

UNIKROMA

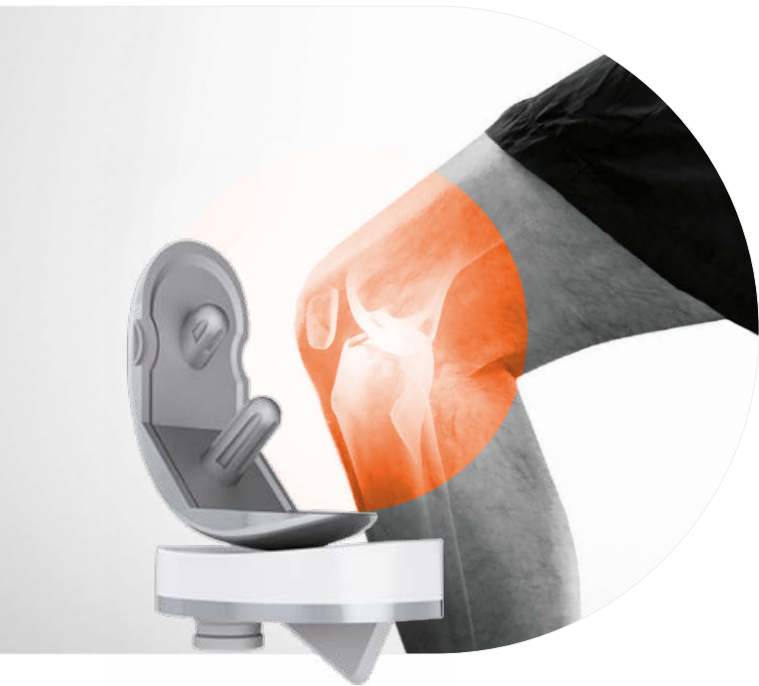
UNICOMPARTMENTAL
KNEE PROSTHESIS



S U R G I C A L T E C H N I Q U E

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KNEE

CONCEPT OVERVIEW



CONTRAINDICATIONS

The **UNI KROMA**[®] prosthesis must not be used in the following cases:

- Inflammatory and microcrystalline rheumatoid damage,
- Functional deficiencies of the cruciate and/or collateral ligaments,
- Excessive fixed flexion or varus deformity,
- Arthritic damage in the femoro-tibial contro-lateral compartment,
- Absence of the anterior cruciate ligament,
- History of high tibial osteotomy.
- Acute and chronic infectious diseases regardless of etiology and location,

INDICATIONS

The **UNI KROMA**[®] prosthesis, unless otherwise stated in the technical documentation, is recommended in the following cases:

- Primary or secondary isolated osteoarthritis.
- Isolated osteonecrosis.
- The prosthesis is indicated for patients whose bone growth is complete.

RISK FACTORS

The following factors should prompt caution regarding implantation of the **UNI KROMA**[®] prosthesis:

- Damage in the patello-femoral compartment.
- Previous UKA (unicompartmental knee arthroplasty).
- Patients who have undergone a previous osteotomy.
- Obesity or excessive weight (body mass index > 30 kg/m²).
- Neuromuscular and psychiatric pathologies which can cause the failure of the fixation and postoperative care.
- The prosthesis is indicated for patients whose bone growth is complete.
- Inadequate or insufficient bone support not allowing proper anchoring of the prosthesis.
- Physical activity.
- Known allergy to one of the materials of the implant.
- Pregnant women.

To make any changes to improve product quality without prior notice. The conditions of use for the implant are detailed in the instructions for use.

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IMPLANTS

- The condyles, baseplates, and inserts are anatomical.
- The condyle is part of a spherical piece enabling surface support designed to reduce PE wear.

MECHANICAL STABILITY

For the cementless versions, press-fit is achieved with the two tapered pegs on the condyle and with the flange and peg on the baseplate.

If necessary, one version of the condyle and two cemented versions of the baseplate are available.

CEMENTLESS ANCHORAGE

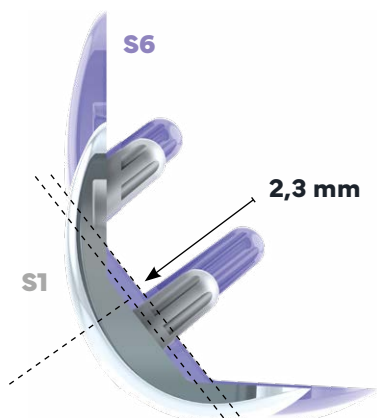
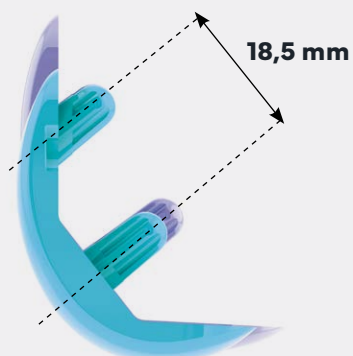
Corundum-blasted surface finish with dual Titanium T40 + HAP coating.



DESIGN OF THE IMPLANTS

Condyles S1 to S4

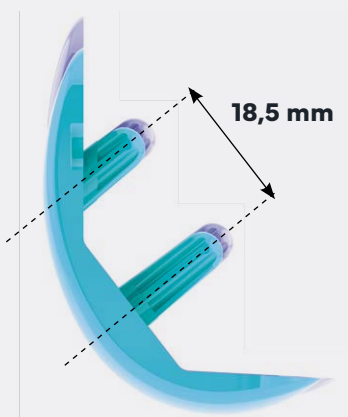
The chamfer and peg locations are identical, with a centre distance of 18.5 mm.



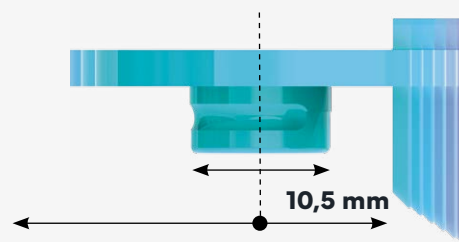
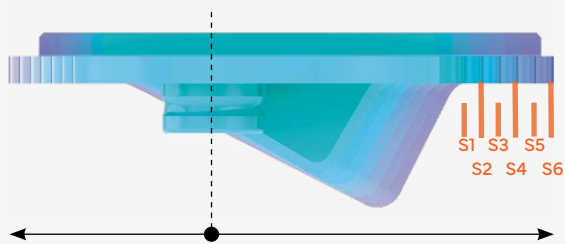
Comparison between condyles S1 and S6

Condyles S5 and S6

The chamfer and peg locations are identical, with a centre distance of 18.5 mm.



Between S4 and S5 there is a change in the chamfer: the cut is larger by 2.3 mm.



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

Anatomical condyle

6 sizes, cemented or cementless.
Made of cast cobalt chrome.
T40 + HAP coating.



Metal anatomical baseplate

6 sizes, metal-backed, cemented or cementless.
Made of cast cobalt chrome for the cemented version.
Made of machined titanium for the cementless version.
T40 + HAP coating.

Anatomical insert

6 sizes, 4 thicknesses, made of polyethylene.
Thicknesses of 9, 10, 11, and 12 mm.
Vacuum packaged.



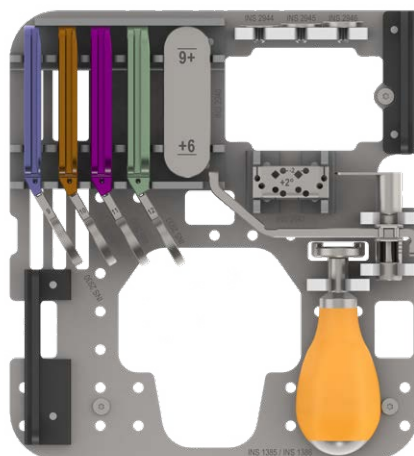
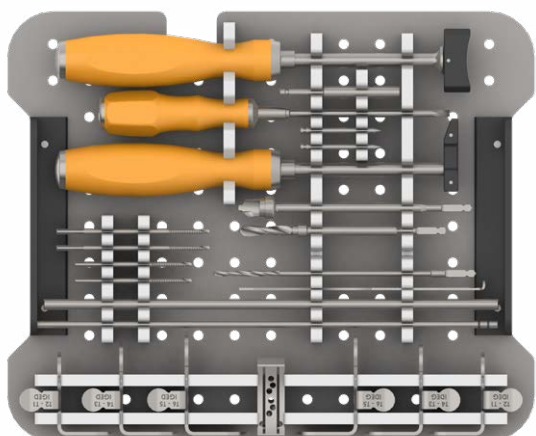
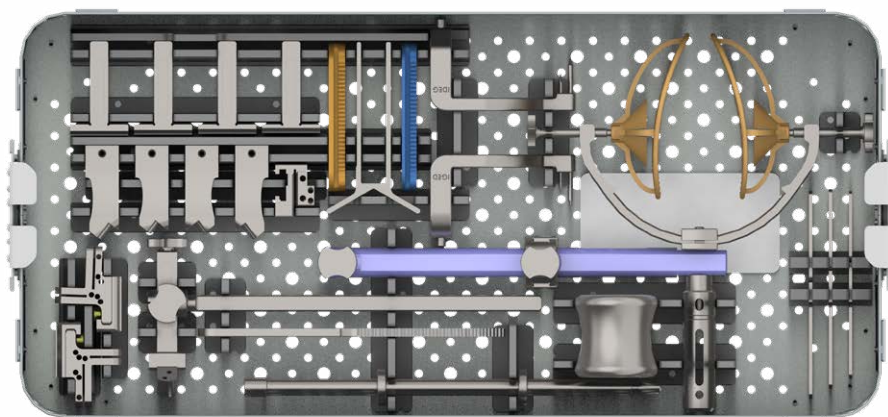
Fixation screws

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

The sizes must be chosen depending on the patient's morphology and the compatibility of the component sizes must be ensured. All of the femoral implant sizes are compatible with all of the tibial baseplate sizes. The tibial insert must match the size of the metal baseplate

INSTRUMENTATION

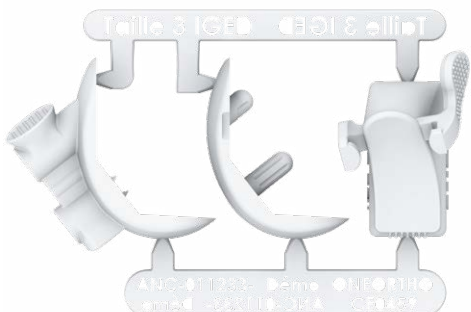
A reduced number of metal instruments to make all of the femoral and tibial bone cuts. This instrumentation is the same for all sizes.



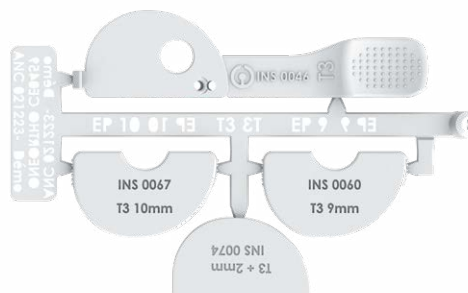
There is a kit of single-use instruments for each femoral and tibial size. The kits are supplied sterile.

Two kits are necessary to implant **UNI KROMA®**.

Condyle kit

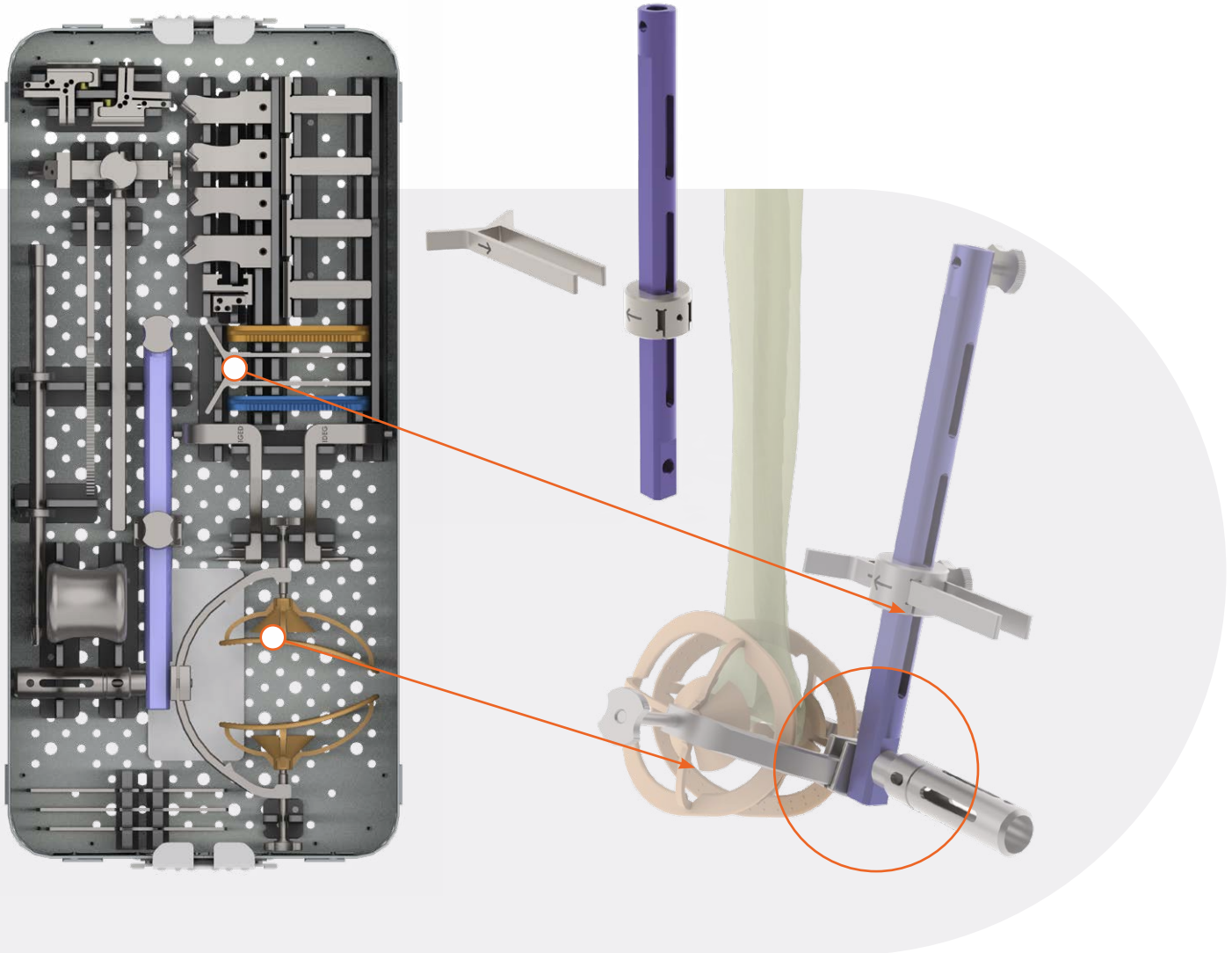


Tibial kit



These kits are used for anchorage and trials for a given size.

TIBIAL CUTS AND EXTRAMEDULLARY ALIGNMENT



To facilitate the positioning of the tibial cutting guide, it is recommended to assemble the ankle clamp, the extramedullary alignment rod, and the anterior V sliding guide.

The ankle clamp is aligned with the bottom of the blue extramedullary alignment rod.

The V sliding guide is placed and locked in a fully anterior position so as not to interfere with the positioning of the extramedullary alignment rod.

FIXATION OF THE LOWER ANKLE CLAMP AND ROTATION ADJUSTMENT

- 1 Locate the centre of the malleoli and secure the ankle clamp by symmetrically tightening the two lateral screws.

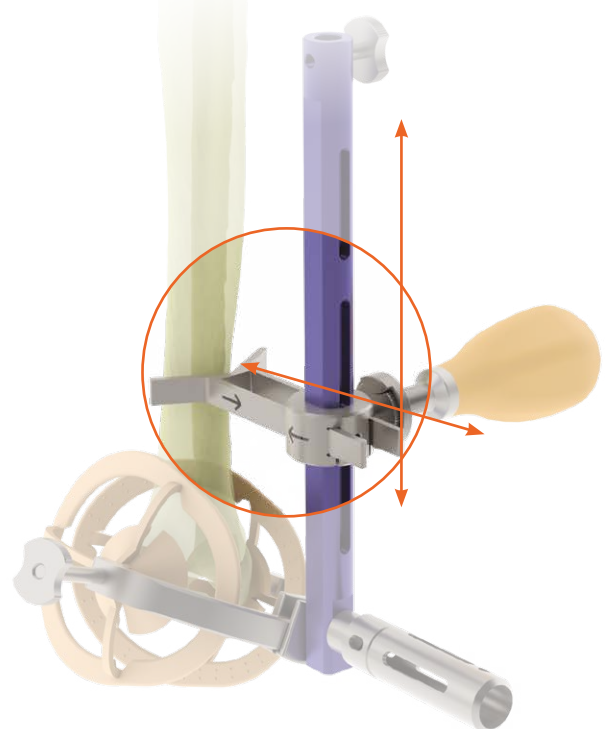
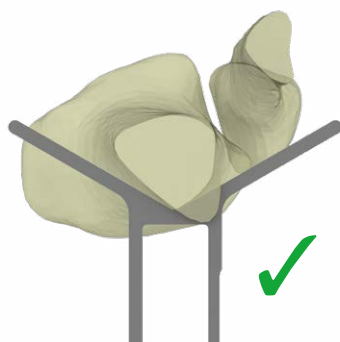
Both screws can be covered with removable plastic caps to protect the malleoli, the longest section of the cap being placed posteriorly.

The ankle clamp must be stable on the medial malleolus.



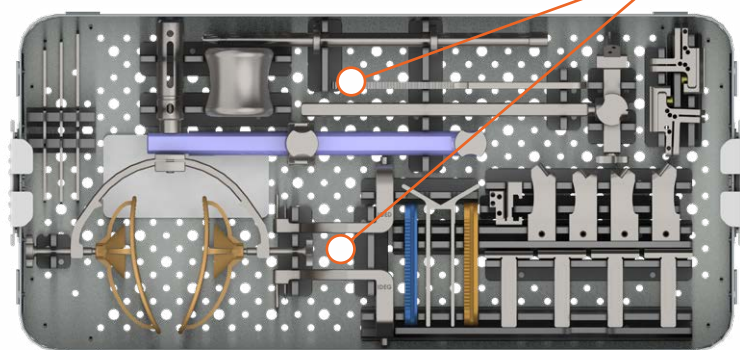
- 2 Support the V sliding guide against the lower third of the tibia and tighten with the lateral screw; the universal clamping handle can be used.

Locate the anterior crest, loosen the knurled handle, and adjust the rotation of the rod relative to the ankle clamp to align the V sliding guide with the crest, then moderately tighten the knurled handle.



POSITIONING AND FIXATION OF THE UPPER CROSSBAR

Assemble the upper section composed of the central slider and the appropriate tibial arm (MRL/MLL). Mount the upper assembly of the extramedullary alignment rod on the already stabilised lower assembly with the extramedullary alignment rod.

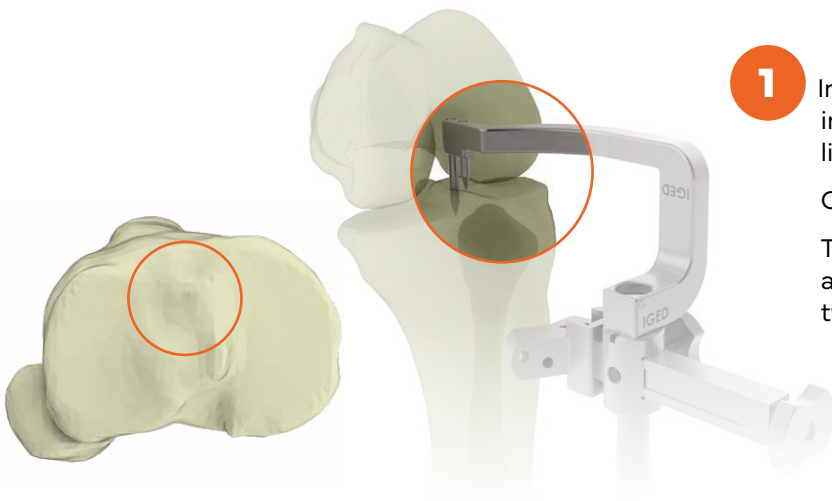


1

Impact the longest spike of the upper crossbar in the insertion point of the anterior cruciate ligament.

Check the rotation of the lateral alignment rod.

The 0° rotation position, the area in which the alignment rod must be situated, is identified by two marks etched on the circular frame.



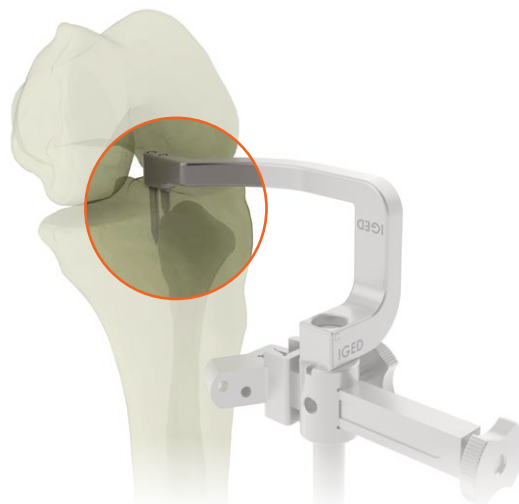
2

Impact the second spike until complete contact with the bone.

The alignment rod is parallel to the mechanical axis of the tibia on the frontal and sagittal planes.

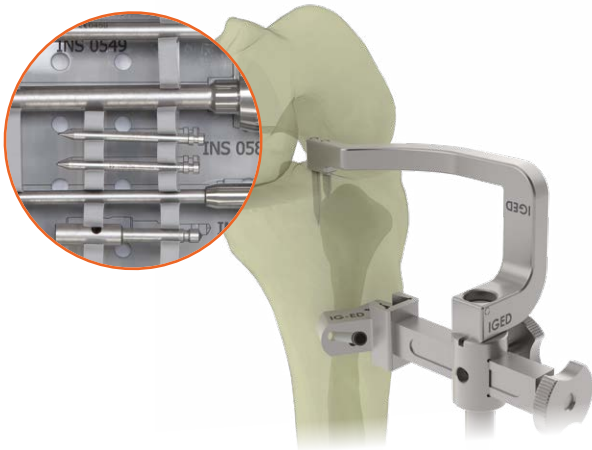
Tighten the screw on the blue slider.

The universal clamping handle can be used to ensure the various knobs are completely tight.

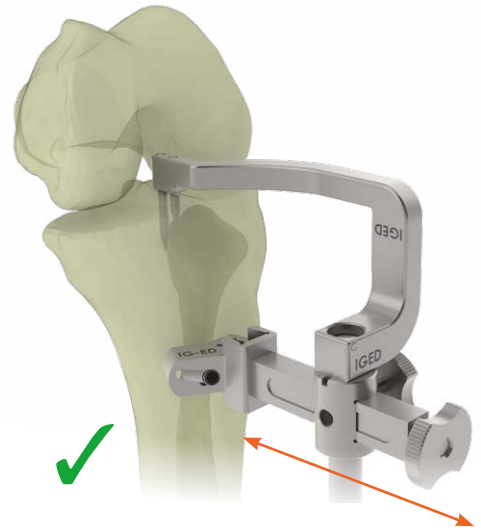
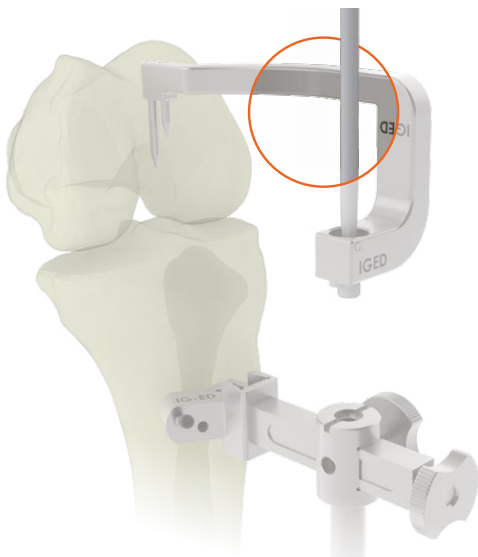


Steps 3 to 5 are optional if the decision is made to leave the upper arm in position.

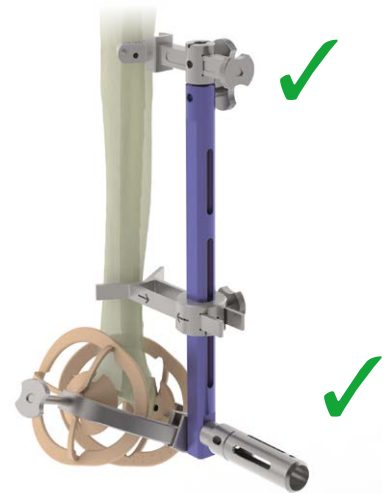
- 3** Apply the slider to the ATT and tighten the lateral screw to immobilise it. Check that the return of the slider with the two fixation holes is on the side of the operated compartment. If not, unscrew the knob in front of you, take out the slider, and position it the right way around.



Make sure that the knob on the extramedullary alignment rod and the lower handle is completely tight. For short tibiae, make sure that the two tightening knobs (on the right here) are on opposite sides to avoid conflict between them.



- 4** Attach the slider against the ATT with one or two headed nails. Make sure that the entire assembly is properly centred and stabilised.

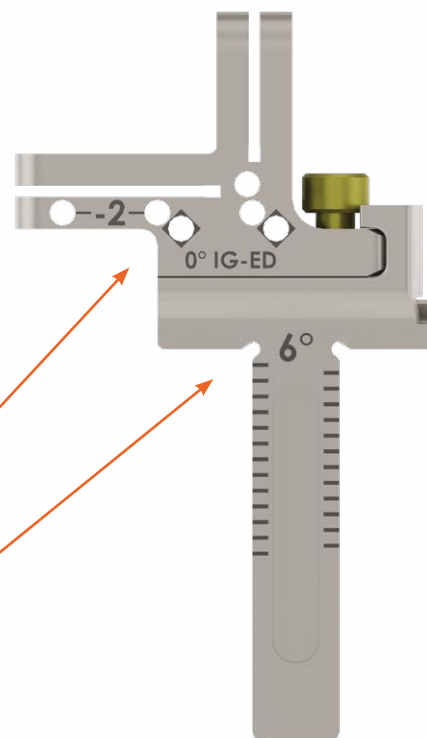
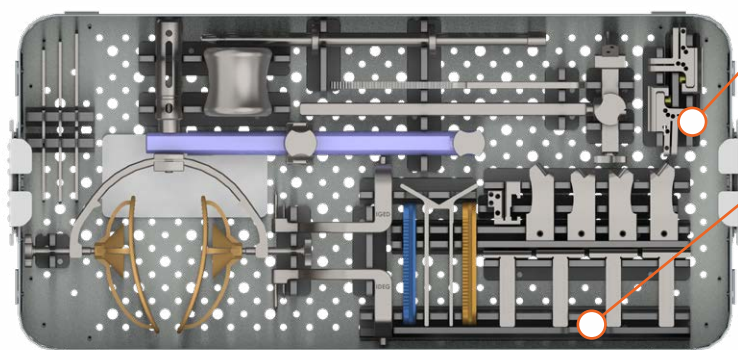


- 5** Remove the crossbar using the mass extractor after completely unscrewing the upper screw with the 3.5 mm screwdriver. The assembly of the mass extractor is described below.



POSITIONING AND FIXATION OF THE CUTTING GUIDE AND PERFORMING THE TIBIAL CUTS

Mount the cutting guide on the guide holder using the slider and the lateral screw.
A 6° posterior slope and 0° varus are illustrated here.

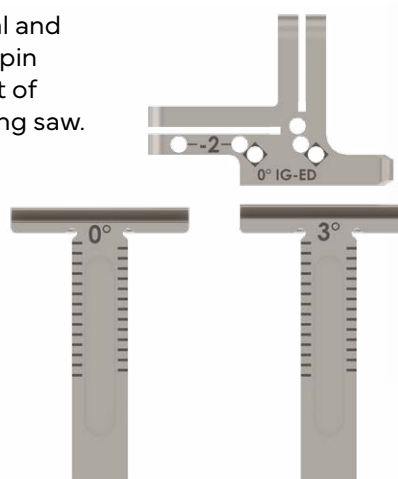
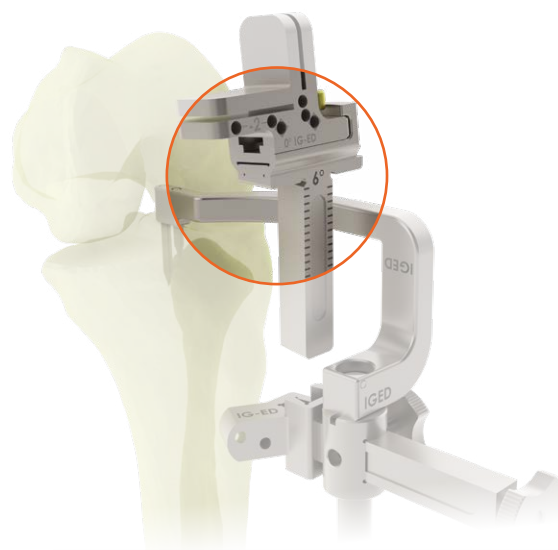


- 1 Select the height and slope adjuster (T piece for the tibial cut (0°, 3°, 6°, 9°) as well as the 0° or 2° varus tibial cutting guide depending on the surgical planning.

Position the whole assembly in the frontal fixation (i.e. on the upper frame), with (or without) the upper arm.

On the tibial cutting guide, the squares surrounding the 2 lower holes indicate the zero position of the pins, using the -2 holes enables a 2 mm recut.

The hole at the intersection of the tibial and sagittal cuts can be used to position a pin that will limit the angular displacement of the oscillating saw and the reciprocating saw.



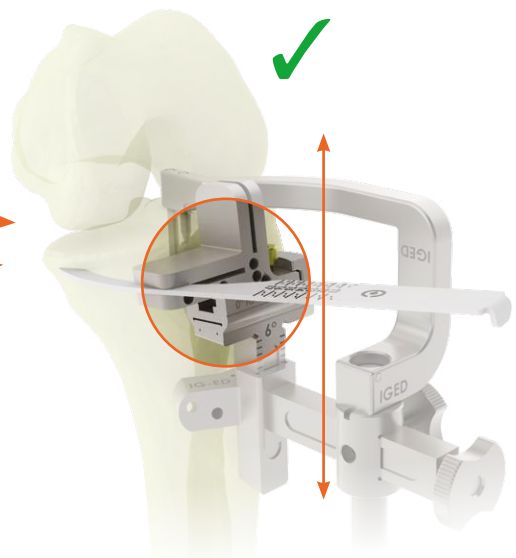
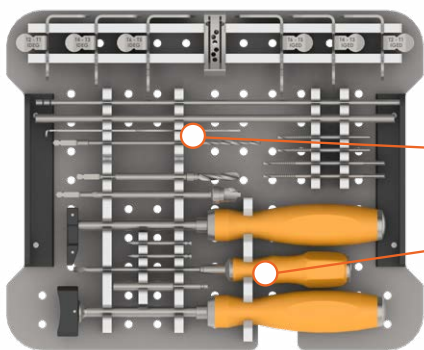
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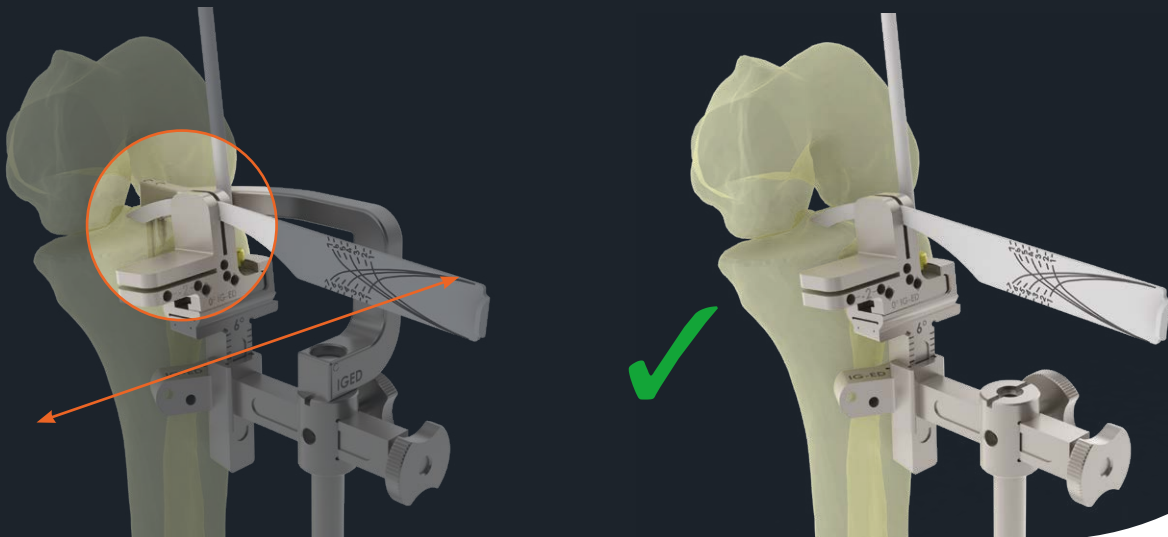
The cut height can be adjusted with:

- the tibial palpator inserted in the cutting slot, the tip of which will palpate the reference point.
- the cutting gauge which will be positioned right beneath the tibial osteophyte.

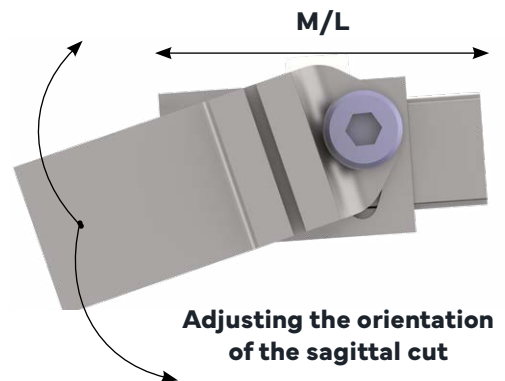
Example :

E.g. if the palpator is set to 6 mm, the cut will thus be located 6 mm below the reference point. Tighten the frontal screw to lock in this height.





- 3** Adjust the M/L orientation and position of the sagittal cut by sliding the cutting gauge in the cutting slot. Position the cutting gauge at the top of the medial tibial spine and tighten the upper screw with the 3.5 mm screwdriver to immobilise this position.



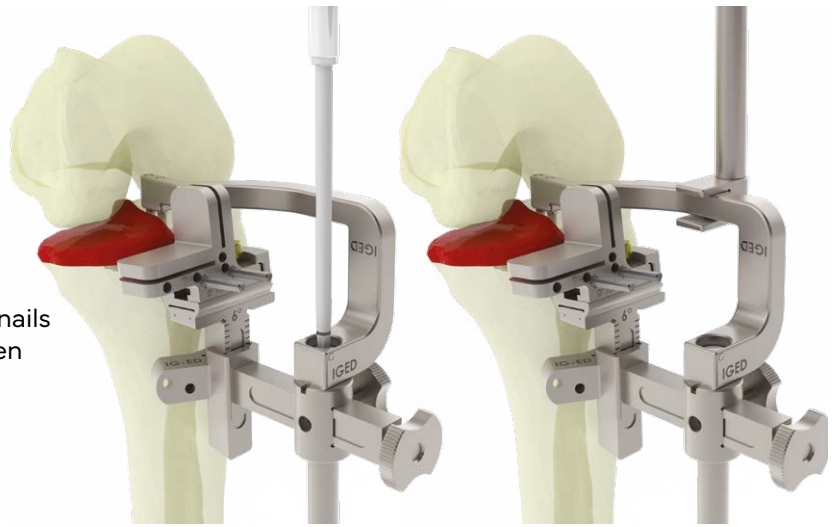
- 4** Attach the block using threaded pins. For this, on the table (or after positioning the pins in the cutting guide), completely insert the whole three-facet tip of the pin into the adaptor. Then position and screw the pin in one of the two holes surrounded by a square.

Then do the same with the second pin.

Perform the cuts through the slots with a straight blade 10 to 15 mm wide and 1.27 mm thick.

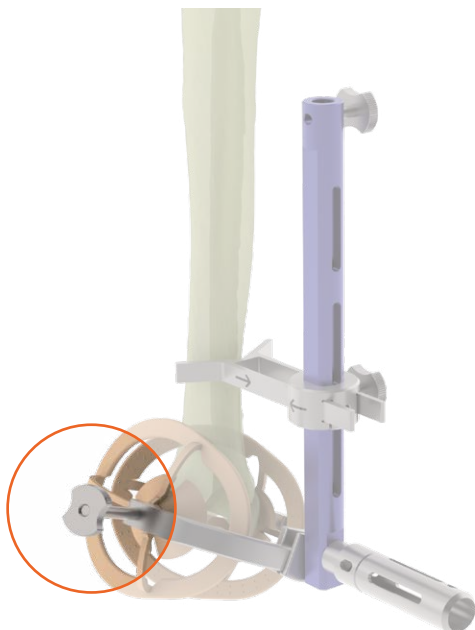
5

Remove the offset arm by completely unscrewing the upper screw, then using the mass extractor. It is also possible to remove the headed nails from the slider if the arm has already been removed.



6

Loosen the upper frontal knob then the knob on the extramedullary alignment rod. Remove the assembly, leaving only the cutting guide with its guide in position.



7

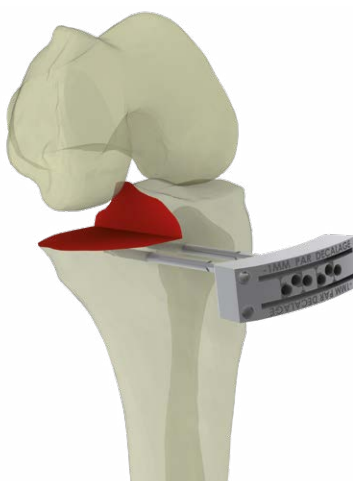
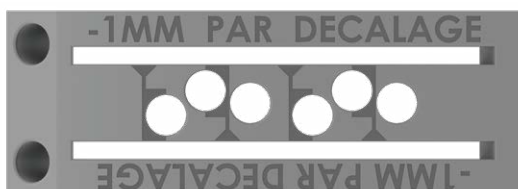
Loosen the knobs at the malleoli and remove the extramedullary alignment frame.

8

If a 2 mm recut is necessary, it can be performed by placing the cutting guide on the pins left in position (the "-2" holes are slid onto the pins).

A 1 mm recut is also possible by positioning the axial cutting guide on the pins left in position.

Position the cutting guide using the holes without laser engraving. Stabilise the recutting guide using a pin inserted into one of the converging holes.

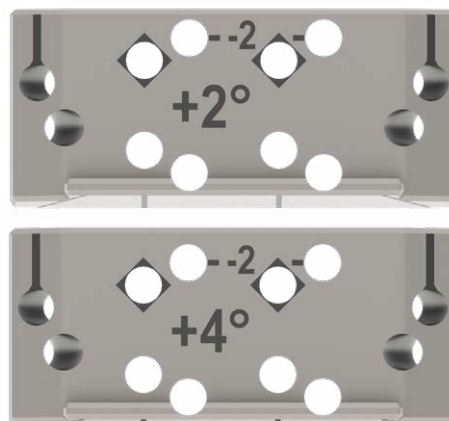


9

If the first cut have not enough tibial slope, the tibial slope cutting guide allows on one side to increase the slope of the initial cut by 2° and on the other side to increase it by 4° .

Place the cutting guide on the tibial pins left in place and using the holes surrounded by a square.

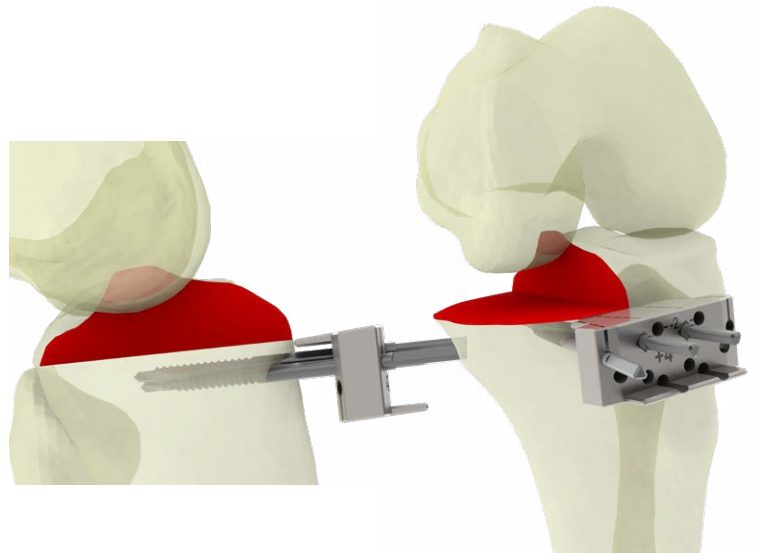
Position the cutting guide against the tibia and lock its position with converging pin placed in one of the 2 holes connected by a laser line (use the internal hole for a medial uni and the external hole for a lateral uni).



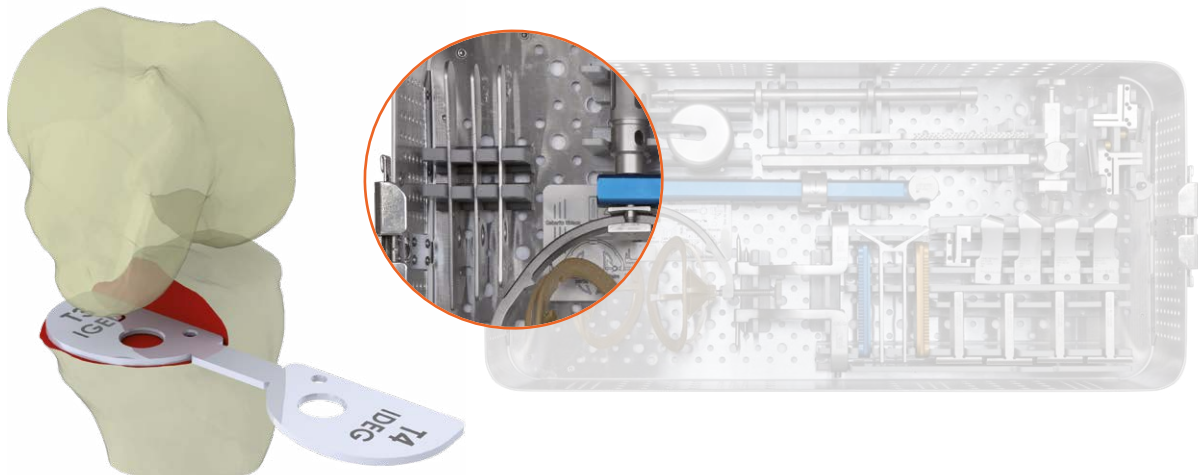
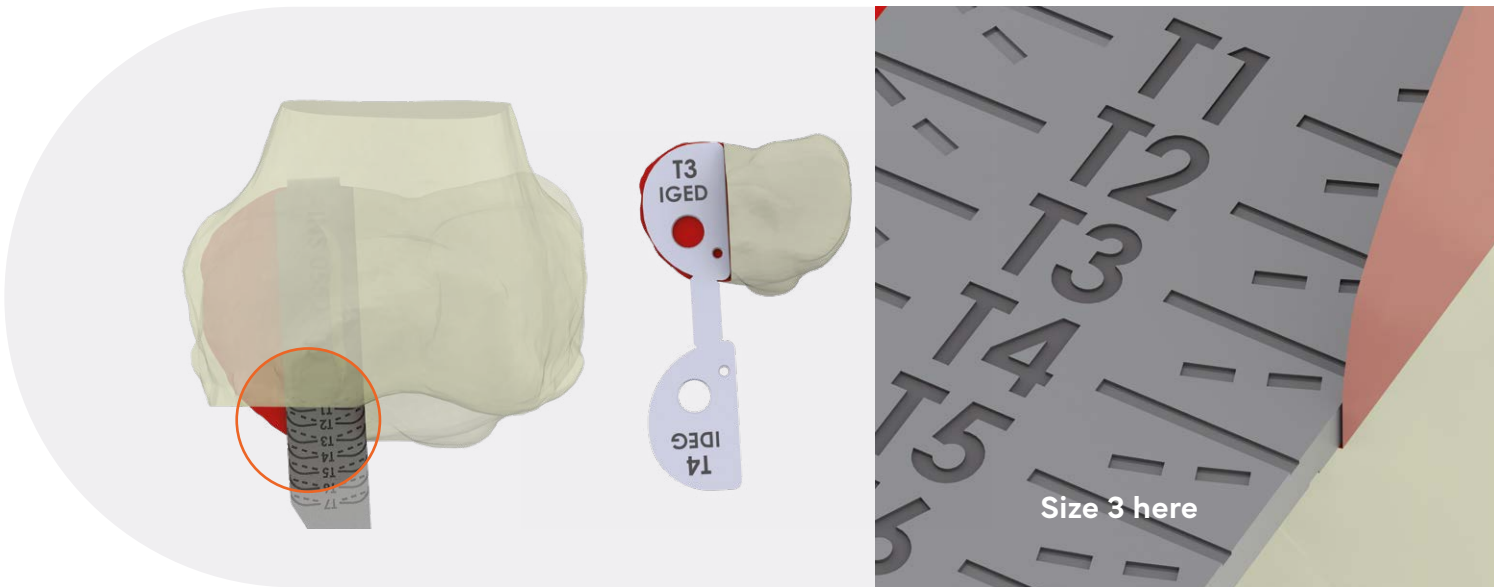
Put the saw blade on the cutting guide and cut again.

It is possible to simultaneously augment the tibial slope and the cutting height by 2mm.

For this, place the tibial slope cutting guide on the pins left in place and using the identified upper holes -2mm.

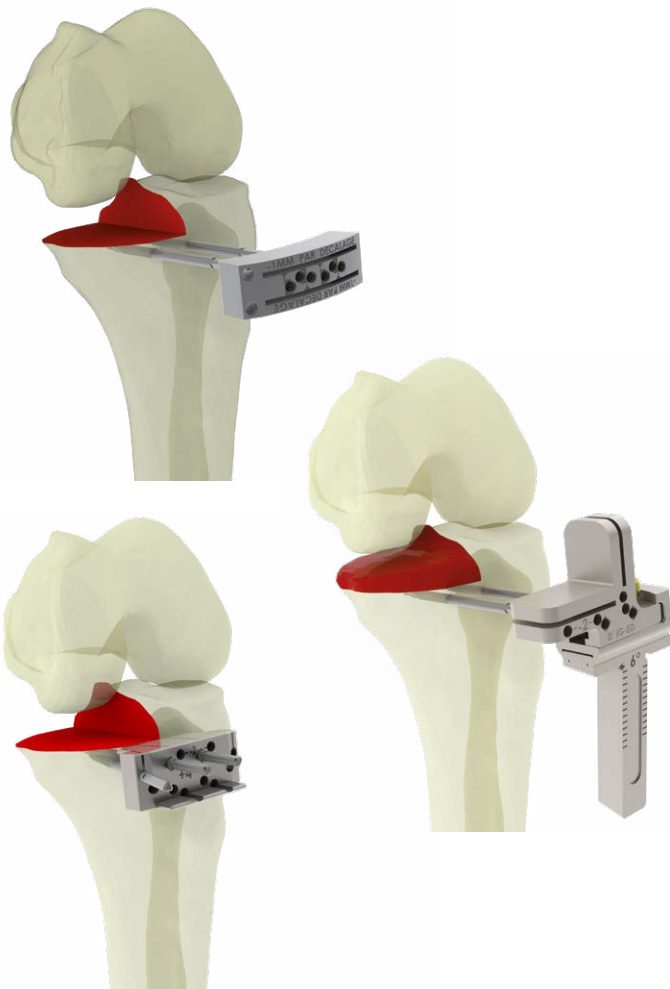
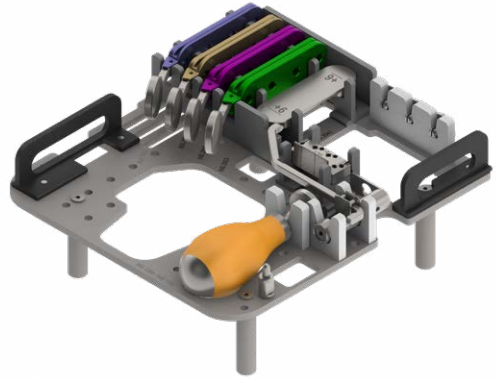


- 10** Identify the size of the tibial implant at the tibial spine ridge, with the cutting gauge positioned — by means of its hook — posterior to the tibial cut. This measurement can also be performed with the tibial sizer.



FEMORAL CUTS AND METAL GUIDES

- 1** To evaluate the flexion and extension gap, use the fixed spacer: 9 mm (blue), 10 mm (yellow), 11 mm (purple), or 12 mm (green). Place the knee in flexion and insert the 9 mm spacer. Estimate the gap (and ensure the presence of safety laxity) and then place in extension to evaluate gap.



Depending on the balancing gap in extension and in flexion it is possible:

- cut the tibia again to 2 mm (with the cutting tibial guide);
- cut the tibia again to 1 mm (with the cutting axial guide);
- augment the tibial slope from 2° to 4°;
- augment the tibial slope from 2° to 4° and augment the thickness of the tibial cut to 2 mm.

See previous pages

If in extension the femoral distal wear is important and it is necessary to cut less than 6mm to compensate for cartilage wear (and decrease the gap in extension), it is possible to use the cylindrical wedges (see next steps).

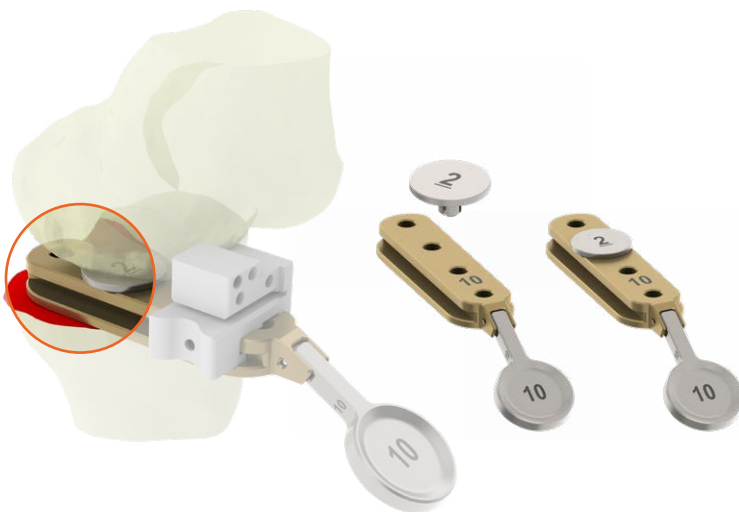
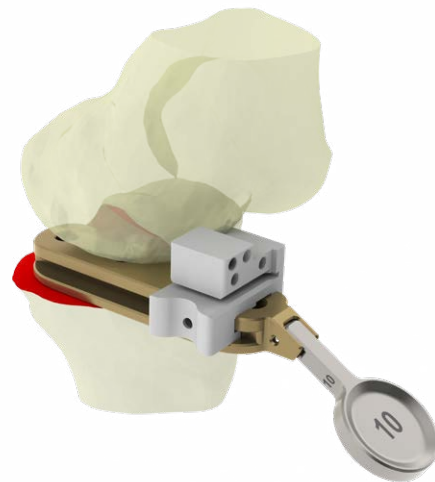
To note:

For external uni if the posterior femoral wear is important and it is necessary to cut less than 6mm to compensate cartilage wear, it is possible to use cylindrical wedges (see femoral cut completion step).

INSTALLATION, FIXING OF THE METAL CUTTING GUIDE AND REALIZATION OF THE DISTAL CUT

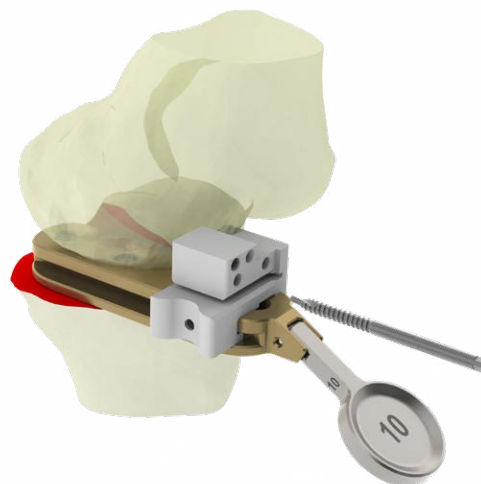
- 1** Position the distal cutting guide on the spacer (pre-approved) and slide it until it comes into contact with the femoral bone.

It is necessary to ensure beforehand that the spacer is well supported on the tibial cut, in order to have parallel cuts.



- 2** In the case of significant distal femoral wear, a 1, 2, or 3 mm compensation spacer can be inserted. Example: a 2 mm spacer will allow a 4 mm distal femur cut. The implant being 6 mm thick, 2 mm of wear will be offset. Assemble the cylindrical compensation spacer (use one of the 2 central holes to be sure of the distal femoral contact). Be careful not to exceed the indications for a unicompartimental prosthesis where there is excessive condyle wear.

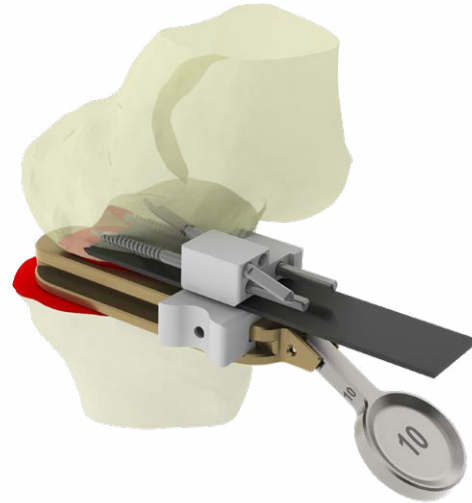
- 3** Attach the cutting guide using threaded pins. These pins are positioned by the power tool with the AO adaptor. A converging hole ensures the stability of this block.



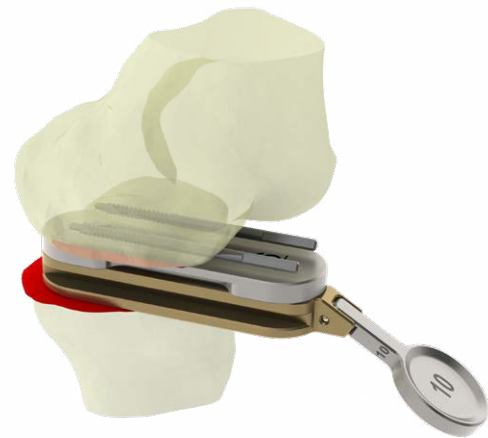
- 4** Perform the cut through the slot with the knee in extension, with a straight blade 10 to 15 mm wide and 1.27 mm thick. Once the cut has been carried out, the converging pin can be removed.

To note:

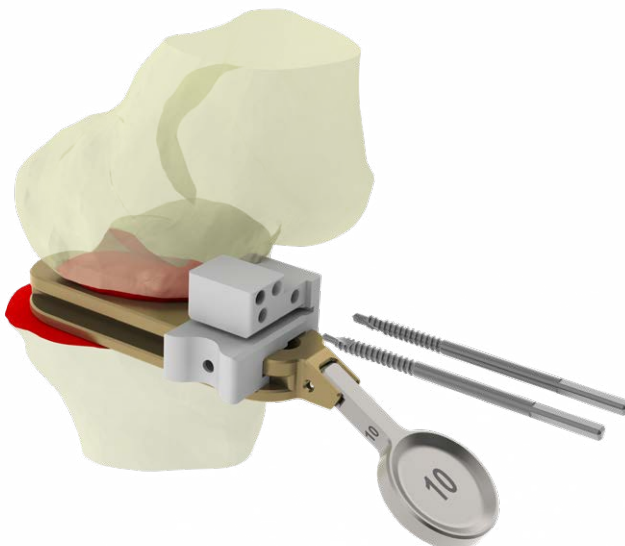
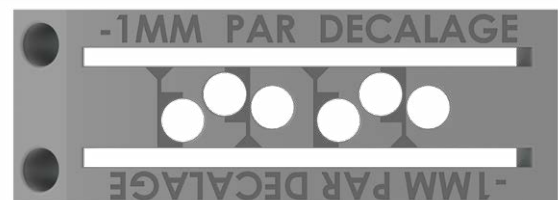
It is possible to perform the cut in extension position if the cylindrical compensation spacer is not used. To do this remove the spacer before the flexion position and making the cut.



- 5** When the femoral distal cut is performed, it is possible to check the new gap created. Remove the spacer and the cutting guide. On the spacer, join the fixed compensation spacer of 6mm that will compensate the thickness of femoral implant and place between the tibial cut and the femoral distal cut. Check the gap created.



A 1 mm recut is possible by placing the axial cutting guide on the pins left in position. Position the cutting guide using the holes without laser engraving. Stabilise the recutting guide using a pin inserted into one of the converging holes.



- 6** Remove the pins from the cutting guide. Remove the spacer with its cutting guide.

7

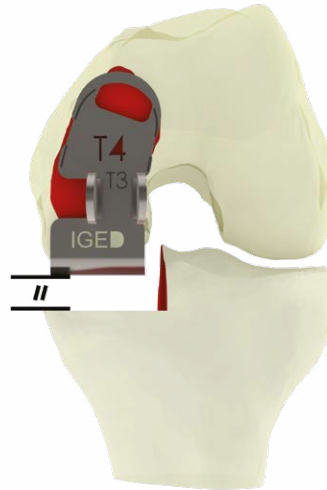
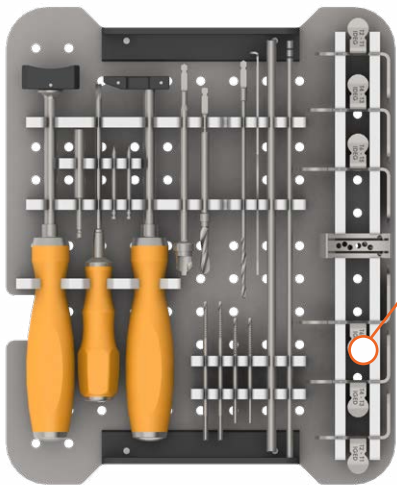
Determine femoral sizing before performing the posterior cut.

Use the femoral sizer for this (available in sizes S1-2, S3-4, and S5-6); apply it flat on the distal cut and the posterior condyle.

The outer edge of the sizers shows the large sizes, 2, 4, and 6, while the side slots and the top of the upper window show the small sizes, 1, 3, and 5.

If in doubt between two sizes, always choose the smaller one.

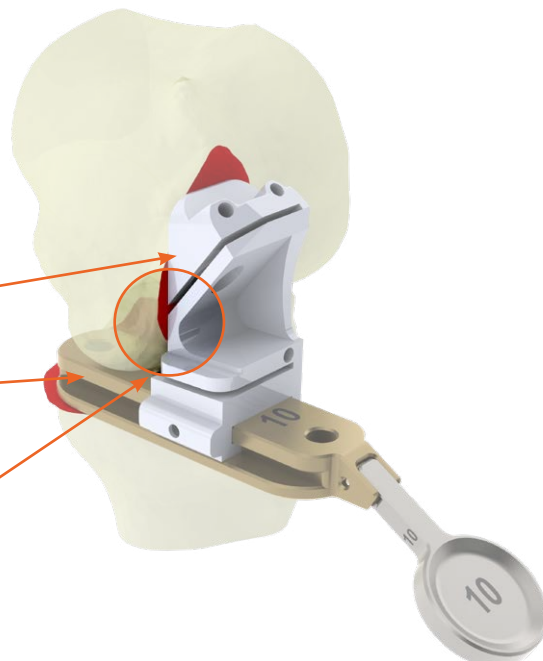
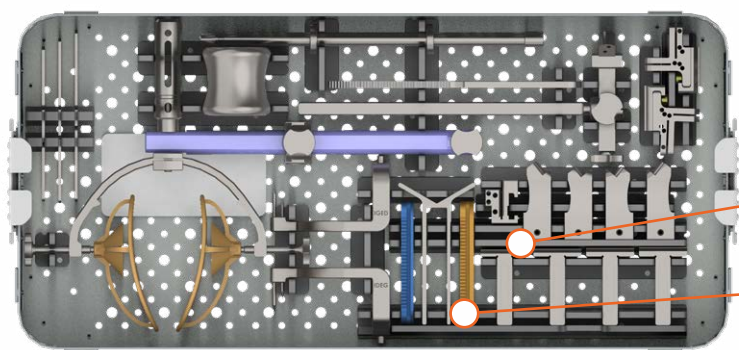
Be careful of the change in the chamfer between sizes 4 and 5 (see page 4).



Size S3 here

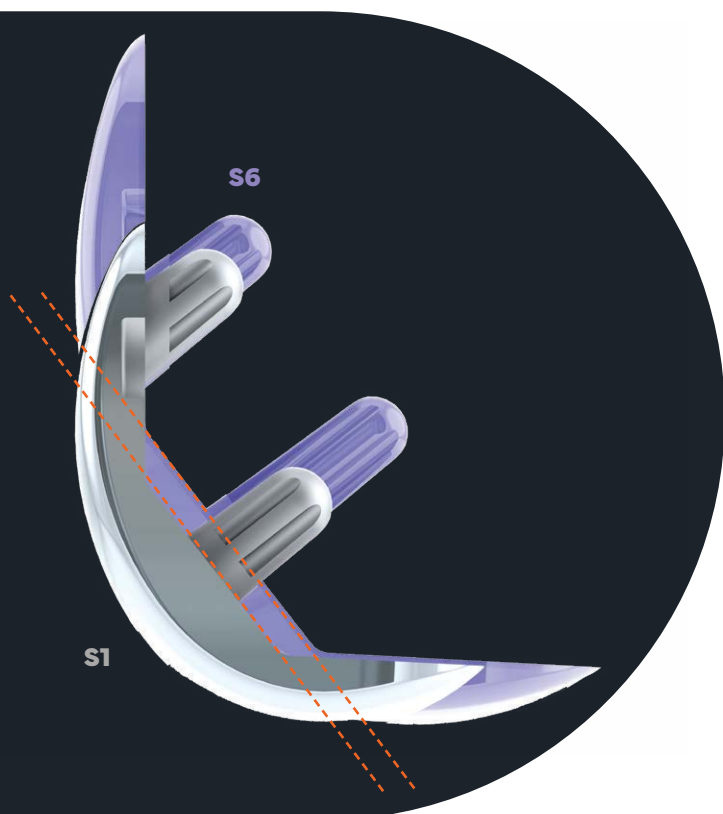
Be careful of rotation with the sizers.
The posterior side must be parallel to the tibial cut.

POSITIONING AND FIXATION OF THE METAL CUTTING GUIDE AND PERFORMING THE POSTERIOR AND CHAMFER CUTS



Mount the cutting guide of the previously chosen size on the spacer used for the distal femoral cut.

While handling, be careful of the cutting edge located at the intersection of the posterior chamfer cut and the distal cut.



1 Choose the cutting guide depending on the femur size determined in the previous step.

2 block sizes are available, one for the S1, S2, S3, and S4 implants, and another for the S5 and S6 implants.

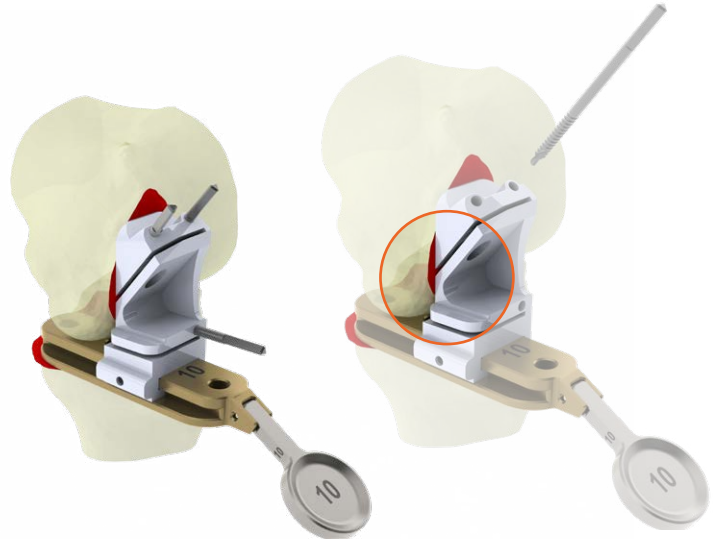
The difference lies exclusively in the chamfer (see the next page).

A change from S4 to S5 requires the chamfer to be recut.

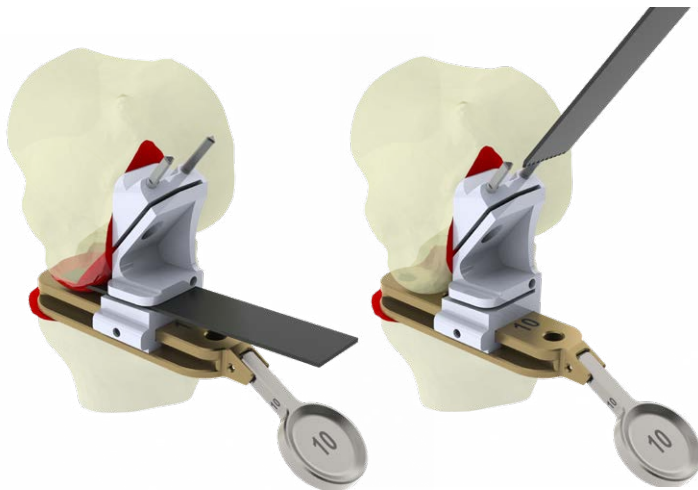
On the other hand, it is not possible to change from S5 to S4 because of the change in the chamfer.

Ensure that there is proper contact between the cutting guide on the distal femur cut and the spacer on the proximal tibial cut before positioning the pins.

- 2** Attach the cutting guide using three 65 mm threaded pins. First, position the anterior pin on the notch side, then the second anterior pin, before finishing with the posterior pin (on the notch side). A 5 mm diameter and 30 mm long central fixation screw can replace a pin.



These pins are positioned by the power tool with the AO adaptor.



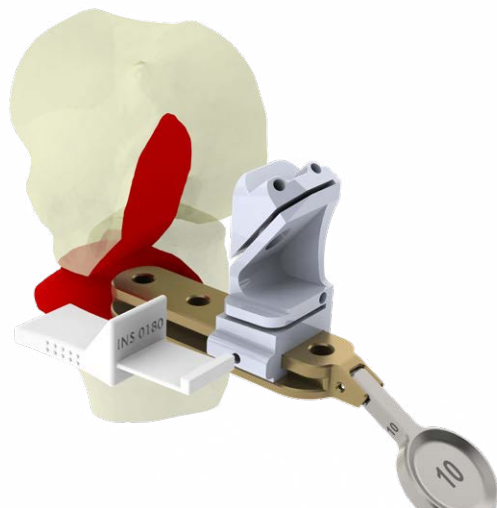
- 3** Perform the cuts through the slot with the knee in flexion, with a straight blade 10 to 15 mm wide and 1.27 mm thick. It is recommended to start with the posterior cut, then the chamfer.

- 4** Remove the pins from the cutting check. Remove the spacer with its cutting guide. If changing to size 5 or 6 after having performed the cuts for sizes 1, 2, 3, or 4, a chamfer recut will be required.

To do this, position the S5-6 cutting guide, then:

- Take the spacer from the S5 femoral kit
- Slide the thinnest part of the spacer into the posterior cutting slot and the thickest part against the posterior condyle cut.
- Apply the angled part flat against the chamfer cut.

Attach the cutting guide as previously described and proceed with the chamfer recut.



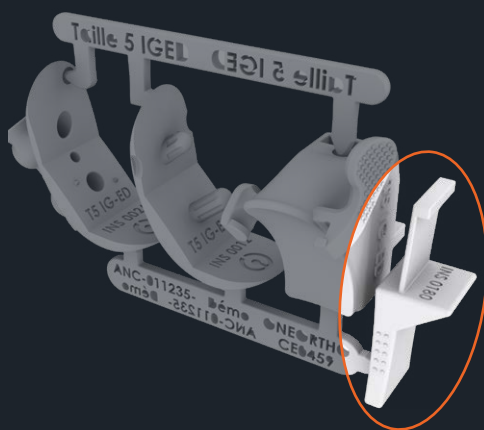
- 5** When the femoral distal cut is performed, it is possible to check the new gap created using the spacer and the fixed 6 mm compensated spacer and place the whole between the tibial slice and the distal femoral slice. Check the gap created.

ANCHORAGE AND TRIALLING

The trial implants are single-use and packaged by size. Open the boxes containing the trial kits for the previously determined tibial and femoral sizes.

The femoral kits include a drill guide for preparing the peg holes, a trial condyle, and an appropriately sized condyle holder tip.

The S5 femoral kit includes a spacer for the posterior chamfer recut.



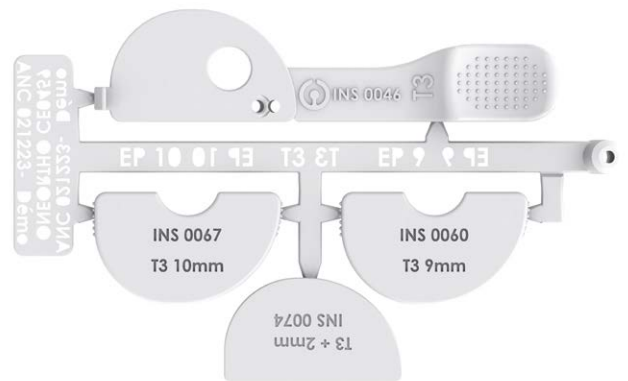
The tibial kits for the metal baseplate include a guide for preparing the peg hole, a drill guide for positioning the tibial screw, and 9 and 10 mm thick trial inserts.

An additional 2 mm removable spacer allows the thicknesses 11 and 12 mm by addition to the trial inserts.

ANCHORAGE AND TRIALLING OF THE METAL BASEPLATE

POSITIONING AND FIXATION OF THE GUIDE AND ESTABLISHING THE TIBIAL PEG

- 1** Detach the different pieces in the kit:
- The trial baseplate.
 - The 9 and 10 mm trial inserts.
 - The drill guide (T-shaped central frame).
 - The 2 mm spacer.



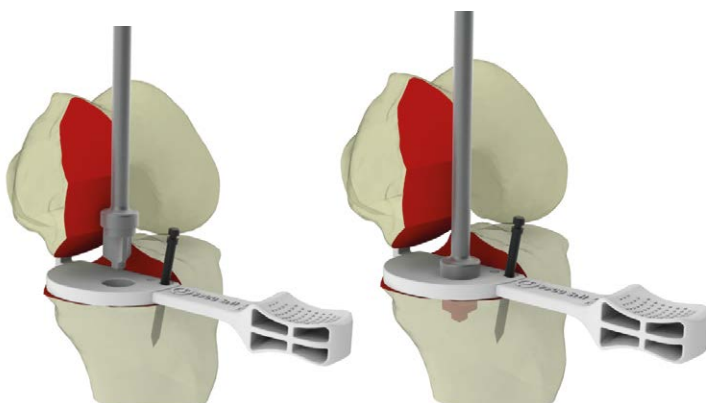
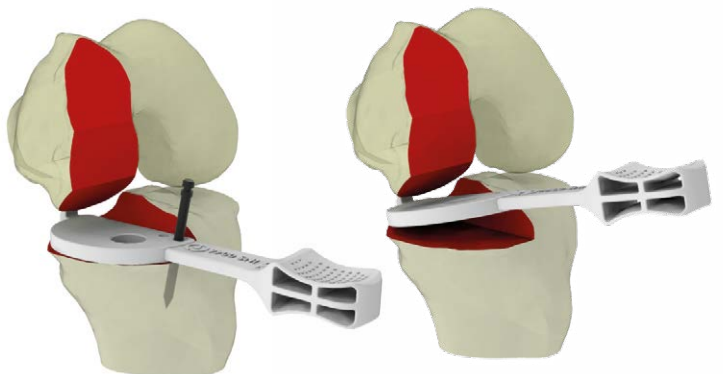
- 2** Remove the osteophytes before positioning the trial baseplate.

Position the trial baseplate on the tibial cut using the posterior hook for the A/P position, and support it against the tibial spine ridge for the M/L position.

NOTE: It is possible to break off the posterior hook that is oriented towards the femur (with a pliers). This will facilitate positioning.

Check that there is proper coverage and cortical support all along the bone periphery by the trial baseplate.

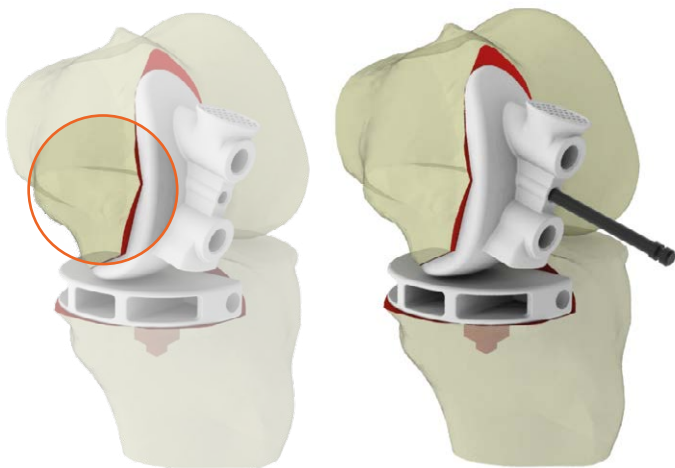
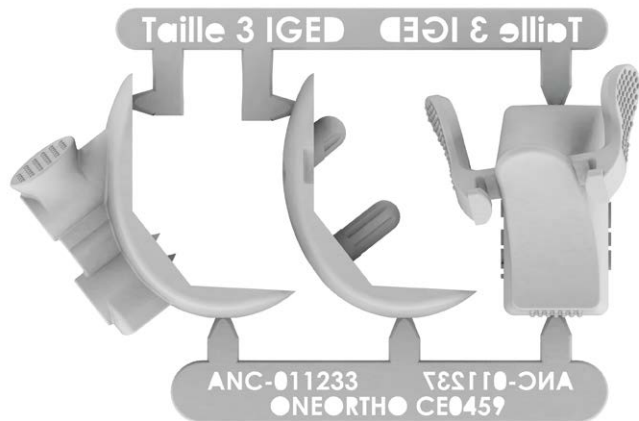
Attach with a partially impacted short headed nail.
Optional extra.



- 3** Drill the hole for the tibial baseplate peg with the 11 mm diameter and 11 mm long drill bit. First, remove the nail using the mass extractor tip, then remove the trial baseplate.

POSITIONING AND FIXATION OF THE GUIDE AND ESTABLISHING THE CONDYLE PEGS

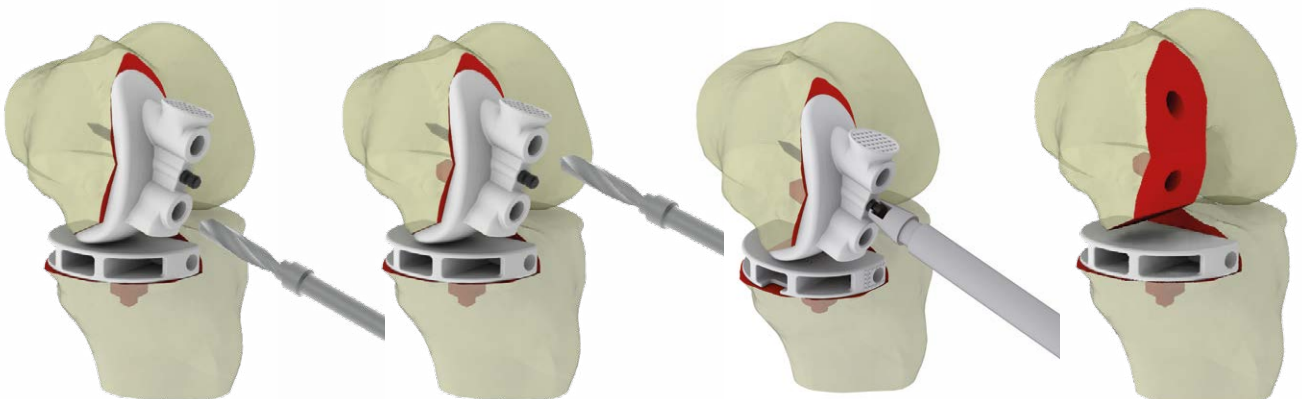
- 1** Detach the different pieces in the kit:
- The drilling guide
 - The trial condyle
 - The condyle holder
 - And in the S5 kit, the chamfer recut spacer.



- 2** Place the drilling guide in the M/L position on the cuts, ensuring there is no overhang laterally or at the femoral notch. Make sure to attach it with a headed nail after drilling with the 3.2 mm diameter drill.

- 3** Drill the holes for insertion of the two pegs with the \varnothing 6 mm 30 mm long drill bit.

Remove the nail with the mass extractor then remove the drilling guide.



POSITIONING AND PERFORMING THE TRIALS

1 Position the tibia and femur trial implants.

If the 10 mm thick tibial trial is not sufficient:

- clip the 2 mm removable spacer on the 9 mm trial implant to obtain a trial implant of 11 mm
- or clip the 2 mm removable spacer on the 10 mm trial implant to obtain a trial implant of 12 mm.

TO NOTE: Tibial trial thickness = thickness of the permanent insert + thickness of the metal baseplate.



Engage the trial condyle pegs in front of the femur holes.

Move the knee into 90° flexion then bring the trial implant as close as possible to the bone.

Remove the condyle holder either by pressing on the lateral tabs or by turning the condyle holder on itself (it unclips automatically).

Maintaining the knee at 90° flexion, impact with the hemispheric impactor.

2 Check the flexion and extension gaps.

Check the centring of the implants: the condyle must be centred on the lateral third of the insert.

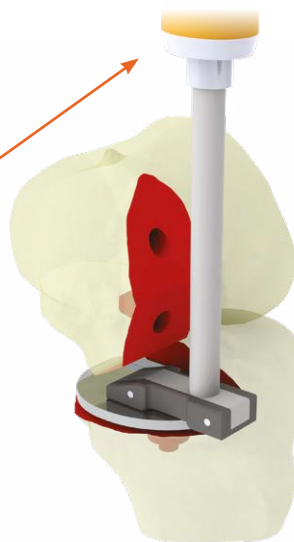
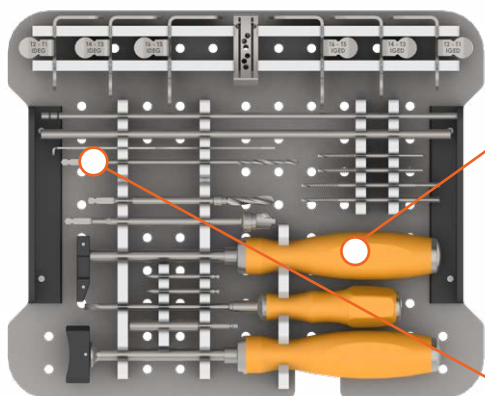
Check the inherent stability of the implants from extension to 130° flexion and rotational movements at 30° flexion.

Remove the posterior osteophytes to avoid limiting flexion and a potential conflict with the insert.



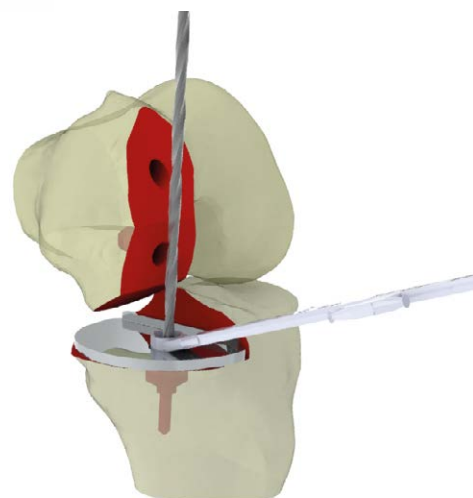
POSITIONING AND FIXATION OF THE PERMANENT IMPLANTS

- 1** Position the tibial baseplate with the peg towards the drilling carried out.
Impact the baseplate using the tibial impactor.
This impaction will directly place the prosthetic tibial flange.

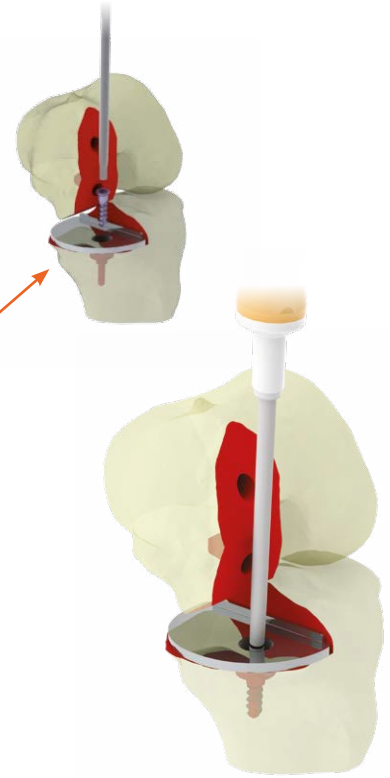
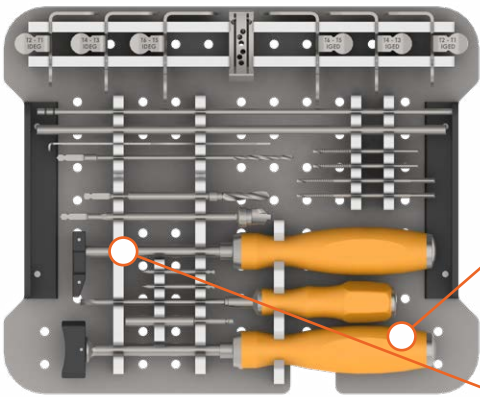


- 2** For the cementless version, position the adjustable drilling guide to guide the 3.2 mm drill (using the 3.2 mm diameter and 145 mm long drill bit) necessary for positioning the 5 or 6 mm diameter and 25, 30, or 35 mm long anterior fixation screw.

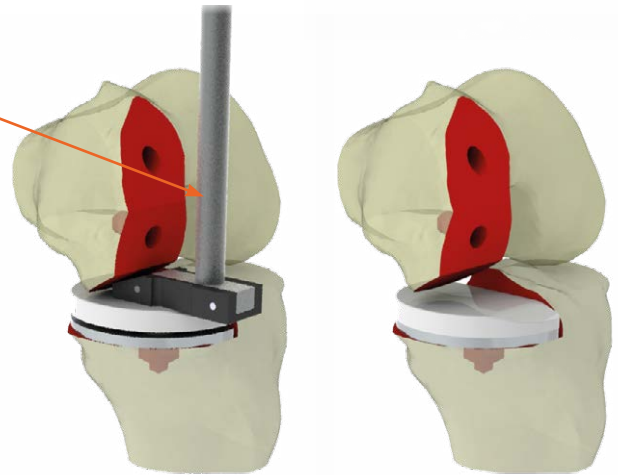
For the cemented version, go directly to step 4.



- 3** Choose the screw of suitable diameter and length.
Tighten the screw.

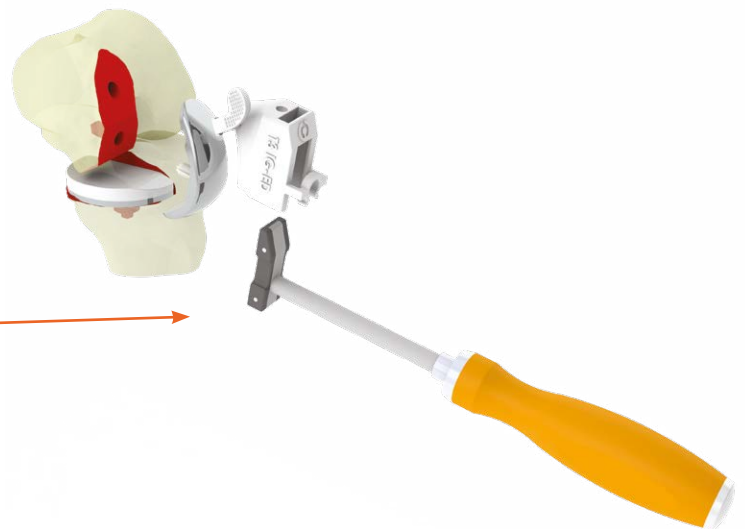
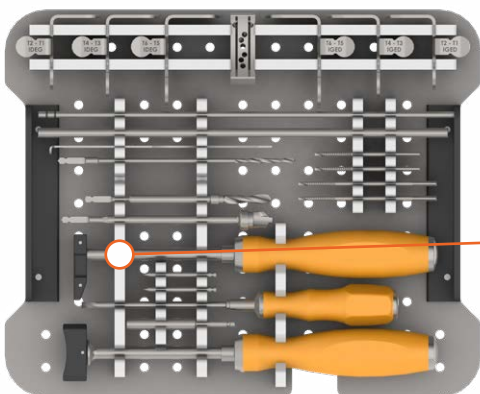


- 4** Position the insert of suitable thickness on the baseplate and impact with the tibial impactor.



- 5** Mount the tibial impactor on the condyle gripper.

Ensure that the metal stem clicks onto the condyle holder properly.



- 6** Position the condyle on the condyle holder, ensuring a perfect grip.

Position your hand under the assembly to prevent the permanent implant from falling.



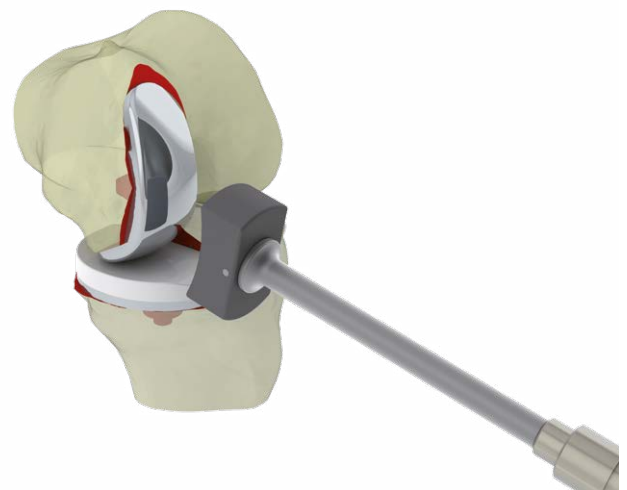
- 7** Engage the condyle pegs in front of the femur holes.

Move the knee into 90° flexion then bring the implant as close as possible to the bone.

Remove the condyle holder either by pressing on the lateral tabs or by turning the condyle holder on itself (it unclips automatically).



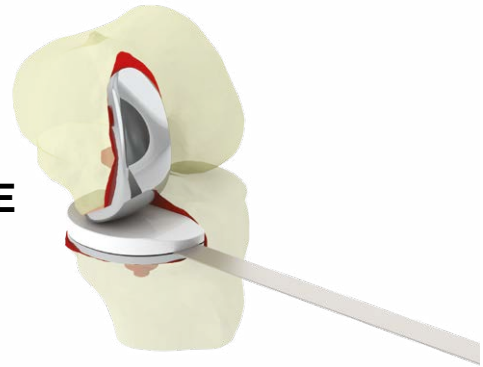
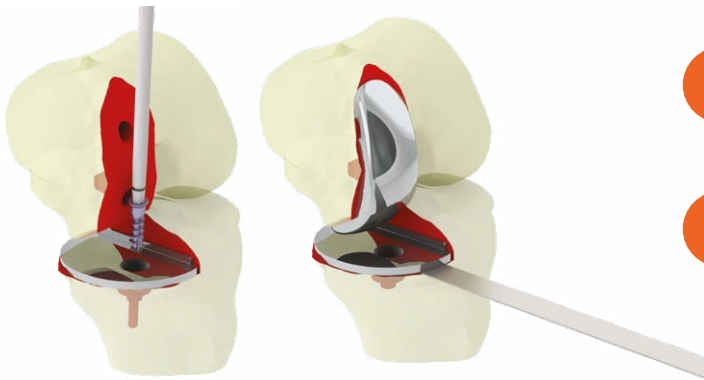
- 8** Maintaining the knee at 90° flexion, definitively impact with the hemispheric impactor.



EXTRACTION OF THE PERMANENT IMPLANTS

EXTRACTION OF THE METAL BASEPLATE

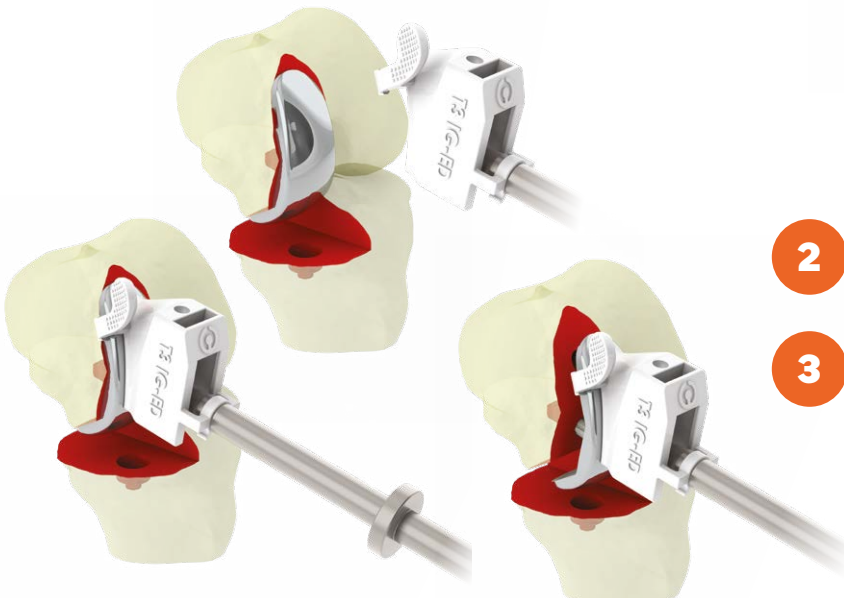
- 1 Remove the metal baseplate insert using a scissors (not provided), then extract it.



- 2 In the case of a cementless tibial baseplate with a screw, unscrew and remove the screw with a 3.5 mm hexagonal screwdriver.
- 3 Remove the metal baseplate by sliding a scissors beneath it to disengage it from its anchorage.

EXTRACTION OF THE CONDYLE

- 1 Slide a scissors between the condyle and the distal cut anteriorly, medially, then laterally to create a small space and begin to disengage the implant.



- 2 Clip the mass extractor onto the condyle holder for the size to be extracted.
- 3 Position the condyle holder on the implanted condyle, then gently extract using the impaction mass.

REFERENCES

IMPLANTS

E.g.: Cemented anatomical condyle Med R - Lat L S5: **RM84 11040 5**

	SIZE		1	2	3	4	5	6
CONDYLE	Anatomical condyle							
	Cemented Med R - Lat L	RM84 11040	1	2	3	4	5	6
	Cemented Med L - Lat R	RM84 11050	1	2	3	4	5	6
	Cementless Med R - Lat L	RM84 12040	1	2	3	4	5	6
	Cementless Med L - Lat R	RM84 12050	1	2	3	4	5	6
BASEPLATE	Fixed-bearing anatomical baseplate							
	Cemented Med R - Lat L	RM84 21040	1	2	3	4	5	6
	Cemented Med L - Lat R	RM84 21050	1	2	3	4	5	6
	Cementless Med R - Lat L	RM84 22040	1	2	3	4	5	6
	Cementless Med L - Lat R	RM84 22050	1	2	3	4	5	6
INSERT	Fixed insert Med R - Lat L							
	9 mm	RM84 3004	11	21	31	41	51	61
	10 mm	RM84 3004	12	22	32	42	52	62
	11 mm	RM84 3004	13	23	33	43	53	63
	12 mm	RM84 3004	14	24	34	44	54	64
	Fixed insert Med L - Lat R							
	9 mm	RM84 3005	11	21	31	41	51	61
	10 mm	RM84 3005	12	22	32	42	52	62
	11 mm	RM84 3005	13	23	33	43	53	63
	12 mm	RM84 3005	14	24	34	44	54	64

SINGLE-USE INSTRUMENTATION

Metal instrument reference: VARAUK01 (UNIKROMA- ONEORTHO ANC0007)

SIZE			1	2	3	4	5	6
Anatomical condyle Medial R - Lateral L	PFRA82	1000	01	02	03	04	05	06
Anatomical condyle Medial L - Lateral R	PFRA82	1000	08	09	10	11	12	13
Fixed-bearing tibial baseplate	PFRA82	1000	15	16	17	18	19	20

FIXATION SCREWS

The cementless tibial baseplate can be attached with screws delivered separately from the implant, references below:

DESCRIPTION	MANUFACTURING REFERENCE	DESCRIPTION	MANUFACTURING REFERENCE
Sterile screw Ø 5 length 25 mm	RM84502581	Sterile screw Ø 6 length 25 mm	RM84602581
Sterile screw Ø 5 length 30 mm	RM84503081	Sterile screw Ø 6 length 30 mm	RM84603081
Sterile screw Ø 5 length 35 mm	RM84503581	Sterile screw Ø 6 length 35 mm	RM84603581

COMPENSATE SPACER ASSEMBLY/ DISASSEMBLY

ASSEMBLY TO FIXED 6 MM COMPENSATE SPACER:

Insert the 2 pegs of the fixed 6 mm compensate spacer in the 2 central holes of the fixed spacer.



Fixed 6 mm spacer: Ref.: INS 2940

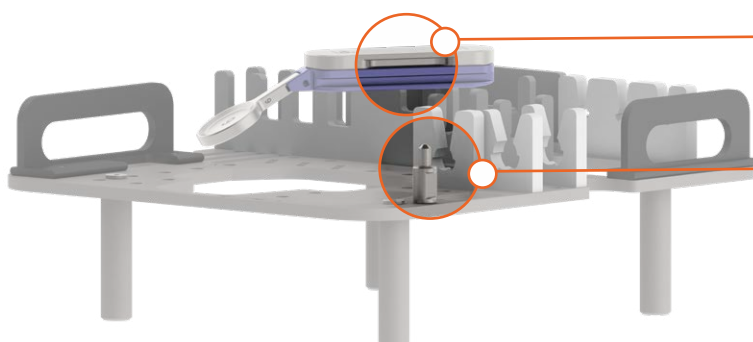


Fixed Spacers:

- 9 mm : Ref. INS 2930
- 10 mm : Ref. INS 2931
- 11 mm : Ref. INS 2932
- 12 mm : Ref. INS 2933

DISASSEMBLY OF FIXED 6 MM COMPENSATE SPACER (AND CYLINDRICAL COMPENSATE SPACER) TO SPACERS:

To disassembly the compensate spacer you can use the 1/2 plate of the tray for spacers, where a metallic stud for the desassembly of the fixed compensate spacer (and the cylindrical compensate spacer).



Prehesion area to disassembly the compensate spacer

Stud to help at the disassembly of the compensate spacer /spacer.



Push the slot peg of the compensate spacer against the stud and extract the compensate spacer by pulling through its middle.

And the compensate spacer is disassemble

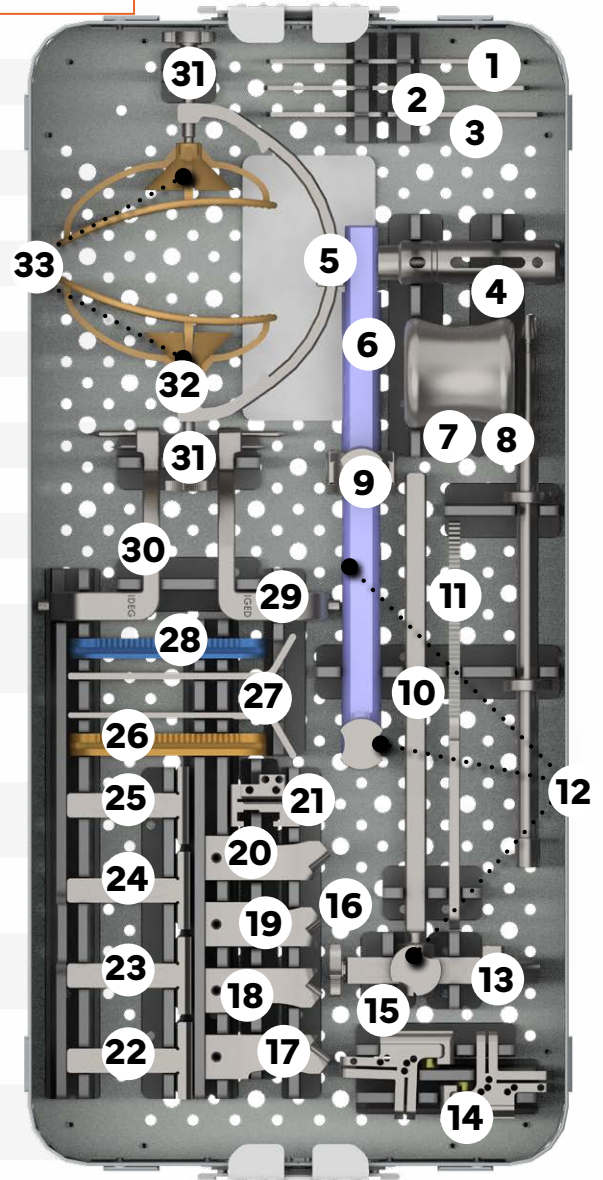


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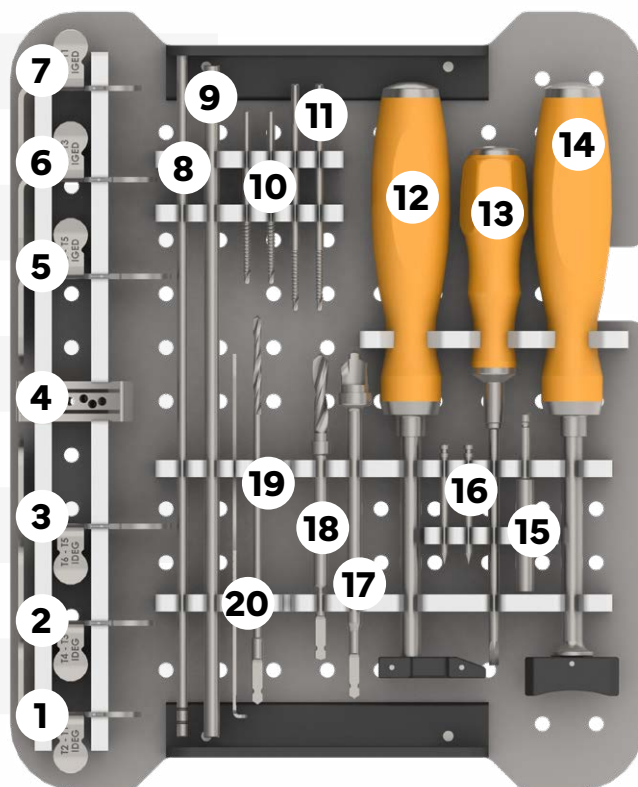
N°	REF.	DESCRIPTION
1	INS 0877	Tibial sizer S2-1
2	INS 0878	Tibial sizer S4-3
3	INS 0879	Tibial sizer S6-5
4	INS 0503	Lower handle M6
5	INS 0551	Ankle clamp holder
6	INS 0501	Lower vertical slider
7	INS 0829	Impaction mass
8	INS 0826	Mass extractor
9	INS 0504	V sliding block
10	INS 0502	Upper vertical slider
11	INS 0780	Bone rasp
12	INS 0506	Locking knob
13	INS 0507	Frontal fixation
14	INS 1500/ INS 1502/ INS 0574	Tibial cutting block 0°
15	INS 1501/ INS 1502/ INS 0574	Ttibial cutting block 2°
16	INS 0578	Height locking screw & Standard knob
17	INS 0625	Posterior and chamfer cutting block 23 mm MRL
18	INS 0624	Posterior and chamfer cutting block 18 mm MRL
19	INS 0626	Posterior and chamfer cutting block 18 mm MLL
20	INS 0627	Posterior and chamfer cutting block 23 mm MLL
21	INS 0584	Cutting block 6 mm
22	INS 0518	Height and 9° slope adjuster
23	INS 0517	Height and 6° slope adjuster
24	INS 0509	Height and 3° slope adjuster
25	INS 0623	Height and 0° slope adjuster
26	INS 0652	Hemi-spacer 10 mm
27	INS 0505	V guide
28	INS 0651	Hemi-spacer 9 mm
29	INS 0694	Mounted tibial arm MLL
30	INS 0580	Mounted tibial arm MRL
31	INS 0576	Ankle pin & Standard knob
32	INS 0498	Circular frame
33	INS 0760	Ankle clamp



INSTRUMENTATION

UNIVERSAL SET

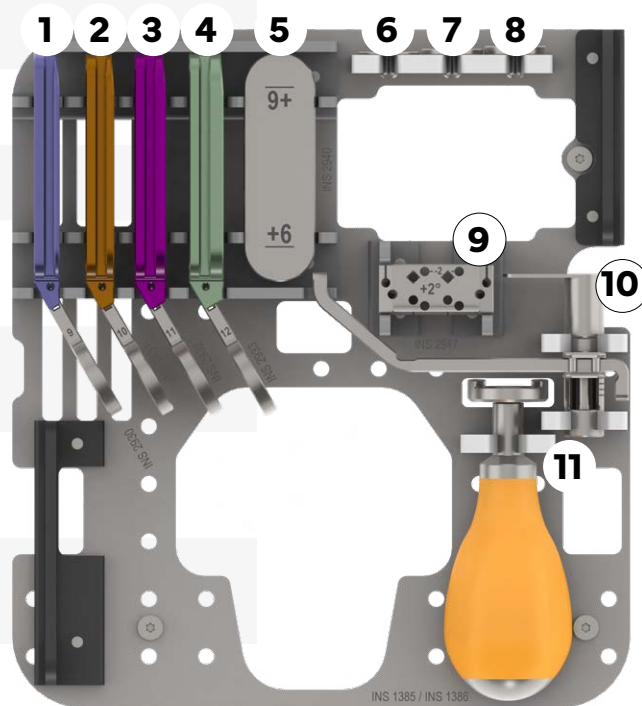
N°	REF.	DESCRIPTION
1	INS 0716	Femoral sizer S2 MR-LL
2	INS 0717	Femoral sizer S4 MR-LL
3	INS 0718	Femoral sizer S6 MR-LL
4	INS 0587	Axial cutting guide
5	INS 0721	Femoral sizer S6 ML-LR
6	INS 0720	Femoral sizer S4 ML-LR
7	INS 0719	Femoral sizer S2 ML-LR
8	INS 0586	Alignment rod extension
9	INS 0124	Alignment rod Ø 6
10	INS 0532	Threaded pin Ø 3.2 L 65
11	INS 0531	Threaded pin Ø 3.2 L 85
12	INS 0946	Monobloc impactor
13	INS 0949	Monobloc hex screwdriver Ø 3.5 mm
14	INS 0947	Monobloc femoral impactor
15	INS 554	Pin mandrel
16	INS 0581	Headed pins Ø 3.2 x 40
17	INS 0549	Drill bit Ø 11x11
18	INS 2668	Drill bit Ø 6x30
19	S2722.098	Drill bit Ø 3.2x145
20	INS 0550	Cutting gauge



INSTRUMENTATION

COMPOSITION OF THE 1/2 SPACERS TRAY

N°	REF.	DESCRIPTION
1	INS 2930	Fixed spacer 9 mm
2	INS 2931	Fixed spacer 10 mm
3	INS 2932	Fixed spacer 11 mm
4	INS 2933	Fixed spacer 12 mm
5	INS 2940	Fixed compensate spacer 6mm
6	INS 2944	Cylindrical compensate spacer 1 mm
7	INS 2945	Cylindrical compensate spacer 2 mm
8	INS 2946	Cylindrical compensate spacer 3 mm
9	INS 2947	Tibial Slope cutting guide
10	INS 1492	Tibial stylus
11	INS 1386	UNI KROMA® knurled clamping handle



TO NOTE:

- NS 0652 and INS 0651 spacers located in the lower tray have the same function and the same dimension as INS 2930 and INS 2931 located in the upper half tray. Only the spacers on the half tray have a grip handle.
- The cylindrical compensate spacer present in the half tray are ONLY compatible with half-tray spacers (INS 2930 and INS 2931 spacers).

Unless they are specifically identified as "not CE marked", all the medical devices mentioned in this document are CE marked in accordance with Directive 93/42/EEC and its amendments and IIa instruments, according to Regulation (EU) 2017/745 for Ir instruments.

The medical devices mentioned in this document are class Ir, IIa, III devices. Class Ir, IIa, III medical devices are marked CE 0459 by GMED. Before using a SERF product, please refer to the instruction leaflet and to the surgical technique.

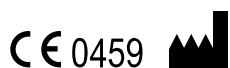
Check the labels and product leaflets for the complete list of indications, contra-indications, risks, warnings, precautions, and instructions for use.

We recommend that you consult the current instructions for the product(s), which is the only document containing the information that is authentic with regard to the CE marking of the product(s).

For further information please contact SERF's local distributor

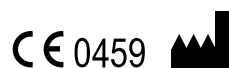
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