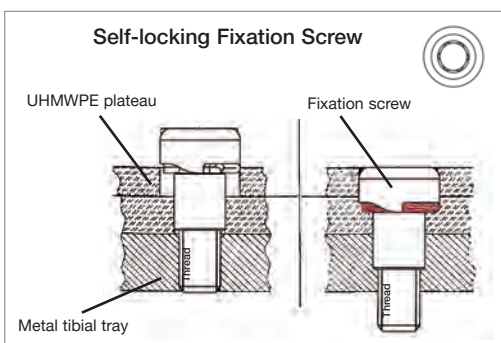
After cementation of the tibial and femoral components, the UHMWPE plateau is removed from the tibial tray by loosening the trial screw. With the knee in flexion, the upper and lower components are assembled.



The tibial plateau is attached to the inserter and slid between the femoral and tibial components into the joint so that the plateau chamber grips over the flange. It must be ensured that the dovetail-shaped incision (fig. A) on the bottom of the UHMWPE plateau locks into the peripheral groove on the metal tibial support.



The UHMWPE plateau is pressed down and fixed into place by the self-locking fixation screw.



Implanted Endo-Model Modular Knee Prosthesis

Endo-Model – M Assembly: Modular Stems

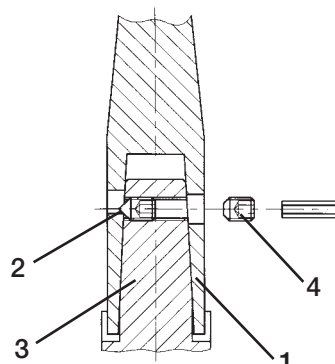
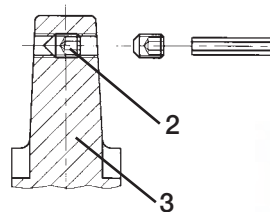


The modular stems are secured by a tapered connection. To ensure rotational stability, the stem has two opposing flanges, which are inserted into the medial and lateral grooves on the femoral/tibial components.

The current version V02 features 6 mm grooves for attachment of modular stems with female taper and 3 mm or 6 mm flanges. When attaching modular stems with 3 mm flanges, the stem must be aligned on the taper so that the threaded hole for the counter screw is not obscured (A). To this end, the alignment aid (15-6096/00) for modular stems is used (B). Modular stems with 6 mm wide flanges cannot be combined with Endo-Model implants having only 3 mm grooves.



The tapered tip of the locking screw (2) in the taper (3) of the tibial or femoral component pushes the stem firmly against the taper as it is screwed further in (1). A counter screw (4) prevents the locking screw from loosening. The screw is secured from medial. **Screws are to be tightened carefully.**



Counter Screw



Important Information:

The locking screw (optionally pre-assembled), the counter screw and one replacement screw each are included separately in the packaging.

LINK PorEx Technology – Hypoallergenic Surface Modification

LINK PorEx Technology

(TiNbN = Titanium-Niobium-Nitride)

The hypoallergenic LINK PorE surface modification results in a ceramic-like surface, which significantly reduces ion release and potentially improves tolerance of chrome and nickel in the case of patients who are sensitive to metal.¹

Thanks to its outstanding hardness, abrasion properties similar to ceramics and larger wetting angle, in contact with liquids the LINK PorE surface modification has a lower coefficient of friction compared to CoCrMo surfaces and thus reduces polyethylene wear.

¹ Internal Study of the influence of TiNbN coatings on ion release from CoCrMo alloys in an SBF buffer after the simulator test.

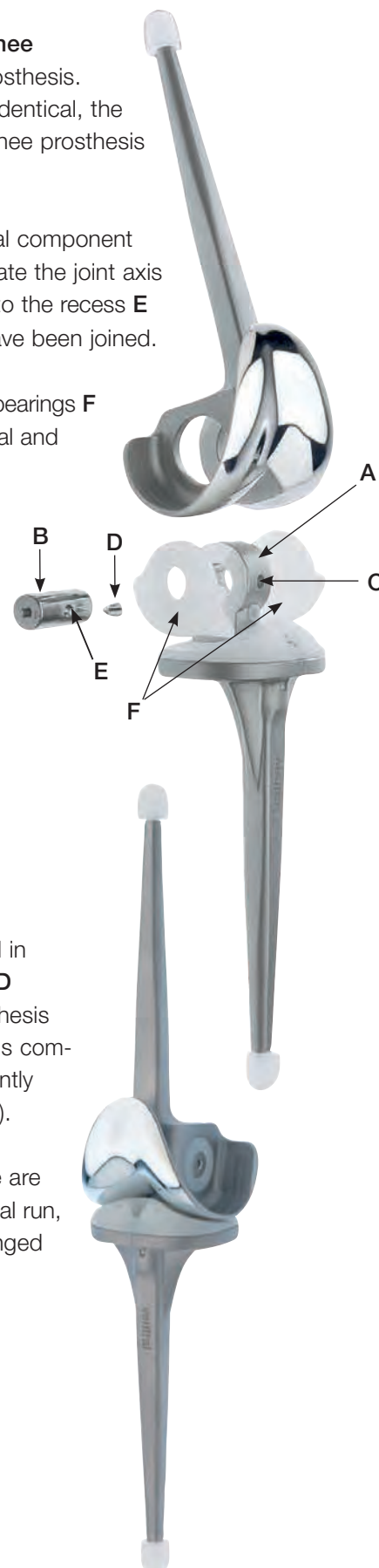


Endo-Model Hinge Knee Prosthesis

The external shape, dimensions and sizes of the **Endo-Model Hinge Knee Prosthesis** correspond to those of the Endo-Model Rotational Knee Prosthesis. As the implant beds required for the hinged and rotational versions are identical, the decision as to whether to use a rotational or a more stabilizing hinged knee prosthesis can be made intraoperatively.

The connecting piece **A**, which is fixed to the hinge knee prosthesis tibial component and links it to the femoral component, has a through-hole to accommodate the joint axis **B**. The ventral hole **C** is provided for the grub screw **D**, whose tip fits into the recess **E** on the axis and locks the latter once the upper and lower components have been joined.

From inside the intracondylar box of the femoral component, polyethylene bearings **F** for the prosthesis axis are pressed into medial and lateral holes. The femoral and tibial prosthesis components are joined by introducing the tibial coupling into the intracondylar box of the femoral component, such that the prosthesis axis can be inserted (always from the medial) using the threaded rod. Articulation takes place between the prosthesis axis and the two bearings.



The **Endo-Model Hinge Knee Prosthesis** is delivered ready assembled in a sterile condition without centralizers. To disassemble, the grub screw **D** is turned counterclockwise. The threaded rod is screwed onto the prosthesis axis **B**, which is then pulled out. The bearings **F** of the femoral prosthesis component are pushed inward and removed (when the bearings are subsequently refitted, it must be ensured that the open bearing is positioned medially!).

The package contains two sterile trial bearings (not autoclavable). These are inserted into the femoral prosthesis component during surgery; after the trial run, they are exchanged for the definitive bearings. These too can be exchanged if necessary in a second intervention.

Specified Indications and Contraindications for Endo-Model Rotating Hinge and Pure Hinge Knee System	Products	Rotating Hinge	Pure Hinge	Components with LINK PorEx (TiNbN) surface modification
General Indications				
<ul style="list-style-type: none"> Mobility limiting diseases, fractures or defects of the knee joint, distal femur or proximal tibia which cannot be treated by conservative or osteosynthetic procedures 		X	X	X
Indications				
<ul style="list-style-type: none"> Primary and secondary osteoarthritis 		X	X	X
<ul style="list-style-type: none"> Rheumatoid arthritis 		X	X	X
<ul style="list-style-type: none"> Revision after primary or revision total knee replacement 		X	X	X
<ul style="list-style-type: none"> Bone necroses which won't compromise the successful implantation of a hinged total knee endoprosthesis 		X	X	X
<ul style="list-style-type: none"> Varus and valgus deformity with contracture or laxity of the medial or lateral stabilizers 		X	X	X
<ul style="list-style-type: none"> Extreme cases of varus/valgus deformities (20-30°), rheumatoid arthritis, muscular deficiency and any kind of genu laxum 		-	X	-
<ul style="list-style-type: none"> Oncological and revision surgery in lower limb (in conjunction with the Endo-Model-W and the Megasytem-C) 		X	X	-
<ul style="list-style-type: none"> Sensitization against one or more components of used CoCrMo implant materials 		-	-	X
Contraindications				
<ul style="list-style-type: none"> Acute or chronic infections, local and systemic insofar as they compromise the successful implantation of a hinged total knee endoprosthesis 		X	X	X
<ul style="list-style-type: none"> Allergies to (implant) materials 		X	X	-
<ul style="list-style-type: none"> Distinctive muscular, nerve, vascular or other diseases which put the affected limb at risk 		X	X	X
<ul style="list-style-type: none"> Insufficient bone integrity which prevents a stable anchorage of the prosthesis 		X	X	X

These indications/contraindications refer to standard cases. The ultimate decision on whether or not an implant is suitable for a patient must be made by the surgeon based on his/her individual analysis and his/her experience.

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Der Orthopäde, Band 38, Heft 10, Oktober 2009 (K96)
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Long-Term Outcome of Total Knee Arthroplasty in Charcot Joint: A 10- to 22- Year Follow-Up
The Journal of Arthroplasty 2009; 24(8):1152-1156 (K98)

Tibial Preparation



01

Mark the entry point and open the tibial canal with the drill (15-6037/00) at the point of attachment of the anterior cruciate ligament. The drill can either be used manually with the T-handle (15-6053/00) or driven mechanically.

02

Assemble the tapered reamer with the T-handle (15-6053/00). The tibial stop plate (15-6062/00) is clicked into the designated groove on the tapered reamer stem. When using cementless modular stems: Ream with increasing diameters until the awl has achieved contact with the cortical bone over a continuous distance of approx. 50 mm. The implant must correspond with the tapered reamer last used in terms of diameter and length.

In the case of cemented modular stems, the tapered reamer should be at least 2 mm larger than the planned stem diameter.

Important information:

The position of the stop plate represents the lower edge of the tibial metal tray. The tapered reamers must not be used with a drive.



Tibial Resection

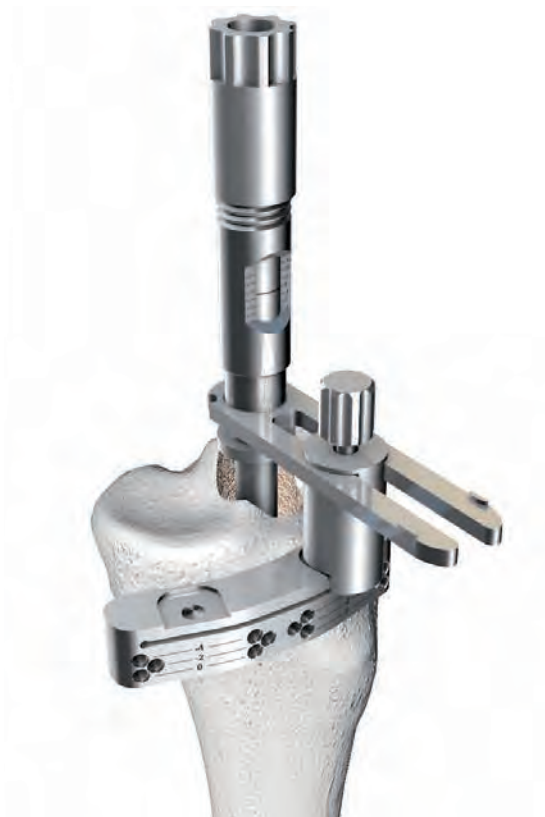


03

Once the tapered reamer is securely positioned by means of contact with the cortical bone, the T-handle and the stop plate are both removed. The tapered reamer remains in the medullary space. The tibial resection alignment instrument (15-6057/00) is attached, in a pre-assembled state (scale setting "0"), onto the tapered reamer. It must be ensured here that the stylus pin, which can be positioned medially or laterally, is guided in the designated groove.

04

The saw guide (15-6058/00) is attached to the alignment guide and placed on the ventral tibia. Ideally, the saw guide is pre-assembled in such a way that tibial resection can be performed from medial.



Tibial Resection



05

By turning the setting screw on the alignment guide, the desired resection height can be set and read off the scale. The cutting template (317-607/50) can be used to check the resection height. For first-time surgery, the resection height should not be greater than 10 mm. For revision surgery, as far as possible very little or no bone should be additionally resected.

Resection is performed without a dorsal slope at a 90° angle to the tibial axis (default setting due to instrument design).

06

After setting the desired resection height, the saw guide is fixed in place using two fixation pins (317-585/65 or /95) or drill pins (319-581/00 or 319-582/00). For this, the pins are initially inserted into the holes on the line marked "0" in the medial holes groups (results in parallel alignment of the pins). After removing the tapered reamer, a third fixation pin or drill pin is inserted at an angle in one of the neighboring hole groups to secure the saw guide in place.



Tibial Resection



07

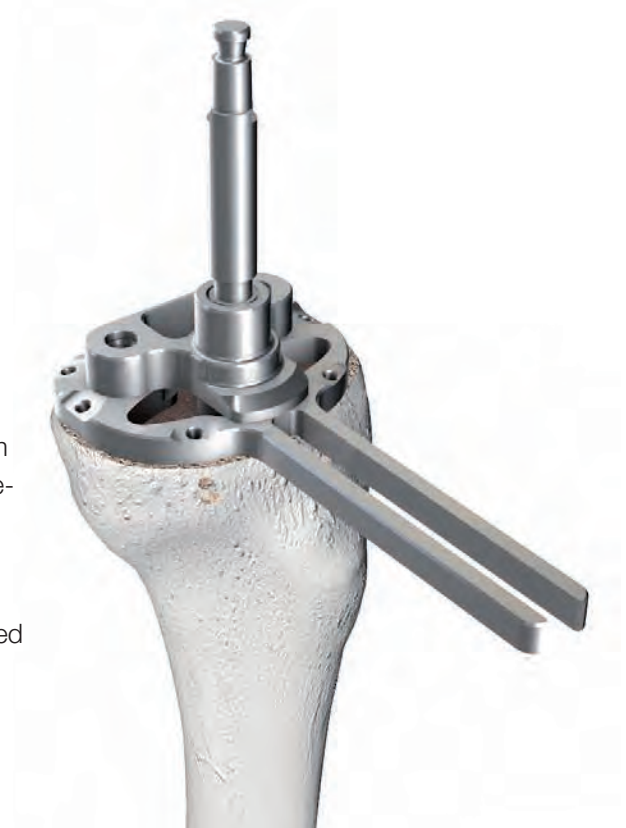
After removing the tapered reamer, the bone can be resected. To achieve an optimal cutting result, saw blades with a width of 1.24 – 1.27 mm are recommended. The fixation pin inserted at an angle is then removed and the saw guide is pulled off toward the front. The two parallel fixation or drill pins can remain in place. These allow the saw guide to be reattached at the +2 or +4 mm level in order to repeat resection later on.

08

The tapered reamer used last is again inserted in the medullary canal with the stop plate attached. The final implant size is determined by applying a drill template (15-6050/01, /02, /03) which corresponds exactly in size with the respective implant. Since the Endo-Model implants are also anchored by the diaphysis, full cortical bone support of the prosthesis is not necessary. The implant must not project over the bone margin.

The alignment guide (15-6051/00) is guided over the stem of the tapered reamer and connected to the cylindrical elevations of the drill template.

For revision surgery, the level of the tibial preparation can be raised to the level of the planned and to be reconstructed joint line. For this, spacers (15-6059/00, /01, /02, /03) of the relevant implant heights can be pushed on the drill template.



Tibial Resection



09

For rotational alignment, the alignment rod (16-3242/00) can be pushed from ventral onto the drill template. The ventral alignment rod must be aligned in the area between the middle of the tibial tuberosity and its medial margin.

10

After rotational alignment, the drill template is fixed with four fixation pins or drill pins. Mark the rotary alignment on the ventral cortical bone of the tibial head.



Tibial Resection



11
Remove the alignment guide, alignment rod and tapered reamer.

12
Attach the drill guide (16-3271/20) to the drill template. The lower collar must sit flush. The collarless area points toward dorsal.

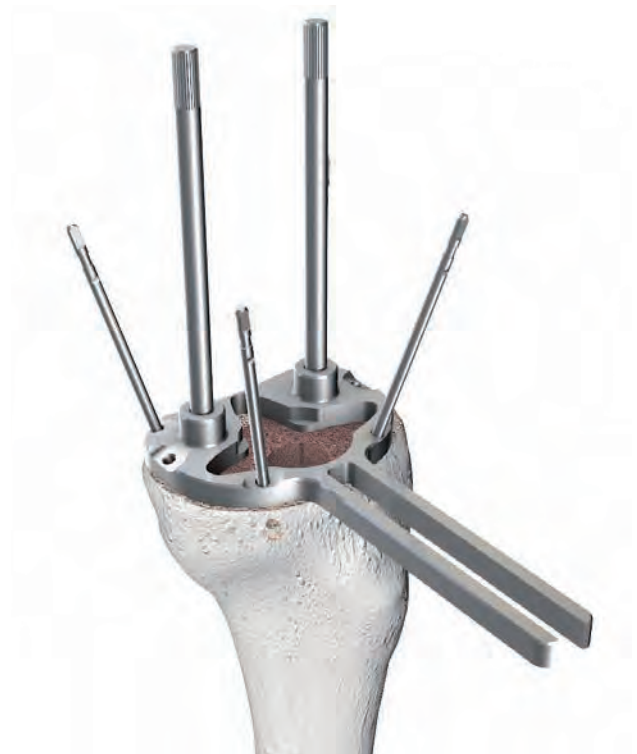


Tibial Resection



13
Insert the drill (16-6052/00) into the proximal tibia as far as it will go.

14
Screw the guide rods (16-3211/00) into the dorsal thread holes of the drill template.



Tibial Resection



15

For Endo-Model – M and Endo-Model Standard tibial components, sizes XS and S

- Screw the compressor stem (15-6056/00, /01) onto the corresponding compressor (15-6054/01).
- Attach the handle (16-3197/00).

For Endo-Model Standard tibial components, sizes M and L

- Attach the compressor addition (15-6055/02) onto the compressor (15-6054/02).
- Screw the stem compressor (15-6056/02) onto the compressor and attach the handle.

16

Insert the compressor via the guide rods as far as possible on the drill template. Finally remove all instruments.



Tibial Resection



17

Assemble the tibial trial.
If necessary, push in trial washers
from medial and/or lateral.

18

Insert the trial prosthesis.



Femoral Preparation



01

Mark the entry point and open the femoral canal with the drill (15-6037/00). The drill can either be used manually with the T-handle (15-6053/00) or driven mechanically.

02

Assemble the tapered reamer with the T-handle (15-6053/00). The femoral stop plate (16-3203/00) is clicked into the designated groove on the tapered reamer stem. When using cementless modular stems: Ream with increasing diameters until the awl has achieved contact with the cortical bone over a continuous distance of approx. 50 mm. The implant must correspond with the tapered reamer last used in terms of diameter and length.

In the case of cemented modular stems, the tapered reamer should be at least 2 mm larger than the planned stem diameter.

Once the tapered reamer is securely positioned by means of contact with the cortical bone, the T-handle and the stop plate are both removed. The tapered reamer remains in the medullary canal.

Important information:

The position of the stop plate represents the level of the joint line. The tapered reamers must not be used with a drive.



Femoral Preparation



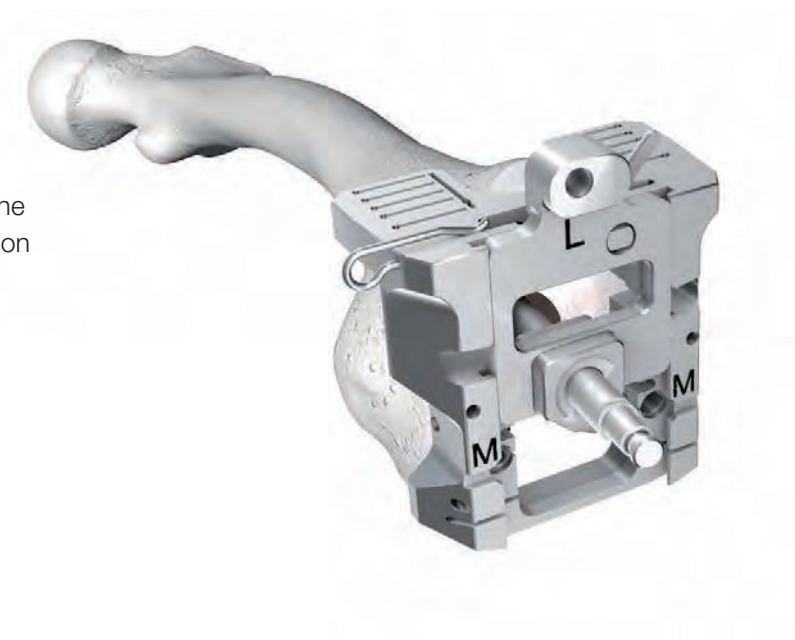
03

Assemble the basic frame (15-6030/01, /02, /03) in line with the size of the tibial preparation:

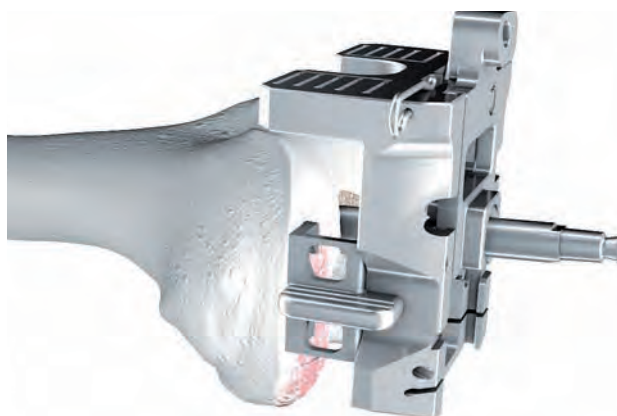
- Insert the interlocking pin (15-6111/00) into the groove on the relevant side **L** (left) or **R** (right).
- Insert the interlocking spring (15-6110/00) into the outer drill hole opposite the interlocking pin.
- The alignment insert (15-6031/00, /01) is then attached to the front of the base frame and secured in place by closing the locking pin.

04

Attach the basic frame onto the stem of the tapered reamer and guide the instrument on the joint surface.



Femoral Preparation

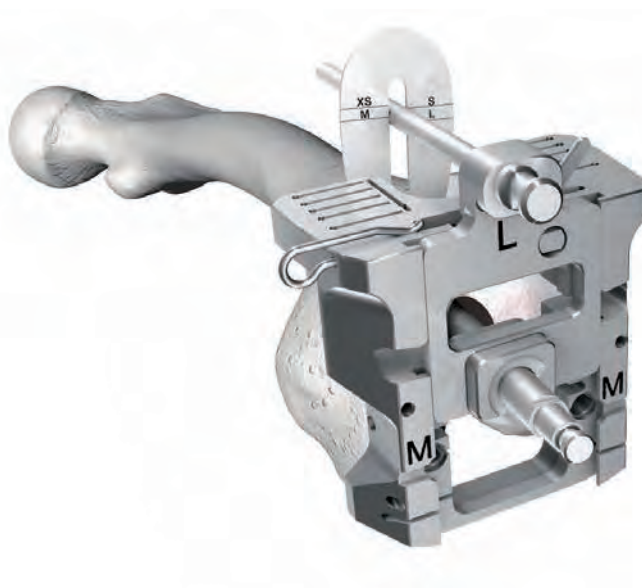


05

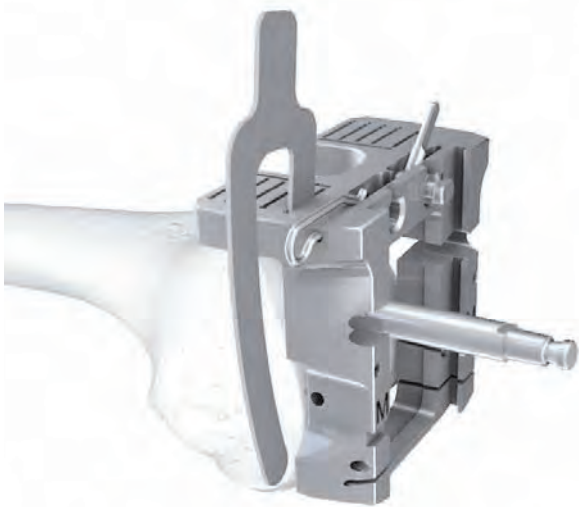
With revision surgery or extreme varus or valgus deformities, different or same-sized spacers (15-6045/00 to/04) can be inserted laterally into the base frame medially, laterally or on both sides for a more stable fixation and distalization of the joint line.

06

Check the emergence point of the angled anterior saw cut. Insert the alignment rod (15-6033/00) as far as possible into the alignment insert. Position the anterior stylus (16-6049/00) in the designated groove in the alignment rod and push up to the ventral bone. If the marking line of the selected prosthesis size is around the middle of the alignment rod, the saw blade will emerge precisely at the contact point of the ventral cortical bone. If the marking is significantly below the lower third or below the alignment rod, the position of the tapered reamer must be corrected to ventral and the emergence point checked again.



Femoral Preparation

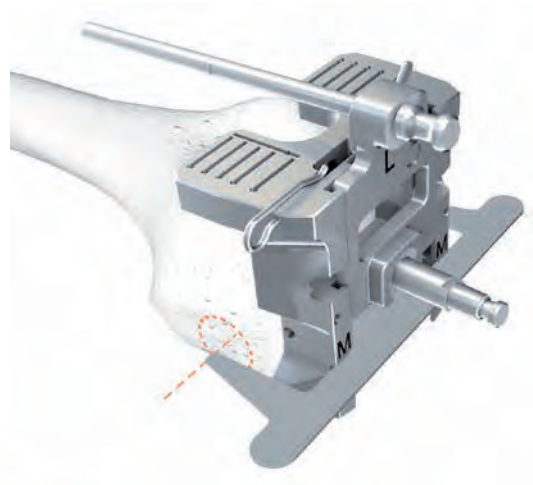


07

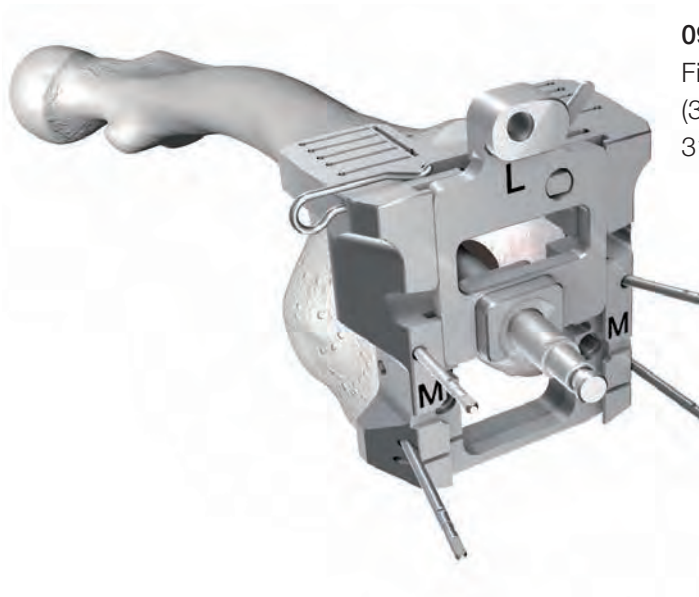
Check the incision for femoral segments (optional) and the anterior and posterior saw cuts using the cutting template (317-607/50).

08

Insert the alignment gauge (15-6040/01) into the slot of both cylindrical drill holes in the base frame as far as possible. Check and determine the rotation/position of the prosthesis axis with respect to the epicondyles. The position of the tips of the alignment gauge represents the distance of the prosthesis axis in relationship to the position of the joint line.



Femoral Preparation

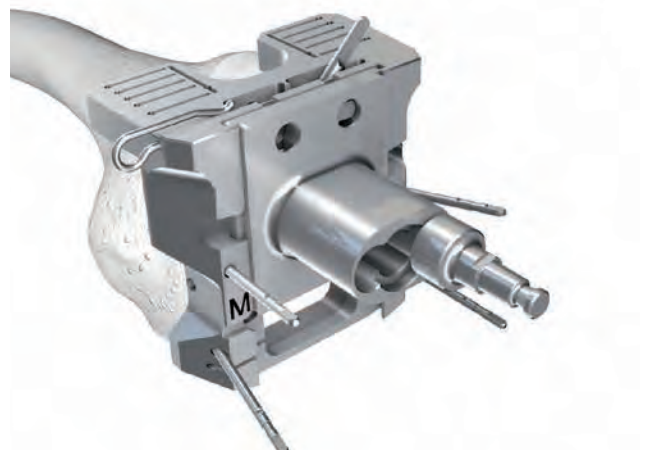
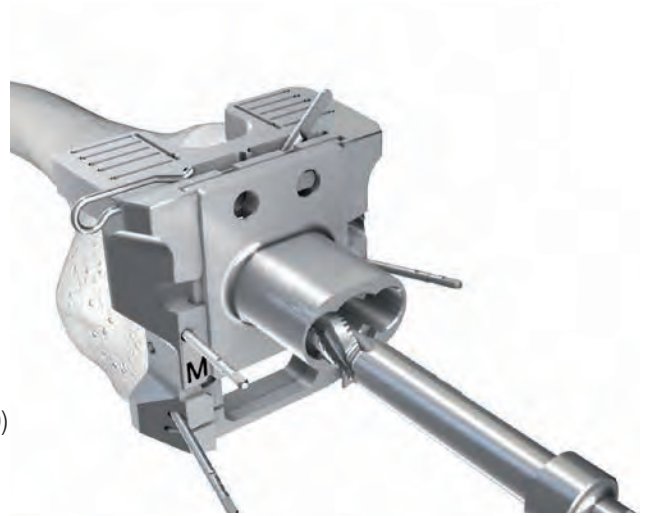


09

Fix the basic frame by inserting four wire pins (317-585/65 or /95) or drill pins (319-581/00 or 319-582/00) in the medial and lateral drill holes.

10

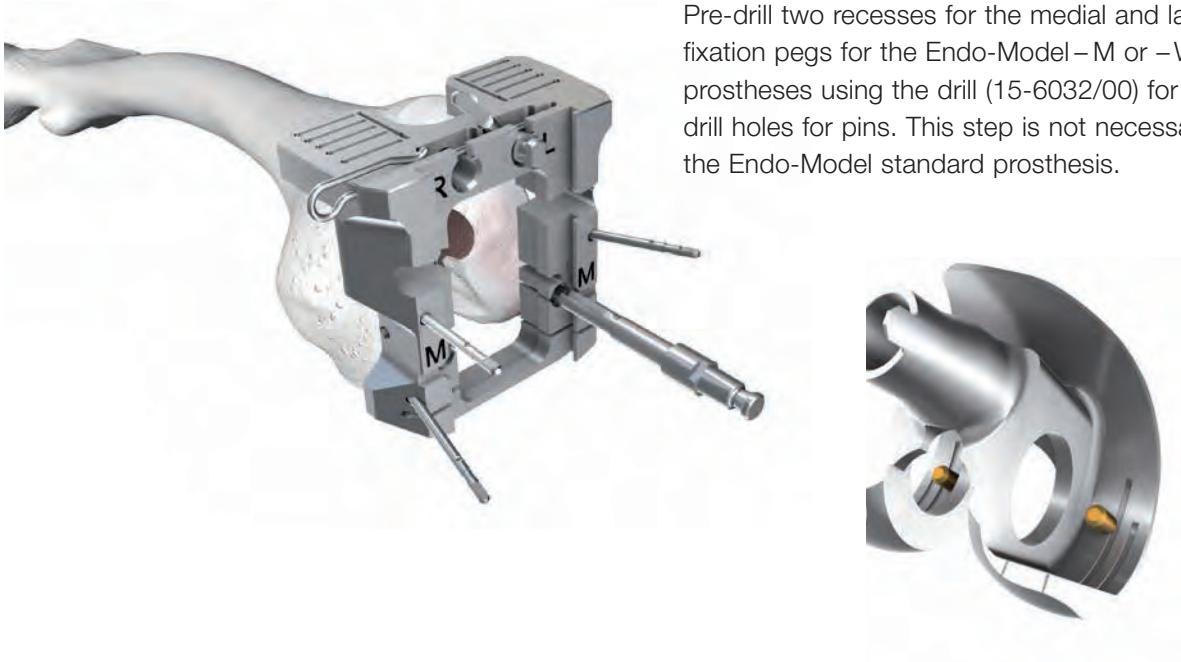
Remove the alignment insert and the tapered reamer. Attach and secure the slide-in module for the ventral bone margin (15-6034/00) in the T-groove of the basic frame from above. Insert the short reamer (15-6042/00) three times as far as it will go.



Femoral Preparation

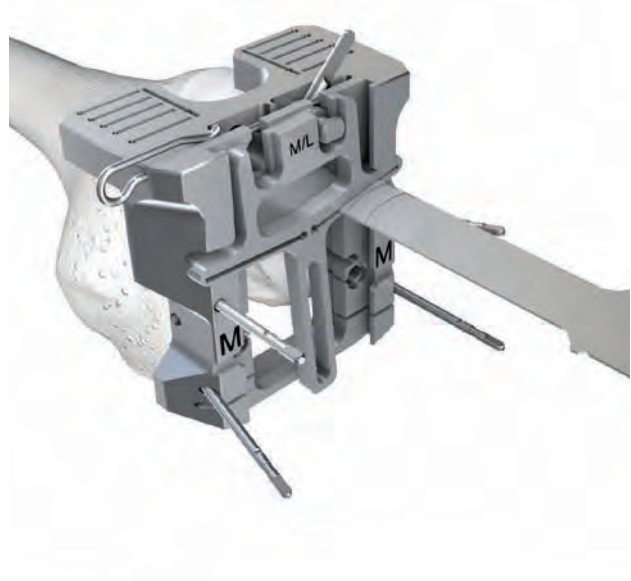
11

Pre-drill two recesses for the medial and lateral fixation pegs for the Endo-Model – M or –W knee prostheses using the drill (15-6032/00) for making drill holes for pins. This step is not necessary for the Endo-Model standard prosthesis.

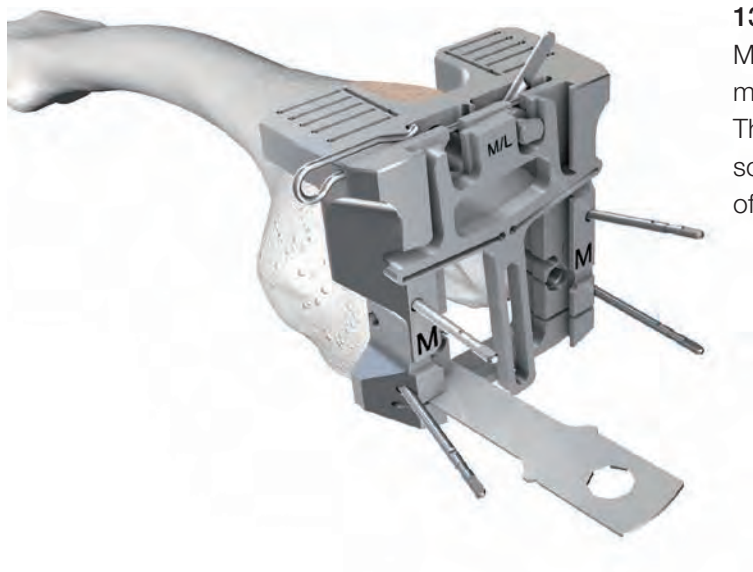


12

Remove the previous insert. Attach and secure the saw guide for the ventral margin (15-6039/00, /01) of the same size in relation to the basic frame. Make the anterior saw cut. To achieve an optimal cutting result, saw blades with a width of 1.24– 1.27 mm are recommended.

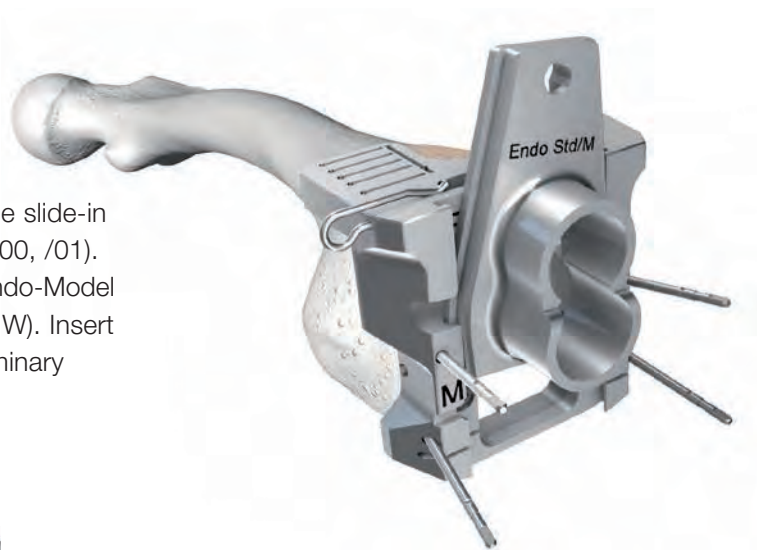


Femoral Preparation

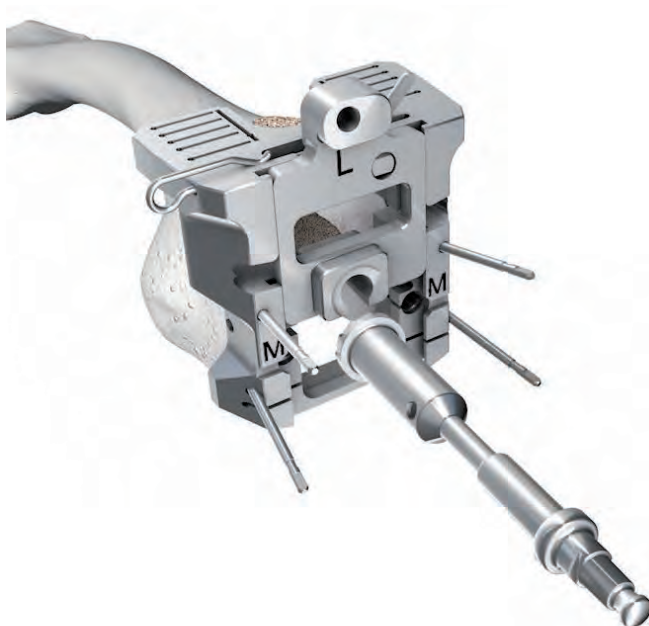


13
 Make the posterior saw cuts through the two medial and lateral saw slots in the basic frame. The saw guide is to remain in the basic frame so as to stop the saw blade from slipping out of the guide and inwards.

14
 Remove the saw guide. Insert and secure the slide-in module for box preliminary milling (15-6035/00, /01). The choice of slide-in unit depends on the Endo-Model prosthesis used (Standard-M or Standard-W). Insert the reamer twice as far as it will go for preliminary milling (15-6036/00).



Femoral Preparation



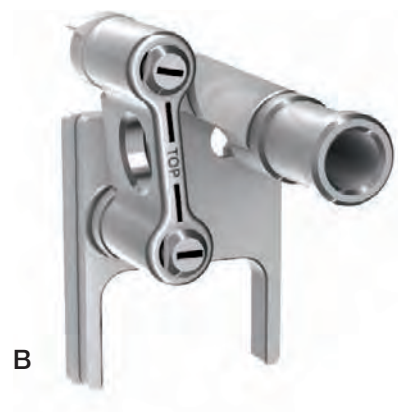
15

Pre-drill the cylindrical part of the tapered coupling when using the Endo-Model–W knee prosthesis. Attach and secure the alignment insert (15-6031/00, /01). Insert the drill (15-6038/00) in the alignment insert with the narrowest part of the drill shank. With the Endo-Model Standard and Endo-Model Standard–M prosthesis this step is not necessary.



16

Assemble the slide-in module for box preliminary milling (15-6041/00) as described in fig. **A** and **B**. The black marking lines must be parallel when assembled.



Femoral Preparation



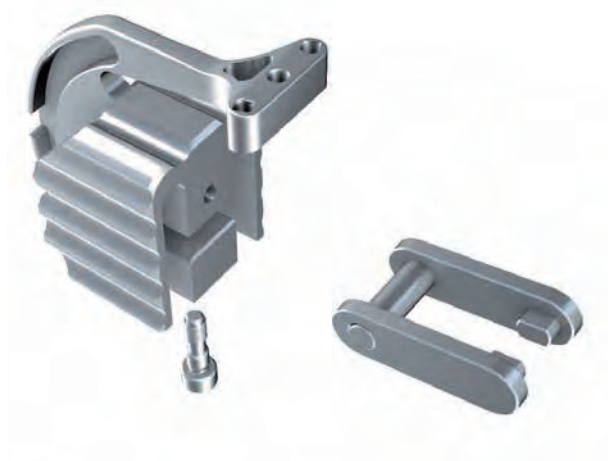
17

For preliminary milling of the box: Attach and secure the slide-in module from above in the T-groove of the basic frame. Starting with the short reamer (15-6042/00) – inserted as far as it will go – the remaining intracondylar bone is milled in a clockwise direction. The individual steps are then repeated with the long reamer (15-6042/01). The bone must be prepared carefully to ensure that the next instrument fits perfectly when inserted.



18

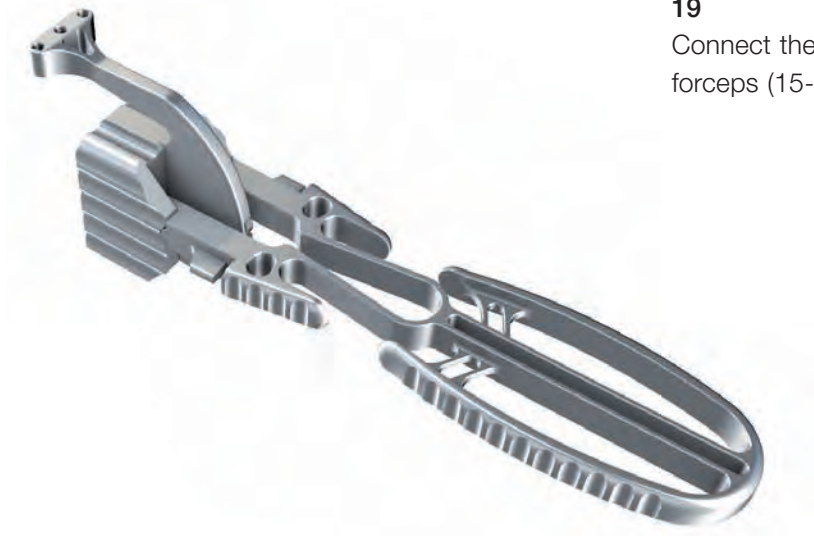
Pre-assemble the base reamer guide to mill the condylar (15-6043/01, /02, /03). Insert the U-shaped lever and tighten the screw using the 3.5 mm hex screwdriver (64-8008/02).



Femoral Preparation

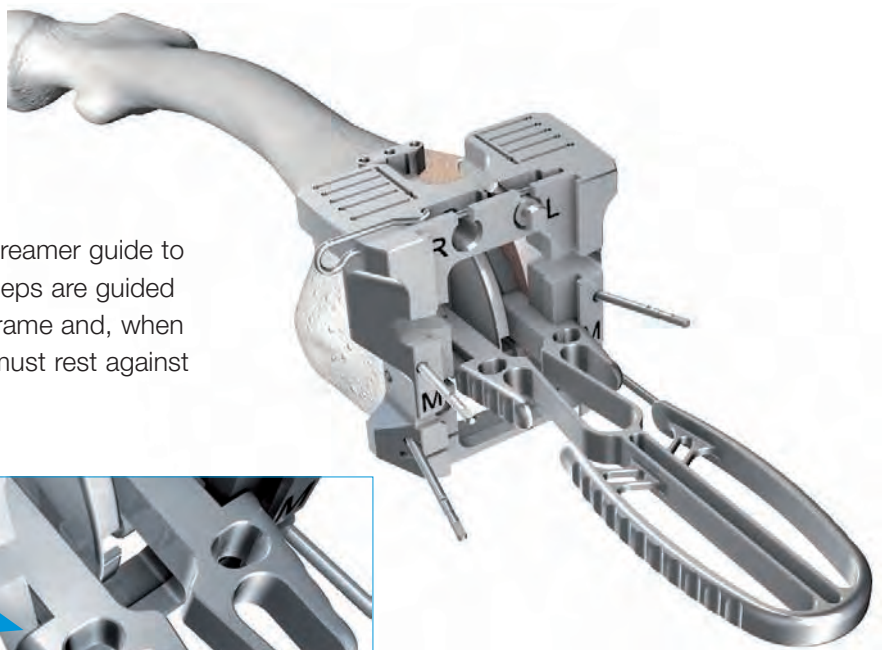
19

Connect the base reamer guide with the inserting forceps (15-6044/01) to mill the condylar.

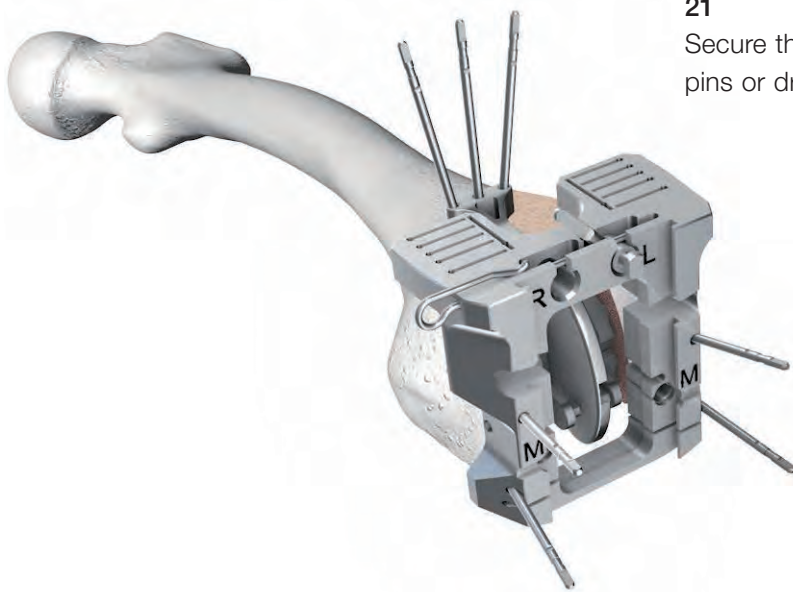


20

Intracondylar insertion of the base reamer guide to mill the condylar. The inserting forceps are guided through the recesses in the base frame and, when finally positioned, their front ends must rest against the frame (see arrow).



Femoral Preparation

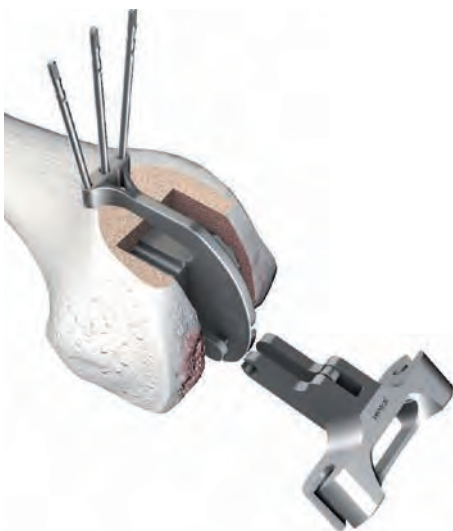
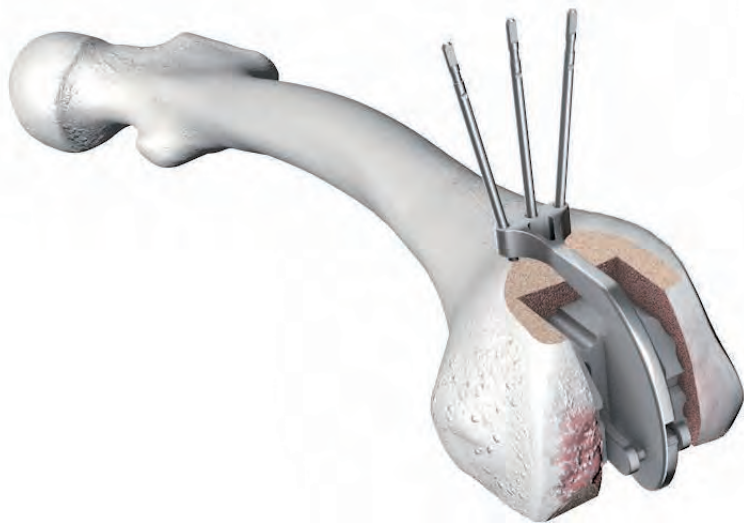


21

Secure the reamer guide in place with three fixation pins or drill pins.

22

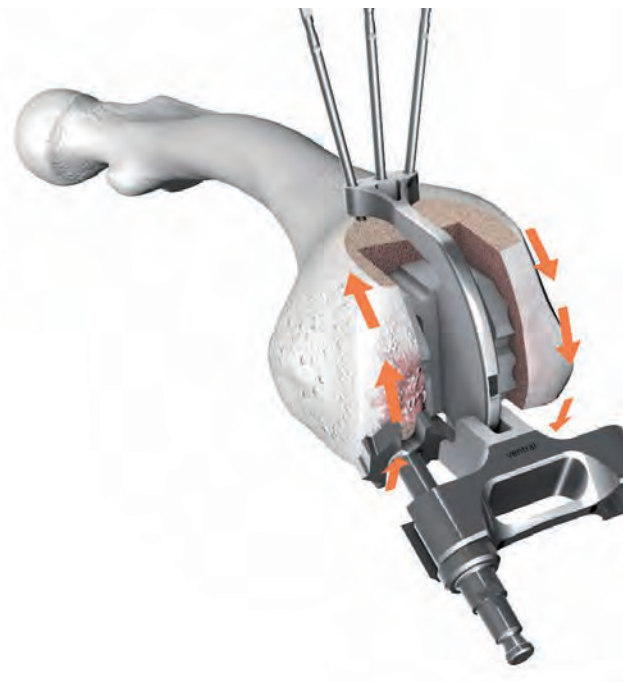
Remove the base frame.



23

Attach the reamer guide (15-6044/00).

Femoral Preparation



24

Insert the reamer for condylar milling (15-6044/02) into the left-hand side of the reamer guide. Once started, the reamer is guided as far as it will go and moved from dorsal to ventral. It may be necessary to repeat this step several times until no more cartilage is removed. The reamer is then reset and the individual steps are repeated on the right-hand side. Here work is from ventral to dorsal.

25

Remove the instruments for condylar milling.



Trial Reduction

26

Assemble and insert the trial femoral component.



27

Insert the trial axis (15-6066/20) in the trial connecting component for the rotational and hinged versions (15-6066/00, /01) and push onto the trial tibial component as far as possible.



Trial Reduction



28

Connect the two joint pieces by inserting the dorsal recess of the trial axis into the axis of the femoral component and then pushing the tibia up. Fix the screw with the hex screwdriver (64-8008/02). Test the prosthesis. Deficits in the flexion and extension gap are compensated for with trial femoral segments and/or trial tibial washers. The components are separated by proceeding in reverse order.

29

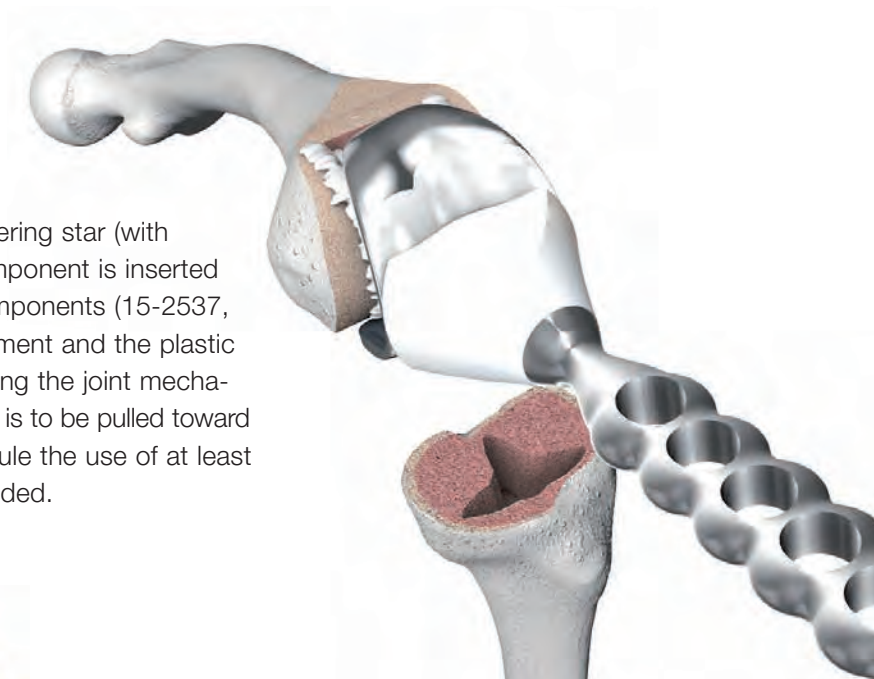
Remove the trial femoral and tibial components with the extraction instrument for trial prostheses (15-6061/00).



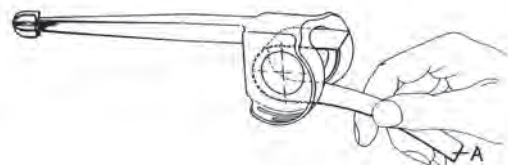
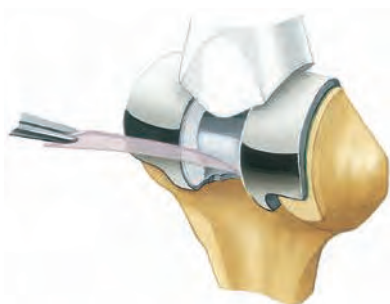
Implantation



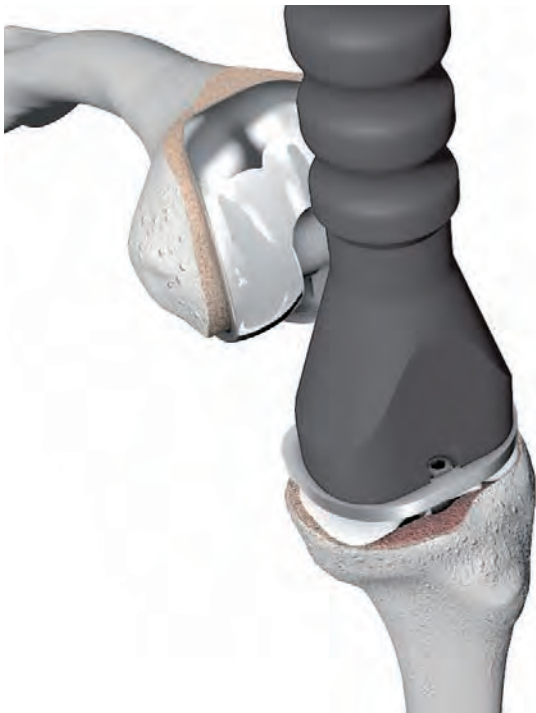
30
 Before inserting the cemented stems, check the depth and suitable diameter of the centering stars (12, 14 or 16 mm) with the stylus for centering stars (15-6060/00, /01, /02).



31
 After assembling the suitable centering star (with cemented stems), the femoral component is inserted using the impactor for femoral components (15-2537, 15-2537/02). Then any excess cement and the plastic connector (prevents cement entering the joint mechanism) are removed. The connector is to be pulled toward dorsal. With full cementation, as a rule the use of at least 80g of bone cement is recommended.



Implantation

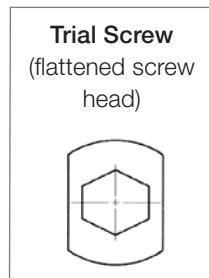


32

After assembling the appropriate centering star (for cemented stems), the tibial component is positioned using the tibial grooved driver (15-6098/00). When aligning the prosthesis, the previously marked rotation setting must be taken into account.

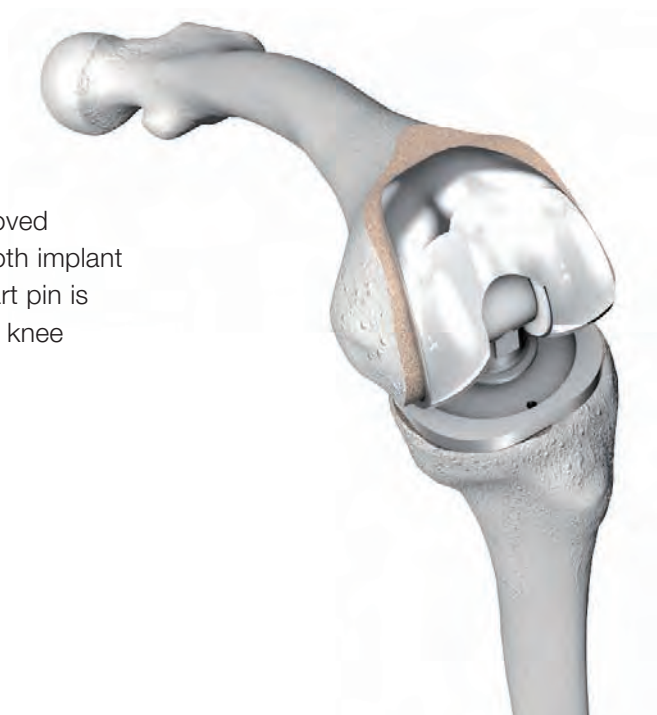
Important:

The tibial component may only be implanted without a polyethylene plateau with a trial screw screwed in as far as possible. To remove the polyethylene plateau, the trial screw is undone with the 3.5 mm hex screwdriver (64-8008/02) and the polyethylene plateau is removed using the inserter positioner (15-8035/02). After that, the trial screw is screwed in as far as it will go. This is the only way to prevent cement entering the drill hole in the metal plateau. Any excess cement is removed afterwards. For complete cementation, as a rule the use of at least 40g of bone cement is recommended.



33

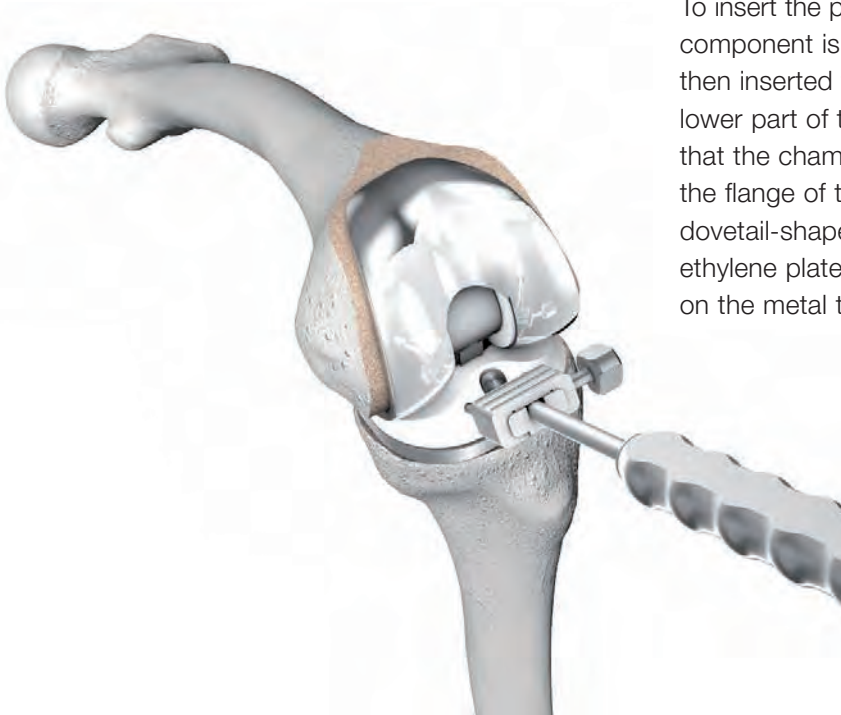
The polyethylene plateau also has to be removed from the tibial metal tray beforehand when both implant components are fitted together. The lower part pin is inserted into the femoral component with the knee flexed.



Implantation

34

To insert the polyethylene tibial plateau, the femoral component is lifted slightly. The tibial plateau is then inserted from ventral between the upper and lower part of the prosthesis. It must be ensured that the chamber of the plastic plateau grips over the flange of the femoral component and that the dovetail-shaped incision on the bottom of the polyethylene plateau fits into the peripheral groove on the metal tibial support.



35

The polyethylene plateau is secured into place on the tibial metal tray using the 3.5 mm hex screwdriver (64-8008/02) and the self-locking fixation screw.

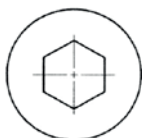
Important:

A self-locking fixation screw may only be used for the final assembly of the plateau. If the fixation screw is undone, the screw lock in the polyethylene plateau is destroyed and a new plateau must be inserted.

The implanted rotational knee prosthesis should enable flexion of up to 90° providing that the soft tissue allows this. When extended, slight elastic extension restriction of around 5° is ideal. This serves to ensure the reliable closure of both prosthesis components.



Self-locking Screw
(round screw head)



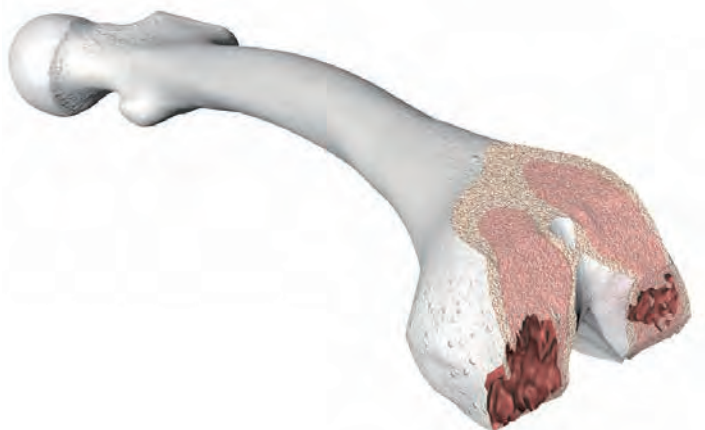
MIRETO Revision Technique

The MIRETO Instrument Set was developed to cover both primary and revision indications.

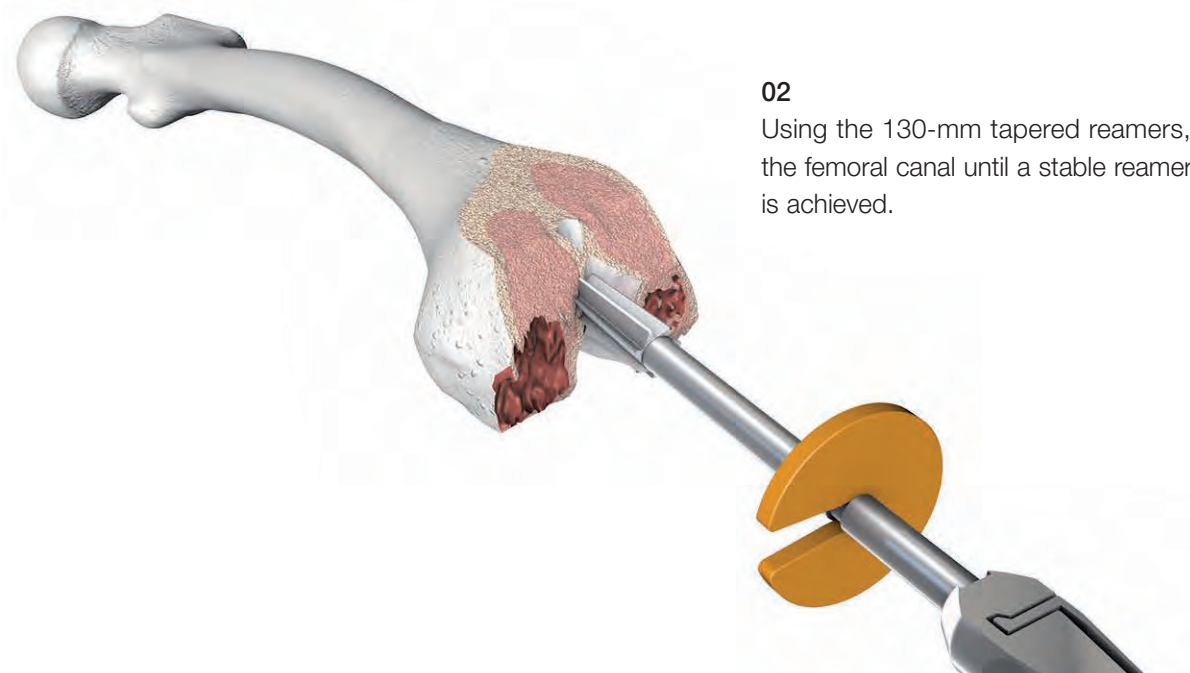
The following chapter of the surgical technique covers the use of the instruments in revision cases and concentrates on steps which are different to the primary procedure described previously. If surgical steps remain identical, we refer to the primary procedure.

Despite good preoperative planning, unforeseeable extensive bone loss in revision cases often presents a challenge for the surgeon. In contrast to the use of normal knee joint prostheses management of extensive bone loss depends on the joint conditions in each individual situation. Structural changes in the muscles and ligaments, fixation conditions etc. increase the operative demands of the prostheses. Accordingly, management of extensive bone loss presents particular problems and is therefore subject to greater risk compared with the use of normal joint prostheses.

Femoral Preparation

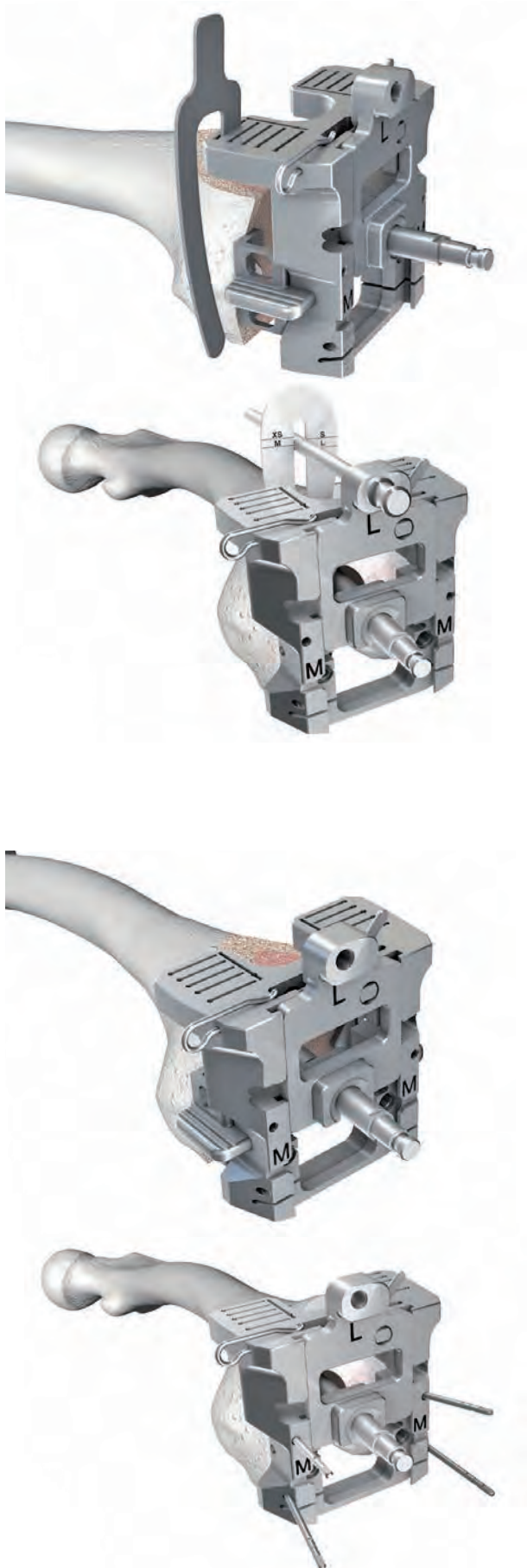


01
Remove in-situ TKR components in the usual manner.



02
Using the 130-mm tapered reamers, ream the femoral canal until a stable reamer position is achieved.

Femoral Preparation

**03**

A) Placement of the basic frame (15-6030/01 to /03) in the proper position is paramount, as all further cuts are based on the basic frame. Place the cutting template (317-607/50) into the proximal slot, labelled 25 mm or use the alignment gauge (15-6040/01). Typically the joint line is 25–30 mm distal to the high point of the medial epicondyle. Consider using spacers (15-6045/00 to /04) to move the basic frame distally, if the cutting template or the alignment gauge is proximal to this landmark.

B) Check the emergence point of the angled anterior saw cut by using the anterior stylus (15-6049/00) and alignment rod (15-6033/00). The line corresponding to the size of the femoral component should be in the region of the rod. Then use the cutting template to check whether the anterior/posterior placement of the basic frame and the medial/lateral placement are correct.

C) If alignment is not acceptable, the reamer should be repositioned in anterior or posterior direction to allow the basic frame to be positioned appropriately.

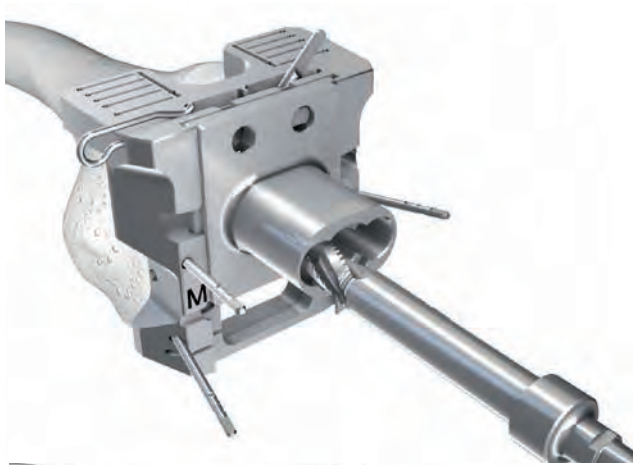
D) Pay special attention to the medial metaphyseal flare. Confirm that the cortex will not be violated by measuring 60 mm from the frontal border of the basic plate (see appendix 1B, page 44).

04

Attach the basic frame (with spacers, if needed). Confirm the position of the basic frame for the joint line in rotation as described in image 09 of the surgical technique for primary indications and fix the basic frame with four pins. Again, proper stable fixation is paramount, as all further cuts and routing steps are based on the basic frame.

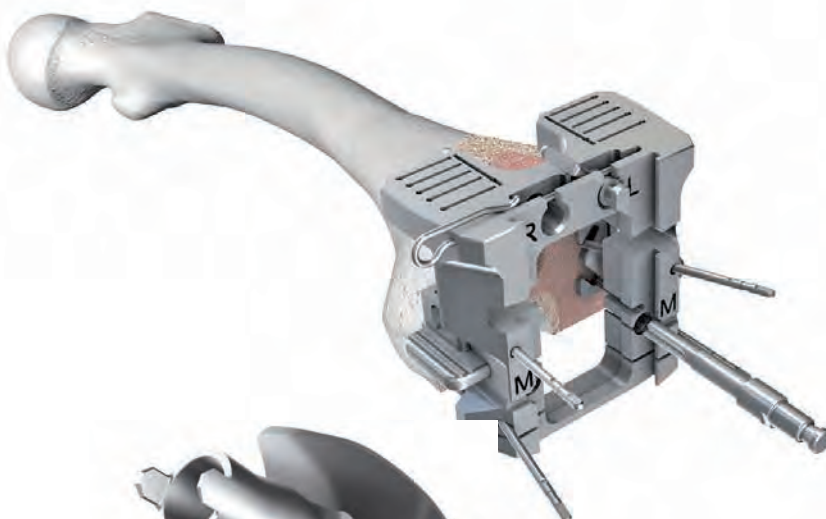
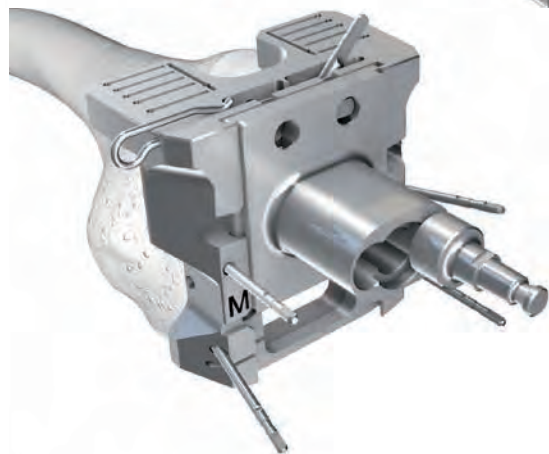
If proper fixation with four pins cannot be achieved, continue with appendix I (as described on page 44).

Femoral Preparation



05

Before carrying out the anterior/horizontal reaming step, remove the alignment insert and the tapered reamer. Attach and secure the slide-in module (15-6034/00) for the ventral bone margin in the T-groove of the basic frame from above. Insert the short reamer (15-6042/00) three times as far as it will go.



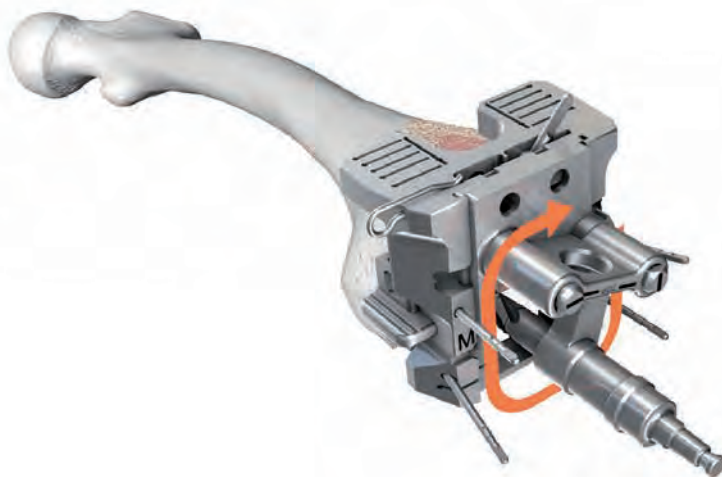
06

Drill femoral peg (when LINK Endo-Model – M modular implants are used).

Femoral Preparation



07
 Ream femoral box; pay attention to appropriate slide-in module for box preliminary milling, **Std/M** or **W** (**W** refers to femoral component with female taper). Put drill on “drill” setting when using reamer (15-6036/00). When reaming the posterior hole, you will engage the solid bone of the roof of the femoral notch. The reamer should be spinning fast before engaging the bone. Then advance the reamer gently until it bottoms out. This helps to reduce excessive torque on the bone.



08
 Finish femoral box with the slide-in module for the profile milling (if possible, set the drill to “drill”). Ream with short reamer first (15-6042/00), then with long reamer (15-6042/01). The joint of the box profile milling is guided with the thumb in a clockwise direction.

Femoral Preparation

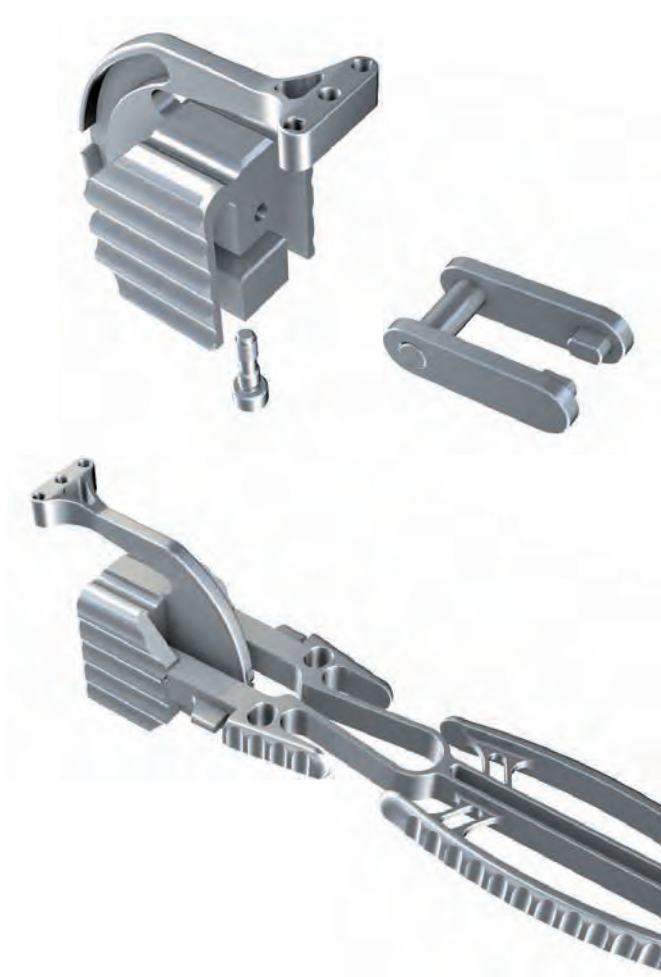
09

Condylar milling:

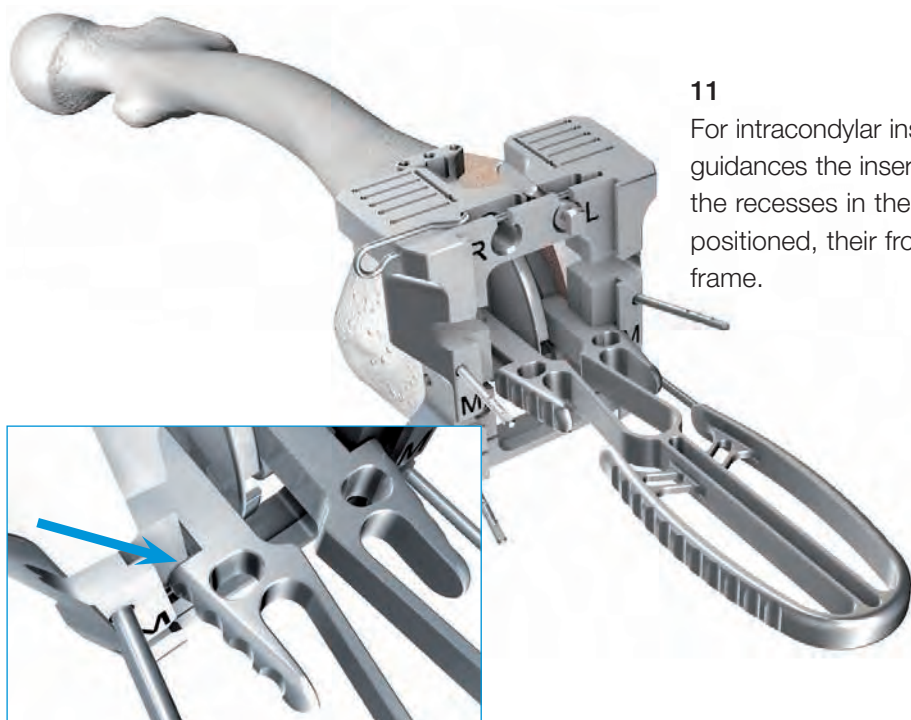
In order to place the basic milling guidance (15-6043/01, 02, 03) correctly for milling the condylar, three long pins are used to fix the reamer guide in a stable position (see illustration 12). Do condylar reaming step.

Note: This step may not be necessary if condyles are already prepared.

Pre-assemble the basic milling guidances (15-6043 /01, /02, /03) to mill the condylar. Insert the U-shaped lever and tighten the screw using the 3.5 mm hex screwdriver (64-8008/02).



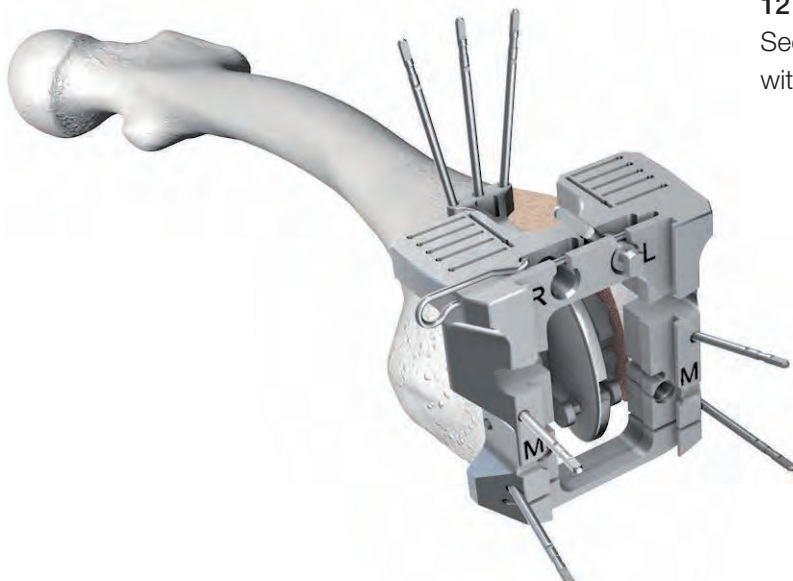
10 Connect the basic milling guidance with the inserting forceps (15-6044/01) to mill the condylar.



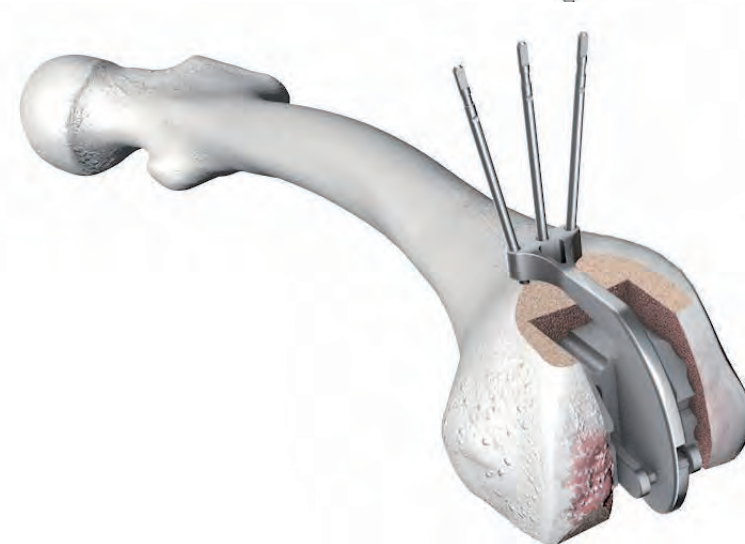
11

For intracondylar insertion of the basic milling guidances the inserting forceps are guided through the recesses in the basic frame and, when finally positioned, their front ends must border on the frame.

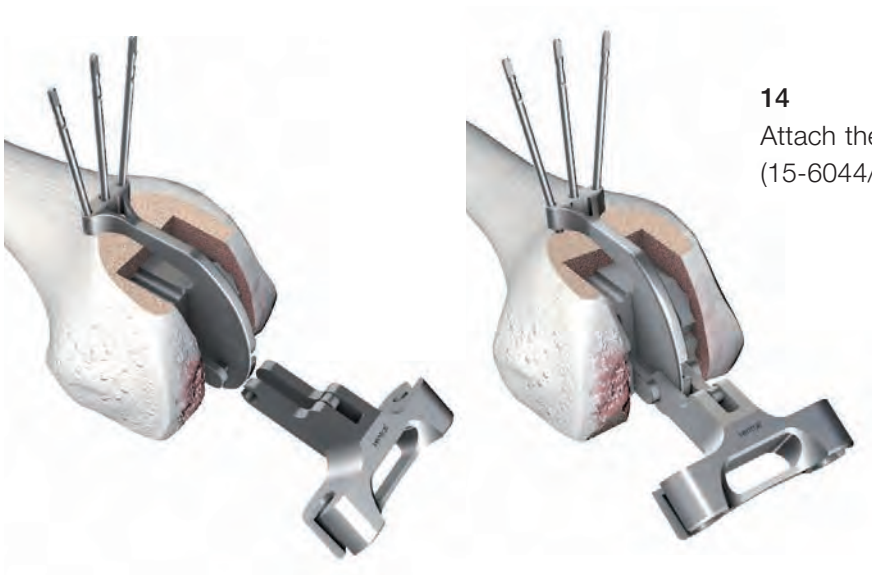
Femoral Preparation



12
Secure the basic milling guidance in place with three fixation pins or drill pins.

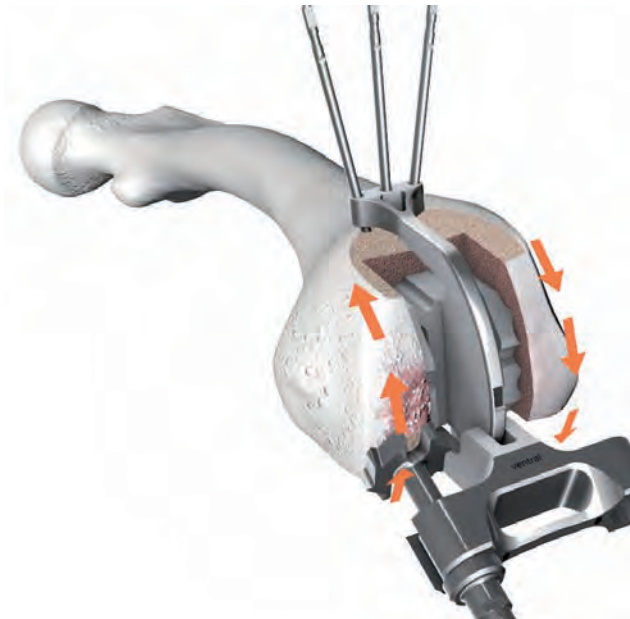


13
Remove the basic frame.



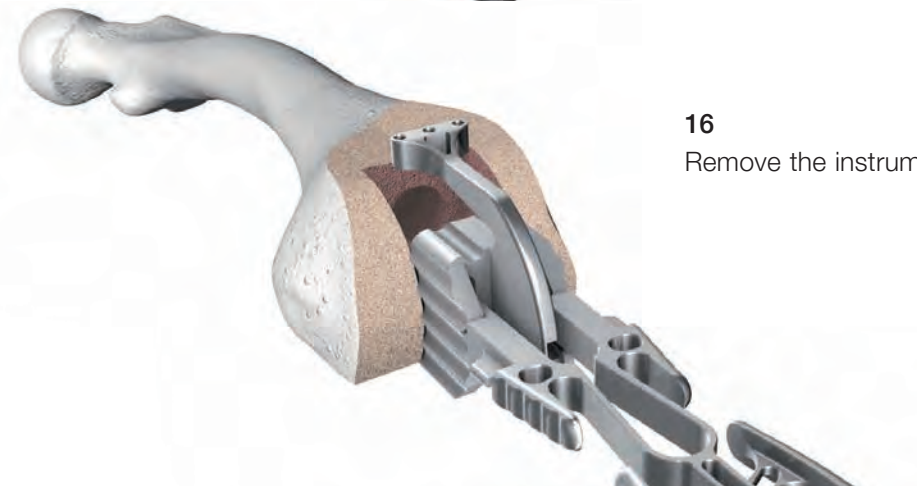
14
Attach the condyle milling guidance (15-6044/00).

Femoral Preparation



15

Fix the reamer (15-6044/02) for condylar milling into the left-hand side of the reamer guide. Once started, the reamer is guided as far as it will go and moved from dorsal to ventral. It may be necessary to repeat this step several times until no more cartilage can be removed. The reamer is then reset and the individual steps are repeated on the right-hand side. Here work is carried out from ventral to dorsal.



16

Remove the instruments for condylar milling.



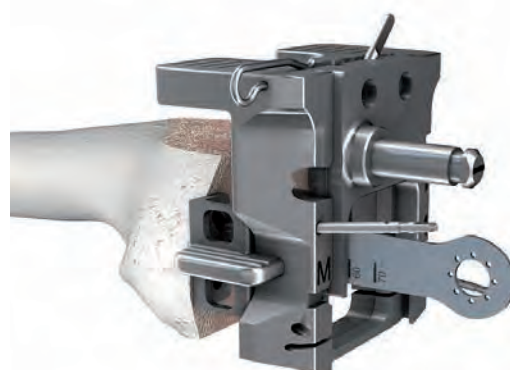
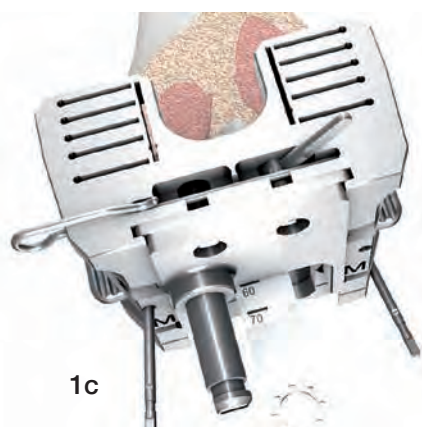
17

Insert femoral trial with appropriate stem, and distal femoral trial segments, if needed.

Femoral Preparation

Appendix I:

If it is not possible to securely fix the basic frame with 4 fixation pins (due to the defect situation or poor bone quality), fix the instrument in the correct position with at least two pins. Slide in the slide-in module (1a) of the box preliminary milling (15-6041/00). Use an oscillating or reciprocating saw to cut along the base plate borders for preparation of the femoral box (1c). The cutting depth for all implant sizes is 60 mm from the frontal border of the base plate (1b). Skip step 05 of the femoral preparation for revision cases. Consider contouring the remaining primary chamfer cuts to achieve a good fit of the femoral trial implant. Instruments for condylar milling (15-6043/01-03, 15-6044/02) must not be used after preparing the intra-condylar box with a sawblade.



Tibial Preparation



01

Using the tapered, 130 mm reamers, ream tibial IM canal until stability is achieved. Use tibial reamer stop plate.

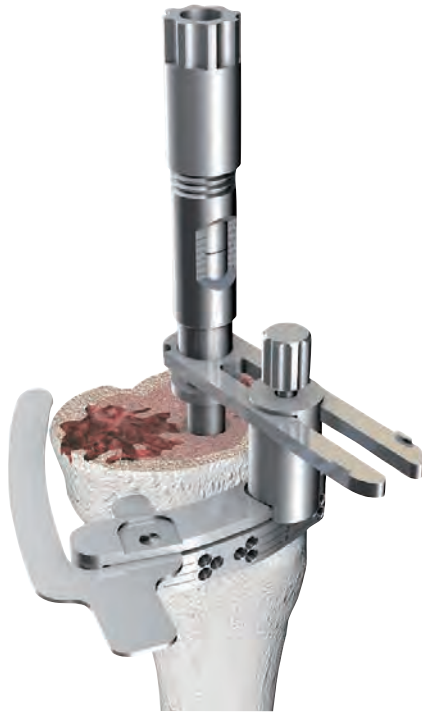


02

Alignment and placement of tibial resection IM alignment instrument and saw guide.



Tibial Preparation



03

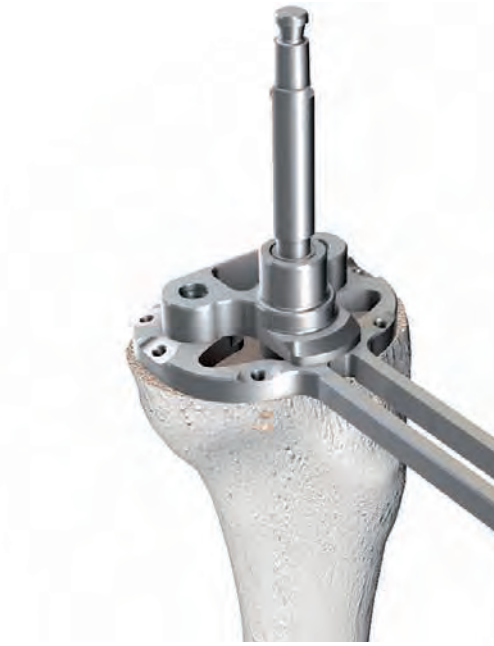
Verify the height of the proximal tibial resection. A minimal resection height is needed. Assess need for tibial spacers in order to restore the correct position of the joint line.



04

Remove IM reamer and perform tibial resection.

Tibial Preparation



05

Re-insert IM reamer. Place tibial base plate on proximal tibia, using the centralizing alignment gauge. Supplement tibial base plate with appropriate spacers when needed (5, 10, 15 mm available).



Tibial Preparation



06

Affix tibial base plate with 4 pins. Remove the alignment gauge with the reamer and place the drill guide in the base plate.



07

Now ream the proximal tibia.



08

Assemble appropriate tibial rasp (tibial compressor), noticing the style of implant to be used.

Tibial Preparation



09

Assemble guide rods onto tibial base plate; prepare the prosthesis profile with the appropriate tibial rasp, by impacting it with the mallet.



10

Insert tibial trial



11

With both femoral and tibial trials inserted, reduce joint and check ROM and stability.

Tibial Preparation

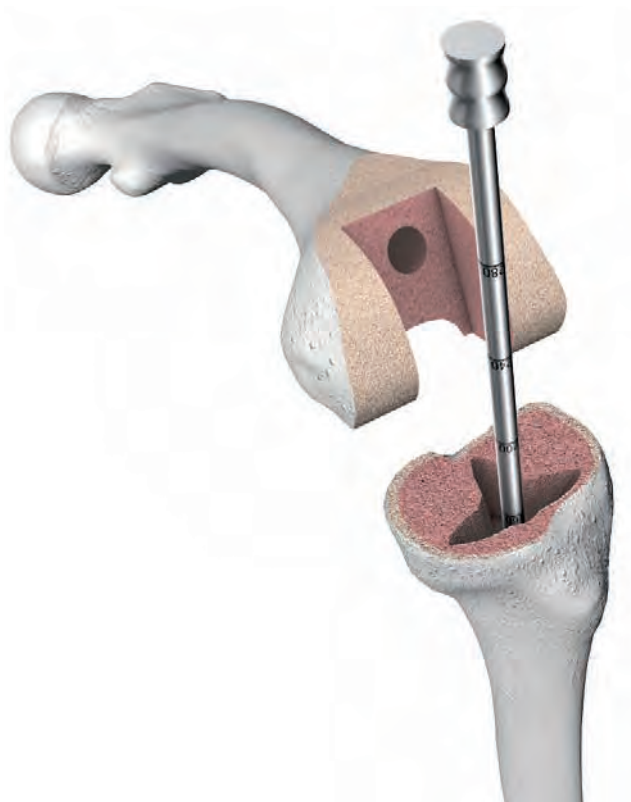


12

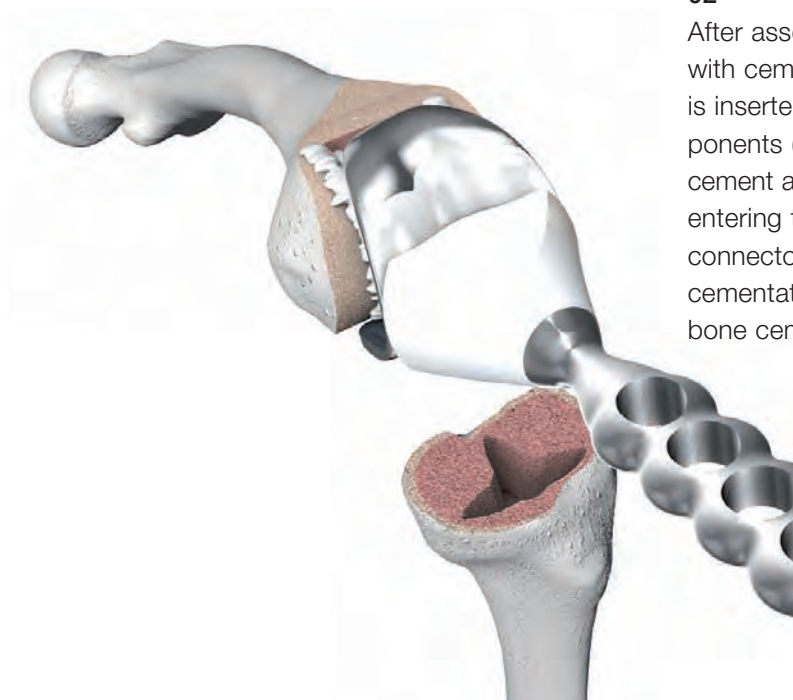
Perform the trial reduction. Place the knee in full extension, and apply longitudinal traction to the limb to check the joint stability. No pistoning of the trial axis should be accepted. If laxity exists, consider the use of femoral segments or tibial spacers to assess the level of the joint line relative to the patella. Tibial spacers will effectively raise the joint line and femoral segments will effectively lower the joint line. Once the trial reduction is satisfactory, final implant components are prepared and cemented following the usual cementing technique.



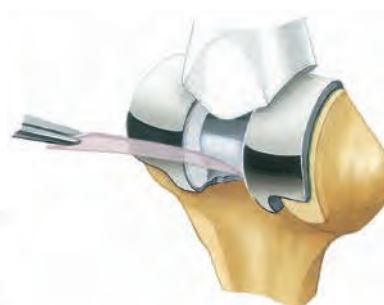
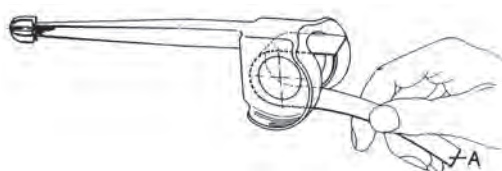
Implantation



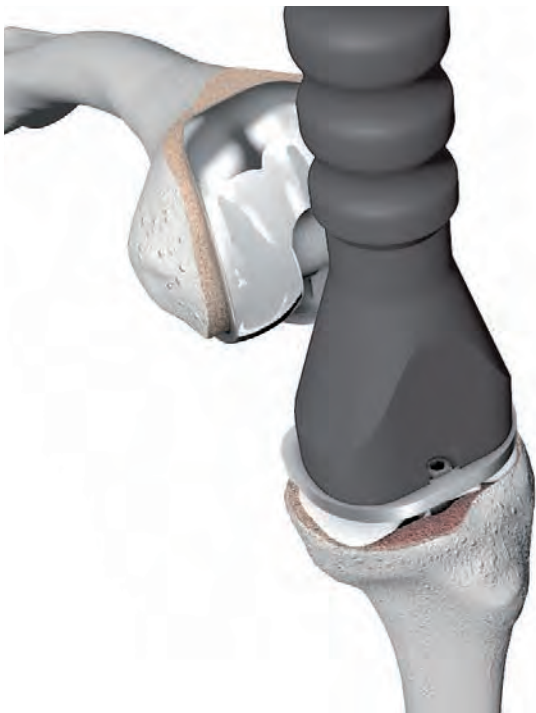
01
 Before inserting the cemented stems, check the suitable diameter of the centering stars (12, 14 or 16 mm) with the stylus for centering stars (15-6060/00, /01, /02).



02
 After assembling the suitable centering star with cemented stems, the femoral component is inserted using the impactor for femoral components (15-2537, 15-2537/02). Then any excess cement and the plastic connector (prevents cement entering the joint mechanism) are removed. The connector is to be pulled toward dorsal. With full cementation, as a rule the use of at least 80g of bone cement is recommended.



Implantation

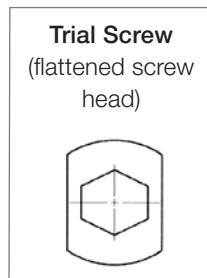


03

After assembling the appropriate centering star for cemented stems, the tibial component is positioned using the tibial grooved driver (15-6098/00). When aligning the prosthesis, the previously marked rotation setting must be taken into account.

Important:

The tibial component may only be implanted without a polyethylene plateau with a trial screw screwed in as far as possible. To remove the polyethylene plateau, the trial screw is undone with the 3.5 mm hex screwdriver (64-8008/02 and the polyethylene plateau is removed using the inserter positioner (15-8035/02). After that, the trial screw is screwed in as far as it will go. This is the only way to prevent cement entering the drill hole in the metal plateau. Any excess cement is removed afterwards. For complete cementation, as a rule the use of at least 40 g of bone cement is recommended.

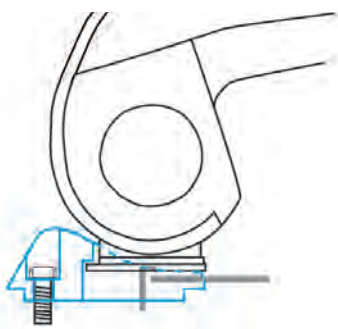


04

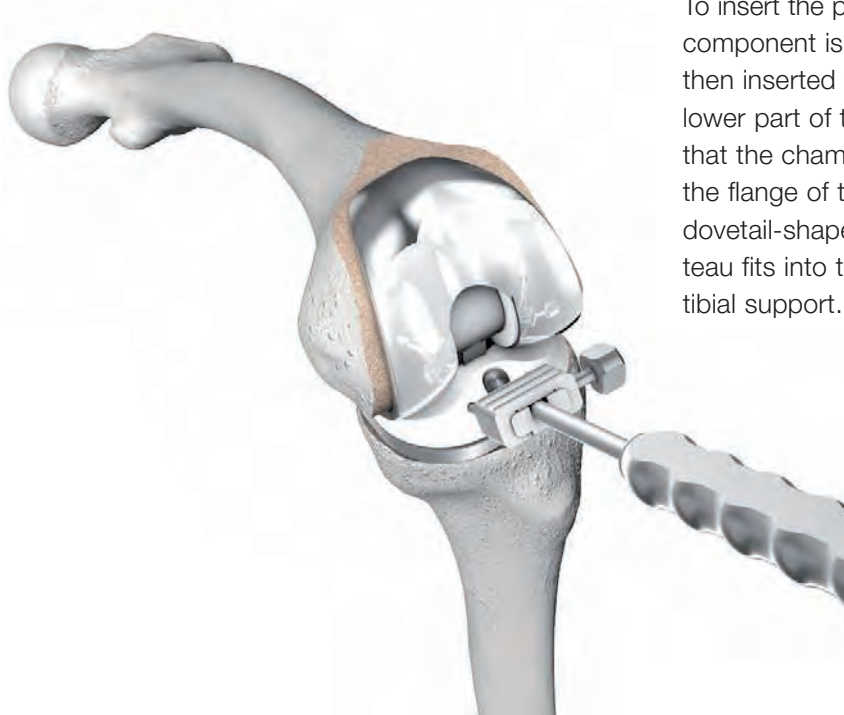
The polyethylene plateau also has to be removed from the tibial metal tray beforehand when both implant components are fitted together. The pin is inserted into the femoral component with the knee flexed.

05

When placing the anti-luxation device, it is important that the femur bone is not lifted up. The anti-luxation device must slide over the flange on the hinge of the femur.



Implantation



06

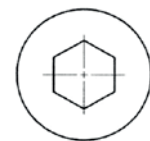
To insert the polyethylene tibial plateau, the femoral component is lifted slightly. The tibial plateau is then inserted from ventral between the upper and lower part of the prosthesis. It must be ensured that the chamber of the plastic plateau grips over the flange of the femoral component and that the dovetail-shaped incision on the bottom of the plateau fits into the peripheral groove on the metal tibial support.



07

The polyethylene plateau is secured into place on the tibial metal tray using the 3.5 mm hex screwdriver (64-8008/02) and the self-locking fixation screw.

Self-locking Screw
(round screw head)



Important:

A self-locking fixation screw may only be used for the final assembly of the plateau. If the fixation screw is undone, the screw lock in the polyethylene plateau is destroyed and a new plateau must be inserted.

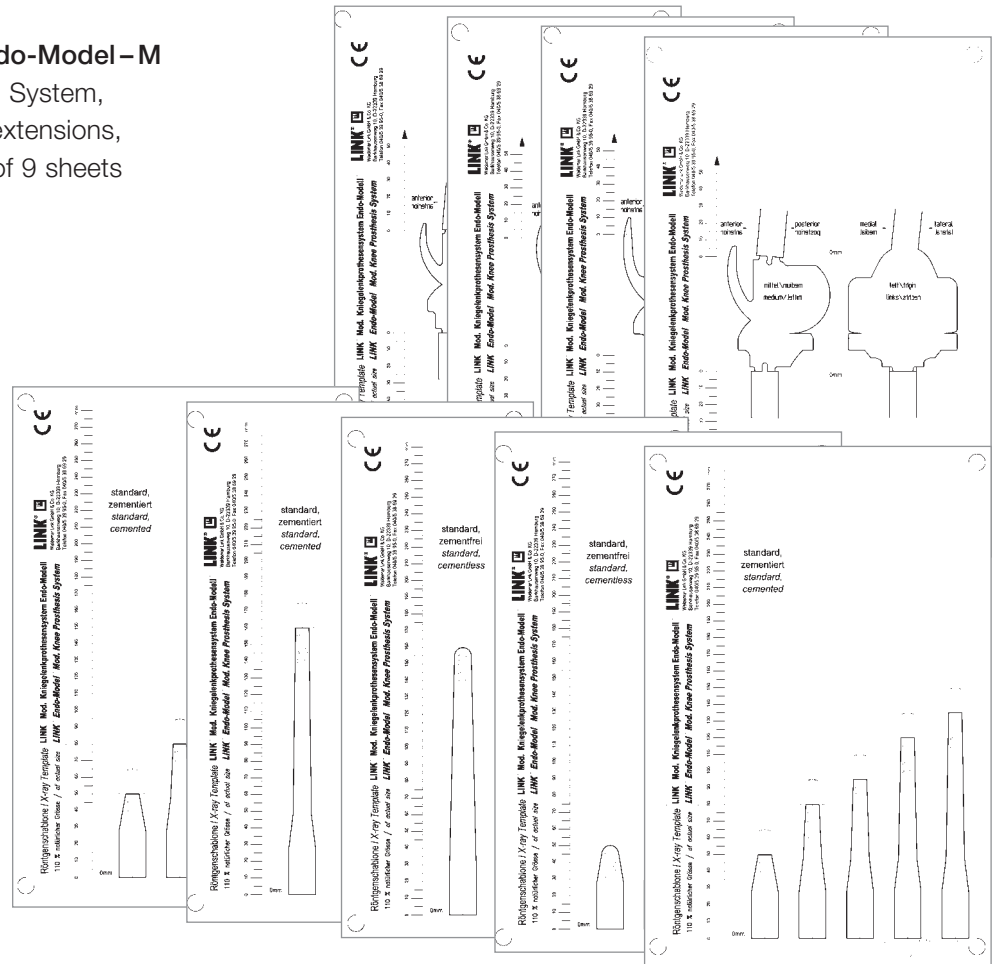
The implanted rotational knee prosthesis should enable flexion of up to 90° providing that the soft tissue allows this. When extended, slight elastic extension restriction of around 5° is ideal. This serves to ensure the reliable closure of both prosthesis components.

X-ray Templates

15-2599/05

X-ray Templates for Endo-Model – M

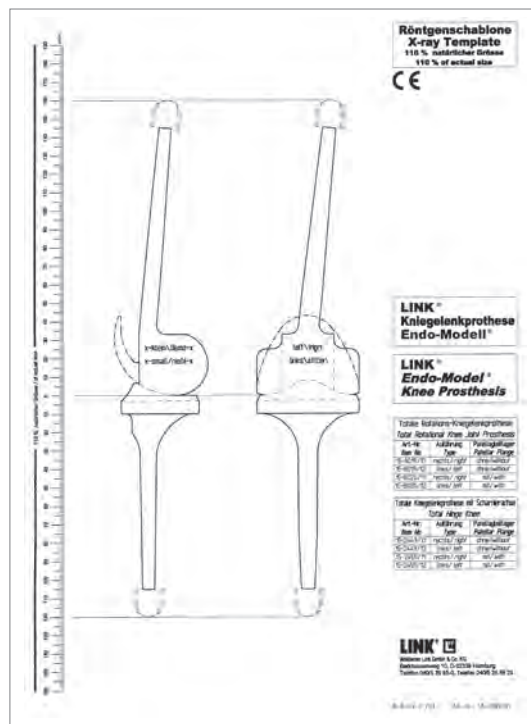
Modular Knee Prosthesis System, including modular stem extensions, 110% actual size, 1 set of 9 sheets

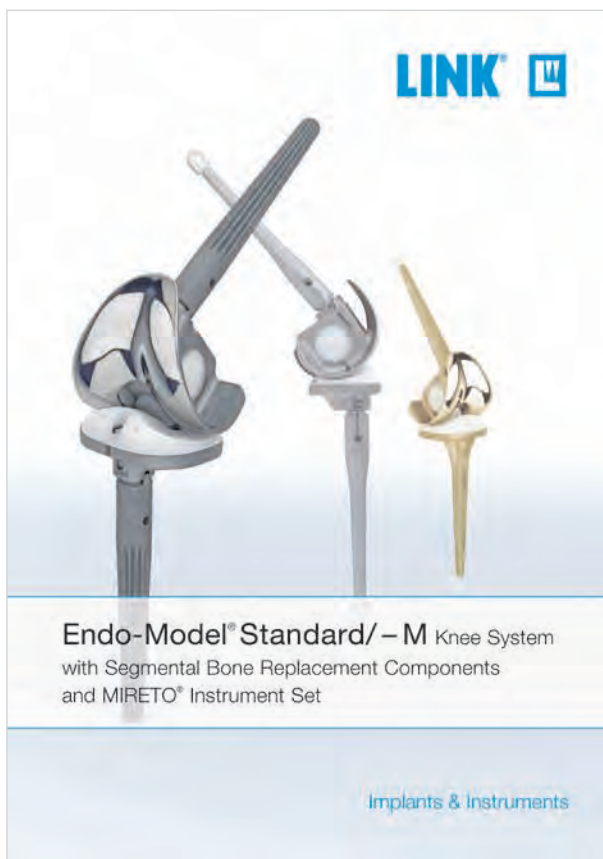


15-2599/01

X-ray Templates for Endo-Model Total Knee Prosthesis (rotational and hinge version)

110% actual size, 1 set of: x-small, small, medium, large





**Endo-Model Standard/ – M,
Knee Prosthesis System** with Segmental Bone
Replacement Components and MIRETO Instruments,
Implants & Instruments

LINK PorEx Technology
(TiNbN = Titanium Niobium Nitride)
for metal sensitive patients,
Materials & Surface Modification



For more information please register for our LINK Media Library (linkorthopaedics.com)

Please note the following regarding the use of our implants:

1. Choosing the right implant is very important.

The size and shape of the human bone determines the size and shape of the implant and also limits the load capacity. Implants are not designed to withstand unlimited physical stress. Demands should not exceed normal functional loads.

2. Correct handling of the implant is very important.

Under no circumstances should the shape of a finished implant be altered, as this shortens its life span. Our implants must not be combined with implants from other manufacturers. The instruments indicated in the Surgical Technique must be used to ensure safe implantation of the components.

3. Implants must not be reused.

Implants are supplied sterile and are intended for single use only. Used implants must not be used again.

4. After-treatment is also very important.

The patient must be informed of the limitations of the implant. The load capacity of an implant cannot compare with that of healthy bone!

5. Unless otherwise indicated, implants are supplied in sterile packaging.

Note the following conditions for storage of packaged implants:

- Avoid extreme or sudden changes in temperature.
- Sterile implants in their original, intact protective packaging may be stored in permanent buildings up until the "Use by" date indicated on the packaging.
- They must not be exposed to frost, dampness or direct sunlight, or mechanical damage.
- Implants may be stored in their original packaging for up to 5 years after the date of manufacture. The "Use by" date is indicated on the product label.
- Do not use an implant if the packaging is damaged.

6. Traceability is important.

Please use the documentation stickers provided to ensure traceability.

7. Further information on the material composition is available on request from the manufacturer.

Follow the instructions for use!

Waldemar Link GmbH & Co. KG, Hamburg

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