permedica

BUTTERFLY

Rotating Hinged Knee

SURGICAL TECHNIQUE

CE 0426

permedica
ORTHOPAEDICS

INDEX OF THE MAIN CHAPTERS

ATTENTION:

This Surgical Technique is to be intended as an example, or an aid for orthopaedic Surgeons already experienced in Knee Arthroplasty, with the objective of demonstrating the correct use of permedica's *GKS BUTTERFLY Instrumentation.*

The Surgeon should in any case rely on his own knowledge and expertise in performing each single step of the intervention.

Both our Sales Representatives and Product Specialists are at Your complete disposal for any further information and/or explanation regarding the contents of this Surgical Technique.

INTRODUCTION

A Total Knee Arthroplasty aims to relieve pain and restore the original mobility and stability of the natural knee joint, in both the shortterm and the longterm.

permedica's *Global Knee System* is a complete system conceived for the different pathological conditions that Total Knee Replacement procedures necessitate. The design of the GKS prostheses guarantees optimal mobility by restoring the muscle-ligamentous funcionnality and ensures correct limb alignment and even load distribution with better fixation and a reduction in material wear, thanks to the special MICROLOY® finishing technology used to achieve the metal articulating surfaces.

GKS Butterfly is a tri-compartimental rotating hinged knee prosthesis stabilized on all planes.

It is available in two versions:

Primary indicated for primary replacements in severe varus/valgus corrections (> 20°) and is without trochlear shield;

Revision presents a trochlear shield to restore the femoro-patellar gliding surface in revision procedures.

Important positive features are represented by the presence of two rotation axis, a deep trochlear groove, asymmetrical shape of the femoral condyles and tibial articular surface allowing the kinematic, dynamic and tribological functions of a natural knee to be best reproduced.

The availability of modular stems (cemented and cementless) and tibial augmentation plates allows the surgeon to choose the most appropriate implant for each single case.

Both the models are also available in MICROLOY®, Antiluxation and BIOLOY® coated version.

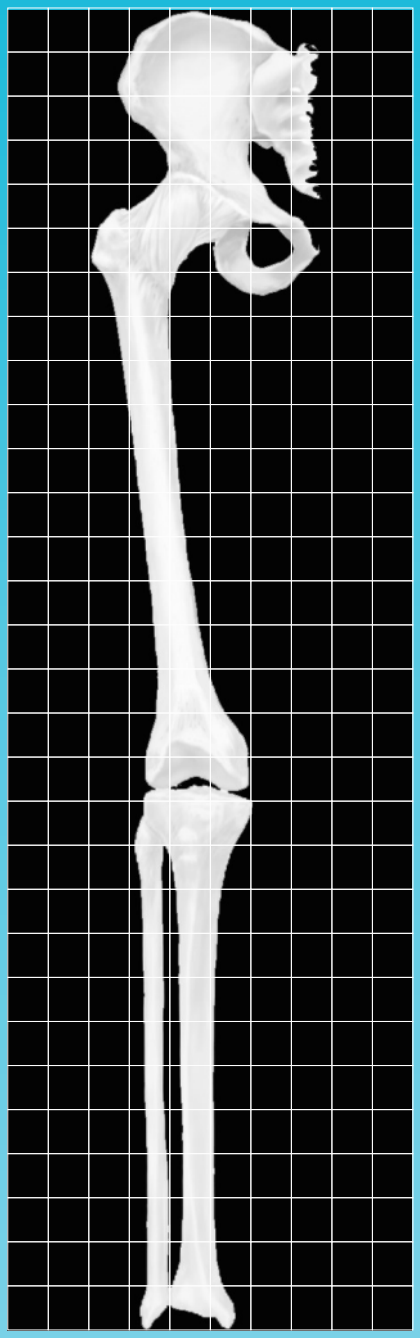
The GKS Butterfly MICROLOY® version is characterized by the special joint between the femoral bush and the tibial pivot providing a metal-on-metal coupling. The femoral component of this prosthesis has a special MICROLOY®metal bush instead of the standard made of polyethylene. Such a coupling avoid the problems due to the wear of the polyethylene bush, thus improving the prosthesis duration

The GKS Butterfly MICROLOY® ANTILUXATION is also provided with MICROLOY® metal-on-metal coupling between the femoral bush and tibial pivot. In this version the femoral bush and the tibial polyethylene insert has been modified in order to avoid luxation of the components once locked.

The main feature of the GKS Butterfly BIOLOY® version is that all the components (except those made of Titanium) are coated by a layer of Titanium Niobium Nitride (TiNbN). Such a coating ensures an improved hardness of the articular surfaces and reduces the ions release by the underlying metal material. They are therefore particularly indicated for patients requiring low metal ions release.

GKS Butterfly

PRE-OPERATIVE PLANNING



Before executing a TKA, a careful evaluation of the clinical case based on a combined clinical and radiological study is recommended, by means of Anterior-Posterior and Medial-Lateral radiographs of the whole lower limb in load conditions in order to determine any extra-articular deviations concerning the femur and/or the tibia and to reveal the presence of dislocations either in the frontal or in the sagittal plane.

Template overlays could help in identifying the optimal evel for both distal femur and proximal tibia resections, as well as the correct centering of femoral and tibial medullary canal during intramedullary rod insertion.

It may be helpful to remind that the template overlay must refer to the best preserved femoral condyle, in order to avoid a higher joint line position and, consequently, a lower patellar placement.

SPECIAL WARNINGS

Before implantation of a GKS BUTTERFLY knee prosthesis it is important to be awared of the following warnings:

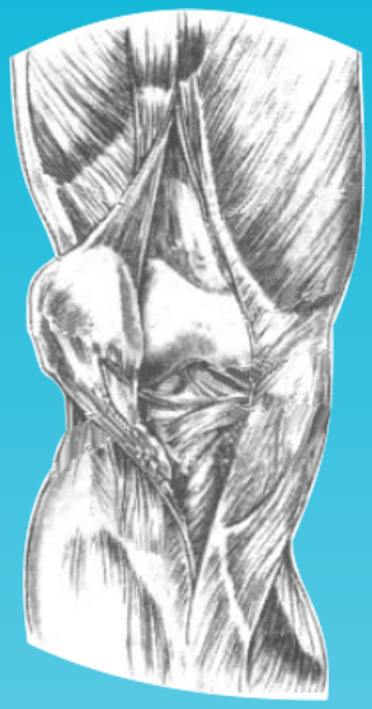
1. Coupling of *Femoral* and *Tibial Components* of different size is not allowed.
2. In selecting the *Intramedullary Stems* it would be advisable to consider the general conditions both of the knee joint and the patient in order to evaluate the best option to achieve a suitable fixation of the device. Generally, in the cemented version, the *Intramedullary Stems* of 105mm length are used as standard option; use of shorter (40 or 90mm) or longer stems should be considered to face particular situations.
3. *Intramedullary Stems* are exclusively intended as anchoring devices for the prosthetic components and they must never be used for intramedullary osteosinthesys purpose. Improper use of *Intramedullary Stems* could promote abnormal stress of the involved components, highly improving risks of coponents fracture.
4. Use of *Cementless Press-Fit Stems* should be considered whenever intramedullary cemented fixation would not be desired. The *Femoral* and *Tibial Components* however MUST ALWAYS BE CEMENTED.
5. Use of *Distal Centralizers* is advisable to allow a correct centering of the *Intramedullary Stems* into the medullary canal and it is possible only on 105 and 160mm length cemented stems.
6. Intrinsic stability of the *Trial Components* is clearly inferior than the definitive prosthesis, particularly under varus-valgus solicitations, due to the missing of the hinge in trial femoral component and the lower height of the tibial pivot in order to allow for easier positioning and removal of the trial components and to dissuade the surgeon in executing wide release of soft tissues and collateral ligaments, thus preserving the prosthesis from excessive stresses that could improve risks of early mobilzation or fatigue failure.

WARNINGS:

Before using the device, it is necessary to understand the surgical requirements of a Total Knee Replacement and become familiar with both the instruments and the implants.

Other than the implementation of a correct Surgical Technique, a good clinical outcome of a joint replacement, also depends upon several factors such as bone stock quality, soft tissue balancing, wear values and correct implant sizing.

SURGICAL APPROACH



Any surgical approach can be used, according to the Surgeon's habits and experience, provided that a satisfactory exposure of the femoral condyles and the proximal tibia can be achieved.

The knee joint should be exposed and any medial and lateral adhesion should be cleared; both the *Cruciate Ligaments* (ACL and PCL) should be removed as well as the residual *Meniscus*.

Collateral Ligaments can be preserved or sacrified. Although preservation should not really be necessary, as the device is totally constrained, it would be preferrable to evaluate this option during the trials or even after the implantation of the defininitive components. Whenever excessive thigthening of the *Collateral Ligaments* and/or *Popliteal Tendon* should be detected, proceed to a total or partial release of the involved structures.

SURGICAL TECHNIQUE

The following procedure describes the basic standard technique for the implantation of all the GKS Buttefly prosthesis versions in both cemented and cementless press-fit stems version.

After complete exposal of the knee joint and removal of any osteophyte from both the femur and tibia margins, in order to restore the normal dimension, it will be possible to proceed in preparing the bony extremities.

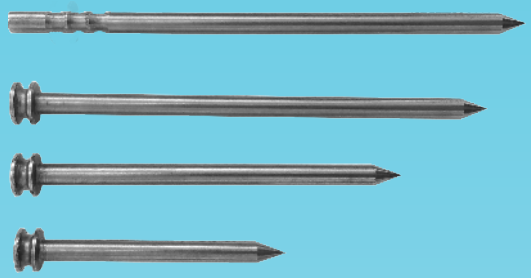
It is up to the surgeon's choice to start the procedure with the tibial or the femoral resection. However it should be considered that the coupling of the Femoral and Tibial components of different size is not allowed as in standard prosthesis. Therefore it is advisable to evaluate the dimensions of both the bony extremities, selecting the size that will better fit.

NOTE: 2 types of pins, in different lengths, are provided with the instrumentation set:

1) GUIDE PINS: without head; used for guide purposes for the cutting masks allowing re-cut option.

2) FIXATION PINS: with head; used for fixation purposes for all the cutting masks.

It is important to choose a length suitable to the dimension of the involved bony part.



TIBIAL RESECTION 1.

With the knee in flexion, lever the tibia anteriorly using a curved retractor ; two Hohmann retractors - one medial and one lateral to retract the patella- are placed for a better exposure. Care must be taken to avoid damages both at the distal femur and the posterior structures of the tibia, as well as to prevent patellar tendon avulsion or neurovascular damages.

To achieve a correctly aligned tibial resection, the Instruments Set provides an external alignment device; an intramedullary alignment guide is also available as optional (refer to procedure described in APPENDIX 1 at page 21).

1.1 USE OF THE EXTERNAL ALIGNMENT GUIDE

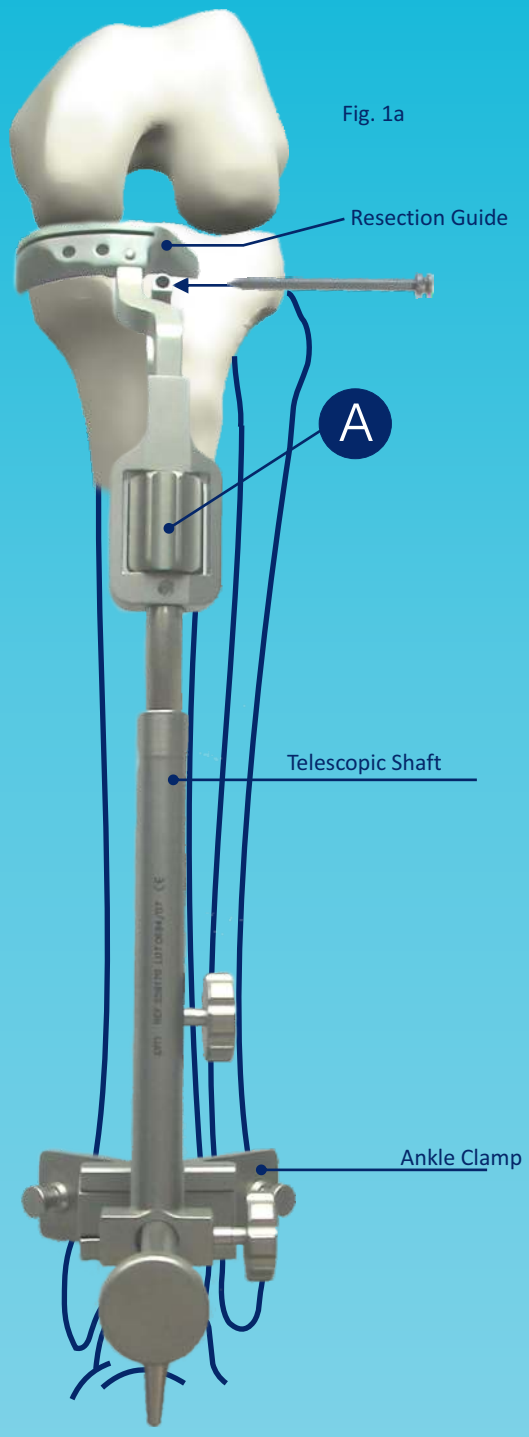


Fig. 1a

This step starts bending the knee over 90°and placing a curved retractor (Freeman) in the posterior face of the tibia. The tibia is then levered anteriorly by pushing onto the distal femur. Care should be taken to avoid any damage to the resected surface and to avoid avulsion of the Patellar Tendon at the tibial insertion.

To achieve the tibial resection, this technique indicates the use of the External Alignment Guide which allows the correct alignment of the Cutting Guide by using an extramedullary reference.

An intramedullary tibial cutting guide is also avialable on request (refer to page 21 for this procedure) .

The External Alignment Guide (S59170) is composed by an Ankle Fork with fixation spring and a Telescopic Shaft supporting the Tibial Cutting Guide. Two Tibial Cutting Guides are available for the RIGHT side (S59198) and the LEFT side (S59199).

Assemble the correct sided Cutting Guide by engaging it into the top of the Telescopic Shaft and screw it in by rotating the knurled knob A. It is advisable to set the position at a middle level in order to allow both upwards and downwards excursion. Once assembled the device, center the upper hole right above the tibial tuberosity and pin it with a Fixation Pin (Fig. 1a).

Align the device to the Mechanical Axis of the tibia (see next page for details) controlling the adjustments on the frontal plane and the sagittal plane. The knobs must be tightened firmly once the desired alignment is achieved.

The correct resection level is adjusted by acting on the knurled knob of the Shaft A which raises or lowers the Cutting Guide. To check the correct level, it is possible to use the "Halfmoon" Resection Gauge (S59107) or the Tibial Stylus Gauge (S59105), both to be inserted into the slot of the Cutting Guide.

The Tibial Stylus Gauge can be used in two positions:

- ✓ by inserting the stylus blade marked "2mm" a resection of 2mm below the tip contact will be achieved. This should refer to the lowest point of the most damaged tibial condyle (Fig. 1b).
- ✓ by inserting the stylus blade marked "10mm" a resection of 10mm below the tip contact will be achieved. This should refer to the lowest point of the most preserved tibial condyle.

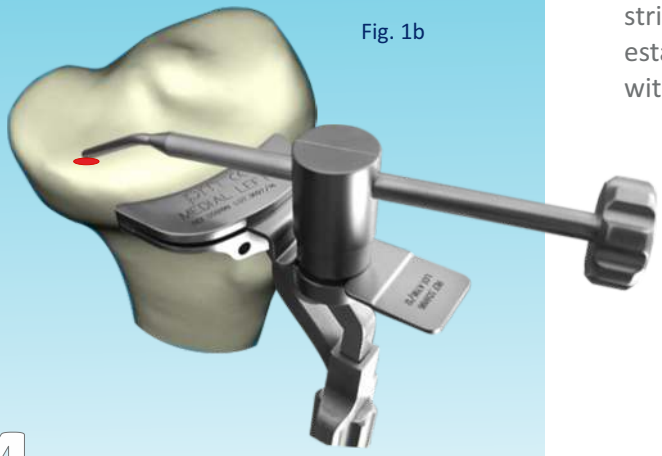


Fig. 1b

The choice between these options is at Surgeon's discretion and is strictly correlated to the morphology of the tibial surface involved. Once established the correct resection level, the Cutting Guide is secured with 2 Fixation Pins - Medium (S53532).

HINTS FOR A CORRECT ALIGNMENT:

Alignment in the frontal plane (Fig. 2a) is correct when the Shaft of the guide runs along the *Mechanical Axis* of the tibia and the distal tip is pointing the second toe of the foot. Use the knob C to achieve this position.

Alignment in the sagittal plane should aim to achieve a resection perpendicular to the Mechanical Axis of the Tibia.

Since the Cutting Guide provides for a 5° posteriorly sloped resection (Fig. 2b) it will be necessary to correct the slope by loosening the knob B and pull the shaft towards the leg to towards the leg to decrease the inclination

Fig. 2b

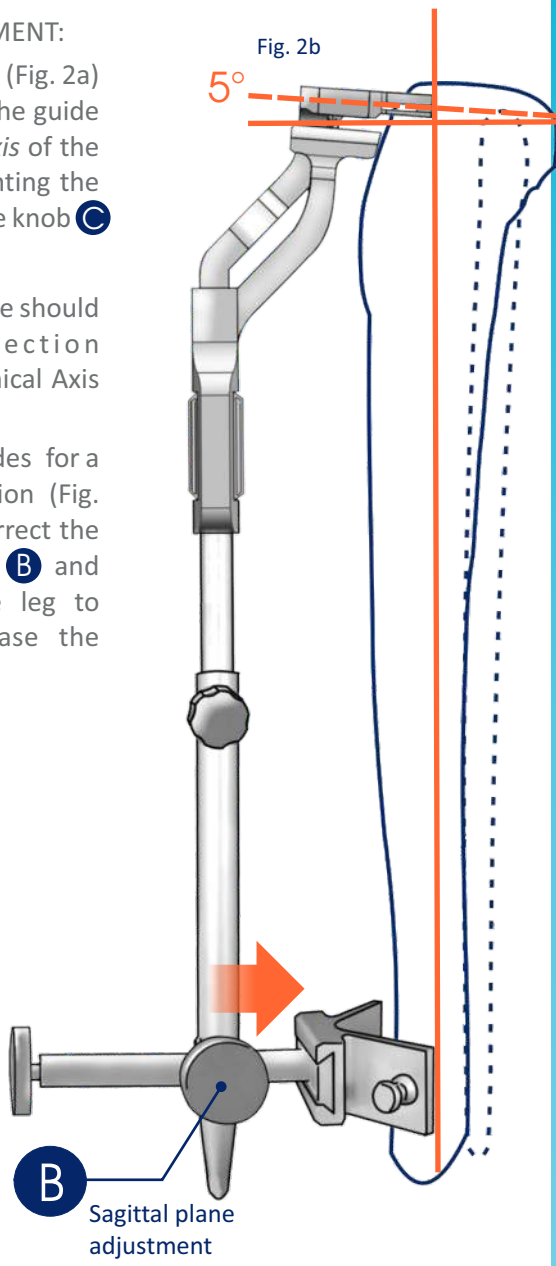
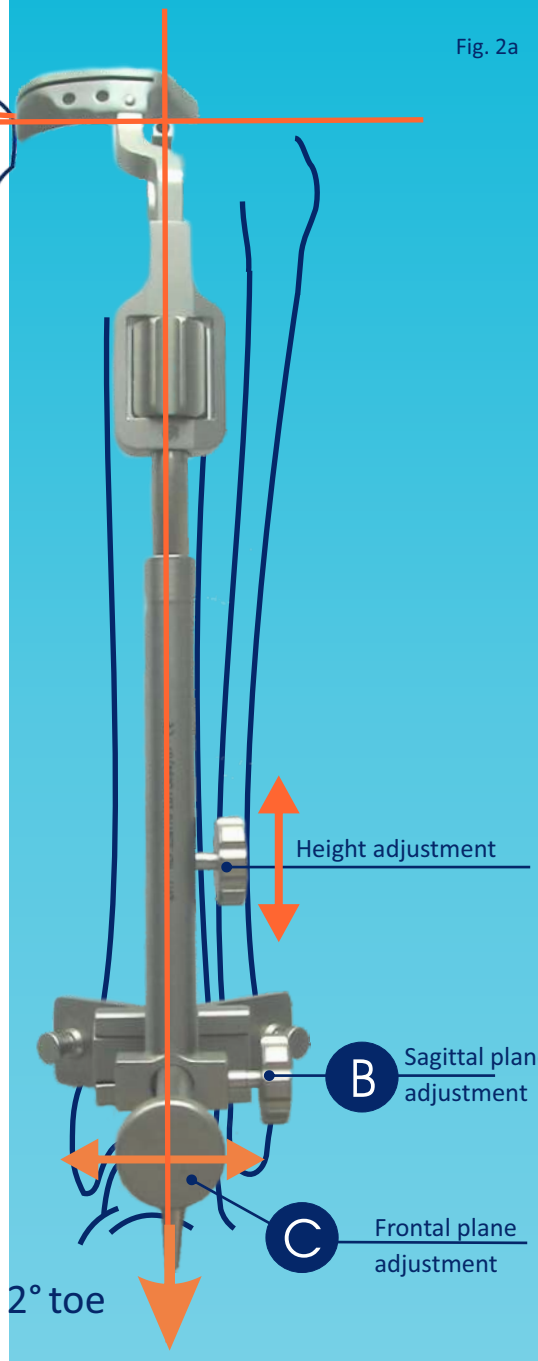


Fig. 2a



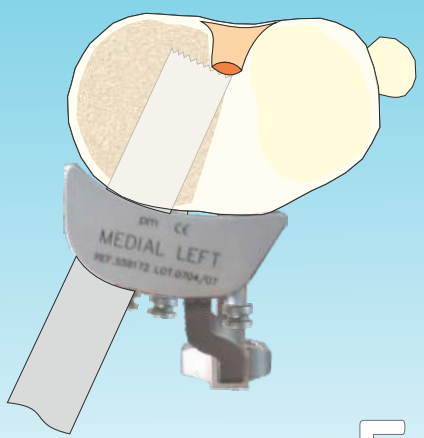
TIBIAL RESECTION 1.2

The resection of the Proximal Tibia can now be performed. Maximum care should be taken in this step, in order to achieve a perfectly levelled surface.

It is advisable to use oscillating saw blades with length between 80 and 100mm, 1,27mm maximum cut thickness (Fig. 3).

Once completed the resection, the Cutting Guide can be removed (by pulling out the Fixation Pins and unscrewing the knurled knob) thus leaving the Alignment Guide in place: if a re-cut should be necessary the Cutting Guide can be repositioned and adjusted at a lower level.

Fig. 3



2 FEMORAL PREPARATION

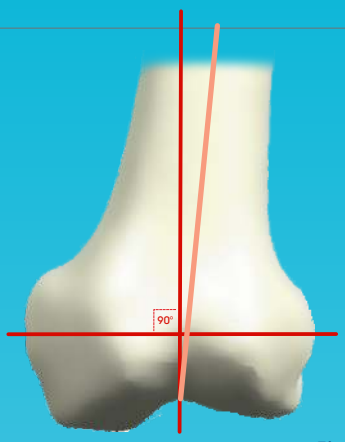
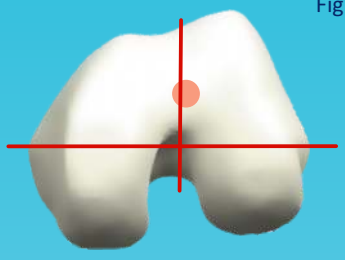


Fig. 4

After the complete exposure of the joint and the removal of the peripheral osteophytes from the articular surface - in order to restore the normal anatomical dimensions of the knee - the insertion point for the introduction of the Intramedullary Rod has to be identified when the knee is in flexion. This point is generally located in the center of the intercondylar notch, about 7-8 mm ahead of the PCL insertion (Fig. 4).

It is important, however, to exactly evaluate - using the appropriate X-Ray templates - the correct location of the intramedullary rod into the femoral canal, in order to identify its exit point in the center of the knee.



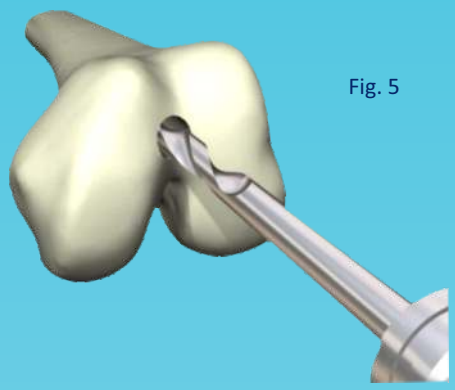


Fig. 5

Using the Ø 8 mm Starter Drill Bit (S40010) the femur is drilled to accomodate the Intramedullary Rod (Fig. 5). In executing this hole it is important to stay parallel to the femoral diaphysis both in the Anterior-Posterior and in the Medial-Lateral plane.

Before operating the Starter Drill it may be helpful to start the femur manually, using an awl, and to verify the medullary canal has been located by touching the cortical walls with a thin and long curette.

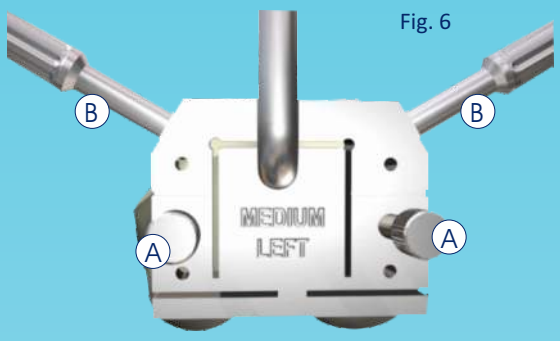


Fig. 6

The Femoral Cutting Guide of the involved side is positioned onto the Intramedullary Rod (S40009) and inserted into the femoral medullary canal (Fig. 6).

The guide can be eventually equipped with two Stabilizing Screws (A) (S40018) and two Handles (B) (S40017) to improve the cutting guide stability while cutting.

About the selection of the correct size (SMALL or MEDIUM), it is important to remind that it is advisable to select the size that will fit better considering both the bony extremities.

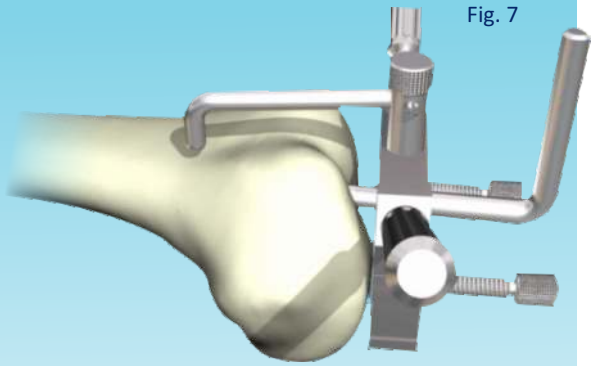


Fig. 7

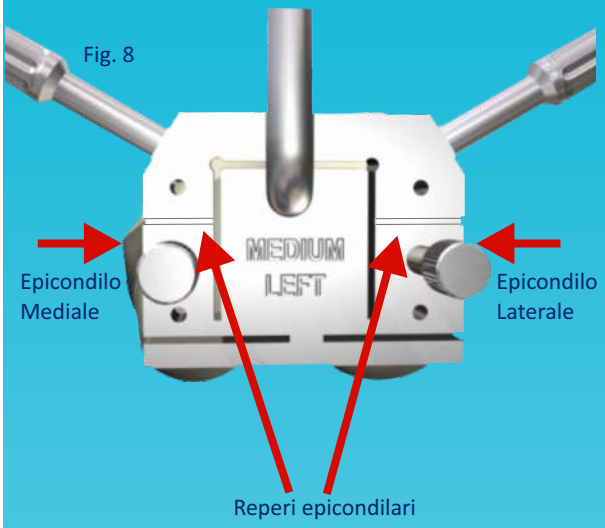
The Femoral Feeler Gauge (S40019) is screwed onto the top of the Cutting Guide: It's tip should only skimm the anterior cortex (Fig. 7). If the tip impinges onto the anterior cortex, use of a larger size should be considered.

NOTE: whenever should not be possible to use a larger size (because it wouldn't fit properly to the tibia or the size selected is the larger one available) it would be convenient to modify the entry hole of the Intramedullary Rod in order to place the Femoral Cutting Guide more anteriorly. It should be considered that this solution will produce a bigger resection of the posterior condyles, consequently widening the flexion gap.

The Femoral Cutting Guide is then set with the correct rotational alignment.

This can be achieved by aligning its landmarks parallel to the transepicondylar axis.

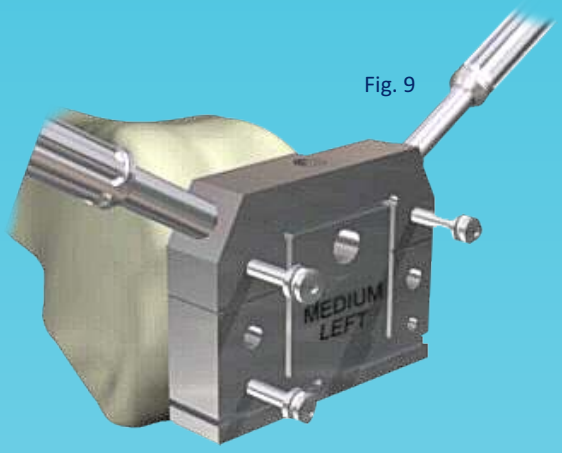
Fig. 8



The Femoral Cutting Guide should lean at least on the most preserved condyle (on the other side, the Stabilizing Screw can be screwed until reaching the bone) and it is stabilized by means of 4 Fixation Pins of appropriate length inserted into the provided holes (Fig. 9).

In presence of hard sclerotic bone, a pre-drilling with the appropriate Drill Bit Ø 3,5 mm (S40069) is advisable.

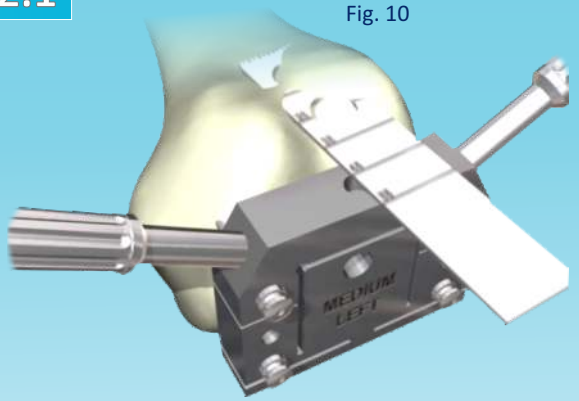
Fig. 9



Once the Femoral Cutting Guide is fixed, the Intramedullary Rod, the Stabilizing Screws and the Feeler Gauge are removed.

FEMORAL RESECTIONS 2.1

Fig. 10

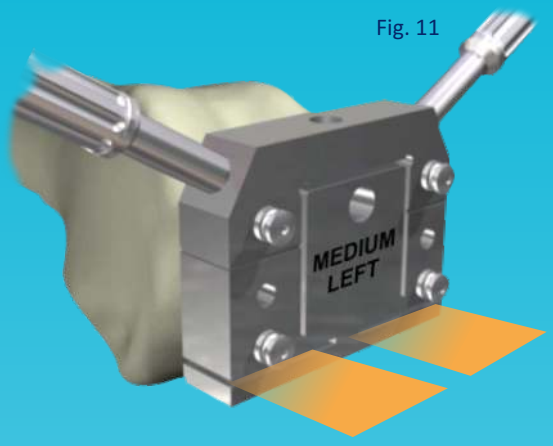


The femoral resections can therefore be performed using an oscillating saw. The optimal blade should be roundabout 90mm long, 20mm wide and 1,37mm thick.

Start with the anterior resection, using the top of the Cutting Guide to drive the blade (Fig. 10) taking care to always keep the blade well resting on the Cutting Guide top in order to avoid an angled resection.

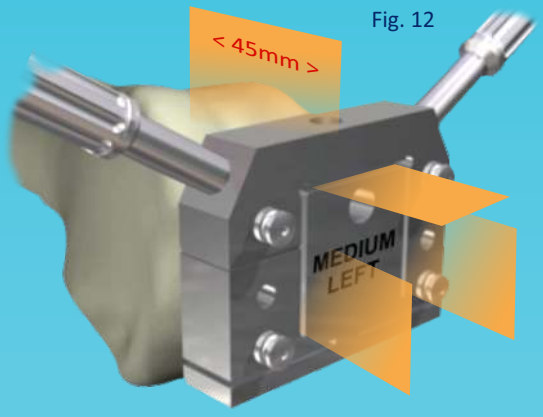
WARNING: if a PRIMARY prosthesis without trochlear shield is selected this resection is not required.

Fig. 11



The posterior condyles are than resected by introducing the saw blade in the posterior slots of the Cutting Guide (Fig. 11).

Fig. 12



Finally, the saw blade is introduced into the central slots for the intercondylar resections (Fig. 12).

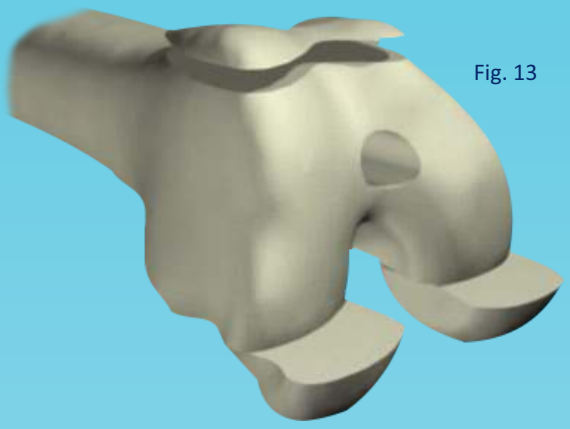
The saw blade should be deepened about 45mm from the external face of the Cutting Guide in order to achieve a sufficient depth of the central box to accept the hinge of the prosthesis.

After completed the resections the Cutting Guide is removed, by extracting the Fixation Pins using the Pins Puller (S40026).

Normally, the vertical resections of the intercondylar box must be completed to reach the posterior condyles resections.

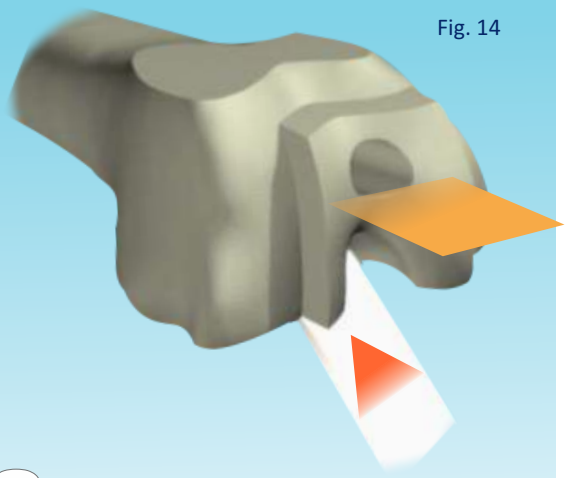
The resected bony parts can now be removed (Fig. 13).

Fig. 13



In order to avoid condylar fractures, particular care should be taken in removing the intercondylar bony block that is still attached to the femur proximally.

Fig. 14



A safe way to remove the intercondylar bony block is to use a large osteotome introducing it posteriorly, with the knee in hyperflexion (when possible), and lever anteriorly to pull out the block.

Otherwise, if a suitable flexion could not be achieved, the block can be split into two parts and then remove them with the osteotome by lever posteriorly.

WARNING: in order to avoid condylar fractures, do not lever laterally or anteriorly. .

Once the bony block is removed, it is necessary to verify the perfect shape of the prepared site, eventually removing residual bony parts that could impinge while introducing the trial component.

PREPARATION OF THE FEMORAL DIAPHYSIS 3

The following chapter describes the procedure for use of the GKS Butterfly prosthesis with cemented or cementless press-fit Intramedullary Stems

USE WITH CEMENTED STEMS

The acces hole to the medullary canal is now visible at the bottom of the intercondylar box. This hole should be enlarged using the Universal Intramedullary Rasp (S40028) in order to allow the introduction of the next instruments.

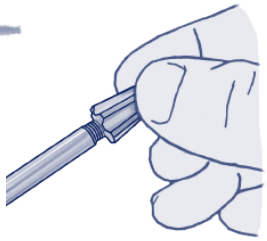
It is advisable to enlarge this hole particularly anteriorly, until reaching the roof of the anterior cortex, and towards the medial condyle (Fig. 15b).

The landmarks onto the Universal Intramedullary Rasp are referred to the length of the Intramedullary Stems: the more distal one refers to the 90mm Stem; the intermediate one refers to the 105mm Stem and the more proximal one to the 160mm Stem.

These landmarks should be aligned with the entry of the medullary canal at the bottom of the intercondylar box.

WARNING:105mm Stems are normally considered as standard option. Use of shorter or longer stems should be considered to face particular situations.

The next step is to evaluate the diameter of the medullary canal in order to select the proper size of Distal Centralizer to be assembled to the Stem.



The Trial Distal Centralizer Ø 12mm is screwed onto the proper Introducer (S40029) and pushed into the medullary canal until the landmark referring to the selected stem length is aligned at the bottom of the intercondylar box (Fig. 16).

If the Ø 12mm Trial Centralizer should be too small, repeat the trial with the Ø 15mm one; on the contrary, if it should be too large (the landmark doesn't reach the correct level) it should be considered the opportunity to use the stem without the centralizer or select a shorter stem.

Fig. 15a

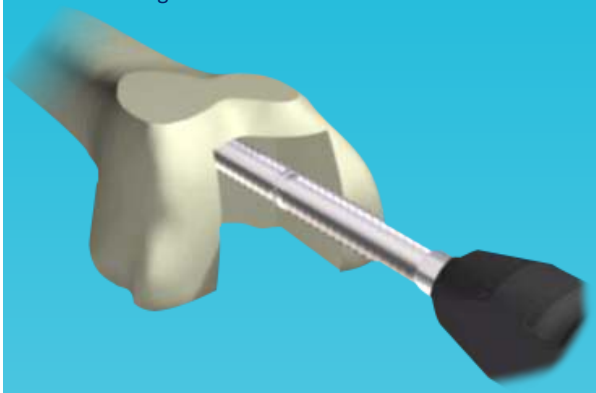


Fig. 15b

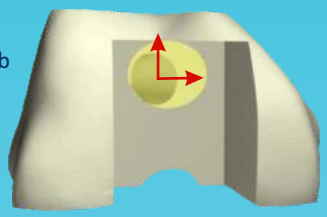
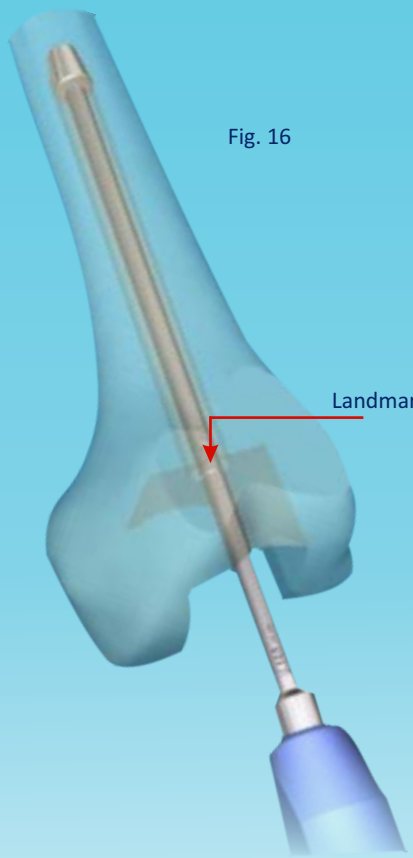


Fig. 16



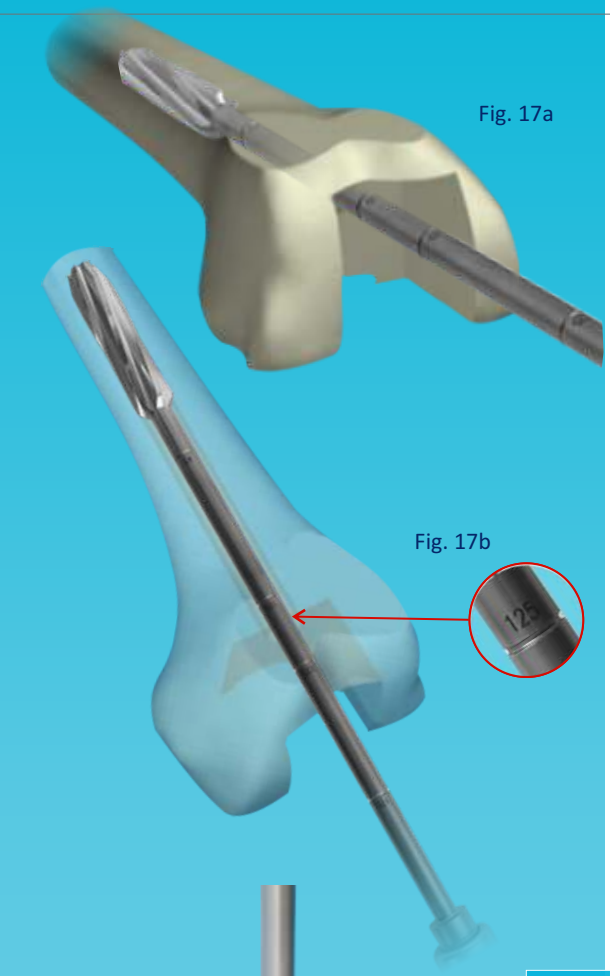


Fig. 17a

Fig. 17b

USE WITH PRESS-FIT CEMENTLESS STEMS

Use of cementless press-fit stems allows to avoid intramedullary cemented fixation and therefore the problems involved with cement removal in case of revision.

The following chapter describes the procedure to be used with cementless stems.

Once executed the bony resections and removed the intercondylar bony wedge as described in chapter 3, proceed enlarging the hole using the Cylindrical Modular Reamers in order to allow the further insertion of the Trial Stems (Fig. 17a).

Start with the thinner reamer, increasing the diameter till reaching the cortical walls. The reamer's shaft is graduated to identify the length of the corrensponding stem (45 - 100 - 125 - 175mm). The marks should be referred to the entry of the medullary canal, at the bottom of the intercondylar box (Fig. 17b).

Once established the diameter and the length of the stem to be used, proceed assembling the Femoral Chamfer together with the Trial Stem of the selected sizes and follow the procedure described at page 11.

3.1 PREPARATION OF THE TIBIAL DIAPHYSIS

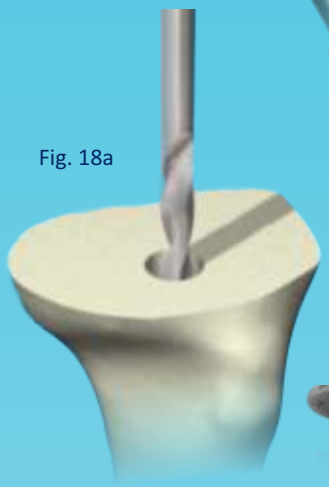


Fig. 18a

The medullary canal of the tibia is identified and opened (Fig. 18a) by means of the Ø 8mm Starter Drill (S40010).

USE WITH CEMENTED STEMS

This hole should be slightly enlarged with the Universal Intramedullary Rasp to allow the positioning of the Cylindrical Extension (S40068) of the Rotating Trial Tibia (Fig.18b).

As previously seen, this Rasp has 3 marks referring to the stems length: 90mm (the most proximal), 105mm (the intermediate mark) and 160mm (at the beginning of the cutting teeth) that should refer in this case to the resection plane of the tibia in order to evaluate the correct length to be used.

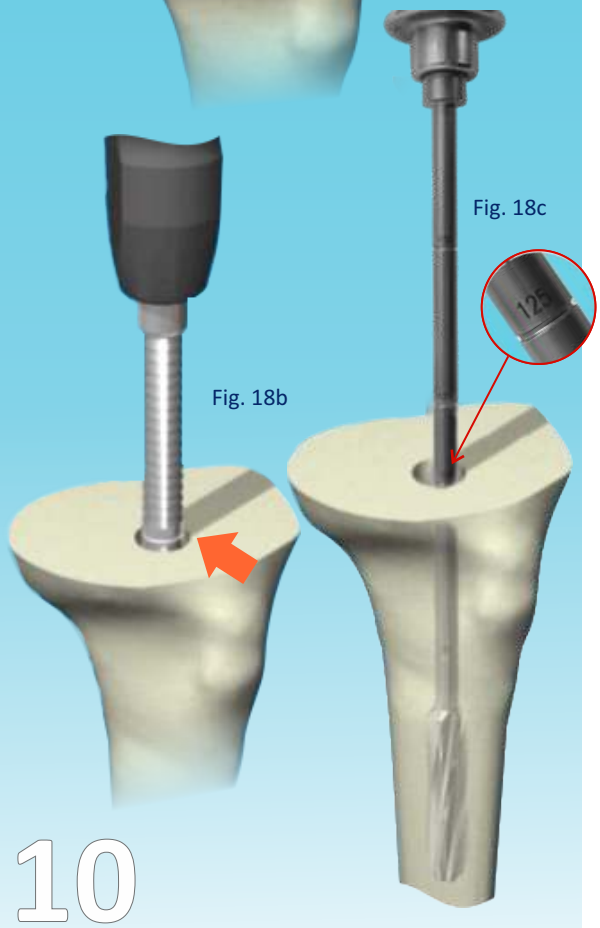


Fig. 18c

Fig. 18b

USE OF THE PRESS-FIT CEMENTLESS STEMS

The tibial diaphysis is prepared by means of the Cylindrical Modular Reamers supplied with the instruments set.

Start with the thinner reamer, Ø 12mm (ref. S42112) increasing the diameter till reaching the cortical walls (Fig.18c).

Use the reference marks on the reamer's shaft to determine the depth and thus the length of the stem to be used.

WARNING: in case a Tibial Compensatory Plate should be used, the thickness of this element must be considered and the reamer should be deepened consequently.

PREPARATION OF THE FEMORAL CONDYLES 4.

The Femoral Chamfer of the selected side and size (identified by the marking SMALL or MEDIUM plus LEFT or RIGHT) is assembled with the selected Trial Stem and teh eventual Trial Centralizer (cemented stems) and is introduced into the prepared femoral (Fig. 19) site by means of the proper Trials Handle (S40030).

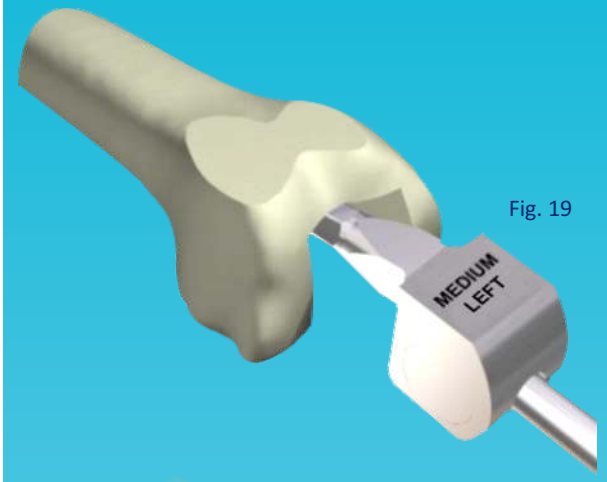


Fig. 19

The Femoral Chamfer reproduce the inner profile of the definitive femoral component and should be deepened until its external surface is 2mm deeper that the most preserved condyle surface (Fig. 20).

If the Femoral Chamfer would not sink enough, it would be necessary to remove it and provide to deepen the site until reaching a suitable sinking.

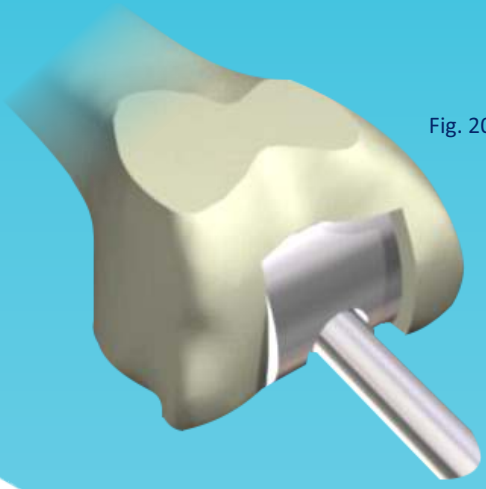


Fig. 20

The condyles are then chamfered following the surface of the Femoral Chamfer with the oscillating saw blade (Fig. 21).

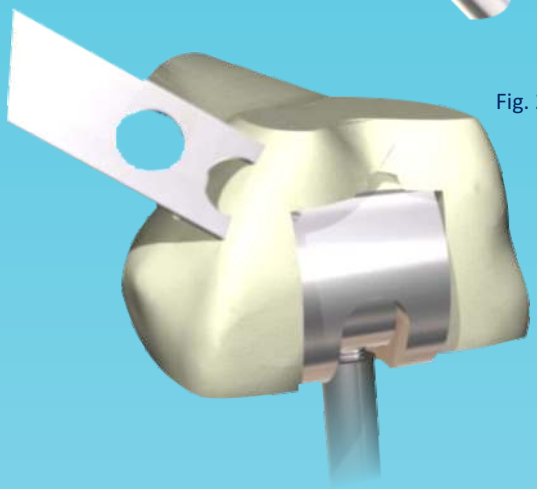
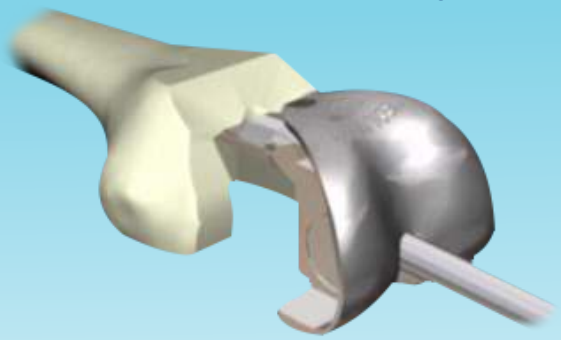


Fig. 21

After chamfering of the femoral condyles, the Femoral Chamfer is removed and replaced by the corrensponding Trial Femoral Component assembled with the selected Trial Stem and eventually Trial Centralizer (Fig. 22).

It is now possible to visually check the congruence between the prosthesis and the bone and evaluate the correct positioning of the component. Whenever needed, provide the necessary adjustments to the make the prosthesis fit.

Fig. 22



4.1 TRIAL EVALUATION

After positioning the Trial Femoral Component the Rotating Trial Tibia of the selected side and size, assembled with the Cylindrical Extension (S40068), is placed onto the resected tibia (Fig. 24).

Fig. 24

Reduce the joint by engaging the pivot of the Trial Tibia into the hinge of the Trial Femur (Fig. 25). Extend the knee and check stability and the range of movement, that should allow full flexion and extension.

Also check the joint tensioning, that should not be too tight or loosen: In case of incomplete extension, a re-cut of the tibia might be necessary (unless the joint is loosen in flexion, then the femoral component shall be raised more proximally).

Whenever an abundant tibial resection has been made instead, and the gap should result excessive both in flexion and extension, it will be necessary to use a *Tibial Augmentation Plate*: remove the Trial Tibia, add a Trial Augmentation Plate (5-10 or 15mm) and repeat the evaluation(fig. 26).

Fig. 25

Fig. 26

NOTE: for use of the Compensatory Plates, refer to chapter 9 of this surgical technique (pag. 18).

After positioning of the trial components, the trial evaluation of the joint is carried out by effecting the usual flexion, extension and axial rotation movements to test the patellar tracking. By performing these movement, the self centering of the tibial component will automatically occur.

With the leg fully extended a landmark is traced onto the anterior tibial cortex, corrensponding to the landmark on the trial tibia (Fig. 27).

This landmark will represent the correct anterior projection of the tibial prosthesis centre.

Fig. 27

PREPARATION OF THE PROXIMAL TIBIA 5

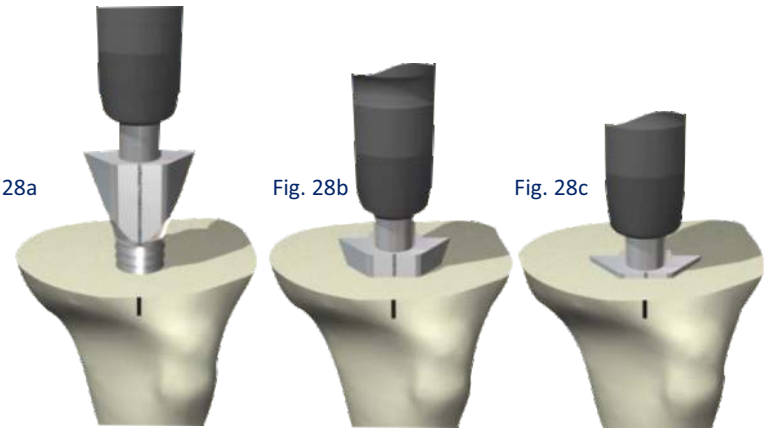


Fig. 28a Fig. 28b Fig. 28c

The Tibial Rasp corrensponding to the selected stem is introduced into the medullary canal, aligning it's central line to the landmark previously marked on the tibia, and deepened until the superior margin of the flange is levelled to the resection surface (Fig. 28a-b-c).

In this way the *Tibial* and the *Femoral Component* will be perfectly aligned therefore avoiding any problem to the *Extensor System* due to malpositioning of the prosthesis.

ATTENTION:

- when using a cementless Press-Fit stem, the 90mm Conical Tibial Rasp can be utilized to prepare the keel.
- in case a Tibial Compensatory Plate is used, the rasp should be deepened considering thethickness of this component.

Whenever a cemented stem is used, it is advisable to size the diameter of the medullary canal in order to determine the properly fitting size of the *Distal Centralizer* to be assembled onto the *Stem* (Fig. 29).

The Trial Distal Centralizer Ø 12mm is screwed onto the proper Introducer (S40029) and pushed into the medullary canal until the landmark referring to the selected stem length is aligned at the level of the tibial resection.

If the Ø 12mm Trial Centralizer should be too small, repeat the trial with the Ø 15mm one; on the contrary, if it should be too large (the landmark doesn't reach the correct level) it should be considered the opportunity to use the stem without the centralizer or select a shorter stem.

It is now possible to proceed with implantation of the definitive prosthesis.

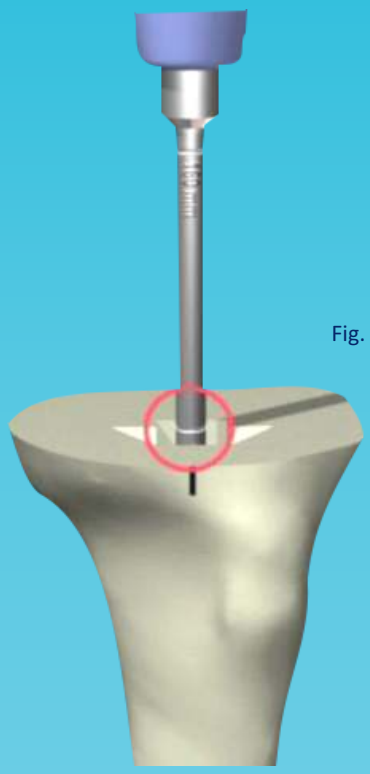


Fig. 29

6 ASSEMBLING OF THE COMPONENTS

All the selected components are pulled out from their packages by following the usual aseptic procedure and disposed onto the sterile trolley.

The selected *Intramedullary Stems*, cemented or cementless, are screwed into the proper sites onto the *Femoral* and *Tibial Components* (Fig. 30a), and tightened (Fig. 30b) using the Tightening Wrench (S42019) and the Open Wrench (S42021) as counterholder.

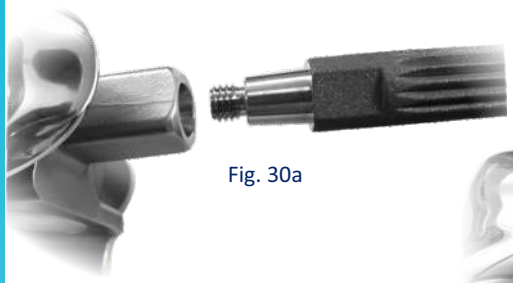


Fig. 30a

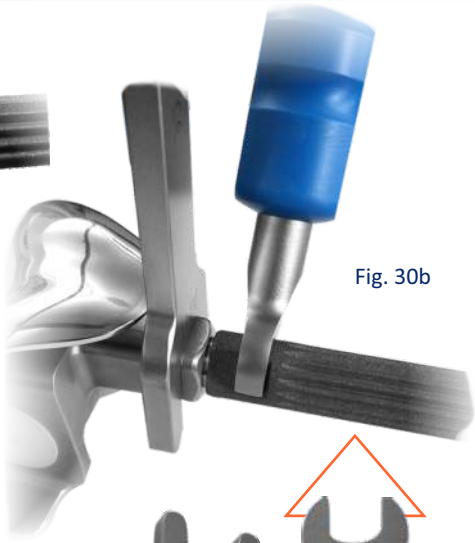


Fig. 30b

Eventual *UHMWPE Distal Centralizers* are inserted at the tip of each *Cemented Stem* (Fig. 31).

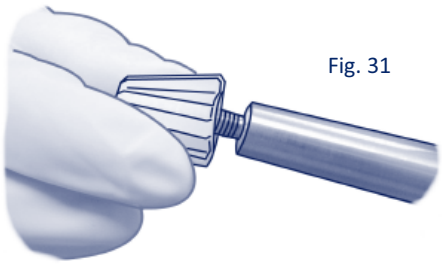


Fig. 31

Any eventual *Tibial Augmentation Plate* is assembled to the inferior face of the *Tibial Component* (Fig. 32a) and secured by means of the proper *Screws* (Fig. 32b) tightened with the Screwdriver on the Tightening Wrench (S42019).

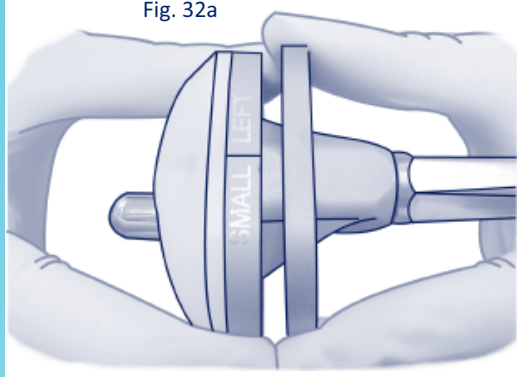


Fig. 32a

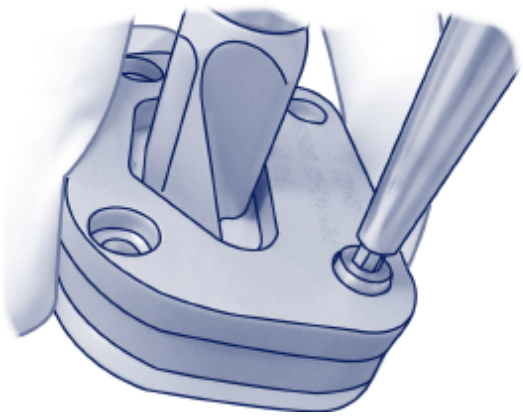


Fig. 32b

NOTE: for the correct assembly of the *Augmentation Plates*, refer to chapter 9 of this surgical technique (pag. 18).

IMPLANTATION OF THE PROSTHESIS 7

It is advisable to proceed first with the implantation of the *Femoral Component* and than, after anterior dislocation of the tibia, the *Tibial Component.* On the contrary, the pivot of the *Tibial Component* could be an obstacle in introducing the *Femoral Prosthesis*.

The medullary canal, both of the femur and the tibia, should be accurately washed and suctioned to remove possible bony fragments or residual blood. Plugging of the medullary canal (by means of UHMWPE, resorbable or bony plugs) and use of a syringe for «retro-filling» cementing technique is advisable in order to achieve a proper filling.

For improved cementing technique it would be advisable to provide a surface as dry as possible, by sucking eventual blood into the medullary canal and tamponing the femoral condyles with a compress

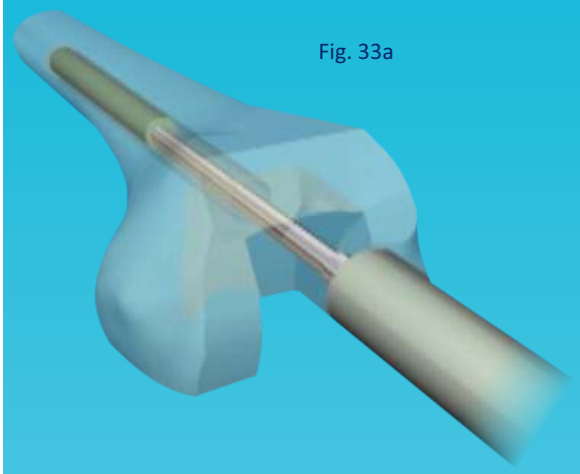


Fig. 33a

IMPLANTATION OF THE FEMORAL COMPONENT 7.1

NOTE: whenever a cementless (Press-fit) stem is used, ignore any reference to intramedullary cementing technique.

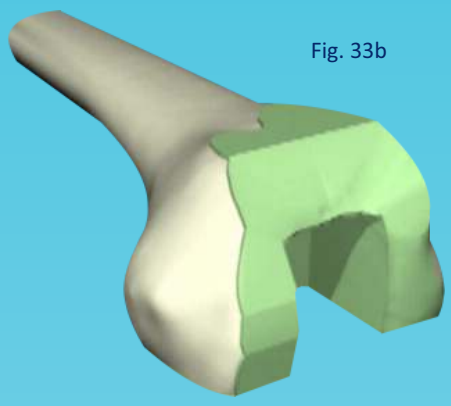
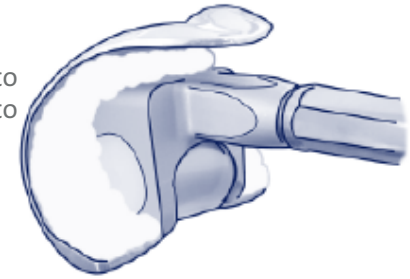


Fig. 33b

The bone cement is injected by means of the syringe until the medullary canal is completely filled and the cement overflows in the intercondylar box (Fig. 33a-b).

Further bone cement can be applied to the posterior part of the prosthesis to fill eventual gaps of the condyles.



The *Femoral Component*, previously assembled with the selected *Intramedullary Stem* and the eventual *Distal Centralizer*, is manually introduced into the prepared site and impacted by means of the Femoral Impactor (S40036) until its final seating (Fig. 34).

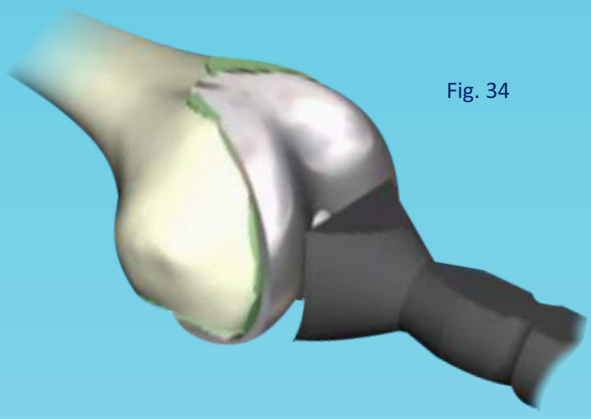


Fig. 34

Pressure should be applied, avoiding any stress to the component, until the final hardening of bone cement.

The exceeding bone cement is removed using a curette. Particular care should be taken to remove completely the bone cement in the posterior part of the hinge.

The plastic strip protecting the hinge of the prosthesis should be removed only once the cement is in a doughing phase (no more sticky) by pulling its posterior edge (Fig. 35).

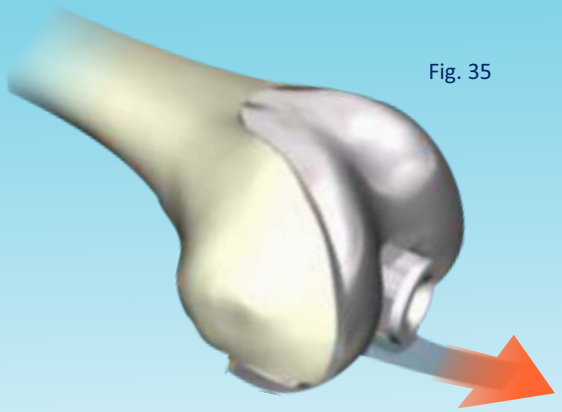


Fig. 35

After removal of the protective film, the mobility of the hinge should be checked.

7.2 IMPLANTATION OF THE TIBIAL COMPONENT

The proximal tibia is dislocated anteriorly by positioning of a Homann retractor to allow insertion of the Tibial prosthesis, taking care in protecting the femoral component previously implanted to avoid any damage. For a better cemented fixation it would be advisable to accurately wash and suction the medullary canal.

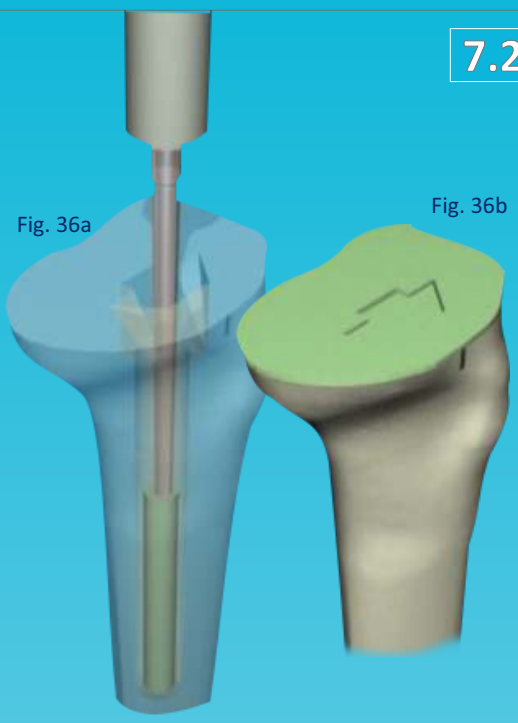


Fig. 36a

Fig. 36b

The bone cement is injected by means of a syringe until the medullary canal is completely filled and the cement overflows onto the resection surface (Fig. 36a-b).

Further bone cement can be applied to the posterior part of the prosthesis.

Whenever cementless stem is used, bone cement is applied to the posterior part of the prosthesis.

Fig. 37

The definitive Tibial Component, previously assembled with the selected Intramedullary Stem and eventual Distal Centralizer, is manually introduced into the prepared site and impacted by means of the Tibial Impactor (S40060) until its final seating.

Pressure should be applied, avoiding any stress to the component, until the final hardening of bone cement. The overflowing bone cement is removed using a curette (Fig. 37).

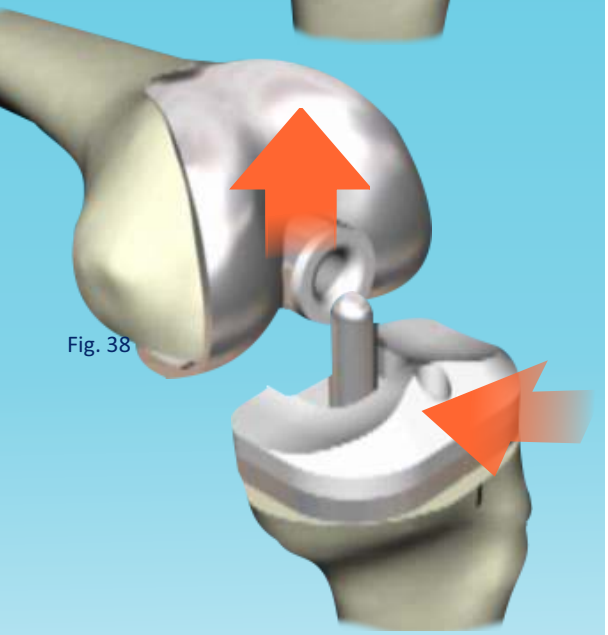


Fig. 38

After complete polimerization of the bone cement, it is possible to perform the final reduction of the prosthesis:

the thigh should be pulled upward to allow the tibial pivot engagement into the femoral hinge, while the tibia should be pulled downward and pushed posteriorly (Fig. 38). Once engaged, extend the Tibia for final reduction (Fig. 39).

In case that reduction should result difficult to be achieved, due to excessive tensioning of the *Collateral Ligaments* (whenever preserved) or the Popliteal Tendon, a total or partial «release» of the involved structures should be provided.

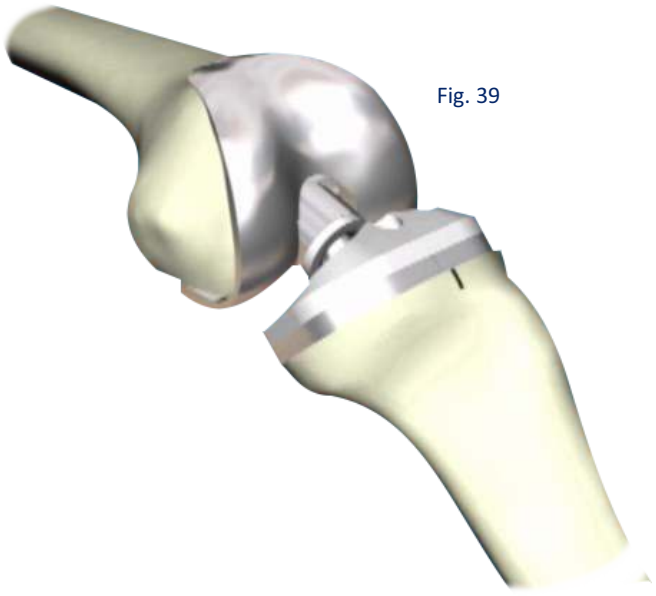


Fig. 39

USE OF THE ANTILUXATION VERSION 8 MICROLOY®

Fig. 8.1

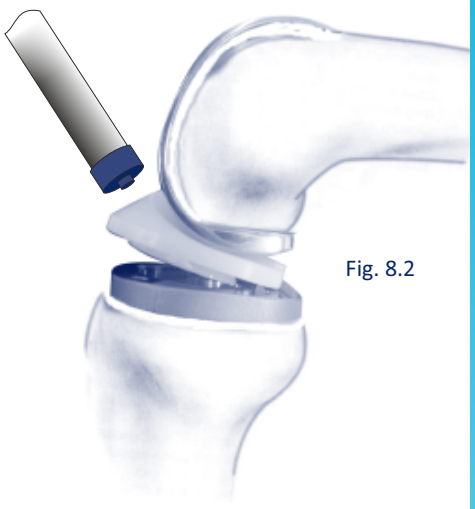


Fig. 8.2

Fig. 8.3

The MICROLOY® ANTILUXATION version is characterized by the presence of a metal sleeve in the femoral bush (instead of Polyethylene) with a wide lip that, once the Femoral and Tibial components are reduced, is locked by the UHMWPE Insert onto the Tibial Plate, thus avoiding the excursion and possible dislocation .

The implantation technique is the same as the standard prosthesis, the only difference is that the *Tibial Component* is implanted without the *UHMWPE Insert*. This will be assembled afterward.

Therefore in implanting the *Tibial Component* it will be advisable to follow some hints:

- the insert *Safety Screw* should be screwed into its threaded seat to avoid this to be filled by bone cement (Fig. 8.1) and removed once cement has hardened.

- Once the prosthesis is reduced, the *Butterfly ANTILUXATION Insert*, included into the same packaging of the prosthesis, is inserted onto the tibial baseplate sloping posteriorly, in order to engage the niche on the baseplate (Fig. 8.2) and impacted with the proper Impactor (S42022).

- After the Insert has been lodged, lock it with the *Safety Screw* supplied with the *Insert* (Fig. 8.3) using the Screwdriver on the Tightening Wrench (S42019).

9. USE OF THE TIBIAL AUGMENTATION PLATES

Augmentation Plates are used to to fill eventual gaps; they are intended to be fixed distally to the definitive *Tibial Component* by means of the proper 8mm long *Locking Screws (Ref. 45008)*.

When gaps more than 15mm are to be filled, 2 *Augmentation Plates* can be overplaced one over the other (Fig. 9.1) using 23mm long *Locking Screws (Ref. 45023)*. In this way it is possible to fill gaps up to 30mm (15+15).

The example shows a 20mm compensation by assembling 1x15mm and 1x5mm Augmentation Plates.

Warning! When overplacing two *Augmentation Plates* (Total or Hemi) a 15mm must always be placed immediately under the tibial component and the second one added distally (the reverse wouldn't allow the assembly because the 23mm screw would be too long).

TOTAL AUGMENTATION PLATES

Fig. 9.1

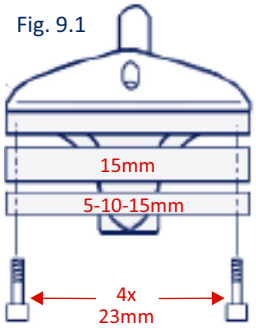
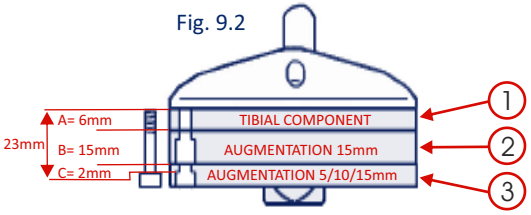


Fig. 9.2



23mm is the length of the screw's stem and thread (without considering the head). This length allows fixation of Augmentation Plates as showed above (Fig. 9.2).

Components #1 and #2 remains the same, only #3 is variable (5, 10 or 15mm for full wide Augmentation Plates, 10 or 15mm for hemi).

As the value c) is the same in all the plates, the 23mm screw fits in any case.

If component #2 should be less than 15mm, the value b) would change and the screw would result too long, pushing up the polyethylene liner.

Fig. 9.3

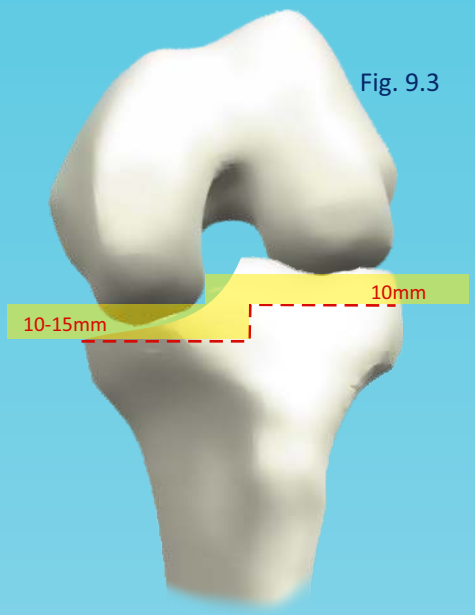


Fig. 9.4

AUGMENTATION HEMI-PLATES

Augmentation Hemi-plates are available in 10 and 15mm thickness and can be used in case only one tibial hemiplate should be ecxessively compromised.

Resection should be carried out in 2 steps: a first resection (Fig. 9.3) of the less involved part in order to achieve the minimum space for the prosthesis (10mm);

afterwards a second cut to provide the space for the *Augmentation Hemi-plate*, using a trial as sample (Fig. 9.4)

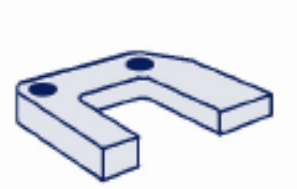
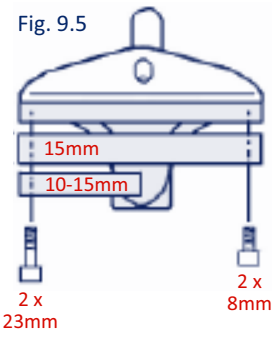


Fig. 9.5



Augmentation Hemi-plates are fixed to the tibial plate in the same way, but using only two 8mm *Locking Screws (Ref. 45008)*.

The Hemi-plates can even be assembled one over the other, using the 23mm long *Locking Screws (Ref. 45023)*.

It is also possible to combine a Hemi-plate with a full wide type: in this case two 23mm screws and two 8mm are needed (Fig. 9.5)..

HINTS FOR USE IN REVISION CASES 10

PREPARING THE FEMUR: as the femoral condyles has been already resected, the only intercondylar box has to be prepared to receive the prosthesis hinge. Use of the Femoral Cutting Guide is therefore superfluous.

After identification of the medullary canal, the Universal Intramedullary Rasp (S40028) is used to enlarge the entry hole. Than proceed whit the sizing of the canal in order to identify the proper diameter of the Distal Centralizer to be used (see page 9). In case of cementless stems, use the proper Modular Reamers (see page 10).

The Femoral Chamfer of the selected side and size (identified by the marking SMALL or MEDIUM plus LEFT or RIGHT) is assembled with the selected Trial Stem and Trial Centralizer and introduced into the enlarged hole by means of the proper Trials Handle (S40030); after determining the correct rotational alignment, the device is impacted until its posterior part reaches the condyle. The resection of the intercondylar box is than effected by means of the oscillating saw, using the Femoral Chamfer as a guide (Fig. 10.1).

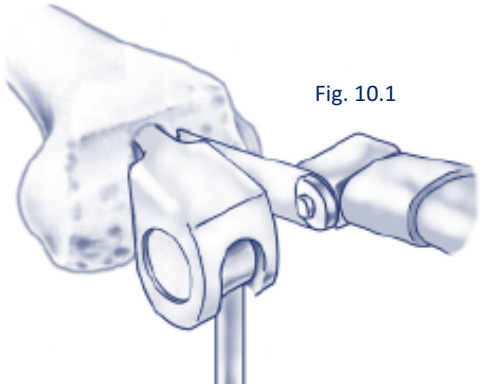


Fig. 10.1

After removal of the Femoral Chamfer, follow the standard procedure as described from page 11.

PREPARING THE TIBIA: proceed as described in the standard technique (pag. 10) only avoiding to drill the tibia because the canal should be already open.

The difference in procedure for revision cases is due to the fact that the involved bony extremities were previously resected and is quiet normal to face bone defects, even of severe entity, due to the mobilization or removal of the previous prosthesis.

After removal of the previous components, eventual bone cement residual should be removed.

Whenever necessary the tibial resection should be levelled to achieve an even surface. In sizing the implant it should be considered that the coupling of the Femoral and Tibial components of different size is not allowed as in standard prosthesis. Therefore it is advisable to evaluate the dimensions of both the bony extremities, selecting the size that will better fit.

INSTRUCTION FOR SPARE PARTS REPLACEMENT 11

Femoral nuts and polyethylene tibial inserts are available as spare parts for those cases when a replacement should be needed in case of wear and/or breakage, thus avoiding the removal of the whole prosthesis. In particular, the following parts are available

- ✓ Standard UHMWPE Insert + Safety Screw
- ✓ ANTILUXATION UHMWPE Insert + Safety Screw
- ✓ UHMWPE Femoral Bush Sleeve (SMALL, MEDIUM, LARGE)
- ✓ MICROLOY® Femoral Bush Sleeve
- ✓ MICROLOY® ANTILUXATION Femoral Bush Sleeve .

Procedure for replacement of the Tibial Polyethylene Insert :

- ✓ The tibia is dislocated anteriorly by positioning a retractor and levering on the femur, taking care to protect the femoral prosthesis to avoid any damage to the articular surface.
- ✓ Unlock the *Safety Screw* of the *Articular Insert* by means of the appropriate screwdriver (Torx or Hexagonal) and remove the damaged insert by levering anteriorly using an osteotome.
- ✓ Replace the *Articular Insert* and lock it with the provided *Safety Screw*;
- ✓ Engage the tibial pivot into the femoral hinge and proceed with the joint reduction.

WARNING: replacement od these components requires use of proper instruments supplied on request.

Use of improper instruments should be avoided.

Fig. 11.1

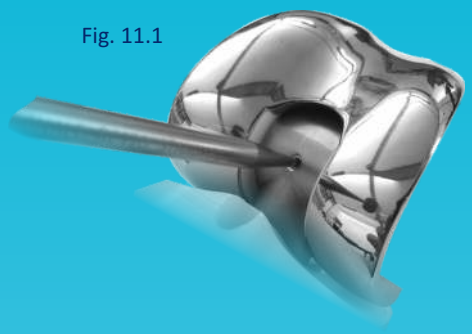


Fig. 11.2

Fig. 11.3

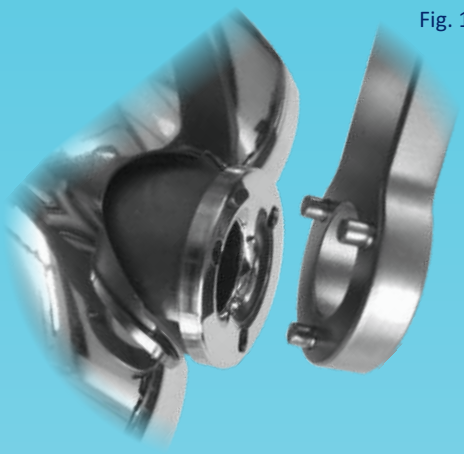


Fig. 11.4

Procedure for replacement of the Polyethylene Sleeve of the hinge:

The polyethylene femoral sleeve can be replaced only on the GKS Butterfly prosthesis intended for this type of nut, and therefore GKS Butterfly e GKS Butterfly BIOLOY standard type.

- ✓ The joint is exposed and, with the knee in flexion, the tibial pivot is disengaged from the femoral hinge.
- ✓ Unlock and remove the small screw placed frontally onto the hinge (Fig. 11.1) by means of the appropriate Screwdriver (S60007).
- ✓ Remove the damaged *Polyethylene Sleeve* and replace it with the new one, by means of the appropriate Clamp.
- ✓ Place the new *Polyethylene Sleeve* and screw it completely into the hinge (Fig. 11.2).
- ✓ Re-position the frontal locking screw and lock it with the appropriate Screwdriver (S60007).
- ✓ Engage the tibial pivot into the femoral hinge and proceed with the joint reduction.

Procedure for teh replacement of the MICROLOY® sleeve:

The MICROLOY® metal sleeve can be replaced only on the GKS Butterfly prosthesis intended for metal-on-metal coupling, and therefore only the GKS Butterfly MICROLOY®. To replace the nut proceed as follows:

- ✓ expose the joint and, with the knee in maximum flexion, disengage the tibial pivot from the femoral hinge;
- ✓ remove the MICROLOY® metal sleeve to be replaced (Fig. 11.3-4) using the proper Wrench for Me/Me sleeve (S42016).
- ✓ place the new MICROLOY® metal sleeve and screw it in completely and tighten;
- ✓ Engage the tibial pivot into the femoral hinge and reduce the joint.

NOTE: the MICROLOY® metal sleeve is available in a STANDARD size, fitting all sizes of prosthesis.

Procedure for teh replacement of the MICROLOY® ANTILUXATION Sleeve:

The MICROLOY® ANTILUXATION metal sleeve can be replaced only on the GKS Butterfly prosthesis intended for metal-on-metal coupling and ANTILUXATION insert, and therefore only the GKS Butterfly MICROLOY® ANTILUXATION. To replace the sleeve proceed as follows:

- ✓ expose the joint and, with the knee in maximum flexion, disengage the tibial pivot from the femoral hinge;
- ✓ unlock the safety screw of the polyethylene *Tibial Insert* using the Screwdriver tip of the Tightening Wrench (S42019)
- ✓ remove the polyethylene insert by levering anteriorly with an osteotome;
- ✓ with the knee in maximum flexion, disengage the tibial pivot from the femoral hinge;
- ✓ remove the MICROLOY® ANTILUXATION metal sleeve to be replaced (Fig. 11.3-4) using the proper Wrench for Me/Me sleeve (S42016).
- ✓ place the new MICROLOY® ANTILUXATION metal sleeve and screw it in completely and tighten;
- ✓ Engage the tibial pivot into the femoral hinge and reduce the joint, then proceed as described in chapter 8 of this technique (pag. 17).

NOTE: the MICROLOY® ANTILUXATION metal sleeve is available in a UNIVERSAL size, fitting all sizes of prosthesis.

ATTENTION: MICROLOY® ANTILUXATION femoral sleeve and the correnspondant ANTILUXATION polyethylene insert (of the correct size and side) can be used onto the standard Butterfly MICROLOY® version to provide ANTILUXATION properties.

SPECIAL WARNINGS FOR USE OF BUTTERFLY MICROLOY® BIOLOY®

Use of the prosthesis providing MICROLOY® metal sleeve femoral hinge is mainly indicated in particularly young and active patients for whom the tribological performances of the metal-on-metal coupling can guarantee improved duration of the device, or in those cases when - in surgeon's opinion - the patient clinical situation could lead to an early wear of the polyethylene femoral nut.

Use of a prosthesis with MICROLOY® metal-on-metal coupling between the femoral hinge and the tibial pivot is not suitable in patients with hypersensitivity to metal ions. In those patients use of GKS Butterfly BIOLOY should be preferred.

Use of a BIOLOY® type prosthesis is particularly indicated for those patients for which a low metal ions release is requested.

NOTE: at the long term reliability of such barrier effect is not known and cannot be guaranteed, it is at surgeon's responsability the choice of use TiNbN coated components in those patients reporting hypersensibility to metals (i.e. Nichel) and the definition of a post-operative monitoring to check the absence of inflammatory phenomema.

GKS Butterfly BIOLOY® is intended to be used with special Titanium stems. Do not use GKS Butterfly BIOLOY® with Cobalt Chrome or Stainless Steel stems.

APPENDIX 1 INTRAMEDULLARY TIBIAL RESECTION GUIDE

Using the Starter Drill Ø 8mm (S40010) supplied with the GKS instrumentation the upper tibia is drilled (Fig. 1), paying attention to keep an axial direction in both planes.

The Intramedullary Alignment Rod (S59103/104) fitted on the I/M Rod Handle (S59100) is carefully inserted into the medullary canal (Fig. 2).

The I/M Rod Handle is removed and the I/M Connection Slide, previously assembled with the I/M Rotating Guide, is inserted in the I/M Rod protruding from the tibia (Fig. 3).

By adjusting the traslation knobs (1) and (2) the Tibial Cutting Guide may be positioned in order to place it on the anterior margin of the tibia (Fig. 4).

It is now possible to check the correct axial placement of the Tibial Cutting Guide, by introducing the External Alignment Rod (S40040) into the anterior bush of the guide and verifying its correspondence to the center of the *Talus* (Fig. 5).

If a wrong positioning of the device is detected - with angular deviations of the resection plane - the alignment may be adjusted simply by loosening the lower knob (3) of the Rotating Guide and by rotating the External Alignment Rod until it is on the same line as the center of the talus, thus automatically correcting the Tibial Resection Guide orientation.

The only caution to be taken in using this alignment option is to verify carefully the ortogonal placement of the Tibial Resection Guide, prior to correct its orientation: it should not be intra nor extra-rotated (Fig.6).

Fig. 1

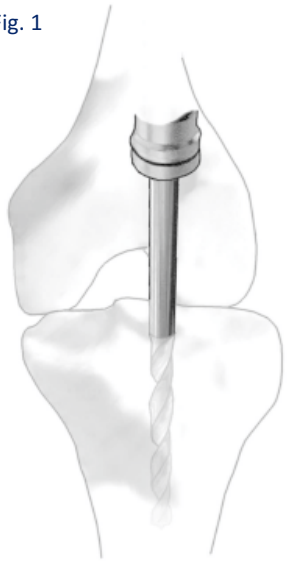


Fig. 2

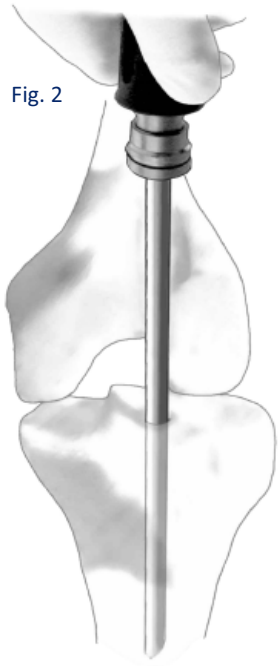


Fig. 3

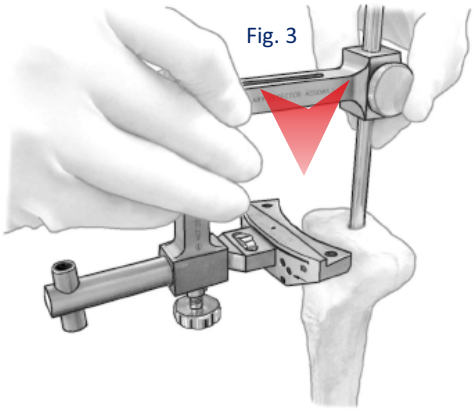


Fig. 4

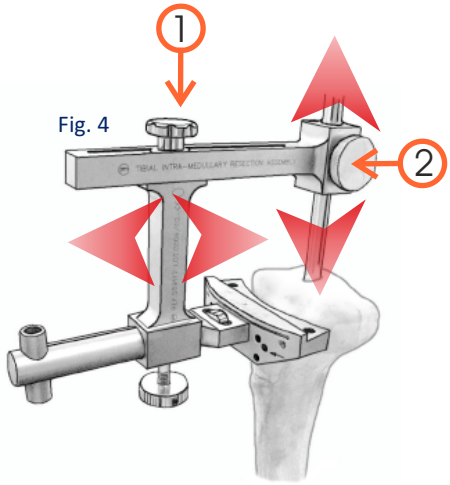


Fig. 5

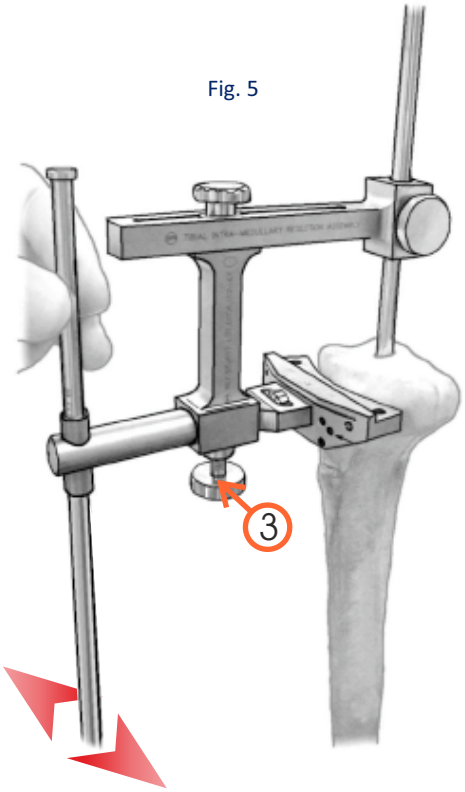


Fig. 6

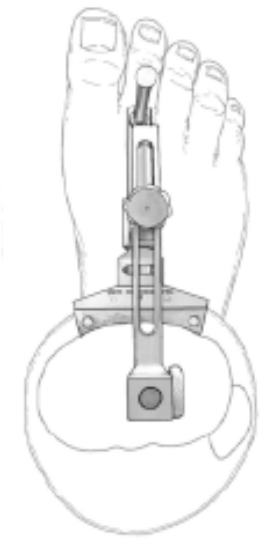


Fig. 7

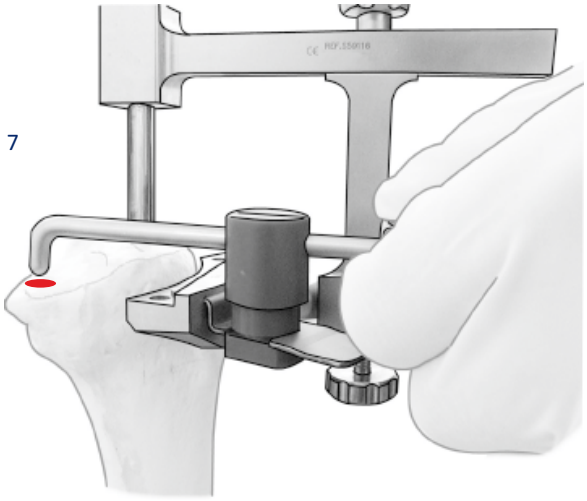


Fig. 8

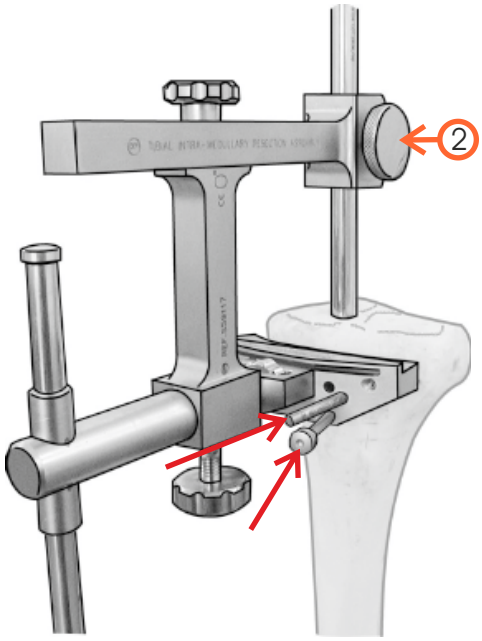


Fig. 9

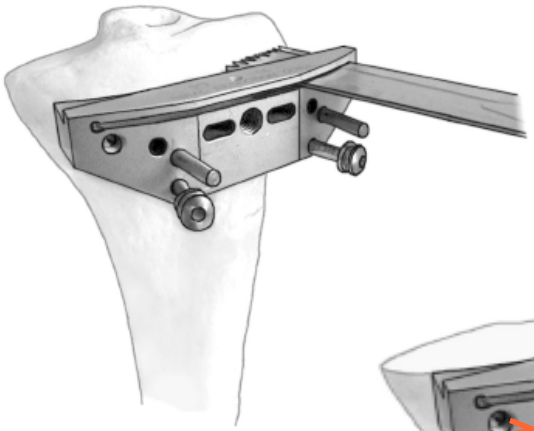
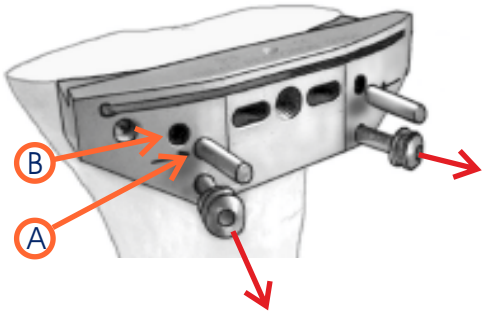


Fig. 10



The correct level of the tibial resection is determined by positioning the Tibial Resection Stylus (S59106) into the slot of the *Cutting Guide* and adjusting the level until it's tip will touch the articular surface (Fig. 7).

The Stylus can be used in two positions:

- by inserting the stylus blade marked "2mm" a resection of 2mm below the tip contact will be achieved. This should refer to the lowest point of the most damaged tibial condyle.

- by inserting the stylus blade marked "10mm" a resection of 10mm below the tip contact will be achieved. This should refer to the lowest point of the most preserved tibial condyle.

The optimal resection level is achieved by loosening the locking knob (2) and consequently adjusting the level of the device.

Once the optimal resection level is determined, two Guide Pins-Long (S40074) are introduced into the parallel holes indicated by arrow landmarks (Fig. 8). This will allow the repositioning of the Tibial Cutting Guide whenever a re-cut should be necessary (see step 6).

A Fixation Pin of appropriate length is introduced into one of the lower converging holes to secure the device to the tibia.

Remove the Alignment Guide leaving the only Cutting Guide in place, and proceed with the tibial resection (Fig. 9) using an oscillating saw blades with length between 80 and 100mm, 1,27mm maximum cut thickness.

After the resection has been carried out it is possible to take off the Cutting Guide by pulling off the Fixation Pins (Fig. 10) using the Pins Extractor (S40026) leaving the Guide Pins in place.

A 2,5mm re-cut may be executed by lowering the Tibial Cutting Guide:

remove it by sliding it on the parallel Guide Pins (A) and reposition it into the more proximal holes (B).

APPENDIX 2 PATELLA PREPARATION

ATTENTION:

The Patella Instruments are not provided with the standard Instruments Set but supplied as optional.

To check out the analitical composition of the GKS BUTTERFLY Instruments Set please reter to the following documents:

SSPE016 Instruments Technical Sheet GKS BUTTERFLY

The GKS PRIME FLEX dome shaped patellar prosthesis is available in 6 sizes (28, 30, 32, 34, 36 and 38mm).

The articulating surface of the patella is resected by means of the oscillating saw (Fig. A), removing about 8/9mm of bone to be replaced by the prosthesis.

The Patella Clamp (S40055) is posistioned onto the resection, slightly medialized and with the handle laying externally and ortogonal to the main axis of the limb (Fig. B).

The Clamp is then equipped with the Patella Drill Guide (S40091). Its correct positioning is guided by a pin; the Patella Drill Bit (S40066) is used to drill the holes for the pegs of the prosthesis (Fig. B).

The Patella Clamp is removed and the Trial Patella of the selected size is positioned in order to evaluate the effectiveness (Fig. C).

The definitive *UHMWPE Patella* can now be cemented: the Patella Clamp is used upside-down to press the prosthesis while bone cement is hardening (Fig. D).

Fig. A

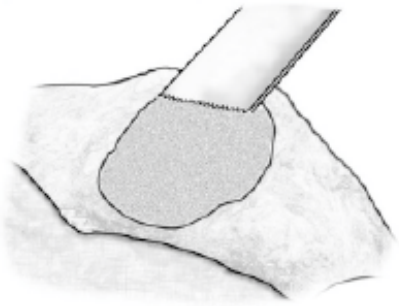


Fig. B

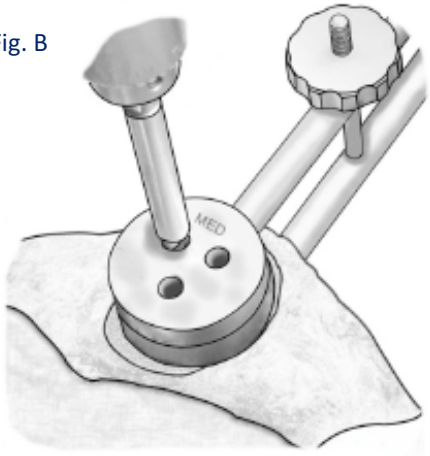


Fig. C

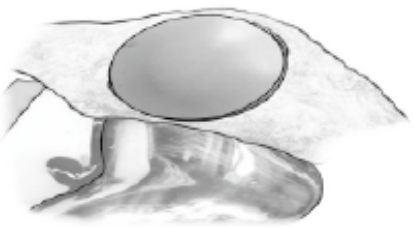
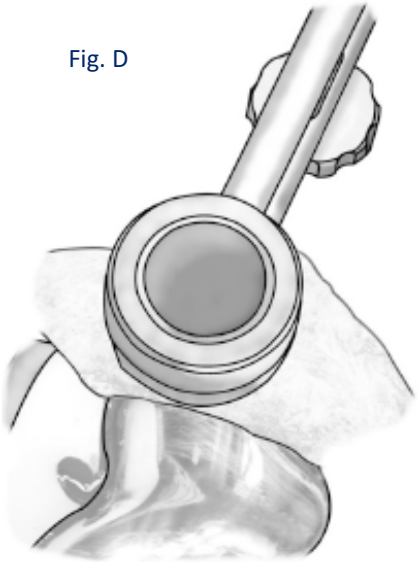


Fig. D



GKS BUTTERFLY Femoral-Tibial components

Size	Side	STANDARD PRIMARY reference	STANDARD REVISION reference	BIOLOY® PRIMARY reference	BIOLOY® REVISION reference	MICROLOY® ANTILUXATION PRIMARY reference	MICROLOY® ANTILUXATION REVISION reference
Small	RIGHT	40601	40101	40701	40201	40901	40401
	LEFT	40602	40102	40702	40202	40902	40402
Medium	RIGHT	40603	40103	40703	40203	40903	40403
	LEFT	40604	40104	40704	40204	40904	40404
Large	RIGHT	*40605*	*40105*	*40705*	*40205*	*40905*	*40405*
	LEFT	*40606*	*40106*	*40706*	*40206*	*40906*	*40406*

GKS BUTTERFLY - Cemented Stems

Length	CrCo reference	BIOLOY® reference
40 mm	41004	41520
90 mm	41509	41521
105 mm	41530	41524
160 mm	41536	41525

Centralizers Ø	reference
12mm	42012
15mm	42015

GKS BUTTERFLY - Press-fit stems

Length	Ø 14mm reference	Ø 15mm reference	Ø 16mm reference	Ø 17mm reference	Ø 18mm reference
45 mm	42401	42501	42601	42701	42801
100 mm	42402	42502	42602	42702	42802
125 mm	42403	42503	42603	42703	42803
175 mm	42404	42504	42604	42704	42804

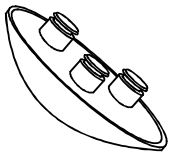
GKS BUTTERFLY - Tibiali Augmentations

Thickness	PM734 SMALL reference	PM734 MEDIUM reference	PM734 LARGE reference	BIOLOY® SMALL reference	BIOLOY® MEDIUM reference	BIOLOY® LARGE reference
5mm	43301	43302	*43303*	43601	43602	*43603*
10mm	43401	43402	*43403*	43701	43702	*43703*
15mm	43501	43502	*43503*	43801	43802	*43803*

AUGMENTS SCREWS

Length	reference
8mm	45008
23mm	45023

GKS PRIME FLEX Patella



size Ø	reference
28mm	53028
30mm	53030
32mm	53032
34mm	53034
36mm	53036
38mm	53038

GKS BUTTERFLY - Tibial Hemi-augmentations

Thickness	PM734 MEDIAL RIGHT - LATERAL LEFT SMALL reference	PM734 MEDIAL RIGHT - LATERAL LEFT MEDIUM reference	PM734 MEDIAL RIGHT - LATERAL LEFT LARGE reference	BIOLOY® LATERAL RIGHT - MEDIAL LEFT SMALL reference	BIOLOY® LATERAL RIGHT - MEDIAL LEFT MEDIUM reference	BIOLOY® LATERAL RIGHT - MEDIAL LEFT LARGE reference
10mm	44201	44203	*44205*	44202	44204	*44206*
15mm	44301	44303	*44305*	44302	44304	*44306*

SPARE PARTS

FEMORAL HINGE SLEEVES

UHMWPE

Size	reference
SMALL	46908
MEDIUM	46909

MICROLOY®

Unique size	reference
Standard	46910
Antiluxation	46923

UHMWPE TIBIAL INSERT + Locking Screw

STANDARD

Side	SMALL reference	MEDIUM reference	LARGE reference
RIGHT	46901	46903	*46905*
LEFT	46902	46904	*46906*

ANTILUXATION

Side	SMALL reference	MEDIUM reference	LARGE reference
RIGHT	46917	46919	*46921*
LEFT	46918	46920	*46922*

Information

INTENDED PURPOSE:

GKS BUTTERFLY is a tri-compartimental gliding knee prosthesis stabilized on all planes to be used in Total Knee Replacement surgeries. Use of the device is indicated in cases of revision due to failure of previous arthroplasties, correction of severe axial deviation in varus/valgus and/or severe joint instability. Fixation of the device onto the bone is achieved by means of bone cement; this can be total (using cemented intramedullary stems) as well as partial (using press-fit stems) whenever intramedullary cement filling is not desired.

MATERIALS:

FEMUR/TIBIA components: *Cobalt Chromium alloy - ISO5832/4;*
CEMENTED STEMS: *Cobalt Chromium forged alloy - ISO5832/12;*
TIBIAL AUGMENTS: *PM734 highly Nitrogenized Stainless Steel forged alloy - ISO5832/9*

The device contains percentages of ferromagnetic materials that could be affected by the magnetic fields generated by diagnostic radiology equipments such as Magnetic Resonance Imaging (MRI).

PRESS-FIT/BIOLOY STEMS - BIOLOY TIBIAL AUGMENTS: *Titanium Aluminium Vanadium alloy - ISO5832/3;*
INSERTS / PATELLA: *UHMWPE without calcium stearate - ISO5834/1/2;*

The devices DOES NOT CONTAIN any ferromagnetic materials.

SURFACE FINISHING:

Articular surfaces: achieved through MICROLOY® *process; roughness in compliance with ISO 7207-2 .*

Bone/Prosthesis contact surface: pelleted with glass beads, with depressions for even acrylic bone cement spreading;

STERILIZATION:

Method: accelerated electron beam irradiation (b rays - nominal dose 25 kGy) in vacuum.
Validità: 5 years

CLASSIFICATION:

Class III *or* ***Class IIb*** *as reported in Directive 2005/50/CE (and related D.lgs 26 april 2007 n.65) concerning re-classification of Hip, Knee and Shoulder joint prostheses which modifies classification criteria of Annex IX of Directive 93/42/CEE and next integrations and amendements.*

NOTES

Warning

Before using a product introduced onto the market by permedica spa, the surgeon is encouraged to carefully study the following recommendations, warnings and instructions as well as the specific product information (surgical techniques and technical product description). **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility**.

Definition

Articular Prosthesis: implantable medical device, including implantable components and materials that is in contact with the surrounding muscle and bones, and carries out functions similar to those of a natural articular joint.

General information

A joint prosthesis should only be considered if all other therapeutic possibilities have been carefully weighed and found unsuitable or inappropriate.
A joint prosthesis, even if successfully implanted will be inferior to a natural, healthy joint. Conversely for the patient, a joint prosthesis can be a beneficial replacement for a severely altered, pathological joint, eliminating pain and restoring good mobility and bearing capacity.
Every artificial joint is subject to unavoidable wear and ageing. Over the course of time, an artificial joint initially implanted in a stable manner can loosen therefore limiting or impairing perfect functionality. Wear, ageing and loosening of an implant can lead to reoperation.

Indications for Use

The following are the general guidelines for the use of prosthetic devices produced by permedica**. For more detailed information refer to the Product Technical Sheet and Surgical Technique of the specific device:**

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic dieases.
- Fractures or avascular necrosis.
- Negative outcome of previous surgeries such as joint reconstruction, osteotomies, arthrodesis, hemi-arthroplasty or total hip prosthesis, total knee prosthesis.

Use of this prosthetic device for reasons other than those prescribed is not permitted.

Controindications

Infections or other septic conditions in the area surrounding the joint, as well as allergies to the implanted material, (cobalt, chrome, nickel, etc) represent absolute contraindications.
Relative factors that could compromise the success of the intervention are:

- Acute or chronic local or systemic infections, even far from the implant site, (risk of haematogenous diffusion of the infection towards the site);
- Insufficient bone structure at the proximal or distal level of the joint that does not guarantee good anchorage of the implant.
- Severe muscular, neural or vascular diseases that endanger the extremities involved.
- Overweight or obesity.
- Osteoporosis.
- Hypertrophy of the muscular tissue surrounding the joint.
- Metabolic disorders or lack of sufficient renal functions;

The patient must also be:

- Capable of understanding and following the doctor's instructions;
- Avoid excessive physical activity such as heavy work or competitive sports that involve intense vibration, jerking motions or heavy loading;
- Avoid excessive weight gain;
- Avoid drug abuse, including nicotine and alcohol.

General Information and precautions for the safe use of the implant

Products of permedica Spa may be implanted only by surgeons who are familiar with the general problems of joint replacement, with implant devices, the surgical instruments and who have mastered the product-specific surgical techniques.
Prostheses and prosthesis parts are always components of a system, and therefore must be combined with original parts belonging to the same system. Note must be taken of the system compatibility according to the 'Product Technical sheet' and/or 'Surgical Techniques.' Prostheses and prosthesis parts from permedica Spa - in particular BIOLOX ceramic components - must never be combined with parts from other manufacturers. permedica excludes all liability for the negligent use of its implants with those of other manufacturers. Specific instruments are available for the implant devices of the various articular prostheses. Improper use of these instruments can cause poor positioning of the implant components. permedica Spa excludes all liability for the negligent use of its instrumentation or the use of that of third parties.
It is forbidden to re-utilize a prosthesis or a prosthesis part that was previously implanted in the body of a patient or another person, or to re-utilize an implant that has come into contact with the body fluid or tissue of another person, or where the mechanical integrity (superficial, geometrical, or biological) cannot be guaranteed. They are single-use devices.
Implants must be stored in their original packaging. Before implantation they must checked for defects such as micro scratches or marks (can cause excessive wear or complications) on the articular surface. And therefore must be handled with extreme attention.
Coated prosthetic components, in particular those coated with Hydroxyapatite, should be handled with extreme care avoiding damage to the surface coating. Contact of prosthetic components coated with Hydroxyapatite with anything other than the original package, clean surgical gloves and patient tissue should be avoided. Hydroxyapatite coated implants should never be cemented, instead should be implanted via 'press fit' method. Hydroxyapatite cannot be substituted with cement nor can it rectify insufficient primary stability.
TiNbN coating acts as an isolation barrier for the release of ions by the surrounding metallic materials. Since the long term duration of this barrier is not known, it cannot be guaranteed and therefore, it is up to the surgeon to determine if the use of TiNbN coated prosthetic components is indicated for patients with noted allergenic sensibility towards metal (nickel) and should carry out the requisite postoperative monitoring for inflammation or allergenic development.
Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long-term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences can not be guaranteed. It is therefore not recommended the of use this joint coupling in female patients of childbearing age and/or people with compromised kidney function.
Literature reports possible adverse reactions caused by elevated blood levels of metal ions in patients with metal-on-metal prosthetic joint surfaces. Long-term systemic effects due to the accumulation of these ions are not known and therefore long term clinical consequences can not be guaranteed. It is therefore not recommended the of use this joint coupling in female patients of childbearing age and/or people with compromised kidney function. Before reduction or assembly, articulating or combined prostheses and prosthesis parts must be thoroughly cleaned; contamination, I.e. foreign particles, bone chips or residues of bone cement, can lead to third-body abrasion, incorrect functioning or fracture of the prosthesis or prosthesis parts.
Joint prosthesis must not be mechanically worked or changed in any way, unless this is expressly envisaged in the design and surgical technique. In case of doubt, recommendation must be obtained in writing from the manufacturer. The surface of the prosthesis must not bear any writing nor be allowed to come into contact with metallic or other hard objects (especially in the case of ceramic implants), unless this is expressly envisaged by the of the 'Surgical Technique' description. Prostheses or prosthesis parts that are contaminated, nonsterile, damaged, scratched or have been improperly handled or alterated without authorization must not be implanted under any circumstances. Reliable seating of femoral cone-ball head combinations is only possible with the completely intact surface of the ball head cone and intact surface of the femoral stem cone. It is absolutely essential that the outer cone of the femoral stem fits perfectly with the inner cone of the ball head. The cone size is indicated on the product label and on the implant itself.
Protective caps or other protective devices must be removed immediately before use. The instruments are inevitably subject to a certain degree of wear and ageing, rarely there could be interoperative breakage, especially if over utilized or misused. permedica recommends verification for breakage, deformation, corrosion and correct functioning, before use. In the case of damage, the instruments must not be utilized but returned to the manufacturer for substitution.
Observation of any additional information to that reported on the information label applied to the primary packaging and/or the secondary packaging relative to the indications for use is encouragement. Complications or other factors that may occur for reasons such as incorrect indication or surgical technique, unsuitable choice of material or treatment, inappropriate use or handling of the instruments, and/or sepsis fall under the responsibility of the operating surgeon and cannot be blamed on the manufacturer.

Possible side effects

The following are among the most frequent possible side effects of implantable devices:

- pain;
- bone fractures due to overloading on one side or weakened bone substance;
- allergy to the implanted material, mainly to metal. This signifies the necessity of ulterior study. Implants made of extraneous material can provoke the formation of histocitosy and consequently osteolysis;
- allergic reactions;
- metalysis and consequent osteolysis in particular for implants with metal/metal surfaces;
- prosthesis or prosthesis parts can fracture or loosen as a result of overloading, non-physiological stresses, and superficial damage;
- prosthesis or prosthesis parts can fracture or loosen as a result of incorrect manipulation or improper implantation *(wrong choice of implant component or size,* improper alignment, incorrect fixation);
- excess wear or loosening of the implant due to breakdown of the osseous bed;
- loosening of the prosthesis due to changed conditions of load transfer (cement disintegration or breakage and/or tissue reactions) or to early or late infections;
- dislocation, subluxation, insufficient range of movement, undesirable shortening or lengthening of the extremity involved due to less than optimal positioning of the implant;
- Inter operative or post operative complications:
  - perforation or fracture of the bone segments;
  - vascular lesions;
  - temporary or permanent nerve lesions that can cause pain and numbness throughout the limb;
  - inter-operative Arterial Hypotension during the cementation;
  - varus or valgus deformity;
  - cardiovascular disturbance including vein thromboses, pulmonary embolism and myocardial heart attack;
  - haematoma;
  - late wound healing;
  - infection.

Pre-operative Planning

Failure to carry out proper preoperative planning can lead to errors (i.e. in regards to candidate selection, type of prosthesis, and correct implant size). The operation should be precisely planned on the basis of the x-ray findings. Testing for eventual allergies to implant component materials should be established.
X-rays templates provide important information on the suitable type of implant, its size and possible combinations. All types of implants and implant parts in the combination recommended by the manufacturer that may possibly be needed for the operation, as well as the instruments needed for their implantation, must be available in case another size or another implant is required. Most prosthesis components are supplied with test or trial parts for the measuring of the size to be implanted.

Patient Information

The doctor must explain the risks involved in the implantation of an endoprosthesis, possible side effects, and intrinsic limitations of the implant as well as the measures to undertake in order to reduce the possible side effects. In particular, the patient should be informed about the impact that the implant will have on his/her lifestyle, and that the prosthesis longevity could depend also on factors such as body weight and level of physical activity. Other factors regarding metal implant devices that should be communicated are:

- can affect the result of computer tomography (CT);
- can be detected by metal detectors;
- in the case of cremation, removal could be required depending on local regulations.

Il The patient should be informed that, whenever the implanted device contains ferromagnetic materials (such as stainless steel or Cobalt Chrome alloys), it is not advised to undergo radiodiagnostic investigations based on magnetic fields (MR scan).

Sterility

General considerations
Implantable devices supplied by permedica spa in a sterile state must remain closed in the original protective packaging until the moment of implantation. Before utilizing the implant, certain controls should be carried out:

- o verify sterility expiration date (month/year) on the label of the product;
- o visually verify that the internal packaging and the label are intact;
- o visually verify that the sterile primary packaging is integral and does not present breakage, tearing, holes or other types of damage.

If the sterile primary package is damaged or the implant or the implant supplied by permedica spa is in a non sterile state, refer to the paragraph "Resterilization.
Ceramic or metal implantable devices
Ceramic or metal implantable devices are supplied sterilized by irradiation of 25 kGy.
Plastic implantable devices
Plastic implantable devices are supplied sterilized by irradiation of 25 kGy or by ethylene oxide. The label of each implantable device specifies the method utilized for sterilization.

Resterilization

If a medical implant device supplied by permedica spa is sterilized or resterilized by the user, this is to be noted in the corresponding patient documentation (i.e. operation report), and must be conserved with the respective accompanying documents. Components can be resterilized provided that they have not come into contact with body fluid, bone and have not previously been implanted.
Validation of the cleaning and sterilization procedures, as well as the proper setting for the corresponding equipment must be checked regularly.
Ceramic or metal implantable devices
Metal implantable devices can be sterilized by the user, via gas (ethylene oxide) or utilyzing superheat steam or vapour. In the case of resterilization with gas, sufficient time must be allowed for degassing.
BIOLOX ceramic components may be re-sterilized only in exceptional cases and exclusively by permedica spa.
"NON STERILE" metal or ceramic implants must not be sterilized in their original protective packages.
Hydroxyapatite coated or pure Titanium metal implantable devices cannot be sterilized with gas (Ethylene Oxide), instead can be sterilized by superheat steam or vapour..
Plastic implantable devices
Implants made wholly or partly of polyethylene (UHMWPE) or Polymethylmethacrylate (PMMA) must not be resterilized utilyzing superheat steam vapour, nor via irradiation nor via gas (ethylene oxide).
Instruments
All pertinent details regarding the cleaning and sterilization of instruments are supplied in the 'Instructions for the cleaning and sterilization of surgical instruments'. Instruments must be sterilized in the correct packaging via gas or vapour. Vapour sterilization should be carried out at a temperature of 121°C for 20 minutes. The sterilization of instruments made wholly or partly of plastic must not be heated above 121°C. In the case of resterilization with gas, sufficient time must be allowed for degassing.

Implant Materials

The label of each medical implant device carries the data relative to the type of material and surface coating utilized.
Endoprostheses by permedica spa are manufactured with the following materials:

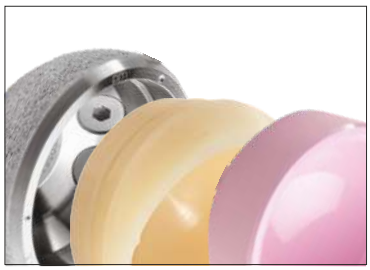
- ❑ Stainless steel 316LVM (normative ISO5832/1)
- ❑ Pure Titanium (normative ISO 5832/2)
- ❑ Titanium alloy Ti6Al4V (normative ISO 5832/3)
- ❑ CrCoMo casting alloy (normative ISO 5832/4)
- ❑ Highly nitrogenized Stainless steel forged alloy – "PM 734" (normative ISO 5832/9)
- ❑ Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- ❑ CrCoMo forged alloy (normative ISO 5832/12)
- ❑ UHMWPE Polyethylene (normative ISO 5834/1 e 2)
- ❑ UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E (VITAL-E)
- ❑ UHMWPE Polyethylene (normative ISO 5834/1) added of Vitamin E and cross-linked (VITAL-XE)
- ❑ Polymethylmethacrylate (PMMA)
- ❑ Alumina based BIOLOX FORTE sintered ceramic (normative ISO6474-1) and BIOLOX DELTA (normative ISO6474-2).

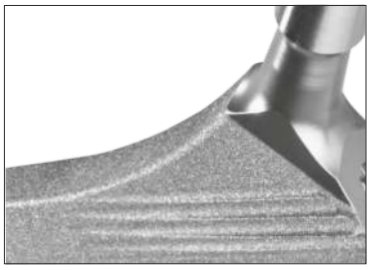
The combination of stainless steel and chrome-cobalt or Titanium implant components can cause corrosion.
The label of the implant carries this warning.
Materials utilised for the surface coating of permedica spa implants are the following:

- ❑ Pure Titanium (normative ISO 5832/2)
- ❑ Hydroxyapatite (norma ISO 13779/2)
- ❑ TiNbN

Custom Made Implant Devices

A custom made implant is foreseen for patients that cannot be fitted with a regular or series implants. This implant is produced as a 'one of a kind' product following the indications of the surgeon and utilyzing a regular implant design. The use of a custom made implant must be evaluated on a case by case basis.
The surgeon must be aware of the limitations inherent in a custom made implant and must take into account the construction and the materials chosen. The surgeon must also have the experience and capabilities necessary for the correct specifications and optimal application of the custom made product. Custom made implants do not have corresponding instrumentation.
Custom made implants are produced utilizing the technical expertise of permedica Spa acquired through series implant design. Because these implants are custom made, there is no clinical nor test data. Risks are higher with custom made products than with series implants. A custom made product must be utilized exclusively for the patient for whom it was designed.





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