

Evolutis

CREATEUR FABRICANT



Rolflex
TONIC[®]
Postero-stabilized PS

Surgical Technique

Evolutis
MOTION INSIDE

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Disclaimer:

This document is intended to be read only by experienced orthopaedic surgeons trained specifically for knee arthroplasty procedures, and by individuals related to or acknowledged by the Evolutis company.

This publication is intended as the recommended procedure for using the Evolutis ROLFLEX TONIC primary knee arthroplasty system. It offers guidance only.

It describes the use of the instruments dedicated to the total knee prosthesis ROLFLEX TONIC.

The indications of this document cannot substitute themselves to the skills of the operator who remains solely responsible for the indication and the choice of the surgical technique used.

Evolutis is the manufacturer of the device. As such and claiming no medical skill, Evolutis does not recommend a specific use of a product or a technique. To favor the situation scenario of the instruments, this document demonstrates their use within certain techniques when they are generally known and described in the scientific literature.

Individual surgeon should consider the particular needs of the patient and make appropriate adjustments where necessary.

For any additional information related to the products, the indications and contra indications, the warnings and precautions of use, and the adverse effects, please refer to the INSTRUCTION FOR USE leaflet included in the packaging of the implants. For further advice please contact your local representative.

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Indications

Total knee replacement (TKR) is a common operation which gives very good functional results. The primary objective is to replace worn articular cartilage in order to allow the patient to obtain pain free function and movement.

The implantation of a ROLFLEX TONIC total knee should only be considered when conservative treatments have failed or when alternative less invasive treatments are no longer appropriate. The implantation of a ROLFLEX TONIC TKR is indicated for the treatment of symptomatic pain with functional difficulties of the knee in adults having attained skeletal maturity, and only when correctly followed conservative analgesic treatments have failed. The anatomy and structure of the articulation must be such that they can receive the selected implants.

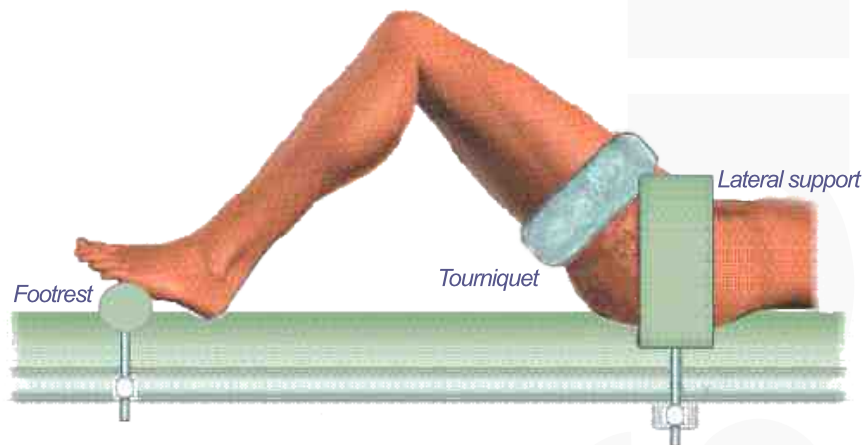
The usual indications for TKR are:

- Non inflammatory degenerative arthropathy (osteoarthritis)
- Inflammatory degenerative arthropathy (rheumatoid arthritis)
- Metabolic arthropathy (chondrocalcinosis)
- Post traumatic degenerative arthropathy
- Avascular necrosis
- Recent trauma (fracture dislocation)
- Revision of previous failed surgery (high tibial osteotomy, previous knee arthroplasty)
- Peri articular tumours

Surgical implantation of a TKR is a major operation which can present risks with all comparable surgeries such as implant loosening, dislocation, infection, allergic (to the materials) reactions, periprosthetic ossifications, thrombosis, cardio vascular problems, haematoma, pulmonary embolisms.

For more information on precautions and contra indications please read the Instructions for use S10 0310 which are to be found in all boxes containing sterile implants.

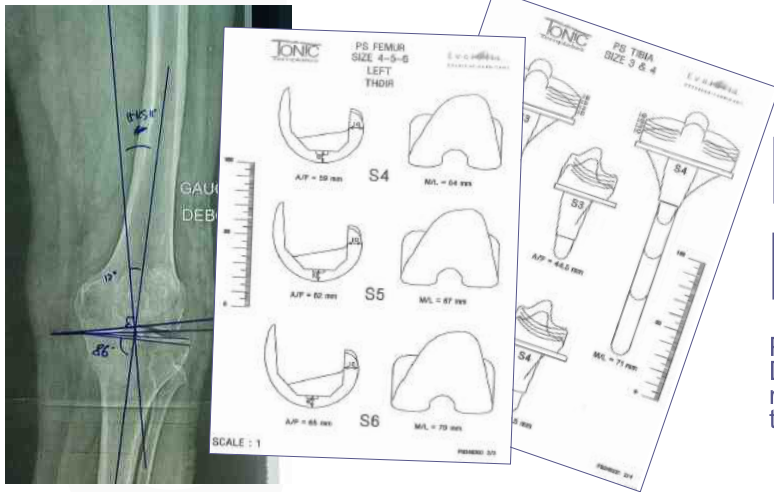
Installation



The patient should be supine.
Lateral support to prevent abduction of the limb.
Footrest in order to maintain the knee at 90° flexion.
Pneumatic tourniquet at the top of the thigh (if used by the surgeon).
Jersey up to 15cm above the knee
Large ioban film around the knee.

Pre-operative planning

Preoperative planning is important. Diagrams of the implants are prepositioned on the x rays to determine the compatibility of the femoral and the tibial implants, and the axial deviations and cuts.



Use the pangonogram of the lower limb:

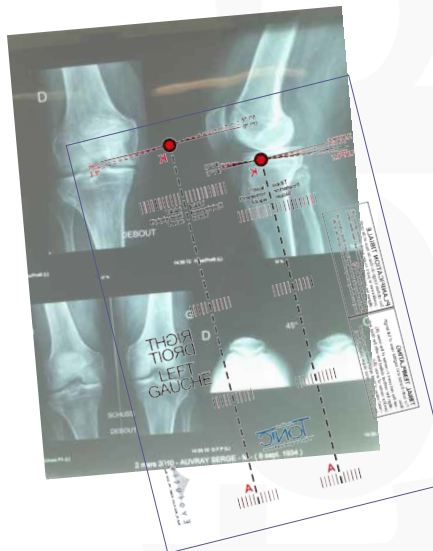
- To measure the pathological HKA axis (varus or valgus knee)
- To measure the epiphyseal axis orthogonal to the frontal tibial axis
- To calculate the correction required to achieve the HKS axis

On frontal x ray of the knee:

- Determine the probable implant sizes and the compatibility between the femoral and the tibial sizes
- Determine the frontal entry point for the centro-medullary rod

On knee profile x rays

- Determine the sagittal entry point for the centro-medullary rod
- Determine the flexum or recurvatum of the knee
- Measure the posterior tibial slope



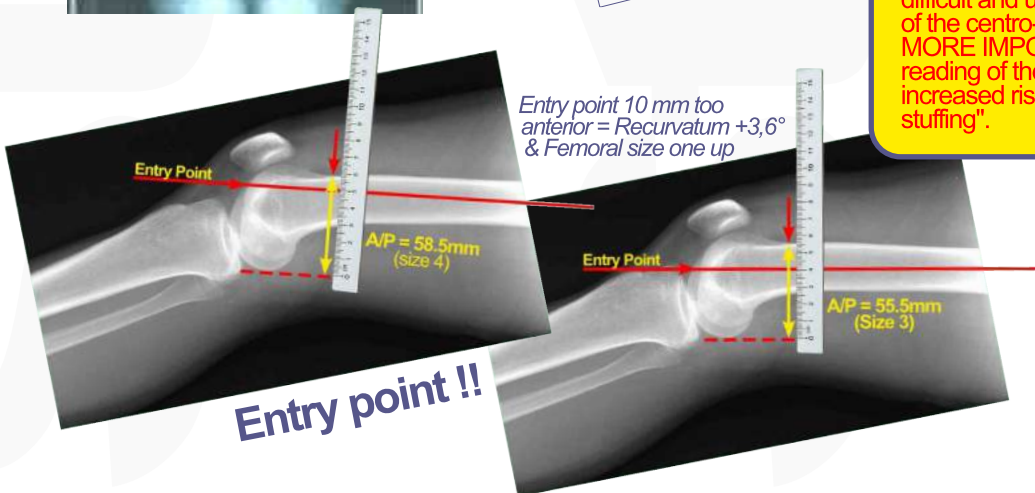
The x rays should also be completed by a sunrise view of the patella with the knee at 30° of flexion. This view gives an idea of how the patella is positioned and worn.

Optionally forced valgus and varus views are useful to estimate the ligament deformity/contraction and its reducibility.

IMPORTANT NOTICE

On knee profile X-ray, determine accurately the centro-medullary entry point which will allow the centro-medullary rod to be parallel to the distal third of the femoral diaphysis, and perpendicular to the femoral epiphysis.

An excessively anterior (often the case) entry point will make it more difficult and unaccurate the introduction of the centro-medullary rod, and **MORE IMPORTANTLY** will modify the reading of the femoral size with an increased risk of prosthetic "over-stuffing".



Entry point 10 mm too anterior = Recurvatum +3,6° & Femoral size one up

Entry point !!

Tibial Step

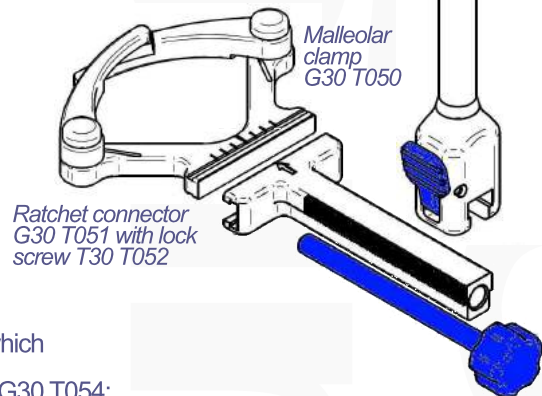
Preparation of the extra-medullary tibial jig

Assemble the extra medullary tibial jig using the following components:

- Malleolar clamp G30 T050
- Ratchet for malleolar clamp G30 T051 with the lock screw G30 T052
- Distal portion of the extramedullary jig G30 T053
- Proximal portion of the extramedullary jig (with millimetric fine tuning) G30 T055
- Left or right tibial cutting guide block G30 T057 or G30 T058



Assemble the ratchet connector onto the distal portion of the extramedullary guide. Pass the lock screw through the T bar connector. Slide the malleolar clamp so that the centre mark is lined up with the arrow of the ratchet connector. Screw down the screw to lock the clamp in this position.



Select the tibial cutting guide G30 T057 or G30 T058 which corresponds to the side being operated on.

Assemble the cutting guide onto the sliding tibial guide G30 T054:

- Press the blue quick release lever
- Introduce the flat beak shaped part into the oblong slot of the cutting guide
- Release the lock tab



Preparation of the **intra-medullar** tibial jig

The **intra-medullar** tibial jig can be used alone or associated with the malleolar clamp and the distal portion of the extra-medullary jig for a combined **intra & extra medullary** reference.

Assemble the intra medullary tibial jig using the following components:

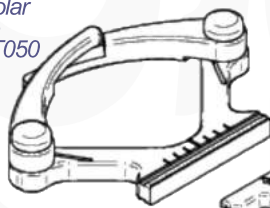
For an **intra medullary reference alone:**

- Ø8mm drill (G30 F023)
- intra medullary rod 1.350mm (G30 101) or 250mm (G30 100)
- tibial pointer (G30 T056)
- proximal portion of the **intra** medullary jig (with millimetric fine-tuning) (G30 T054)
- left or right tibial cutting guide block (G30 T057 et G30 T058)
- tibial stylus (G30 T059)

For a combined **intra extra medullary reference,**

- complete the above list with:
- malleolar clamp (G30 T050)
 - ratchet connector for malleolar clamp (G30 T051) et sa vis (G30 T052)
 - distal portion of the extra medullary jig (G30 T053)

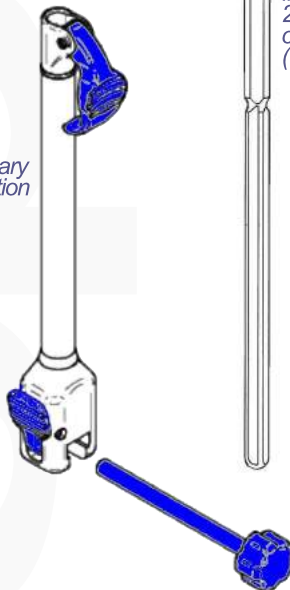
Malleolar clamp
G30 T050



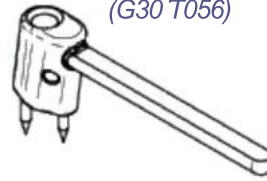
Extramedullary jig distal portion
G30 T053



Ratchet connector
G30 T051 with lock
screw T30 T052



Tibial pointer
(G30 T056)



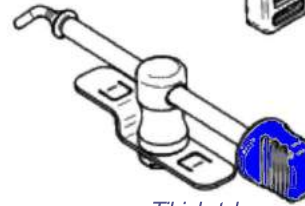
Tibial cutting guide,
right or left
(G30 T057 or
G30 T058)



Intramedullary jig
proximal portion
(G30 T054)



Tibial stylus
(G30 T059)



Intra medullary rod
250mm (G30 100)
or 350mm
(G30 101)



Select the tibial cutting guide G30 T057 or G30 T058 which corresponds to the side being operated on.

Assemble the cutting guide onto the sliding tibial guide G30 T054:

- Press the blue quick release lever
- Introduce the flat beak shaped part into the oblong slot of the cutting guide
- Release the lock tab



Positioning of the tibial jig

(extra medullary version)

After surgical exposure of the knee articulation and removal of the meniscus and cruciate ligaments, introduce a homann type retractor behind the tibia at the area of insertion of the posterior cruciate ligament, push against the femoral condyles to expose the tibial epiphysis.

Removal of the patella bursa helps improve the exposure to the medial and lateral compartments of the knee.

Before positioning the guide it is advisable to remove the more prominent osteophytes, especially medially and laterally as they could affect ligament balance.



Pre- adjust the proximal part of the jig using the large nut by screwing it up or down so that the indicator is at 0.

Place the malleolar clamp around the patient's ankle and ensure that they clamp it securely.

Place the cutting guide in contact with the anterior part of the tibia, about 5 to 7mm below the anterior edge of the lateral compartment.



Mount the quick drive bit for pin with square head section onto a power tool with a small AO adaptor.

Place a threaded pin into the quick drive bit.

Drill the pin into the tibia through the vertical slot in the 0 position.

The guide is therefore held in the "approach" position which still allows the operator to adjust:

- The varus/valgus tilt by loosening the blue screw of the ratchet connector on the malleolar clamp, and sliding the ratchet one way or another to adjust.
- The posterior tibial slope by sliding the distal portion of the guide back or forward over the ratchet.

The estimation of both of these values remains "visual" and can be further assisted by inserting the control blade in the slot of the cutting guide in order to determine the correspondence of the position (varus/valgus and posterior slope) of the guide to the epiphyseal morphology of the tibia.

Positioning the tibial cut stylus and fixation of the cutting guide

Insert the stylus into the slot of the cutting guide, note there are two positions possible, 2mm and 10mm:

-The 10mm position allows for a resection of 10mm beneath the tip of the stylus. It is used when the lateral compartment is relatively unworn, and so allows a cut of the least worn compartment.

-The 2mm position allows for a resection of 2mm beneath the tip of the stylus. It is used on the most worn compartment (usually medial).

The point of the stylus is placed horizontally when introduced into the cutting guide slot.

Once in place the stylus is turned 90° so that the tip is vertical and above the reference point of the tibia, its vertical position is felt as it clips into position.



The height of the stylus can be fine-tuned by turning the large nut which is part of the proximal jig. A complete turn corresponds to a correction of 1mm.

When a satisfactory cut height has been selected, the cutting guide is locked into place by drilling two threaded pins through the 0 holes using the quick drive bit.



Remove the extramedullary jig from the cutting guide by pressing the blue lever in the proximal portion and also removing the clamp from the ankle.





A fourth locking pin is inserted obliquely through the hole with a padlock sign. Remove the stylus from the cutting guide.



Remove the extramedullary jig from the cutting guide by pressing the blue lever in the proximal portion and also removing the clamp from the ankle.



Control of the tibial axis

Knee in flexion position.
Place the cutting guide orientation check handle into the slot of the cutting guide.

Place a long orientation rod from top to bottom in one of the holes.
Place the check handle so that rod is aligned with the anterior tibial tuberosity.

Check visually that the cut will be aligned with the tibial tuberosity in the frontal plane, and check the slope -if any required- when viewed from the side.

Cut the tibia using a long and 1.27mm thick sawblade.

Remove the resected proximal part of the tibia using an osteotome if necessary.

Remove the pins by using the pin extractor.



Control of the tibial cut:

Place the 10mm FLEXION spacer baseplate over the resected part of the tibia into the articular space.
If it is a bit tight, the 8mm EXTENSION spacer baseplate can be inserted instead.

Place an orientation rod through one of the holes, from top to bottom towards the ankle and between the two toes to check if the cut orientation is correct.

1mm to 5mm augments (refs G34 0033 to G34 0037) can be placed on the spacer in order to:

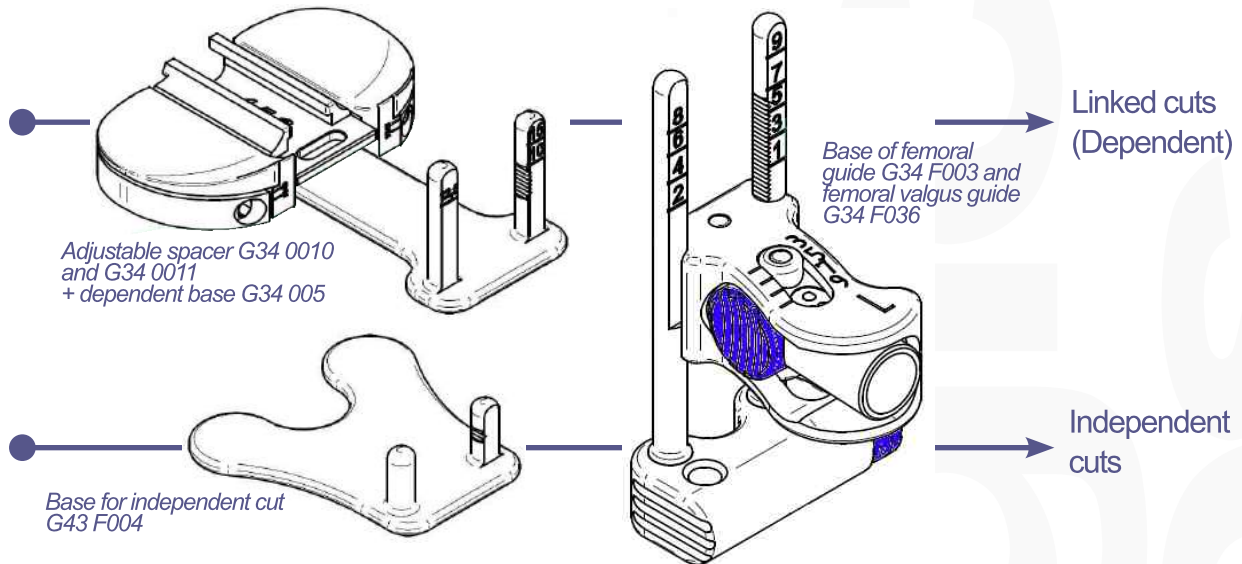
- Check the ligament balance in flexion
- In extension to check the value of the femoral valgus angle when a second orientation rod from bottom to top is added. This is done by checking the HKA angle which should be 180°

Femoral Step

The femoral cuts can be dependent or independent (of the tibial cut)

The **independent femoral cutting technique** uses the same instruments as the **dependent femoral cutting technique** with the exception that the Independent base G34 F004 is used instead of the two part Dependent base G34 F005 with spacer G34 0010/11.

Dependent cutting is dependent on ligament tension/balance.

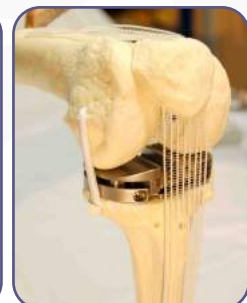
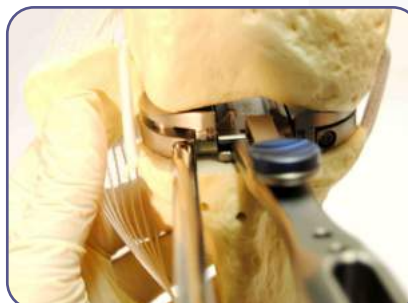


Measurement of the ligament tension in flexion for dependent cuts

Assemble the adjustable spacer of the corresponding tibial size onto the clip-on handle and introduce it into the articular space. Place the knee into 90° flexion.

Use the 3,5mm screwdriver fine-tune the lateral compartment up until the collateral ligament tension is balanced. Be careful NOT to over tighten the lateral collateral ligament as the adjustable distraction system is quite powerful.

Remove the clip-on handle, replace the patella and proceed with the stability tests in flexion/extension.



Assembly of the femoral jig

Instruments required:

- G34 F005 : Dependent cutting base
- G34 F003 : Femoral guide base
- G34 F036 : Femoral valgus angle guide
- G34 F006 : Cutting bloc holder
- G34 F031 or G34 F032: 0° or 2° flesum cut guide
- G34 F001 : Distal femoral cut block
- G34 F002 : Anterior femoral stylus

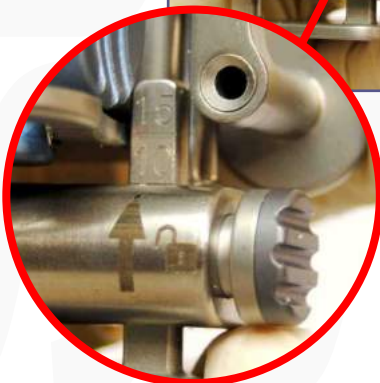
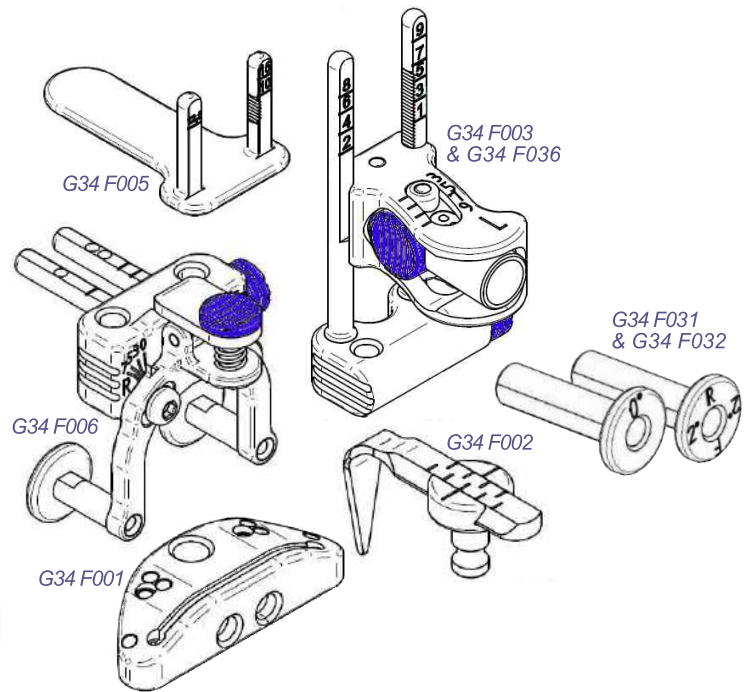
- Assemble the femoral guide base onto the two posts of the dependent cutting base by pressing on the blue release button.

- Select the side to be operated L or R, readable of the femoral valgus guide and slide it over the two posts of the femoral guide base
 - Adjust the valgus angle by pressing the blue release button and sliding to the chosen angle.

- Assemble the cutting bloc holder G34 F006 on the two posts of the femoral base guide by pressing the release button. Leave it in one of the highest positions.

- Introduce one of the femoral flesum guide (either 0° or 2°) into the valgus angle guide. Careful that the F is facing up for the 2° guide.

- The distal femoral cutting block G34 F001 and the anterior femoral stylus G34 F002 are added when the instruments are in place and the knee at 90° flexion.



Important:

For dependent cuts it is essential to pre adjust the dependent base on the femoral guide base at a standard posterior cut of 10mm

Note that this pre adjustment is not necessary when using the independent cutting base G34 F004



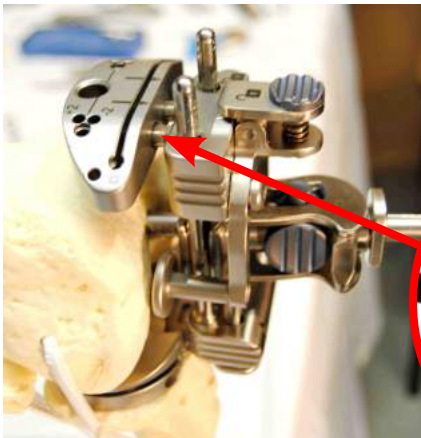
Measurement and adjustment of the femoral guide assembly

With the knee in 90° of flexion, prepare the entry point for the intramedullary femoral rod by drilling a hole with the Ø8mm drill supplied. Usually 1cm above the inter condylar notch and slightly lateral. Insert the intramedullary guide rod.

Place the adjustable spacer with the corresponding adjustments as described previously (*page 11: Measurement of the ligament tension in flexion for dependent cuts*). Slide the guide assembly over the intramedullary rod, and into the adjustable spacer.

Ensure that the external rotation is at 0°. This is fundamental for dependent cuts. External rotation should only be adjusted to values other than 0° with independent cuts.

Check that the femoral valgus angle corresponds to the value chosen before the operation, and check this by seeing if there is a gap between the distal lateral condyle and the guide stop G34 F006.



Place the distal femoral cutting bloc on over the two posts of the guide in the 8mm position.



Measurement of the femoral size.

Choosing the A/P (antero/posterior) size

The increment between two sizes of femur in the ROLFLEX TONIC range is 3mm, which means that for any given morphology the size of implant will never be more than 1,5mm over or undersized from the morphological ideal.

When the size measured on the guide post corresponds exactly to an A/P size, then that size of implant should be chosen and cuts for it undertaken.

When the A/P size indicator is between two sizes, it is generally advised to select the smaller value to improve flexion and also prevent any potential M/L overhang which might cause pain.

Should the size indicator be smaller by more than 2mm from a selected component size, then the surgeon has two choices.

- Use the size just above which might slightly tighten the knee in flexion and so reduce the flexion.
- Instead of using the 0° femoral flexum guide, the surgeon can opt to use the 2° femoral flexum guide, which will tilt the femoral condyles into 2° of flexum and so slightly augment the distance between the posterior condyles and the proximal trochlea. In this case also the size below the measure should be used.

Snap into place the two blue epicondylar axis collimators.
The axis of these collimators will follow the trans-epicondylar axis.

If necessary spacers can be added between the adjustable spacer and the posterior condyles by 1mm increment to correct the external rotation.

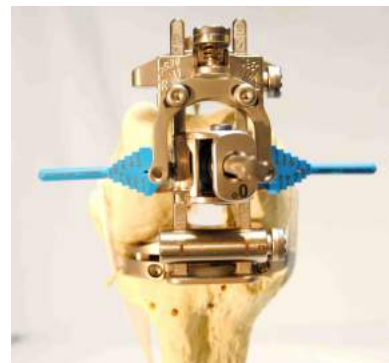
The epicondylar collimators also show the different condyle sizes in the Medio Lateral plane. The size of the prosthetic condyle can be evaluated compared to the M/L volume of the bone.

The anterior femoral stylus is then put into place. It is made to be put in and taken off at 45° relative.
The anterior femoral stylus can be adjusted at a medium size or to one corresponding to the closest femoral size.

The cutting block can then be lowered by pressing the release button and sliding it down the posts, until the tip of the stylus touches the anterior femoral cortex.

The A/P size of the femur can be read on the guide base posts.

The anterior femoral stylus can be fine-tuned in size in the distal/proximal sense to match the A/P size.
It will then point the exact proximal border of the prosthetic femoral trochlea.



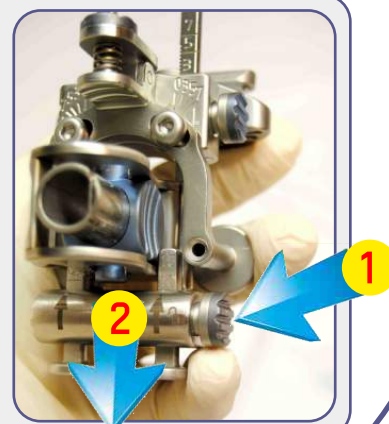
Anterior or posterior femoral reference?

The Rolflex TONIC instrumentation enables to switch easily from an anterior to a posterior femoral A/P alignment of the femoral condyles.

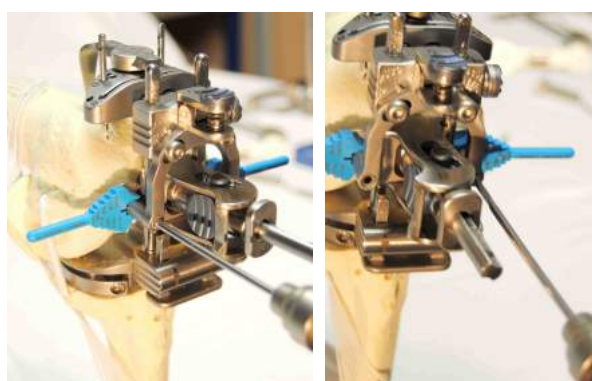
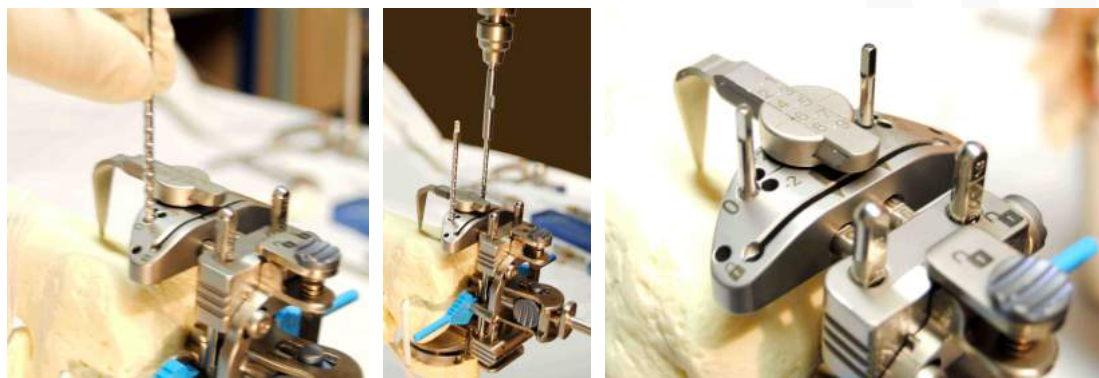
The default setting of the femoral jig is the **anterior reference**: the implant is aligned on the anterior cortex of the femur. Any dimensional difference between the implant and the femur measure A/P comes in addition (case of smaller implant) or in subtraction (case of bigger implant) to the resection value of the posterior condyles.

Optionally, the surgeon can choose to preserve the posterior femoral cut and the posterior gap by switching the dimensional difference to the anterior femoral resection. The posterior cut, set at 10mm, will then equal the thickness of the prosthetic posterior condyles.

This reference switch is easily achieved by pushing on the blue knob at the lower right part of the femoral jig (1), and sliding down the whole jig for 1, 2 or 3mm (2) according to the A/P difference between the natural femur and the prosthetic condyles.



Fixation of the distal femoral cutting bloc and distal cut



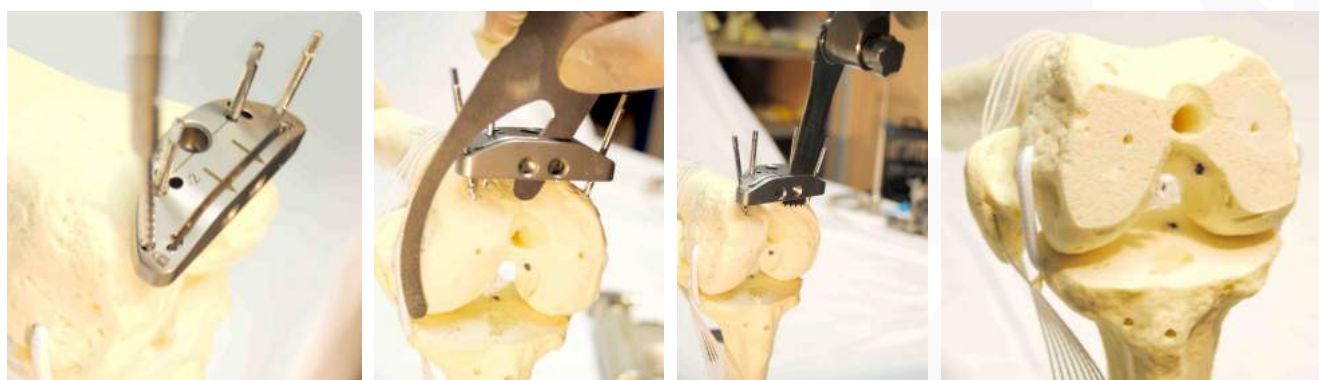
Drill into place two fixation pins in the 0 holes of the distal cutting block.

Using the Ø3.2mm drill bit, drill two holes through the distal guide holes of the femoral jig (G34 F006) which will serve to position the 4 in 1 cutting block of the selected size.

Remove the entire assembly leaving in place only the distal cutting block suspended on the pins.

Remove the intramedullary rod.

Remove the stylus and press the cutting block down to be in contact with the anterior cortex.



The block is then further secured by placing 2 convergent pins through the lock holes on either side of the block. The thickness and orientation of the cut can be verified with the verification blade (G34 0021). The distal cut is then undertaken using an oscillating saw.

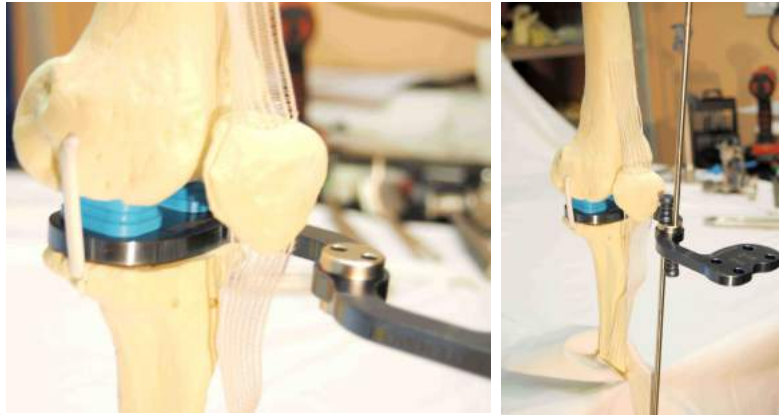
Anterior, posterior and chamfer cuts

Verify that the cut is flat and that the 2 distal holes for the 4 in 1 block are apparent.

Place the knee in extension. Put two blue 10mm spacers on the EXTENSION (8mm) spacer baseplate and place the assembly into the articular space.

The articular space should be balanced and correspond to 10mm tibial resection plus 8 mm distal femoral resection.

The HKA axis can be verified by placing two long rods into the spacer baseplate holes orientated up and down.



If satisfactory select the 4 in 1 cutting bloc selected during the A/P measurement and impact the 2 pegs into the holes previously drilled distally with the 3,2mm drill.

The rotation and posterior cuts to be undertaken can be checked visually.

Check the level of the anterior cut with the verification blade to ensure that there will not be any notching, and nor that the cut will be too little.

The 3,2mm drill can be used to drill through the hole above the size number in the centre of the top of the block to see precisely where the saw blade will exit the cut.

Firmly maintain the block in contact with the distal cut and secure it in place with two 3,2mm 50mm long screws with hexagonal heads, tightening them progressively. First one side not too tight, then the second tight, then finish tightening the first one.



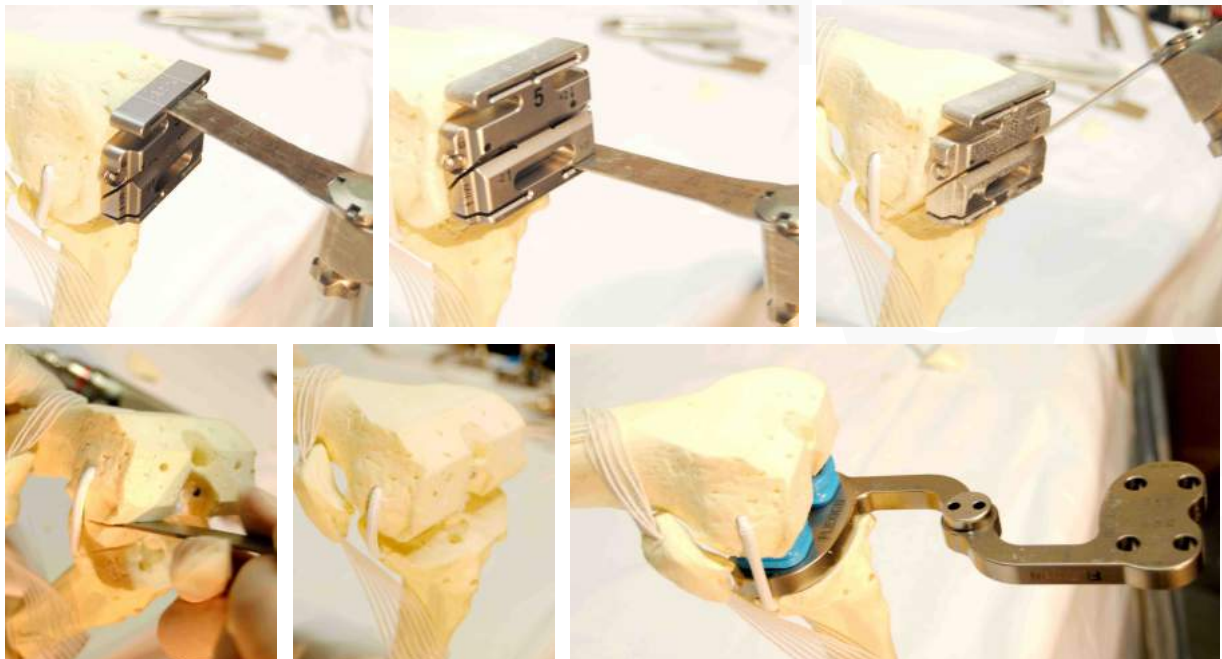


Femoral cuts

OPTION: In order to make more space between the tibial cut and the posterior femoral cuts the surgeon can place the FLEXION spacer baseplate (10mm) with two 5mm spacers under the inferior edge of the 4 in 1 block.

Undertake the cuts, anterior, posterior, anterior chamfer and posterior chamfer with an oscillating saw.

Remove the cut bone fragments. Check that the cuts are flat.

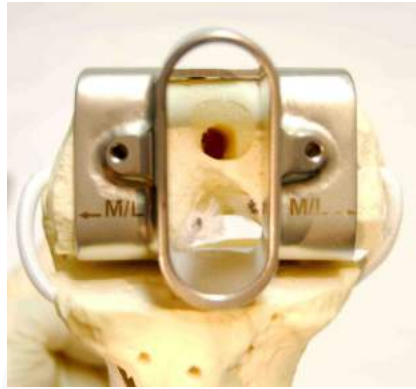


Checking the ligament balance in flexion and extension

Use the spacer baseplate in FLEXION (10mm thick) and EXTENSION (8mm thick) completed with two blue 10mm spacers to check the ligament balance in flexion and extension.



Preparation of the intercondylar box



Select the appropriate sized box guide the same size as the 4 in 1 block. Centre the guide over the femur.

The distal section is the same size in the M/L plane as the distal part of the final implant. Anterior left and right trochlear dimensions are on the same guide and the position can be visualised.

Secure the guide in place with an anterior and 2 distal pins.

Use the specific intercondylar box drill corresponding to the femur size as follows

- Sizes 1,2 or 3 : G34 F033
- Sizes 4,5 or 6 : G34 F034
- Sizes 7,8 or 9 : G34 F035

Assemble the appropriate box drill onto a reamer. Ream the intercondylar box in 3 stages.

1. With reamer turning, in the most posterior part of the opening, marked 1, up to the stop.

2. Remove it and repeat the reaming but in the most anterior part of the opening marked 2.

3. Without stopping nor removing the reamer slide the turning reamer down towards the posterior end, via the mark 3.



Trials

Impact into place with the femoral condyle impactor G30 F007 the same size trial condyle as the 4 in 1 block and of the correct side.

Place the knee in hyperflexion and remove any accessible posterior osteophytes with the curved osteotome supplied in the instrument tray.

Select the best size tibial base plate by placing trials over the cut tibial surface.

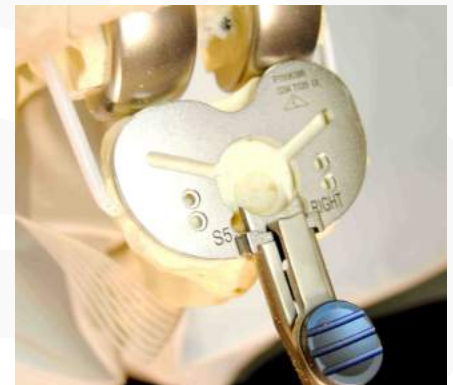


Note that the tibial baseplates are asymmetric, where the lateral compartment is shorter than the medial one. This shape is well adapted to 65% of tibial anatomies, 20% are symmetric and 15% reverse symmetric where the medial compartment is shorter than the lateral one. In the case of a reverse anatomy, the tibial trial should be flipped over so that a left is used on a right and vice versa. This adaptation should be followed in the choice of definitive implant selection, but otherwise has no influence on knee kinematics.



Place a trial insert on the tibial base trial:

- Select a PS trial insert corresponding to the size of the femur for a rotating platform system or corresponding to the tibial base for a fixed platform system.
- Use an appropriate intermediate thickness spacer for rotating trial or for fixed trial.
- Add to this the size trial
- Introduce the base with the two piece trial insert into the articular space using the quick release handle.



Undertake trial movements in flexion/extension checking range of motion and balance.

Important: sizing match

- Fixed bearing models, the insert must be the same size as the tibial base. Each femur size can be used with tibia base N-1, N or N+1

- Rotating bearing models the insert must be the same size as the femur implant. Each rotating model femur PE can be used with tibial base N-1 or N, NOT N+1 because of overhang.



Implantation of final implants

Preparation of the tibial keel

Secure the tibial trial base plate with 2 Ø3.5mm 20mm screws.

Select the corresponding size keel instruments: keel guide (G34 T065, G34 T066 or G4 T067), preparation drill (G34 T061) and keel conformator (G34 T062, G34 T063 or G34 T064).

Place the keel guide on the tibial base and lock the assembly with the quick fit handle.

Place the drill guide G34 T060 onto the keel guide.

Drill through the guides using the G34 T061 drill, up to the stop.

Remove the drill and drill guide.



Assemble the keel conformator onto the impactor handle (G34 0040).

Introduce it into the keel guide and impact it up to the stop.

Impaction of the implants



Start with the tibial baseplate.

For a cemented version, clean and dry the bone as much as possible, place cement inside the keel hole and also on the flat inferior surface of the baseplate. Place a limited amount of cement at the posterior edge of the baseplate. Place the baseplate by hand ensuring that the keel wings are properly aligned with the imprints in the bone. Impact firmly, and remove any excess of cement in cases of cemented versions.

Femoral condyles.

For a cemented version avoid putting too much cement on the posterior condyles as excess posterior cement is hard to remove and can inhibit flexion.

Place the implant by hand (or with the Impactor for Condyles G34 F008) over the femoral cuts ensuring correct position with reference to the anterior cortex, M/L position and intercondylar box.

Assemble the impactor (Impaction handle G34 0040 & Impaction tip G30 117), the position onto the implant and impact fully until the implant is in firm contact with the cuts. Remove excess cement.

Fixed polyethylene versions.

Slide the PE insert towards the posterior part of the base so that it engages with the central locking mechanism. Push firmly so that the posterior edges of the PE engage in the posterior slots of the base. Use the impaction forceps to engage the PE fully.

Order of implantation of the implants

Due to the difficulty of introducing the inferior peg of the PE of rotating systems once the tibial baseplate and the femoral condyles have been impacted, the order of implantation of the 3 components can be different between fixed and rotating bearings.

TKR with fixed bearings

- 1- Tibial baseplate
- 2- Femoral condyles
- 3- Place the knee in high flexion
- 4- Polyethylene insert by sliding from front to back before clipping into place

TKR with rotating bearings

- 1- Tibial baseplate
- 2- Polyethylene insert
- 3- Place the knee in high flexion
- 4- Femoral condyles

Reference list of instruments

Instrument Tray G34 9100 FEMORAL GUIDE

Ref. Code	Description
G34 0010	Adjustable trial spacer S1 to 6
G34 0011	Adjustable trial spacer S4 to 9
G34 0013	6mm tibial baseplate for spacer S1 to 3
G34 0014	2mm spacer augment S1 to 6
G34 0015	2mm spacer augment S4 to 9
G34 0017	Handle for spacer
G34 0018	6mm tibial baseplate for spacer S4 to 6
G34 0023	Baseplate for extension test
G34 0024	Baseplate for flexion test
G34 0025	Augment for spacer h.10
G34 0026	Augment for spacer h.12.5
G34 0027	Augment for spacer h.15
G34 0028	Augment for spacer h.18
G34 0033	Augment for spacer h.1
G34 0034	Augment for spacer h.2
G34 0035	Augment for spacer h.3
G34 0036	Augment for spacer h.4
G34 0037	Augment for spacer h.5
G34 F001	Distal femoral cutting guide
G34 F002	Anterior femoral stylus
G34 F003	Base for femoral guide
G34 F004	Baseplate for independant cuts
G34 F005	Baseplate for linked cuts
G34 F006	Bracket for cutting guide
G34 F007	Epicondylar axis collimator
G34 F011	4/1 cutting guide S.1
G34 F012	4/1 cutting guide S.2
G34 F013	4/1 cutting guide S.3
G34 F014	4/1 cutting guide S.4
G34 F015	4/1 cutting guide S.5
G34 F016	4/1 cutting guide S.6
G34 F017	4/1 cutting guide S.7
G34 F018	4/1 cutting guide S.8
G34 F019	4/1 cutting guide S.9
G34 F031	0° femoral flexum guide
G34 F032	2° femoral flexum guide
G34 F036	Femoral valgus guide
S01 015	Hexagonal screwdriver H3.5

Instrument Tray G34 9101 TIBIAL GUIDE

Ref. Code	Description
G30 100	Intramedullary rod l.250
G30 101	Intramedullary rod l.350
G30 102	T handle
G30 P007	Calliper
G30 T050	Malleolar clamp
G30 T051	Ratchet for malleolar clamp
G30 T052	Centering guide wheel
G30 T053	Tibial extension keel
G30 T054	Tibial cut mount for intra. Jig
G30 T055	Tibial cut mount for extra. Jig
G30 T056	Tibial pointer for extra. Jig
G30 T057	Left tibial cutting guide
G30 T058	Right tibial cutting guide
G30 T059	Anterior femoral stylus
G34 0009	Quick-drive shaft for broach
G34 0019	Long limb control axis rod
G34 0020	Support plate for axis control rod
G34 0021	Resection control blade
G34 0022	Screwdriver bit with mini AO
G34 0038	Fixation screw l.50mm
G34 0039	Fixation screw l.20mm
G34 F023	Centromedullary & pegs Ø8 drill
GP001.089.032	Ø3.2 self-tapping broach
M 504018 AB0346	Pin/broach extractor
S01 014	Ø3.2 drill, length 145mm

**Instrument Tray G34 9102
FEMORAL TRIALS RIGHT PS**

Ref. Code	Description
G34 FPD01	Right PS trial condyles S.1
G34 FPD02	Right PS trial condyles S.2
G34 FPD03	Right PS trial condyles S.3
G34 FPD04	Right PS trial condyles S.4
G34 FPD05	Right PS trial condyles S.5
G34 FPD06	Right PS trial condyles S.6
G34 FPD07	Right PS trial condyles S.7
G34 FPD08	Right PS trial condyles S.8
G34 FPD09	Right PS trial condyles S.9

**Instrument Tray G34 9103
FEMORAL TRIALS LEFT PS**

Ref. Code	Description
G34 FPG01	Left PS trial condyles S.1
G34 FPG02	Left PS trial condyles S.2
G34 FPG03	Left PS trial condyles S.3
G34 FPG04	Left PS trial condyles S.4
G34 FPG05	Left PS trial condyles S.5
G34 FPG06	Left PS trial condyles S.6
G34 FPG07	Left PS trial condyles S.7
G34 FPG08	Left PS trial condyles S.8
G34 FPG09	Left PS trial condyles S.9

**Instrument Tray G34 9104
FEMORAL TRIALS RIGHT UC**

Ref. Code	Description
G34 FUD01	Right UC trial condyles S.1
G34 FUD02	Right UC trial condyles S.2
G34 FUD03	Right UC trial condyles S.3
G34 FUD04	Right UC trial condyles S.4
G34 FUD05	Right UC trial condyles S.5
G34 FUD06	Right UC trial condyles S.6
G34 FUD07	Right UC trial condyles S.7
G34 FUD08	Right UC trial condyles S.8
G34 FUD09	Right UC trial condyles S.9

**Instrument Tray G34 9105
FEMORAL TRIALS LEFT UC**

Ref. Code	Description
G34 FUG01	Left UC trial condyles S.1
G34 FUG02	Left UC trial condyles S.2
G34 FUG03	Left UC trial condyles S.3
G34 FUG04	Left UC trial condyles S.4
G34 FUG05	Left UC trial condyles S.5
G34 FUG06	Left UC trial condyles S.6
G34 FUG07	Left UC trial condyles S.7
G34 FUG08	Left UC trial condyles S.8
G34 FUG09	Left UC trial condyles S.9

**Instrument Tray G34 9106
TIBIAL TRIALS**

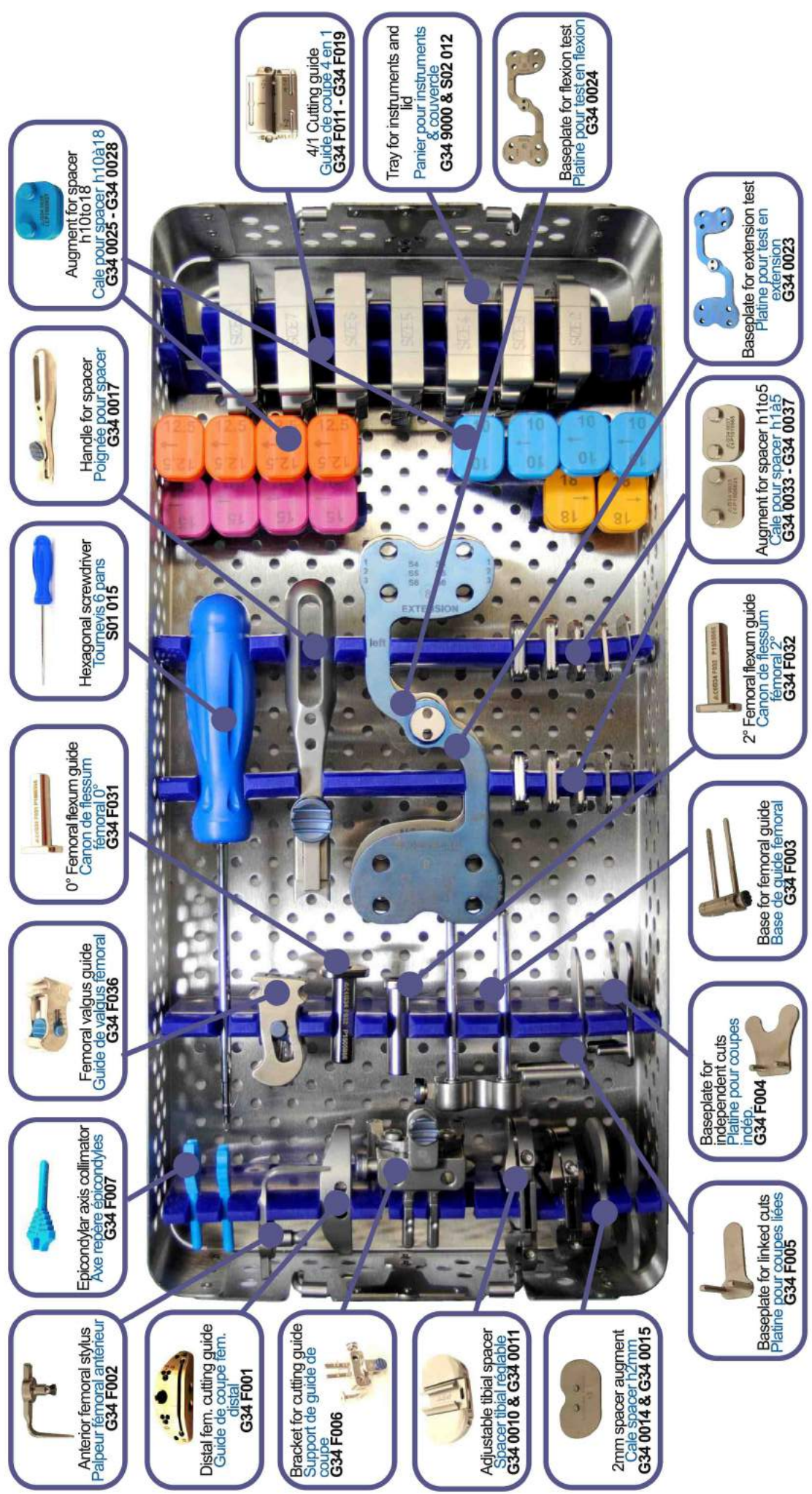
Ref. Code	Description
G34 T001	Wrench for keels and plugs
G34 T011	Tibial trial baseplate Left S.1
G34 T012	Tibial trial baseplate Left S.2
G34 T013	Tibial trial baseplate Left S.3
G34 T014	Tibial trial baseplate Left S.4
G34 T015	Tibial trial baseplate Left S.5
G34 T016	Tibial trial baseplate Left S.6
G34 T017	Tibial trial baseplate Left S.7
G34 T018	Tibial trial baseplate Left S.8
G34 T021	Tibial trial baseplate Right S.1
G34 T022	Tibial trial baseplate Right S.2
G34 T023	Tibial trial baseplate Right S.3
G34 T024	Tibial trial baseplate Right S.4
G34 T025	Tibial trial baseplate Right S.5
G34 T026	Tibial trial baseplate Right S.6
G34 T027	Tibial trial baseplate Right S.7
G34 T028	Tibial trial baseplate Right S.8
G34 T030	Trial spacer for rotating liner h.10
G34 T031	Trial spacer for rotating liner h.12.5
G34 T032	Trial spacer for rotating liner h.15
G34 T033	Trial spacer for rotating liner h.18
G34 T035	Trial spacer for fixed liner h.10
G34 T036	Trial spacer for fixed liner h.12.5
G34 T037	Trial spacer for fixed liner h.15
G34 T038	Trial spacer for fixed liner h.18
G34 T041	UC trial liner S.1
G34 T042	UC trial liner S.2
G34 T043	UC trial liner S.3
G34 T044	UC trial liner S.4
G34 T045	UC trial liner S.5
G34 T046	UC trial liner S.6
G34 T047	UC trial liner S.7
G34 T048	UC trial liner S.8
G34 T049	UC trial liner S.9
G34 T051	PS trial liner S.1
G34 T052	PS trial liner S.2
G34 T053	PS trial liner S.3
G34 T054	PS trial liner S.4
G34 T055	PS trial liner S.5
G34 T056	PS trial liner S.6
G34 T057	PS trial liner S.7
G34 T058	PS trial liner S.8
G34 T060	Drill guide for keel
G34 T061	Keel and femoral peg drill
G34 T062	Conformator for keel S.1 to 3
G34 T063	Conformator for keel S.4 to 6
G34 T064	Conformator for keel S.7 & 8
G34 T065	Guide for preparation of keel S.1 to 3
G34 T066	Guide for preparation of keel S.4 to 6
G34 T067	Guide for preparation of keel S.7 & 8
G34 T068	Keel peg for conformator S.1 to 3
G34 T069	Keel peg for conformator S.4 to 6
G34 T070	Keel peg for conformator S.7 & 8
G34 T072	Rasp for keel extension 40mm
G34 T073	Rasp for keel extension 70mm
G34 T074	Rasp for keel extension 110mm

**Instrument Tray G34 9107
PS BOX**

Ref. Code	Description
G30 117	Impaction tip for condyles (large)
G30 F029	Gouge scissor
G34 0040	Impaction handle
G34 0041	Impaction tip for condyles (small)
G34 F008	Impactor for condyles
G34 F021	PS box preparation guide S.1
G34 F022	PS box preparation guide S.2
G34 F023	PS box preparation guide S.3
G34 F024	PS box preparation guide S.4
G34 F025	PS box preparation guide S.5
G34 F026	PS box preparation guide S.6
G34 F027	PS box preparation guide S.7
G34 F028	PS box preparation guide S.8
G34 F029	PS box preparation guide S.9
G34 F033	PS box reamer S.1 to 3
G34 F034	PS box reamer S.4 to 6
G34 F035	PS box reamer S.7 to 9

**Instrument Tray G34 9108
PATELLA**

Ref. Code	Description
G34 P001	Patellar clamp
G34 P002	Depth-stop for reamer
G34 P003	Anterior bit for patella
G34 P004	Posterior bit for patella
G34 P023	Trial patella Ø23
G34 P025	Trial patella Ø25
G34 P028	Trial patella Ø28
G34 P123	Patellar reamer Ø23
G34 P125	Patellar reamer Ø25
G34 P128	Patellar reamer Ø28
G34 P223	Reamer guide Ø23
G34 P225	Reamer guide Ø25
G34 P228	Reamer guide Ø28



Anterior femoral stylus
Palpeur fémoral antérieur
G34 F002

Distal fem. cutting guide
Guide de coupe fém.
distal
G34 F001

Bracket for cutting guide
Support de guide de
coupe
G34 F006

Adjustable tibial spacer
Spacer tibial réglable
G34 0010 & G34 0011

2mm spacer augment
Cale spacer h2mm
G34 0014 & G34 0015

Epicondylar axis collimator
Axe repère épicondyles
G34 F007

Femoral valgus guide
Guide de valgus fémoral
G34 F036

0° Femoral flexum guide
Canon de flexum
fémoral 0°
G34 F031

Hexagonal screwdriver
Tournevis 6 pans
S01 015

Handle for spacer
Poignée pour spacer
G34 0017

Augment for spacer
h10to18
Cale pour spacer h10à18
G34 0025 - G34 0028

4/1 Cutting guide
Guide de coupe 4 en 1
G34 F011 - G34 F019

Tray for instruments and
lid
Panier pour instruments
& couvercle
G34 9000 & S02 012

Baseplate for flexion test
Platine pour test en flexion
G34 0024

Baseplate for linked cuts
Platine pour coupes liées
G34 F005

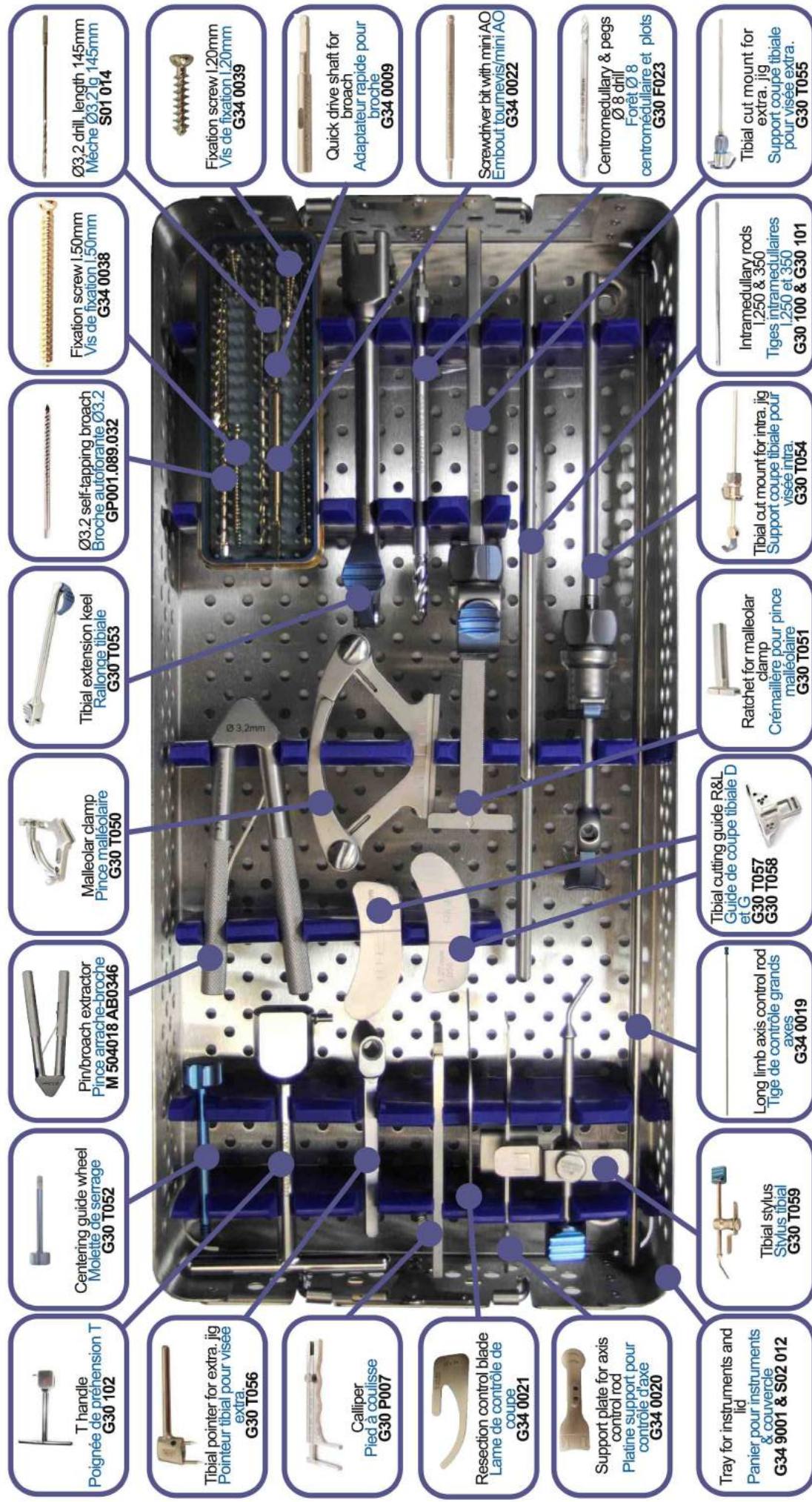
Baseplate for
independent cuts
Platine pour coupes
indép.
G34 F004

Base for femoral guide
Base de guide fémoral
G34 F003

2° Femoral flexum guide
Canon de flexum
fémoral 2°
G34 F032

Augment for spacer h1to5
Cale pour spacer h1 à5
G34 0033 - G34 0037

Baseplate for extension test
Platine pour test en
extension
G34 0023



T handle
Poignée de préhension T
G30 102

Centering guide wheel
Molette de serrage
G30 T052

Pin/broach extractor
Pince arrache-broche
M 504018 AB0346

Malleolar clamp
Pince malleolaire
G30 T050

Tibial extension keel
Rallonge tibiale
G30 T053

Ø3.2 self-tapping broach
Broche auto-tornante Ø3.2
GP001.089.032

Fixation screw 1,50mm
Vis de fixation 1,50mm
G34 0038

Ø3.2 drill, length 145mm
Meche Ø3.2 lg 145mm
S01 014

Tibial pointer for extra. jig
Pointeur tibial pour visée
extra
G30 T056

Calliper
Pied à coulisse
G30 P007

Resection control blade
Lame de contrôle de
coupe
G34 0021

Support plate for axis
control rod
Platine support pour
contrôle d'axe
G34 0020

Tray for instruments and
lid
Panier pour instruments
& couvercle
G34 9001 & S02 012

Ø 3.2mm

Quick drive shaft for
broach
Adepteur rapide pour
broche
G34 0009

Screwdriver bit with mini AO
Embout tournevis/mini AO
G34 0022

Centromedullary & pegs
Ø 8 drill
Foret Ø 8
centromedullaire et plots
G30 F023

Tibial cut mount for
extra. jig
Support coupe tibiale
pour visée extra.
G30 T055

Intramedullary rods
Tiges intramedullaires
1,250 & 350
G30 100 & G30 101

Tibial cut mount for intra. jig
Support coupe tibiale pour
visée intra.
G30 T054

Ratchet for malleolar
clamp
Crémaillère pour pince
malleolaire
G30 T051

Tibial cutting guide R&L
Guide de coupe tibiale D
et G
G30 T057
G30 T058

Long limb axis control rod
Tige de contrôle grands
axes
G34 0019

Tibial stylus
Stylus tibial
G30 T059

Ref : G34 9102 & G34 9103



RIGHT PS trial condyles S1 to S9
Condyles d'essai PS DROITS T1 à T9
G34 FPD01 totà G34 FPD09



LEFT PS trial condyles S1 to S9
Condyles d'essai PS GAUCHES T1 à T9
G34 FPG01 totà G34 FPG09



Tray for instruments & lid
Panier pour instruments
& couvercle
G34 9002 & S02 014

Ref : G34 9104 & G34 9105



RIGHT UC trial condyles S1 to S9
Condyles d'essai UC DROITS T1 à T9
G34 FUD01 totà G34 FUD09

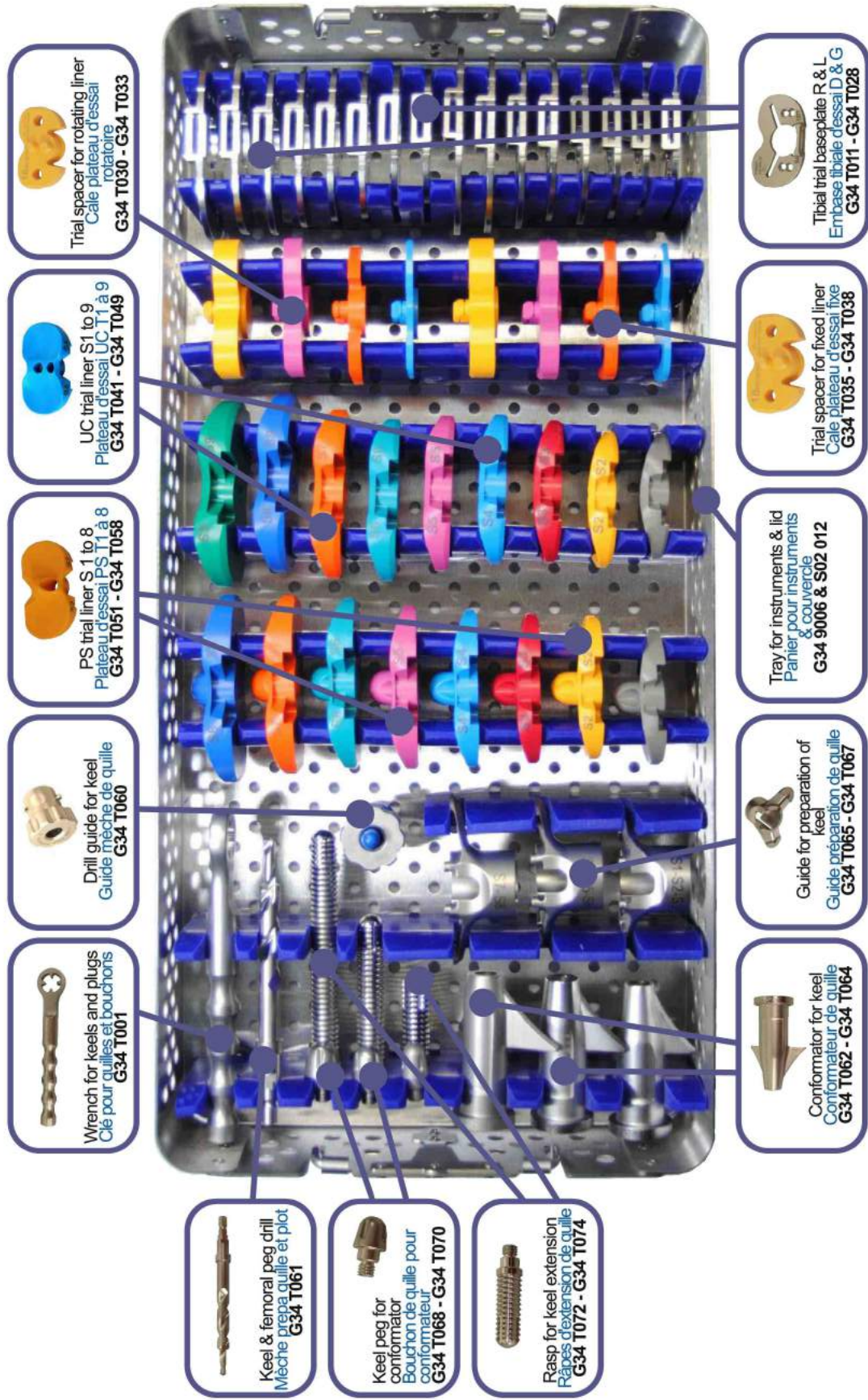


LEFT UC trial condyles S1 to S9
Condyles d'essai UC GAUCHES T1 à T9
G34 FUG01 totà G34 FUG09



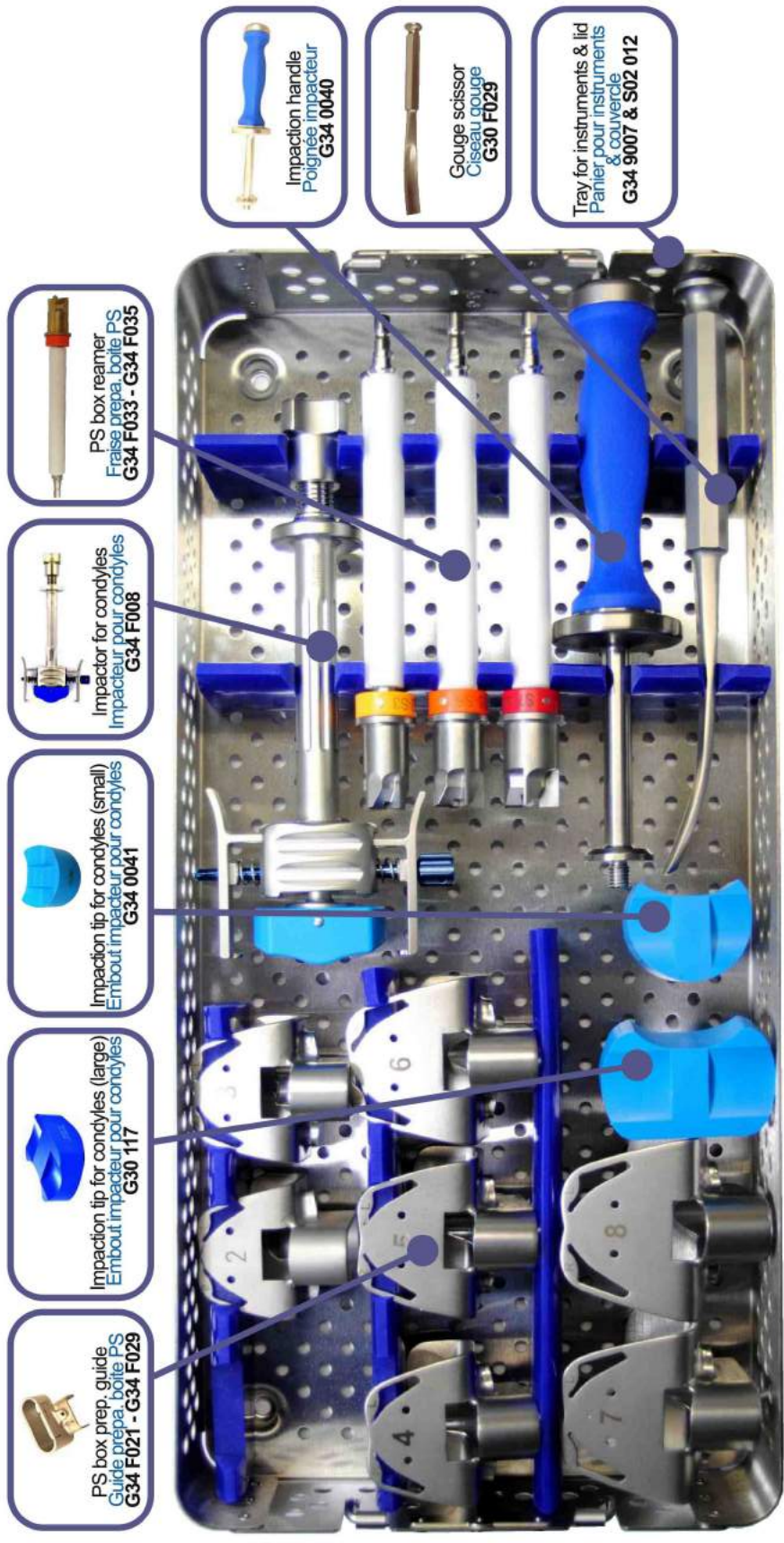
Tray for instruments & lid
Panier pour instruments
& couvercle
G34 9002 & S02 014

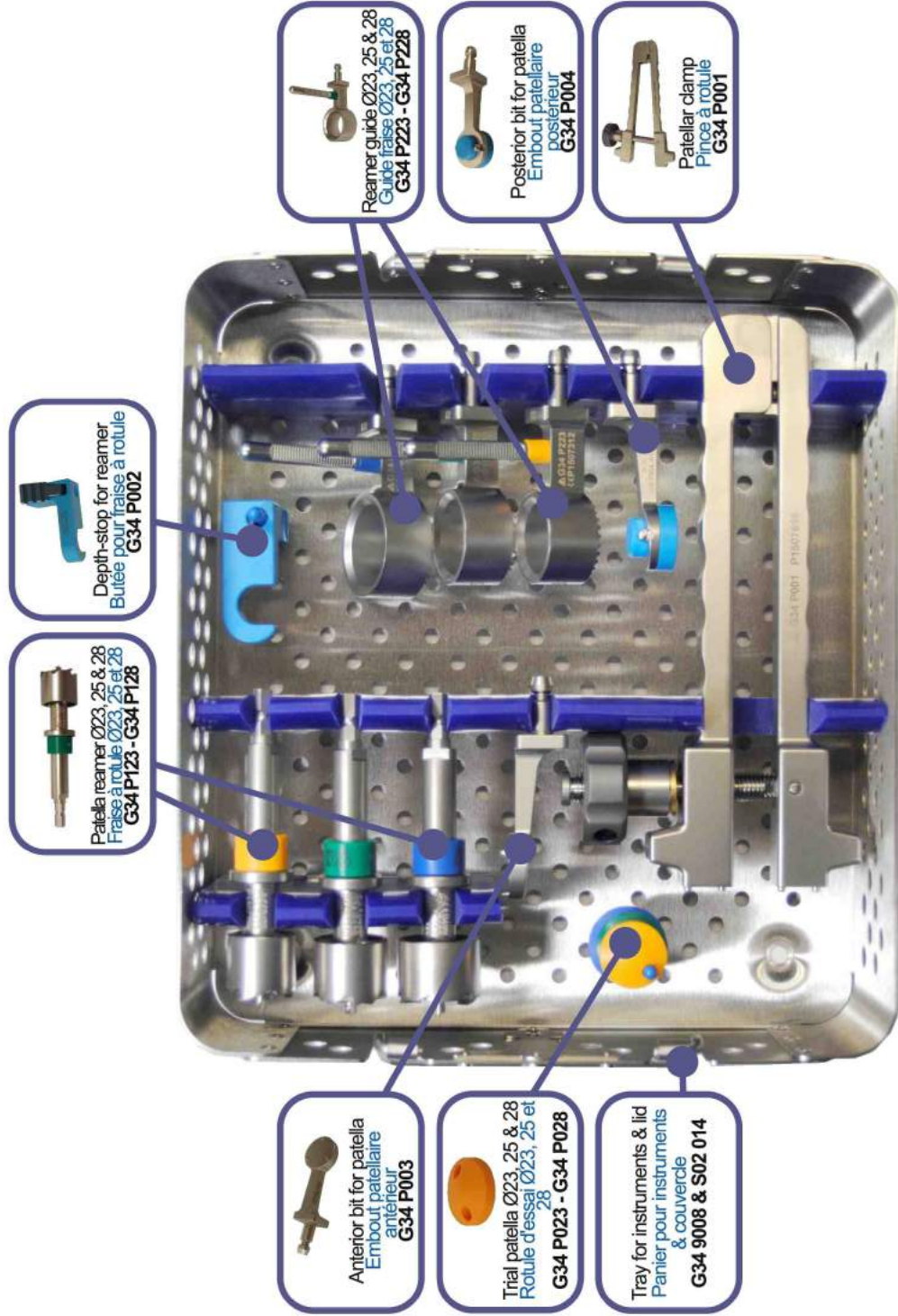




Instrumentation SNAPSHOT

Ref : G34 9107
ROLFLEX TONIC compl. PS / PS compl.





REFERENCES



- 1 • PS or UC Condyles
- 2 • PS or UC Inserts
- 3 • Fixed or Rotating Baseplate
- 4 • Cementless or Cemented versions
- 5 • 20 and 40mm Extension Keel
- 6 • Femoral and Tibial Augments

Condyles Condyles	PS / Postéro-Stabilisés				UC / Ultra-congruents				Patella Rotule	
	Cemented / A cimenter		Cementless / Sans ciment		Cemented / A cimenter		Cementless / Sans ciment			
	R/D	L/G	R/D	L/G	R/D	L/G	R/D	L/G		
Sz./T 0	G33 FPCD00	G33 FPCG00	G33 FPRD00	G33 FPRG00	G33 FUCD00	G33 FUCG00	G33 FURD00	G33 FURG00	ø23	G33 ROT023
Sz./T 1	G33 FPCD01	G33 FPCG01	G33 FPRD01	G33 FPRG01	G33 FUCD01	G33 FUCG01	G33 FURD01	G33 FURG01	ø25	G33 ROT025
Sz./T 2	G33 FPCD02	G33 FPCG02	G33 FPRD02	G33 FPRG02	G33 FUCD02	G33 FUCG02	G33 FURD02	G33 FURG02	ø28	G33 ROT028
Sz./T 3	G33 FPCD03	G33 FPCG03	G33 FPRD03	G33 FPRG03	G33 FUCD03	G33 FUCG03	G33 FURD03	G33 FURG03		
Sz./T 4	G33 FPCD04	G33 FPCG04	G33 FPRD04	G33 FPRG04	G33 FUCD04	G33 FUCG04	G33 FURD04	G33 FURG04		
Sz./T 5	G33 FPCD05	G33 FPCG05	G33 FPRD05	G33 FPRG05	G33 FUCD05	G33 FUCG05	G33 FURD05	G33 FURG05		
Sz./T 6	G33 FPCD06	G33 FPCG06	G33 FPRD06	G33 FPRG06	G33 FUCD06	G33 FUCG06	G33 FURD06	G33 FURG06		
Sz./T 7	G33 FPCD07	G33 FPCG07	G33 FPRD07	G33 FPRG07	G33 FUCD07	G33 FUCG07	G33 FURD07	G33 FURG07		
Sz./T 8	G33 FPCD08	G33 FPCG08	G33 FPRD08	G33 FPRG08	G33 FUCD08	G33 FUCG08	G33 FURD08	G33 FURG08		
Sz./T 9	G33 FPCD09	G33 FPCG09	G33 FPRD09	G33 FPRG09	G33 FUCD09	G33 FUCG09	G33 FURD09	G33 FURG09		

Tibial Baseplate Embase tibiale	Fixed / Fixe				Rotating / Rotatoire				Tibial Keel Quille Tibiale		
	Cemented / A cimenter		Cementless / Sans ciment		Cemented / A cimenter		Cementless / Sans ciment				
	R/D	L/G	R/D	L/G	R/D	L/G	R/D	L/G			
Sz./T 0	G33 TFCD00	G33 TFCG00	G33 TFRD00	G33 TFRG00	G33 TMCD00	G33 TMCG00	G33 TMRD00	G33 TMRG00	ø13	1.20mm	G33 QT1320
Sz./T 1	G33 TFCD01	G33 TFCG01	G33 TFRD01	G33 TFRG01	G33 TMCD01	G33 TMCG01	G33 TMRD01	G33 TMRG01	ø13	1.40mm	G33 QT1340
Sz./T 2	G33 TFCD02	G33 TFCG02	G33 TFRD02	G33 TFRG02	G33 TMCD02	G33 TMCG02	G33 TMRD02	G33 TMRG02	ø13	1.70mm	G33 QT1370
Sz./T 3	G33 TFCD03	G33 TFCG03	G33 TFRD03	G33 TFRG03	G33 TMCD03	G33 TMCG03	G33 TMRD03	G33 TMRG03	ø13	1.110mm	G33 QT13110
Sz./T 4	G33 TFCD04	G33 TFCG04	G33 TFRD04	G33 TFRG04	G33 TMCD04	G33 TMCG04	G33 TMRD04	G33 TMRG04	ø14	1.20mm	G33 QT1420
Sz./T 5	G33 TFCD05	G33 TFCG05	G33 TFRD05	G33 TFRG05	G33 TMCD05	G33 TMCG05	G33 TMRD05	G33 TMRG05	ø17	1.20mm	G33 QT1720
Sz./T 6	G33 TFCD06	G33 TFCG06	G33 TFRD06	G33 TFRG06	G33 TMCD06	G33 TMCG06	G33 TMRD06	G33 TMRG06			
Sz./T 7	G33 TFCD07	G33 TFCG07	G33 TFRD07	G33 TFRG07	G33 TMCD07	G33 TMCG07	G33 TMRD07	G33 TMRG07			
Sz./T 8	G33 TFCD08	G33 TFCG08	G33 TFRD08	G33 TFRG08	G33 TMCD08	G33 TMCG08	G33 TMRD08	G33 TMRG08			

Tibial insert Plateau tibial	Fixed / Fixe				Rotating / Rotatoire				UC / Ultra-congruent		
	PS / Postéro-stabilisé				PS / Postéro-stabilisé				UC / Ultra-congruent		
	h.10mm	h.12mm	h.15mm	h.18mm	h.10mm	h.12mm	h.15mm	h.18mm	h.10mm	h.12mm	h.15mm
Sz./T 0	G33 IFP010	G33 IFP012	G33 IFP015	-	G33 IMP010	G33 IMP012	G33 IMP015	-	G33 IMU010	G33 IMU012	G33 IMU015
Sz./T 1	G33 IFP110	G33 IFP112	G33 IFP115	G33 IFP118	G33 IMP110	G33 IMP112	G33 IMP115	G33 IMP118	G33 IMU110	G33 IMU112	G33 IMU115
Sz./T 2	G33 IFP210	G33 IFP212	G33 IFP215	G33 IFP218	G33 IMP210	G33 IMP212	G33 IMP215	G33 IMP218	G33 IMU210	G33 IMU212	G33 IMU215
Sz./T 3	G33 IFP310	G33 IFP312	G33 IFP315	G33 IFP318	G33 IMP310	G33 IMP312	G33 IMP315	G33 IMP318	G33 IMU310	G33 IMU312	G33 IMU315
Sz./T 4	G33 IFP410	G33 IFP412	G33 IFP415	G33 IFP418	G33 IMP410	G33 IMP412	G33 IMP415	G33 IMP418	G33 IMU410	G33 IMU412	G33 IMU415
Sz./T 5	G33 IFP510	G33 IFP512	G33 IFP515	G33 IFP518	G33 IMP510	G33 IMP512	G33 IMP515	G33 IMP518	G33 IMU510	G33 IMU512	G33 IMU515
Sz./T 6	G33 IFP610	G33 IFP612	G33 IFP615	G33 IFP618	G33 IMP610	G33 IMP612	G33 IMP615	G33 IMP618	G33 IMU610	G33 IMU612	G33 IMU615
Sz./T 7	G33 IFP710	G33 IFP712	G33 IFP715	G33 IFP718	G33 IMP710	G33 IMP712	G33 IMP715	G33 IMP718	G33 IMU710	G33 IMU712	G33 IMU715
Sz./T 8	G33 IFP810	G33 IFP812	G33 IFP815	G33 IFP818	G33 IMP810	G33 IMP812	G33 IMP815	G33 IMP818	G33 IMU810	G33 IMU812	G33 IMU815
Sz./T 9	-	-	-	-	G33 IMP910	G33 IMP912	G33 IMP915	G33 IMP918	G33 IMU910	G33 IMU912	G33 IMU915

Augment Cale	Tibial / Tibiale		Femoral / Fémorale			
			Distal / Distale		Posterior / Postérieure	
	h.5mm	h.10mm	h.4mm	h.8mm	h.4mm	h.8mm
Sz./T. 0	G33 CT0500	G33 CT1000	G33 CFD400	G33 CFD800	G33 CFP400	G33 CFP800
Sz./T. 1	G33 CT0501	G33 CT1001	G33 CFD401	G33 CFD801	G33 CFP401	G33 CFP801
Sz./T. 2	G33 CT0502	G33 CT1002	G33 CFD402	G33 CFD802	G33 CFP402	G33 CFP802
Sz./T. 3	G33 CT0503	G33 CT1003	G33 CFD403	G33 CFD803	G33 CFP403	G33 CFP803
Sz./T. 4	G33 CT0504	G33 CT1004	G33 CFD404	G33 CFD804	G33 CFP404	G33 CFP804
Sz./T. 5	G33 CT0505	G33 CT1005	G33 CFD405	G33 CFD805	G33 CFP405	G33 CFP805
Sz./T. 6	G33 CT0506	G33 CT1006	G33 CFD406	G33 CFD806	G33 CFP406	G33 CFP806
Sz./T. 7	G33 CT0507	G33 CT1007	G33 CFD407	G33 CFD807	G33 CFP407	G33 CFP807
Sz./T. 8	G33 CT0508	G33 CT1008	G33 CFD408	G33 CFD808	G33 CFP408	G33 CFP808



Materials:
 Condyles: CoCr according ISO5832-4 (cemented) or CoCr according ISO5832-4 coated with macroporous Ti (cementless)
 Tibial Baseplate: CoCr according ISO5832-4 (cemented) and UHMWPE according ISO 5834-1 & 2 or CoCr according ISO5832-4 coated with macroporous Ti (cementless) and UHMWPE according ISO 5834-1 & 2
 Tibial Insert and Patella: PEXEL® UHMWPE according ISO 5834-1 & 2 and Stainless Steel according ISO 5832-1
 Tibial keel: CoCr according ISO5832-12. Augment: CoCr according ISO5832-4
 Vacuum packaging VacUPac®. Gamma ray sterilised.

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