permedica
ORTHOPAEDICS

PRIME *FLEX*

Knee System

SURGICAL TECHNIQUE

CE
0426

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 PRIMEFLEX ATTITUDE 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.

G.K.S. PRIME *FLEX*
Knee System

GLOBAL KNEE SYSTEM

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 PRIME *FLEX* represents the evolution of the PRIME range providing MOBILE BEARING and FIX BEARING options, preserving or sacrifying the Posterior Cruciate Ligament.

GKS PRIME *FLEX* Mobile BIOLOY®

The femoral component provides 10 anatomical sizes in Cobalt Chromium Molibdenium alloy available in both cemented or cementless option (with porous Titanium and HA coated bone contact surfaces) even with ***BIOLOY®*** coating.

The tibial component comes in 7 sizes made of Titanium Aluminium Vanadium alloy*, available in both cemented or cementless option (with **HaX-Pore** porous Titanium and HA coated bone contact surfaces).

The UC ultra-congruent joint liner refers to the femoral component and comes in 5 thicknesses for each size. It is made of UHMWPE and also available in ***VITAL-E®*** (UHMW PolyEthylene added with antioxidant Vitamin E).

** Also available in CrCoMo alloy.*

GKS PRIME *FLEX* Mobile BIOLOY®

GKS PRIME *FLEX* CR

PRIME *FLEX* is the fixed bearing version designed for Posterior Cruciate Ligament preservation. The femoral component is the same of the Mobile bearing version.

The TOP Tibial component comes in 10 sizes made of Titanium Aluminium Vanadium alloy available in both cemented or cementless option (with porous Titanium and HA coated bone contact surfaces).

The joint liner is available in 5 sizes (each size matching with 2 sizes of Tibia). It is made of UHMWPE and also available in ***VITAL-E®*** (UHMW PolyEthylene added with antioxidant Vitamin E). It refers to the TIBIAL component and comes in 5 thicknesses for each size in two types:

CR preserving the Posterior Cruciate Ligament

AS Anterior-Stabilized, anatomically shaped with a high medial anterior lip that avoids posterior slipping of the tibia when the PCL functions are compromised.

GKS PRIME *FLEX* CR

GKS PRIME *FLEX* PS

The CrCoMo femoral component is available in 10 anatomical sizes both in ***MICROLOY®*** and ***BIOLOY®*** version and for cemented application only.

The Titanium Aluminium Vanadium alloy Tibial component is available in both cemented or cementless option (with **HaX-Pore** porous Titanium and HA coated bone contact surface). It is characterized by a symmetrical plate supported by a central flange with conical body and lateral wings. It comes in 10 sizes divided into 5 colour coded groups each one fitting with 1 insert size.

The joint liner is made of UHMWPE also available in ***VITAL-E®*** version (UHMW polyethylene added with antioxidant Vitamin E). It is designed to allow a wide Femur/Tibia pairing guaranteeing for each femoral size the coupling with 6 tibial sizes. Each size of insert fits with 2 sizes of Tibial Plate and is available in 5 thicknesses (refer to the tables at the end of this Surgical Technique).

GKS PRIME *FLEX* PS

Section 1°

General principles for Total Knee Replacement

KNEE PROSTHESIS IMPLANTATION:
GENERAL GUIDELINES

One of the most important aspects for the correct implantation of a knee prosthesis is a thorough understanding of the principles on which the use of the instrumentation is based. This implies knowledge of the type of alignment that the instruments refer to and how that type of instrument conducts itself through the various stages up to the positioning of the prosthesis and asists the Surgeon in obtaining proper ligaments balance.

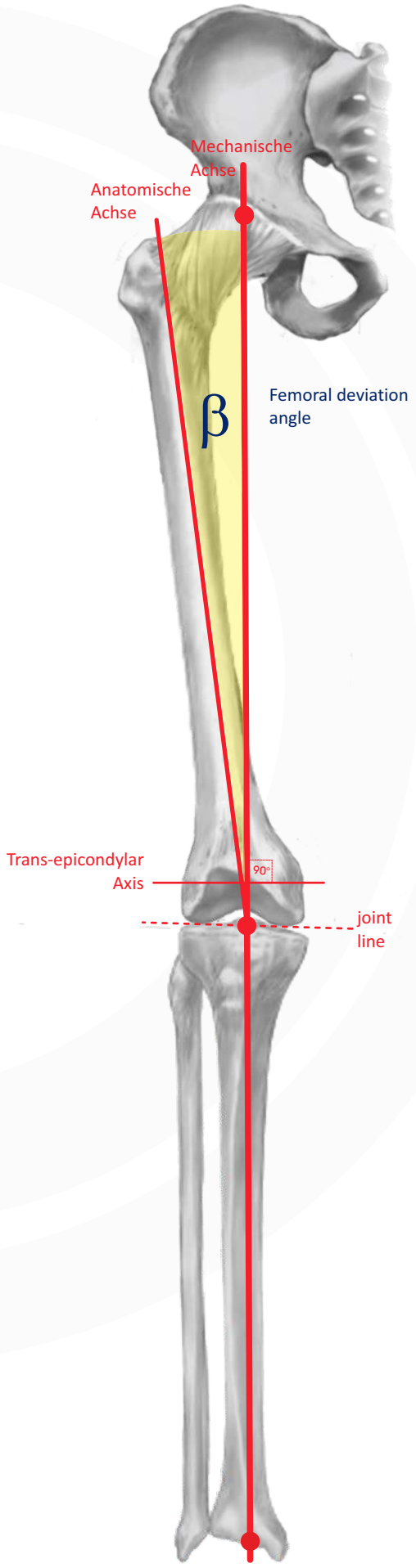
In addition to the use of the standard instrumentation, the knowledge of alternative techniques is also required, so they may be used as variations to the standard procedure or in the absence of precise reference points which can occur in cases of anatomical variability.

A correctly implanted knee prosthesis should restore a normo-aligned valgus knee in standing position, allowing a range of motion from 0 ° to around 125°, keep the patella gliding centrally on the trochlea throughout the full range of motion, and finally, present a proper balancing of the ligaments in full extension and flexion.

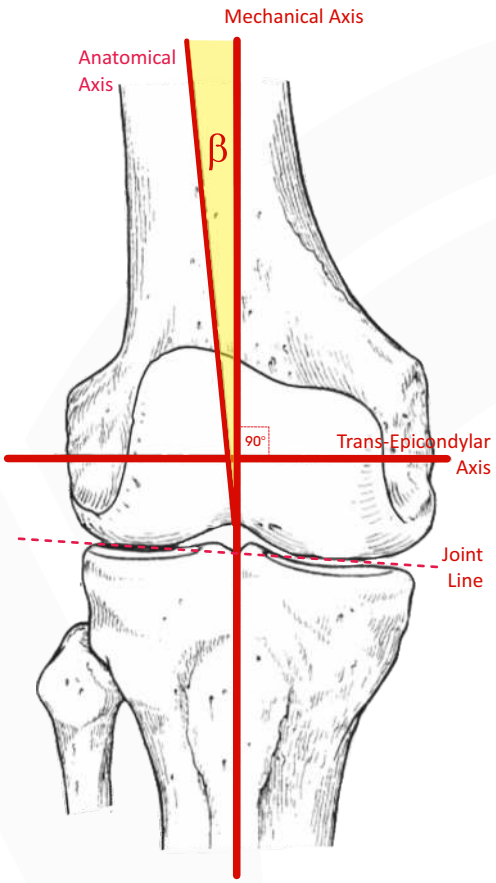
In most cases a knee which is affected by arthrosis, or by problems and pathologies that would require an arthroplasty intervention, there are usually also present severe alterations at both the bone and the ligament level. Total Knee Replacement surgery should therefore provide, by the implanting of prosthetic components, an initial recovery period to allow for the correct conformation of the involved bone ends into a proper geometric relationship to the main referring axes, and following that, a period to re-balance the "soft tissues", ie ligaments, capsule and muscles.

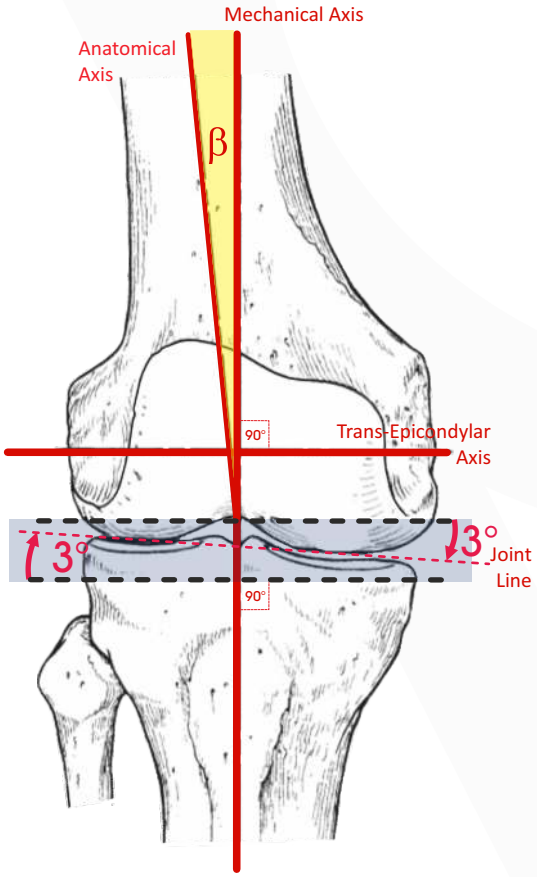
The prosthesis must in fact be **properly aligned** with the bony parts and **properly balanced** with the musculo-ligamentous structures. For this reason it is necessary in the first instance **align the resection cuttings to the bone structures without considering the ligaments (alignment of the implant) and only in a second time balance the ligaments (ligament balance). It is conceptually wrong**, in our opinion, **to counterbalance a ligament gap with an anomalous resection or, contrarily to compensate for a deviate bony resection by operating on the soft tissues**, even if the final result of the global alignment of the limb may look the same.

For this reason, in developing the GKS instrumentation, special attention has been dedicated to this apsect of the surgical technique, in order to achieve an extremely flexible and multifunctional system, which allows the Surgeon to change the references when positioning the cutting guides, to accurately determinate the optimal rotational degree of the femoral component, and at the same time to evaluate the quality of the flexion and extension gaps, both before and after the resections.



KNEE PROSTHESIS IMPLANTATION:
GENERAL GUIDELINES





Concerning the **alignment in the coronal plane**, the GKS prothesis uses the "classic" scheme. The target of this scheme is to achieve a joint line perpendicular to the Mechanical Axis.

Remember that in normal conditions the alignment of the lower extremity is generally considered to be correct when the centers of the hip, knee and ankle joints lie on the same line, called the *Mechanical Axis* (MA).

At the leg level the *Mechanical Axis* (MA) corresponds to the *Anatomical Axis* (AA), while in the thigh it forms an angle of 5 - 7 degrees with respect to the femoral axis (**femoral deviation angle**). This angle, indicated as 'Beta angle' defines the physiological valgus condition of the knee. It depends only on the femur geometry, in particular on the length of the femoral diaphysis and on the length, antiversion and angle degree of the femoral neck.

ATTENTION: A normal femoral "Beta angle" can accompany a deviation of the knee in varus and valgus in that the two parameters are independent of one another.

In the tibia, the *Anatomical Axis* (AA) coincides with the *Mechanical Axis* (MA) of the lower limb.

The femoral trochlea is aligned with the *Mechanical Axis* of the inferior limb and is perpendicular to the *Trans-Epicondylar Axis* (TEA), which is the axis that connects the two epicondyles of the knee, from which comes the flexion-extension movement. This *Trans-Epicondylar Axis* is perpendicular to the *Mechanical Axis* of the inferior limb.

In extension, the joint line (JL), or the plane that has the stress points of the femoral condyle of the tibial surface, is inclined 3° medially.

The **tibial resection** must be carried out perpendicularly to the Mechanical Axis of the lower limb which, as we previously stated, coincides with the Tibial Anatomical Axis. The tibial resection has 3° of valgus in respect to the joint line.

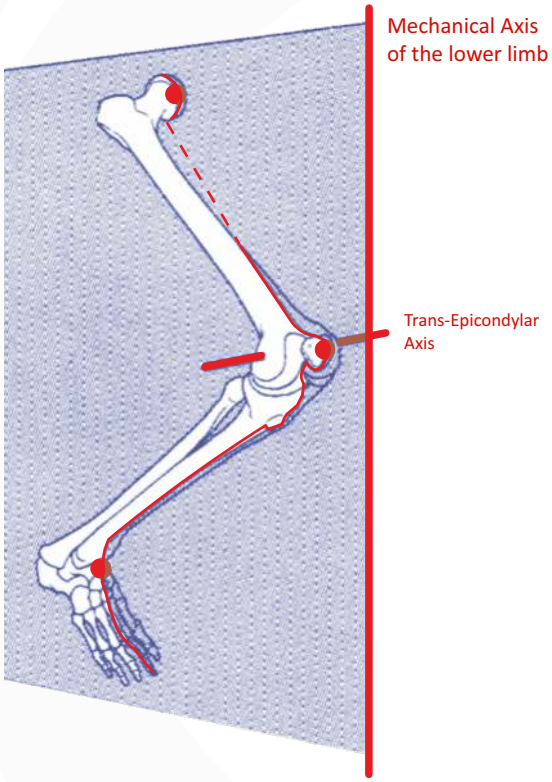
The **femoral distal resection** must also be carried out perpendicularly to the Mechanical Axis which,as we previously stated, has a 5 - 7° valgus in respect to the femoral Anatomical Axis; the resection surface has 3° of varus in respect to the joint line.

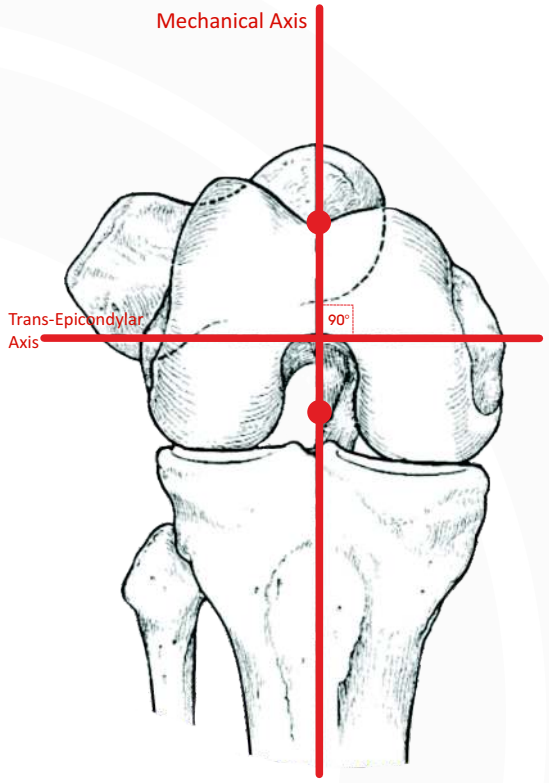
This difference of 3° between the femoral and tibial resections is reciprocally compensated and therefore, the surfaces are parallel between themselves and are both parallel to the Epicondylar Axis.

The Mechanical Axis of the lower limb becomes a plateau where you can see the flexion-extension in a three dimensional way.

In the flexion-extension movement range, the center of the hip, knee and tibial tarsical remain on this same plane. The Femoral trochlea is found on this plane and forms the Anterior-posterior femoral axis (Apf): the patella simply glides on it like a rope on a pulley.

The Trans-Epicondylar Axis is perpendicular to the Anterior-posterior surface, which is none other than a lower limb Mechanical axis reproduction, with the femur flexed at 90° on the tronchlea.



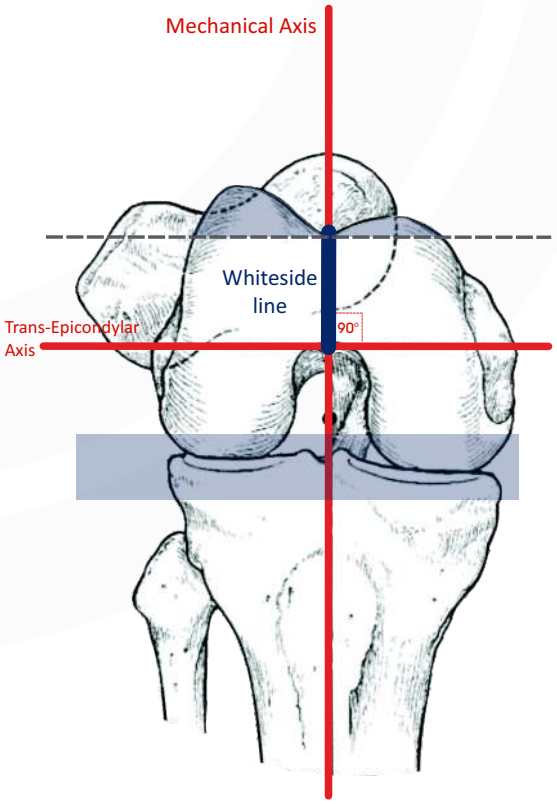


With the knee flexed at 90°, the **tibial** and **femoral anterior and posterior resections** are parallel to the Epicondylar axis and perpendicular to the femoral Anterior-Posterior axis.

*Attention: It is fundamental to achieve an equal and rectangular space between the femoral resections (distal & posterior) the the tibial resections (**extention gap = flexion gap**), in order to equally distribute the forces between the femoral condyle and the tibial hemi plates.*

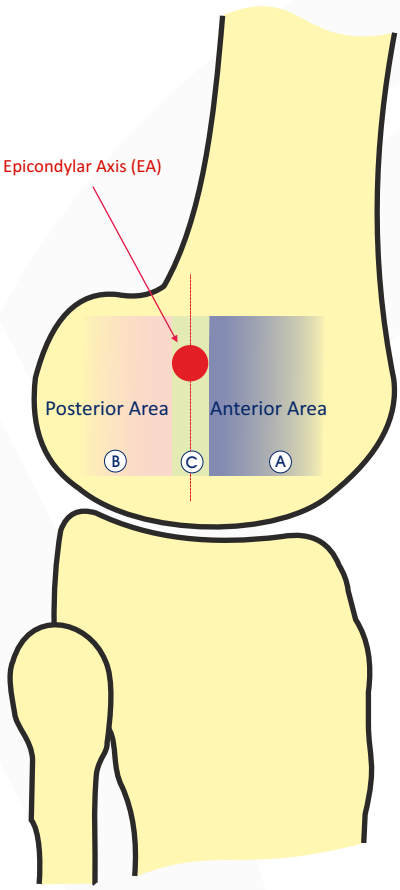
In the sagittal plane the tibial components must take into account the physiological posterior inclination of the joint profile (Posterior slope), specially when the PCL is preserved. This inclination must be restored during the tibial cut, keeping in mind that the GKS polyethylene inserts already have an intrisic 5° inclination.

Attention: to correctly carry out a posteriorly sloped tibial resection, it is necessary to precisely establish the neutral point of rotation before positioning the cutting guides.



KNEE PROSTHESIS IMPLANTATION:

SOFT TISSUE BALANCING GUIDELINES



Once the cuts are made, you can procede with the balancing of the ligaments and the soft tissues. Fundamental to understanding the basic theories of our surgical era is the function of the **Epicondylar Axis** : this is the axis that joins the two epicondylars and which carries out the flexion-extension movement and is always perpendicular to the lower limb mechanical axis at any degree of flexion-extension.

The structures that are inserted **anteriorly to the epicondyles** (area A) tightens in flexion and loosens in extension *(Anterior fibers of the Medial collateral ligament, Anterior Lateral surface of the Posterior cruciate ligament*).

The structures that are inserted **posteriorly to the epicondyles** (area B) tighten in extension and loosen in flexion (*posterior-lateral capsule, ilio-tibial band* for the lateral compartment*; posterior-medial capsule, posterior fiber of the Medial collataral ligament* for the medial compartment).

The structure that is instead inserted **near the epicondyles** (area C) tighten and stabilize the movement for the entire arc of flexion-extension (*lateral tendons of the gastrocnemius, posterior-lateral angle of the capsule, lateral collateral ligament and popliteal tendon* for the lateral compartment; *Medial collateral ligament* for the medial compartment).

By keeping in mind these aspects, the surgeon, after positioning the trial prosthesis can verify the stability of the knee in varus and valgus flexion as well as in extension and procede to a selective release of the excessively tense structures.

Section 2°

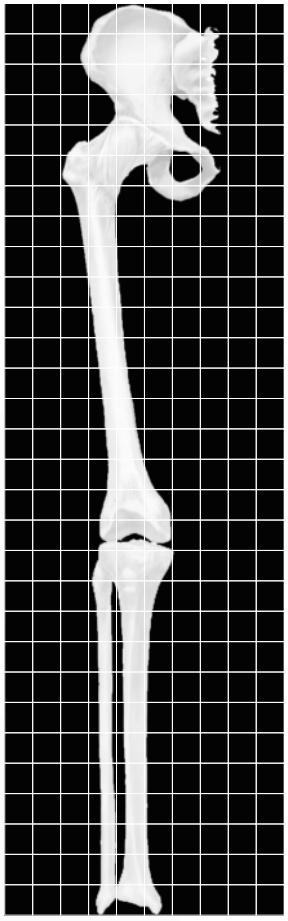
Implantation Procedure

GKS PRIME *FLEX*
- Mobile Bearing
- Fixed Bearing CR
- Fixed Bearing PS

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, wear values and correct implant sizing.



PRE-OPERATIVE PLANNING

Before carrying out a Total knee arthroplasty, a careful evaluation of the clinical case based upon a combined clinical and radiological study is recommended.

Anterior-Posterior and Medial-Lateral radiographs of the entire lower limb allow:

- ✓revelation of the presence of angular varus-valgus deviations with respect to the mechanical axis;
- ✓evaluation of the femoral deviation angle;
- ✓underlining of the presence of extra-articular deviations concerning the femur and/or the tibia;
- ✓revelation of dislocations either in the frontal or in the sagittal plane and/or osteophyte formations that could limit joint mobility.

A careful clinical evalution will allow a better interpretation of complex deformities casued by combined axial and rotational alterations, as well as contractures.

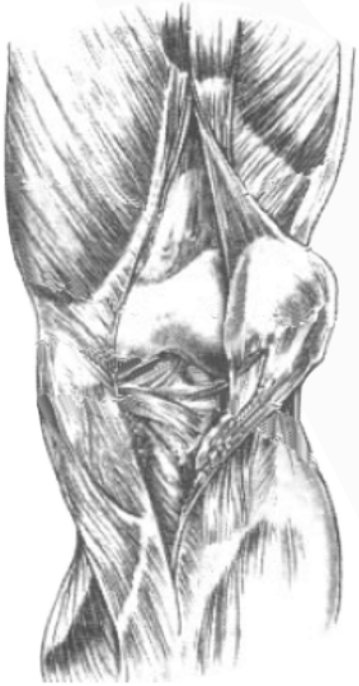
Template overlays could help in identifying the optimal resection level for both distal femur and proximal tibia, as well as the correct centering of femoral and tibial medullary canal during intramedullary rod insertion.

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

SURGICAL ACCESS

For the GKS PRIME *FLEX* prosthetic implants any surgical approach can be used, according to the surgeon's choice, provided that a satisfactory exposure of the femoral condyles and the proximal tibia can be achieved.

The patient is in a supine position, with the limb to be operated on held by the apposite supports, which allow easy access and manueverability in flexion and extension. It is up to the surgeon to apply or not a hemostatic belt to the proximal thigh.



For example purposes, in this surgical technique, we propose a **medial parapatellar** approach with an anterior skin incision vertically over the patella. The skin incision maybe straight or slightly curved, medial to the patella, beginning approximately 6 cm. above the patellar apex and extending down to the tibial tubercle.

In the subcutaneous plane, the incision will run through the quadriceps tendon, or just medial to it, going down following the internal patellar margin and ending at the medial insertion of the patellar ligament. It is advisable to preserve a medial margin on the patella of at least 5mm for suturing.

Laterally dislocate the patella. The mini-invasiveness of the instruments does not necessitate the eversion of the patella.

Once the joint is exposed, the following steps should be taken for cleaning and preparation of the bone extremities for the prosthesis:

- ✓ the knee joint should be exposed and any medial and lateral adhesions should be cleared;
- ✓ the meniscus is removed (in this phase the anterior portion);
- ✓ Removal of the Anterior cruciate Ligament;
- ✓ Removal of any osteophytes from both the femur and tibia margins.

The Posterior Cruciate Ligament must be preserved in case of GKS PRIME *FLEX* CR implantation.

In case of implantation of the GKS PRIME *FLEX Mobile*, having a posterior stabilizing insert thanks to the ultracongruence with the femoral condyles, it is advised to resect the Posterior Cruciate Ligament.

PRELIMINARY NOTES

PINS

The Instruments Set provides 2 types of regular PINS (to be inserted by hammer) in different lenghts:

- ✓ Headless Pins: they have the function of guiding the cutting blocks which offer the possibility of recuts. In the surgical technique they are defined as GUIDE PINS.
- ✓ Headed Pins: they have the function of fixating all cutting blocks. In the surgical techniques they are referred to as FIXATION PINS.

The Pins are also available in "*Fast Drive*" version, with partial thread to be utilized by means of a special Adapter fitting the surgical power tool ZIMMER/HALL compatible).

WARNING:

- ✓ The proper length of the pins to be used in each step should be chosen considering the dimension of the interested part, in way to avoid the pin to pierce the bone completely which could cause unwanted lesions to tendon, ligament or vascular structures.
- ✓ When using "Fast Drive" Headed Pins, be careful to stop screwing as soon as the head of the pin comes into contact with the instrument to be fixed.

DRILL BITS

All the GKS Drill Bits provided with the ATTITUDE Instruments Set have a quick coupling connection compatible with ZIMMER/HALL drilling adapters.

QUICK-FIX coupling system

The Impacting Ends for the the prosthetic components and the Tibial Punches provided with the ATTITUDE Instruments Set have a Quick-Fix coupling system fitting the Universal Handle.

Assembly is achieved by pulling the Knob, inserting the End then release.

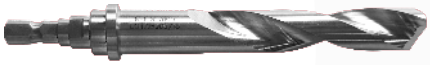
PINS

"*Fast Drive*" PINS

Fast Drive Adapter

DRILL BITS

Starter Drill Bit Ø 8/12mm



Tibial Drill Bit

Drill Bit for Femoral Pegs

Patellar Drill Bit

Universal Handle

Femoral Impactor

Fixed Bearing Tibia Impactor

Mobile Bearing Tibia Impactor

Tibial Liners Impactor

Tibial Punches

SURGICAL TECHNIQUE

This proposed surgical technique is meant as a guide to illustrate the use of the various components of the permedica GKS PRIME *FLEX* instrumentation.
It is up to the surgeon to decide to begin the intervention with a **distal femoral resection** or with a **tibial resection** since these cuts are constrained to the mechanical axis and are absolutely independent from one another.
For ease purposes, we advise the surgeon to begin with the distal femoral resection because this improves the exposure of the tibial surface and facilitates inspection during tibial resection.

1 STARTING THE FEMORAL CANAL

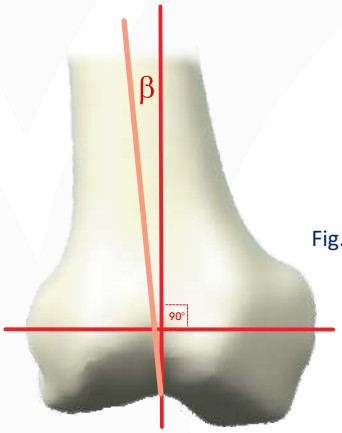


Fig. 1a

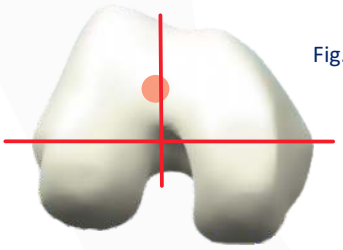


Fig. 1b

After the complete exposure of the joint and the removal of the peripheral osteophytes from the articular surface 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 7-8mm ahead of the PCL insertion (**Fig. 1a/b**).

It is important, however, to evaluate exactly - with the support of 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.

Using the Ø 8/12mm Starter Drill Bit (S53060) the femur is drilled to accomodate the Intramedullary Rod (**Fig. 2**). In drilling this hole it is important to run 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 that the medullary canal has been located by touching the cortical walls with a thin long curette.

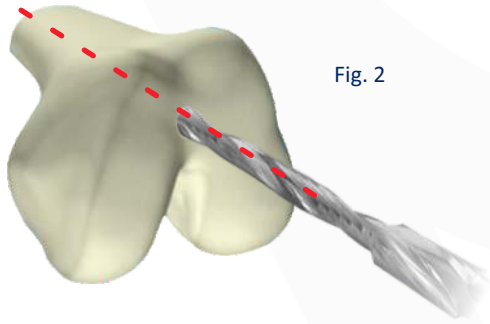


Fig. 2

The Intramedullary Rod (S59103) is connected to the Rod Handle (S53080) and slowly introduced into the medullary canal, from which it should protrude by at least 10 cm. (**Fig. 3**). The smooth edge of the rod allows a self-centering action by the side of the canal, thus avoiding risks of incidental perforation of the femoral cortical walls.

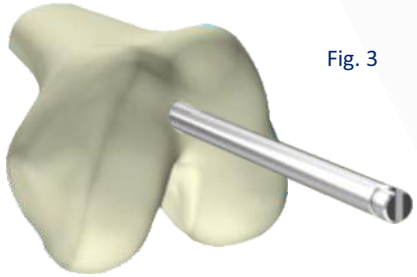


Fig. 3

POSITIONING OF THE VALGUS GUIDE 1.1

The Femoral Valgus Guide (S59168) allows to place the Distal Femur Cutting Guide (S53070) orthogonal to the mechanical axis.

The instrument allows setting of the femoral deviation angle and the resection level in a simple and precise way thanks to specially designed adjusting knobs.

After removal of the I/M Rod Handle the Femoral Valgus Guide is introduced onto the Intramedullary Rod and pushed against the femoral condyles, lifting the sliding head to override the trochlea (**Fig. 4**).

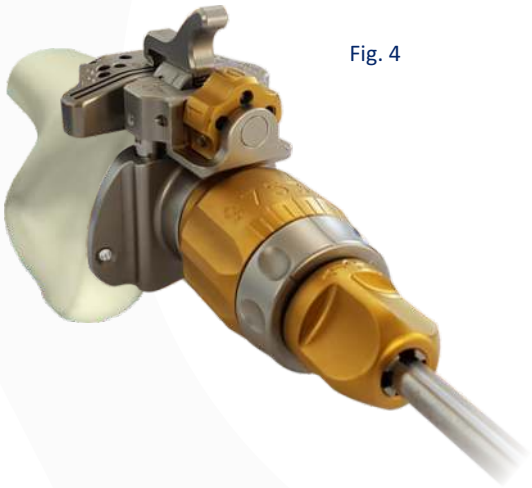


Fig. 4

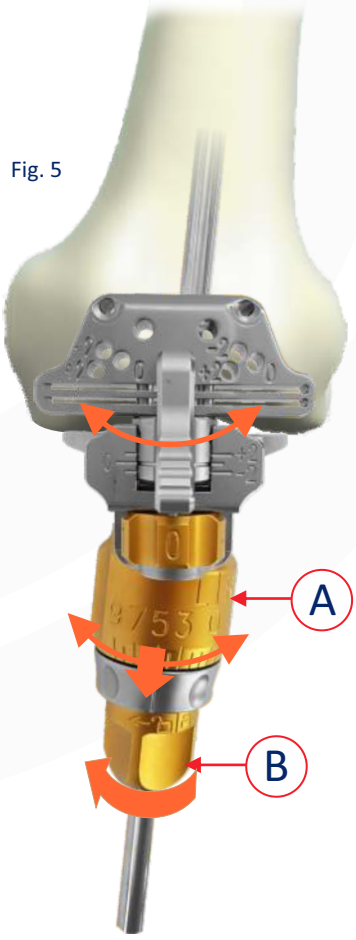


Fig. 5

It is possible to set the femoral deviation angle with the Guide inserted onto the Intramedullary Rod (**Fig. 5**): pull and rotate the knob (A) to set the position of the adjustable head on the desired angle (according to the involved side).
Once achieved the desired setting, turn the knob (B) to lock the Guide onto the I/M Rod. It is also possible to pin the Guide with a Fixation Pin in one of the posterior holes (**Fig. 6**).

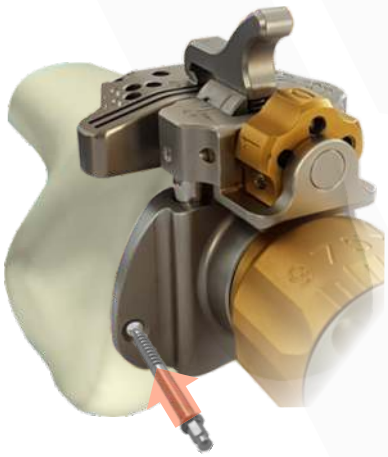


Fig. 6

SETTING THE RESECTION LEVEL

1.2

With the Femoral Valgus Guide locked the resection level can be checked by inserting the "Halfmoon" Resection Gauge (S59107) into the more distal slot of the Distal Femur Cutting Guide.

The "0" position allows the removal of a minimum quantity of bone, corresponding to the distal thickness of the femoral prosthesis (8mm). This is to be considered the standard position since the cut defined here will not move the joint line of the knee, fundamental for good patella tracking. By cutting in the more proximal slot, the resection level will increase of +3mm.

By rotating the knob (C) of the device is otherwise possible a millimetrical adjustment of the Cutting Guide position in proximal or distal direction.

Once achieved the optimal setting, pin the Distal Femur Cutting Guide inserting two Guide PINS in the central couple of holes (marked 0 - **Fig. 7**). The positioning of the guide pins into these holes will allow, if necessary, to shift the resection level of +2mm or -2mm by positioning the cutting block in the more distal or proximal couple of holes .

A Fixation Pin is inserted in one of the angled holes in the proximal corners to stabilize the Distal Femur Cutting Guide.

WARNING: It is advisable to select the proper pin length in order to avoid complete piercing of the femur. In the presence of particularly hard sclerotic bone, pre-drilling with Ø 3,5mm drill bit (S40069) would be advisable

The I/M Alignment Rod is then removed, by unlocking the knob (B) and removing the pin eventually used to stabilize the Femoral Valgus Guide (**Fig. 8**).

Push the upper tooth to remove the Femoral Valgus Guide leaving in place the Distal Femur Cutting Guide ready for the cut (**Fig. 9**).

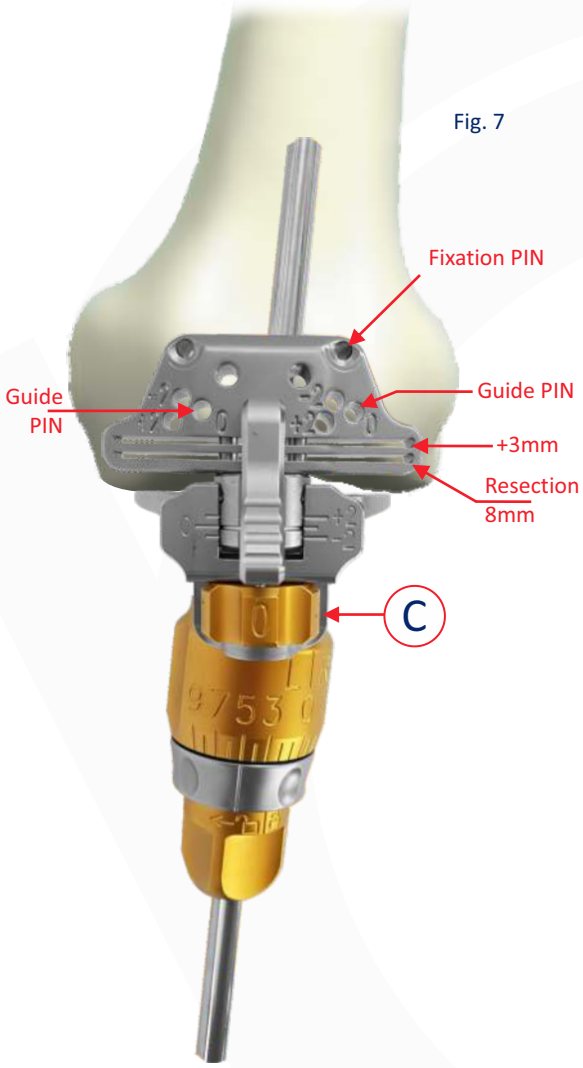


Fig. 7

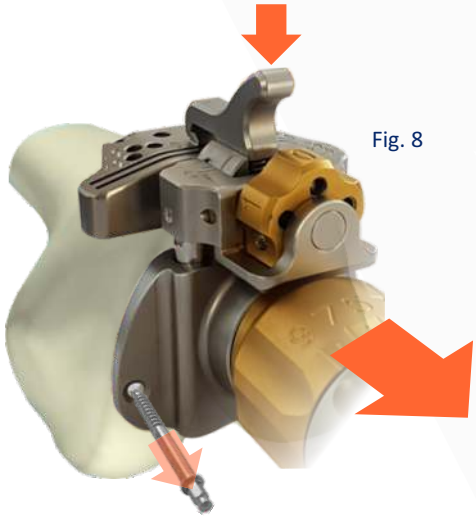
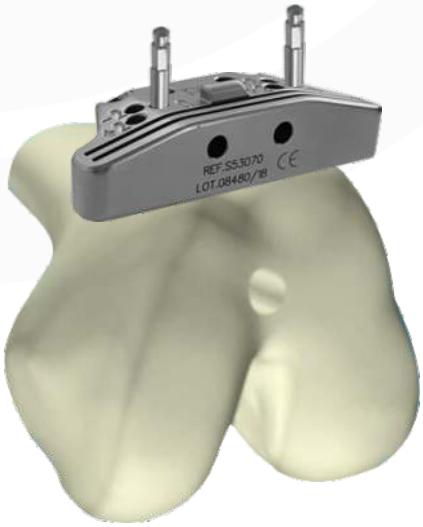


Fig. 8

Fig. 9



DISTAL FEMUR RESECTION 1.3

Now it is possible to proceed with the distal femur resection (**Fig.10**).

It is extremely important to execute this step with maximum care to achieve a perfectly leveled resection as it will represent the reference for all the other femoral resections. At the intercondylar notch level, for instance, the presence of hard sclerotic bone could lead to bend the cutting blade thus giving an uneven resection surface.

It is advisable to use oscillating saw blades with length between 80 and 100mm and 1,27mm maximum cut thickness; thinner saw blades could in fact bend during cut.

Perform the cut inserting the saw blade into the most distal cutting slot. It is eventually possible to make a 3mm recut by inserting the sawblade into the second (most proximal) cutting slot.

Once the resection has been carried out, the Fixation Pins are removed using and the Distal Femur Cutting Guide is removed by sliding it on the Guide PINS which will be left in place to allow a re-cut in case of need (**Fig. 11**).

Fig. 10

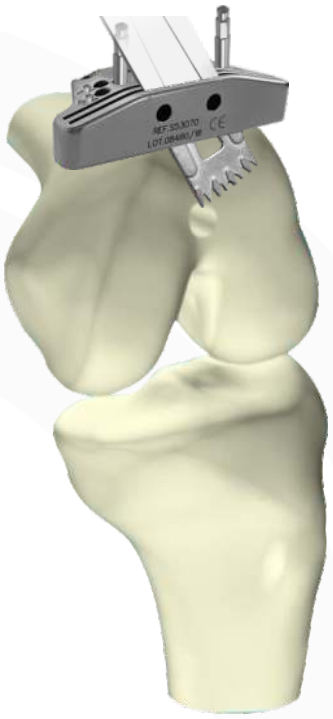
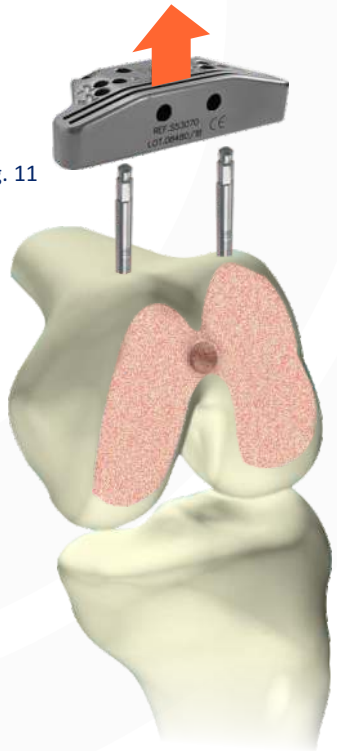


Fig. 11



2. PROXIMAL TIBIA RESECTION

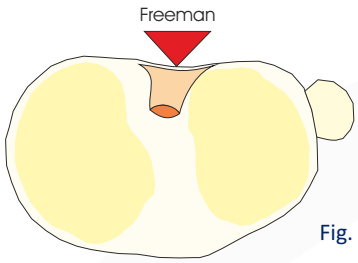


Fig. 12

This step starts bending the knee over 90°and luxating the tibia anteriorly by placing a curved retractor (Freeman) in the posterior face of the tibia (**Fig. 12**). Care should be taken to avoid any damage to the resected femoral surface and to avoid avulsion of the Patellar Tendon at the tibial insertion.

WARNING: in the case of a **GKS PRIME FLEX CR** make sure to protect the Posterior Cruciate ligament to avoid any damage.

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.

ASSEMBLY OF THE EXTERNAL ALIGNMENT GUIDE

The External Alignment Guide is composed by an Anatomic Ankle Clamp (S53055A), on which is inserted a Rack Rod (S53055B) and the Main Body (S53055) supporting the Tibial Cutting Guide. Two Tibial Cutting Guides are available for the RIGHT side (S53056) and the LEFT side (S53057).

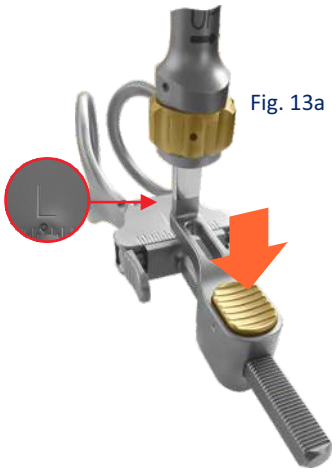


Fig. 13a

Assembly the Anatomic Ankle Clamp and the Rack Rod as shown (**Fig. 13a**) by inserting it with the mark of the involved side (R or L) visible upwards.

Fig. 13b

Assembly the Tibial Cutting Guide of the corresponding side onto the Main Body (**Fig. 13b**).

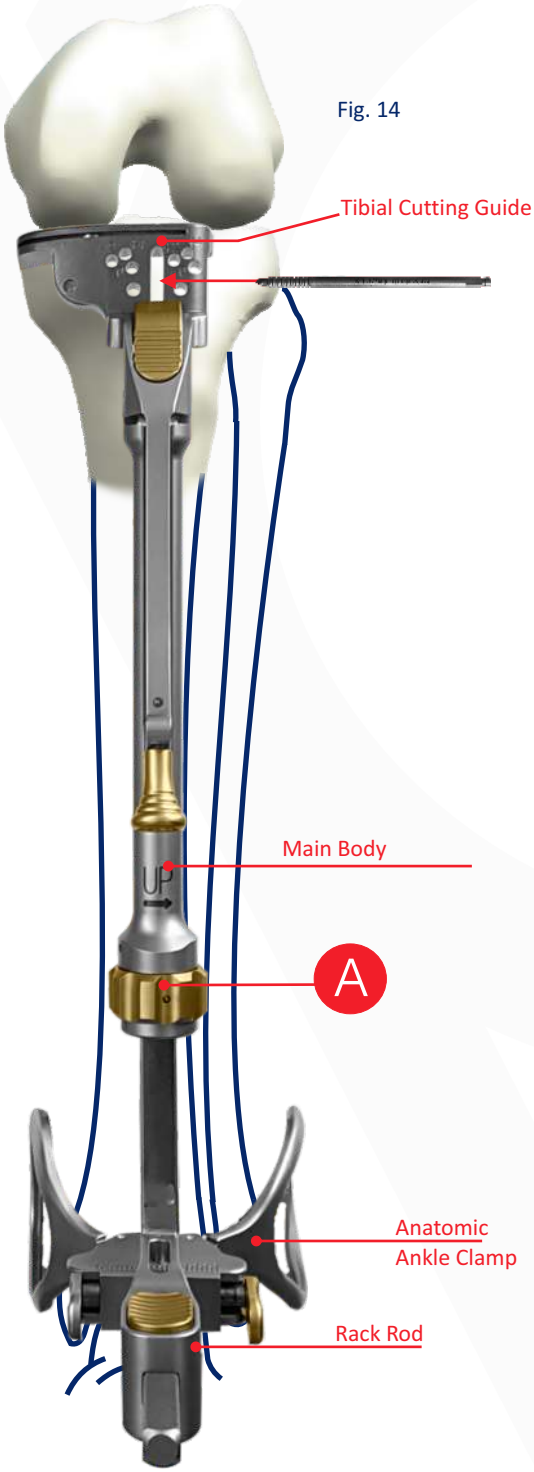


Fig. 14

Once the device is properly assembled, apply the Guide to the ankle and adjust the excursion of the Main Body by pushing the knob A in order to place the Cutting Guide at the approximate level of the resection, centered on the proximal Tibia, then insert a Guide PIN in the central slot to set the position (**Fig. 14**). This will allow, once achieved the correct alignment, to adjust the excursion of the Cutting Guide (micrometric adjustment) to achieve a precise resection level.

Align the device to the Mechanical Axis of the tibia (see next page for details).

The correct resection level is adjusted by rotating the knurled knob A which raises or lowers the Cutting Guide. To check the correct level, it is possible to use the "Halfmoon" Resection Gauge (S59107) inserted into the slot of the Cutting Guide or the Tibial Stylus Gauge (S53058) inserted into the hole on the top .

The Tibial Stylus Gauge can be used in two positions:

- ✓the longest tip of the gauge (marked 2mm) will lead to a minimal bone resection of 2 millimeters below the lowest point of the most damaged tibial condyle;
- ✓the shortest tip of the gauge (marked 10mm) will lead to a bone resection of 10 millimeters below the lowest point of the most preserved tibial condyle, which corresponds to the minimum thickness of the tibial liner.

S53058

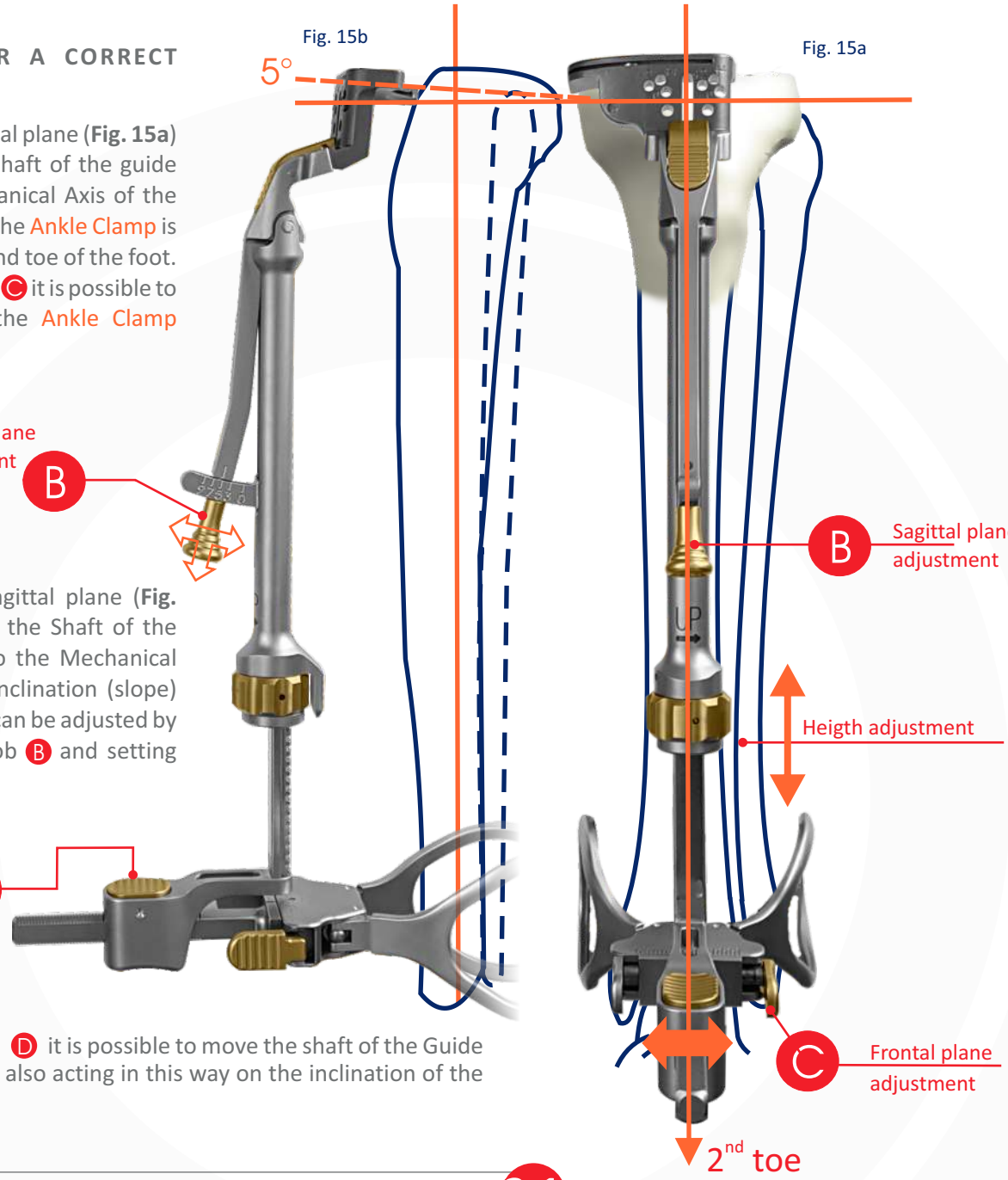
The choice between these options is at Surgeon's discretion and is strictly correlated to the morphology of the tibial surface involved.

INDICATIONS FOR A CORRECT ALIGNMENT:

Alignment in the frontal plane (**Fig. 15a**) is correct when the Shaft of the guide runs along the Mechanical Axis of the tibia and the shaft of the Ankle Clamp is aligned with the second toe of the foot. By pushing the button C it is possible to move the shaft of the Ankle Clamp medially or laterally.

Alignment in the sagittal plane (**Fig. 15b**) is correct when the Shaft of the guide runs parallel to the Mechanical Axis. The backward inclination (slope) of the Cutting Guide can be adjusted by pulling down the knob B and setting the desired value.

By pushing the button D it is possible to move the shaft of the Guide forward or backward, also acting in this way on the inclination of the cutting plane.



TIBIAL RESECTION 2.1

Once established the correct resection level, insert two Guide PINS in the couple of holes marked "0" and a Fixation Pin (of proper length) in the medial hole to fix the Cutting Guide. The alignment device can be left in place or removed by pushing the release button.

The resection of the proximal tibia can thus be performed by using an adequate oscillating saw blade (advised 90x19mm, thickness 1,27mm) in the slot of the Cutting Guide (**Fig. 16**).

In case that a GKS PRIME *FLEX* CR Cruciate Retaining implant option is selected, the PCL should be protected by inserting an osteotome anteriorly to its tibial insertion.

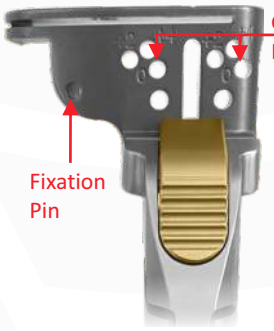
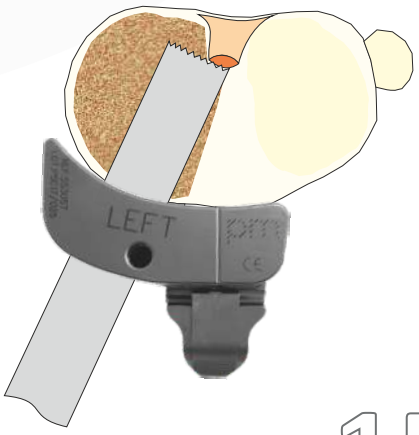


Fig. 16



Once completed the resection the Cutting Guide can be removed (by pulling out the medial Fixation Pin) leaving the Guide PINS in place: in case, after the evaluation of the Extension Gap, it would be necessary to lower the tibial resection it will be possible to reposition the Guide in one of the upper couple of holes (marked +2 or +4mm) for a re-cut.

3. JOINT VOLUMES EVALUATION

After performing the resections, the spaces obtained are checked by means of the MODULAR SPACER, a device that allows volumetric and angular balancing and, depending on the configuration, can be used for:

- ☑ verify and balance the joint volumes in EXTENSION;
- ☑ verify and balance the joint volumes in FLEXION;
- ☑ provide indications for a correct FEMORAL ROTATION.

The device consists of 4 elements to be assembled together:

A HANDLE

B BASE to be connected to the Handleand used for any function. The various elements are assembled to it.

C PROXIMAL PART: it has 3 different types of spacers to be connected to the Base and to be used in three moments of the intervention:

1 EXTENSION PLATE symmetrical block to be used for the evaluation of the gap in extension (utilizable in flection as well, after performing the femoral resections).

2 FLEXION PLATE block with step to be used for the evaluation of the flexion gap (interposed to the Femoral Resection Guide, before performing the cuts).

3 ANGLED PLATES asymmetrical blocks with inclined planes from 1 to 7 degrees to be used in flection to balance the femoral rotation (interposed to the still intact femoral condyles) .

D DISTAL PART consisting of symmetrical blocks (Lower Thicknesses) with an increase in thickness corresponding to that of the tibial inserts.

The main peculiarity of the instrument is to measure volumes and rotation (which can and must be checked) before proceeding with the definitive cuts, giving the possibility to make corrections.

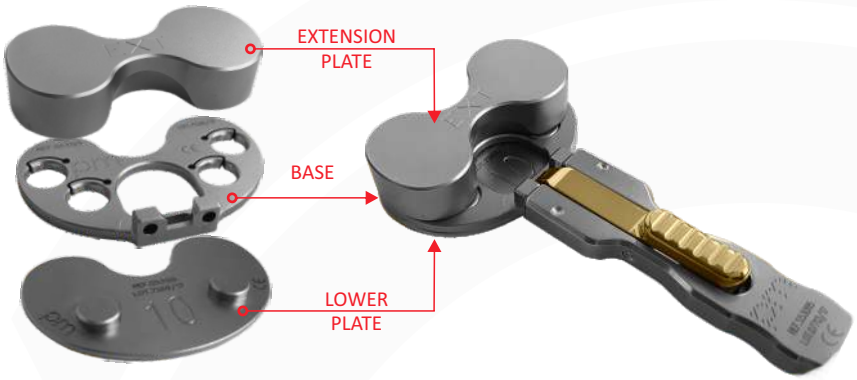
Being based on the volumetric and angular filling of the spaces it cannot be considered neither a spacer nor a tensioner, although it brings together the aims of both these instruments.

ANGLED PLATES

LOWER PLATES

EXTENSION GAP 3.1

To evaluate the ***EXTENSION GAP*** assembly the BASE with the EXTENSION PLATE and the LOWER PLATE of 10mm (corresponding to the minimum thickness of the polyethylene tibial inserts).



After performing the tibial resection (orthogonal to the mechanical axis) and the distal femur resection (with the valgus angle determined by the pre-operative planning) the extension bone gap is verified by inserting the assembled instrument, which will allow to evaluate the bone gap volume and its symmetricity by testing the stability in varus-valgus stress.

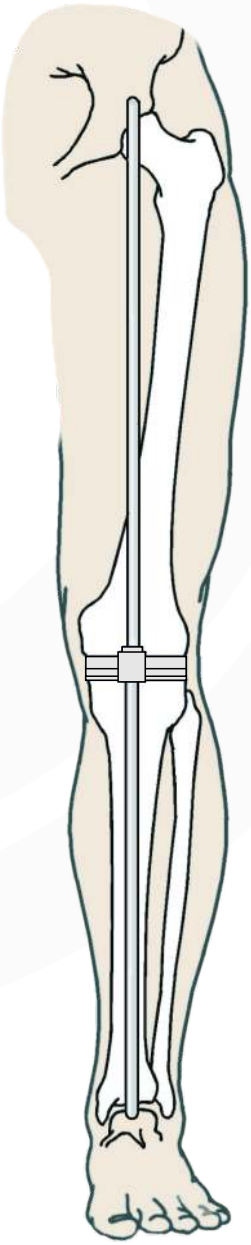
If the space is symmetrical and stable in this configuration, the volume in extension is already correct and will be filled by the final prosthetic components with a 10mm insert.

If the volume to be filled is symmetrical but higher than the inserted instrument, the gap will be tested again by replacing the LOWER PLATE with the 12mm one (or higher if necessary) thus establishing the "virtual" thickness of the insert that will fill the gap.

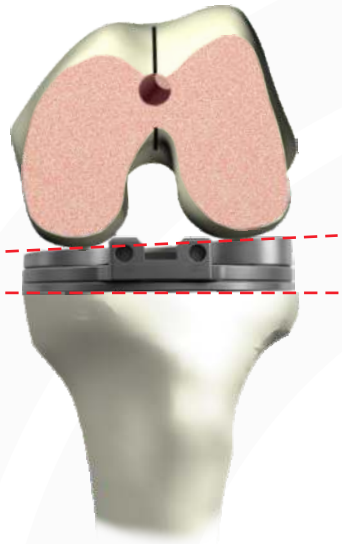
If the volume to be filled should be less and the instrument could not be inserted, proceed removing the LOWER PLATE. The instrument thus configured will have a virtual volume corresponding to 8mm: this situation should foresee a ***tibial re-cut*** if the volume should result to be 8mm in the subsequent tests in flexion (tight both in extension and in flexion); on the other hand, a ***femoral re-cut*** should be provided if the volume is 10mm in flexion (volume tight in extension and correct in flexion).

If the volume is asymmetrical with medial or lateral laxity, soft tissue release will be performed (according to the most appropriate techniques) or the degree of valgus of the distal femoral osteotomy could be corrected in case it should be inappropriate (it is possible to check the correct alignment to the mechanical axis by inserting an External Alignment Rod in the handle).

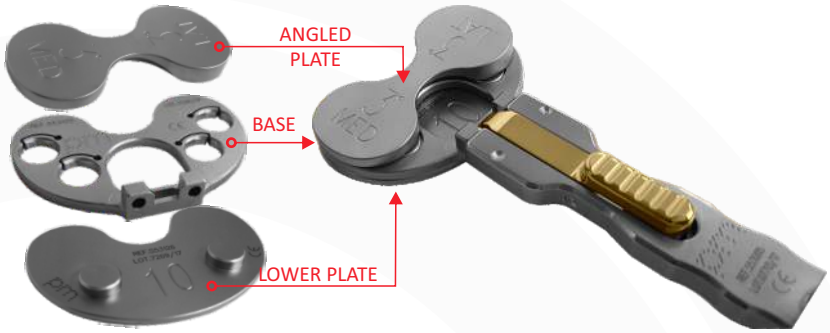
The purpose of the modular device therefore is to balance the volume in extension by filling the gap with the sum of the volumes of the final prosthetic components (femur, tibia and polyethylene insert), more than verify the alignment by means of the External Alignment Rod.



3.2 FLEXION GAP AND FEMORAL ROTATION



In order to evaluate the ***FLEXION GAP*** and determine the ***ROTATION DEGREE*** the BASE is assembled with the LOWER PLATE corresponding to the gap measured in extension (in the example 10mm) and an ANGLED PLATE .



The ANGLED PLATE should be chosen with the adequate degree to fill the asymmetric space between the posterior condylar plane of the femur and the plane of the tibial osteotomy. Eventually repeat the evaluation, changing the angled plate, until an optimal volumetric filling is achieved.

The angle thus measured will correspond to the adequate femoral rotation to be used to balance the femoral and tibial planes in flexion, while the Il volume will be given by the LOWER PLATE corrisponding to the thickness of the tibial polyethylene insert.

With the knee at 90° flexion the stability is checked by stressing the joint in Varus/Valgus also verifying that the medial and lateral volumes are correctly filled by the instrument.

4. FEMORAL SIZING & ROTATIONAL ALIGNMENT

A correct alignment in the transverse (rotational) plane, is basic for the restoration of a correct femoro-patellar kinematic more than to redistribute the forces between the medial and lateral condyles of the prosthesis in a homogeneous way.

The optimization of the patellar gliding onto the femoral trochlea aims to reduce the contact stresses on the femoro-patellar joint, thus avoiding complications and clinical discomfort due to patella maltracking. It is important to remember how this kind of complications relates to about the 50% of the knee revision surgeries and patellar maltracking is one of the main etiological factors.

The GKS ATTITUDE instrumentation provides a special Femoral Sizing/Orienting Device (S53059) designed to set the orientation of the Femoral Resection Guide exactly perpendicular to the *Mechanical Axis* of the lower limb, taking advantage of the classic alignment options.

This instrument has two pairs of sleeves which allow to place the Guide PINS for the Resection Guide with the option to choose between ANTERIOR or POSTERIOR reference.

The Femoral Sizing/Orienting Device is positioned onto the resected distal femur, taking care to put it perfectly adherent to the resection plane, centered to the intercondylar notch and the posterior supports close-fitting to the posterior condyles (**Fig. 17**). Eventually the instrument can be fixed to the bone with a Fixation Pin - Short inserted into the holes in the lower part of its base.

The angular degree evaluated (in the example 3 degrees LEFT) is transferred to the instrument by adjusting the central knob: by pressing the knob, set the desired value according to the involved side (**Fig. 17a**).

The size is determined by the distance between the posterior feet of the Guide and the contact point of the stylus feeler onto the anterior cortex, and the corresponding value can be detected on the frontal scale reporting the sizes of the femoral components(**Fig. 17b**). In this step the tip of the stylus must touch the central area of the anterior cortex.

It is important to free the anterior femoral cortex from any soft tissue (the tip of the stylus has to touch the bone) and make sure that there are no relevant depressions in the point of contact.

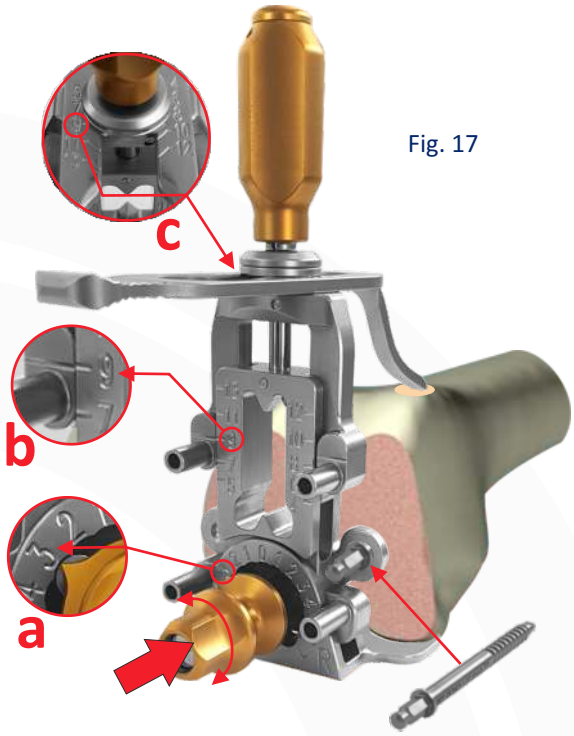


Fig. 17

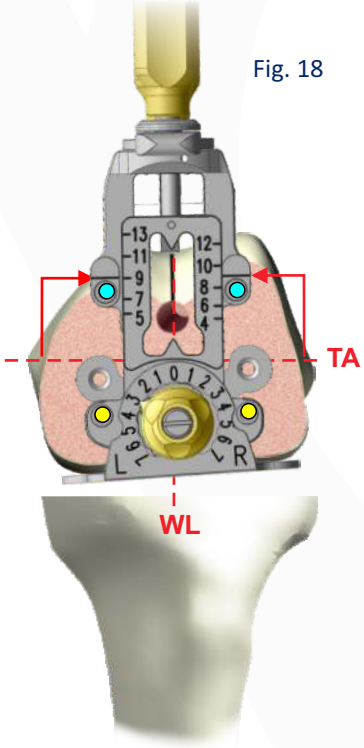
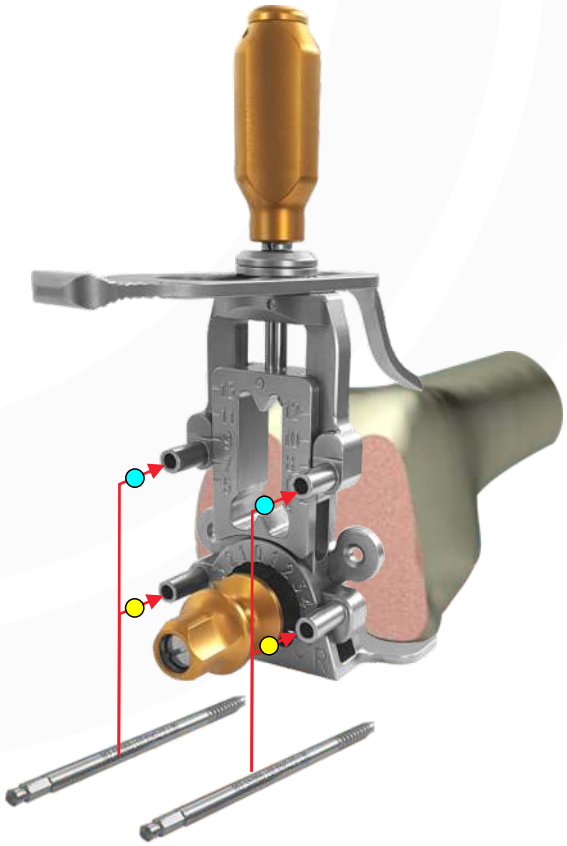


Fig. 18

During this phase has to be also verified the correspondence between the rotation degree determined with the Spacer and the alignement to the *Trans-epicondylar Axis* (TA) and the *Whiteside Line* (WL) (**Fig. 18**).

Whenever there should not be a correspondence with the anatomical landmarks, it would be necessary to re-check the correctness or the orthogonality to the anatomical axis of the tibial resection, which in this case acts as a reference for the rotation.



Once determined the size, set the same value on the stylus scale (**Fig. 17c**) to reproduce the ending point of the prosthesis shield, then turn the upper knob to lock the instrument.

At this point it is possible to insert the Guide PINS for the Femoral Resection Guide in one of the two pairs of sleeves available on the instrument:

☑ ● ANTERIOR REFERENCE

☑ ● POSTERIOR REFERENCE

The choice between these options are at Surgeon's discretion .

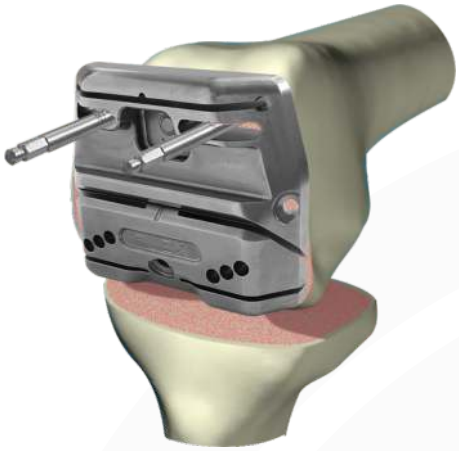


Fig. 19

After removal of the Femoral Sizing/Orienting Device, the Femoral Resection Guide of the selected size is positioned on the Guide PINS (**Fig. 19**).

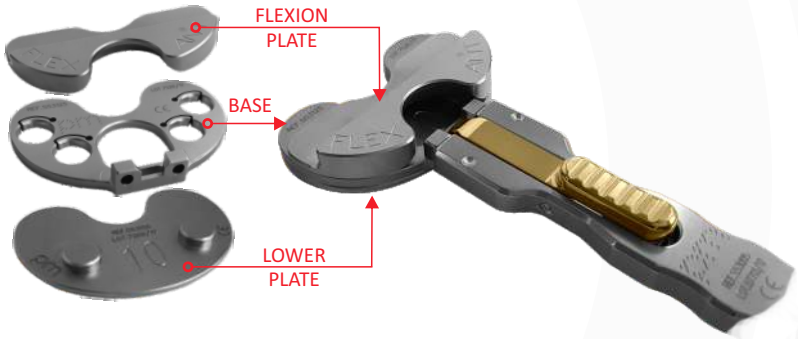
It is possible to verify the congruence of the volumes utilizing the Spacer assembled with the BASE, the LOWER PLATE selected and the FLEXION PLATE .

The instrument thus configured allows to further check the volumes before proceeding with the definitive femoral resections and eventually modify the reference (anterior/posterior) and the femoral size depending on the need to close or open the flexion space (always with respect to the posterior condylar axis).

How to proceed with the adjustment of the volume in flexion:

whenever in extension a good stability and volumetric filling was detected with a 10 mm insert, then the BASE will be assembled consequently with the LOWER PLATE of 10mm and the FLEXION PLATE to reproduce the same volume.

Fig. 20



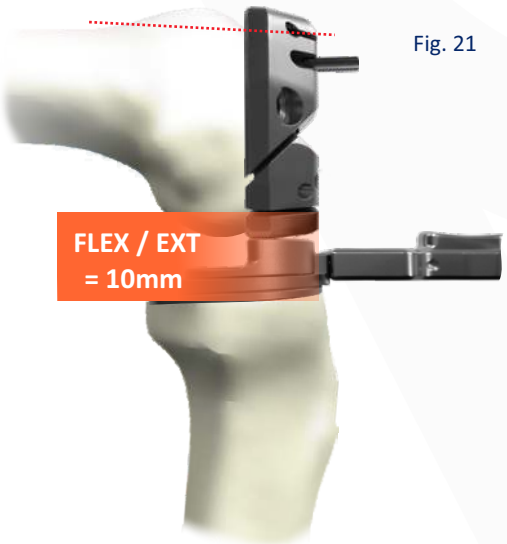


Fig. 21

With the selected Femoral Resection Guide placed over the Guide PINS (**Fig. 20**) the assembled Spacer is inserted between the Guide and the tibia (**Fig. 21**).

The spacer reproduces the volume that will be obtained with the resection of the posterior condyles: if this corresponds and the joint is stable we will have the certainty of obtaining, after the femoral cuts, the same balanced volumes in flexion and extension with a 10mm thick insert .

Whenever *the volume in flexion results to be **larger*** (**Fig. 22**) and a LOWER PLATE of 12mm should be necessary, then we will need to CLOSE the gap in flexion (reducing the resection of the posterior condyles) and this can be achieved in two ways:

❶ increasing the femoral size (**Fig. 22A**):
maintaining the anterior reference given by the Guide PINS, replace the resection block with a larger size;

Fig. 22A

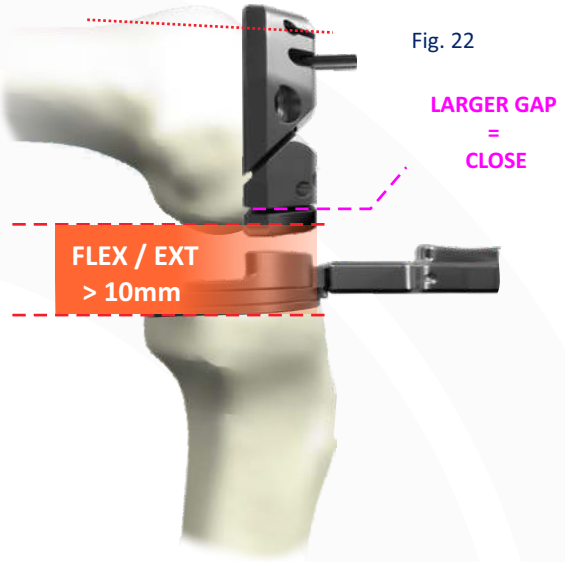


Fig. 22

❷ maintaining the same size (**Fig. 22B**):
moving the resection block 2 mm **posteriorly**, but making sure not to produce anterior "notching".
If the POSTERIOR reference was chosen, just remove the resection block and reposition it in the most anterior pair of holes; if, on the other hand, the ANTERIOR reference was chosen, it will be necessary to insert two PINS in the central pair of the posterior holes then remove the anterior PINS and move the cutting block as described above.

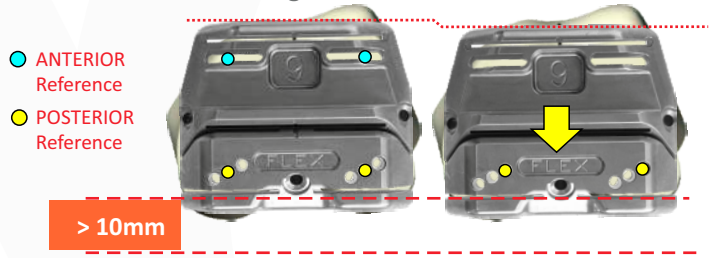


Fig. 22B

In both cases we will act by **FILLING** the volume in flexion.

Whenever *the volume in flexion results to be **lesser*** (**Fig. 23**) and a LOWER PLATE of 10mm should not fit, then we will need to OPEN the gap in flexion (increasing the resection of the posterior condyles) and this can be achieved in two ways:

❶ reducing the femoral size (**Fig. 23A**):
maintaining the anterior reference given by the Guide PINS, replace the resection block with a smaller size;

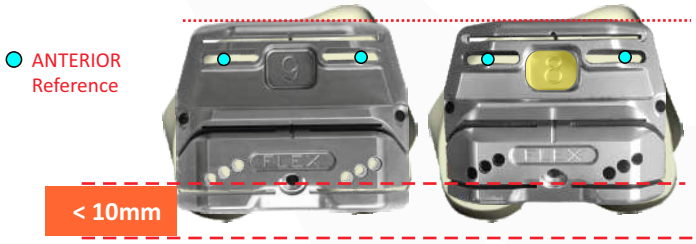


Fig. 23A

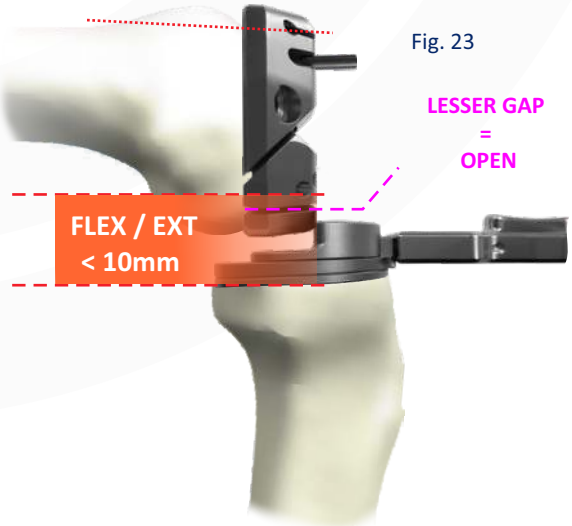


Fig. 23

❷ maintaining the same size (**Fig. 23B**):
moving the resection block 2 mm **anteriorly**, but making sure not to produce anterior "overstuffing".
If the POSTERIOR reference was chosen, just remove the resection block and reposition it in the most posterior pair of holes; if, on the other hand, the ANTERIOR reference was chosen, it will be necessary to insert two PINS in the central pair of the posterior holes then remove the anterior PINS and move the cutting block as described above.

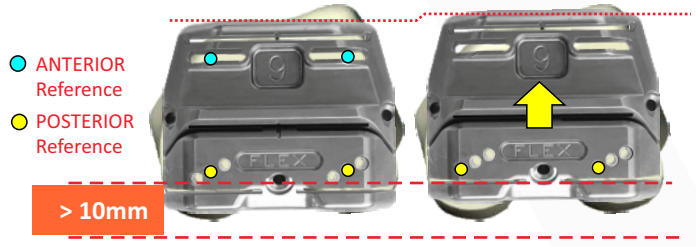


Fig. 23B

In both cases we will act by **SUBTRACTING** volume in flexion.

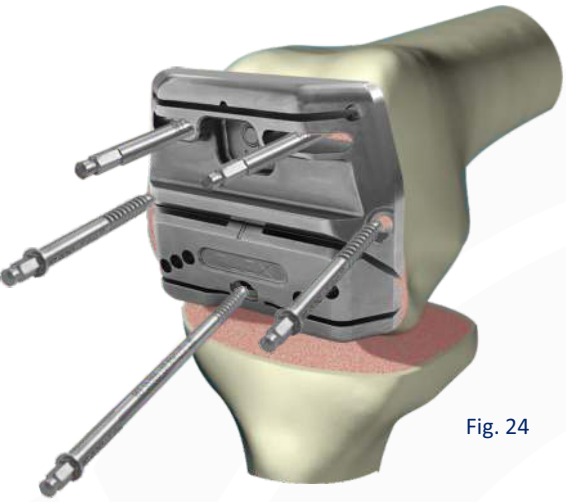


Fig. 24

Considerations:

if the volume in extension is correct and balanced but the volume in flexion is greater or smaller, in order to decide the correct strategy to follow it is necessary to consider other factors that determine the success of the intervention in terms of joint functionality

Increasing the femoral size to fill the volume in flexion should not generate a medial/lateral "overhang". In this case, if the risk of medial/lateral protrusion is consistent by increasing the size, the compromise is to translate the femoral component 2 mm posteriorly without increasing the size and accepting 1 mm of anterior notching

By reducing the femoral size to subtract volume in flexion, the posterior condylar offset must not be sacrificed, otherwise the quadriceps lever arm will be reduced and consequently the performance in flexion. In this case, by sacrificing the PCL, the flexion space should automatically open a few millimeters ensuring the balance.

5. FEMORAL RESECTIONS

The Femoral Resection Guides PLUS reproduces the medial-lateral size of the definitive prosthesis and it has to be as centrally placed as possible onto the resected femur by sliding over the GUIDE PINS .

Once achieved the optimal centering, pin the guide with two Fixation Pins the lateral holes and a third in the central hole (**Fig. 24**).

Remove the GUIDE PINS and proceed with the resections.

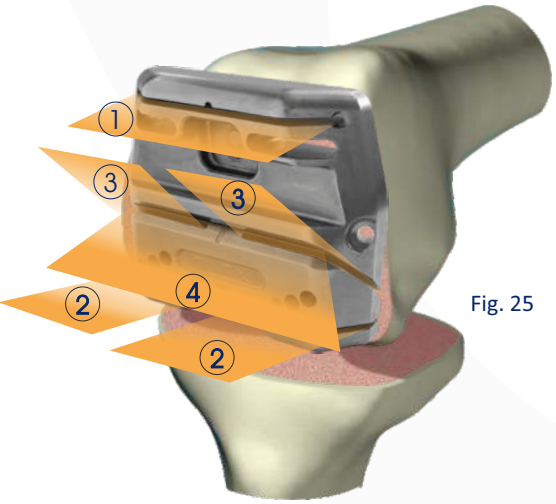


Fig. 25

Femoral resections, as well as all the other resections, must be executed using an oscillating saw with blade of suitable length (80-100 mm) and maximum thickness of 1,27 mm.

In order to preserve an optimal resting surface, thus achieving maximum stability of the Femoral Cutting Guide while cutting, it is advisable to chamfer the femur in accordance with the following sequence (**Fig. 25**):

① anterior cortex;
② posterior condyles;
③ anterior chamfer
④ posterior chamfer

WARNING: while cutting, care should be taken to protect soft tissues (collateral ligaments, skin, etc...) using appropriate instruments.

After the cuts has been performed, remove the Fixation Pins and the Cutting Guide, then proceed to remove the resected bone parts.

WARNINGS:

☒ *The GKS PRIME FLEX femoral components have a deep trochlear groove with protruded inner profile which could obstruct the proper fitting onto the resections (in particular in presence of hard sclerothic bone). It is therefore advisable to perform a light groove on the femur in correspondance of the protrusion(**Fig. 26**) using the Rasp (S50011) provided with the instruments set.*

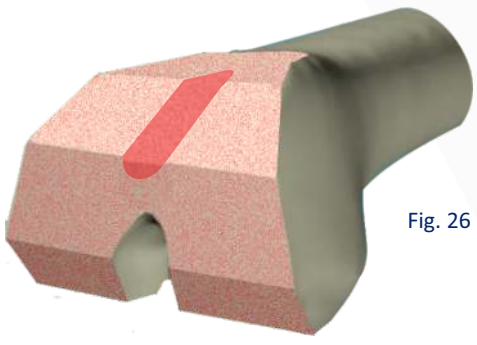
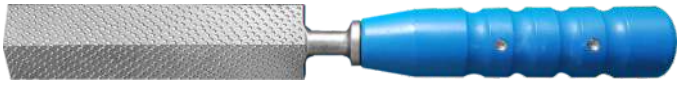


Fig. 26



☒ *The GKS PRIME FLEX PS femoral components does not need such expedient, the femoral preparation must be completed with the resections of the intercondylar box.*

INTERCONDYLAR RESECTION 6.

GKS PRIME *FLEX* PS

Once performed the resections and removed the Femoral Cutting Guide, it is necessary to prepare the lodge for the intercondylar box of the **GKS PRIME *FLEX* PS** femoral component(**Fig. 27**).

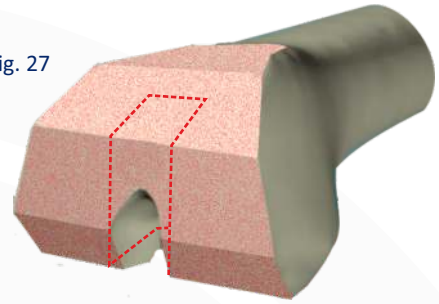


Fig. 27

For this purpose the selected size Intercondylar Cutting Guide is placed onto the resected condyles(**Fig. 28**). The Intercondylar Cutting Guide is unique for both sides and reproduces the overall dimension of the definitive component. The anterior shield is marked to reproduce the trochlear shield profile in order to allow a correct centering on the femoral condyle (**Fig. 29**).

Fig. 28

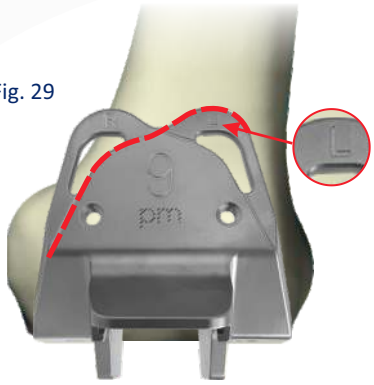


Fig. 29

Once determined the optimal position, pin the Guide with 2 or more Fixation Pins in the provided distal or anterior holes (**Fig. 30**).

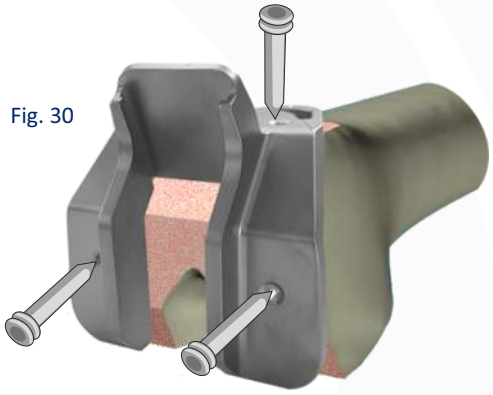


Fig. 30

With the Guide secured, insert the corresponding size Intercondylar Box Chisel (**Fig. 31**) in the anterior slot ((**Fig. 32**) and sink it into the bone by beating with a hammer then leave it in place.

Fig. 31

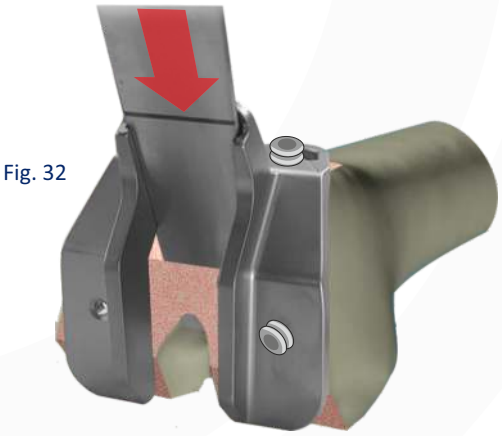


Fig. 32

The resection is performed by using an oscillating saw along the walls of the Guide (the Chisel inserted acts as depth limiter). Once done, sink the chisel further to completely remove the intercondylar bone dowel (**Fig. 33**).

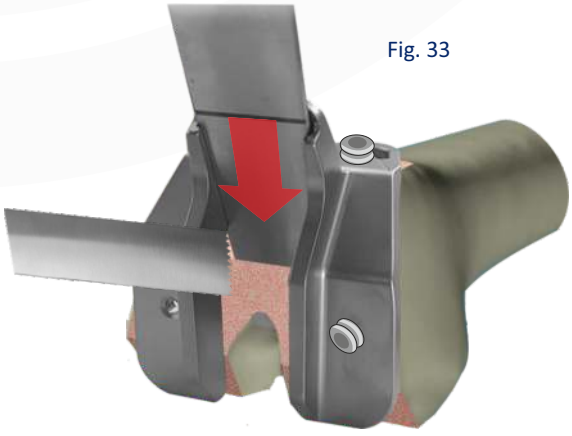
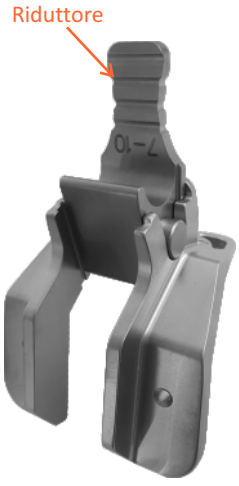


Fig. 33

NEW INTERCONDYLAR CUTTING GUIDES PS/SS



The new Intercondylar Cutting Guide PS/SS have been introduced in anticipation of the new SS (Super Stabilized) joint liners.

These liners, which will be introduced in the near future, provide a higher post than that of the PS liners and will be also compatible with new RK (Revision Knee) Femurs when these will come available.

In case of use with the actual PS liner the Intercondylar Cutting Guide PS/SS must be equipped with the proper Adapter of corresponding size.

The preparation procedure remains the same as described in this page.

7. TIBIAL SIZING

ATTENTION:

the Trial Tibial Baseplates have the same dimensions but are different, since the keel is displaced slightly more anteriorly in the the PRIME FLEX *fixed bearing Tibia than in the* PRIME *FLEX Mobile. Of course, the Trial Inserts are also different: CR, PS or AS inserts fits directly onto the trial baseplate without the need of any adapter.*

Define the size of the tibia using the specific *Trial Tibial Baseplates* of the selected prosthesis. The correct size should fit the tibial resection laying as more as possible onto the outer cortical without overflowing the bone (**Fig. 34**).

8. FUNCTIONAL EVALUATION

For the functional evaluation, different trial components are available depending on the selected GKS PRIME FLEX prosthesis model:

1. **Mobile Bearing**
2. **Fixed Bearing CR**
3. **Fixed Bearing PS**

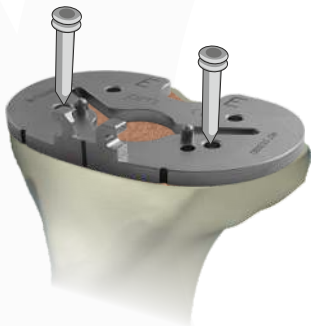


Fig. 36a

The selected Trial Femoral component is secured to the Femoral Holder (S59153) by lodging the teeth of its clamps into the lateral niches (**Fig. 35**), taking care to tighten the posterior knob (A) to push the impacting end against the component. The central knurled knob (B) should not be tightened, but only slightly screwed to prevent accidental opening of the jaws during the impaction.

Fig. 35

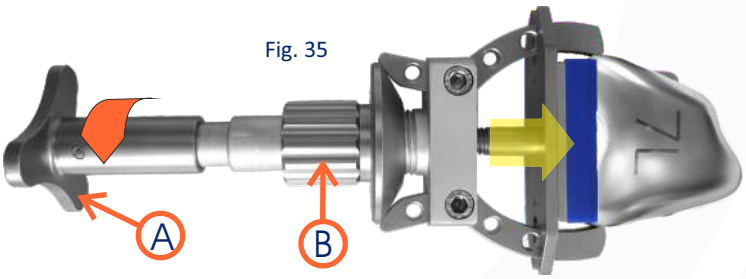


Fig. 36b

GKS PRIME *FLEX* Mobile:

In the GKS PRIME *FLEX MOBILE version, the size of the Insert refers to the FEMORAL component.*

Since the prosthesis has a MOBILE insert it is possible to orientate the tibial baseplate in way to achieve the best covering of the resection, as the rotating insert will anyway align itself in repsect to the femoral component position. After identification of the optimal size, is then possible to fix the Trial Tibial Baseplate to the tibia (**Fig. 36a**) by means of 2 Fixation Pins - ExtraShort (S53530).

The rotating Trial Insert has an Adapter allow the assembling onto the Trial Tibial Baseplate.

S53098

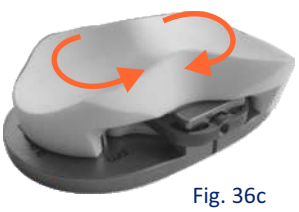


Fig. 36c

After lodging the Adapter onto the Baseplate place the Tibial Trial Insert of the selected size and thickness (determined with the Spacer) secure the Locking Clip (S53097) onto the Locking Clip Holder (S53096) and insert it into the frontal slot of the Baseplate (**Fig. 36b**).

In this way the Insert will be stable but free to rotate while running the intraoperative trial evaluation (**Fig. 36c**).

Lift the femoral condyles in order to have them overlapping the assembled Tibia/Insert Trial components previously pinned on the tibia. In slight hyperflexion engage the Trial Femur onto the femoral condyles(**Fig. 37a**). Returning the knee at 90° impact the Trial Femur while sliding onto the Trial Insert (**Fig. 37b**).

Use of the Femoral Holder (S59153) is advised to better drive the component insertion. The trial component can be further impacted using the Femoral Impactor - Quick Fix (S53140) assembled to the Universal Handle - Quick Fix (S19501).

The correct medial-lateral positioning of the femoral component can be checked by means of a compared inspection of the Femoral Epicondyles.

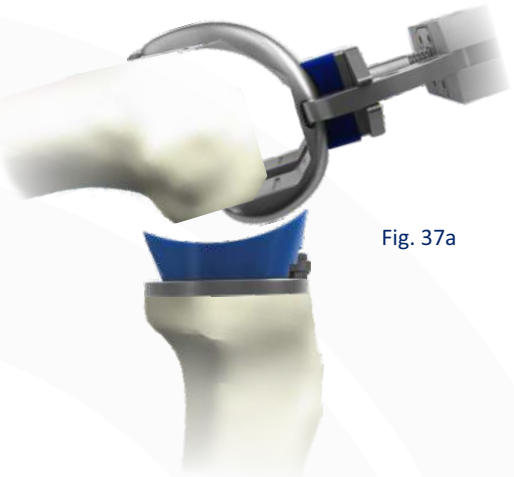


Fig. 37a

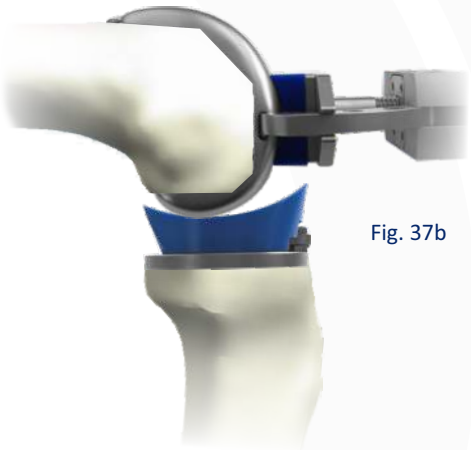


Fig. 37b

GKS PRIME *FLEX* CR FIXED BEARING:

In case of GKS PRIME *FLEX CR the size of the insert refers to the TIBIAL COMPONENT.*

With a fixed bearing baseplate, it is advisable to It is advisable to establish the correct positioning with respect to the femoral component by means of the trial evaluation.

After determining the optimal size, assembly the selected Trial Insert onto the Baseplate and lock it with the Handle (S53095). This will permit its positioning onto the tibial surface and the intraoperative functional evaluation (**Fig. 38a**).

As alternative it is also possible to use the Locking Clip as described in the Mobile bearing version (**Fig. 38b**).

Fig. 38a

Fig. 38b

With the knee at 90° flexion, engage the Trial Femur onto the femoral condyles. Use of the Femoral Holder (S59153) is advised to better drive the component insertion (**Fig. 39**). The trial component can be further impacted using the Femoral Impactor - Quick Fix (S53140) assembled to the Universal Handle - Quick Fix (S19501).

Fig. 39

Place the previously assembled Tibia/Insert Trial components onto the tibia, sliding them underneath the posterior condyles of the Trial Femur (**Fig. 40**).

The correct orientation of the tibial component is obtained by testing the joint with flexion-extension and internal-external rotation movements, thus allowing the self-centering of the tibial component.

The correct medial-lateral positioning of the femoral component can be checked by means of a compared inspection of the Femoral Epicondyles.

After all checks has been performed and the correct positioning of the components has been determined, the Proximal Tibia is marked with methylene blue (or electrocautery) next to the anterior tally marks of the Trial Tibial Baseplate .

In case the anterior-posterior stability should result unsatisfactory, use of an AS anterior stabilized insert could be evaluated.

Finally, with the knee in flexion the femur is drilled using the Femoral Pegs Drill Bit (S53062) through the holes of the Trial Femoral Component to prepare the seat for the pegs of the definitive femoral implant (**Fig. 40**).

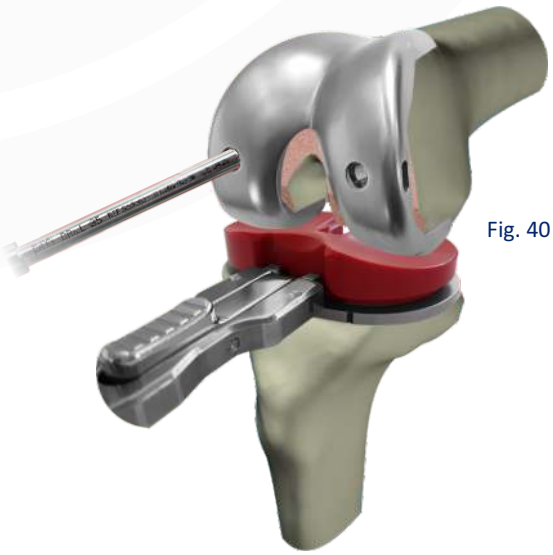


Fig. 40

Fig. 41a

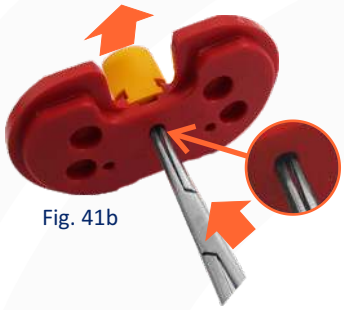


Fig. 41b

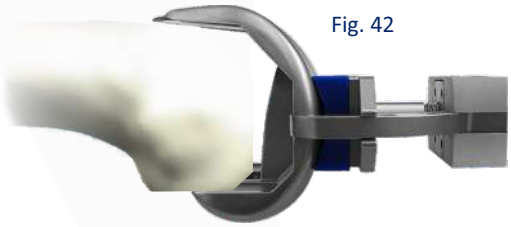


Fig. 42

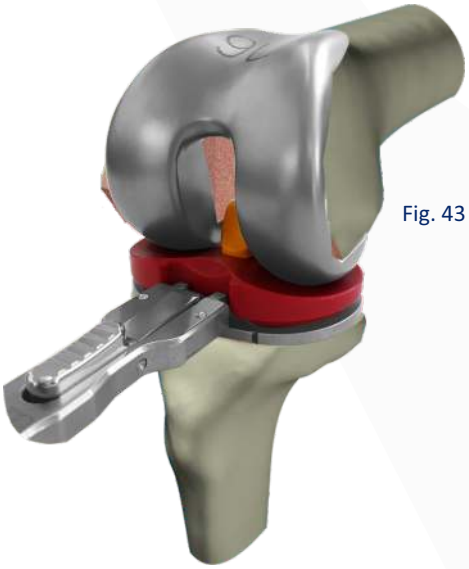


Fig. 43

GKS PRIME *FLEX* PS FIXED BEARING:

In case of GKS PRIME *FLEX PS the size of the insert refers to the TIBIAL COMPONENT.*

With a fixed bearing baseplate, it is advisable to establish the correct positioning with respect to the femoral component by means of the trial evaluation.

Once determined the size, select the corresponding Trial Insert (of the thickness defined in the extension gap evaluation) equipped with the Trial Post compatible with the size of the femoral component, by inserting it posteriorly (**Fig. 41a**).

To remove the Trial Post, insert the tip of a clamp into the hole in the bottom of the Trial Insert to push the spring pin, then slide the Post posteriorly (**Fig. 41b**).

ATTENTION:

the Trial Posts are available in 3 different sizes: each one fits a group of Femoral sizes. Refer to the COLOUR CODE for the correct compatibility between the components.

GREY
Size 4-5-6

YELLOW
Size 7-8-9-10

BLACK
Size 11-12-13

With the knee at 90° flexion, engage the Trial Femur onto the femoral condyles. Use of the Femoral Holder (S59153) is advised to better drive the component insertion (**Fig. 42**). The trial component can be further impacted using the Femoral Impactor - Quick Fix (S53140) assembled to the Universal Handle - Quick Fix (S19501).

Place the previously assembled Tibia/Insert Trial components onto the tibia, sliding them underneath the posterior condyles of the Trial Femur (**Fig. 43**).

The correct orientation of the tibial component is obtained by testing the joint with flexion-extension and internal-external rotation movements, thus allowing the self-centering of the tibial component.

The correct medial-lateral positioning of the femoral component can be checked by means of a compared inspection of the Femoral Epicondyles.

After all checks has been performed and the correct positioning of the components has been determined, the Proximal Tibia is marked with methylene blue (or electrocautery) next to the anterior tally marks of the Trial Tibial Baseplate.

FITTING THE TIBIAL KEEL 9.

This procedure is the same for both *Mobile* and *Fixed Bearing* versions, although the Trial Baseplates are different.

With the knee in flexion the trial components are removed. Whenever the Baseplate was pinned to the tibia, remove only the Trial Insert.

Place the Tibial Punch Guide Sleeve of corresponding size onto the Trial Baseplate (**Fig. 44a**) engaging the pins in the dedicated holes and impacting it until seated . Then place the Tibial Drill Guide Sleeve of the corresponding size (**Fig. 44b**).

Fig. 44a

Fig. 44b

Drill the Tibia using the Tibial Drill (S53105) untill its complete sinking (**Fig. 44c**)

Fig. 44c

Remove the Tibial Drill Guide Sleeve and complete the procedure with the Tibial Punch, of the corresponding size assembled onto the Universal Handle Quick Fix (S19501) until complete sinking (**Fig. 44d/e**).

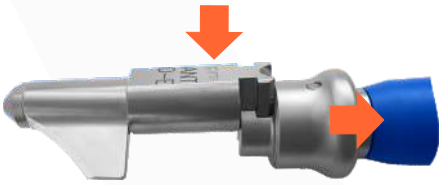


Fig. 44d

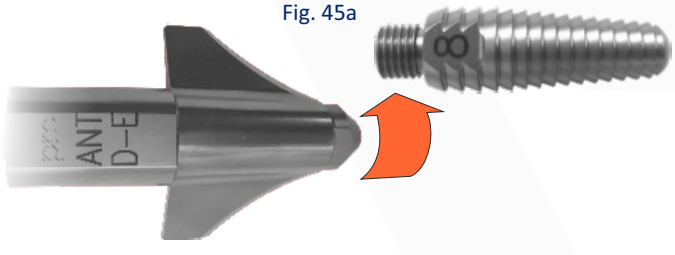
Fig. 44e

Whenever it is deemed necessary to implement the stability of the tibial component with a Tibial Extension housing must be prepared using the specific Broach.

Unscrew and remove the distal cap of the Tibial Punch using the Open Wrench (S50112) and replace it with the Broach (**Fig. 45a**) then proceed with punching (**Fig. 45b**).

The Broaches are available for each size of the Extension Stems (8 and 10mm).

Fig. 45a



S50112

Fig. 45b

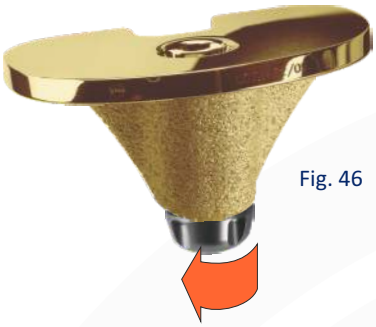


Fig. 46

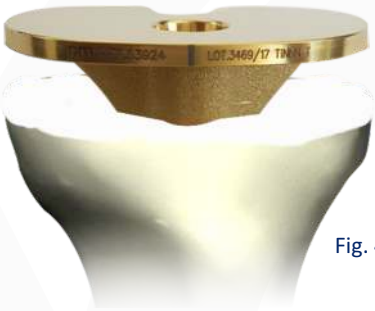


Fig. 47

Fig. 48

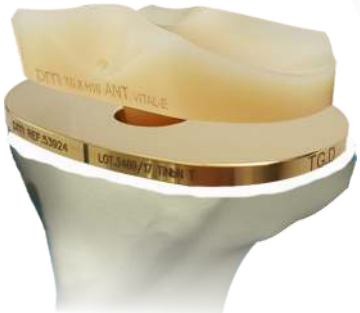


Fig. 49

10. IMPLANTATION OF THE COMPONENTS

ATTENTION:

- ✓ *The* GKS PRIME *FLEX definitive components are available in both cemented and cementless version. In case of cementless application, follow the procedure ignoring any reference to cementing technique.*
- ✓ *The* GKS PRIME *FLEX Tibial components can be equipped with Tibial Extensions to improve the stability whenever desired. To eventually assemble the extension, unlock and remove the distal plug of the keel using the Screwdriver (S50112) supplied and replace it with the Extension, tightening it using the wrench available on the other end of the instrument (**Fig. 46**).*

WARNING: the Tibial Extensions are different for the MOBILE and the TOP Tibial components: please refer to the reference table to identify the correct Extension to be used.

The trial components are removed and the prepared bony surfaces are carefully cleansed by repeated irrigation whit sterile physiological solution (use of pulsed lavage would be suggested, specially in cemented application).

The prosthetic components selected in the previous stages are unpacked and placed on a clean drape onto the sterile nurse's trolley.

The implantation procedure is different for the PRIME *FLEX Mobile* and the PRIME *FLEX CR/PS* fixed bearing prostheses.

10.1 GKS PRIME *FLEX* MOBILE

WARNING: in the GKS PRIME *FLEX MOBILE the size of the UHMWPE INSERT refers to the FEMORAL COMPONENT.*

When using cemented option, it is possible to proceed with one step cementing procedure (40g of bone cement will be sufficient for both the components) starting from the tibial baseplate.

A layer of bone cement is applied to the bottom of the tibial component (or directly on the prepared bony tibial surface). The prosthetic component is manually positioned, with reference to the previously marked landmarks or anyway following the existing keel trace (**Fig. 47**).

Assembly the Mobile Tibia Impactor (S53141) onto the Universal Quick Fix Handle (S19501) and proceed impacting the prosthesis until its until it is completely settled on the tibial surface, gradually removing the exceeding bone cement (**Fig. 48**).

S53141

S19501

The PRIME UC Uhmwpe Rotating Insert **corresponding to the size of the femoral component** is positioned on the implanted tibial plate (**Fig. 49**) making sure that the tibial plate surface is prefectly clean and the conical seat of the insert is free of any bony or cement debris.

The anterior part of the insert is lasermarked with the word "ANT" to indicate the correct positioning side

Lift the femur and make the tibial insert slide below the femoral condyles, taking care to hold the mobile insert.

The PRIME *FLEX Mobile* Femoral Component of the previously selected size is prepared by applying a layer of bone cement on the inner surface (or directly on the bony femoral surface, taking care that the holes for the fixation pegs are still visible).

The femoral prosthesis is engaged onto the femoral condyles manually or using the Femoral Holder (refer to page 24 for assembly) making sure to align the anchoring pegs to the previously drilled holes(**Fig. 50**).

NOTE: use of the Femoral Holder (S59153) allows for a better driving of the prosthesis in the insertion phase;

Once the component is engaged, the implant is finally seated (**Fig. 51**), by using the Femoral Impactor (S53140) assembled onto the Universal Quick Fix Handle (S19501).

Remove the exceeding bone cement all around the contour of the component and extend the knee: the contact between the femoral and tibial components will provide a suitable adjustment of the prosthesis to its final position. Go back to flexion and check for any further bone cement exceed (in case remove it).

Extend the knee and keep the position until the final hardening of bone cement is achieved.

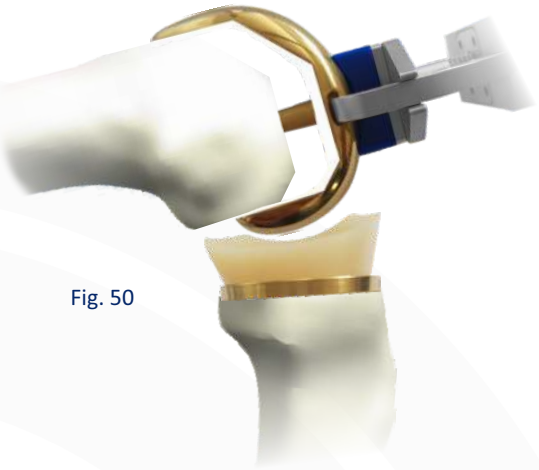


Fig. 50


Fig. 51

GKS PRIME *FLEX* CR 10.2

WARNING: CAREFULLY FOLLOW THE COLOUR CODE for the correct coupling between Tibial Component and UHMWPE Insert.

When using cemented option, it is possible to proceed with one step cementing procedure (40g of bone cement will be sufficient for both the components) starting from the tibial baseplate.

A layer of bone cement is applied to the bottom of the tibial component (or directly on the prepared bony tibial surface). The prosthetic component is manually positioned, with reference to the previously marked landmarks or anyway following the existing keel trace (**Fig. 52**).

Assembly the Tibial Impactor of compatible size onto the Universal Quick Fix Handle (S19501) and proceed impacting the prosthesis until its until it is completely settled on the tibial surface, gradually removing the exceeding bone cement (**Fig. 53**) .


Fig. 52


Fig. 53

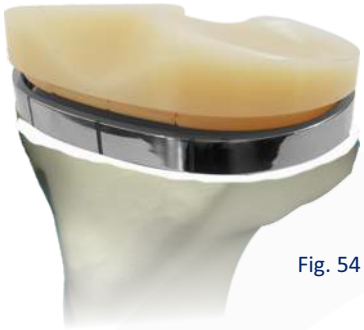


Fig. 54

After checking that the hosting site of the baseplate is free of any bony or cement debridements, the PRIME *FLEX CR* Uhmwpe Insert, of the previously selected thickness and corresponding to the implanted Tibial Component size, is inserted onto the tibial plate engaging it in the posterior slots of the baseplate (**Fig. 54**) and definitely seated (**Fig. 55**) using the Tibial Insert Impactor - Quick Fix (S53145) assembled onto the Universal Quick Fix Handle (S19501).

Fig. 55

The GKS PRIME *FLEX* Femoral Component of the previously selected size is prepared by applying a layer of bone cement to the inner surface (or directly onto the bony femoral surface, taking care to keep visible the holes for the fixation pegs).

The femoral prosthesis is engaged onto the femoral condyles manually or using the Femoral Holder, making sure to align the anchoring pegs to the previously drilled holes.

NOTE: use of the Femoral Holder (S59153) allows for a better driving of the prosthesis in the insertion phase.

Once the component is engaged, the implant is finally seated (**Fig. 56**), by using the Femoral Impactor (S53140) assembled onto the Universal Quick Fix Handle (S19501).

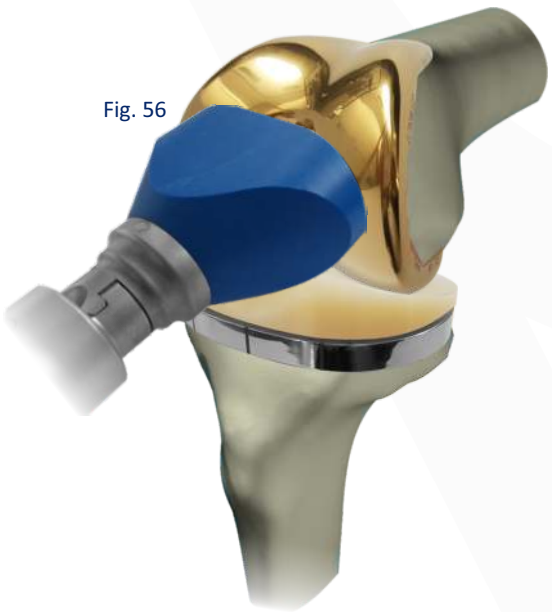


Fig. 56

Remove the exceeding bone cement all around the contour of the component and extend the knee: the contact between the femoral and tibial components will provide a suitable adjustment of the prosthesis to its final position. Go back to flexion and check for any further bone cement exceed (in case remove it).

Extend the knee and keep the position until the final hardening of bone cement is achieved.

WARNING:

CAREFULLY FOLLOW THE COLOUR CODE for the correct coupling between the Components.The PS Tibial Insert has a double colour code: the upper band refers to the compatible FEMORAL size while the lower band refers to compatible TIBIAL size.

Femoral Component

Insert

Tibial Component

When using cemented option, it is possible to proceed with one step cementing procedure (40g of bone cement will be sufficient for both the components) starting from the tibial baseplate.

A layer of bone cement is applied to the bottom of the tibial component (or directly on the prepared bony tibial surface). The prosthetic component is manually positioned, with reference to the previously marked landmarks or anyway following the existing keel trace (**Fig. 57**).

Fig. 57

Assembly the Tibial Impactor of compatible size onto the Universal Quick Fix Handle (S19501) and proceed impacting the prosthesis until its until it is completely settled on the tibial surface, gradually removing the exceeding bone cement (**Fig. 58**) .

Fig. 58

Fig. 59

The GKS PRIME *FLEX PS* Femoral Component of the selected size is prepared by applying a layer of bone cement on the inner surface (or directly on the bony femoral surface).

after protecting the already implanted tibial component with a sterile gauze, The femoral prosthesis is engaged onto the femoral condyles (**Fig. 59**) manually or using the Femoral Holder making sure to properly align the intercondylar box to the prepared site .

NOTE: use of the Femoral Holder (S59153) allows for a better driving of the prosthesis in the insertion phase.

Once the component is engaged, the implant is finally seated (**Fig. 60**), by using the Femoral Impactor (S53140) assembled onto the Universal Quick Fix Handle (S19501).

Fig. 60

S53140

S19501

Carefully remove the exceeding bone cement all around the contour of the prosthesis.

After checking that the hosting site of the baseplate is free of any bony or cement debridements, the PRIME *FLEX PS* Uhmwpe Insert, of the selected thickness and corresponding to the implanted Tibial Component size, is inserted onto the tibial plate engaging it in the posterior slots of the baseplate (**Fig. 61**) and definitely seated by hitting it anteriorly with the using the Tibial Insert Impactor - Quick Fix (S53145) assembled onto the Universal Quick Fix Handle (S19501).

Fig. 61

S53145

S19501

The joint is then reduced ant the knee extended: the contact between the femoral and tibial components will provide a suitable adjustment of the prosthesis to its final position. Go back to flexion and check for any further bone cement exceed (in case remove it).

Extend the knee once again and keep the position until the final hardening of bone cement is achieved.

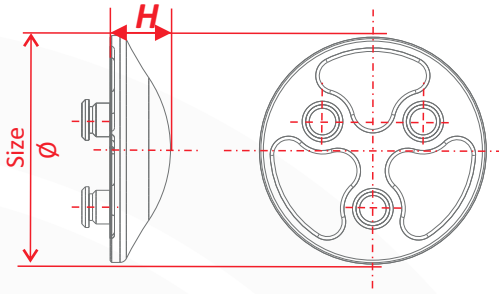
PATELLA REPLACEMENT 14.

The GKS WING patellar prosthesis has a circular dome shaped design and is available in 6 sizes (28, 30, 32, 34, 36 and 38mm).

The 3 anchoring pegs are arranged simmetrycally, thus allowing free orientation of the component.

The thickness varies according to the size as shown in the table alongside:

SIZE	H Thickness
28	8.0mm
30	8.0mm
32	8.5mm
34	9.0mm
36	9.5mm
38	10.0mm



INSTRUMENTS OVERVIEW

ATTENTION:

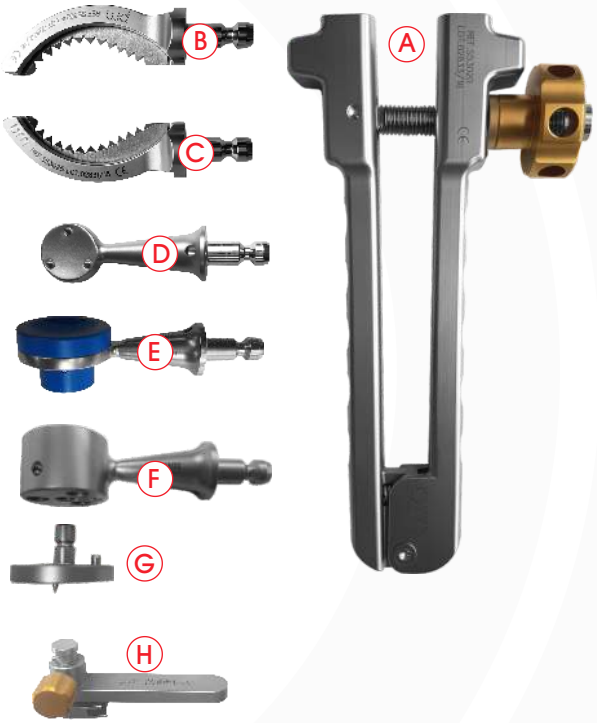
The Patella Instruments are not provided with the standard Instruments Set but supplied as optional.

Please refer to the Check List of the Patella Instruments Set at the end of this Surgical Technique for the composition.

The Patella Instruments Set provides a modular Patella Clamp that can be configured with different accessories for the different steps of the preparation.

It is composed of:

- (A) S53020 PATELLAR CLAMP - Main Body
- (B) S53024 PATELLAR CLAMP - Resection Guide RIGHT
- (C) S53025 PATELLAR CLAMP - Resection Guide LEFT
- (D) S53021 PATELLAR CLAMP - Lower Pressor
- (E) S53022 PATELLAR CLAMP - UpperPressor
- (F) S53172 PATELLAR CLAMP - Modular Drill Guide
- (G) S73173-78 PATELLAR CLAMP - Modular Drill Guide Ring (Ø28 to 38mm)
- (H) S53026 PATELLAR CLAMP - Resection Sizer



PREPARATION PROCEDURE

Prepare the patella by flipping it externally and freeing the synovial tissue and retinaculum from the periphery, downwards to the quadriceps tendon plane.

The thickness of the patella is then measured by means of the Patellar Caliper S53017 (**Fig. 1a**). The thickness will be detected on the upper scale of the instrument (**Fig. 1b**).

This step will help in determining the amount of bone to be resected and replaced by the patellar prosthesis (8.5mm).

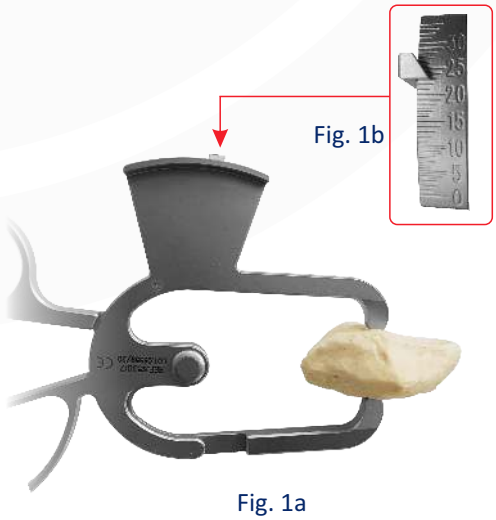


Fig. 1a

PATELLA RESECTION

The Patella Clamp is configured with the components **A**+**B**+**C**.

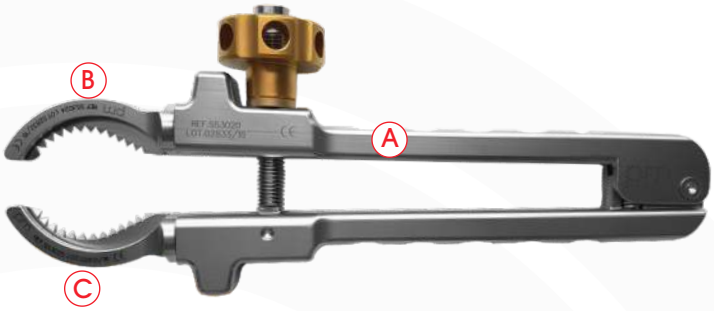


Fig. 2a

Fig. 2b

Place the Patella Clamp around the patellar bone positioning the resection guides at the appropriate resection level with the aid of the Resection Sizer inserted in the slot of the resection guide (**Fig. 2a**).

The resection level is set by locking the Resection Sizer at the notch of the desired value (**Fig. 2b**). It is possible to set the resection level in order to cut 6.5mm, 8.5mm and 10.5mm.

CAUTION

- ☑ Before proceed with the resection, make sure that the Resection Guides are correctly placed to achieve a parallel cut;
- ☑ In setting the resection level make sure to keep at least 13mm of remnant bone after resection.

Fig. 3

Firmly lock the Clamp by screwing the thumbwheel and perform the patellar resection using an oscillating saw through the slots of the Resection Guides (**Fig. 3**).

SIZE EVALUATION

The size of the patellar component that is best suited to cover the resected surface is evaluated with the aid of the Patella Templates S53171 (**Fig. 4**).

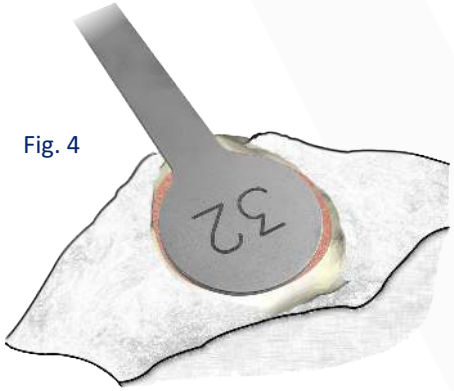


Fig. 4

PATELLA DRILLING

The Patella Clamp is configured with the components **A**+**D**+**F**+**G**.

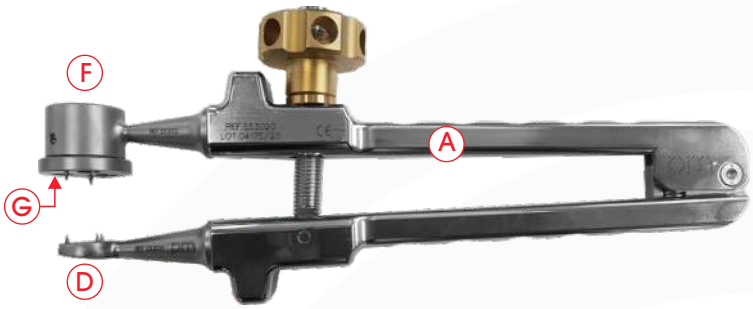


Fig. 5

The Modular Drill Guide (F) is equipped with the corresponding size Drill Guide Ring (G), which reproduces the effective diameter of the component allowing its proper centering (**Fig. 5**).

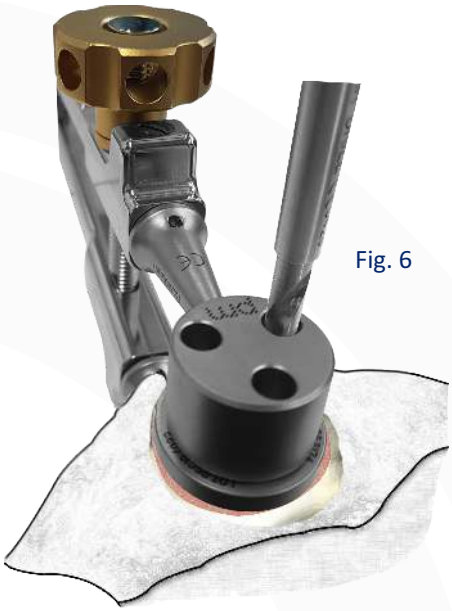


Fig. 6

Apply the Drill Guide onto the resected surface as shown (**Fig. 6**). Firmly lock the Clamp by screwing the thumbwheel and proceed with drilling using the Patellar Drill Bit S53063.

FUNCTIONAL EVALUATION

After placement of the other trial components (femur, tibia and insert) and the Trial Patella of the selected size (**Fig. 7**) the joint can be reduced and the knee tested through its full range of motion .

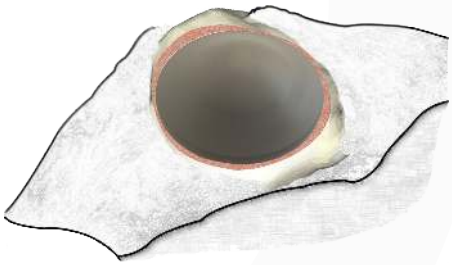
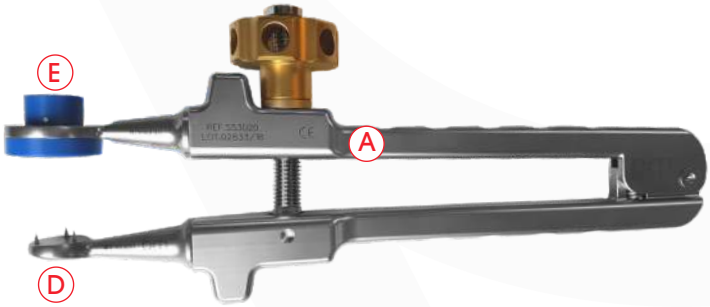


Fig. 7

IMPLANTING THE FINAL PATELLA

The Patella Clamp is configured with the components **A**+**D**+**E**.



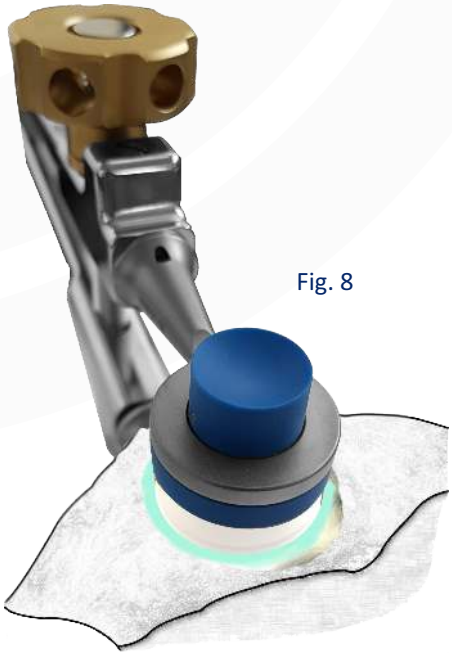


Fig. 8

Apply a layer of bone cement to the back face of the Patellar Prosthesis or directly onto the bone surface.

Place the definitive UHMWPE Patellar Prosthesis onto the prepared surface (the symmetrical pegs allow for free positioning) then place the Clamp to press the component and lock it by screwing the thumbwheel (**Fig. 8**).

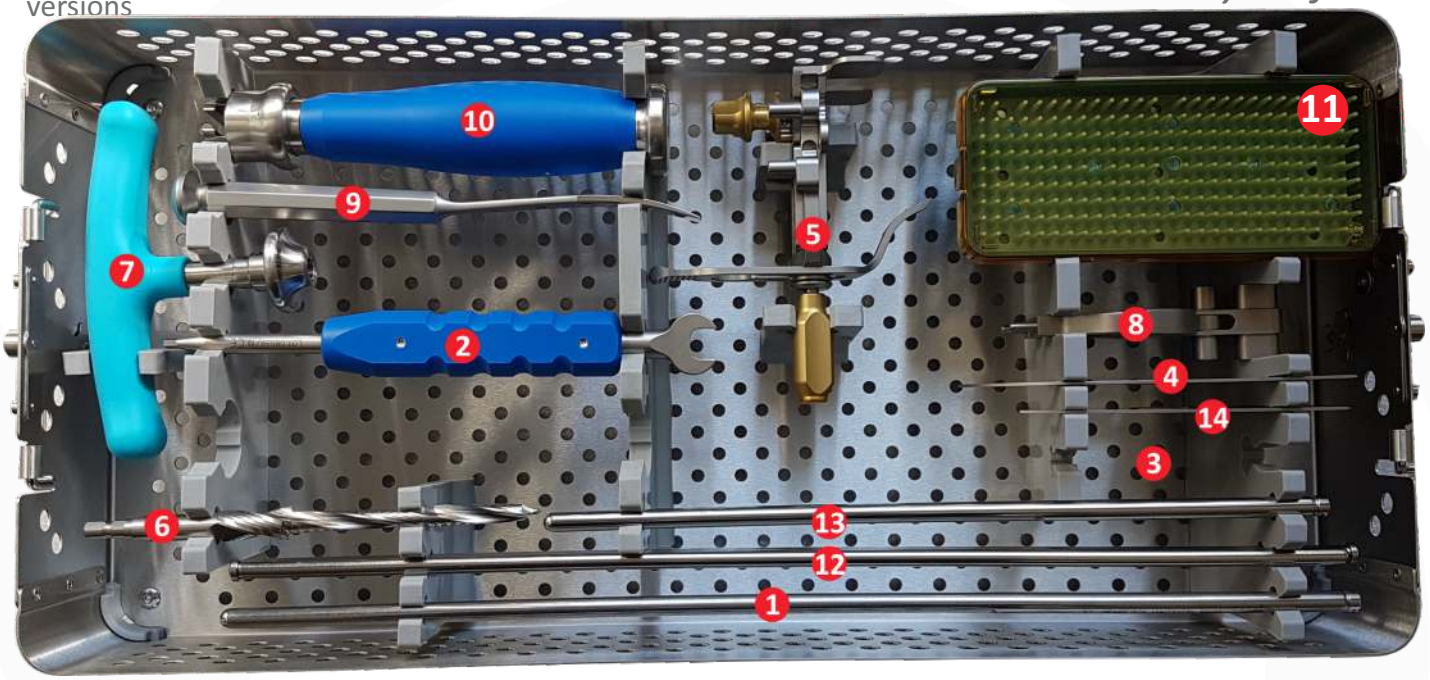
Apply pressure until final hardening of the bone cement, carefully removing its exceeding meanwhile.

S50300 GKS PRIME *FLEX*
ATTITUDE Instruments Set

S50301 BASIC SET (3 trays)

Generic instruments common to all versions

Tray 1 of 3

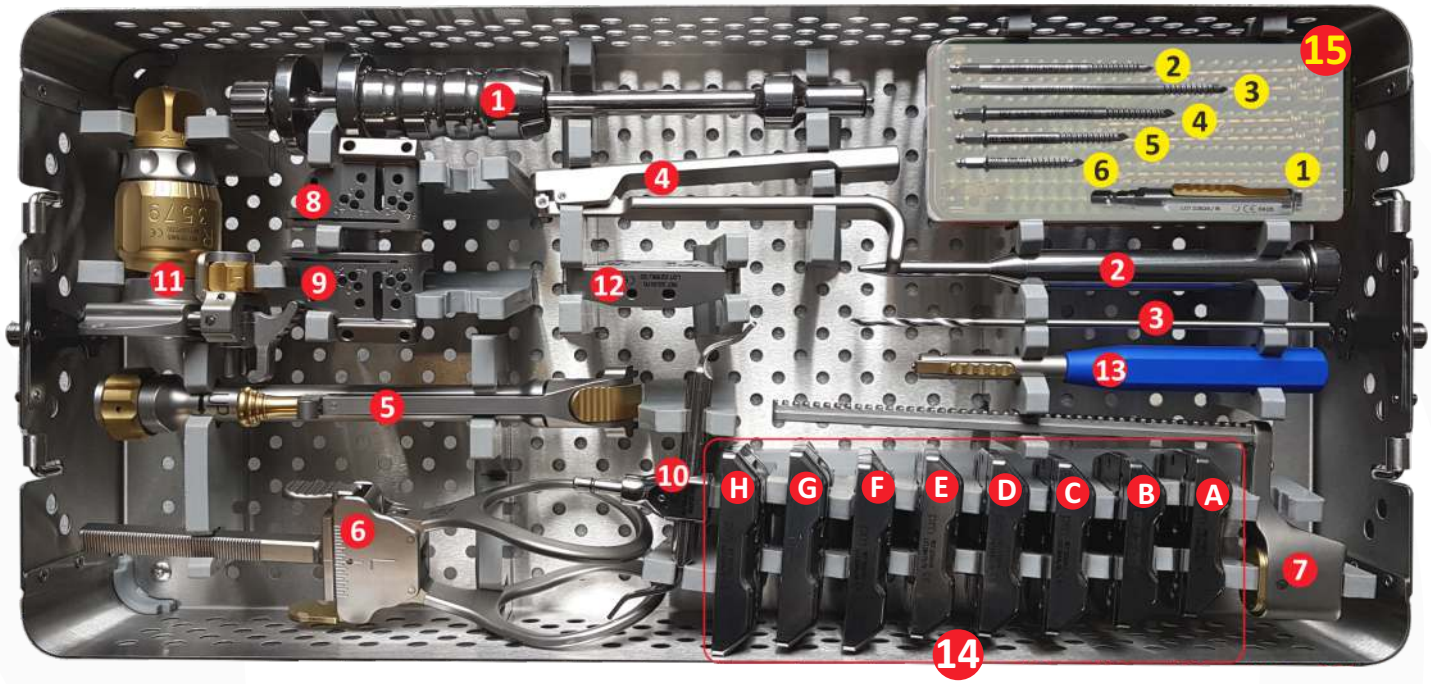


	S50241	**GKS PRIME FLEX: TRAY n° 1 silicone supp. - Generic Instruments**
1	S40040	GKS: EXTERNAL ALIGNMENT ROD Ø 7mm
2	S50112	GKS: OPEN WRENCH with SCREWDRIVER 3,5mm
3	S53050	GKS: Tibial Protection
4	S53054	GKS: Half-moon Resection Gauge - Large
5	S53059	GKS: Femoral Sizing/Orienting Device
	S53059A	GKS: Femoral Sizing/Orienting Device - STYLUS
6	S53060	GKS: Starter DRILL BIT Ø 8/12mm - Quick coupling
7	S53080	GKS: Ergonomic Intramedullary Rods Handle
8	S53081	GKS: Bridge for External Alignment Control
9	S53082	GKS: Curved Osteotome
10	S19501	GKS PRIME FLEX: Universal Handle - Quick Fix
	200037	PINS BOX (PET)
	S40074	GKS: GUIDE PIN Ø 3,5mm - LONG
	S53097	GKS PRIME FLEX: Trial Inserts Locking CLIP v.2
11	S53530	GKS: FIXATION PIN low profile - EXTRA SHORT
	S53531	GKS: FIXATION PIN low profile - SHORT
	S53532	GKS: FIXATION PIN low profile - MEDIUM
	S53533	GKS: FIXATION PIN low profile - LONG
12	S59103	GKS: I/M ROD Ø 8mm - LONGG
13	S59104	KS: I/M ROD Ø 8mm - SHORT
14	S59107	GKS: Half-moon Resection Gauge

S50301 BASIC SET (3 trays)

Generic instruments
common to all versions

Tray 2 of 3



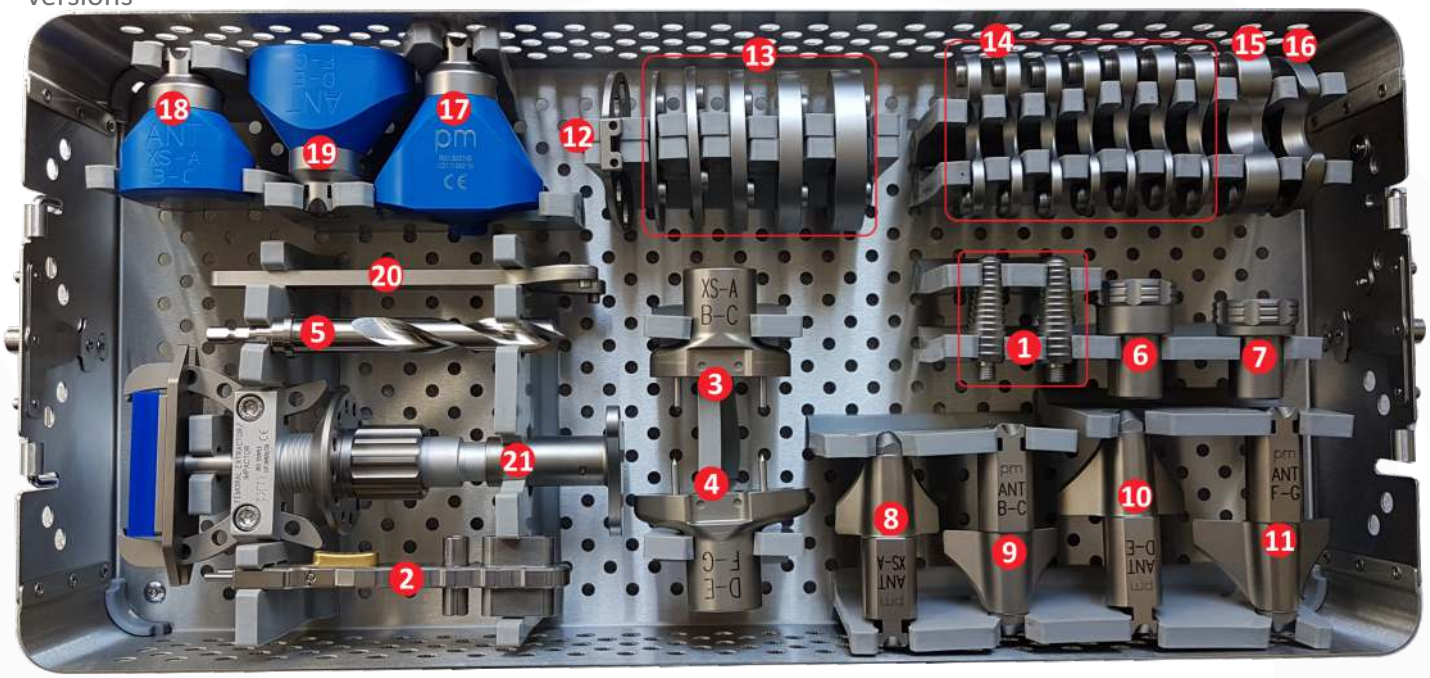
	S50242	**GKS PRIME FLEX: TRAY n° 2 silicone supp. - Generic Instruments**
1	S40026	GKS: HEADED PINS EXTRACTOR
2	S40067	GKS: FIXATION PINS IMPACTOR
3	S40069	GKS: DRILL BIT Ø 3,5x180mm
4	S40088	GKS: PINS PULLER (Pliers)
5	S53055	GKS: Ext. Tibial Alignment Guide, Variable Slope - Main Body
6	S53055A	GKS: Ext. Tibial Alignment Guide, Variable Slope - Ankle Clamp
7	S53055B	GKS: Ext. Tibial Alignment Guide, Variable Slope - Rack Rod
8	S53056	GKS: Repositionable Tibial Cutting Guide - RIGHT
9	S53057	GKS: Repositionable Tibial Cutting Guide - LEFT
10	S53058	GKS: Tibial Resection Gauge for Repositionable Cutting Guides
11	S53065	GKS: Femoral Valgus Guide - Main Body
	S53065A	GKS: Femoral Valgus Guide - Cutting Guide Support
12	S53070	GKS: Distal Femur Cutting Guide
13	S53096	GKS PRIME FLEX: Locking CLIP Positioner v.2
A	S59245	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 5 - Post. Ref.
B	S59246	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 6 - Post. Ref.
C	S59247	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 7 - Post. Ref.
D	S59248	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 8 - Post. Ref.
E	S59249	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 9 - Post. Ref.
F	S59250	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 10 - Post. Ref.
G	S59251	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 11 - Post. Ref.
H	S59252	GKS PRIME FLEX: Femoral Resection Guide PLUS - Size 12 - Post. Ref.
	S53150	***PINS BOX (PET)***
	200037	*GKS: Fast Drive PINS DRIVER*
A	*S53151*	*GKS: Fast Drive Headless PIN - MEDIUM*
B	*S53154*	*GKS: Fast Drive Headless PIN - LONG*
C	*S53155*	*GKS: Fast Drive Fixation PIN - EXTRA SHORT*
D	*S53161*	*GKS: Fast Drive Fixation PIN - SHORT*
E	*S53162*	*GKS: Fast Drive Fixation PIN - MEDIUM*
F	*S53163*	*GKS: Fast Drive Fixation PIN - LONG*

S50300 GKS PRIME *FLEX*
ATTITUDE Instruments Set

S50301 BASIC SET (3 trays)

Generic insrtuments common to all versions

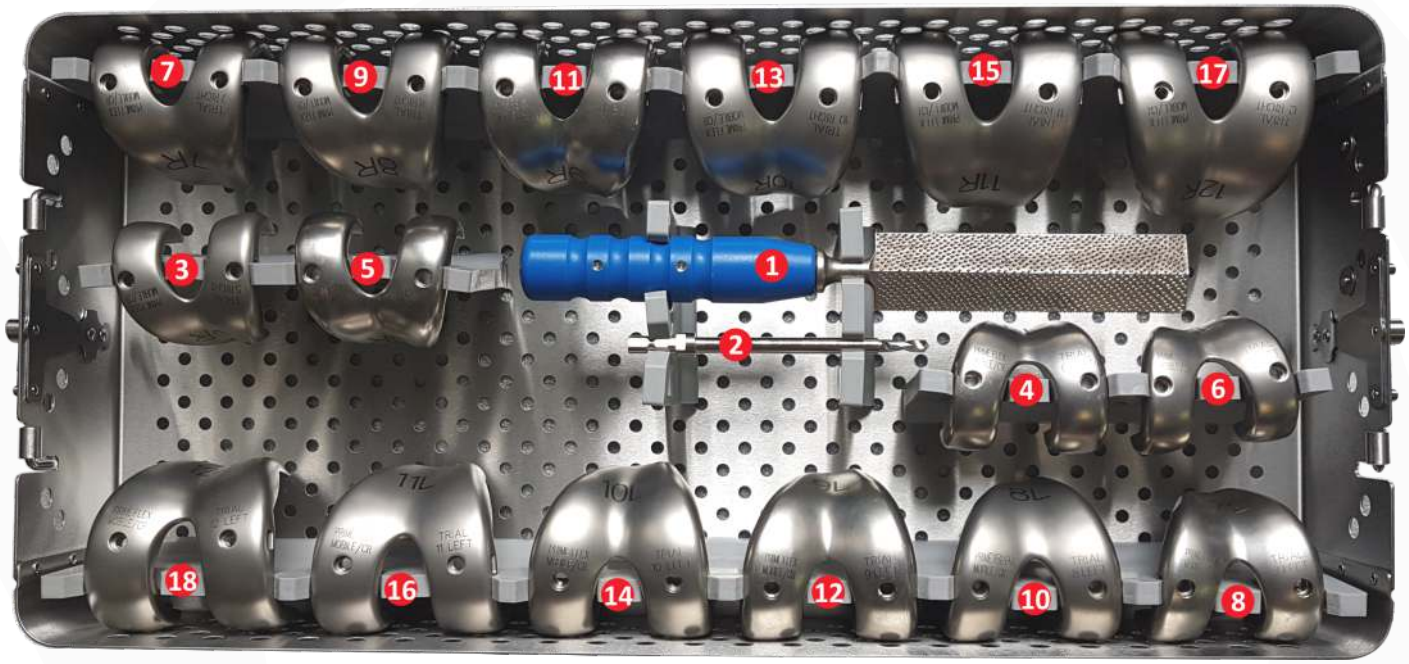
Tray 3 of 3



	S50243	**GKS PRIME FLEX: TRAY n° 3 silicone supp. - Generic Instruments**
1	S51011	GKS PRIME FLEX: Rasp for Extension stem Ø 14/8mm
1	S51012	GKS PRIME FLEX: Rasp for Extension stem Ø 14/10mm
2	S53095	GKS PRIME FLEX: Trial Tibial Baseplate TOP - HANDLE
3	S53102	GKS PRIME FLEX: TOP Tibial Punch Guide Sleeve - Size XS-A-B-C
4	S53103	GKS PRIME FLEX: TOP Tibial Punch Guide Sleeve - Size D-E-F-G
5	S53105	GKS PRIME FLEX: TOP Tibial Drill - Quick Coupling
6	S53106	GKS PRIME FLEX: TOP Tibial Drill Guide Sleeve - Size XS-A-B-C
7	S53107	GKS PRIME FLEX: TOP Tibial Drill Guide Sleeve - Size D-E-F-G
8	S53119	GKS PRIME FLEX: Tibial Punch Quick Fix - Size XS - A
9	S53120	GKS PRIME FLEX: Tibial Punch Quick Fix - Size B - C
10	S53121	GKS PRIME FLEX: Tibial Punch Quick Fix - Size D - E
11	S53122	GKS PRIME FLEX: Tibial Punch Quick Fix - Size F - G
12	S53125	GKS: MODULAR SPACER - Baseplate
	S53126	GKS: MODULAR SPACER - Lower Plate - 10mm
	S53127	GKS: MODULAR SPACER - Lower Plate - 12mm
13	S53128	GKS: MODULAR SPACER - Lower Plate - 14mm
	S53129	GKS: MODULAR SPACER - Lower Plate - 17mm
	S53130	GKS: MODULAR SPACER - Lower Plate - 20mm
	S53131	GKS: MODULAR SPACER - Angled Plate - 1°
	S53132	GKS: MODULAR SPACER - Angled Plate - 2°
	S53133	GKS: MODULAR SPACER - Angled Plate - 3°
14	S53134	GKS: MODULAR SPACER - Angled Plate - 4°
	S53135	GKS: MODULAR SPACER - Angled Plate - 5°
	S53136	GKS: MODULAR SPACER - Angled Plate - 6°
	S53137	GKS: MODULAR SPACER - Angled Plate - 7°
15	S53138	GKS: MODULAR SPACER - Extension Plate
16	S53139	GKS: MODULAR SPACER - Flexion Plate
17	S53140	GKS PRIME FLEX: FEMORAL IMPACTOR Quick Fix
18	S53142	GKS PRIME FLEX: TIBIA IMPACTOR Size XS-A-B-C - Quick Fix
19	S53143	GKS PRIME FLEX: TIBIA IMPACTOR Size D-E-F-G - Quick Fix
20	S59132	GKS: LOCKING WRENCH for FEMORAL HOLDER
21	S59153	GKS: FEMORAL HOLDER

S50302 FEMORAL TRIALS SET CR/MOBILE

Trial Femoral Components for
GKS PRIME *FLEX* CR fixed bearing
GKS PRIME *FLEX* MOBILE



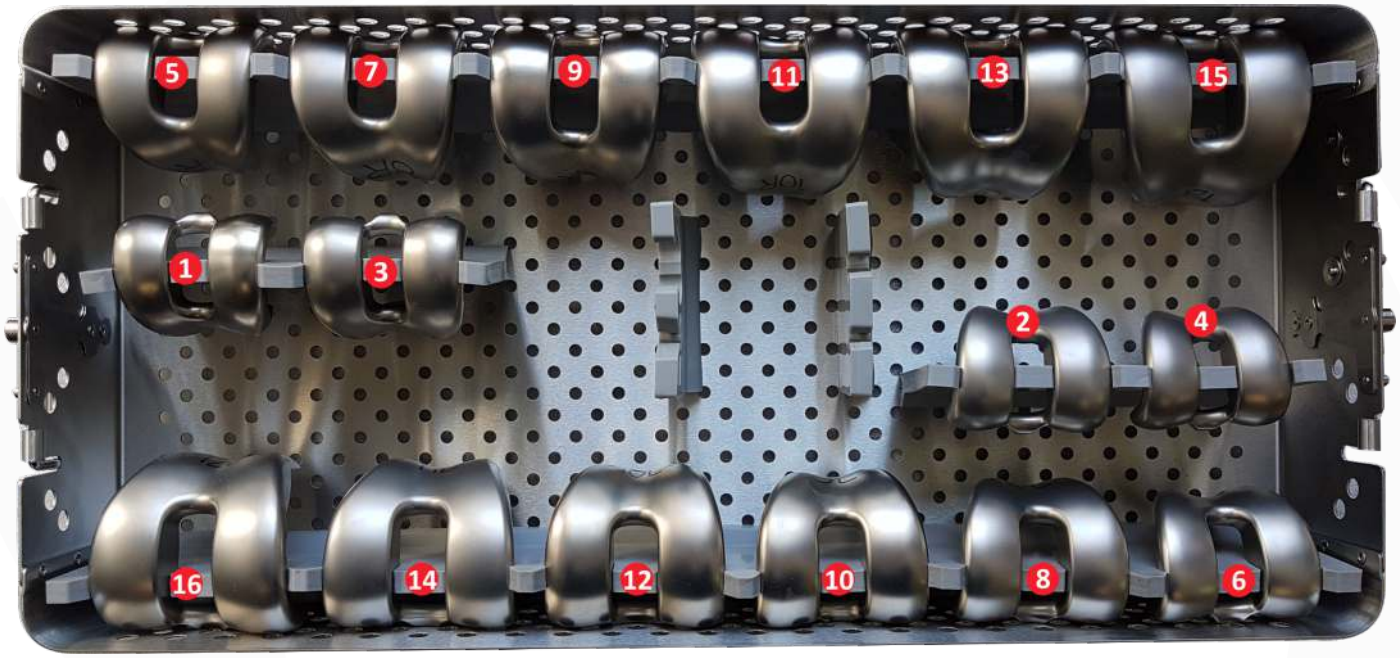
	S50244	**GKS PRIME FLEX: TRAY n° 4 silicone supp. - Femoral Trials**
1	S50111	GKS: RASP
2	S53062	GKS: DRILL BIT for Femoral Pegs - Quick coupling
3	S53503	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 5 Right
4	S53504	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 5 Left
5	S53505	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 6 Right
6	S53506	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 6 Left
7	S53507	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 7 Right
8	S53508	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 7 Left
9	S53509	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 8 Right
10	S53510	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 8 Left
11	S53511	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 9 Right
12	S53512	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 9 Left
13	S53522	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 10 Right
14	S53523	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 10 Left
15	S53513	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 11 Right
16	S53514	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 11 Left
17	S53526	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 12 Right
18	S53527	GKS PRIME FLEX: MOBILE/CR Trial Femur - Size 12 Left

S50300 GKS PRIME *FLEX*
ATTITUDE Instruments Set

S50303 FEMORAL TRIALS SET + BOX PS (2 Trays)

Trial Femoral Components and Intercondylar Cutting Guides for GKS PRIME *FLEX* PS fixed bearing

Tray 1 of 2



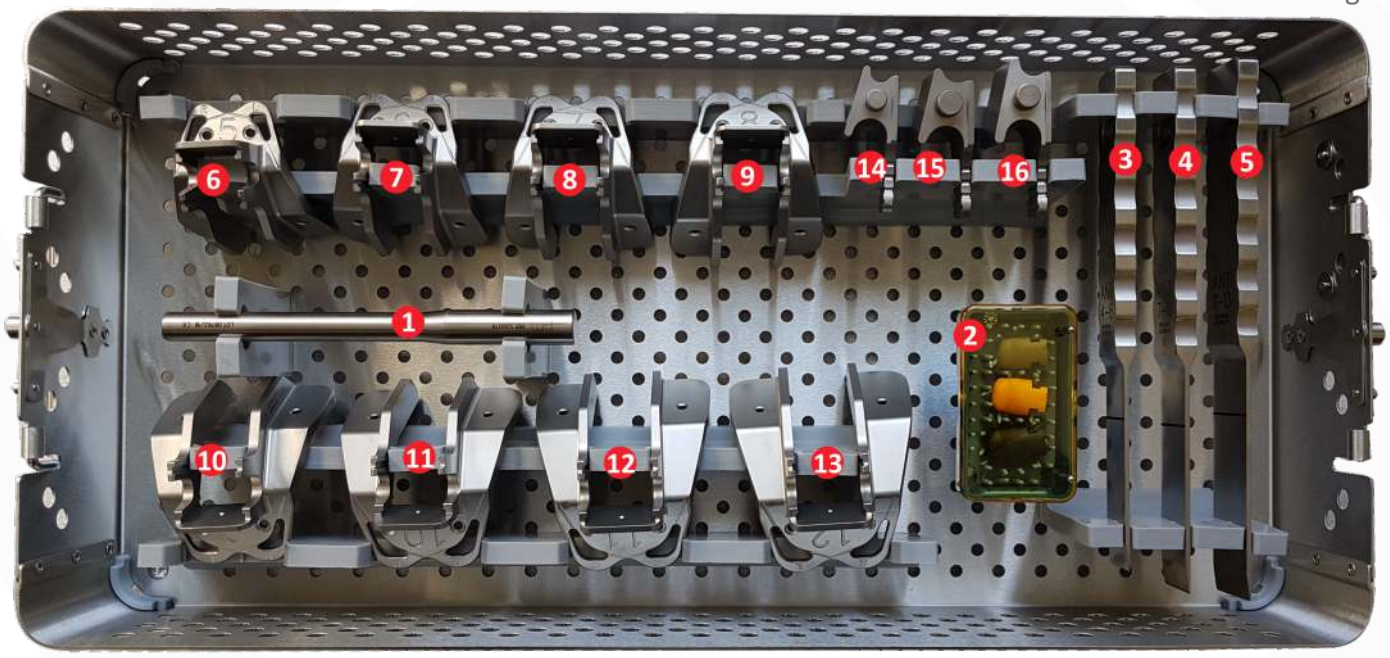
	S50244	**GKS PRIME FLEX: TRAY n° 4 silicone supp. - Femoral Trials**
1	S54403	GKS PRIME FLEX: PS Trial FEMUR - Size 5 RIGHT
2	S54404	GKS PRIME FLEX: PS Trial FEMUR - Size 5 LEFT
3	S54405	GKS PRIME FLEX: PS Trial FEMUR - Size 6 RIGHT
4	S54406	GKS PRIME FLEX: PS Trial FEMUR - Size 6 LEFT
5	S54407	GKS PRIME FLEX: PS Trial FEMUR - Size 7 RIGHT
6	S54408	GKS PRIME FLEX: PS Trial FEMUR - Size 7 LEFT
7	S54409	GKS PRIME FLEX: PS Trial FEMUR - Size 8 RIGHT
8	S54410	GKS PRIME FLEX: PS Trial FEMUR - Size 8 LEFT
9	S54411	GKS PRIME FLEX: PS Trial FEMUR - Size 9 RIGHT
10	S54412	GKS PRIME FLEX: PS Trial FEMUR - Size 9 LEFT
11	S54415	GKS PRIME FLEX: PS Trial FEMUR - Size 10 RIGHT
12	S54416	GKS PRIME FLEX: PS Trial FEMUR - Size 10 LEFT
13	S54413	GKS PRIME FLEX: PS Trial FEMUR - Size 11 RIGHT
14	S54414	GKS PRIME FLEX: PS Trial FEMUR - Size 11 LEFT
15	S54417	GKS PRIME FLEX: PS Trial FEMUR - Size 12 RIGHT
16	S54418	GKS PRIME FLEX: PS Trial FEMUR - Size 12 LEFT

GKS PRIME *FLEX* S50300
ATTITUDE Instruments Set

S50303 FEMORAL TRIALS SET + BOX PS (2 Trays)

Trial Femoral Components and Intercondylar Cutting Guides for GKS PRIME *FLEX* PS fixed bearing

Tray 2 of 2



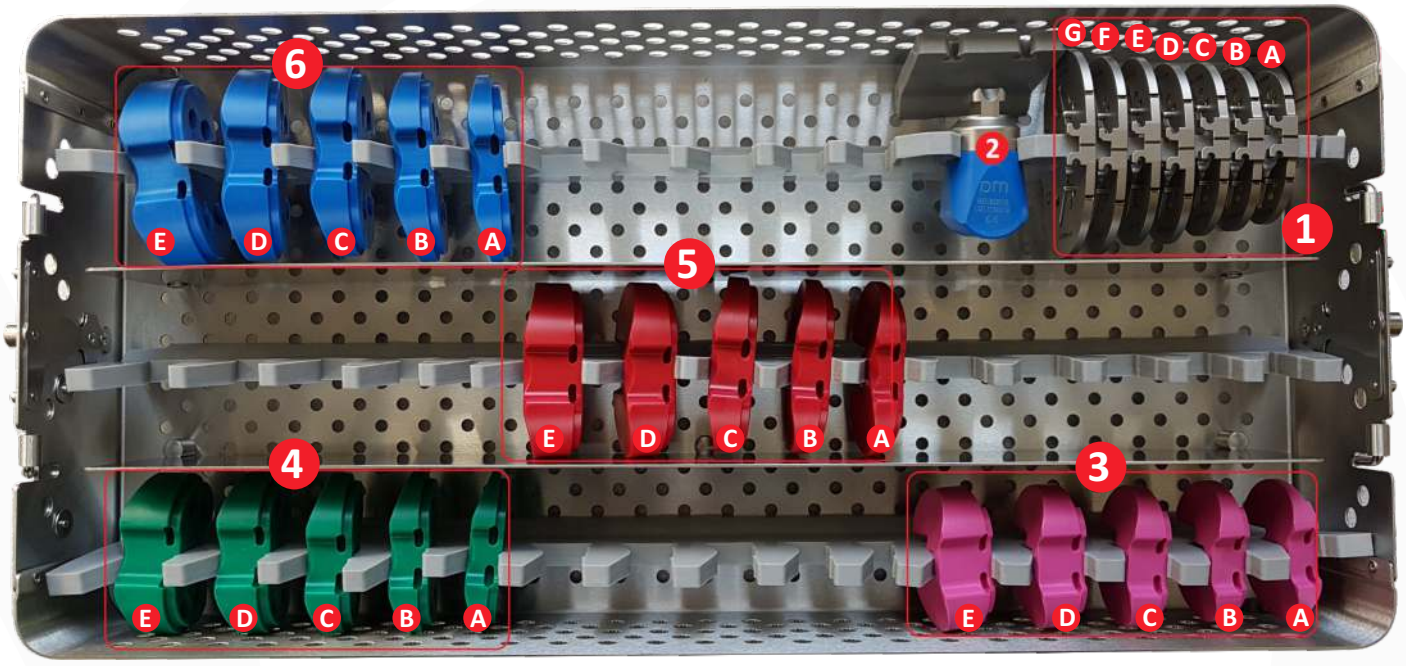
S50246 GKS PRIME FLEX: TRAY n° 6 silicone supp. - PS Integration

1	S30079	TOMMY BAR
2	S54375	GKS PRIME FLEX PS: TRIAL POST for Femurs 4-5-6 GREY
	S54376	GKS PRIME FLEX PS: TRIAL POST for Femurs 7-8-9-10 YELLOW
	S54377	GKS PRIME FLEX PS: TRIAL POST for Femurs 11-12-13 BLACK
3	S54384	KS PRIME FLEX PS: Intercondylar Box CHISEL Size 4-5-6
4	S54385	GKS PRIME FLEX PS: Intercondylar Box CHISEL Size 7-8-9-10
5	S54386	GKS PRIME FLEX PS: Intercondylar Box CHISEL Size 11-12-13
6	S54452	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 5
7	S54453	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 6
8	S54454	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 7
9	S54455	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 8
10	S54456	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 9
11	S54457	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 10
12	S54458	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 11
13	S54459	GKS PRIME FLEX: Intercondylar CUTTING GUIDE PS/SS - Size 12
14	S54461	GKS PRIME FLEX: ADAPTER x Intercondylar CUTTING GUIDE PS/SS - Size 5-6
15	S54462	GKS PRIME FLEX: ADAPTER x Intercondylar CUTTING GUIDE PS/SS - Size 7-10
16	S54463	GKS PRIME FLEX: ADAPTER x Intercondylar CUTTING GUIDE PS/SS - Size 11-12

S50300 GKS PRIME *FLEX*
ATTITUDE Instruments Set

S50304 TIBIAL TRIALS SET CR/PS

Tibial Trial Components for
GKS PRIME *FLEX* CR fixed bearing
GKS PRIME *FLEX* PS fixed bearing



	S50225	**GKS PRIME FLEX: TRAY n° 5 silicone supp. - Tibial Trials**
	A S53086	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size A
	B S53087	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size B
	C S53088	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size C
1	**D** S53089	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size D
	E S53090	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size E
	F S53091	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size F
	G S53092	GKS PRIME FLEX: Trial Tibial Baseplate TOP - Size G
2	S53145	GKS PRIME FLEX: TIBIAL INSERT IMPACTOR - Quick Fix
	A S54350	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size XS-A x 10mm - MAGENTA
	B S54351	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size XS-A x 12mm - MAGENTA
3	**C** S54352	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size XS-A x 14mm - MAGENTA
	D S54353	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size XS-A x 17mm - MAGENTA
	E S54354	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size XS-A x 20mm - MAGENTA
	A S54355	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size B-C x 10mm - GREEN
	B S54356	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size B-C x 12mm - GREEN
4	**C** S54357	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size B-C x 14mm - GREEN
	D S54358	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size B-C x 17mm - GREEN
	E S54359	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size B-C x 20mm - GREEN
	A S54360	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size D-E x 10mm - RED
	B S54361	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size D-E x 12mm - RED
5	**C** S54362	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size D-E x 14mm - RED
	D S54363	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size D-E x 17mm - RED
	E S54364	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size D-E x 20mm - RED
	A S54365	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size F-G x 10mm - BLUE
	B S54366	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size F-G x 12mm - BLUE
6	**C** S54367	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size F-G x 14mm - BLUE
	D S54368	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size F-G x 17mm - BLUE
	E S54369	GKS PRIME FLEX: Trial Insert TOP CR/PS - Size F-G x 20mm - BLUE

GKS PRIME *FLEX* S50300
ATTITUDE Instruments Set

S50305 TIBIAL TRIALS SET MOBILE
Trial Tibial components for
GKS PRIME *FLEX* MOBILE bearing

S50225 GKS PRIME FLEX: TRAY n° 5 silicone supp. - Tibial Trials

1 S53098 GKS PRIME FLEX: Trial Inserts Rotating Adapter v.2

A S53110 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size A
B S53111 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size B
C S53112 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size C
2 D S53113 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size D
E S53114 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size E
F S53115 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size F
G S53116 GKS PRIME FLEX: MOBILE Trial Tibial Baseplate v.2 - Size G

3 S53141 GKS PRIME FLEX: MOBILE TIBIA IMPACTOR - Quick Fix

A S51930 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 5x10mm
B S51931 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 5x12mm
4 C S51932 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 5x15mm
D S51933 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 5x18mm
E S51934 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 5x20mm

A S51935 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 6x10mm
B S51936 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 6x12mm
5 C S51937 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 6x15mm
D S51938 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 6x18mm
E S51939 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 6x20mm

A S51940 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 7x10mm
B S51941 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 7x12mm
6 C S51942 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 7x15mm
D S51943 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 7x18mm
E S51944 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 7x20mm

A S51945 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 8x10mm
B S51946 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 8x12mm
7 C S51947 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 8x15mm
D S51948 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 8x18mm
E S51949 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 8x20mm

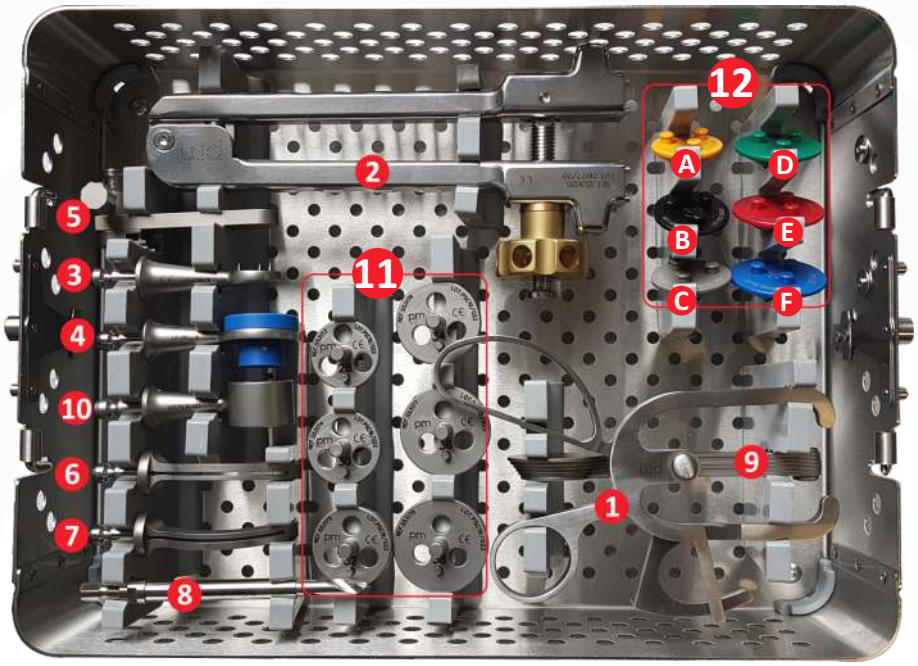
A S51950 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 9x10mm
B S51951 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 9x12mm
8 C S51952 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 9x15mm
D S51953 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 9x18mm
E S51954 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 9x20mm

A S51955 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 10x10mm
B S51956 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 10x12mm
9 C S51957 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 10x15mm
D S51958 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 10x18mm
E S51959 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 10x20mm

A S51960 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 11x10mm
B S51961 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 11x12mm
10 C S51962 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 11x15mm
D S51963 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 11x18mm
E S51964 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 11x20mm

A S51965 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 12x10mm
B S51966 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 12x12mm
11 C S51967 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 12x15mm
D S51968 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 12x18mm
E S51969 GKS PRIME FLEX: Trial Insert MOBILE v.2 Size 12x20mm

S50210 GKS PATELLA INSTRUMENTS SET



	S50249	**GKS PRIME FLEX: TRAY n° 9 silicone supp. - Patella**
1	S53017	GKS: PATELLAR CALIPER
2	S53020	GKS: PATELLAR CLAMP - Main Body
3	S53021	GKS: PATELLAR CLAMP - Lower Pressor
4	S53022	GKS: PATELLAR CLAMP - Upper Pressor
5	S53026	GKS: PATELLAR CLAMP - Resection Sizer
6	S53024	GKS: PATELLAR CLAMP - Resection Guide RIGHT
7	S53025	GKS: PATELLAR CLAMP - Resection Guide LEFT
8	S53063	GKS: Patellar Drill Bit - Quick coupling
9	S53171	GKS: PATELLA TEMPLATES
10	S53172	GKS: PATELLAR CLAMP - Modular Drill Guide
11	S53173	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 28mm
	S53174	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 30mm
	S53175	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 32mm
	S53176	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 34mm
	S53177	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 36mm
	S53178	GKS: PATELLAR CLAMP - Modular Drill Guide Ring - Ø 38mm
12	S53179	GKS: WING Trial Patella Ø 28mm
	S53180	GKS: WING Trial Patella Ø 30mm
	S53181	GKS: WING Trial Patella Ø 32mm
	S53182	GKS: WING Trial Patella Ø 34mm
	S53183	GKS: WING Trial Patella Ø 36mm
	S53184	GKS: WING Trial Patella Ø 38mm

*Articles with asterisk are available ON REQUEST

GKS PRIME FLEX - Femoral Component

SIZE	SIDE	CrCo Cemented Reference	CrCo HaX-Pore® Reference	BIOLOY® Cemented Reference	BIOLOY® HaX-Pore® Reference
4	RIGHT	54002*	54291*	54078*	54295*
	LEFT	54003*	54292*	54079*	54296*
5	RIGHT	54013	54033	54083	54211
	LEFT	54014	54034	54084	54212
6	RIGHT	54025	54035	54085	54213
	LEFT	54026	54036	54086	54214
7	RIGHT	54017	54037	54087	54215
	LEFT	54018	54038	54088	54216
8	RIGHT	54027	54039	54089	54217
	LEFT	54028	54040	54090	54218
9	RIGHT	54021	54041	54091	54219
	LEFT	54022	54042	54092	54220
10	RIGHT	54006	54045	54095	54221
	LEFT	54007	54046	54096	54222
11	RIGHT	54023	54043	54093	54223
	LEFT	54024	54044	54094	54224
12	RIGHT	54008	54047	54097	54225
	LEFT	54009	54048	54098	54226
13	RIGHT	54004*	54293*	54099*	54297*
	LEFT	54005*	54294*	54100*	54298*

GKS PRIME FLEX - Tibia TOP

Nickel Free

SIZE	Cemented Reference	HaX-Pore® Reference
XS	54471	54491
A	54472	54492
B	54473	54493
C	54474	54494
D	54475	54495
E	54476	54496
F	54477	54497
G	54478	54498
H	54479	54499
I	54480	54500

GKS PRIME FLEX - Tibial Extensions

Nickel Free

For Tibia TOP Fix Bearing

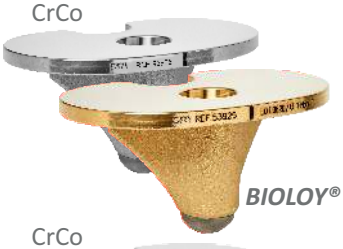
SIZE	Reference
40x8mm	54201
40x10mm	54202

For Tibia MOBILE

SIZE	Reference
40x8mm	51011
40x10mm	51012

GKS PRIME FLEX - Mobile Bearing Tibia

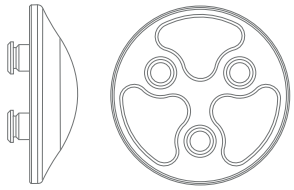
CrCo



CrCo

SIZE	CrCo Cemented Reference	CrCo HX-Pore Reference	BIOLOY® Cemented Reference	BIOLOY® HaX-Pore Reference
A	53801	53901	53921	53951
B	53802	53902	53922	53952
C	53803	53903	53923	53953
D	53804	53904	53924	53954
E	53805	53905	53925	53955
F	53806	53906	53926	53956
G	53807	53907	53927	53957

GKS - WING Patella



SIZE	UHMWPE Reference	VITAL-E® Reference
28mm	53128	53128E
30mm	53130	53130E
32mm	53132	53132E
34mm	53134	53134E
36mm	53136	53136E
38mm	53138	53138E

GKS PRIME FLEX - Joint Liners

GKS PRIME FLEX - CR Liners

SIZE	Thickness	UHMWPE Reference	VITAL-E® Reference
XS-A	9mm	54406	54406E
	10mm	54401	54401E
	11mm	54407	54407E
	12mm	54402	54402E
	13mm	54408*	54408E*
	14mm	54403	54403E
	15mm	54409*	54409E*
	17mm	54404	54404E
	20mm	54405*	54405E*
B-C	9mm	54416	54416E
	10mm	54411	54411E
	11mm	54417	54417E
	12mm	54412	54412E
	13mm	54418*	54418E*
	14mm	54413	54413E
	15mm	54419*	54419E*
	17mm	54414	54414E
	20mm	54415*	54415E*
D-E	9mm	54426	54426E
	10mm	54421	54421E
	11mm	54427	54427E
	12mm	54422	54422E
	13mm	54428*	54428E*
	14mm	54423	54423E
	15mm	54429*	54429E*
	17mm	54424	54424E
	20mm	54425*	54425E*
F-G	9mm	54436	54436E
	10mm	54431	54431E
	11mm	54437	54437E
	12mm	54432	54432E
	13mm	54438*	54438E*
	14mm	54433	54433E
	15mm	54439	54439E*
	17mm	54434	54434E
	20mm	54435*	54435E*
H-I	9mm	54446	54446E
	10mm	54441	54441E
	11mm	54447	54447E
	12mm	54442	54442E
	13mm	54448*	54448E*
	14mm	54443	54443E
	15mm	54449*	54449E*
	17mm	54444	54444E
	20mm	54445*	54445E*

*The correct coupling between **Tibial Component** and **Joint Liner** is guided by the colour code reported on the packaging labels.*

GKS PRIME FLEX - Anterior-Stabilized Liners

*For the matching between **AS** Articular Insert and Femoral Component refer to the table below.*

			RIGHT		LEFT	
			UHMWPE	VITAL-E®	UHMWPE	VITAL-E®
SIZE	Compatible FEMUR	Thickness	Reference	Reference	Reference	Reference
XS-A	4-5-6	9mm	55121	55121E	55122	55122E
		10mm	55021	55021E	55022	55022E
		11mm	55123	55123E	55124	55124E
		12mm	55023	55023E	55024	55024E
		13mm	55125*	55125E*	55126*	55126E*
		14mm	55025	55025E	55026	55026E
		15mm	55127*	55127E*	55128*	55128E*
		17mm	55027	55027E	55028	55028E
		20mm	55029*	55029E*	55030*	55030E*
B-C	5-6-7-8	9mm	55129	55129E	55130	55130E
		10mm	55035	55035E	55036	55036E
		11mm	55131	55131E	55132	55132E
		12mm	55037	55037E	55038	55038E
		13mm	55133*	55133E*	55134*	55134E*
		14mm	55039	55039E	55040	55040E
		15mm	55135*	55135E*	55136*	55136E*
		17mm	55041	55041E	55042	55042E
		20mm	55043*	55043E*	55044*	55044E*
D-E	7-8-9 10-11	9mm	55137	55137E	55138	55138E
		10mm	55049	55049E	55050	55050E
		11mm	55139	55139E	55140	55140E
		12mm	55051	55051E	55052	55052E
		13mm	55141*	55141E*	55142*	55142E*
		14mm	55053	55053E	55054	55054E
		15mm	55143*	55143E*	55144*	55144E*
		17mm	55055	55055E	55056	55056E
		20mm	55057*	55057E*	55058*	55058E*
F-G	9-10 11-12	9mm	55145	55145E	55146	55146E
		10mm	55063	55063E	55064	55064E
		11mm	55147	55147E	55148	55148E
		12mm	55065	55065E	55066	55066E
		13mm	55149*	55149E*	55150*	55150E*
		14mm	55067	55067E	55068	55068E
		15mm	55151*	55151E*	55152*	55152E*
		17mm	55069	55069E	55070	55070E
		20mm	55071*	55071E*	55072*	55072E*
H-I	9-10 11-12-13	9mm	55153	55153E	55154	55154E
		10mm	55077	55077E	55078	55078E
		11mm	55155	55155E	55156	55156E
		12mm	55079	55079E	55080	55080E
		13mm	55157*	55157E*	55158*	55158E*
		14mm	55081	55081E	55082	55082E
		15mm	55159*	55159E*	55160*	55160E*
		17mm	55083	55083E	55084	55084E
		20mm	55085*	55085E*	55086*	55086E*

GKS PRIME FLEX - MOBILE UC Joint Liners

SIZE	Compatible TIBIA	Thickness	UHMWPE Reference	VITAL-E Reference
4	A-B-C-D E-F-G	9mm	51986	51986E
		10mm	51925	51925E
		11mm	51987	51987E
		12mm	51926	51926E
		13mm	51988*	51988E*
		14mm	51989*	51989E*
		15mm	51927	51927E
		17mm	51990*	51990E*
		18mm	51928	51928E
		20mm	51929	51929E
5	A-B-C-D E-F-G	9mm	51991	51991E
		10mm	51930	51930E
		11mm	51992	51992E
		12mm	51931	51931E
		13mm	51993*	51993E*
		14mm	51970*	51970E*
		15mm	51932	51932E
		17mm	51971*	51971E*
		18mm	51933	51933E
		20mm	51934	51934E
6	A-B-C-D E-F-G	9mm	51994	51994E
		10mm	51935	51935E
		11mm	51995	51995E
		12mm	51936	51936E
		13mm	51996*	51996E*
		14mm	51972*	51972E*
		15mm	51937	51937E
		17mm	51973*	51973E*
		18mm	51938	51938E
		20mm	51939	51939E
7	B-C-D E-F-G	9mm	51997	51997E
		10mm	51940	51940E
		11mm	51998	51998E
		12mm	51941	51941E
		13mm	51999*	51999E*
		14mm	51974*	51974E*
		15mm	51942	51942E
		17mm	51975*	51975E*
		18mm	51943	51943E
		20mm	51944	51944E
8	C-D-E F-G	9mm	52000	52000E
		10mm	51945	51945E
		11mm	52001	52001E
		12mm	51946	51946E
		13mm	52002*	52002E*
		14mm	51976*	51976E*
		15mm	51947	51947E
		17mm	51977*	51977E*
		18mm	51948	51948E
		20mm	51949	51949E
9	D-E-F-G	9mm	52003	52003E
		10mm	51950	51950E
		11mm	52004	52004E
		12mm	51951	51951E
		13mm	52005*	52005E*
		14mm	51978*	51978E*
		15mm	51952	51952E
		17mm	51979*	51979E*
		18mm	51953	51953E
		20mm	51954	51954E
10	E-F-G	9mm	52006	52006E
		10mm	51955	51955E
		11mm	52007	52007E
		12mm	51956	51956E
		13mm	52008*	52008E*
		14mm	51980*	51980E*
		15mm	51957	51957E
		17mm	51981*	51981E*
		18mm	51958	51958E
		20mm	51959	51959E
11	E-F-G	9mm	52009	52009E
		10mm	51960	51960E
		11mm	52010	52010E
		12mm	51961	51961E
		13mm	52011*	52011E*
		14mm	51982*	51982E*
		15mm	51962	51962E
		17mm	51983*	51983E*
		18mm	51963	51963E
		20mm	51964	51964E
12	F-G	9mm	52012	52012E
		10mm	51965	51965E
		11mm	52013	52013E
		12mm	51966	51966E
		13mm	52014*	52014E*
		14mm	51984*	51984E*
		15mm	51967	51967E
		17mm	51985*	51985E*
		18mm	51968	51968E
		20mm	51969	51969E
13	F-G	9mm	52015	52015E
		10mm	52016	52016E
		11mm	52017	52017E
		12mm	52018	52018E
		13mm	52019*	52019E*
		14mm	52020*	52020E*
		15mm	52021	52021E
		17mm	52022*	52022E*
		18mm	52023	52023E
		20mm	52024	52024E

Information

INTENDED PURPOSE: GKS PRIME FLEX is a three-compartimental knee prosthesis available in MOBILE and fixed bearing CR and PS option to be used in Total Knee Replacement procedures. Indicated for primary Total Knee Arthroplasties in cases of advanced osteo-cartilagineous degeneration of the knee joint mainly due to arthrosis, rheumatoid arthritis, post-traumatic factors, and outcomes of corrective osteotomies. Anchorage of the device to the bone may be cementless or cemented, depending upon the selected version.

SURFACE FINISHING:

Articular surface (Femur): achieved through the ***MICROLOY®*** technological process. ***BIOLOY®*** version with TiNbN coating. Roughness is in compliance with ISO 7207-2 Standards.

Bone-Implant surface:

- *Cemented version*: pelleted surface with depressions for even acrylic cement spreading;
- *Cementless version (Tibia)*: ***HaX-Pore®*** coating (300µm pure Titanium + 60µm Hydroxyapatite $Ca_{10}(OH)_2(PO_4)_6$

STERILIZATION:

Method: Ethylene Oxyde (*EtO*) or irradiation (*Beta* or *Gamma* - nominal dose 25 kGy) in vacuum.

Validity: 5 years (*Beta*) - 10 years (Et*O*/*Gamma*).

CLASSIFICATION: Class III 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.

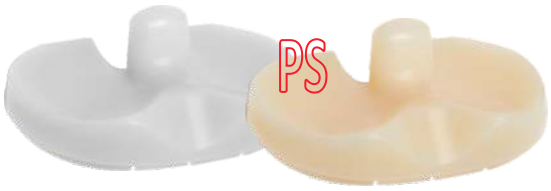
GKS PRIME FLEX - PS Femoral Component

BIOLOY®

SIZE	SIDE	MICROLOY® Cemented Reference	BIOLOY® Cemented Reference
4	RIGHT	54301	54351
	LEFT	54302	54352
5	RIGHT	54303	54353
	LEFT	54304	54354
6	RIGHT	54305	54355
	LEFT	54306	54356
7	RIGHT	54307	54357
	LEFT	54308	54358
8	RIGHT	54309	54359
	LEFT	54310	54360
9	RIGHT	54311	54361
	LEFT	54312	54362
10	RIGHT	54313	54363
	LEFT	54314	54364
11	RIGHT	54315	54365
	LEFT	54316	54366
12	RIGHT	54317	54367
	LEFT	54318	54368
13	RIGHT	54319*	54369*
	LEFT	54320*	54370*

GKS PRIME FLEX - PS Inserts

Refer to the COLOR CODE reported on the products label for the correct coupling between the components.



SIZE	Thickness	UHMWPE Reference	VITAL-E® Reference
4-6 XS-A	9mm	54546	54546E
	10mm	54501	54501E
	11mm	54547	54547E
	12mm	54502	54502E
	13mm	54548*	54548E*
	14mm	54503	54503E
	15mm	54549*	54549E*
	17mm	54504	54504E
	20mm	54505	54505E
4-6 B-C	9mm	54550	54550E
	10mm	54506	54506E
	11mm	54551	54551E
	12mm	54507	54507E
	13mm	54552*	54552E*
	14mm	54508	54508E
	15mm	54553*	54553E*
	17mm	54509	54509E
	20mm	54510	54510E
4-6 D-E	9mm	54554	54554E
	10mm	54511	54511E
	11mm	54555	54555E
	12mm	54512	54512E
	13mm	54556*	54556E*
	14mm	54513	54513E
	15mm	54557*	54557E*
	17mm	54514	54514E
	20mm	54515	54515E

SIZE	Thickness	UHMWPE Reference	VITAL-E® Reference
7-10 B-C	9mm	54588	54588E
	10mm	54516	54516E
	11mm	54589	54589E
	12mm	54517	54517E
	13mm	54590*	54590E*
	14mm	54518	54518E
	15mm	54591*	54591E*
	17mm	54519	54519E
	20mm	54520	54520E
7-10 D-E	9mm	54592	54592E
	10mm	54521	54521E
	11mm	54593	54593E
	12mm	54522	54522E
	13mm	54594*	54594E*
	14mm	54523	54523E
	15mm	54595*	54595E*
	17mm	54524	54524E
	20mm	54525	54525E
7-10 F-G	9mm	54596	54596E
	10mm	54526	54526E
	11mm	54597	54597E
	12mm	54527	54527E
	13mm	54598*	54598E*
	14mm	54528	54528E
	15mm	54599*	54599E*
	17mm	54529	54529E
	20mm	54530	54530E

SIZE	Thickness	UHMWPE Reference	VITAL-E® Reference
11-13 D-E	9mm	54600	54600E
	10mm	54531	54531E
	11mm	54601	54601E
	12mm	54532	54532E
	13mm	54602*	54602E*
	14mm	54533	54533E
	15mm	54603*	54603E*
	17mm	54534	54534E
	20mm	54535	54535E
11-13 F-G	9mm	54604	54604E
	10mm	54536	54536E
	11mm	54605	54605E
	12mm	54537	54537E
	13mm	54606*	54606E*
	14mm	54538	54538E
	15mm	54607*	54607E*
	17mm	54539	54539E
	20mm	54540	54540E
11-13 H-I	9mm	54626	54626E
	10mm	54541	54541E
	11mm	54627	54627E
	12mm	54542	54542E
	13mm	54628*	54628E*
	14mm	54543	54543E
	15mm	54629*	54629E*
	17mm	54544	54544E
	20mm	54545	54545E

WARNINGS, INDICATIONS AND CONTRAINDICATIONS

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). It is also advisable to check the website for the availability of any updates to this Instructions for Use. **Negligence or lack of observance of this aspect exonerates the manufacturer from all responsibility.**

Definition

Joint 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 (check on the website for the availability):**

- Advanced wear of the joint due to dysplasia, degenerative, post-traumatic, or rheumatic diseases.
- 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 the prosthetic devices for purposes different than those intended 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 vascular, neurological or muscular diseases compromising 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 ioint 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 types of joint 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 third parties instruments.

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 be 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.

Prolonged contact - direct or indirect – of the electrocautery with implantable components, in particular in the vicinity of the femoral stems neck, can result in structural alterations which may modify the characteristics of resistance to fatigue of the material with consequent risks of breakage and must therefore be carefully avoided.

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 a substitute for bone cement, nor can it compensate for insufficient primary stability.

TiNbN coating acts as an isolation barrier for the release of ions by the underlying 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 cannot 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 sterile implants are removed from the packaging, the protective packaging must be examined for possible damage as this could impair the sterility. The expiration date for the sterility of the product must be observed and expired products must be returned to the manufacturer. Observation of the common aseptic procedures must be respected when opening the package.

Prior to reduction or assembly, prostheses or articular prosthetic components 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 adapted or modified 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 connection of femoral ball-heads with conical coupling is only possible with the completely intact surface of both the ball head cone and 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.

Observe any additional information, i.e. those reported in the information label applied to the primary and/or the secondary packaging relating to possible limitations for use.

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; excessive weight; non-physiological stresses; superficial damage; partial or total lost of fixation; incorrect manipulation or improper implantation (wrong choice of implant component or size, improper alignment, incorrect components connection, insufficient fixation);
- excess wear or loosening of the implant due to breakdown of the osseous bed;
- dislocation 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;
- Intra-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-operational 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 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 of the prosthesis components are supplied with trial parts or measuring instruments that should be accurately used to determine the correct 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. The patient must also be informed that the devices implanted, due to the presence of metal components:

- 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.

Implantable prosthetic devices containing metal and / or magnetic and / or electro conductive elements have not been evaluated for safety and compatibility in an electromagnetic environment. Related risks, including heating, migration and imaging artifacts next to the implants are known, but have not been evaluated for these components. For this reason, the patient should be informed that, whenever the implanted devices contain such materials, it is not advised to undergo radio diagnostic investigations based on magnetic fields (MR scan).

Components made only in UHMWPE or VITAL-E or VITAL-XE are made of non-metallic, non-conductive and non-magnetic materials. Therefore, according to the ASTM F-2503 standard, the devices are defined as "MR Safe".

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:

- verify sterility expiration date (month/year) on the label of the product;
- visually verify that the internal packaging and the label are intact;
- 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 expiration date of sterility has passed, do not use the product and return it to permedica.

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

The implantable devices supplied by permedica in the "STERILE" state cannot be resterilized by the user. In case of accidental opening, sterility expiration or damaged packaging, do not use the product and return it to the manufacturer.

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 140°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 – "PM 734" (normative ISO 5832/9)
- Titanium alloy Ti6Al7Nb (normative ISO 5832/11)
- CrCoMo casting 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 utilized 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 utilizing 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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