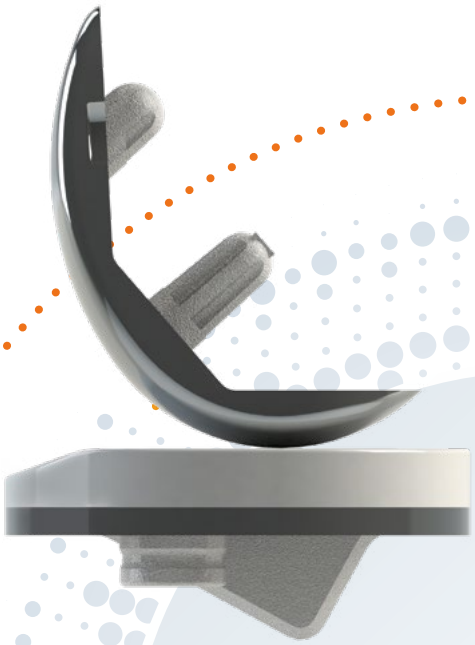
serf

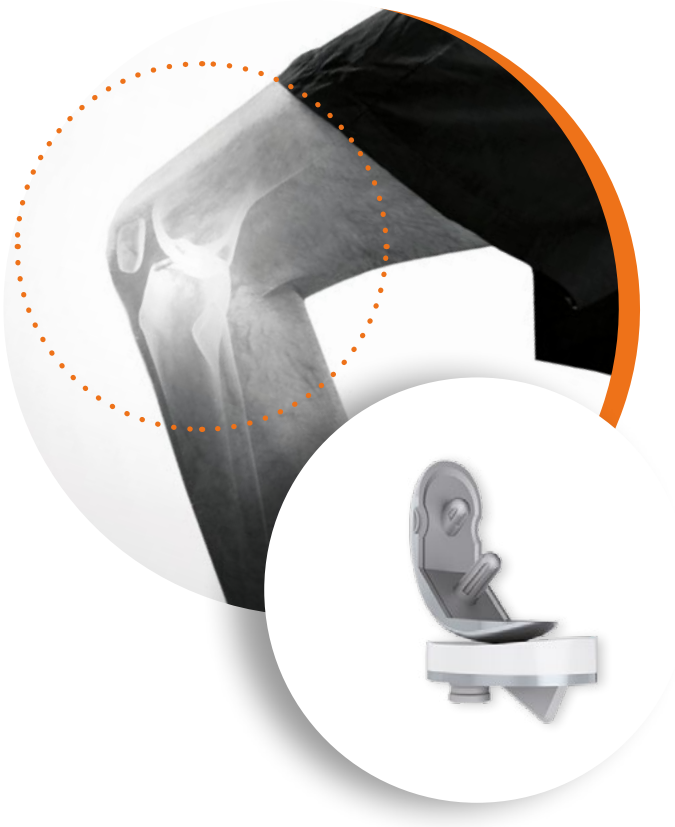


UNI KROMA®

Unicompartmental Knee Replacement

SURGICAL TECHNIQUE

Concept Overview



Indications

The **Uni Kroma®** prosthesis, unless otherwise stated in the technical documentation, is indicated in the following conditions:

- Isolated primary or secondary osteoarthritis of the medial or lateral tibiofemoral compartment.
- Isolated osteonecrosis of the medial or lateral condyle.

Contraindications

Contraindications for **Uni Kroma®** knee arthroplasty include the following:

- Crystalline inflammatory arthropathy.
- Cruciate and/or collateral ligament deficiency.
- Irreducible flexum or major genu recurvatum.
- Contralateral tibiofemoral joint arthritis .
- Severe malalignment of the limb in the frontal plane.

Risk Factors

The following factors should prompt caution regarding implantation of **Uni Kroma®**:

- Osteoarthritis of the patellofemoral joint.
- Previous osteotomy (may lead to complications: bone collapse, early loosening, etc...).
- Revision UKA.
- High body mass index (>30kg/m^2).

Acknowledgments

We wish to express our heart-felt thanks to **Docteur Guiton,** Clinique de l'Europe (Rouen), for his valuable cooperation and a vailability throughout the development of this unicompartmental replacement prosthesis.

The present document has not contractual value, the manufacturer reserves the right to make design and specification changes for product improvement without prior notice. The implant conditions of use are detailed in the IFU.

Table of Contents

Implants

- Anatomically designed femoral condyles, tibial baseplates and inserts.
- The condyle is part of a spherically designed section for enhanced articulating surface and reduced PE wear.

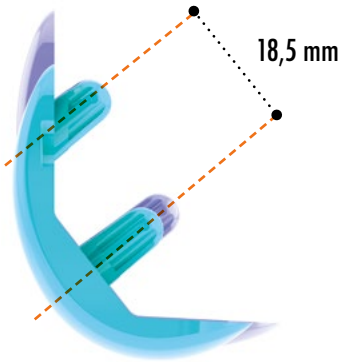
Mechanical stability:

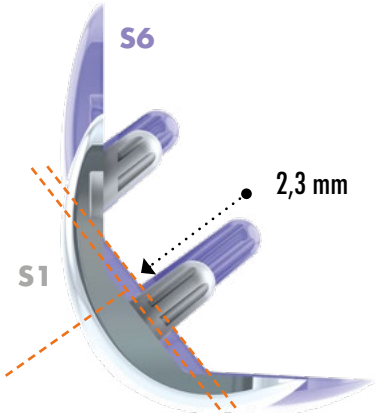
For a cementless configuration, press-fit is achieved with the two-peg design of the condylar component and the flange and peg design of the tibial baseplate. A cemented condyle and tibial baseplate are also available, where necessary.

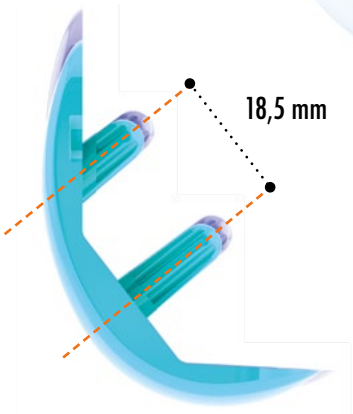
Cementless fixation:

Corundum blasted surface finish with dual Titanium T40 + HAP coating.

Implants design







Condyles sizes 1 to 4

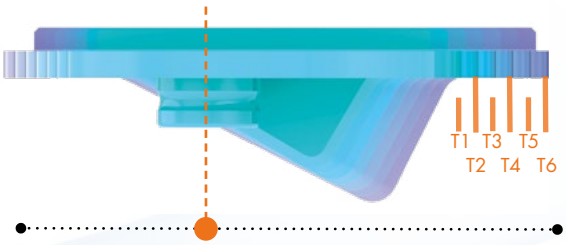
Share same chamfer and peg locations, 18,5 mm interval.

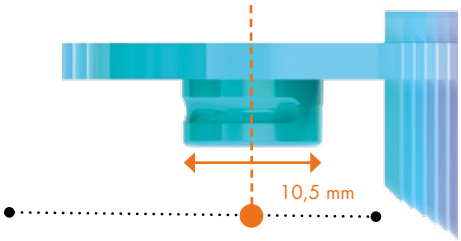
Sizes 1 and 6 condyle comparison

Condyles sizes 5 and 6

Share same chamfer and peg locations, 18,5mm interval.

Between S4 and S5, there is a change in the mortise featuring a larger chamfer of 2.3 mm.





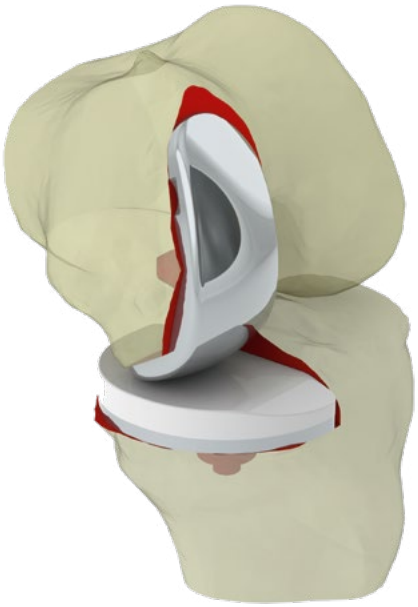
Progressively increasing sizes around the peg in the frontal and sagittal planes.

Anatomical c ondyle

6 sizes, cemented or cementless.

Made of cast cobalt chromium.

T 40 + HAP coating.

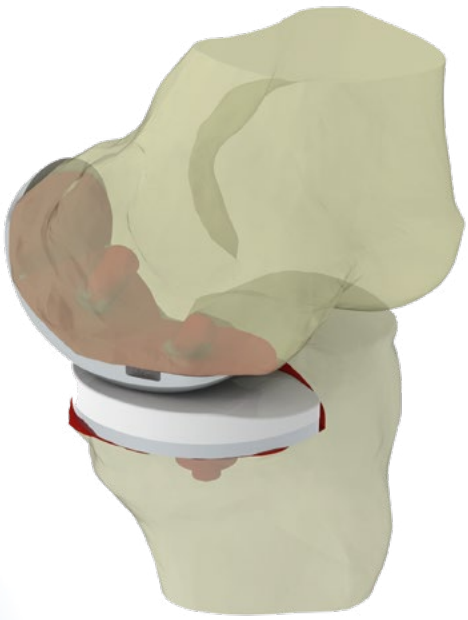


Anatomical tibial base plate

6 sizes, metal back, cemented or cementless.

The cemented configuration is made of cast cobalt chromium.

Cementless configuration manufactured from machined titanium.
T40 + HAP coating.



Anatomical insert

6 sizes, 4 thicknesses in HDPE.

Thicknesses 9-10-11 and 12 mm.

Vacuum packaged.

Fixation screws

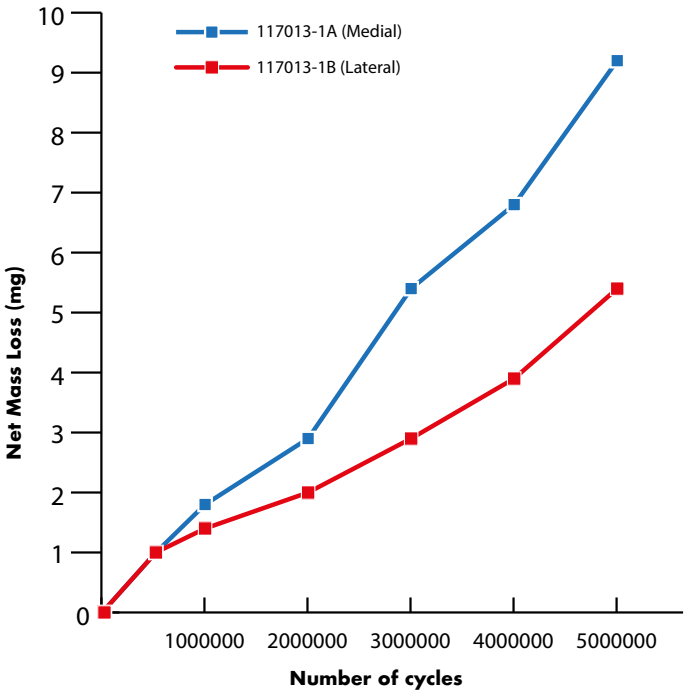
Titanium fixation screws available in Ø 5 and 6 mm and lengths 25, 30 and 35 mm.

Tribology and testin

Polyethylene insert wear is one of the leading causes for failure in unicompartmental knee arthroplasty (UKA).
In collaboration with the CETIM (Centre technique des industries mécaniques) in Saint - Etienne, 4 **Uni Kroma®** implants were tested using wear simulators that replicate the full range of real-world knee forces and motion during the gait cycle according to applicable ISO 14243 -1, ISO 14243 -2 and ISO 14243-3 standards. Two unicompartmental knee prostheses simulating a total knee prosthesis, and two UKP used as control for gravimetric me asurements to comply with standard requirements. Testing was carried out at a frequency of 1 Hz to 5 million cycles. According to published data, the mean PE wear rate for fixed UKP is reported to be 3 to 4 mg/million cycles.
Wear testing was successful for all implants that could reach a total of 5 million cycles without wear failure, fracture or damage.

A wear rate of 1.8 mg/million cycles for the medial compartment and 0.9 mg/million cycles for the lateral compartment were reported.

Net mass loss according to the number of cycles



References:

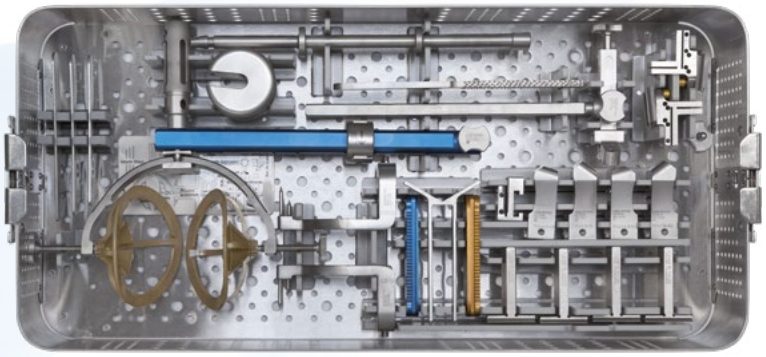
[1] J Mater Sci Mater Med. 2013 May; 24(5):1319-25. doi: 10.1007/s10856-013-4883-8. Epub 2013 Feb 17. The influence of third-body particles on wear rate in unicondylar knee arthroplasty: a wear simulator study with bone and cement debris.
Schroeder C, Grupp TM, Fritz B, Schilling C, Chevalier Y, Utzschneider S, Jansson.

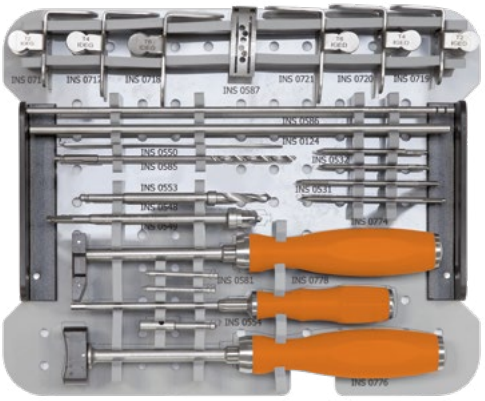
[2] Orthopade. 2012 Apr;41(4):298-302. doi: 10.1007/s00132-011-1857-8.
[Does increased tibial slope reduce the wear rate of unicompartmental knee prostheses? An in vitro investigation].
Weber P, Schröder C, Utzschneider S, Schmidutz F, Jansson V, Müller PE. Orthopädische Klinik und Poliklinik, Klinikum der Ludwig-Maximilians-Universität, Campus Großhadern, Marchioninistr. 15, 81377, München, Deutschland. Patrick.Weber@med.uni-muenchen.de

[3] 015;2015:736826. doi: 10.1155/2015/736826. Epub 2015 Jan 15.
Increase in the tibial slope reduces wear after medial unicompartmental fixed-bearing arthroplasty of the knee.
Weber, Schröder, Schwiesau, Utzschneider, Steinbrück, Pietschmann, Jansson, Müller.

Instrumentation

Reduced metal instrumentation designed to complete all femoral and tibial cuts .
These instruments are suitable for all implant sizes.

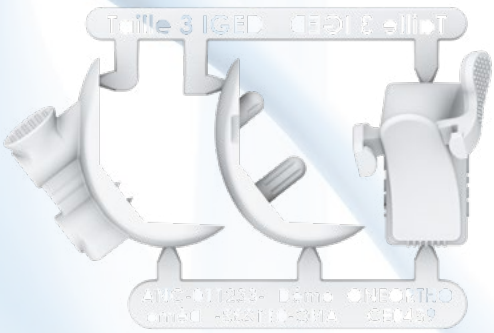




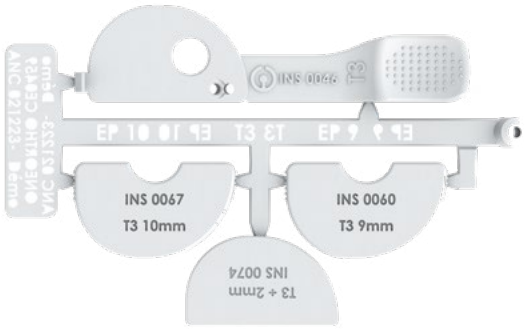
A single use instrument kit is available for each femoral and tibial size. Instrument kits are supplied sterile.

Three instrument kits are required for **Uni Kroma®** implantation.

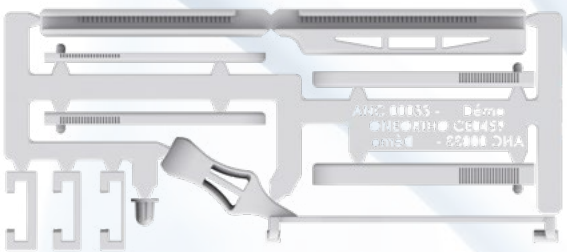
Condylar kit



Tibial kit



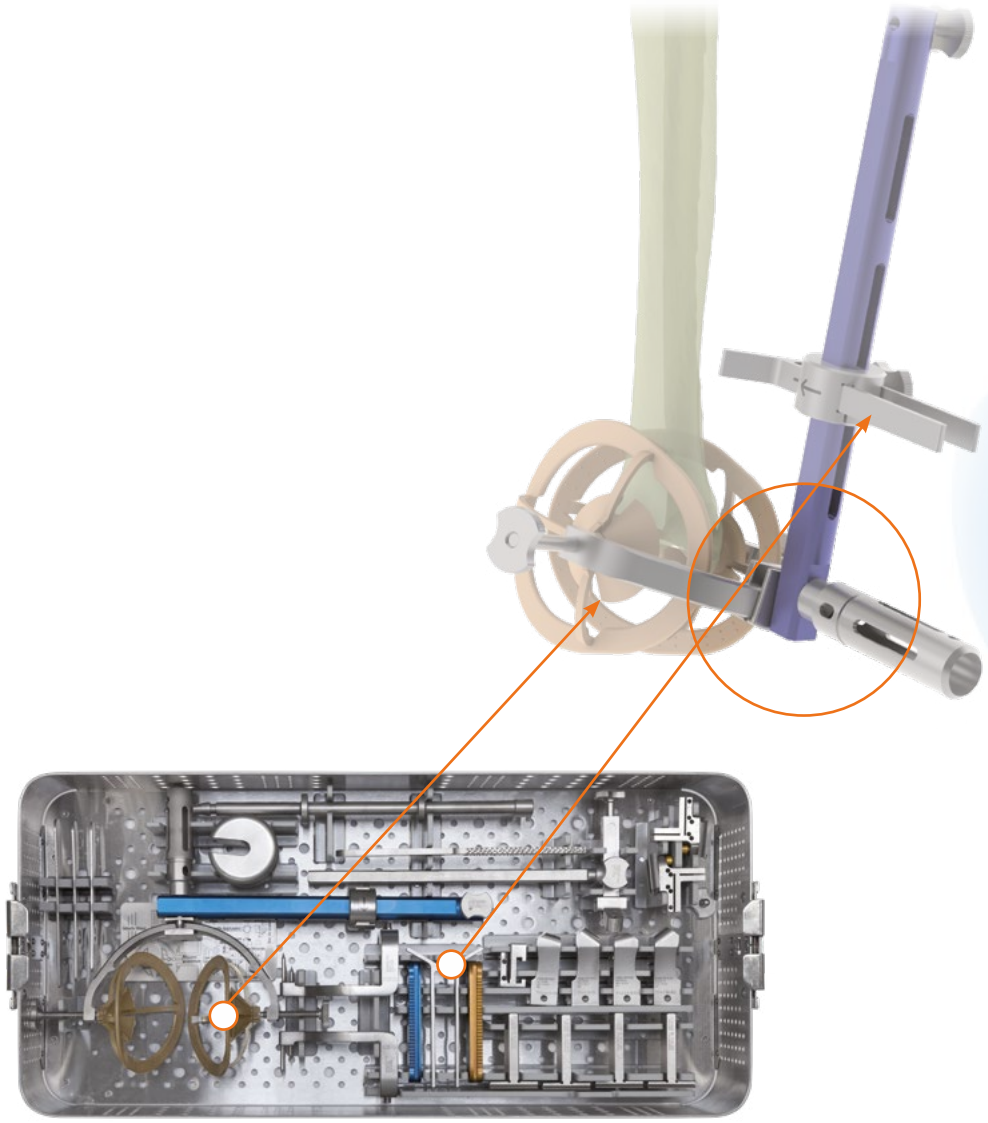
These two kits are intended to be used for component anchorage preparation and trialing, for a given size.



Spacer kit

Used for flexion and extension gap assessment.

Tibial resection, extramedullary alignment



For easier positioning of the tibial cutting guide, it is recommended to assemble the ankle clamp, the extramedullary distal rod and the anterior V sliding guide.
The ankle clamp should be aligned with the bottom section of the blue extramedullary distal rod.

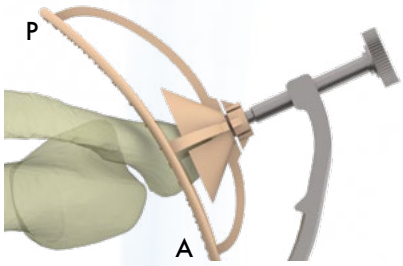
The V sliding guide is placed and locked in the most anterior position so as not to interfere with placement of the extramedullary proximal rod.

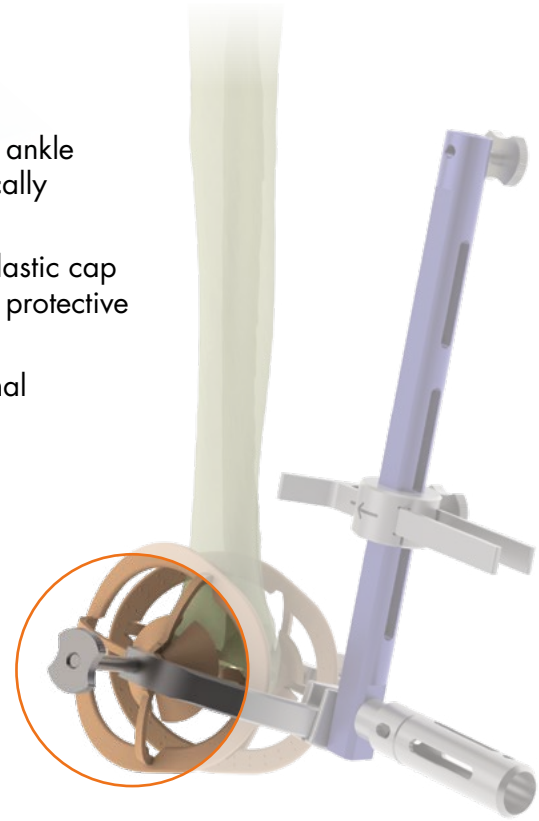
Ankle clamp fixation and rotation adjustment

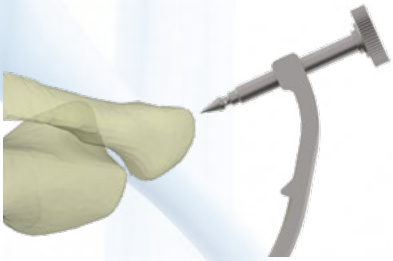
1 Identify the center of the malleoli and secure the ankle clamp by means of two lateral screws symmetrically tightened.

Each screw can be covered with a removable plastic cap to protect the malleoli, the longest portion of the protective cap being placed posteriorly.

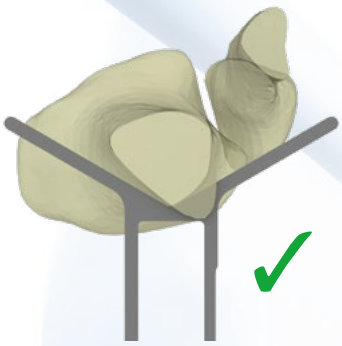
The ankle clamp should be stable over the internal malleolus.

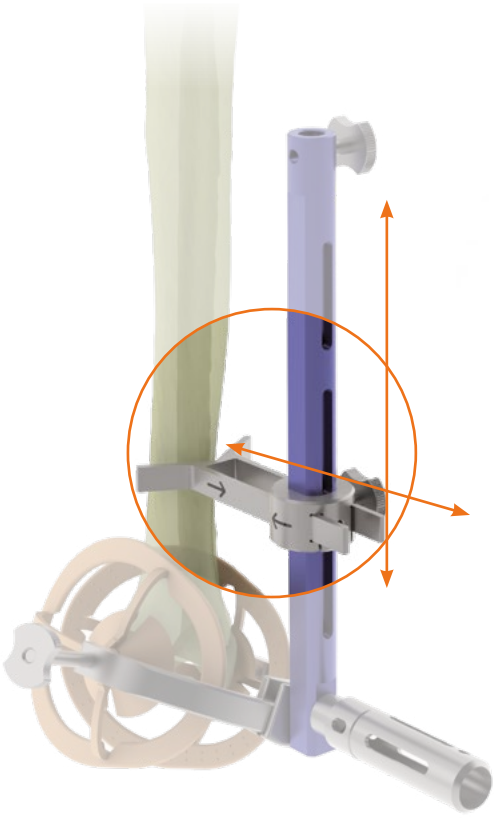






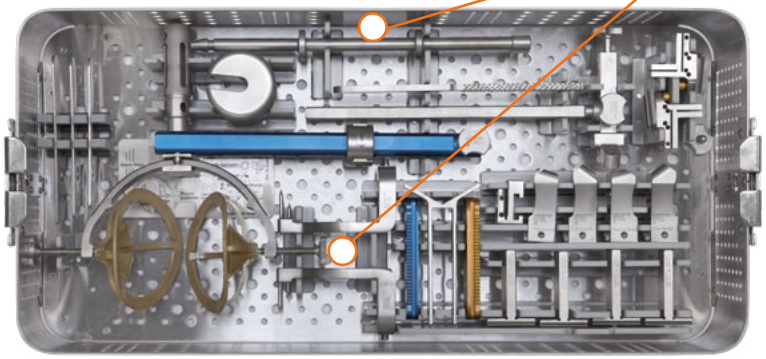
2 The V sliding guide should rest against the tibial lower third.
Identify the anterior tibial crest, loosen the knurled handle, set the tube ro tation relative to the ankle clamp so that the V sliding guide is aligned with the tibial crest then retighten the handle.

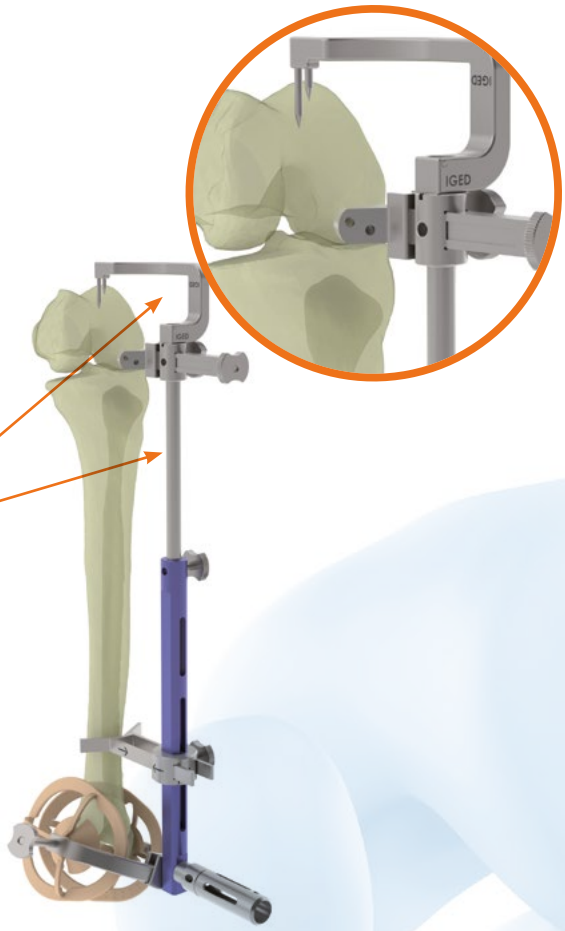


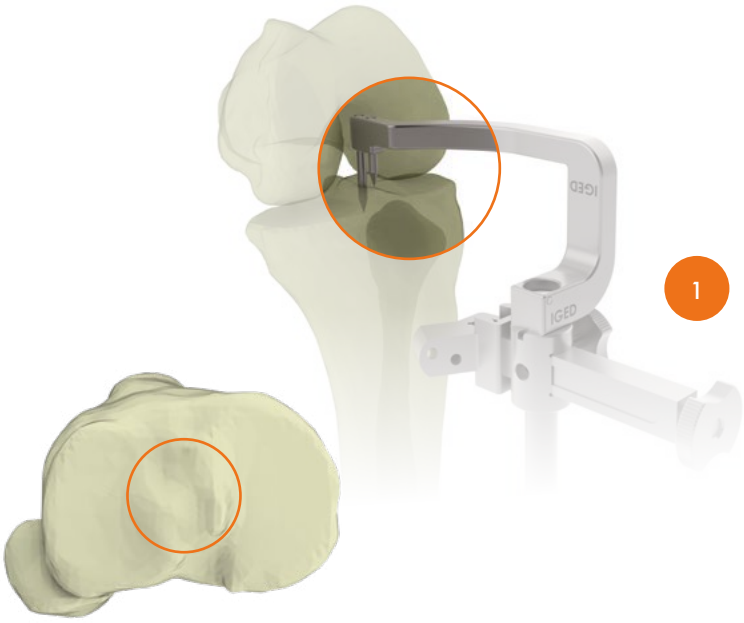


Upper assembly positioning and fixation

The upper assembly is comprised of the central slider and the appropriate tibial arm (IREL/ILER).
Connect the proximal assembly to the already stabilized distal assembly using the extra medullary up rod.

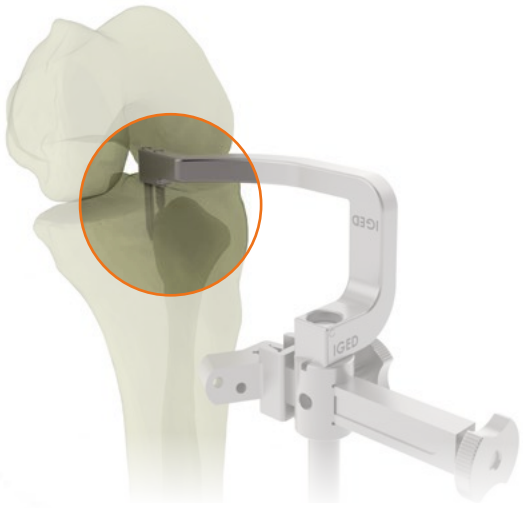






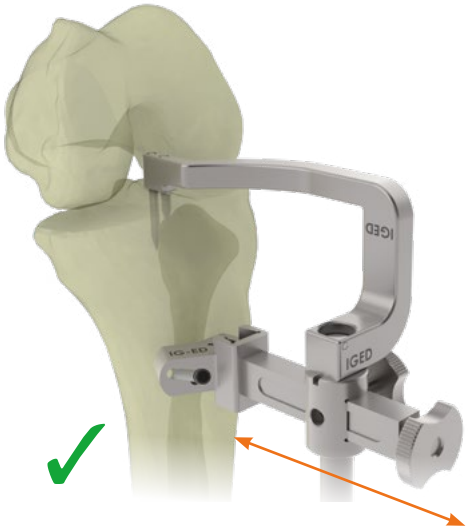
1 Impact the longest spike of the upper arm at the level of the anterior cruciate ligament insertion point.

Properly adjust rotation of the extramedullary up rod.

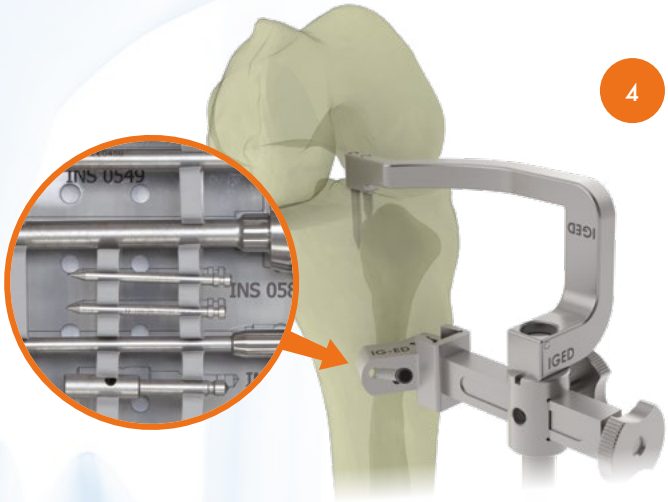


2 The second spike is impacted until complete contact with bone is achieved.
The up rod should be parallel to the mechanical axis of the tibia in both frontal and sagittal planes.
Tighten the screw on the blue distal rod.

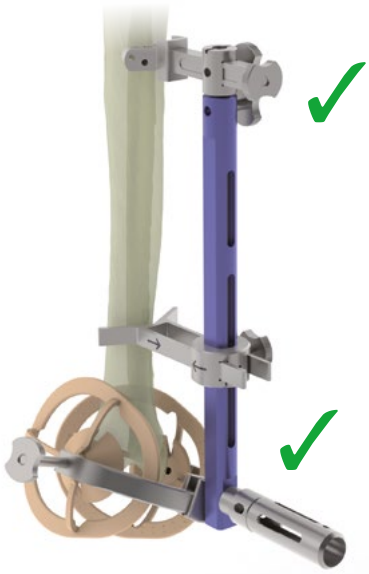
Step 3 to 5 are optional if upper arm is left in place.



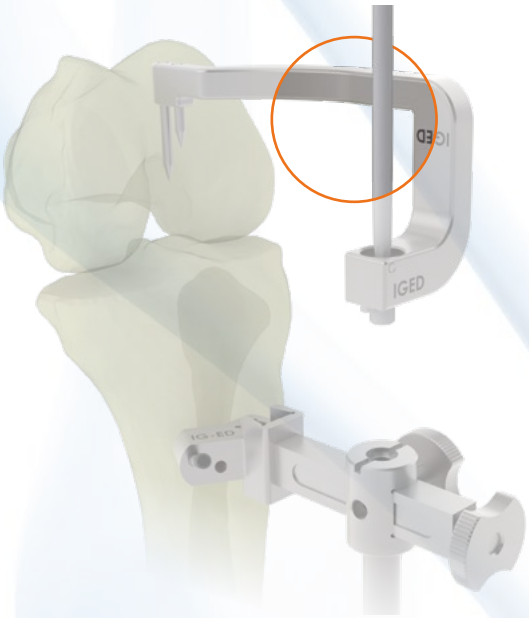
3 The slider is applied against the ATT and locked by means of a lateral screw with both fixation holes facing the operated compartment.



4 The slider is secured against the ATT using one or two headed pins.
The whole assembly should be well centered and stabilized.



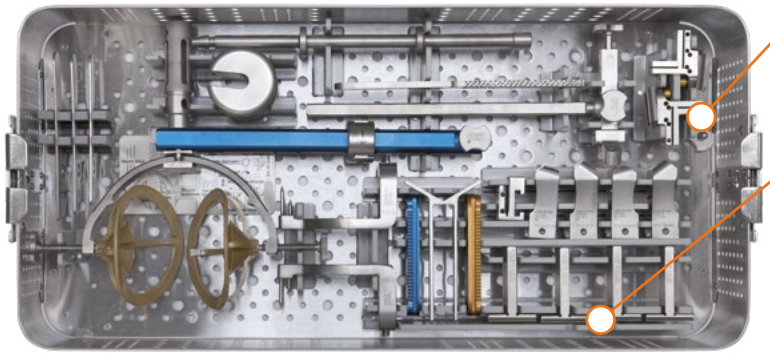
Check for complete tightening of the extramedullary rod knob and handle.

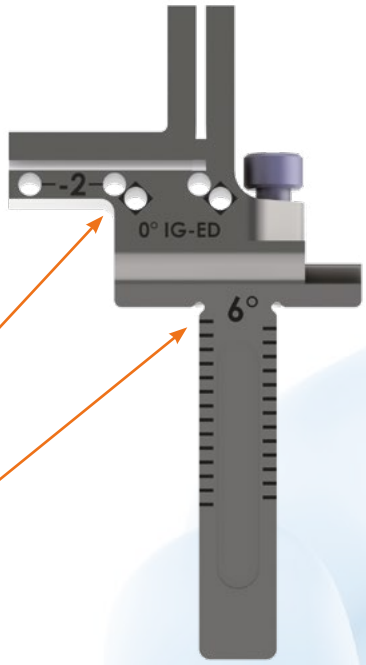


5 Remove the upper arm after having unscrewed the upper screw by means of the 3.5 mm screwdriver.

Tibial cutting block positioning and fixation and tibial resection

The cutting block is mounted onto the cutting block holder using the slider and lateral screw. A 6° posterior slope and 0° varus are illustrated here.

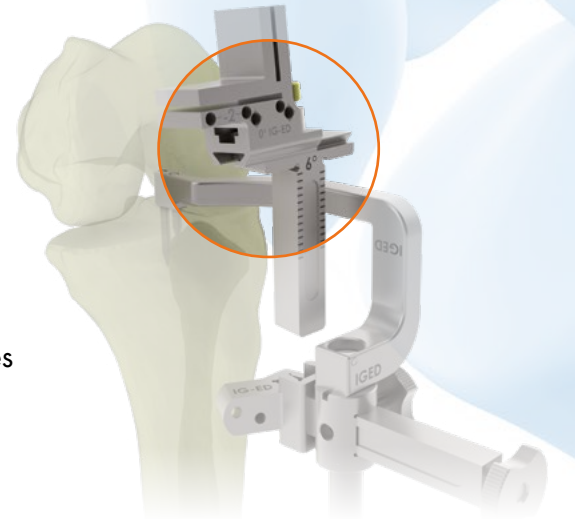


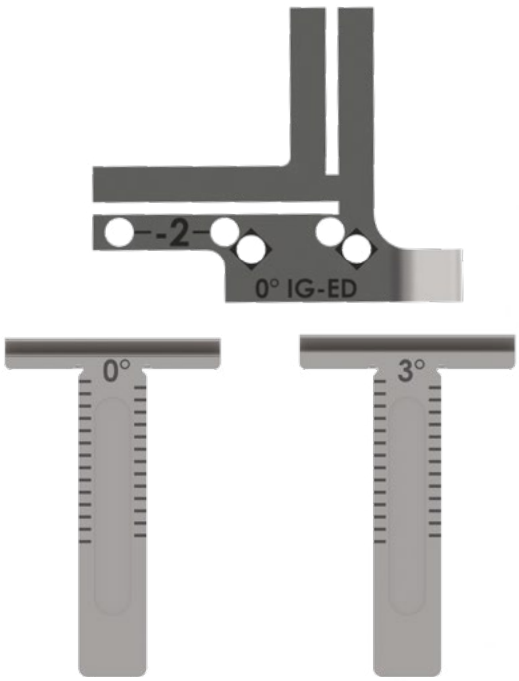


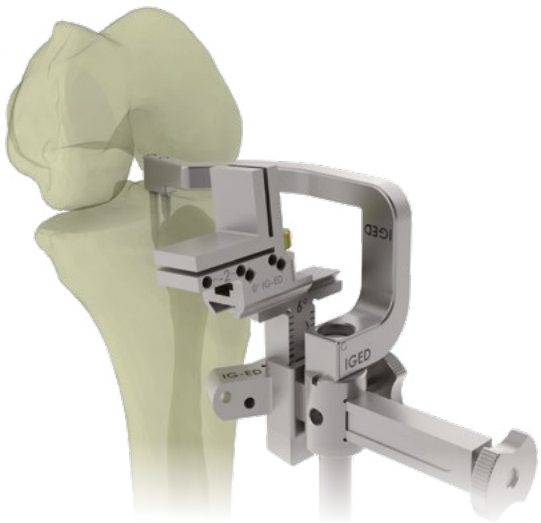
1 Select the tibial height and slope adjustment T (0°-3°-6°-9°) as well as the appropriate 0 or 2° tibial cutting block based on the preoperative planning.

Both devices are introduced into the previously positioned assembly featuring or not the upper arm.

Squares surrounding the 2 inferior holes indicate the zero position for the pins whereas using the -2 holes will correspond to a 2 mm recut.

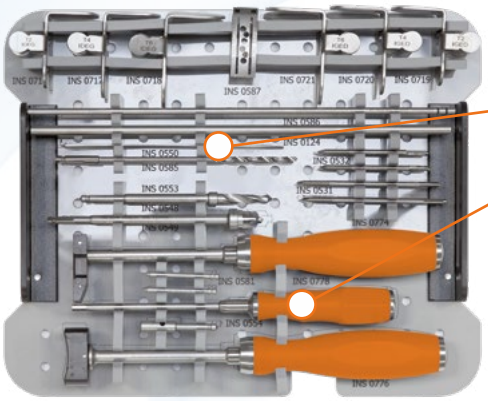


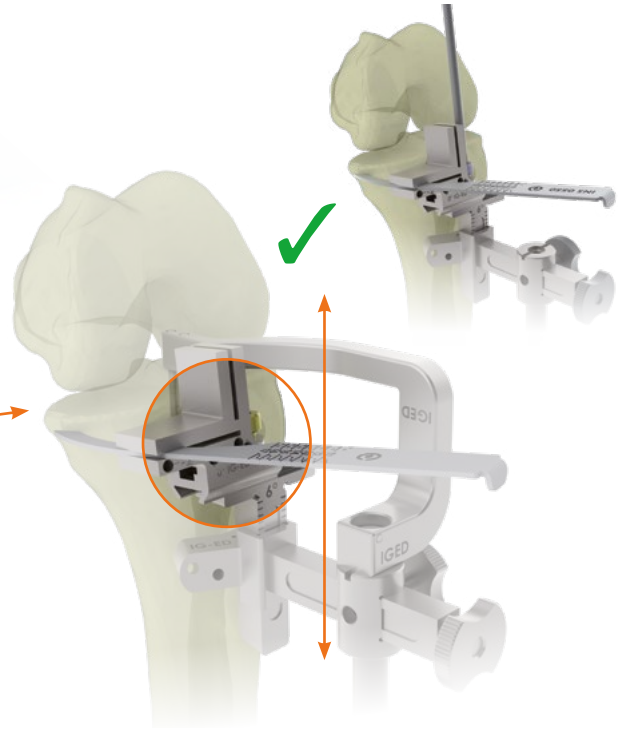


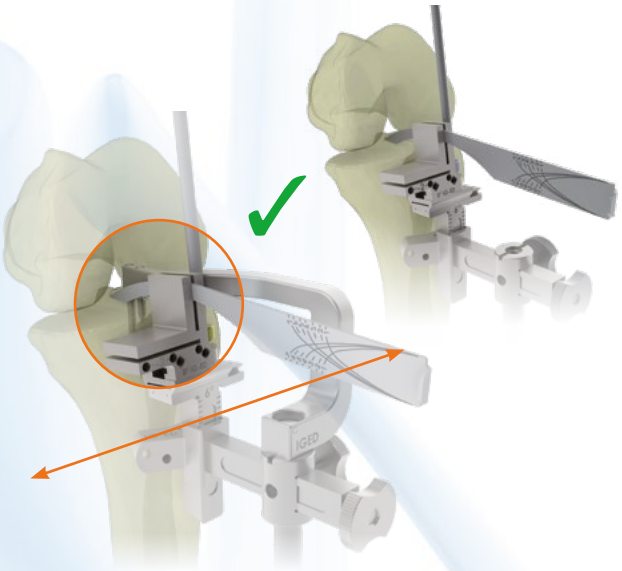


2 Set the resection height using the cutting gauge which is inserted just below the tibial osteophyte.

Tighten the frontal screw to lock the selected height.

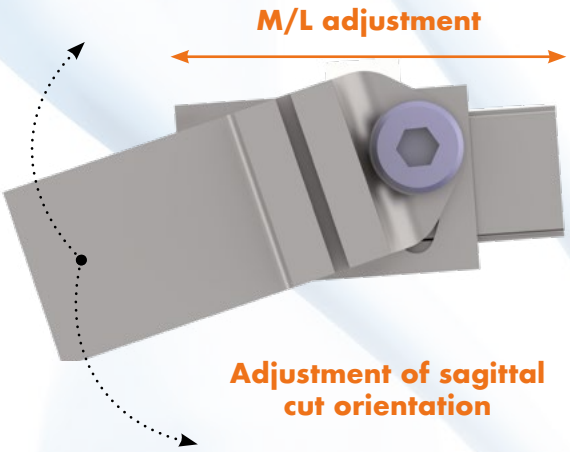






3 M/L orientation and position of the sagittal cut is set using the cutting gauge which is placed at the top of the medial tibial spine.

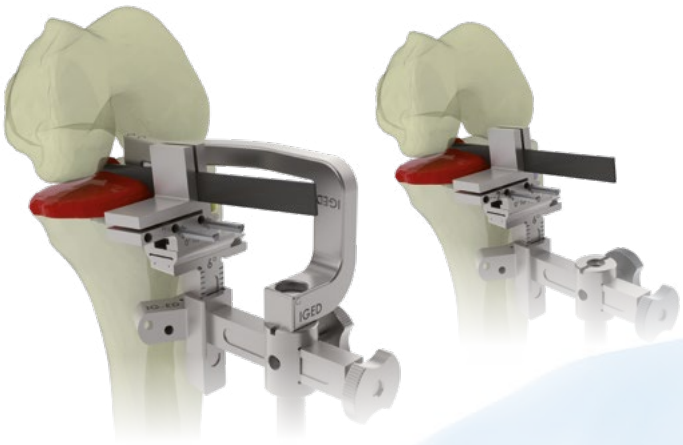
Tighten the upper screw with the 3.5 screwdriver to lock the selected M/L position.



4 Secure the block by means of threaded pins.

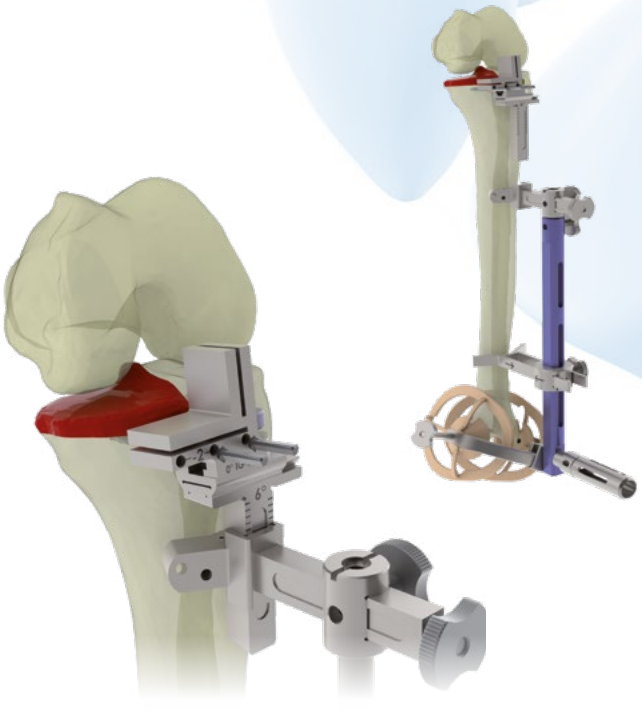
These pins are inserted using the AO adaptor.

Perform resections through the slots using a 10 to 15 mm wide and 1.27 mm thick thin blade.



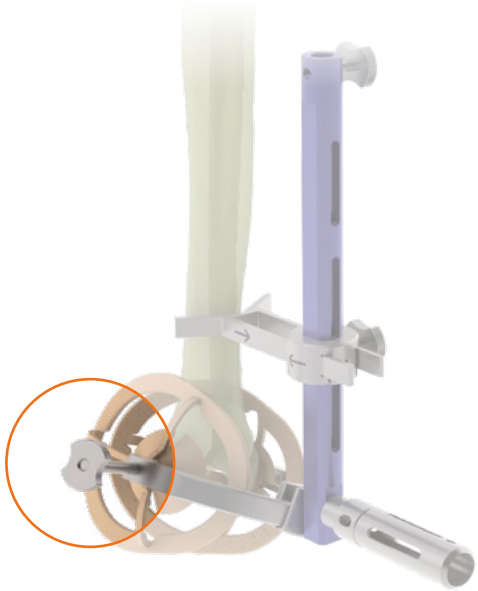
5 Disconnect the upper arm by completely unscrewing the upper screw then using a mass holder.

It is also possible to remove the headed pins from the slider if the arm has already been disconnected.



6 Loosen the upper frontal knob as well as the extramedullary rod knob .

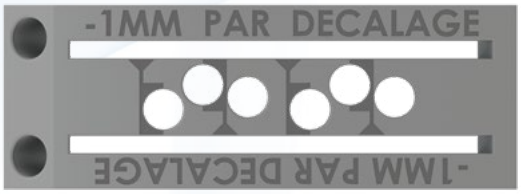
Slide down the assembly leaving in place the cutting block with its guide .

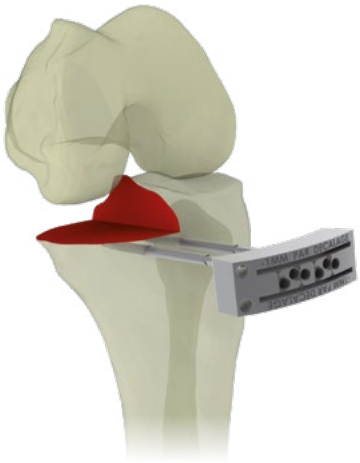


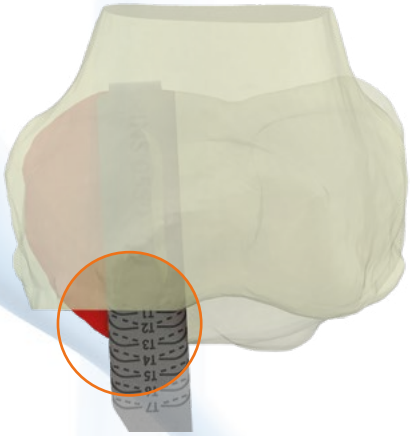
7 Loosen the ankle knobs and remove the extramedullary alignment jig.

8 When an additional 2 mm recut is required, the cutting block can be shifted over the pins left in place.

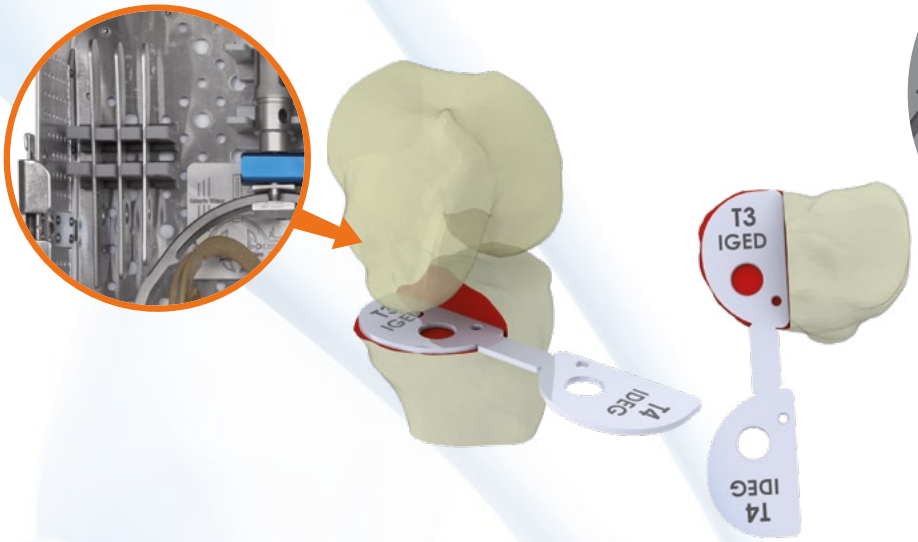
A 1 mm recut is also possible using the dedicated recutter applied over the pins left in place .







9 Tibial sizing is performed at the level of the tibial spines using the resection blade and its hook placed posteriorly on the tibial cut. Such measurement can also be performed using the tibial sizer.

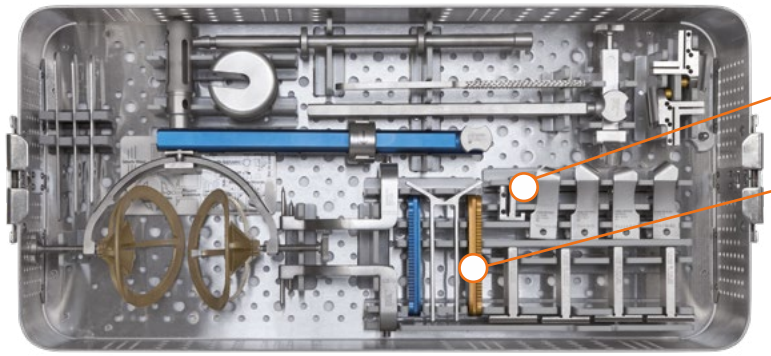


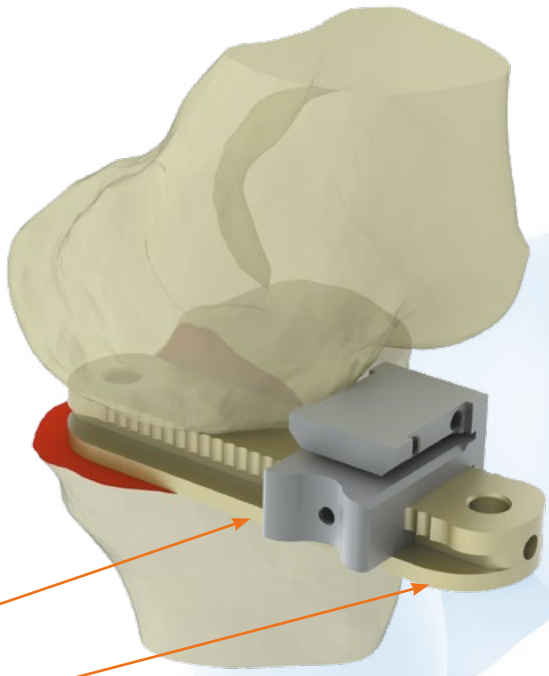
Here S3

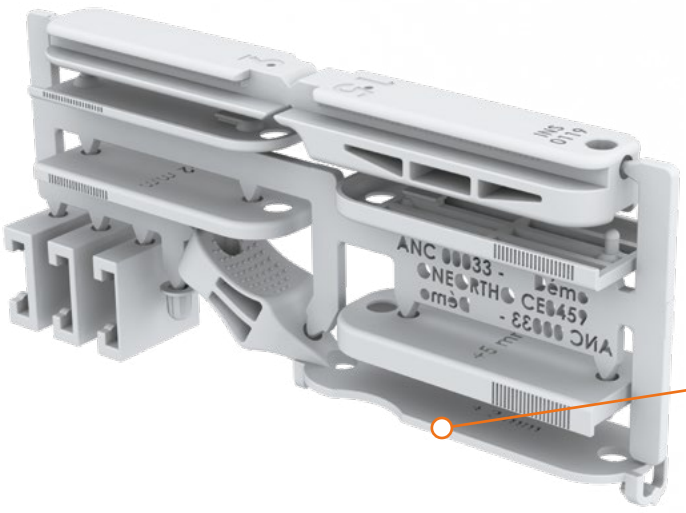
Femoral resections, metal cutting block

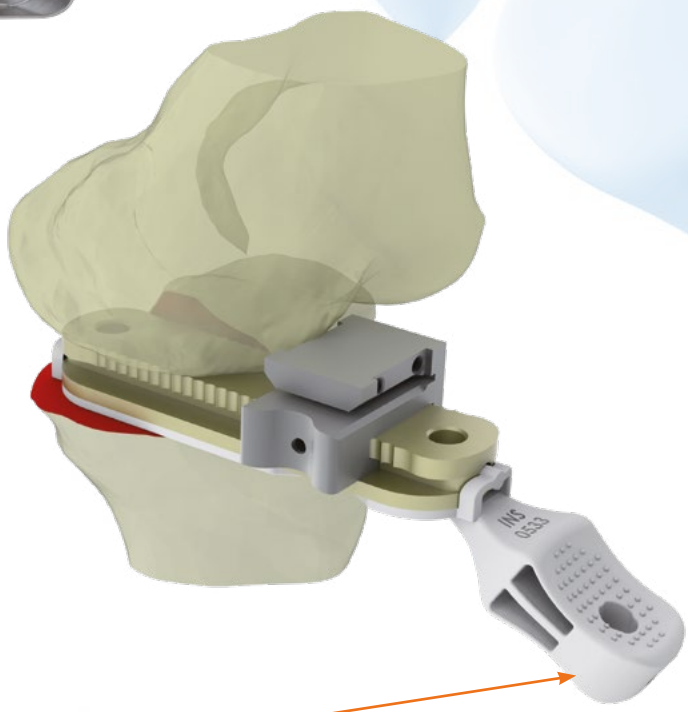
Assemble the distal cutting block to the spacer of appropriate thickness.

Spacer are available in 9 and 10 mm thicknesses. An additional 2 mm thickness removables him is available on the spacer kit to achieve 11 and 12 mm thicknesses when added to the 9 and 10 mm spacer.







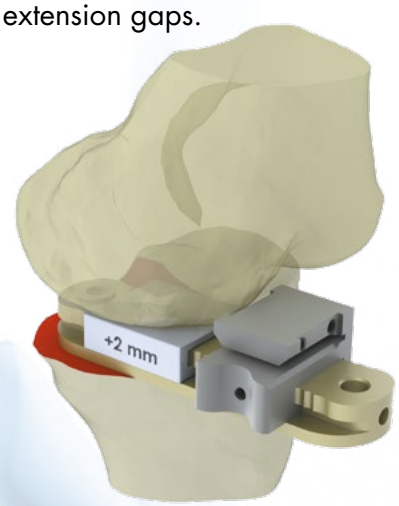


Distal cutting block positioning and fixation, distal femoral cut

1 With the knee placed at 90° of flexion, introduce the distal cutting block with any attached spacer into the joint space to determine the flexion gap.

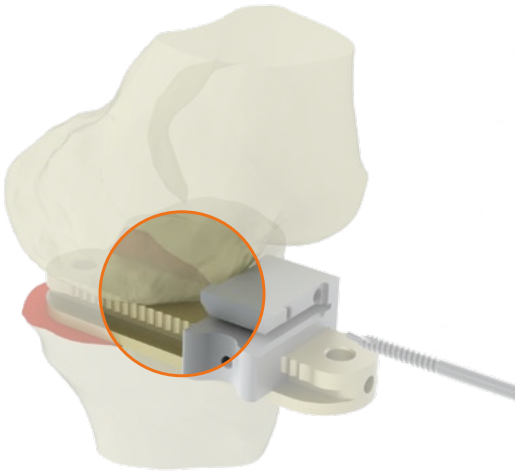
Spacers are available in 9 and 10 mm thicknesses, with an additional disposable 2 mm spacer to achieve 11 and 12 mm thicknesses.

With the knee in extension, introduce the appropriate spacer into the joint space to check the flexion / extension gaps.



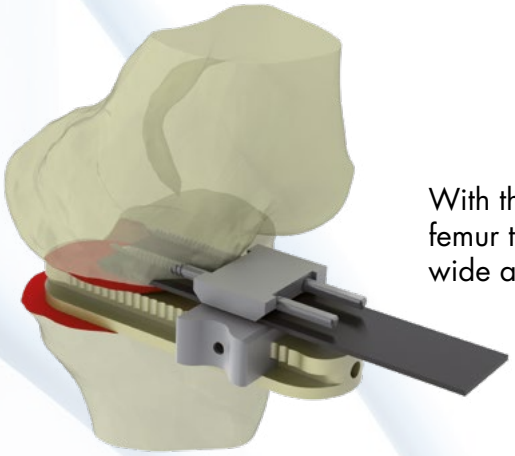
2 Assemble the distal cutting block to the spacer and introduce the assembly until full contact with the femoral bone is obtained.
In case of severe distal wear, a defect spacer (1, 2 or 3 mm) can be selected.

However, care should be taken not to exceed the indications for unicompartmental replacement in the presence of severe condylar wear.



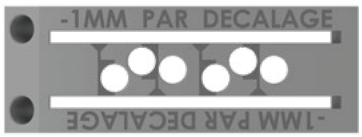
3 Use threaded pins to fix the block in place.

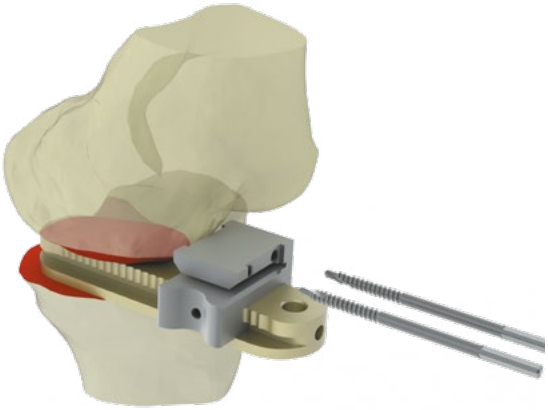
Pin insertion is performed with the power tool or AO adaptor.



With the knee in extension, resect the distal femur through the slot using a 10 to 15 mm wide and 1.27 mm thick saw blade.

An additional 1 or 2 mm of bone can be removed with the dedicated recutter placed over the pins already in place.



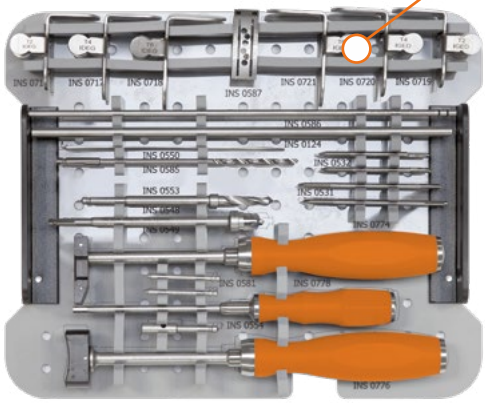


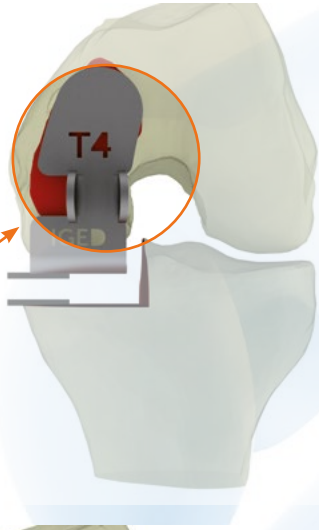
4 Remove the pins from the cutting block.
Remove the spacer and cutting block assembly.

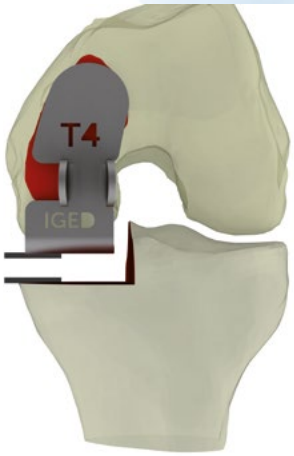
5 Femoral sizing should be performed prior to the posterior resection is made.

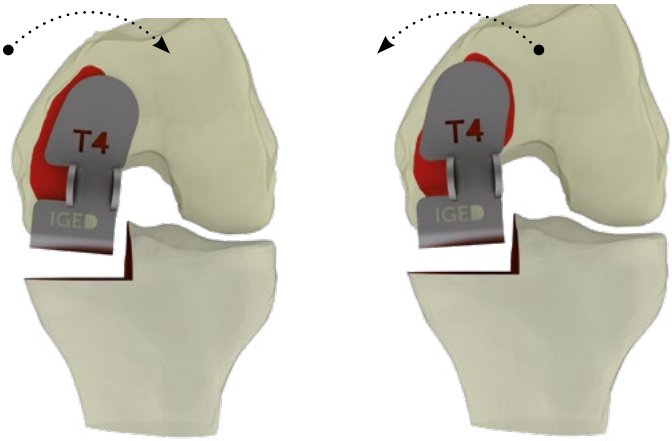
The femoral sizer (available in sizes 2 - 4 - 6) is applied flat against the distal resected surface and the posterior condyle.

In case of doubt between two sizes, always select the smaller one. The change in the mortise between sizes 4 and 5 should be taken into account (see page 4).



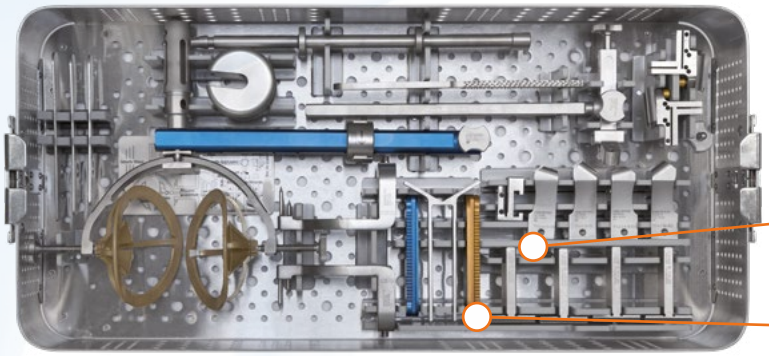


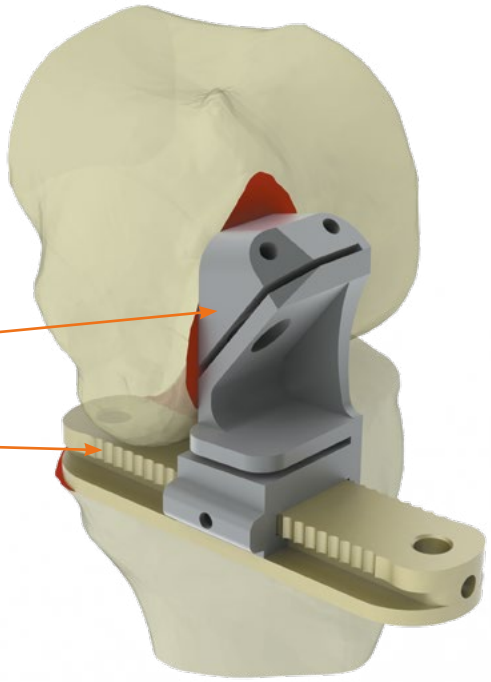




Care should be taken when rotating the sizers. The posterior face must remain parallel to the tibial cut .

Positioning and fixation of the metal cutting block, femoral posterior and chamfer cuts



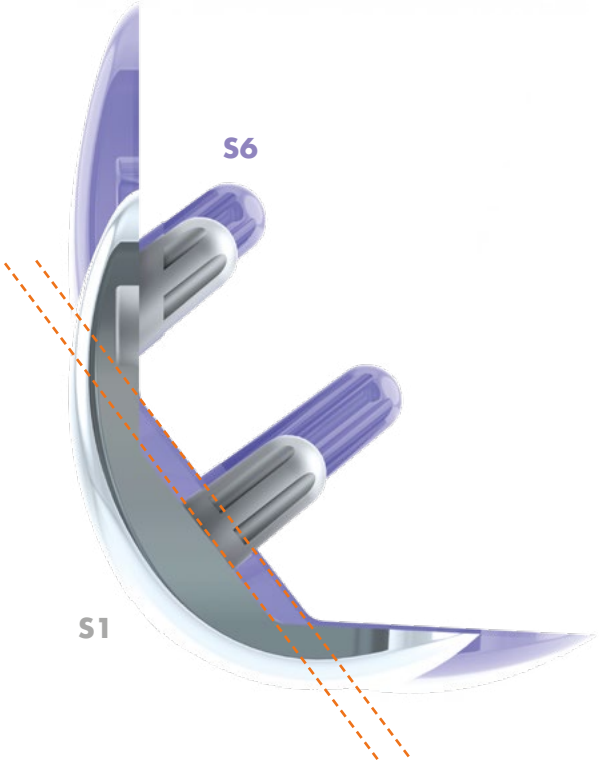


The cutting block is assembled to the spacer of appropriate thickness.

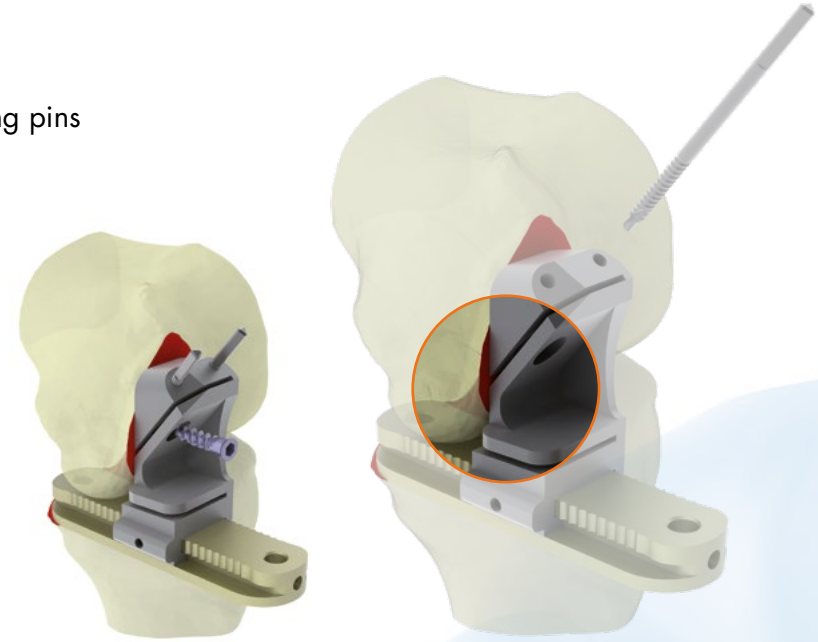
1 The cutting block should be selected according to the previously determined femoral size.

The block is available in two sizes: one size for S1 - S2 - S3 - S4 implants and the other size for S5 - S6 implants.
The difference lies exclusively in the chamfer.

A change from S4 to S5 requires the chamfer to be recut. However, it is not possible to switch from S5 to S4 due to the change in the mortise .



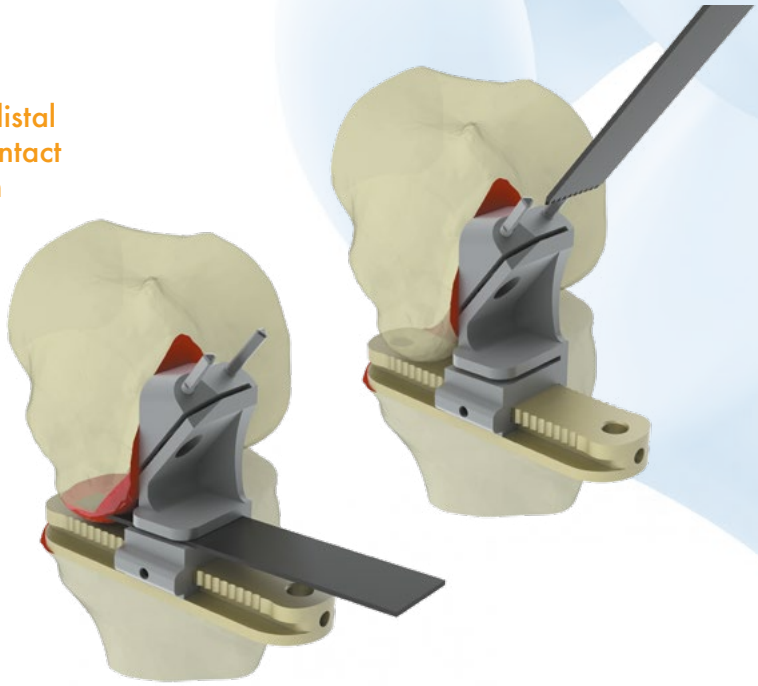
2 Use two threaded 65 or 85 mm long pins to secure the cutting block in place. A central Ø 5 mm and 30 mm long fixation screw can be used to replace one pin.

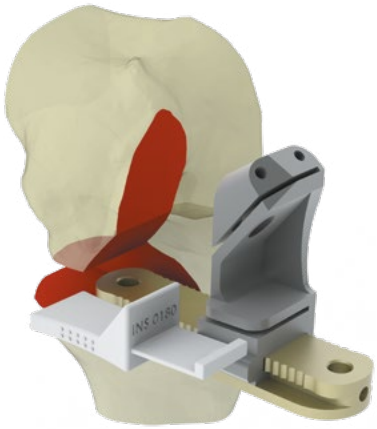


These pins are inserted with the power tool or AO a daptor.

The cutting block should be flush with the distal femoral surface and the spacer in close contact with the proximal tibial surface prior to pin insertion.

Resect the femoral bone with the knee in flexion, through the slot using a 10 to 15 mm wide and 1.27 mm thick saw blade.





An additional spacer from the S5 femoral kit can be selected to recut the posterior chamfer where necessary.

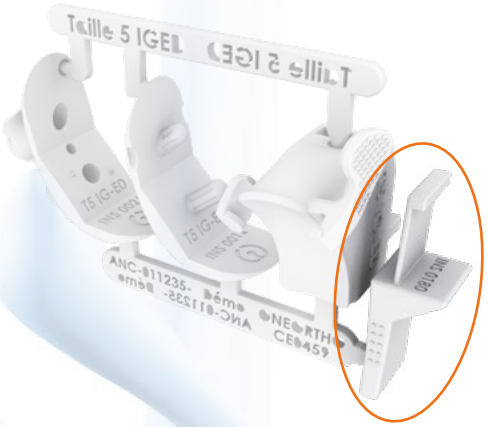
3 Remove the pins from the cutting block.

Remove the spacer and cutting block assembly.

Anchorage and trialing

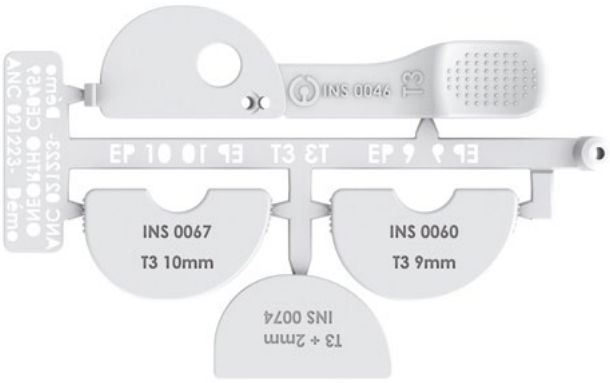
The trial implants are single-use and packaged by size.
Open the boxes containing the trial kits that correspond to the previously determined tibial and femoral sizes.
The femoral kits include a drill guide for peg hole preparation, a trial condyle and an appropriately sized condyle holder.

The S5 femoral kit includes a spacer designed to be used for posterior chamfer recut.



The tibial kits include a guide for peg hole preparation, a drill guide for tibial screw insertion as well as 9 and 10 mm thick inserts. An additional removable 2 mm spacer allows to reach 11 and 12 mm thicknesses when added to trial inserts.

Tibial guide positioning and fixation, peg hole preparation



1 Detach the different components of the set:
Trial baseplate.

Trial inserts 9 and 10 mm.

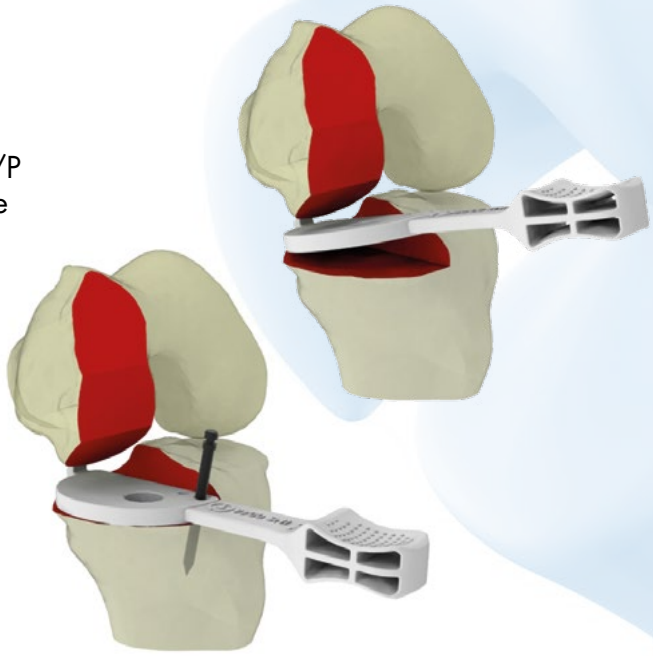
Drill guide (T shaped central frame).
2 mm spacer.

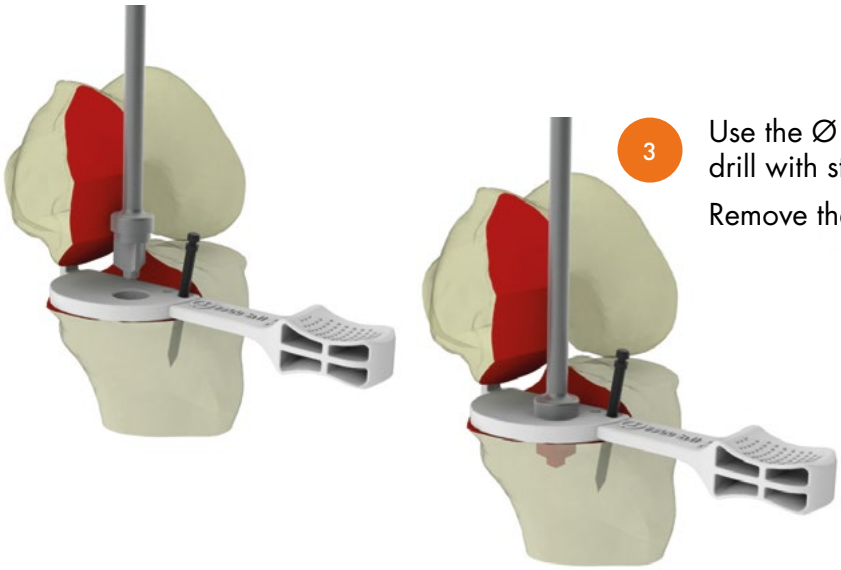
2 Place the trial baseplate flush onto the resected tibial surface using the posterior hook to set the A/P orientation and resting over the tibial spines for the M/L position./L.

Remove any osteophytes prior to trial baseplate positioning.

Check for appropriate bony coverage of the trial baseplate.

Secure with a short headed pin, optionnal.



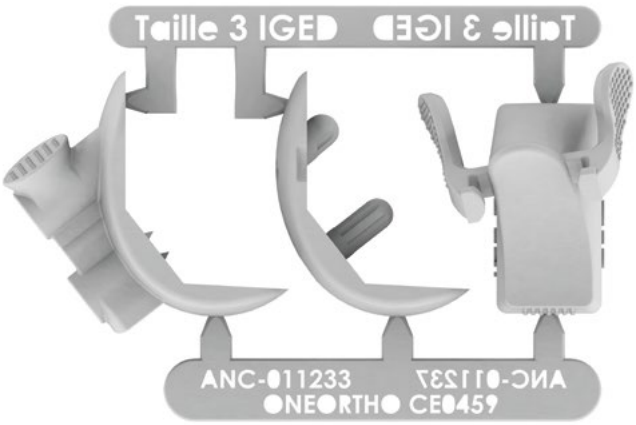


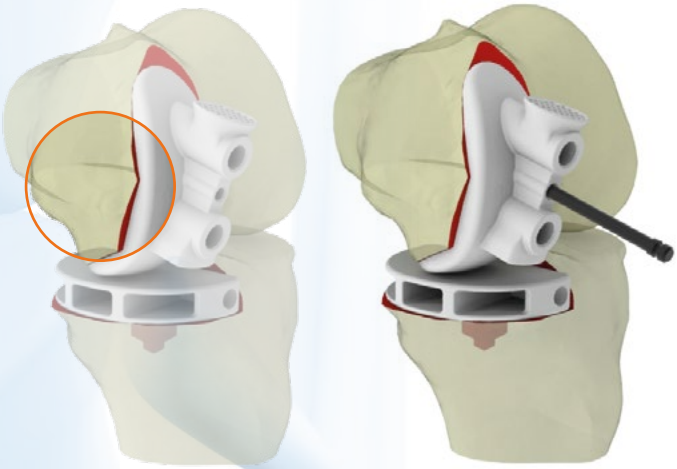
3 Use the Ø 11 mm and 11 mm long tibial drill with stop to prepare the tibial peg hole.

Remove the pin and trial base plate.

Femoral drill guide positioning and fixation, peg hole preparation

1 Detach the different components of the set:
Femoral drill guide
Femoral trial
Condyle holder
And only for S5, a shim for chamfer recut



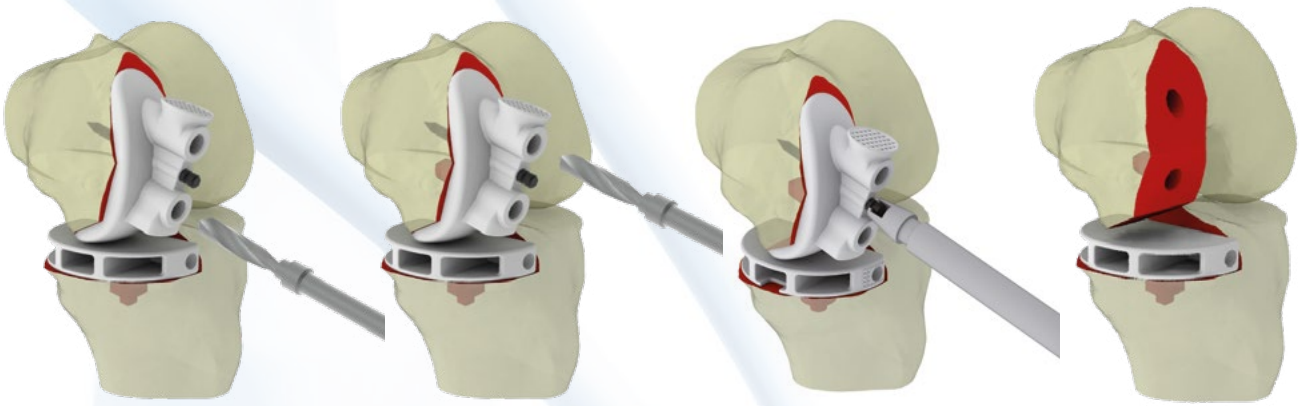


2 Place the drill guide on the resected femoral surface ensuring there is no lateral overhang and no impingement into the intercondylar notch for the M/L position.

The drill guide must be adequately secured to the bone using a headed pin after drilling with the Ø 3.2 mm drill bit.

3 Drill the anterior and posterior femoral peg holes using the Ø 6 mm and 30 mm long drill with stop.

Remove the headed pin with mass extractor then remove the drill guide.



Trial reduction

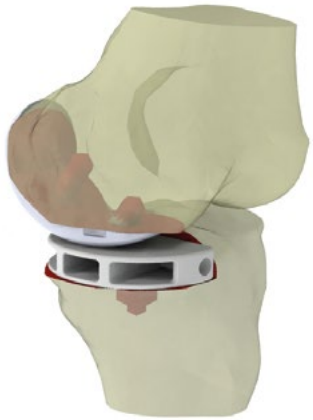
1 Place the tibial and femoral trial implants on the resected surfaces.

The tibial implant corresponds to the tibial baseplate plus insert thicknesses, that is 9 and 10 mm. For 11 and 12 mm thicknesse, the 2 mm removable spacer is added to the 9 mm or 10 mm trial.

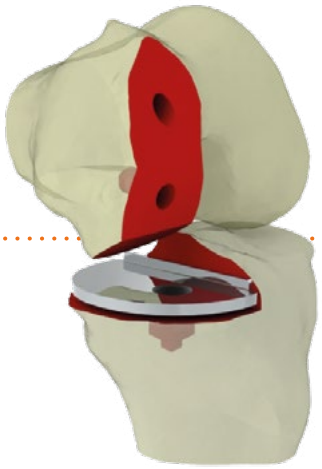
The femoral component can be impacted with the condyle holder which is connected to the tibial impactor.

2 Assess soft-tissue balance in flexion and extension. The implants should be properly fitted and seated with the condyle well centered on the lateral third of the insert.
Manipulate the knee from extension to 130° of flexion and perform rotational movements at 30° of flexion to assess joint stability.

Remove any posterior osteophytes that may prevent proper flexion and cause impingement with tibial insert.

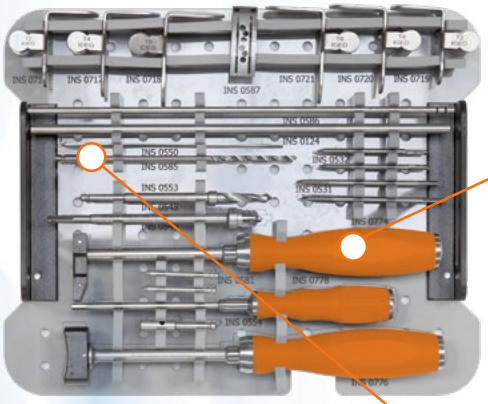


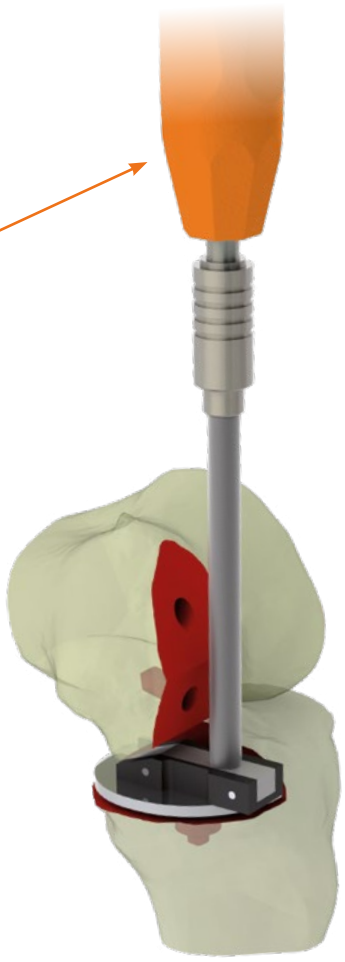
Implanting final components



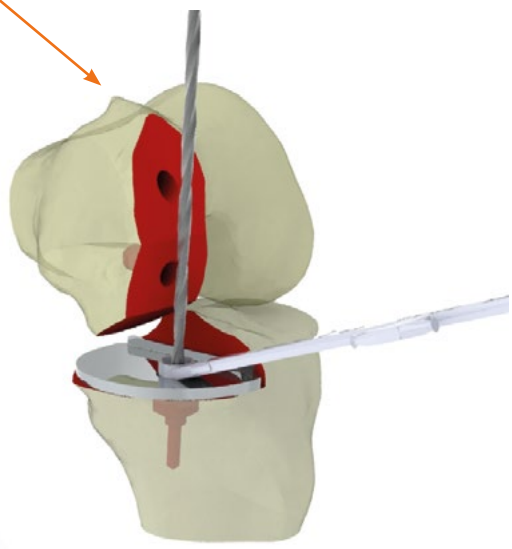
1 Locate the tibial baseplate by aligning and inserting the tibial peg into the prepared peg hole in the tibia.

Impact the tibial baseplate using the tibial impactor.



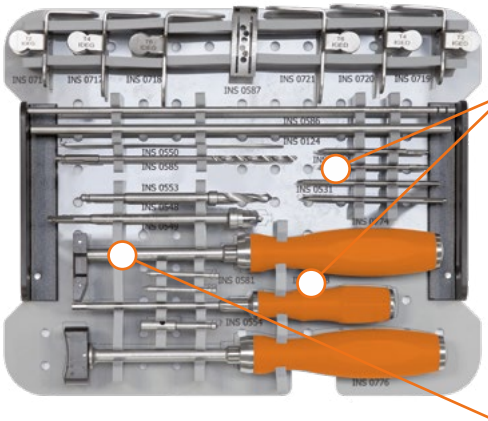


2 For a cementless technique, place the drill guide to perform a 3.2 mm hole (using the Ø 3.2 mm and 145 mm long drill bit), to prepare insertion of the Ø 5 mm or 6 mm and 25, 30 or 35 mm long anterior fixation screw.

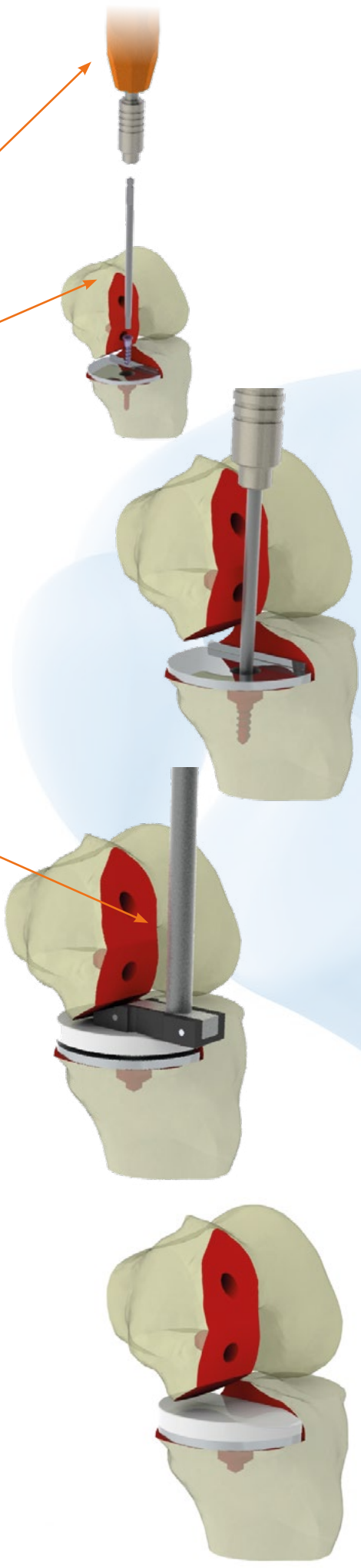


3 Select the screw of appropriate diameter and length.

Tighten the screw.

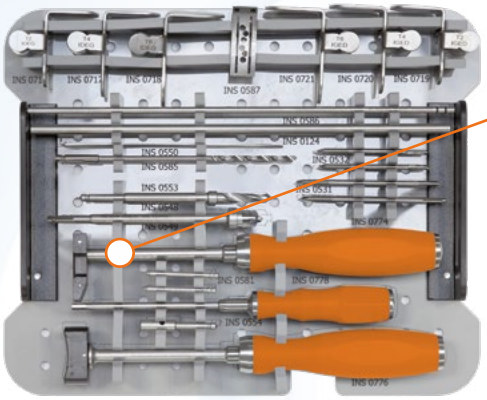


4 Install the appropriate thickness insert and impact it using the tibial impactor.



5 Attach the tibial impactor to the condyle holder.

Complete and proper coupling of the metal rod to the condyle holder is confirmed with an audible click.

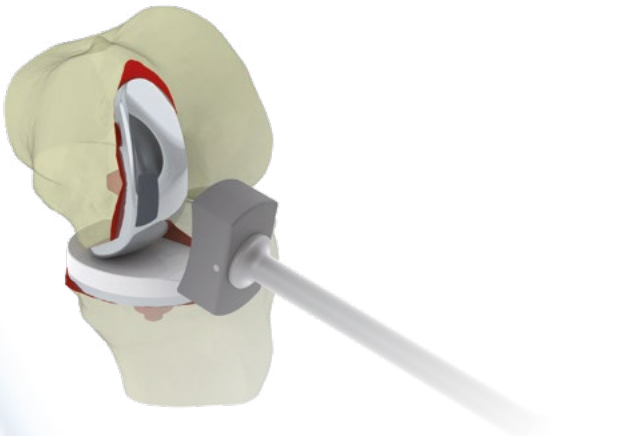


6 The condyle is assembled to the condyle holder taking care to ensure it is fully secured.

As a precautionary measure, place one hand beneath the assembly in case the final implant is dropped.

7 Impact the femoral component while keeping the impactor axis aligned with the condyle pegs.

Release the condyle holder either by pressing the lateral clip or by rotating the condyle holder (which is automatically disconnected).



8 Definitive impaction is performed using the hemispheric impactor.

Seven step digital technique

1 CONNECT

TO: ONEFORYOU.FR

The management software is the global control tool of the individualized design process of OneOrtho implants. It is accessible on **oneortho-medical.com** website or directly on **oneforyou.fr**

2 CREATE

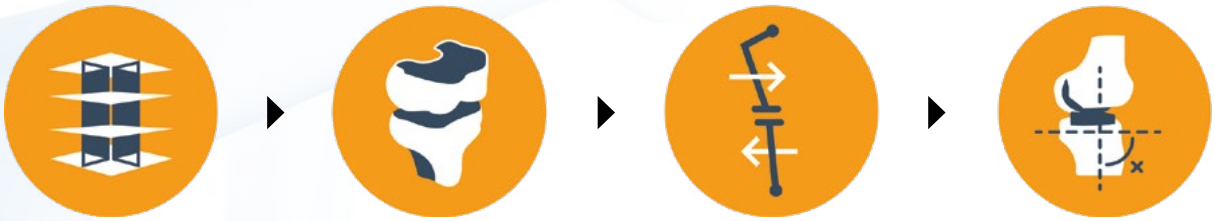
YOUR PATIENT CASE AND IMPORT HIS MEDICAL IMAGING

3 CONFIGURE

THE IMPLANT DESIGN THAT BEST FITS YOUR PATIENT JOINT WITH **DIGITAL Fit**

This implant design tool allows the surgeon to define the global design of the components, the fixation technique and anchorage topology.

4 PRE-PLAN
AND VISUALIZE THE ANATOMICAL RECONSTRUCTION IN 3D



5 PLAN
AND CUSTOM BUILD YOUR IMPLANT WITH **DIGITAL PLANNER**

6 VALIDATE
THE CUSTOM MANUFACTURE VIA 3D PRINTING TECHNOLOGIES

Implant and instrument production is made within a **strict regulatory framework** and benefits from a rapid manufacturing process in order to deliver a complete tailor-made kit within a **reduced time frame.**

7 IMPLANT
THE TAILOR-MADE PROSTHESIS USING ADAPTED TOOLS

The mini-invasive technique is recommended when implanting the **Uni Kroma®** prosthesis. The mini-invasive approach consists in implanting a UCP through a 6 to 10 cm incision without requiring patella dislocation. In order to be as precise, reliable and reproducible as the invasive technique, the implantation process starts with a key surgical step which is **performing the tibial and distal femoral cuts.** These resections are made using a four-part intra-articular cutting guide.

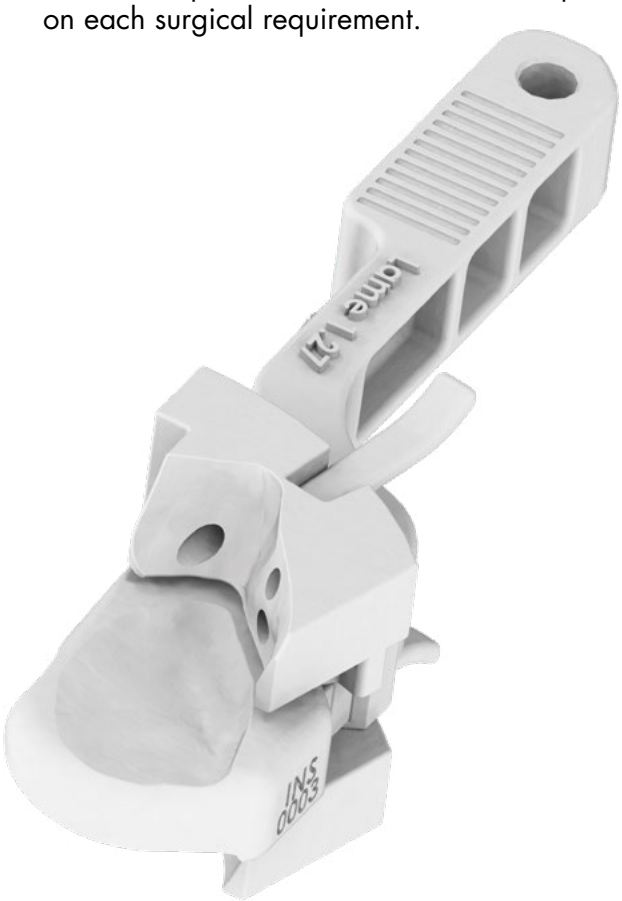
Then, the last femoral cuts: **posterior and chamfer cuts,** are performed in relation with the tibial cut.
Lastly, **bone anchorages** are prepared. Final components are then implanted after **trialing in flexion and extension.** Proper respect of these indications, which are specifically designed for implantation of the **Uni Kroma®** prosthesis with its specific instrumentation, ensures **optimal results.**

Tibial and femoral cuts using a customised template block

The customised template block is an optional solution for implantation of **Uni Kroma®** prosthesis.

This tailor-made solution is associated with our OneForYou digital solution.

Various template blocks are available depending on each surgical requirement.



The first and simplest one, is a unique template block designed to achieve tibial cuts only; the second one is a two-part template block intended for a single-stage tibial and distal femoral cut technique performed with the knee in extension; the third one is a three-part template block to be used for tibial and distal femoral cuts in flexion. This template block is made from a biocompatible material according to applicable ISO standard: NF EN ISO 10993-1.

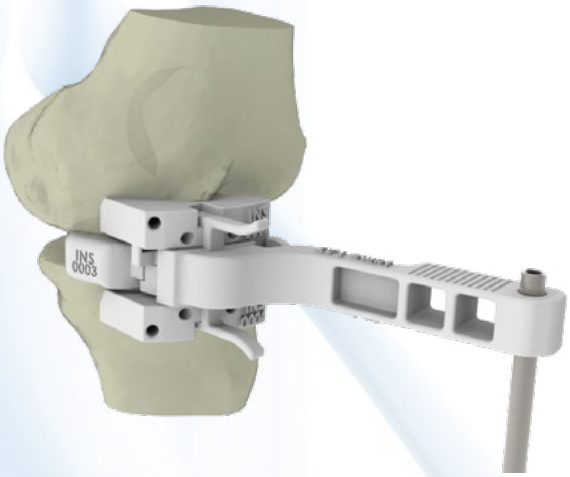
Customised template block positioning and fixation: tibial and distal femoral cuts

1 With the knee in extension, once the meniscus and cartilage have been removed while leaving the osteophytes in place, the template block is introduced in an antero-posterior direction between the femoral condyle and the tibial plateau in the middle section of the compartment. It allows single-stage restoration of the tibial cut height, posterior slope, valgus and femoral cut height.

For easier template block positioning, this latter may be inserted with the knee flexed then placed progressively in extension.

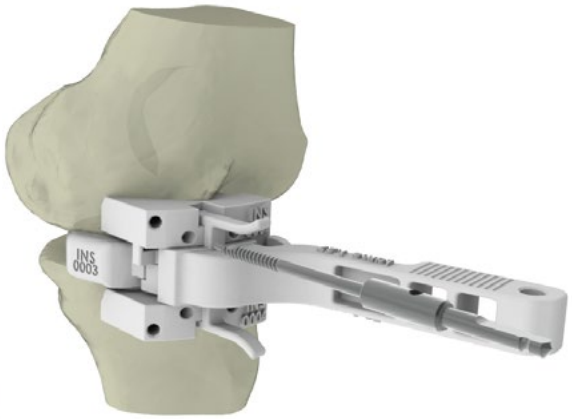
The template block should achieve close anterior contact with tibial and femoral cortex.

Care should be taken to control there is no impingement between the template and the patella which could lead to improper positioning of the template.



2 Proper positioning is assessed with the extra-medullary telescopic rod.

In the event of a non reducible tibial or femoral decoaptation of the guide, the ex tramedullary alignment guide should be used in place of the customised template block.

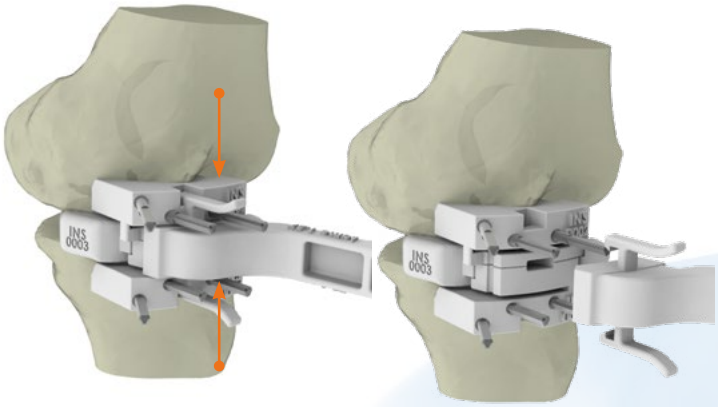


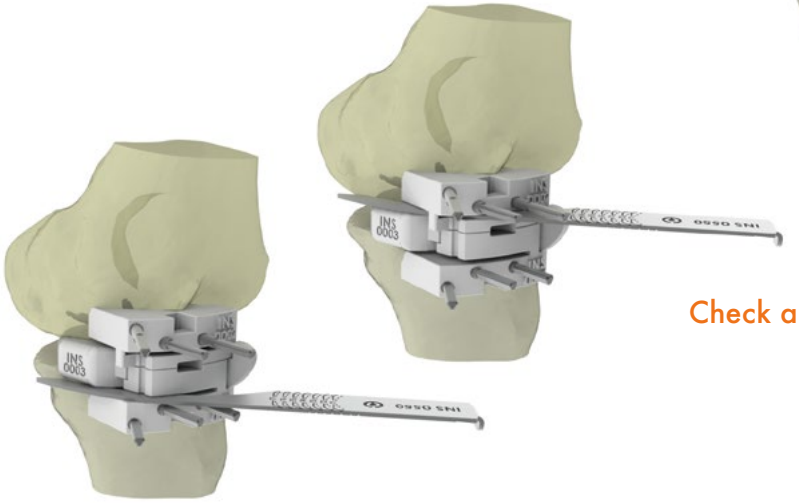
3 The block is secured using threaded pins inserted with the power tool of AO adapt or, starting with parallel pins then both divergent pins.

Verify secure fit of the femoral pins that may engage the empty space of the distal femoral notch.

4 Remove the handle by pressing both clips vertically.

Confirm proper anterior contact between the template block and the tibial and femoral cortices.



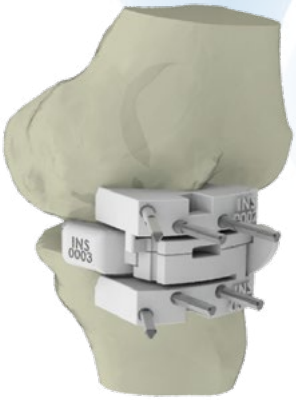


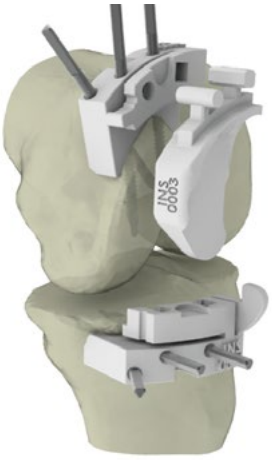
Check all resections with the cutting gauge.

5 Select the two-part template block to perform proximal tibial and distal femoral cuts.

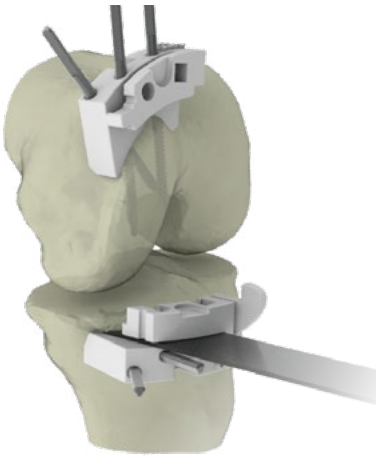
Remove the divergent pins and femoral block by placing the knee in slight flexion.

Perform the sagittal cut.





6 After selecting the three-part template block, the knee is progressively flexed to disconnect the distal cutting block from the intra-articular block and the tibial cutting block.

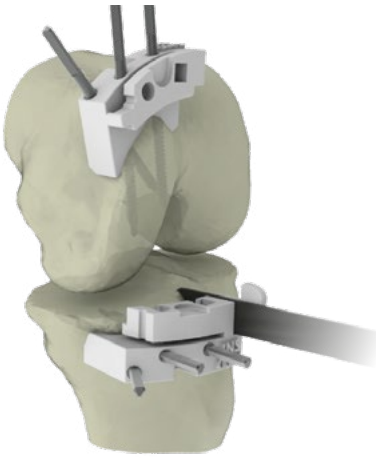


7 Resections are performed through the slots using a 10 to 15 mm wide and 1.27 mm thick blade.

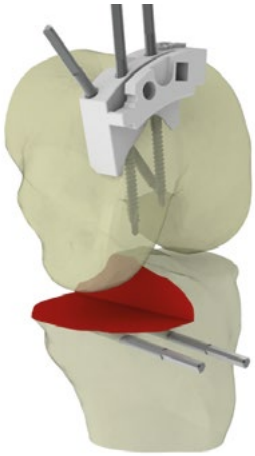
The sagittal cut can be made using the reciprocating saw with a blade of up to 1.27 mm.

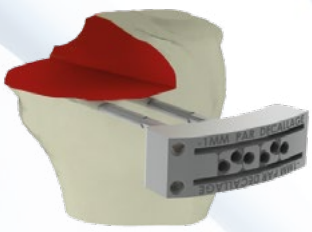
Remove the divergent pin and tibial cutting block while maintaining the two parallel pins in place.

Check the tibial cut performed with the appropriate spacer.



8 In any case, resections can be performed either using the customised template block of biocompatible material or the metal cutting block repositioned over the two parallel pins left in place.





9

With the knee in flexion, perform the distal femoral cut through the slot using a 10 to 15 mm wide and 1.27 mm thick blade. A 1 or 2 mm recut is possible using the dedicated recutter installed over the pins already in place.

The blade progression should be controlled throughout the whole cutting process to prevent under-resection in recurvatum.

In the case of a very dense femoral bone, it is recommended to perform the distal cut with the metal cutting block, repositioned over the two parallel pins left in place.

After completion of the tibial and distal femoral cuts, continue through the various stages detailed on pages 18 to 27.

References

Implants

Ex: Cemented anatomic condyle Int R - Ext L S 5: PFRM84 11040 5

	Sizes			1	2	3	4	5	6
Condyle	**Anatomic condyle**								
	Cemented Int R - Ext L	PFRM84	11040	1	2	3	4	5	6
	Cemented Int L - Ext R	PFRM84	11050	1	2	3	4	5	6
	Cementless Int R - Ext L	PFRM84	12040	1	2	3	4	5	6
	Cementless L - Ext R	PFRM84	12050	1	2	3	4	5	6
Baseplate	**Anatomic fixed baseplate**								
	Cemented Int R - Ext L	PFRM84	21040	1	2	3	4	5	6
	Cemented Int L - Ext R	PFRM84	21050	1	2	3	4	5	6
	Cementless Int R - Ext L	PFRM84	22040	1	2	3	4	5	6
	Cementless L - Ext R	PFRM84	22050	1	2	3	4	5	6
Insert	**Fixed insert Int R - Ext L**								
	9 mm	PFRM84	3004	11	21	31	41	51	61
	10 mm	PFRM84	3004	12	22	32	42	52	62
	11 mm	PFRM84	3004	13	23	33	43	53	63
	12 mm	PFRM84	3004	14	24	34	44	54	64
	Fixed Insert Int L - Ext R								
	9 mm	PFRM84	3005	11	21	31	41	51	61
	10 mm	PFRM84	3005	12	22	32	42	52	62
	11 mm	PFRM84	3005	13	23	33	43	53	63
	12 mm	PFRM84	3005	14	24	34	44	54	64

Instrumentation

Metal instruments reference: VARAUK01
(UNIKROMA-ONEORTHO ANC0007)

Single-Use Instrumentation

Taille		1	2	3	4	5	6
Anatomic condyle Int R - Ext L	PFRA821000	01	02	03	04	05	06
Anatomic condyle Int L - Ext R	PFRA821000	08	09	10	11	12	13
Fixed baseplate	PFRA821000	15	16	17	18	19	20
Spacer	PFRA821000	24	24	24	24	24	24

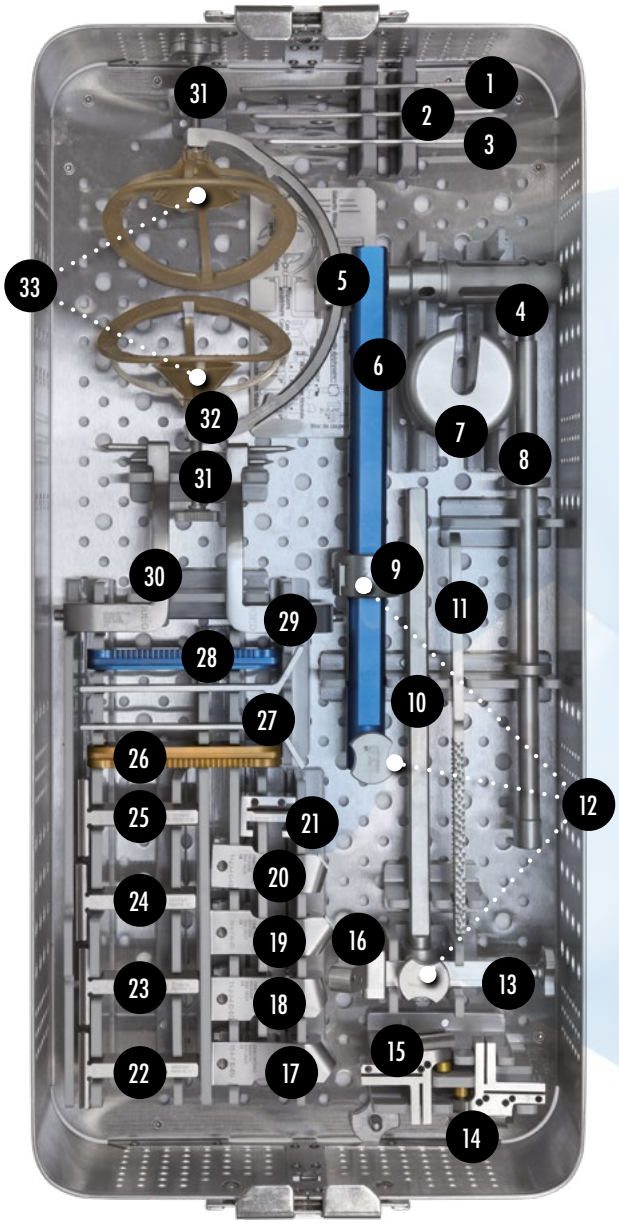
Fixation screw

The tibial baseplate can be secured using screws, supplied separately from the implant and which references are indicated below:

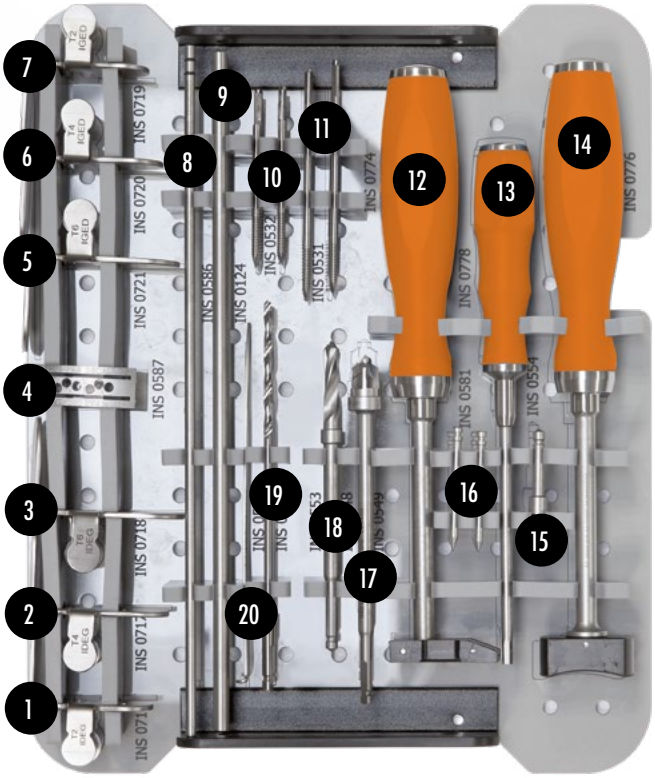
Designation	Manufacture reference	Commercial reference
Screw Ø 5 length 25 mm sterile	33472STER	PFRM84600051
Screw Ø 5 length 30 mm sterile	33473STER	PFRM84600052
Screw Ø 5 length 35 mm sterile	33474STER	PFRM84600053
Screw Ø 6 length 25 mm sterile	35008STER	PFRM84600061
Screw Ø 6 length 30 mm sterile	35009STER	PFRM84600062
Screw Ø 6 length 35 mm sterile	35010STER	PFRM84600063

Instrumentation • Universal set

N°	Qty	Designation
1	1	INS 0877 - Tibial sizer T2
2	1	INS 0878 - Tibial sizer T4
3	1	INS 0879 - Tibial sizer T6
4	1	INS 0503 - Lower handle M6
5	1	INS 0551 - Ankle clamp holder
6	1	INS 0501 - Extramedullary distal rod
7	1	INS 0829 - Impaction mass
8	1	INS 0826 - Extractor/mass holder
9	1	INS 0504 - V sliding guide
10	1	INS 0502 - Extramedullary up rod
11	1	INS 0780 - Bone rasp
12	3	INS 0506 - Locking knob
13	1	INS 0507 - Frontal fixation
14	1	Tibial cutting block 0°
15	1	Tibial cutting block 2°
16	1	INS 0578 - Height locking screw & Standard knob
17	1	INS 0625 - Posterior and chamfer cutting block 23 mm IREL
18	1	INS 0624 - Posterior and chamfer cutting block 18 mm IREL
19	1	INS 0626 - Posterior and chamfer cutting block 18 mm ILER
20	1	INS 0627 - Posterior and chamfer cutting block 23 mm ILER
21	1	INS 0584 - Cutting block 6 mm
22	1	INS 0518 - Height and 9° slope adjustor
23	1	INS 0517 - Height and 6° slope adjustor
24	1	INS 0509 - Height and 3° slope adjustor
25	1	INS 0623 - Height and 0° slope adjustor
26	1	INS 0652 - Hemi-spacer 10 mm
27	1	INS 0505 - V guide
28	1	INS 0651 - Hemi-spacer 9 mm
29	1	INS 0694 - Mounted tibial arm ILER
30	1	INS 0580 - Mounted tibial arm IREL
31	2	INS 0576 - Ankle pin & Standard knob
32	1	INS 0498 - Circular frame
33	2	INS 0760 - Ankle clamp



N°	Qty	Designation
1	1	INS 0716 - Femoral sizer T2 IR-EL
2	1	INS 0717 - Femoral sizer T4 IR-EL
3	1	INS 0718 - Femoral sizer T6 IR-EL
4	1	INS 0587 - Axial cutting guide
5	1	INS 0721 - Femoral sizer T6 IL-ER
6	1	INS 0720 - Femoral sizer T4 IL-ER
7	1	INS 0719 - Femoral sizer T2 IL-ER
8	1	INS 0586 - Alignment rod extension
9	1	INS 0124 - Alignment rod Ø 6
10	4	INS 0532 - Threaded pin Ø 3.2 L65
11	4	INS 0531 - Threaded pin Ø 3.2 L85
12	1	INS 0946 - Monobloc impactor
13	1	INS 0949 - Monobloc hex screwdriver Ø 3.5 mm
14	1	INS 0947 - Monobloc femoral impactor
15	1	INS 0947 - AO adaptor
16	2	INS 0581 - Headed pins Ø 3.2 x 40
17	1	INS 0581 - Drill bit Ø 11 x 11
18	1	INS 0548 - Drill bit Ø 6x30
19	1	INS 0585 - Drill bit Ø 3.2x145
20	1	INS 0550 - Cutting gauge



Notes

Notes

www.serf.fr

Distribué par

85 avenue des Bruyères
69150 Décines-Charpieu
FRANCE

Tel. +33 (0)4 72 05 60 10
Fax +33 (0)4 72 02 19 18
serf@serf.fr

All the medical devices mentioned in this document are CE marked in accordance with Medical Device Directive 93/42/EEC and its amendments unless they are specifically identified as "not CE marked".
The medical devices mentioned in this document are class I, IIa, IIb and III devices.

Class IIa, IIb and III medical devices are marked "CE 0459" by LNE/G-MED.

Before using any product, make sure to read the instructions for use and the surgical technique. Refer to the labels and instruction leaflets for the complete list of indications, contraindications, risks, warnings, precautions and directions for use. For further information please contact SERF's local distributor.

©2018 SERF. All rights reserved. **Uni Kroma®** is a trademark of SERF.

Distributed by

CE 0459

ONEORTHO MEDICAL – France
Parc INOPOLIS - 206 Route de Vourles
69230 Saint-Genis Laval, France

SFRAT020007-B Édition n°2 - 2018

DESIGN \ HARVEST.AGENCY