evolutis-group.com

Rolflex TONIC®

Surgical Technique

Independent cuts

Rolflex TONIC **PS**

Rolflex TONIC **UC**

Evolutis GROUP

This surgical technique manual describes the use of the instruments dedicated to the Rolflex TONIC® total knee prosthesis.
The indications of the manual cannot substitute the skills of the operator who remains solely responsible for the choice of the indication and of the surgical techniques.
This surgical technique document proposes information on certain techniques when they are known and usually described in the scientific literature.

Table of contents

Introduction and generalities

The Rolfex TONIC® system comprises a range of primary postero-stabilized total knee prosthesis.
The range comprises 10 sizes of femoral condyles and 9 sizes of tibial baseplates. The tibial baseplates are asymmetric with the aim of optimising the cover of the tibial cut. The dimensional ratio of the range of condyles evolves according to the size: the small sizes have an A/P-to-M/L ratio more "feminine", the larger sizes are more "male".
The Rolflex TONIC® range offers a choice of 2 modes of postero-stabilization - UC " deep dish " or PS with cam and peg mechanism, 2 options of bone fixation for both tibial and femoral components - cemented or pure-titanium macro-porous cementless fixation, and a choice between fixed or rotating bearings. The femoro-patellar joint can optionally be resurfaced with an "inlay" polyethylene cemented button.
In case of significant bone or ligament deformation, it is possible to improve the tibial fixation with hemi-augments and extension keels.

The Rolflex TONIC® instrumentation was designed to remain compact with only 3 main trays required for the implantation of a UC version (4 in case of a PS version), to which are added a half-tray of trial condyles and a half-tray of patellar preparation. However this compactness does not make concessions on the precision, nor on its adaptability to usual approaches to the surgical technique. The operator can choose to perform linked or independent tibio-femoral cuts, to start with the tibial side (standard) or the femoral side (optional), to use anterior or a posterior referencing for the femoral sizing, to manage the external femoral rotation in reference to the Whiteside line, to the trans-epicondylar axis, to the posterior bi-condylar plane, or more conventionally centred on the intra-medullary axis.

The tibio-femoral congruence was designed to present a large contact area at all the degrees of flexion up to 120 °, while preserving medio-lateral stability which is beneficial to proprioception. This results in a compatibility of femoral and tibial components sizes from N-1, N and N+1 (3 choices per size). This compatibility must be adapted depending if a fixed or a rotating tibial baseplate is used. The chart below summarizes every situation.

Rationale for tibial and femoral size-match

The Rolflex TONIC® implants are available with fixed or rotating bearing (baseplate and insert).
The sizing mix-and-match logic is different according to the type of bearing.
The PS condyles are compatible with 2 types of bearings, the UC condyles can only be associated with a rotating bearing.

FIXED baseplate and insert
When a FIXED tibial baseplate is implanted, the insert used will be necessarily of the same size as the baseplate.

Size **N** Condyles →
- Fixed insert size **N-1** → Fixed baseplate size **N-1**
- Fixed insert size **N** → Fixed baseplate size **N**
- Fixed insert size **N+1** → Fixed baseplate size **N+1**


Rollfex TONIC PS with fixed bearing

ROTATING baseplate and insert
When a ROTATING baseplate is implanted, the insert used will be generally of the same size as the femoral condyles.

Size **N** Condyles → Rotating Insert size **N**
- → Rotating baseplate size **N-1**
- → Rotating baseplate size **N**
- → Rotating baseplate size **N+1**


Rollfex TONIC UC with rotating bearing

Indications

Total knee replacement (TKR) is a common operation which gives very good functional results.
The primary objective is to replace the 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 tumors

In primary surgery, and even more in tumoral surgery or in revision, an important articular deviation (varus knee or valgus knee deviated more than 15 ° from the normal axis) or the poor osseous density and the possible bone loss resulting from the retreival of a previous implant, can limit the indications of a prosthesis not possessing the necessary elements for an adapted fixation.

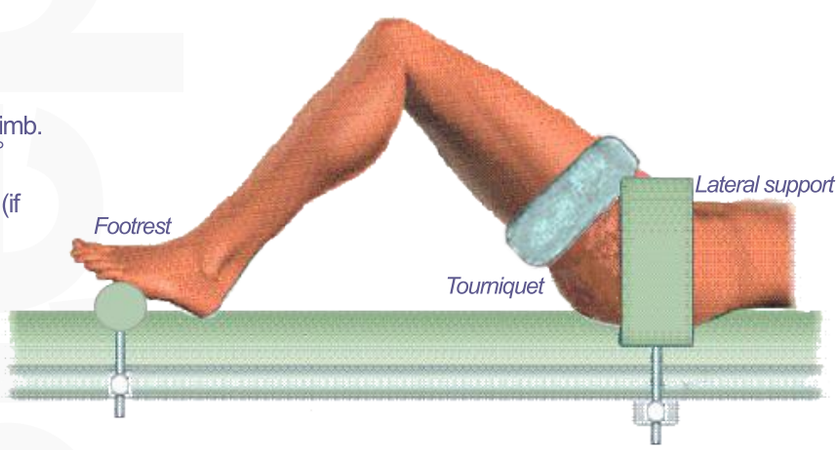
Surgical implantation of a TKR is a major operation which can present risks with all comparable surgeries such as implant loosening, dislocation, infection, allergic (to the materials) reactions, periprosthetic ossifications, thrombosis, cardio vascular problems, hematoma, pulmonary embolisms.

The total knee replacement can be dissuaded in the cases of local or systematic infection, mental deficit, neuromuscular disease, neurological or vascular affliction, patients with alcoholic or psychotropics addiction, of abuse of medicine, excessive functional demand (practice of a sport at risk of fall or functional use beyond the limits of resistance of the prosthetic materials), of being over-weight, insufficient osseous stock or important demineralization compromising the prosthetic fixation, and severe extra-articular deformation.

For more information on precautions and contra indications please read the Instructions for Use leaflet Ref.S10 0313 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.



Preliminary notes on the positioning of the implants

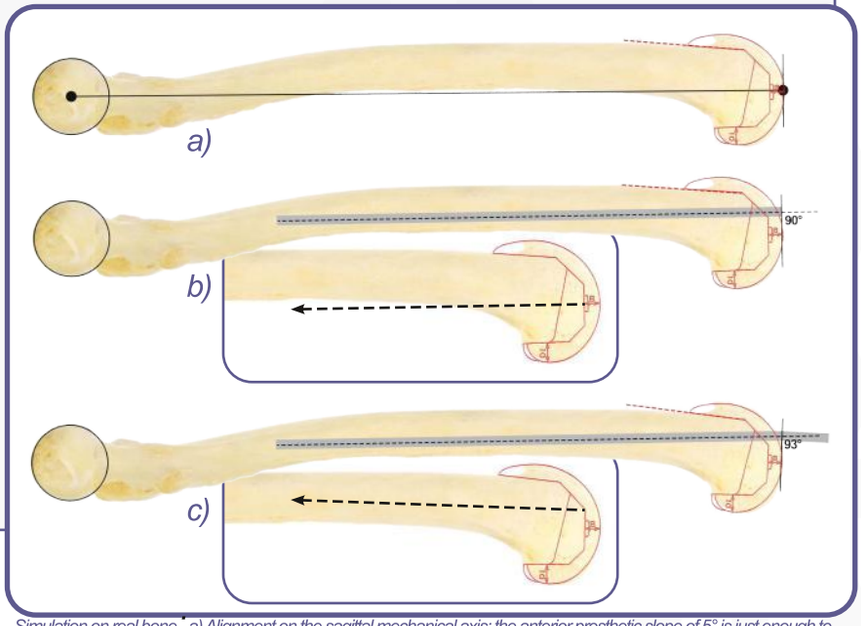
Correct alignment of the components of a total knee prosthesis are an essential condition for the long-term success of the arthroplasty.
In recent studies, Ritter and al. (1) and Fang and al. (2) demonstrate that the risk of failure is multiplied by 2.3 and 3.1 for the TKR (Total Knee Replacement) implanted with a post-operative femoro-tibial angle outside of the 2.5° to 7.5° range.
Besides the coronal alignment, the data of femoral rotation and tibial rotation are many. For the tibia, Nicoll and Rowley (3) demonstrated that an internal rotation exceeding 9° translated into a major risk of pain and functional deficit.
The sagittal alignment is less documented. Gromov and al. (4) regret that few studies are interested in the sagittal positioning of the TKR, but conclude that the sagittal femoral positioning has to be between 0 and 3° of flexum, and the tibial positioning between 0 and 7° of posterior slope.

In practice, even if it is quite simple to produce an accurate posterior tibial slope cut, the question of the sagittal femoral alignment is less reproducible notably because of the important variations of the sagittal femoral curvatures and the more or less reliable positioning of the intra-medullary rod which is highly influenced by the entry point chosen by the operator. Jai-Gon and al. (5) demonstrate an average deviation of 4.1 ° [1 .5° - 11 .7°] between the antero-distal femoral cortical plane and the sagittal mechanical axis, and Tang and al. (6) observed that the intra-medullar rod tended to move anteriorly during its progressive introduction due to the diaphyseal curvature, and thus to move towards a reference in recurvatum with regard to the sagittal mechanical axis. Accordingly Tang and al. recommends to adapt the diameter of the femoral entry point to the diameter of the intra-medullary rod and not to widen it, in order in particular to limit the risks of anterior notching.
Tang and al. ends his discussion claiming that the femoral component should best reproduce the distal sagittal shape of the native femur, but that the evaluations on the optimal positioning of the femoral component in the sagittal plan and its effects on the long term are still lacking in the bibliography. Especially as those available often evaluate the results of components positioned with more than 3° of flexum but designed to be orthogonally aligned with the sagittal mechanical axis.

To limit the uncertainty associated to the variations of femoral curvatures, and the risks of positioning in recurvatum and of anterior notching, Evolutis designed the Rolflex TONIC® components to be aligned to the morphology of the distal 1 /3 of the femur only. The Rolflex TONIC® femoral components are designed to be positioned between 0 and 3° of the distal sagittal axis. The components integrate a recurvatum blocking mechanism which acts at 10° and which allows to combine up to 7° of posterior slope and 3° of femoral flexum while still allowing for full extension of the patient.

Evolutis recommends the systematic use of the 3° intra-medullar rod.

Optionally it is possible to use a straight intramedullary rod combined with 4° femoral flexum guide.



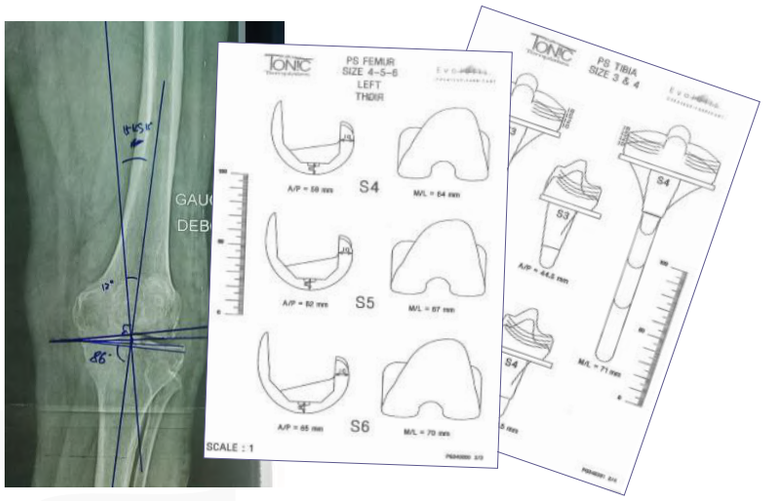
Simulation on real bone : a) Alignment on the sagittal mechanical axis: the anterior prosthetic slope of 5° is just enough to avoid notching of the anterior cortex. b) Alignment on the intra-medullary axis with an anteriorly translated entry point: the alignment of the prosthetic trochlea is very close to the anterior cortex with high risk of notching in case of more important femoral curvature. c) Alignment at 3° of the intra-medullary axis: the anterior cut angle is significantly different from the anterior cortex angle reducing strongly the risk of anterior notching and allowing an arbitration in posterior referencing if necessary.

Straight intra-medullary rod G30 101

3° intra-medullary rod G34 0047

2° and 4° Flessum sleeves (G34 F032 & G34 F010)

(1) *Ritter M A, Davis K E, Meding J B, Pierson J L, Berend M E, Malinzak RA. The effect of alignment and BMI on failure of total knee replacement. J Bone Joint Surg (Am) 2011; 93 (17): 1588–96.*
(2) *Fang D M, Ritter M A, Davis K E. Coronal alignment in total knee arthroplasty. J Arthroplasty 2009; 24 (6): 39–43.*
(3) *Nicoll D, Rowley D I. Internal rotational error of the tibial component is a major cause of pain after total knee replacement. J Bone Joint Surg (Br) 2010; 92 (9): 1238–44.*
(4) *Gromov K, Korchi M, Thomsen MG, Husted H, Troelsen A. What is the optimal alignment of the tibial and femoral components in knee arthroplasty. An overview of the literature. Acta Orthopaedica 2014; 85 (5): 480-487.*
(5) *Jai-Gon S, Byung-Kuk K, Young-Wan M, Jong-Hyun K, Byeong-Ho Y, Tae-Keun A, Dong-Hoon L. Bony landmarks for determining the mechanical axis of the femur in the sagittal plane during TKA. Clinics in Orthopaedic Surgery 2009; 1:128-131.*
(6) *Tang WM, Chiu KY, Kwan MF, Ng TP, Yau WP. Sagittal bowing of the distal femur in Chinese patients who require total knee arthroplasty. J Orthop Res. 2005;23(1):41-5.*



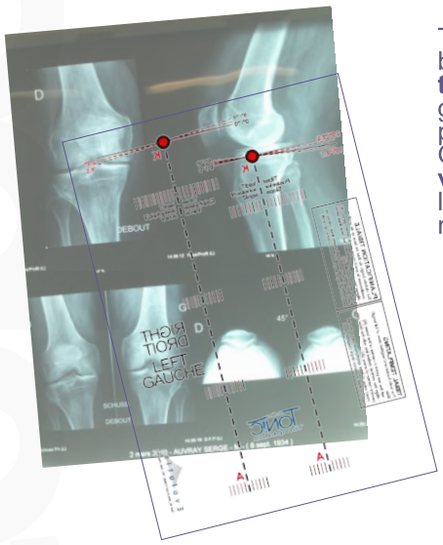
Pre-operative templating

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 intra-medullary rod

On knee profile x-rays:
- Determine the sagittal entry point for the intra-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 flexio**n. 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.

Selection of the Surgical Technique and plan

The Rolflex TONIC® instrumentation allows the operator to choose and plan the most adapted surgical technique:

Independent cuts
Bone cuts according to a purely pre-planned reference which is not linked to ligament tension, followed by a ligament release if required.

Partially linked cuts
Tibial and distal femoral bone cuts, ligament liberation, followed by femoral rotation adapted to the ligament tension.

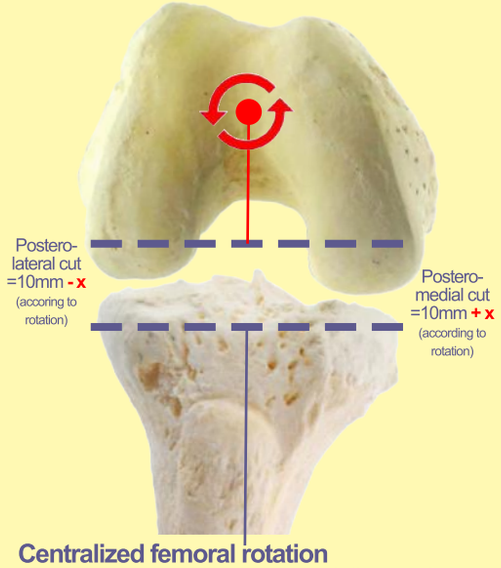
Linked cuts
Tibial and femoral bone cuts adapted to the ligaments in extension (*femoral valgus* + *tibial epiphyseal varus*) and in flexion (*external femoral rotation*).

Independent cuts
- Tibial cut first (*)
- Distal femoral cut in line with the HKS angle and after setting of the femoral external rotation *(3° or parallel to the trans-epicondylar axis)*
- Femoral 4-in-1 cuts *(anterior, posterior and chamfers)*
- Ligament release with help of spacers

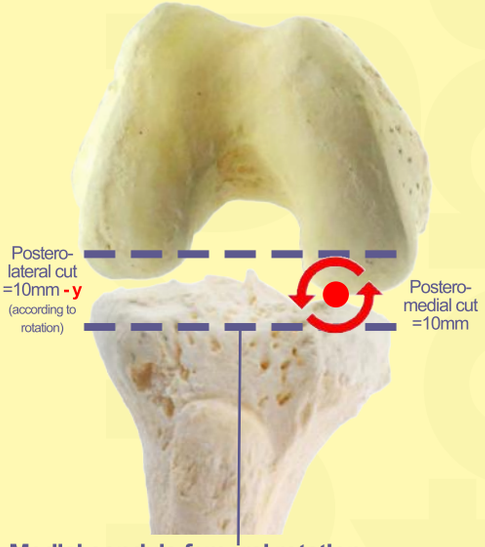
Linked cuts
- Preliminary calculation of the angles of resection of the proximal tibia and of the distal femur on x-ray images to obtain a quadrangular ligament space in EXTENSION (availability of x-ray images in reduction recommended)
- Tibial cut first
- Distal femoral cut according to the HKS angle (Hip-Knee-Shaft) according to the templating
- Choice of the femoral rotation to obtain a quadrangular ligament space in FLEXION.

2 options of rotation:

This Surgical Technique manual describes the "Independent cuts" surgical plan
For indications for the "Linked cuts" surgical plan, please refer to the corresponding manual.



Centralized femoral rotation
(Rotation around the intra-medullary rod)
- Increases the medial gap
- Reduces the lateral gap
- Adapted for a medially "tight" Varus knee



Medial condyle femoral rotation
(Rotation around the posterior medial condyle)
- The medial gap stays equal
- The lateral gap is reduced by the same amount in mm as the lateral spacers used for the rotation stability
- Adapted for a Valgus knee to reduce the medial laxity in flexion

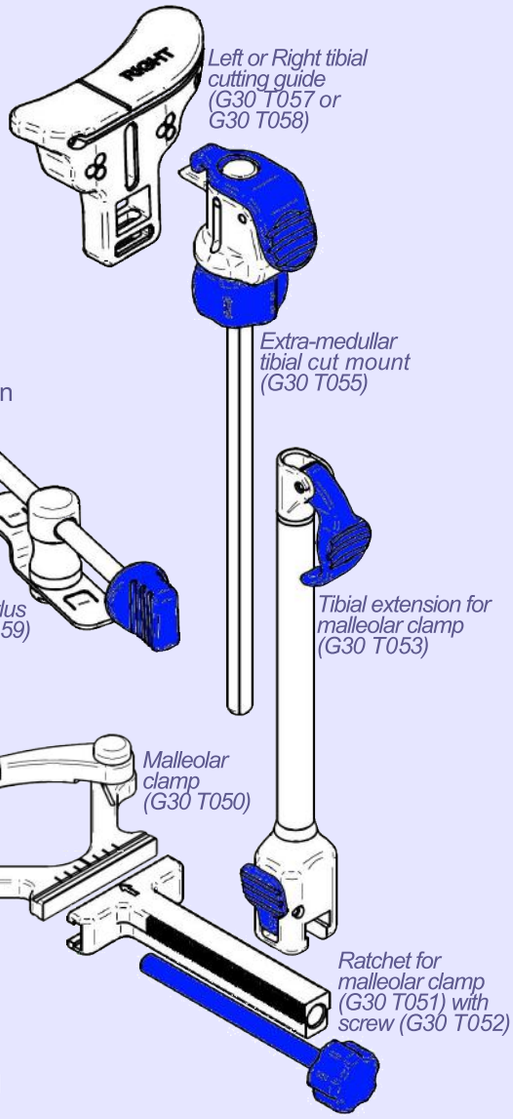
(*) *Distal femoral cut possible with optional instruments to be specifically ordered: distal cut spacer (G34 F009) and 4-in-1 cutting blocks without pegs (G34 F061 to G34 F069)*

Tibial preparation with the extra-medullary guide

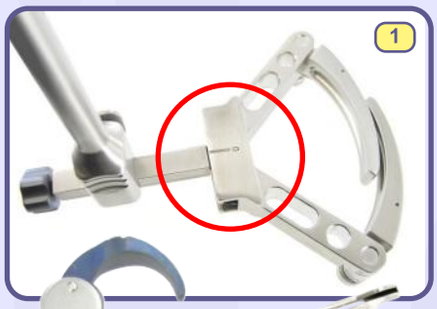
Assembly of the extra-medullar guide

Assemble the extra-medullary tibial cutting guide using the following parts:

- Malleolar clamp *(G30 T050)*
- Ratchet for malleolar clamp *(G30 T051)* with screw *(G30 T052)*
- Tibial extension for malleolar clamp *(G30 T053)*
- Extra-medullary tibial cut mount *(with micro-millimetric adjustment) (G30 T055)*
- Left or right tibial cutting guide *(G30 T057 or G30 T058)*



Assemble the ratchet for malleolar clamp with the tibial extension for malleolar clamp.
Introduce the screw into the ratchet body.
Slide the malleolar clamp on the ratchet and position the cental mark on the clamp in front of the arrow of the ratchet. 1
Tighten the screw to lock the malleolar clamp in this position.

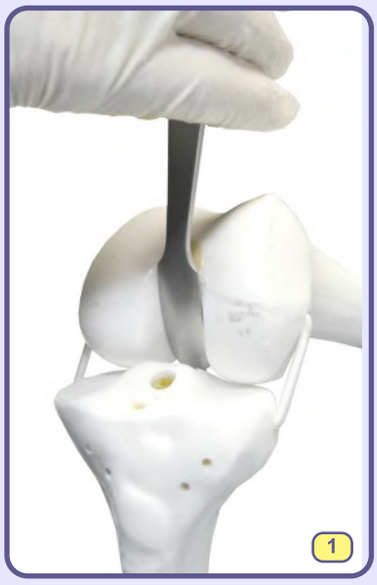


Select the tibial cutting guide *(G30 T057 or G30 T058)* corresponding to the operated side.
Assemble the tibial cutting guide on the extra-medullary tibial cut mount *(G30 T055)*:

- press the blue trigger 2
- introduce the beak of the tibial cut mount into the elongated hole of the tibial cutting guide
- release the trigger 3

Preset the micro-millimetric cursor of the tibial cut mount so that the mark is aligned with the 0 graduation, by turning the blue thumb wheel. 4

Positioning of the extra-medullary guide



Following surgical exposure of the knee joint, resection of menisci and cruciate ligaments, introduce a Hohmann retractor at the level of the tibial insertion of the PCL, then recline the femoral condyles posteriorly to expose the tibial epiphysis. 1

The excision of all or part of the patellar fat pad improves the visibility to the knee. Before introducing the instruments, it is recommended to remove the osteophytes both medially and laterally, as these may affect the ligament balance.

Place the malleolar clamp on the ankle of the patient, and make sure that the branches of the clamp hold the ankle firmly.
Position the tibial cutting guide in contact with the anterior tibial cortex and approximately 5-7mm below the anterior edge of the lateral compartment of the tibia. 2

Introduce the quick drive shaft for broach *(G34 0009)* on a power tool equipped with a "small AO" adapter. 3

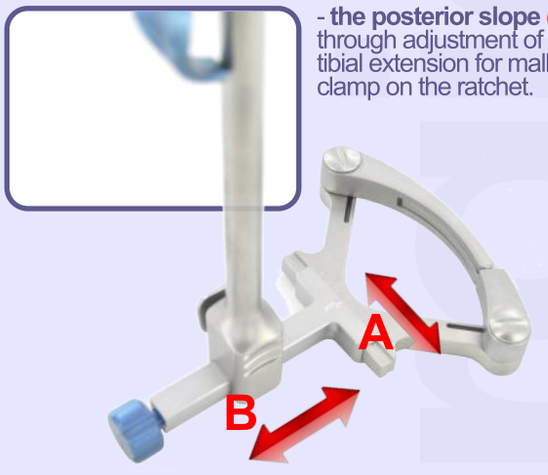
Introduce one Ø3.2 self taping-pin *(GP001.089.032)* in the quick drive shaft.

Position the Ø3.2 self taping-pin into the tibial cutting guide at the level of the mark 0. 4

The tibial cutting guide is now stable in position "of approach". The operator can then choose to correct:

- **the epiphyseal varus/valgus (A)** through adjustment of the malleolar clamp on the ratchet.

- **the posterior slope (B)** through adjustment of the tibial extension for malleolar clamp on the ratchet.



The appreciation of the value of these 2 corrections stays "visual" and can be assisted with the introduction of resection control blade *(G34 0021)* in the slot of the cutting guide to validate the correspondence of the orientation of the cutting guide with the proximal morphology of the tibia. 5

Setting of the resection level *(extra-medullary guide)*

[aparté]

Set up the tibial stylus *(G30 T059)* in the slot of the cutting guide:

The tibial stylus can be set on 2 possible positions: 2mm and 10mm.

- The 10mm position allows to make a 10mm cut below the tip of the stylus. It is generally used on an LATERAL compartment of a Varus knee and allows to determine a 10mm cut below this "healthy" compartment. This position can be also used on a LATERAL compartment in a Valgus knee under the condition that the articular wear is low.

- The 2mm position allows to make a 2mm cut below the tip of the stylus. It is generally used to determine an "economic" 2mm cut below the joint line such as on a MEDIAL compartment of a Valgus knee.

Place the tibial stylus with its tip shifted in a horizontal position. (1)
Once the tibial stylus is introduced in the slot of the cutting guide, position the horizontal tip directly above the tibial compartment and rotate the tip 90° in a vertical position. (2)
The vertical position is validated by a perceptible "clic" at the end of the rotation.

Adjust the level of the tibial stylus by rotating the blue thumb wheel situated on the extra-medullar tibial cut mount. Each turn of thumb wheel corresponds to a correction of +/- 1mm. (3)

When the resection level is satisfactory (4), introduce two Ø3.2 self-taping pins in the two holes marked "0" of the tibial cutting guide with the help of a power drill. (5) (6)

Introduce a Ø3.2 self-taping pin into the convergent locking hole marked with a padlock (🔒). (7)

Remove the tibial stylus from the tibial cutting guide.

Tibial preparation with the intra-medullary guide

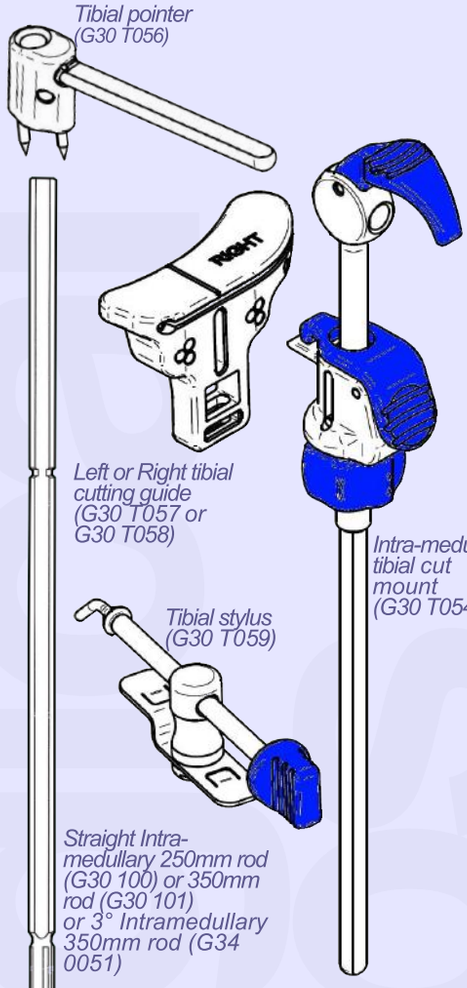
Assembly of the intra-medullary guide

The intra-medullary guide can be used alone or in combination with the malleolar clamp for combined intra and extra-medullary guidance.

Assemble the intra-medullary guide with the following parts:
- *350mm straight (G30 101) or 3° (G34 0051) or 250mm (G30 100) intra-medullary rod*
- *Tibial pointer (G30 T056)*
- *Intra-medullary tibial cut mount (with micro-millimetric adjustment) (G30 T054)*
- *Left or right tibial cutting guide (G30 T057 or G30 T058)*

Select the tibial cutting guide *(G30 T057 or G30 T058)* corresponding to the operated side.
Assemble the tibial cutting guide on the intra-medullary tibial cut mount *(G30 T054)*:

- press the blue trigger (1)
- introduce the beak of the tibial cut mount into the elongated hole of the tibial cutting guide
- release the trigger (2)



Tibial pointer (G30 T056)

Left or Right tibial cutting guide (G30 T057 or G30 T058)

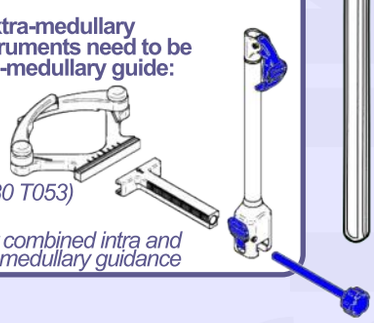
Intra-medullary tibial cut mount (G30 T054)

Tibial stylus (G30 T059)

Straight Intra-medullary 250mm rod (G30 100) or 350mm rod (G30 101) or 3° Intramedullary 350mm rod (G34 0051)

Option **for combined intra and extra-medullary guide**

For a combined intra and extra-medullary guidance, the following instruments need to be used in addition to the extra-medullary guide:
- Malleolar clamp *(G30 T050)*
- Ratchet for malleolar clamp *(G30 T051)* and screw *(G30 T052)*
- Tibial extension for malleolar clamp *(G30 T053)*



Additional instruments for combined intra and extra-medullary guidance

3° Intra-medullary rod (G34 0051)

Preparing for a 5° tibial epiphyseal posterior slope

The cutting guide is set for a systematic 2° of tibial epiphyseal posterior slope.

In cases where a more important tibial epiphyseal posterior slope is required to respect the anatomy, use the 3° Intramedullary rod:

- select the G34 0051 intramedullary-rod

- introduce the intramedullary-rod in the epiphyseal drilled hole
*- make sure the "**TOP**" sign is placed anteriorly (facing the operator)*
- stop introduction at the grooved section of the rod

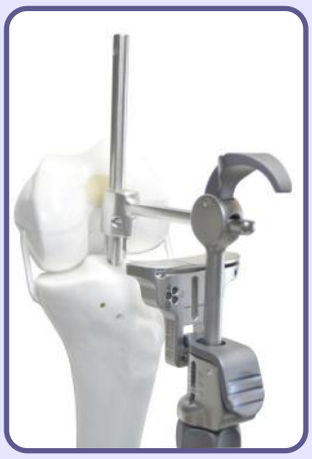
Positioning of the intra-medullary guide

Following surgical exposure of the knee joint, resection of menisci and cruciate ligaments, introduce a Hohmann retractor at the level of the tibial insertion of the PCL, then recline the femoral condyles posteriorly to expose the tibial epiphysis. 1

The excision of all or part of the patellar fat pad improves the visibility to the knee.
Before introducing the instruments, it is recommended to remove the osteophytes both medially and laterally, as these may affect the ligament balance.

Adapt the intra-medullary Ø8mm drill *(G30 F023)* on a power tool and drill the entry hole for the diaphyseal axis on the tibial spines and at the level of the tibial insertion of the ACL. 2

Introduce an intra-medullary rod *(G30 100, G34 0051 or G30 101)* down to the grooved mark. 3



Orthopedic mallet not included in the Rolfex TONIC instrumentation set.

Introduce the tibial pointer *(G30 T056)* into the upper part of the intra-medullary tibial cut mount 4 and lock both parts together with the blue trigger. 5

Adjust the height of the intra-medullary tibial cut mount turning the blue thumb wheel to bring the cursor at the level of the mark "0". 6

Place the tibial pointer on the intra-medullary rod.
Bring the pointer down until contact of the longest spike of the pointer with the tibial spines.
Hammer in the first spike but not the second. 7

Check the alignment of the intra-medullary tibial cut mount slightly medial to the anterior tibial crest and align the tibial cutting guide with regard to the anterior tibial crest.

Hammer in the second spike. 8

Setting the resection level
(intra-medullary guide)

[aparté]

The tibial stylus can be set on 2 possible positions: 2mm and 10mm.

- The 10mm position allows to make a 10mm cut below the tip of the stylus. It is generally used on an LATERAL compartment of a Varus knee and allows to determine a 10mm cut below this "healthy" compartment. This position can be also used on a LATERAL compartment in a Valgus knee under the condition that the articular wear is low.

- The 2mm position allows to make a 2mm cut below the tip of the stylus. It is generally used to determine an "economic" 2mm cut below the joint line such as on a MEDIAL compartment of a Valgus knee.

Set up the tibial stylus *(G30 T059)* in the slot of the cutting guide:

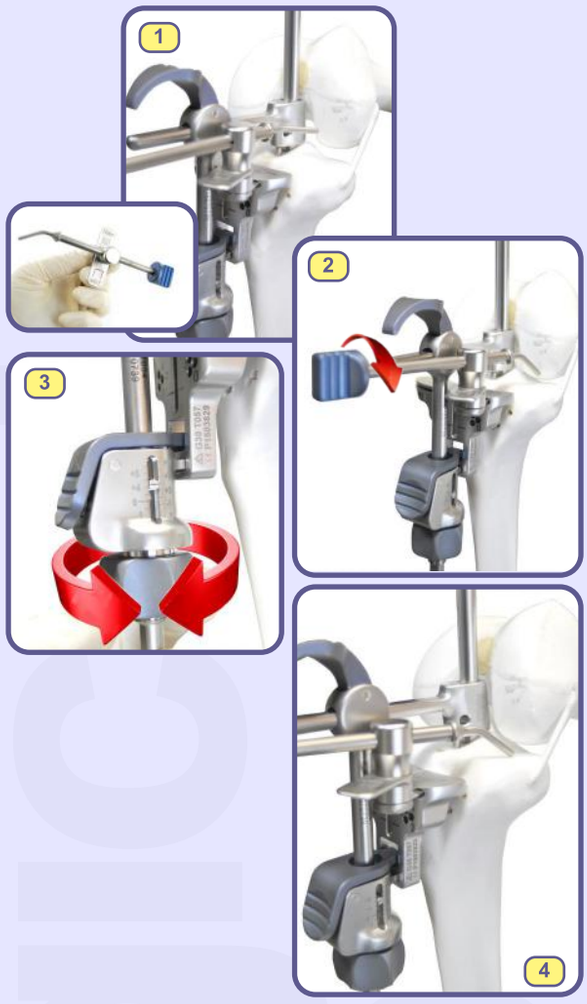
Place the tibial stylus with its tip shifted in a horizontal position. (1)
Once the tibial stylus is introduced in the slot of the cutting guide, position the horizontal tip directly above the tibial compartment and rotate the tip 90° in a vertical position. (2)
The vertical position is validated by a perceptible "clic" at the end of the rotation.

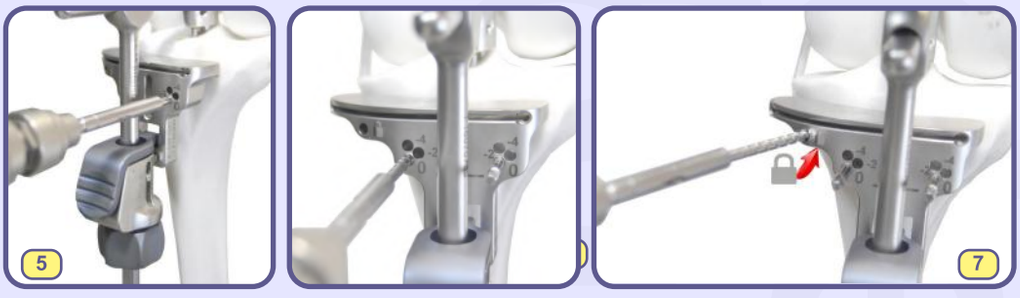
Adjust the level of the tibial stylus by rotating the blue thumb wheel situated on the extra-medullar tibial cut mount. Each turn of thumb wheel corresponds to a correction of +/- 1mm. (3)

When the resection level is satisfactory (4), introduce two Ø3.2 self-taping pins in the two holes marked "0" of the tibial cutting guide with the help of a power drill. (5) (6)

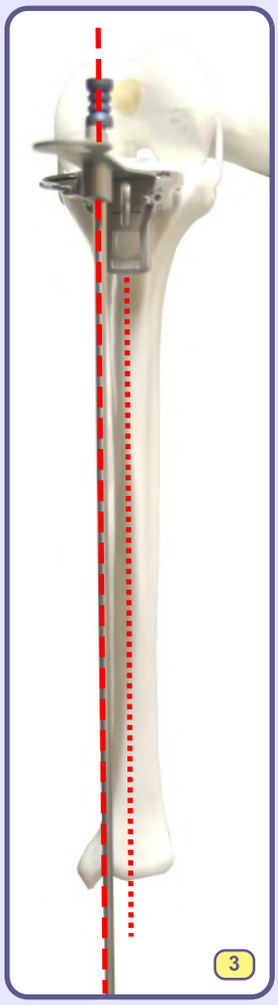
Introduce a Ø3.2 self-taping pin into the convergent locking hole marked with a padlock ( ). (7)

Remove the tibial stylus from the tibial cutting guide.





Resection of the tibial epiphysis



Validation of the tibial axis

Introduce the support blade for axis control *(G34 0020)* in the slot of the tibial cutting guid 1
Introduce an axis control rod *(G34 0019)* into one hole of the support blade from top to botton 2

Adjust the position of the support blade so that the axis control rod is aligned on the anterior tibial crest, and check that the axis control rod points in direction of the 2nd metatarsal.

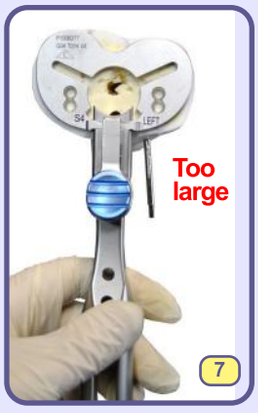
Check visually the orthogonality of the axis control rod with the anterior tibial crest, and estimate the angle of the tibial slope. 3

Making of the tibial cut

Perform the tibial cut using an oscillating saw with a 1.27mm thick sawblade. 4

Remove the convergent broach ( ). 5
Remove the tibial cutting guide. 6

Estimate the tibial size using the trial baseplates *(G34 T011 to G34 T028)* assembled on the handle *(G34 0017)*. 7 8
Remember the tibial size to anticipate its correspondence with the size of the femur.



Control of the flexion and extension gap

Control of the extension gap

With the knee in extension, introduce the10mm spacer *(marked FLEXION)* corresponding to the thickness of the tibial cut in the articular space in extension. (1)
Should the conservative tibial cut be less than 10mm, use the 8mm spacer *(marked EXTENSION)*.

Estimate the stability of the knee in extension, and test if there is any medial or lateral instability.


1

Control of the flexion gap

With the knee in flexion, introduce the 10mm spacer *(marked FLEXION)* or in case of tight knee the 8mm spacer *(marked EXTENSION)* usually a Valgus knee. (2)
To compensate for the asymmetric tibial cut *(orthogonal cut)*, there should normally remain a lateral instability in flexion.

Evaluation of the laxity in flexion

Clip a 3mm hemi augment for spacer *(G34 0035)* on the (3) lateral side of the spacer used at the previous step (10mm or 8mm).
A hemi-augment of 3mm positioned under the lateral posterior condyle creates a rotation angle of 3° to 5° depending on the M/L size of the knee *(refer to the correspondence table below)*.


2

3


4

Reintroduce the spacer and the hemi-augment in the knee in flexion. (4)

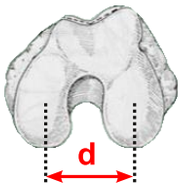
Estimate the medio-lateral stability.
If required, change the thickness of the hemi-augment *(available range from 1 to 10mm)* until good medio-lateral stability in flexion is achieved.
Remember the thickness of the best adapted hemi-augment.

Hemi-augments for spacer are available in millimetric increments from 1mm to 5mm, and can be combined with one 5mm hemi-augment.

The total height of available hemi-augments is thus between 1mm and 10mm.

[aparté]

Correspondence table between mm and degrees:



	Thickness of the lateral spacer						
	1mm	2mm	3mm	4mm	5mm	6mm	7mm
d=35mm	1,6°	3,2°	4,8°	6,4°	8,1°	9,7°	11,3°
d=40mm	1,4°	2,8°	4,3°	5,7°	7,2°	8,6°	10°
d=45mm	1,3°	2,5°	3,8°	5,1°	6,4°	7,6°	8,9°
d=50mm	1,1°	2,3°	3,5°	4,6°	5,8°	6,9°	8,1°
d=55mm	1°	2,1°	3,1°	4,2°	5,2°	6,2°	7,3°
d=60mm	0,9°	1,9°	2,9°	3,8°	4,8°	5,8°	6,7°

Femoral preparation

This paragraph describes the "independent cuts" surgical technique.
This technique consists in making tibial and femoral cuts equivalent to the thickness of the replacing implants *(10mm in tibial, 8mm in distal femur, 10mm in posterior femur), and then to balance the flexion and extension gap with the thickness of the different inserts and/or with a ligament release.*

Careful: the distal femoral first surgical technique cannot be made with the standard Rolflex TONIC® instrumentation set, and requires the optional Distal condyles spacer *(G34 F009)*.

Assembly of the femoral guide

Required instruments
- G34 F004: Baseplate for independent cuts
- G34 F003: Base for femoral guide
- G34 F036: Femoral valgus guide
- G34 F006: Bracket for cutting guide
- G34 F032 or G34 F010: 0°, 2° or 4° Femoral flexum sleeves
- G34 F001: Distal femoral cutting guide
- G34 F002: Anterior femoral stylus

Assembly
- Assemble the Base for femoral guide *(G34 F003)* with the Baseplate for independent cuts *(G34 F004)* by pressing on the blue side button. 1 2 1

- Flip the Femoral valgus guide *(G34 F036)* to reveal the letter L or R on the top corresponding to the operated side and adjust it to the selected femoral valgus angle value, then slide it over the two posts of the Base for femoral guide. 3 2

- Introduce a 0°, 2° or 4° *flexum sleeve (G34 F031, G34 F032 or G34 F010)* into the Femoral valgus guide.
Careful: the 2° Femoral valgus guide is reversible, unless otherwise specified, please direct the Femoral valgus guide with the "F" mark upward to make a flexum cut. 4 4' 3

- Assemble the Bracket for cutting guide *(G34 F006)* over the two posts of the Base for femoral guide by pressing on the blue button. Set the Bracket for cutting guide on the highest notches of the posts of the Base for femoral guide 5 4

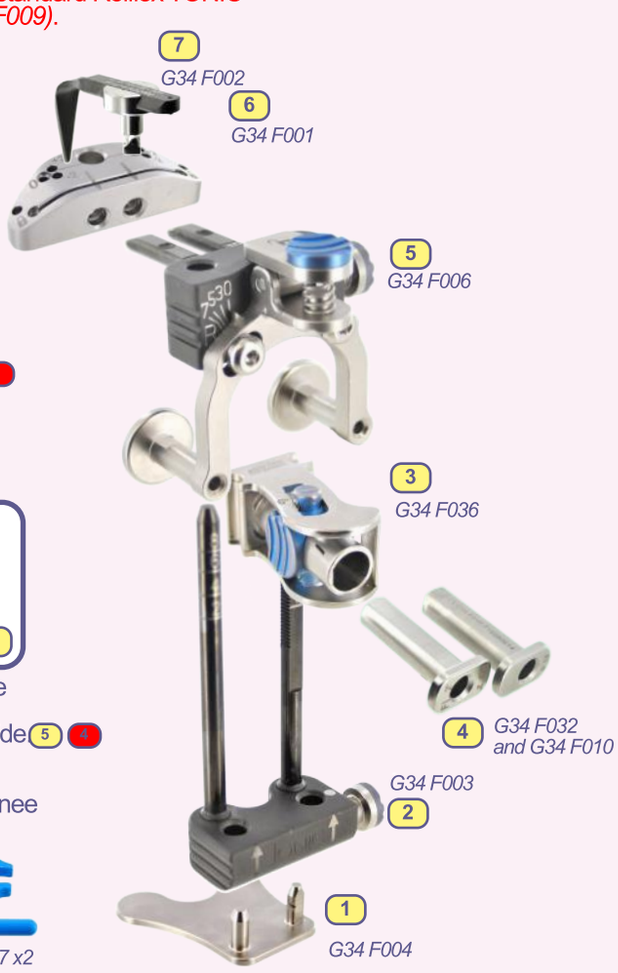
- The Distal femoral cutting guide *(G34 F001)* and the Anterior femoral stylus *(G34 F002)* will then be added after having positioned the assembly on the knee at 90° of flexion. 6 7

- The Epicondylar axis indicators *(G34 F007)* are optional.


G34 F007 x2

- Before presenting the femoral guide assembly on the intra-medullary rod, set the value of external femoral rotation: pinch the blue button positioned on the front Bracket for cutting guide 5, then turn the arch *(to the left for a right femur and to the right for a left femur)* until the cursor indicates the right external rotation value. 6 7

Illustration of external rotation adjustment: 3° for a left side knee.



Positioning of the femoral guide

With the knee bent at 90°, prepare the entry point of the intra-medullary rod with the Ø8mm drill *(G30 F023)*. 1
The A/P position of the entry point should be previously identified on a profile x-ray of the femur during the templating.
In the cases where the introduction of the intra-medullary rod is made difficult by the shape of the femoral bow, it is possible to widen the entrance of the tunnel by using the Ø10mm Tibial keel drill *(G34 T061)*.

Introduce the intra-medullary rod. 2
It is preferable to use the 3° intra-medullary rod (G34 0051) - *see the explanatory "aparté" below on the same page.*
Introduce the intra-medullary rod down to the circumferential mark, leaving approximately 9 cms of rod outside the femur. 3
Make sure that the "**TOP**" mark on the extremity of the 3° intra-medullary rod is directed upward.

Present the femoral guide set with the Baseplate and hemi-augments on the intra-medullary rod, and push the femoral guide into contact with the distal condyles. 4

[aparté]

Selection of the femoral flexum

The Rolflex TONIC® condyles are designed to be positioned in the sagittal alignment of the distal 1/3 of the femur. *By reducing the patello-femoral pressure, this positioning also optimizes the efficiency of the quadricipital moment and reduces the risks of anterior notching.*

It is recommended to obtain a ***true flexum of minimum 3°*** *with regard to the full sagittal femoral axis.*

To facilitate the positioning in flexum, the Rolflex TONIC® instrumentation includes a intra-medullary rod with a distal angulation of 3° *(G34 0051).*
When using the 3° intra-medullary rod it is important to make sure that the "TOP" mark on the extremity of the 3° intra-medullary rod is directed upward.

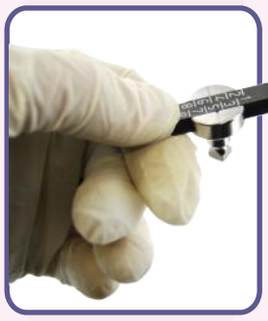
The flexum can be also obtained by using a straight intra-medullary rod (G30 101) used in association with a Femoral flexum guide sleeve of 2° or 4° (G34 F032 and G34 F010) to be selected according to the sagittal positioning of the intra-medullary rod (entry point and femoral bow).

IMPORTANT: *Never combine a 3° intra-medullary rod with a 4° Femoral flexum sleeve!*

Introduce the Distal femoral cutting guide on the femoral guide assembly 5
Place the Femoral stylus on the Distal femoral cutting guide. 6
The stylus will be presented at first at 45° of the Distal cutting guide, then turned back in the alignment of the femoral axis to lock the stylus into place.

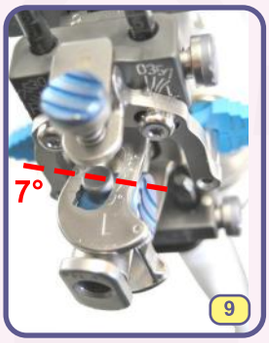
Press on the blue button situated to the right of the femoral guide assembly, and bring the tip of the stylus down until soft contact with the anterior cortex. 7 8

DO NOT FORCE ON THE GUIDE at the risk of distorting the reading of the true femoral size.



Confirm the femoral valgus setting. 9

The standard distal femoral cut should be 8mm thick. 10
The 8mm cut corresponds to the positioning of the Distal cutting guide in abutment on the Bracket for cutting guide.
In case of important gap (> 2mm) between one of the distal condyles and the femoral guide assembly, it is advised to increase the value of the cut to 10mm by moving the Distal cutting guide to the 10mm mark. 11

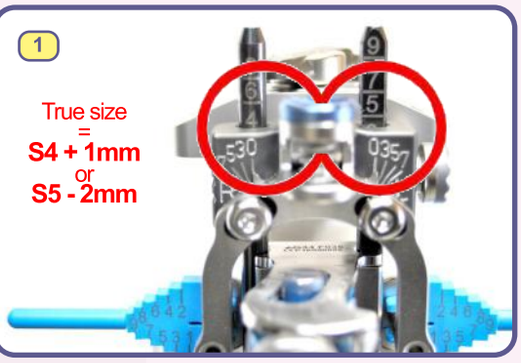


Reading of the femoral size

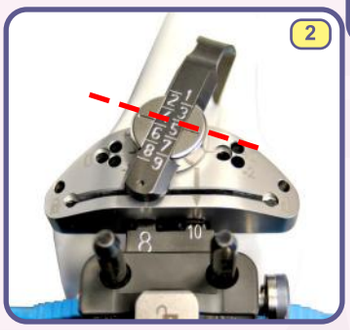
On the upper part of the axis of the femoral assembly, read the A/P *(antero-posterior)* size of the implant the best adapted to the morphology of the patient. 1
If necessary, adjust the position of the Femoral stylus using the A/P size read on the axis of the femoral assembly, and fine-tune again the contact of the stylus with the anterior cortex. 2

The Epicondylar axis indicators *(G34 F007)* have indicating marks showing the M/L *(medio-lateral)* size of the condylar implants. 3 These can be used to visually confirm the adaptation of the prosthetic condyles to the M/L dimension of the distal femur.

1



2



3

[aparté]

Selecting the A/P (antero-posterior) size

The increment between two sizes of femoral ROLFLEX TONIC® implant is of 3mm, consequently any native morphology will differ at maximum of 1.5mm from one of the implants available in the range.

***When the measure read on the upper axis of the femoral guide corresponds exactly to an A/P size** of implant in the range (the size mark is aligned or very close to the basis of the guide), it is advised to select that size of implant and to pursue the femoral preparation on this basis.*

***When the measure read on the guide is situated between two A/P sizes** of implant in the range, it is generally recommended to select the smallest size to improve mobility, flexion, and to avoid pain related to the possible M/L overhang of the implant.*

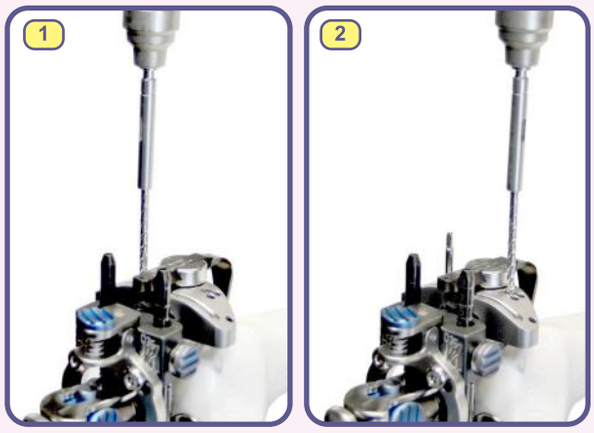
Cutting guide fixation and performing the distal cut

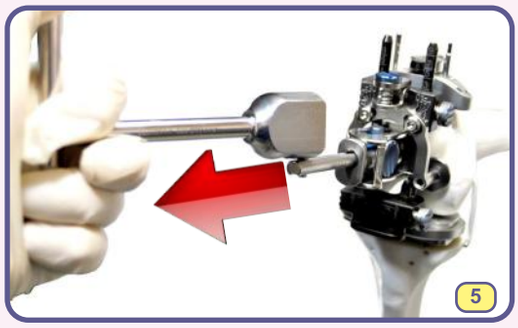
Place two pins in the Distal femoral cutting guide in the holes marked "0". 1 2

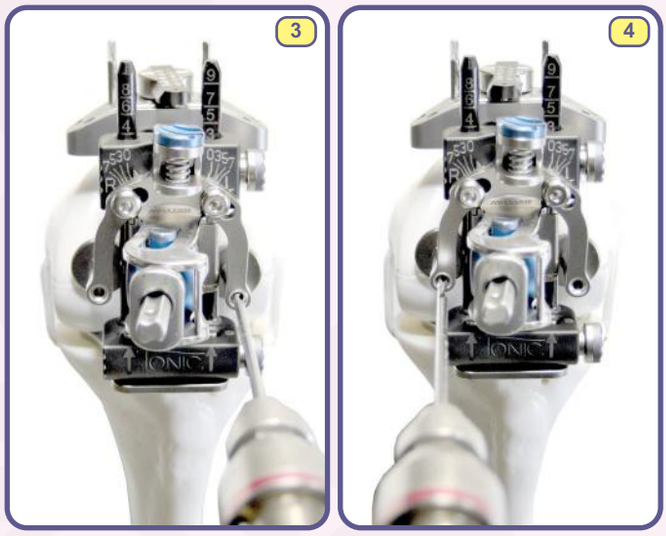
Use the drill Ø3.2mm to prepare the two fixation holes for the 4-en-1 cutting guide. 3 4

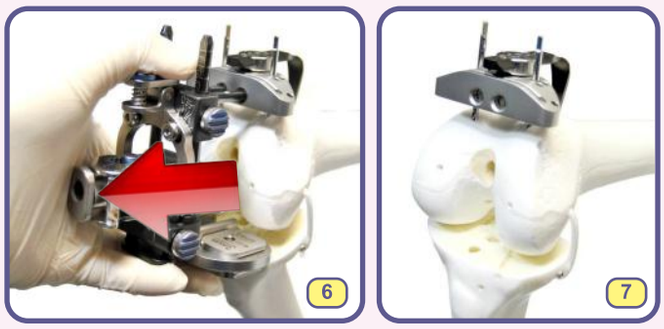
Remove the femoral guide assembly and leave the Distal cutting guide in position:

- Remove the intra-medullary rod, 5
- Remove the femoral guide assembly all together as a single unit, 6
- Remove the anterior stylus and bring the Distal cutting guide down until it is in contact with the anterior cortex, 7
- Introduce a convergent pin in the hole marked with a padlock ( ) to stabilize the Distal cutting guide. 8

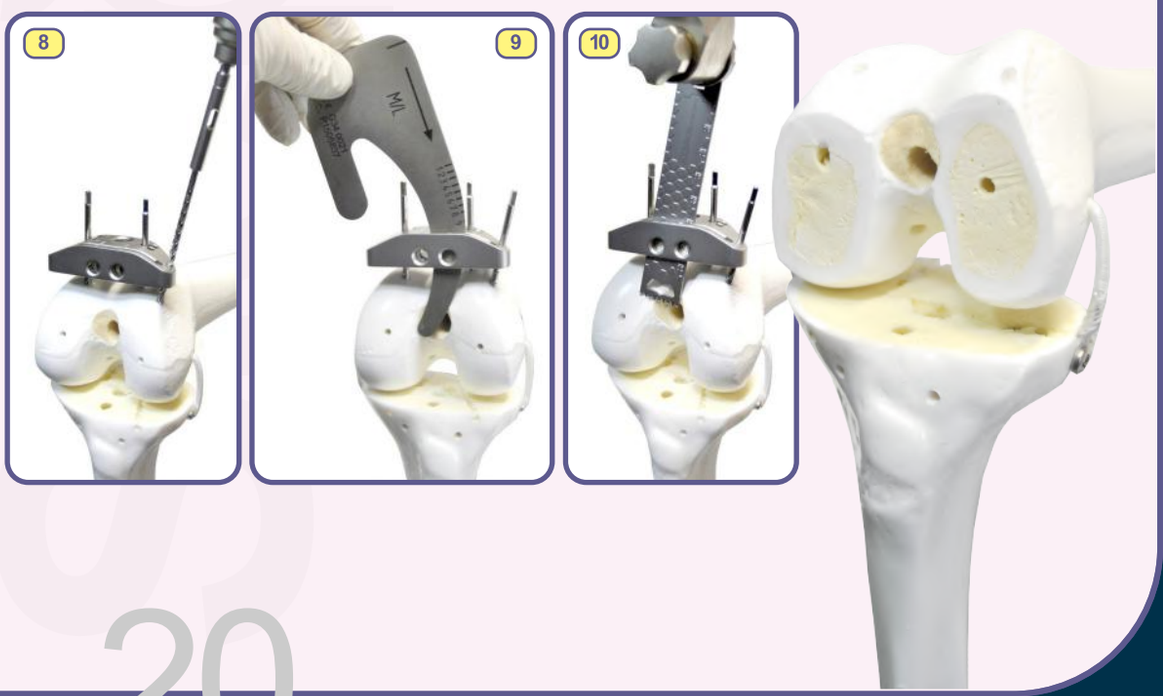








Visually check the thickness and orientation of the distal cut with the Resection control blade *(G34 0021)*. 9
Perform the distal cut with an oscillating saw with a 1.27mm sawblade. 10



Final femoral cuts

Control of the articular gap in extension

Assemble the EXTENSION spacer *(G34 0023)* with two BLUE *(10mm)* hemi-augments *(G34 0025)* (1) and introduce the assembly into the articular space of the knee in EXTENSION. (2) The spacer should be equal to an articular space including 10mm of tibial resection + 8 mm of distal femoral resection.

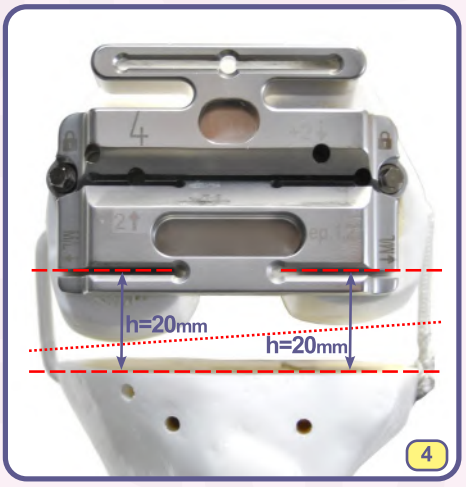
Check the stability of the knee in extension.

Check the HKA axis by introducing two limb axis control rods (G34 0019) in the holes of the EXTENSION spacer, from bottom to top for the femoral axis, and from top to bottom for the tibial axis. (3)

Positioning of the 4-in-1 cutting guide

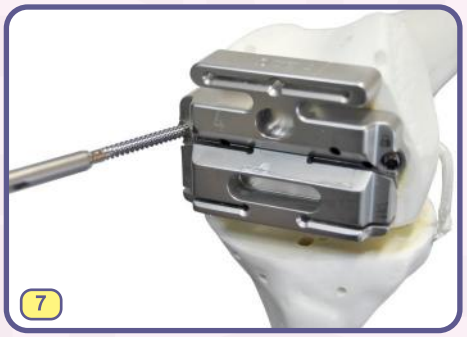
Check the flatness of the cut.
Locate the two holes previously drilled with the Ø3.2mm drill through the distal condyles for placing of the 4-in-1 cutting guide.
Select the 4-in-1 cutting guide of the size corresponding to the A/P size of the femur.
Position the two pegs of the 4-in-1 guide in front of the 2 holes and hammer the guide down to firm flat contact with the distal femoral cut.

Visually check that the cut of the posterior condyles corresponds to the value of the external rotation. (4)



Check with the Resection control blade *(G34 0021)* that the 4-in-1 guide is correctly aligned with the anterior cortex. The blade should indicate that there is no risk of anterior notching, and no overhang of the blade at distance of the anterior cortex. (5)

Maintain the 4-in-1 cutting guide firmly against the distal femur, then lock the guide with two Ø3.2/50mm hexagonal screws *(G34 0046)*:
- Introduce a first screw until contact with the cutting guide but without tightening, (6)
- Introduce the second screw and tighten it, (7)
- Re-tighten the first screw.



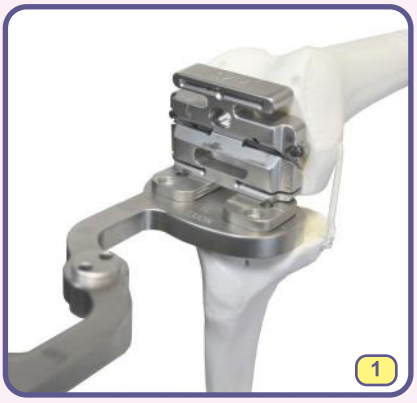
Anterior, posterior and chamfers cuts

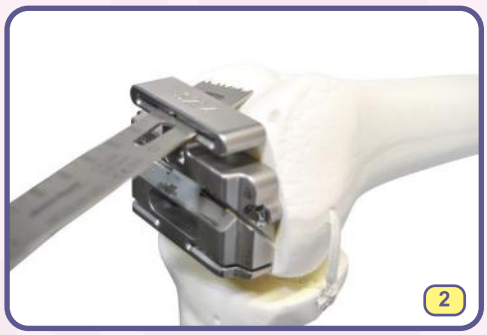
OPTION: in order to protect the tibial cut while resecting the posterior condyles place the FLEXION spacer (G34 0024) with two 5mm hemi-augments (G34 0037) below the lower border of the 4-in-1 cutting guide. (1)

Make the anterior, posterior, anterior chamfer and posterior chamfer cuts with an oscillating saw and a 1.27mm thick sawblade. (2) (3) (4)

Remove the bone fragments and osteophytes with a bone chisel.

Check the flatness of the cuts.





Control of the articular gap in flexion

Knee bent at 90°, introduce the FLEXION spacer (thickness 10mm, G34 0024) completed with two 10mm BLUE hemi-augments (G34 0025) (5) , and check the stability of the knee in flexion. (6)
The resulting joint space must correspond to **the minimum thickness of the 2 implants in FLEXION**: 10mm of tibial resection + 10mm of posterior femoral resection.

Preparation of the PS box

Important: this step is not to be undertaken for a UC version of the Rolflex TONIC®.

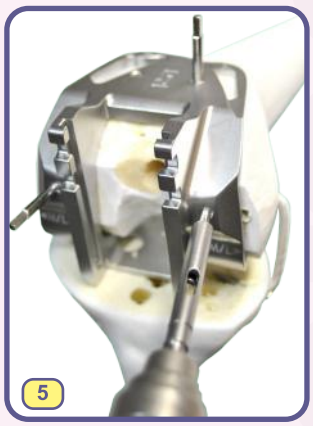
Position the Reamer guide for intercondylar box of the size corresponding to the 4-in-1 cutting guide used at the previous step.(1)

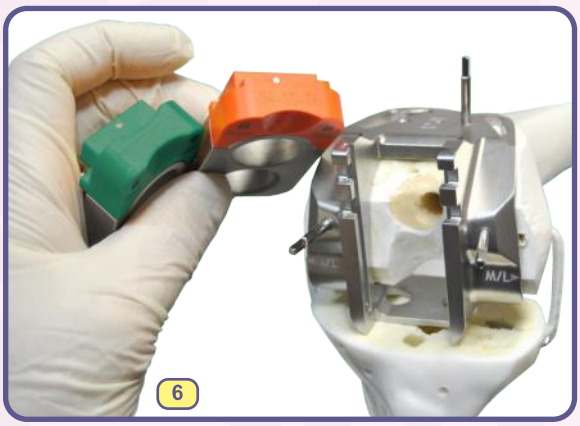
Center the Reamer guide on the femur (2) : the dimensions of the reamer guide show:
- the M/L dimension of the final condyles
- the outer shape of the final prosthetic trochlea.

The reamer guide is not side dependent: the geometry of the trochlea for left implant and the geometry of the trochlea for right implant are illustrated on the same instrument.(3)

Pin the Reamer guide with two distal and one anterior pins.(4)(5)

Select the Locking sleeve for PS box reamer (6) and the reamer of the diameter corresponding to the reamer guide:
- Size 1, 2 or 3: locking sleeve and reamer G34 F045 and G34 F033
- Size 4, 5 or 6: locking sleeve and reamer G34 F046 and G34 F034
- Size 7, 8 or 9: locking sleeve and reamer G34 F047 and G34 F035





Unlock the Locking sleeve, then slide it on the Reaming guide.(7)
Lock the Locking sleeve in the most posterior position of the Reaming guide.(8)

Assemble the Reamer of the right diameter *(G34 F033, F034 or F035)* on a power tool.

Reaming the intercondylar space:

1- Introduce the reamer with the power tool **running** into the lower hole of the Locking sleeve. Ream down until abutment of the reamer with the sleeve. 9

2- Remove the reamer from the lower hole and repeat the reaming in the upper hole of the Locking sleeve. Ream down until abutment of the reamer with the sleeve. 10

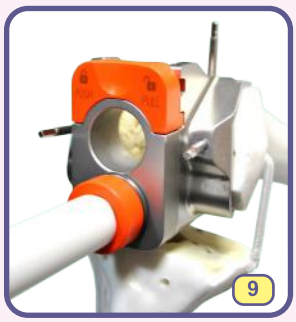
3- Unlock the Locking sleeve, slide it up 1cm, and then lock it in the most anterior position of the Reaming guide. 11

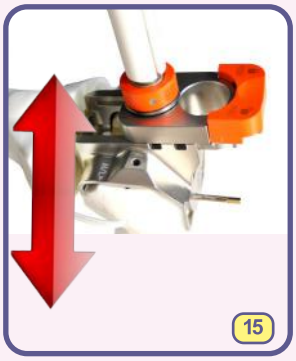
4- Introduce the reamer with the power tool **running** into the upper hole of the Locking sleeve. Ream down until abutment of the reamer with the sleeve. 12

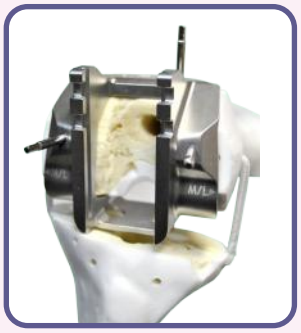
5- Remove the reamer from the upper hole and repeat the reaming in the lower hole of the Locking sleeve. Ream down until abutment of the reamer with the sleeve. 13

6- Without removing the reamer, unlock the Locking sleeve 14 and finalize reaming up-and-down all through the intercondylar space to flatten and clean the sides of the PS box. 15

Remove the 3 pins and the Reaming guide. 16

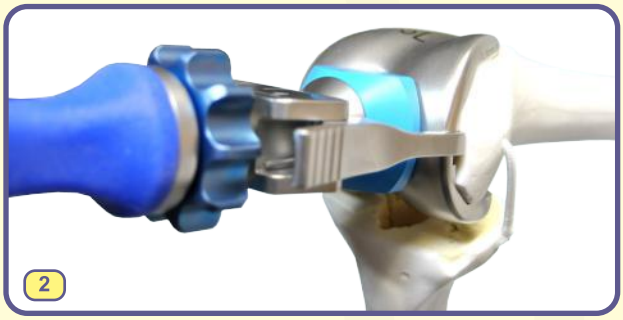




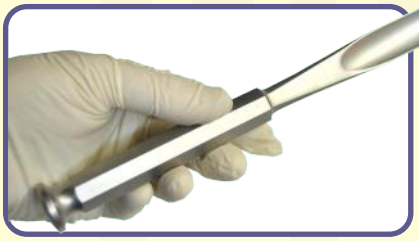


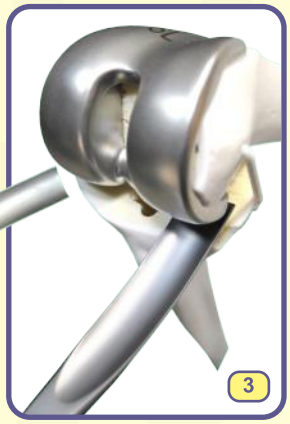
Positioning of the trial implants

Femoral trials



Select the trial condyles *(PS or UC)* of the side and size corresponding to the previous steps. 1
Assemble the trial condyles on the condyles Holding clamp *(G34 F037)* 2 , and hammer the trial condyles onto the femur.





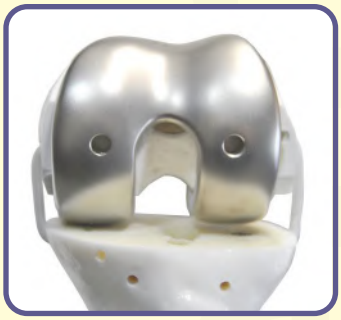
Place the knee in hyper-flexion, then resect any superfluous posterior bone overflowing the trial implant with the Gouge chisel *(G30 F029)* supplied in the instrumentation. 3

Drilling of the fixation pegs for UC condyles

This step is NOT to be performed for implantation of PS condyles.

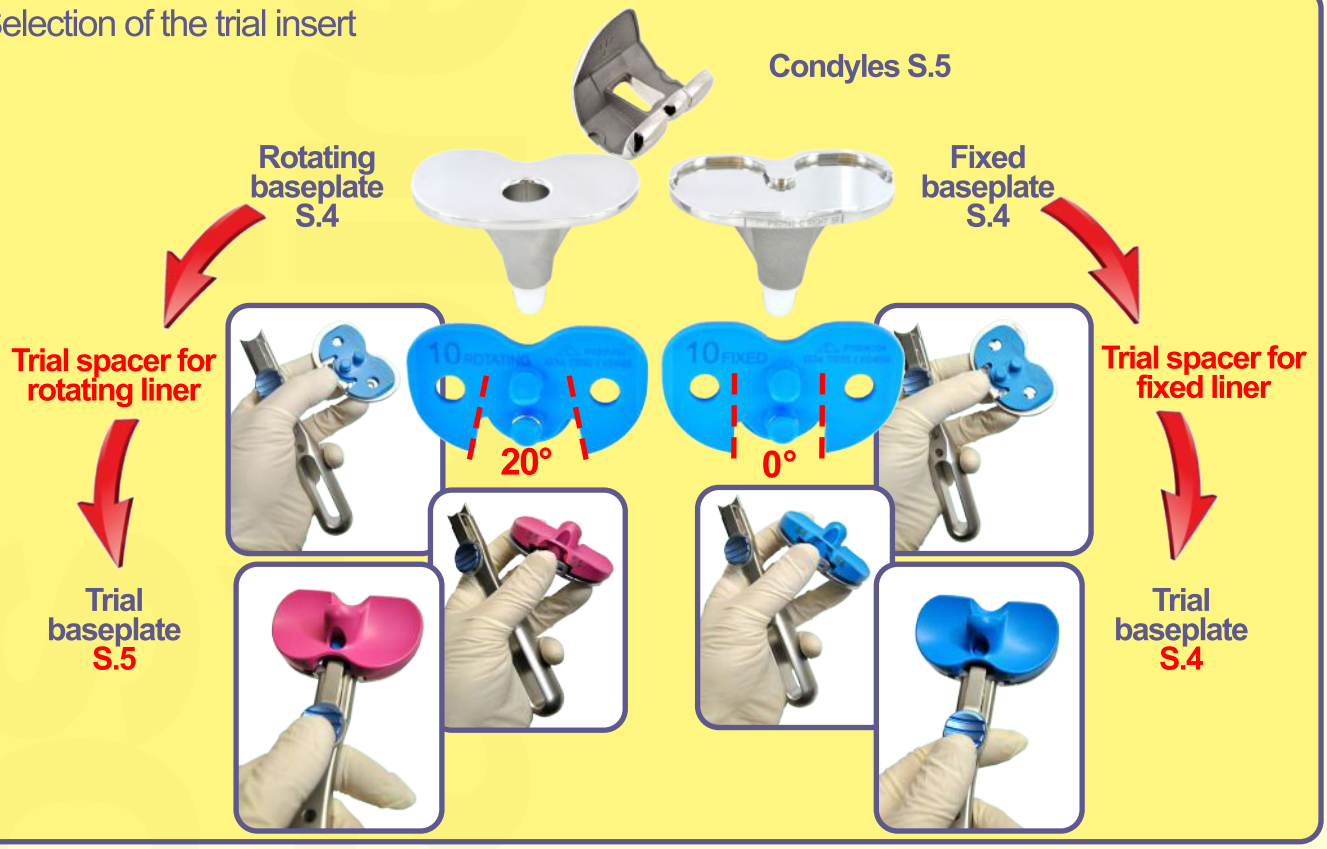
After impacting the UC trial condyles in the optimum M/L position, use the Ø10mm drill *(G34 T061)* to drill two holes of the trials distal condyles to prepare for the fixation of the definitive implant. 4


Drill for keel preparation and condylar pegs G34 T061



Tibial trials

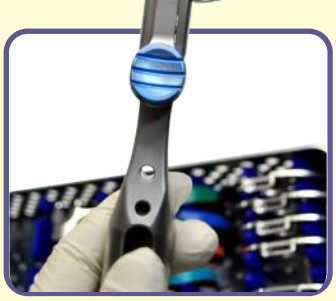
Selection of the trial insert

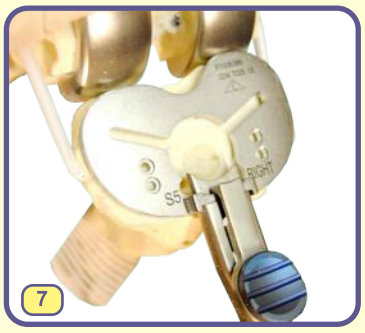


Select the trial tibial baseplate of the size corresponding to the size of the condyles and/or corresponding to the size estimated during the validation of the tibial cut *(see page 11)*.

Use the dedicated handle *(G34 0017)* to extract directly the baseplate from the instrument tray. (5)

Position the trial baseplate on the tibial cut or on the resected tibial fragment to validate the implant size. (6) (7)

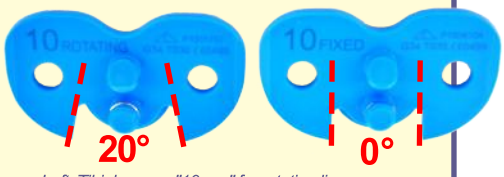




[aparté]

The Trial tibial baseplates are asymmetric: the lateral compartment is shorter than the medial compartment. This geometry is adapted to 65% of the anatomies and will improve the surface coverage of the tibia for optimum stability.
15% of the anatomies are also reported to be "reverse" anatomic with a medial compartment shorter than the lateral compartment.
In these "reverse" cases, it will be necessary to select a tibial baseplate (trial and final) of the opposite side: right baseplate for a left knee and vice-versa.
This adaptation does not affect the kinematics of the knee, and must be reproduced when selecting the definitive implant.

Confirm the compatibility between the femoral size and the tibial size:
- If a Rotating tibial baseplate is selected, the tibial size can be larger (without limitation), equal to, or smaller by one size strictly than the femoral size.
- If a Fixed tibial baseplate is selected, the tibial size can be larger by one size strictly, equal to, or smaller by one size strictly than the femoral size.



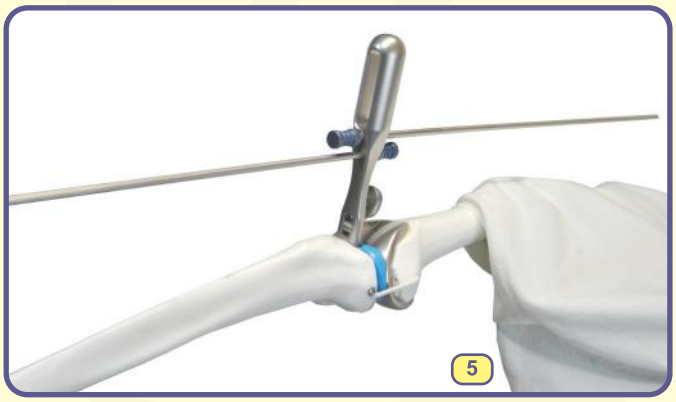
Left: Tibial spacer "10mm" for rotating liner G34 T030
Right: Tibial spacer "10mm" for fixed liner G34 T035

Place a Trial spacer for liner "10" mm *(G34 T030 for rotating baseplate or G34 T035 for fixed baseplate)* on the trial baseplate. Lock the trial spacer on the trial baseplate with the handle. (1)

Place a trial insert on the trial spacer. The trial insert should be EQUAL to the size of the condyles for rotating bearing or EQUAL to the size of the tibial baseplate for fixed bearing. And according to the principle of correspondence presented in page 26 *(Selection of the trial insert)* should be adapted to the type of postero-stabilization selected *(UC trial liner G34 T04x or PS trial liner G34 T05x)*. (2)

Introduce the tibial trial assembly into the joint. (3) (3')
Remove the handle and revert the patella into position.
Perform mobility and stability tests. (4)

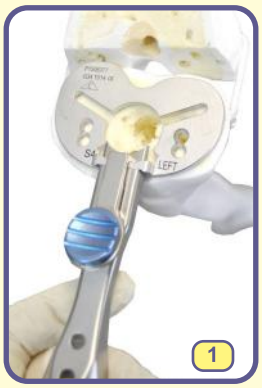
Knee in extension, check the mechanical alignment with two Limb axis control rods placed in the holes of the tibial baseplate handle. (5)



Preparation of the tibial keel and fins

Once the trial tibia assembly has been selected and validated, (1) fix the trial baseplate into position with two Ø3.2/30mm hexagonal screws *(G34 T0044)* using the quick drive tip *(small AO)* and a power tool. (2)

Select the Guide for the preparation of the tibial keel of the size corresponding to the size of the tibial trial baseplate *(1-3: G34 T065, 4-6: G34 T066, or 7-9: G34 T067)*.
Place the preparation Guide on the tibial trial baseplate and lock it with the handle for baseplate. (3)



Diameter reducer for the reamer for keel

Adjustment of the reamer for keel to the size of the tibial implant

5

Introduce the diameter reducer into the Guide for keel preparation. (4)

Adjust the abutment of the Reamer for tibial keel to the size of the tibial baseplate. (5)

Adapt the Reamer for tibial keel *(G34 T076)* on a power tool and introduce it into the reducer. (6)
Ream the conical imprint of tibial keel.

Remove the Reamer and the diameter reducer.

Assemble the Conformator of the tibial keel of the size *(G34 T062, G34 T063, G34 T064)* corresponding to the size of the tibial baseplate on the universal impaction handle *(G34 0040)*. (7)

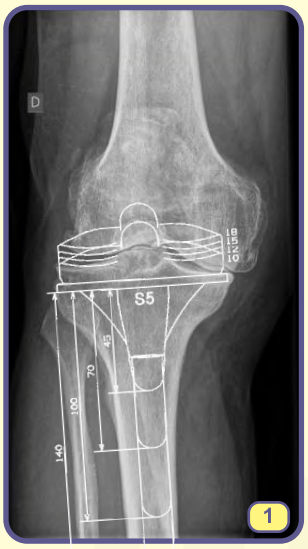
Introduce the Conformator into the Guide for keel preparation, and hammer until it is fully descended. (8)

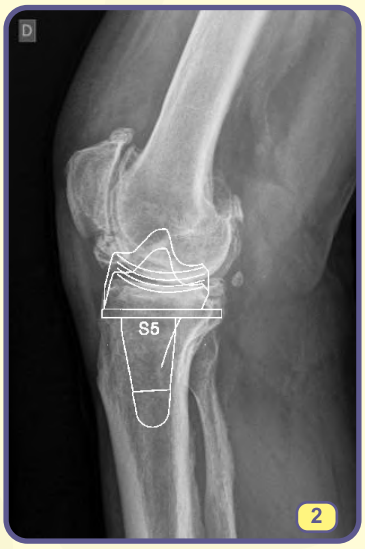
Preparation for placement of an extension keel

The use of a tibial extension keel is recommended in cases of demineralized or osteoporotic bone stock, fracture of a tibial compartment, of bone defect or revision of a uni-compartmental knee prosthesis.

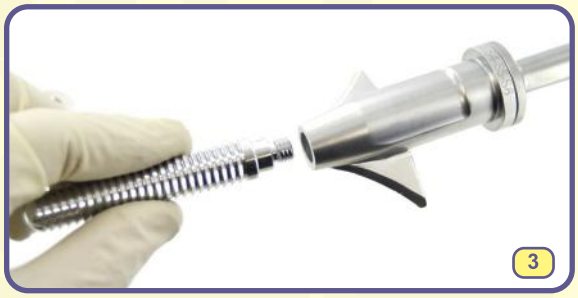
Assess the front and profile x-ray images (1) (2) of the intra-medullary bone space, and template preoperatively the length of the extension keel in order to anticipate any contact of the keel with the cortical bone and to calculate if a posterior tibial slope is required to optimize the sagittal centering of the extension keel.

After step #6 of the "Preparation of the tibial keel and fins" *(page 28)*, assemble one of the 3 Rasps for keel extension *(G34 T072, G34 T073 or G34 T074 according to the length templated)* on the Conformator for keel *(G34 T062, G34 T063 or G34 T064)* corresponding to the size of the tibial baseplate selected and on the Universal impaction handle *(G34 0040)*.(3) (4)





Tibial keel extension:
3 lengths (40, 70 or 110mm)
in Ø13mm



Introduce the conforming set (handle, conformator, and keel extension rasp) into the Guide for preparation of keel (5) , and hammer it down to the abutment.(6)

Positioning of the final implants

[aparté]

Implantation sequence of the components of the TKA
Because of the difficulty to introduce the rotating tibial insert once the baseplate and the condyles have been implanted, the implantation sequence of a Rotating Rolflex TONIC® is different from that for a Fixed Rolflex TONIC®.

TKA with rotating bearing:
- Position the tibial baseplate
- Introduce the tibial insert on the tibial baseplate
- Put the knee in high flexion
- Position the femoral condyles on the femur, then hammer.

TKA with fixed bearing:
- Position the tibial baseplate
- Place a compress covering the posterior part of the baseplate
- Put the knee in high flexion
- Position the femoral condyles on the femur, then hammer
- Slide the tibial insert on the tibial baseplate, then use the Liner insertion forceps to lock the insert.

Implants with a rotating bearing

Begin the implantation starting with the tibial baseplate.

For cemented fixation, coat the implant with bone cement on the proximal part alone, clean and thoroughly dry the bone.

Tibial baseplate:
Position and introduce the tibial baseplate manually, taking care to align the fins of the baseplate with the imprint in the bone. (1)

Assemble the Impaction tip for rotating baseplate *(G34 T077)* on the Impaction handle *(G34 0040)* (2) and hammer until the definitive position of the baseplate (3)

In case of cemented fixation, remove the excess cement.

Introduce the tibial insert. (4)

Femoral Condyles:
Assemble the definitive condyles on the Holding clamp for condyles *(G34 F037)*.

In case of cemented fixation, avoid putting cement on the posterior condyles.

Position the implant on the femur taking care to align the implant with the anterior cut in the sagittal plan and in front of the M/L positioning marks *(inter-condylar box for the PS version, distal pegs for the UC version)*.
Hammer the condyles into position. (5)

Assemble the Condyles impaction tip *(G30 117)* on the Impaction handle *(G34 0040)*, and finalize the impaction until the definitive position of the condyles. (6)

In case of cemented fixation, remove the excess cement.

Reduce the knee.
Check the stability and the mobility.
Wash thoroughly.

Implants with a fixed bearing

Begin the implantation starting with the tibial baseplate.

For a cemented fixation, coat the implant with bone cement on the proximal part alone, clean thoroughly and dry the bone.

Tibial baseplate:
Position and introduce the tibial baseplate manually, taking care to align the fins of the baseplate with the imprint in the bone. 1

Assemble the Impaction tip for fixed baseplate *(G34 T059 or G34 T071)* on the Impaction handle *(G34 0040)* 2 and hammer until the definitive position of the baseplate. 3

In case of cemented fixation, remove any excess cement.

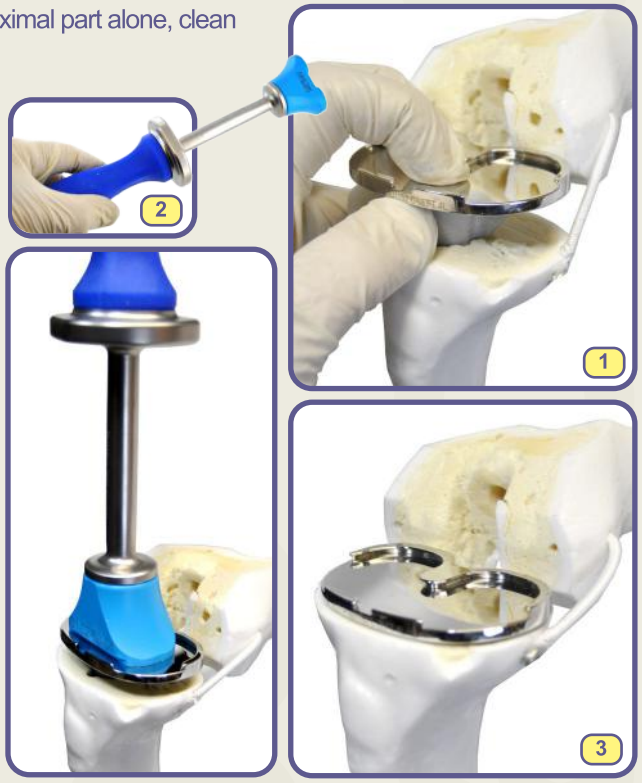
Femoral Condyles:
Assemble the definitive condyles on the Holding clamp for condyles *(G34 F037)*. 4 4'

In case of cemented fixation, avoid putting some cement on the posterior condyles.

Position the implant on the femur taking care to align the implant with the anterior cut in the sagittal plan and in front of the M/L positioning marks *(inter-condylar box for the PS version, distal pegs for the UC versi* 5
Hammer the condyles into position.

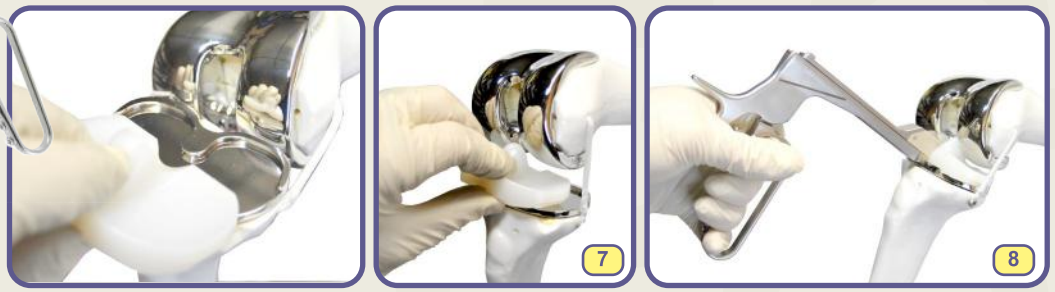
Assemble the Condyles impaction tip *(G30 117)* on the Impaction handle *(G34 0040)*, and finalize the impaction until the definitive position of the condyles. 6

In case of cemented fixation, remove any excess cement.



Tibial insert:
Position manually the tibial insert on the baseplate by sliding the insert over the dovetail of the baseplate. 7
Finalize locking of the insert with the Insertion forceps for fixed insert *(G34 T075)*. 8

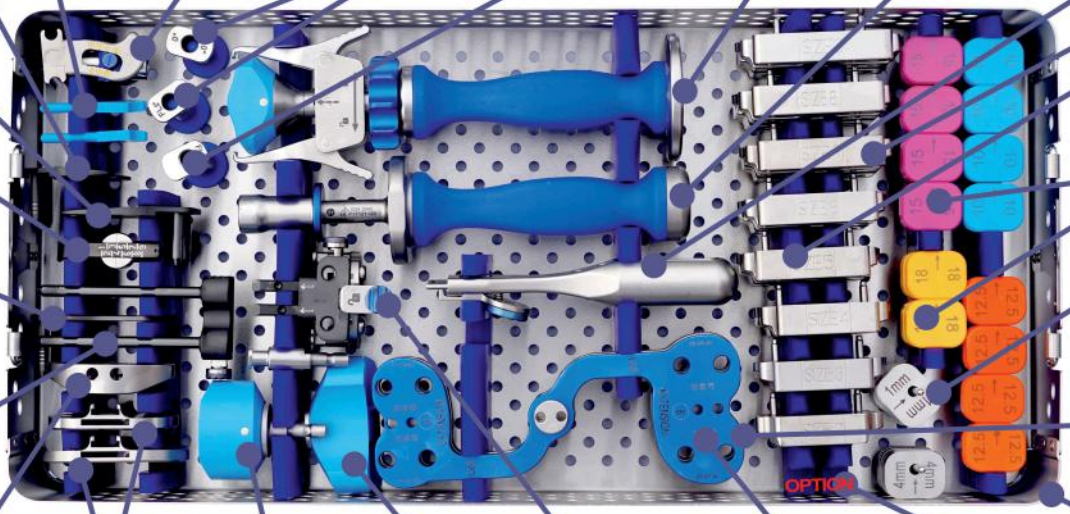
Insertion forceps for fixed insert G34 T075



Reduce the knee.
Check the stability and the mobility.
Wash thoroughly.

Instrumentation SNAPSHOT

Ref : G34 9100
ROLFLEX TONIC viseur fémoral / femoral guide



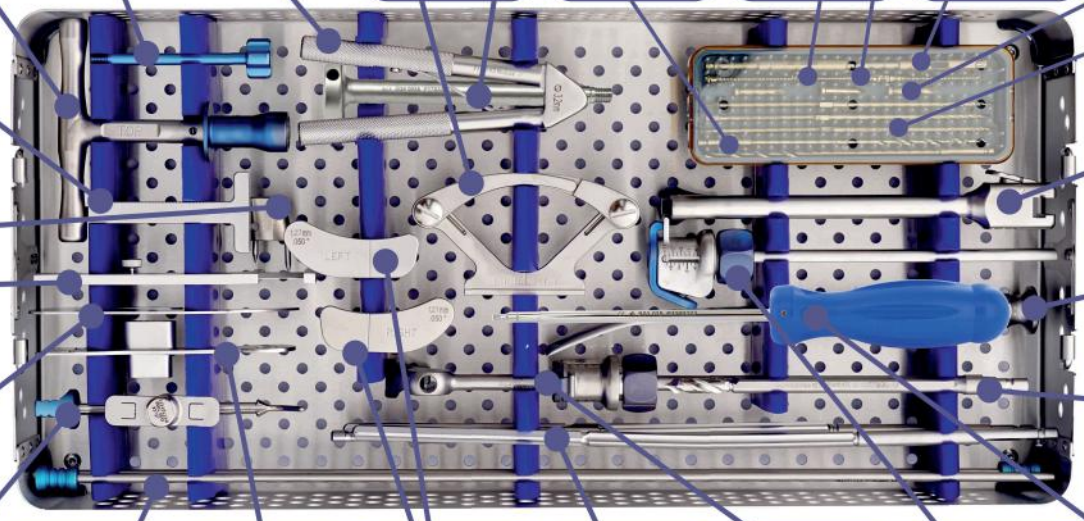
- Baseplate for independent cuts S.1 to 4 — Platine pour coupes indép. T 1 à 4 — G34 F020
- Epicondylar axis collimator — Axe repère épicondyles — G34 F007
- Femoral valgus guide — Guide de valgus fémoral — G34 F036
- G34 F031 et G34 F032 — 0° and 2° Femoral flexum guides / Canons de flessum fémoral 0° et 2°
- OPTION — G34 F010 — 4° Femoral flexum guide / Canon de flessum fémoral 4°
- Holding clamp for condyles — Préhenseur pour condyles — G34 F037
- Impaction handle — Poignée impacteur — G34 0040
- Handle for spacer — Poignée pour spacer — G34 0017
- Baseplate for independent cuts S5 to 9 — Platine pour coupes indép. T5 à 9 — G34 F004
- 4/1 Cutting guides S2 to 9 — Guides de coupe 4/1 T2 à 9 — G34 F062 - G34 F069
- Anterior femoral stylus — Palpeur fémoral antérieur — G34 F002
- Augments for spacer h10to18 — Cales pour spacer h10à18 — G34 0025 - G34 0028
- Baseplate for linked cuts — Platine pour coupes liées — G34 F005
- Augment for spacer h1to5 — Cale pour spacer h1à5 — G34 0033 - G34 0037
- Base for femoral guide — Base de guide fémoral — G34 F003
- Baseplate for flexion test — Platine pour test en flexion — G34 0024
- Distal fem. cutting guide — Guide de coupe fém. distal — G34 F001
- Tibial baseplate for spacers — Embase tibiale pour spacers — G34 0013 & G34 0018
- Impactor tip for condyles (small) — Embout impacteur pour condyles (petit) — G34 0041
- Impactor tip for condyles (large) — Embout impacteur pour condyles (grand) — G30 117
- Bracket for cutting guide — Support de guide de coupe — G34 F006
- Baseplate for extension test — Platine pour test en extension — G34 0023
- OPTION — 4/1 Cutting guides S1 — Guides de coupe 4/1 T1 — G34 F061
- Tray for instruments and lid — Panier pour instruments & couvercle — G34 9000 & S02 012
- OPTION — Adjustable ibial baseplate — Embase tibiale réglable — G34 0010 & G34 0011

www.evolutisfrance.com / Evolutis, 10 Place des Tuiliers, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Mai 2022 / Ref: BI_ROLFLEX TONIC SNP G34 9100

Instrumentation SNAPSHOT

Ref : G34 9101
ROLFLEX TONIC viseur tibial / tibial guide



- OPTION — Extension for pin/broach extractor — Rallonge pour pince arrache-broche — G30 0055
- OPTION — Ø4 self-tapping pins for cutting guide — Pins autoforant Ø4 pour guide de coupe — G34 0046
- T handle — Poignée de préhension T — G34 0050
- Centering guide wheel — Molette de serrage — G30 T052
- Pin/broach extractor — Pince arrache-broche — G34 0054
- Malleolar clamp — Pince malléolaire — G30 T050
- Ø3,2 drill, length 145mm — Mèche Ø3,2 lg 145mm — S01 014
- Ø4 self-tapping screw for cutting guide — Vis autoforeuses Ø4 pour guide de coupe — G34 0043
- Quick drive shaft for broach — Adaptateur rapide pour broche — G34 0009
- Fixation pin Ø4 fortibial baseplate l.27mm — Clou de fixation Ø4 pour embase tibiale l.27mm — G34 T082
- Ratchet for malleolar clamp — Crémaillère pour pince malléolaire — G30 T051
- Ø3.2 self-tapping broach — Broche autoforante Ø3.2 — G34 0053
- OPTION — Tibial pointer for extra.jig — Pointeur tibial pour visée extra — G30 T056
- Tibial extension keel — Rallonge tibiale — G30 T053
- Calliper — Pied à coulisse — G30 P007
- Gouge scissors — Ciseau gouge — G30 F029
- Resection control blade — Lame de contrôle de coupe — G34 0021
- Centromedullary & pegs Ø 8 drill — Forêt Ø 8 centromédullaire et plots — G30 F023
- Tibial stylus — Stylus tibial — G30 T059
- Long limb axis control rod — Tige de contrôle grands axes — G34 0019
- Support plate for axis control rod — Platine support pour contrôle d'axe — G34 0020
- Tibial cutting guide R&L — Guide de coupe tibiale D et G — G30 T057 G30 T058
- Intramedullary rods l.250 straight &1.350 3° — Tiges intramedullaires l.250 droite et l.350 à 3° — G30 100 & G34 0051
- OPTION — Tibial cut mount for intra. jig — Support coupe tibiale pour visée intra. — G30 T054
- Tibial cut mount for extra. jig — Support coupe tibiale pour visée extra. — G30 T055
- OPTION — H3.5 screwdriver — Tournevis H3.5 — S01 015
- Tray for instruments and lid — Panier pour instruments & couvercle — G34 9001 & S02 012
- OPTION — Straight intramedullary rod l. 350 — Tige intramedullaire droite l. 350 — G30 101

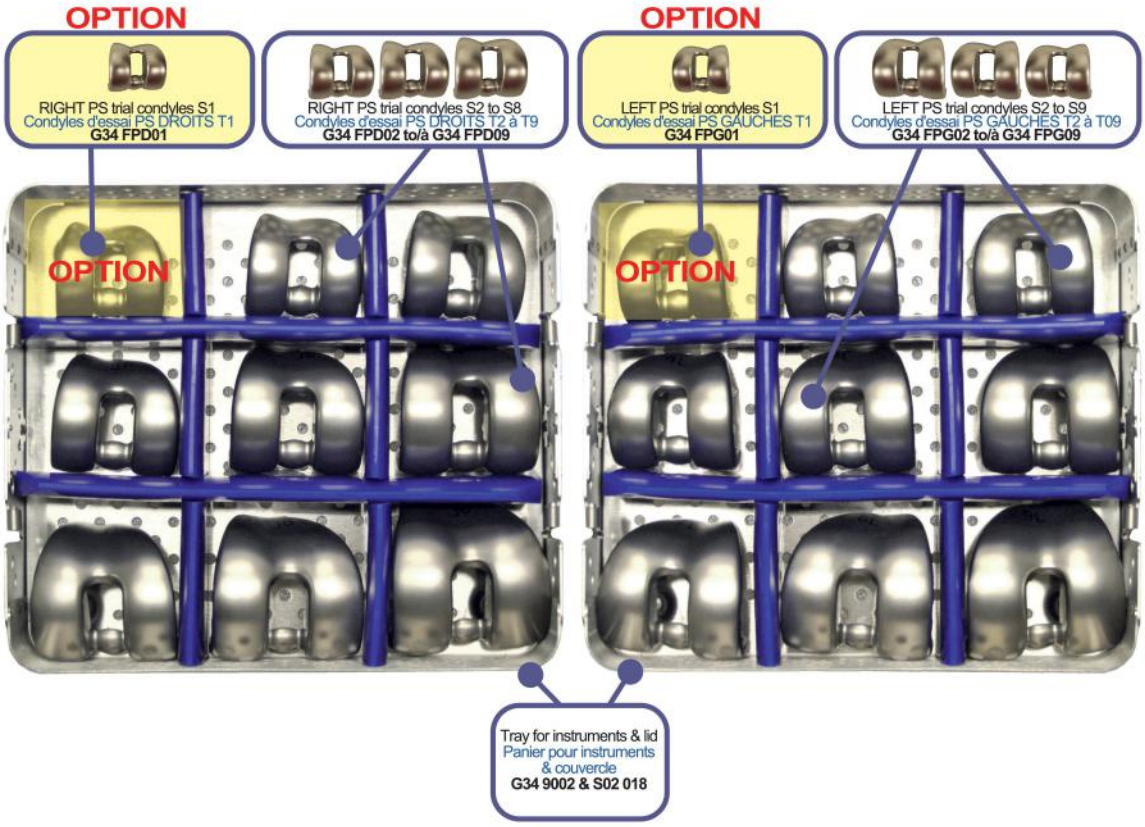
www.evolutisfrance.com / Evolutis, 10 Place des Tuiliers, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Mai 2022 / Ref: BI_ROLFLEX TONIC SNP G34 9101

Instrumentation SNAPSHOT

ROLFLEX TONIC Condyle d'essai PS D et G / PS Trial condyles R & L

Ref : G34 9102 & G34 9103

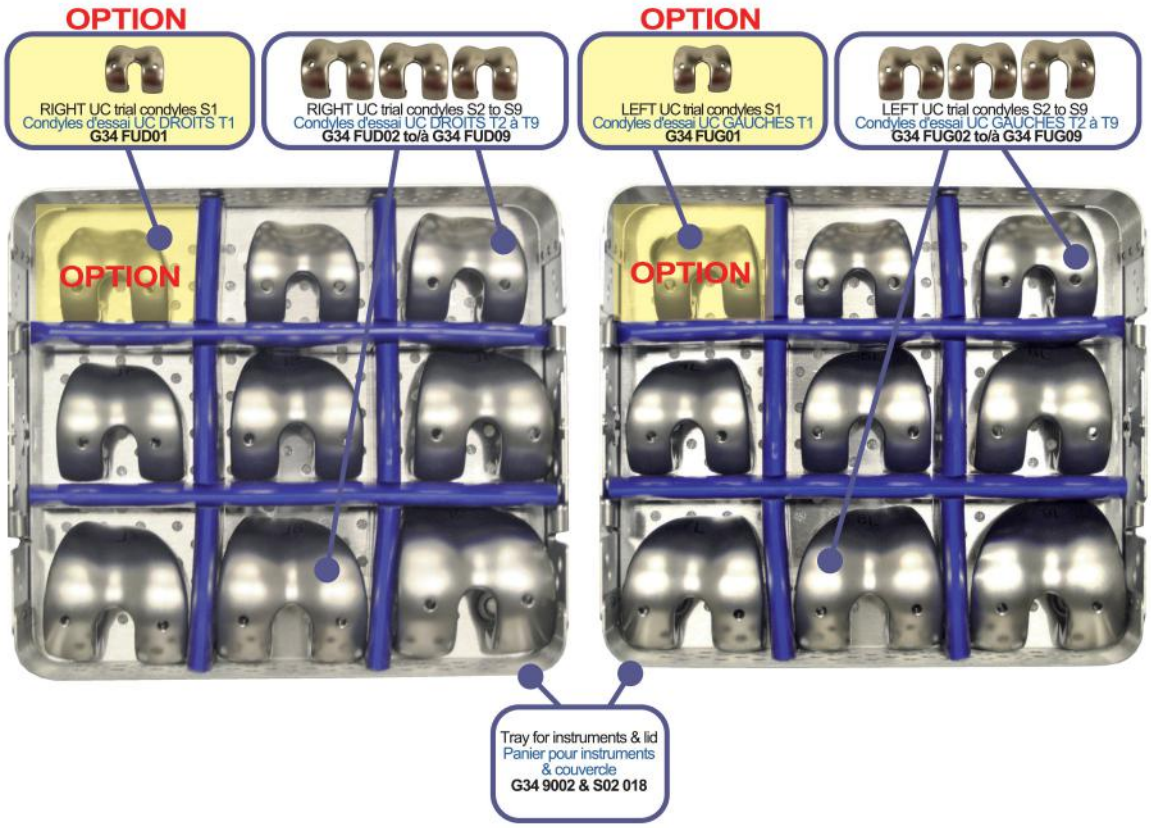


www.evolutisfrance.com / Evolutis, 10 Place des Tuiliers, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Instrumentation SNAPSHOT

ROLFLEX TONIC Condyle d'essai UC D et G / UC Trial condyles R & L

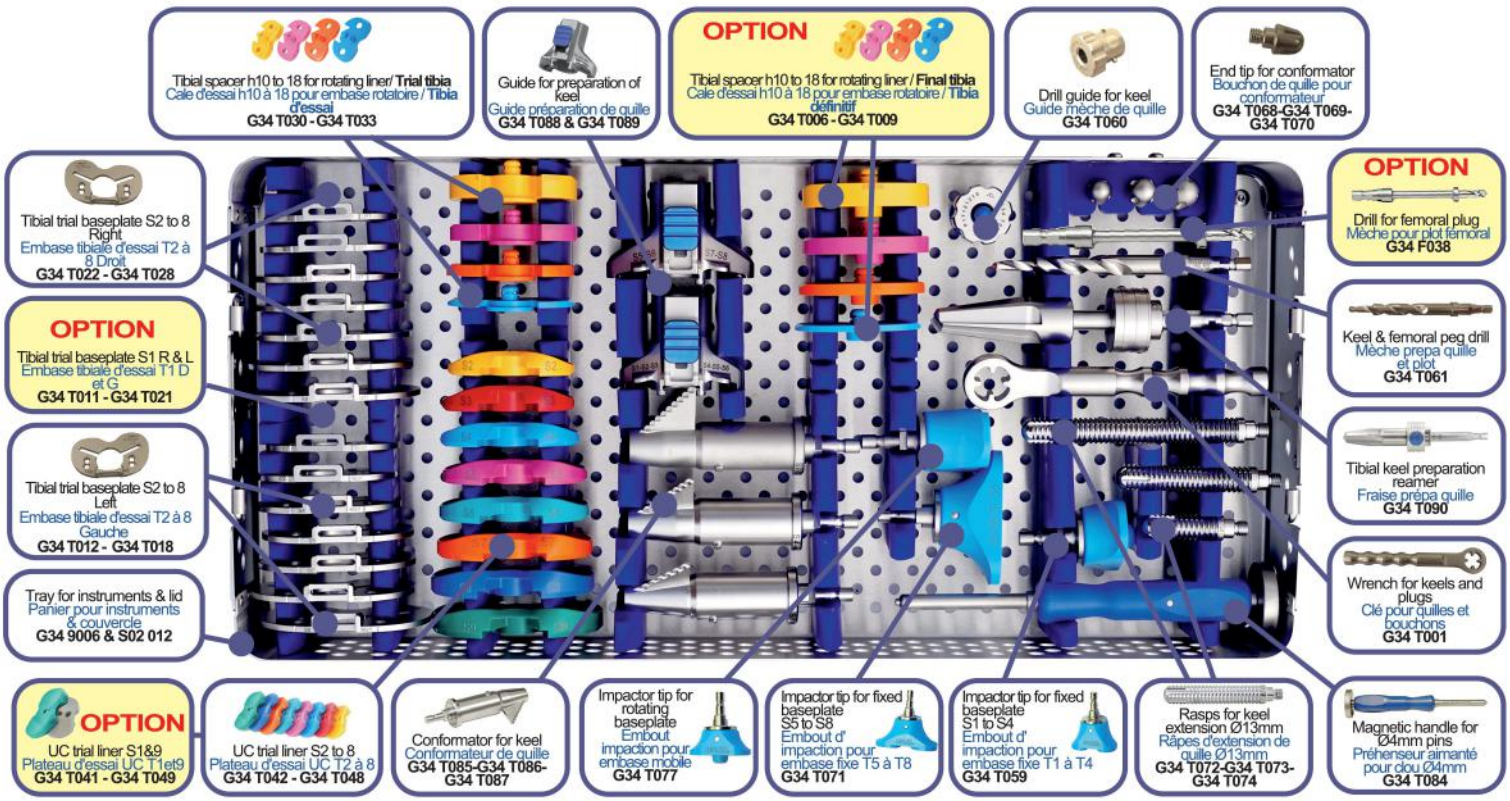
Ref : G34 9104 & G34 9105



www.evolutisfrance.com / Evolutis, 10 Place des Tuiliers, 42720 Briennon, France. Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Instrumentation SNAPSHOT

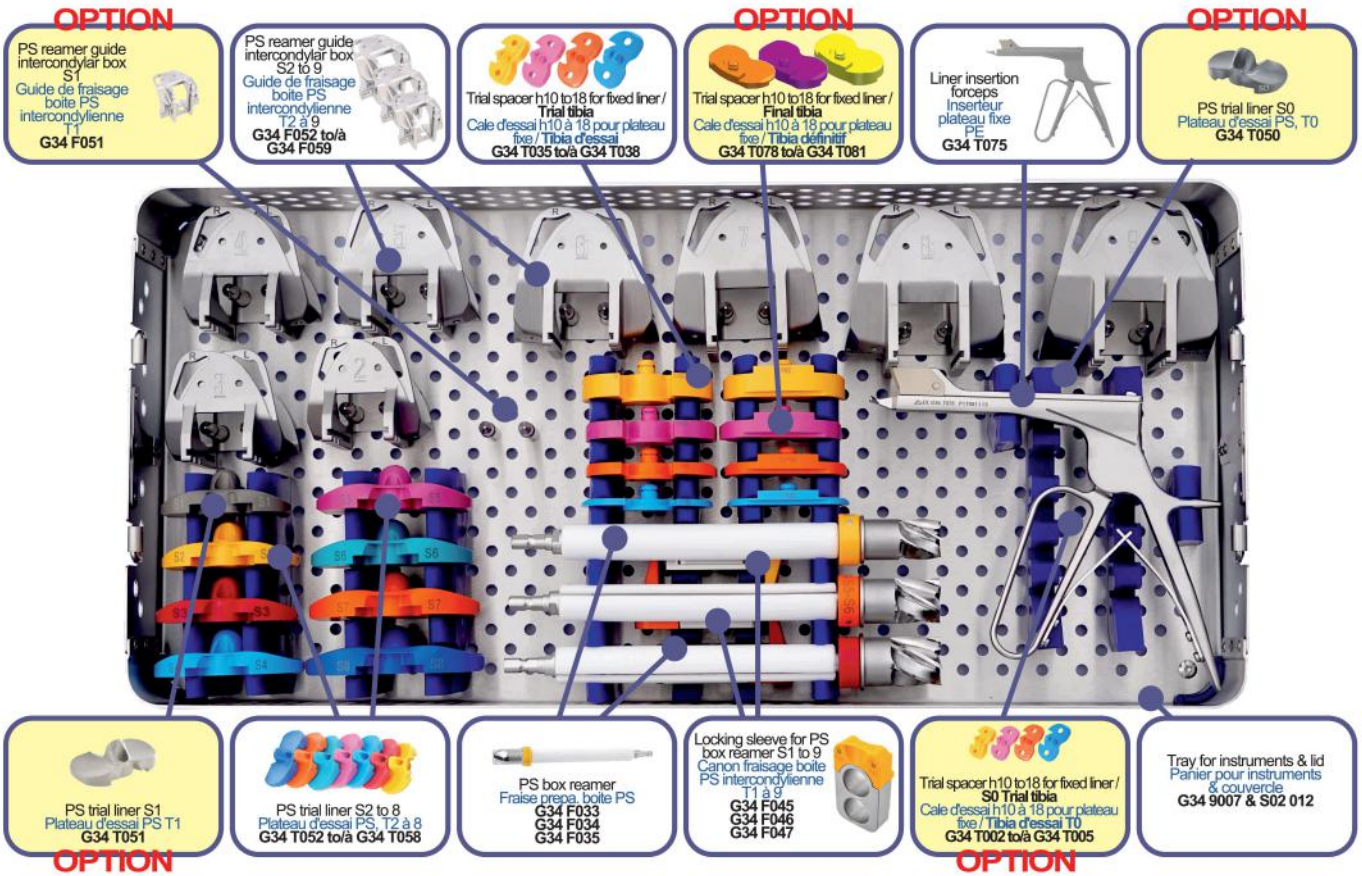
Ref : G34 9106
ROLFLEX TONIC essai tibial / tibial trials



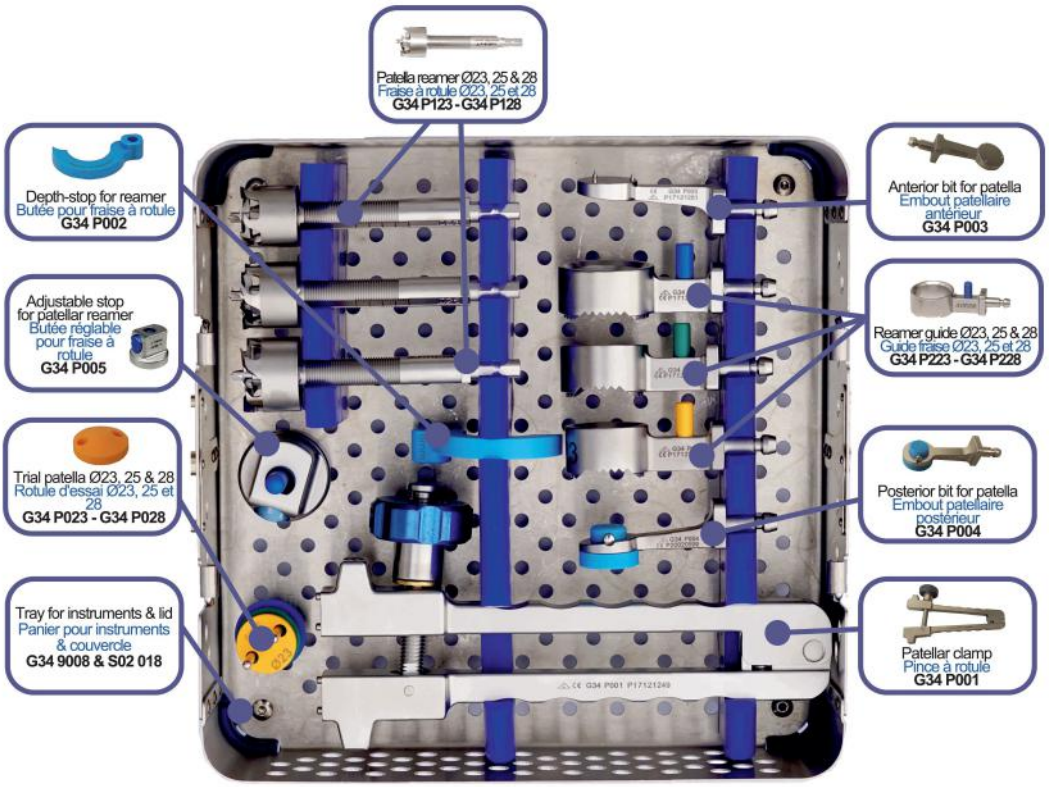
Mai 2022 / Ref: BI_ROLFLEX TONIC SNP G34 9106

Instrumentation SNAPSHOT

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



Mai 2022 / Ref: BI_ROLFLEX TONIC SNP G34 9107



Mai 2022 / ref: IT_ROLFLEX TONIC SNP G34 9108

Notes

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 Keels
6 • Tibial Augments

Condyles / Condyles

	PS / *Postéro-Stabilisés*				UC / *Ultra-congruents*			
	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 1	G33 FPCD01 (1)	G33 FPCG01 (1)	G33 FPRD01 (1)	G33 FPRG01 (1)	G33 FUCD01 (1)	G33 FUCG01 (1)	G33 FURD01 (1)	G33 FURG01 (1)
Sz./T 2	G33 FPCD02	G33 FPCG02	G33 FPRD02	G33 FPRG02	G33 FUCD02	G33 FUCG02	G33 FURD02	G33 FURG02
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 (1)	G33 FPCG09 (1)	G33 FPRD09 (1)	G33 FPRG09 (1)	G33 FUCD09 (1)	G33 FUCG09 (1)	G33 FURD09 (1)	G33 FURG09 (1)

Patella Rotule	
Ø23	G33 ROT023
Ø25	G33 ROT025
Ø28	G33 ROT028

(1) Sizes of implants available only on request, not included in the standard set.
(1) Taille d'implants disponibles uniquement sur demande, non inclus dans la gamme livrée en standard.

Tibial Baseplate / Embase tibiale

	Fixed / *Fixe*				Rotating / *Rotatoire*			
	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 (1)	G33 TFCG00 (1)	G33 TFRD00 (1)	G33 TFRG00 (1)	G33 TMCD00 (1)	G33 TMCG00 (1)	G33 TMRD00 (1)	G33 TMRG00 (1)
Sz./T 1	G33 TFCD01 (1)	G33 TFCG01 (1)	G33 TFRD01 (1)	G33 TFRG01 (1)	G33 TMCD01 (1)	G33 TMCG01 (1)	G33 TMRD01 (1)	G33 TMRG01 (1)
Sz./T 2	G33 TFCD02	G33 TFCG02	G33 TFRD02	G33 TFRG02	G33 TMCD02	G33 TMCG02	G33 TMRD02	G33 TMRG02
Sz./T 3	G33 TFCD03	G33 TFCG03	G33 TFRD03	G33 TFRG03	G33 TMCD03	G33 TMCG03	G33 TMRD03	G33 TMRG03
Sz./T 4	G33 TFCD04	G33 TFCG04	G33 TFRD04	G33 TFRG04	G33 TMCD04	G33 TMCG04	G33 TMRD04	G33 TMRG04
Sz./T 5	G33 TFCD05	G33 TFCG05	G33 TFRD05	G33 TFRG05	G33 TMCD05	G33 TMCG05	G33 TMRD05	G33 TMRG05
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 (1)	G33 TFCG08 (1)	G33 TFRD08 (1)	G33 TFRG08 (1)	G33 TMCD08 (1)	G33 TMCG08 (1)	G33 TMRD08 (1)	G33 TMRG08 (1)

Tibial Keel Quille Tibiale		
Ø13	l.20mm	G33 QT1320
Ø13	l.40mm	G33 QT1340
Ø13	l.70mm	G33 QT1370
Ø13	l.110mm	G33 QT13110
Ø15	l.20mm	G33 QT1520
Ø17	l.20mm	G33 QT1720

Tibial insert / Plateau tibial

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

Augment / Cale

	Tibial / *Tibiale*	
	h.5mm	h.10mm
Sz./T. 0	G33 CT0500 (1)	G33 CT1000 (1)
Sz./T. 1	G33 CT0501 (1)	G33 CT1001 (1)
Sz./T. 2	G33 CT0502 (1)	G33 CT1002 (1)
Sz./T. 3	G33 CT0503 (1)	G33 CT1003 (1)
Sz./T. 4	G33 CT0504 (1)	G33 CT1004 (1)
Sz./T. 5	G33 CT0505 (1)	G33 CT1005 (1)
Sz./T. 6	G33 CT0506 (1)	G33 CT1006 (1)
Sz./T. 7	G33 CT0507 (1)	G33 CT1007 (1)
Sz./T. 8	G33 CT0508 (1)	G33 CT1008 (1)

Important Notice:
The Rolflex TONIC implants belong to the class III implantable medical device classification. The Rolflex TONIC implants are indicated for primary and revision total knee arthroplasty procedures.
The surgeon is required to read the instructions for use (IFU) S12 0305 included in the packaging of the implant or available for download from the www.evolutis-group.com website, as well as the surgical technique manual G34 461 (Independant cutting sequences) or G34 462 (Dependant cutting sequences) initially delivered with the instrument set, or equally available for download from the www.evolutis-group.com website.

Materials:
Condyles : CrCo 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 and 2 or CoCr according ISO5832-4 coated with macroporous Ti (cementless) and UHMWPE according ISO 5834-1 and 2
Tibial insert and patella : UHMWPE PEXEL® according ISO 5834-1 and 2, and Stainless Steel according ISO 5832-1
Tibial keel : CoCr according ISO5832-12, Augment : CoCr according ISO5832-4
VacUPac® vacuum packaging. Gamma sterilized.

CE 2797 Evolutis
10 Place des Tuiliers, 42720 Briennon, France
Tel : +33. (0)477.60.79.99 – Fax : +33. (0)477.60.79.90

Evolutis GROUP

July 2024 / Ref: EN_ROLFLEX TONIC IND STC G34 (G34 461)

evolutis-group.com