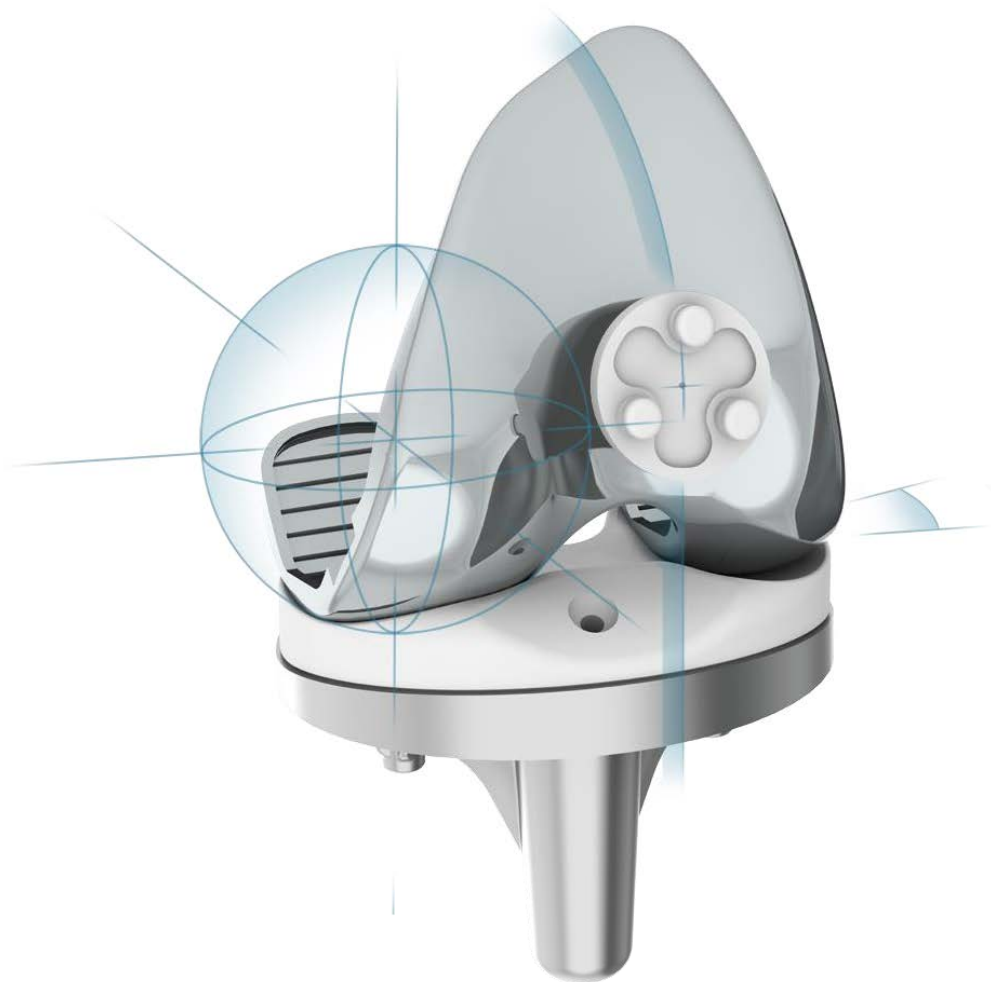




SAIPH[®] Knee System

Operative Technique

Inherent Stability
Uniquely Normal

Forever **Active**

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Patents

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Introduction

Before Using the SAIPH® Knee System

This is the prescribed Operative Technique manual for the SAIPH® Knee System and should be read in full and followed to ensure a good outcome for the patient. Any deviation from this technique is not approved by MatOrtho® and is the responsibility of the clinician.

The SAIPH® Knee System comprises a cemented femoral component, a cemented tibial component assembled with a modular Tibial Insert bearing, and, optionally, a cemented or cementless patella. The Femoral and Tibial Insert components are asymmetric: left or right components must be selected accordingly. Always check the sizing chart for component size and left/right compatibility. SAIPH® Knee components must not be used in combination with any other components.

The SAIPH® Knee instruments are intended to be used with the SAIPH® Knee implants only and should not be considered interchangeable with any other instrumentation unless specifically noted in the operative technique.

Always refer to the package inserts, product label and [Instructions for Use](#) (part number 400-480) before using the SAIPH® Knee implants.

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Operative Technique

Section 1 | General Preparation

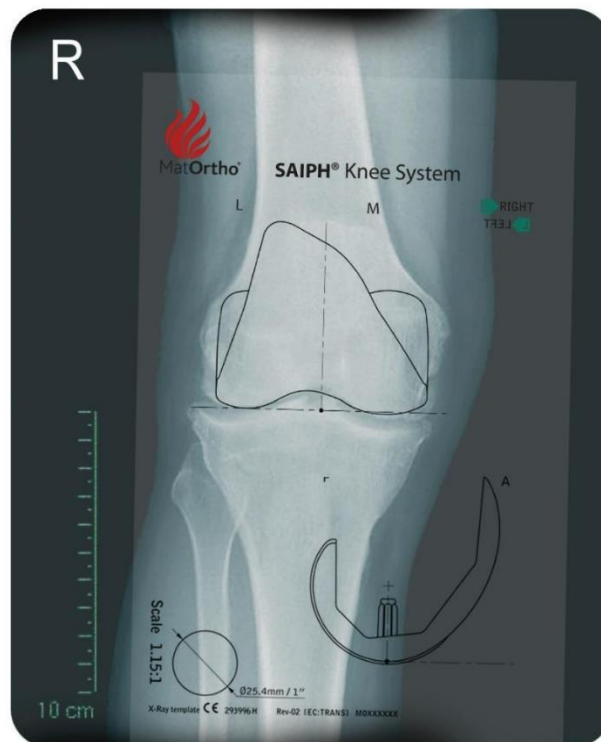
Step 1

Preoperative Assessment

Using the SAIPH® Knee templates provided, assess the x-ray to approximate the most suitable femoral and tibial component sizes and positions.

Please refer to the size compatibility chart (page 60) for suitably paired components.

Component sizes are confirmed intraoperatively.



Step 2

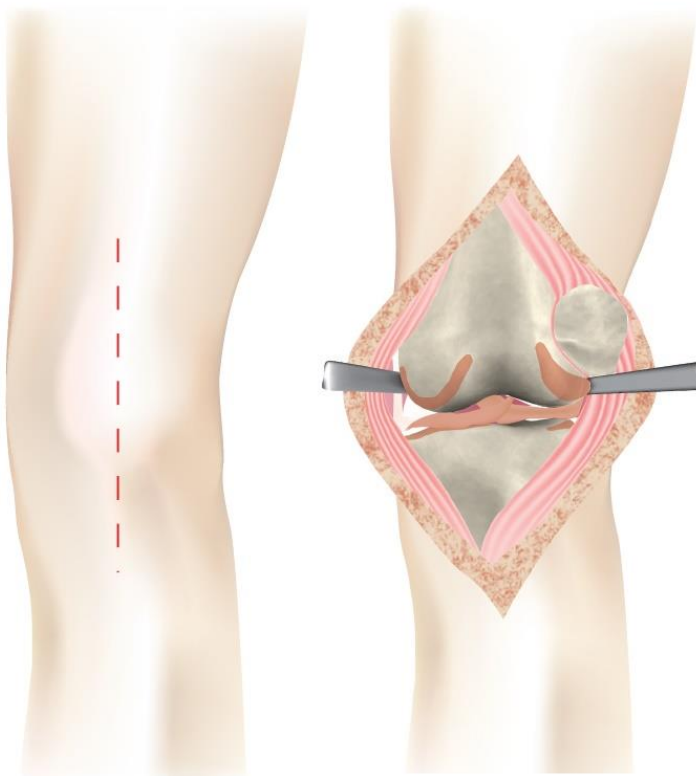
Exposure

The medial parapatellar approach is recommended for the SAIPH® Knee.

Make a straight-line skin incision from the superior pole of the patella, passing over the patella and extending distally to the tibial tubercle. Extend proximally and/or distally as required. Make a medial parapatellar arthrotomy.

Remove all osteophytes and release any adhesions.

The SAIPH® Knee is a cruciate-substituting design. Resect the posterior cruciate ligament for better access to the knee and to enable the full ROM intended with this design.



Section 2 | Tibial Preparation

- Notes:**
1. This operative technique describes tibial resection first. However, femur first is permissible.
 2. For tibial preparation using Intra-medullary Alignment, refer to Appendix B, page 32.
 3. For tibial preparation using BESPOKE™ instrumentation, refer to Appendix C, page 33.

Note: Preparation of the Tibial Alignment Guide is shown in Appendix E, page 44.

Step 3

Assemble the Tibial Alignment Guide

To stabilise the distal end of the assembly: position the Ankle Clamp around the ankle with the long axis of the Guide positioned to the anterior and tighten the Ankle Clamp.

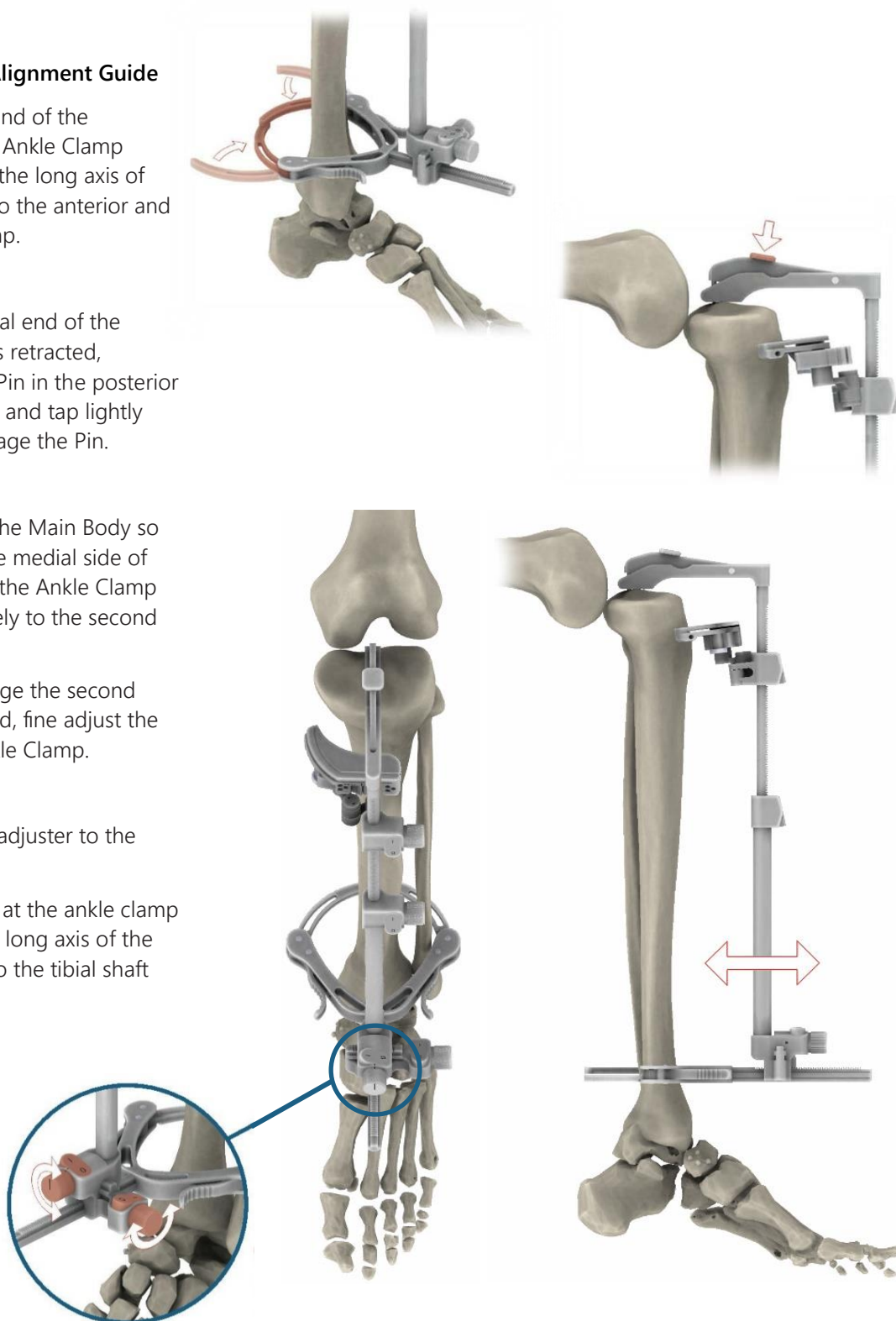
To stabilise the proximal end of the assembly: with the Pins retracted, position the posterior Pin in the posterior third of the tibial spine and tap lightly with a hammer to engage the Pin.

Align the long axis of the Main Body so that it is centred on the medial side of the tibial tubercle and the Ankle Clamp rail points approximately to the second metatarsal.

Using a hammer, engage the second proximal Pin. If required, fine adjust the ML position at the Ankle Clamp.

Switch the Main Body adjuster to the locked position.

Adjust the AP position at the ankle clamp as required so that the long axis of the Main Body is parallel to the tibial shaft when viewed laterally.



Step 4

Position Tibial Cutting Block

Set the Tibial Stylus: to reference the defect, set the stylus to cut 2mm below the defect; to reference the non-defective side, set the stylus to 10mm, which is equal to the thinnest tibial component assembly.

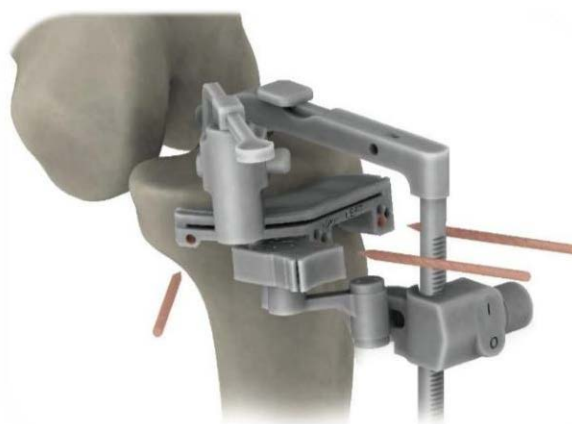
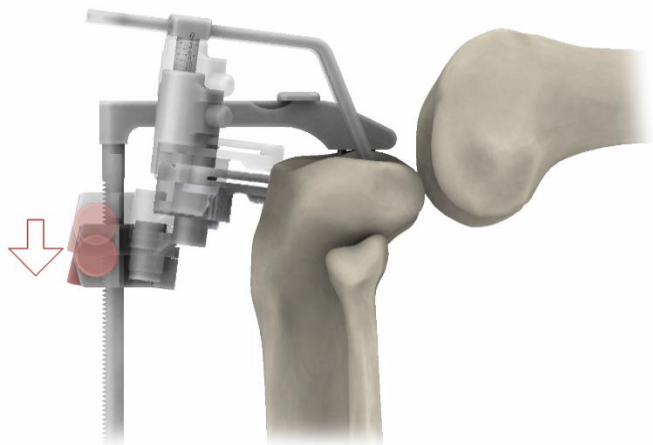
Attach the Tibial Stylus to the Tibial Cutting Block on the side of the chosen reference condyle.

Switch the Tibial Cutting Block adjuster to the unlocked position and lower the Tibial Cutting Guide until the stylus lightly contacts the chosen reference condyle.

An Angel Wing can be used at any time to visualise the cutting plane.

When the appropriate tibial resection height is obtained, switch the Tibial Cutting Block adjuster to the locked position.

Pin the Tibial Cutting Block through the two lowest anterior holes (0mm position). Slide the Tibial Cutting Guide towards the tibia as far as it will go and insert a medial oblique Pin.



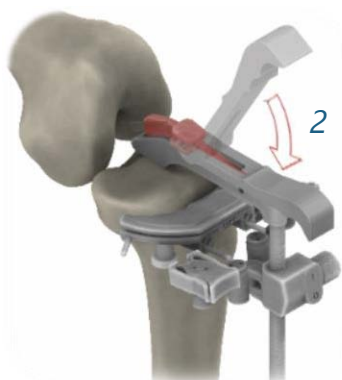
Step 5

Remove Tibial Alignment Guide

1 Release the clip from the Tibial Cutting Block.



2 Using the Extractor Lever, retract the proximal Pins.



3 Release the Ankle Clamp and withdraw the Tibial Alignment Guide.



Step 6

Resect Tibia

Resect the tibia with a 1.27mm thick saw blade.

After removing the bone, check that the cut is flat.

Remove the medial oblique Pin and slide the Tibial Cutting Block off the anterior Pins, leaving the anterior Pins in place.

The Angel Wing can be used at any time to visualize the tibial resection.



Step 7

Check Tibial Resection (Optional)

To check alignment, and that the minimum thickness of Tibial Component Assembly can be used:

With the leg at about 90° flexion, insert the 10mm Tibial Spacer. If it cannot be inserted, additional tibial resection will be required.

Ensuring that the side of the Tibial Spacer marked TOP is facing the femur, insert the External Alignment Rod through the Tibial Spacer guide hole and check tibial alignment.

Note: Refer to the Implant Sizing Chart on page 60 for available thicknesses.



Additional Tibial Resection (If Required)

If additional resection is required, replace the Tibial Cutting Block on the two anterior Pins at the -2mm or -4mm position depending on the additional resection required. Resect the tibia.

Recheck the knee in flexion with the Tibial Spacer.

Correction of Tibial Resection Angle (If Required)

If the angle of tibia resection requires correction, reassemble the Tibial Alignment Guide on the tibia. With the Tibial Cutting Block adjuster switched to the unlocked position, reconnect the Tibial Cutting Guide to the Tibial Cutting Guide Mount. Remove one anterior Pin and slide the Tibial Cutting Guide onto the remaining Pin (if varus/valgus adjustment) or remove both Pins (if posterior slope adjustment).

Adjust the alignment of the Main Body as required.

Replace the anterior Pin(s). If the adjusted angle is small, it may be necessary to select an alternative hole to avoid re-pinning in the original position.



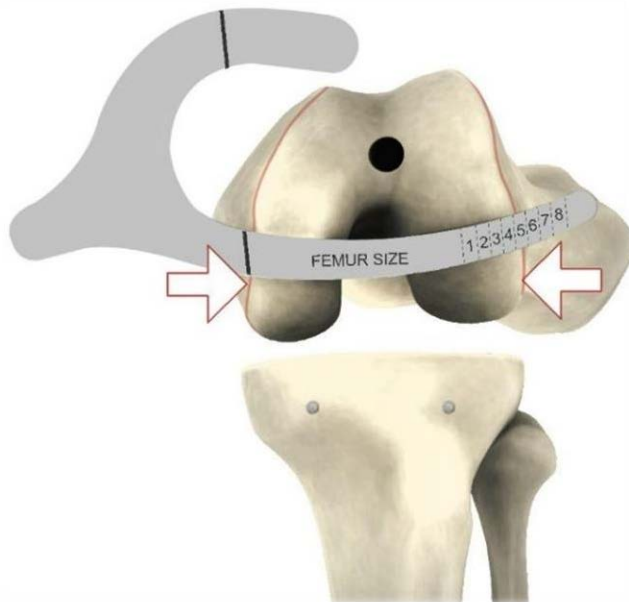
Section 3 | Femoral Preparation

- Notes:**
1. This section describes femoral preparation for the Distal Cut First operative technique.
 2. For femoral preparation using the Anterior Cut First technique, refer to Appendix A, page 27.
 3. For femoral preparation using the BESPOKE™ Instruments, refer to Appendix C, page 38.

Step 8

Sizing the Femur

Estimate the femur size according to its width at the widest point using the Femoral Angel Wing. Note the size indicated between the two adjacent lines that best fit the femur width.

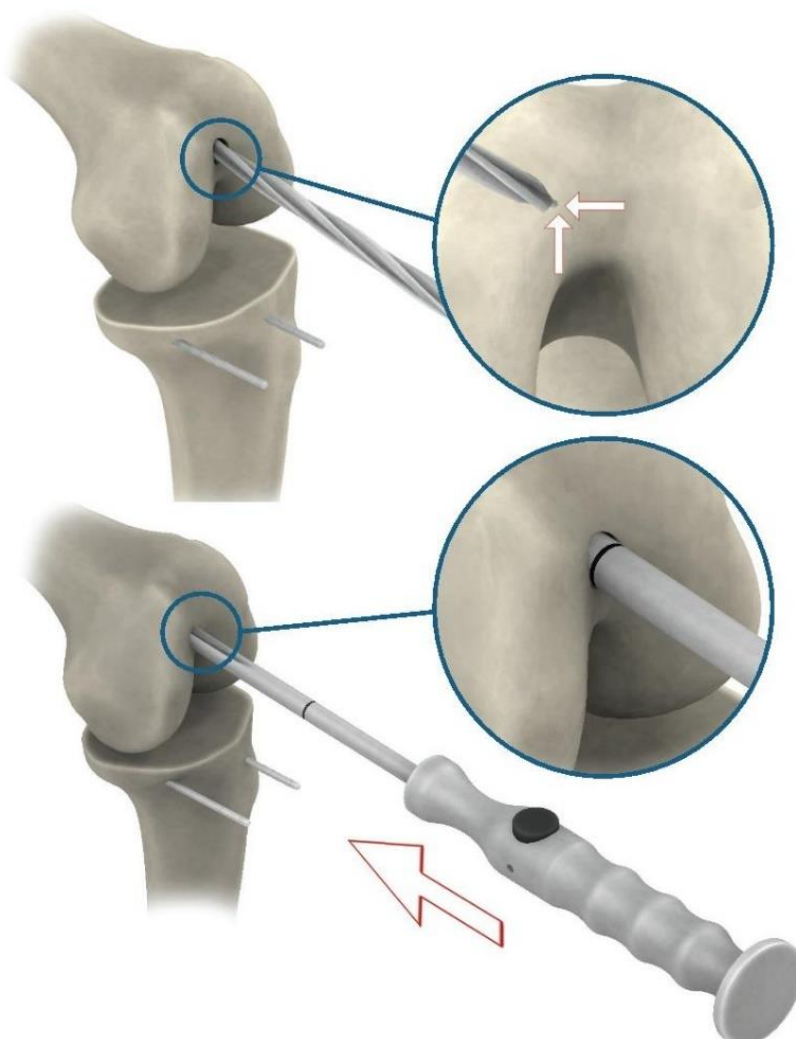


Step 9

Insert IM Rod

Position the tip of the Femoral IM Drill 5-10mm proximal from the intercondylar notch and 5-10mm medial from the midline. Advance the IM Drill until the depth reference line meets the femur, taking care to find the correct path of the femoral canal. Avoid rotating the IM Drill axis or otherwise widening the hole.

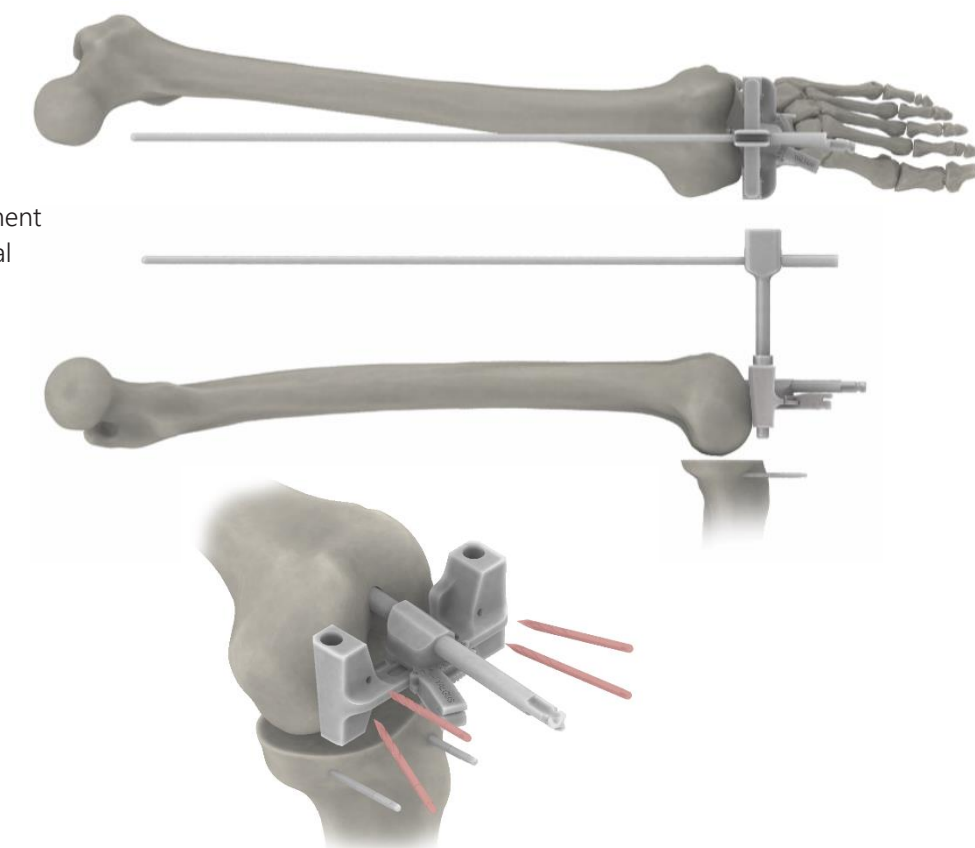
Insert the IM Rod until the depth reference line meets the femur. Remove the Large Handle.



Step 10

Set Valgus Alignment

- 1 Set the valgus angle on the Distal Femoral Alignment Guide for the left or right as required. An angle between 5° and 7° is recommended.
- 2 Slide the Distal Femoral Alignment Guide over the IM Rod until the Jig is positioned up against the distal femoral condyles.
- 3 Rotate the Distal Femoral Alignment Guide so that the ML ridge is aligned with the surgical epicondylar axis. Centre the Distal Femoral Alignment Guide mediolaterally to ensure contact on both distal condyles.



Optionally, using the External Alignment Rod and its Mount, check the femoral axis alignment.

Secure the Distal Femoral Alignment Guide with Long Pins.

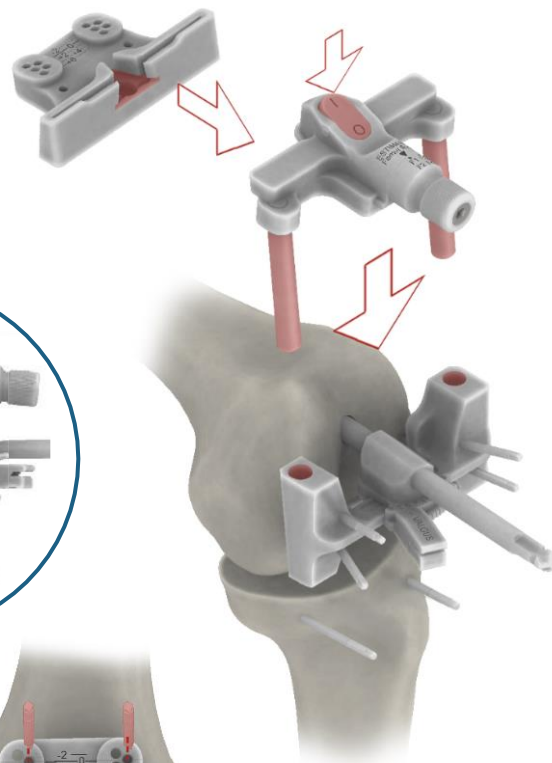
Step 11

Assemble Distal Cutting Block

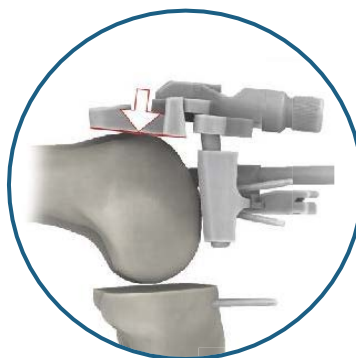
Adjust the 'Estimate Femur Size' dial according to the femoral ML size estimation (Step 8).



Attach the Distal Cutting Block to the Distal Cutting Block Mount and lock in place.



Slide the Distal Cutting Block Mount onto the Distal Femoral Alignment Guide main body so that the Distal Cutting Block rests against the anterior femur.



Pin the Distal Cutting Block through the 0mm position pin holes.

Add additional oblique Pins as required to ensure that the Distal Cutting Block is secure to the bone.

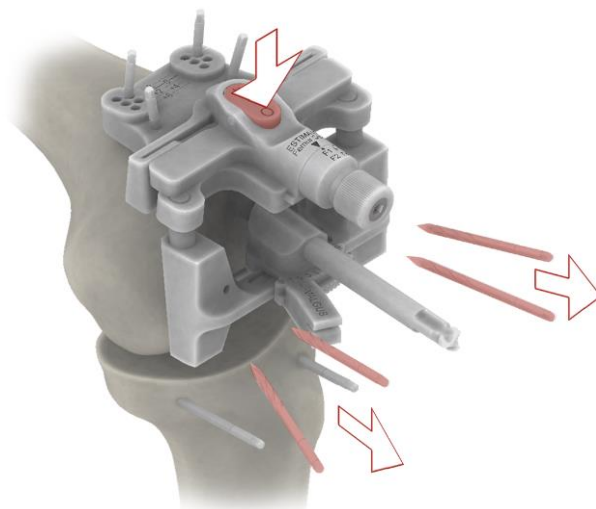


Step 12

Remove Distal Cutting Block assembly

Remove the long securing Pins.

Unlock the Distal Cutting Block Mount. The Distal Femoral Alignment Guide assembly and IM rod can now be removed, leaving only the Distal Cutting Block for resection.



Step 13

Resect the Distal Femur

Cut the distal femur and check that it is flat.

Remove the oblique Pins and the Distal Cutting Block.

Optional:

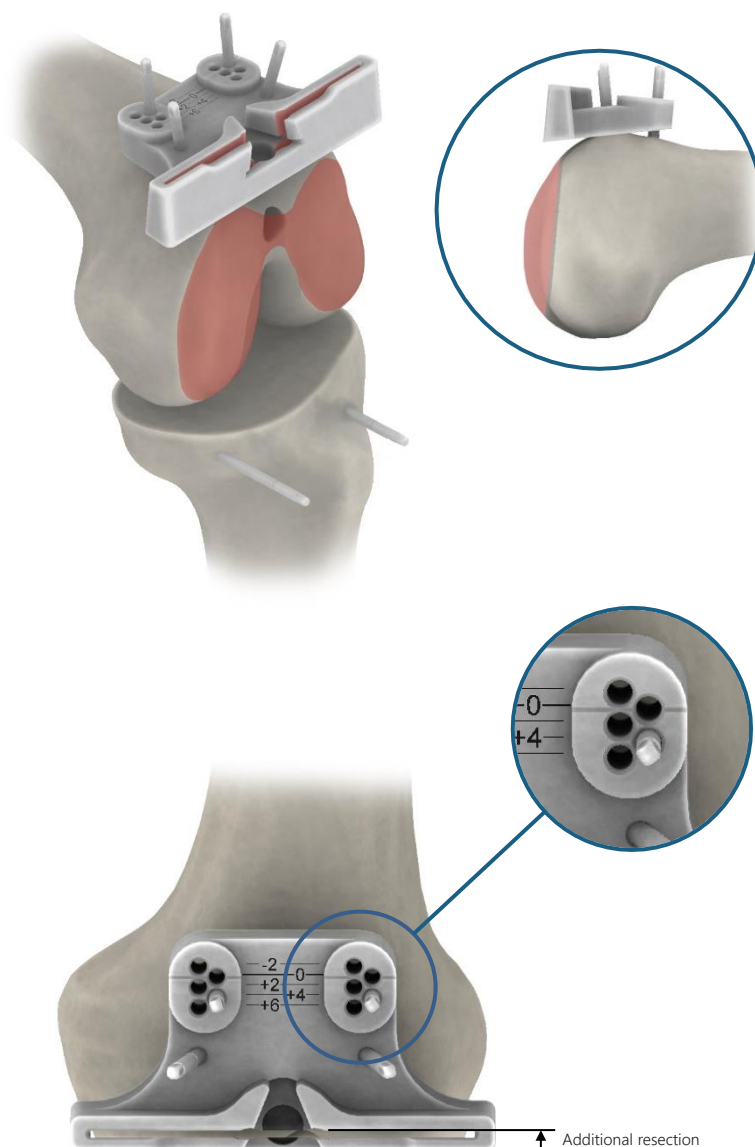
Adjustment of Distal Resection Depth

In case of any requirement to adjust the distal resection, always pin the guide first at the 0mm position.

If additional distal resection is required, shift the Distal Cutting Block on the pins to the +2/+4mm position as required.

If reduced distal resection is required (for example if there is marked defect on the reference distal condyle), shift the Distal Cutting Block to the -2mm position.

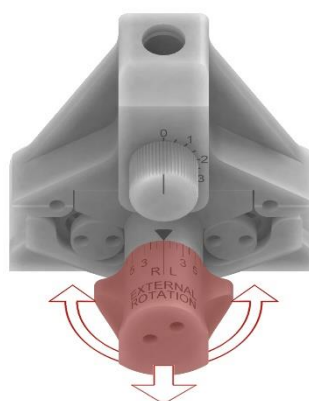
It is recommended that any adjustment is made following assessment of the flexion and extension joint space.



Step 14

Set Femoral Sizing Jig

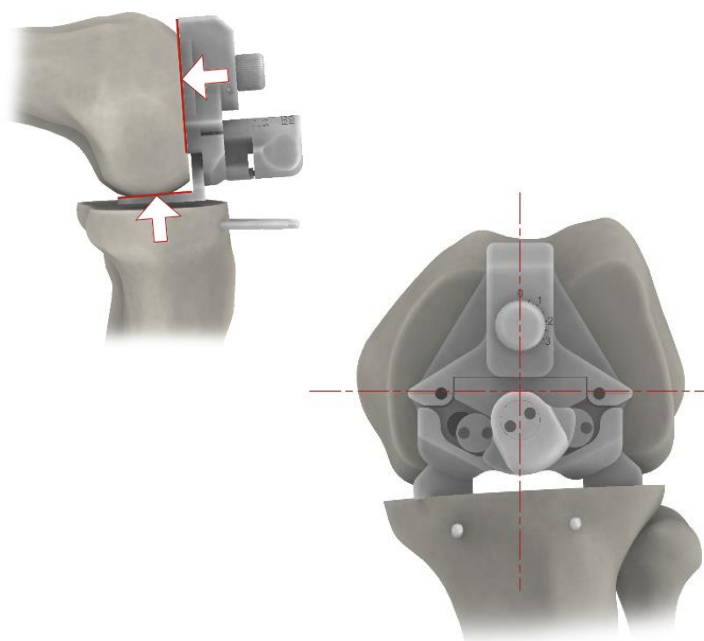
Set the external rotation on the Femoral Sizing Jig to the desired angle for the left or right leg. An external rotation of 3° is the recommended default setting.



Place the Jig over the femur until it is positioned flush against the distal cut bone, with the posterior condyles resting on the posterior footplates of the jig.

With the knee at 90° flexion, allow the weight of the femur to sit down onto the posterior footplate and the tibia. Ensure that there is direct contact between both posterior femoral condyles and the footplate.

Note: External rotation can also be determined using Whiteside's line aligned with the vertical shaft of the Jig or using the epicondylar axis aligned with the horizontal pointers on the Jig, according to the surgeon's preference.

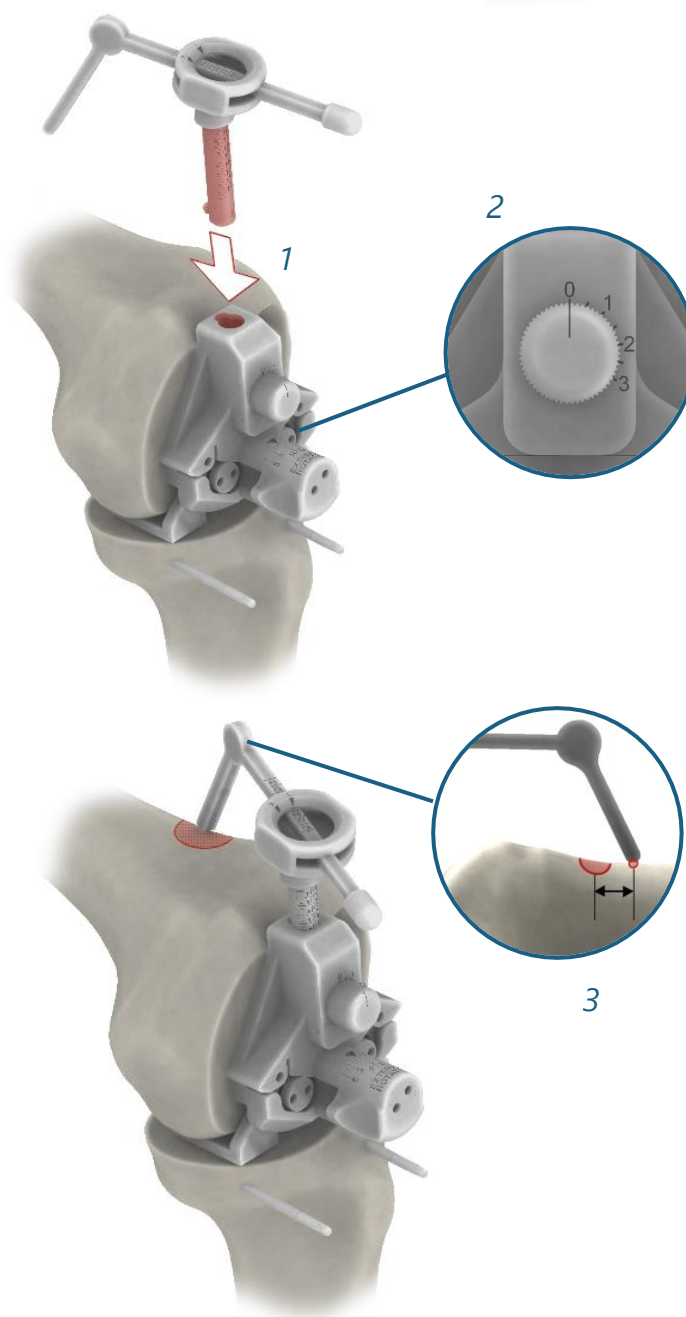


Step 15

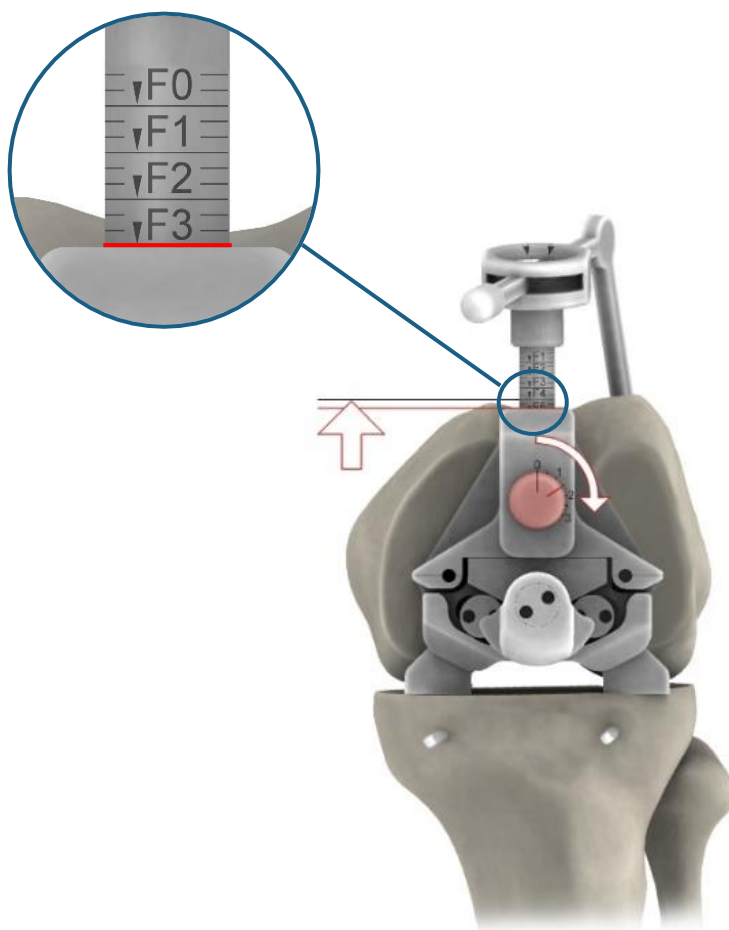
Measure Femoral Size

- 1 Assemble the Femoral Stylus on the Femoral Sizing Jig.
- 2 Check that the central dial of the Sizing Jig is set to the zero position (0mm posterior offset).
- 3 Locate the proximal extent of the anterior lateral femoral ridge. Lower the Femoral Stylus until its tip contacts the anterior femoral cortex 1cm proximal of the lateral femoral ridge.

Note: The anterior reference point for the SAIPH® Knee differs from other devices. Failure to position the stylus correctly can lead to an oversizing of the component.



Observe the indicated femoral size, shown at the intersection between the Stylus and the Sizing Jig.



Should an 'in-between' size be recorded, turn the centre dial clockwise to raise the carriage so that the intersection between the Stylus and the Sizing Jig is aligned with the smaller size.

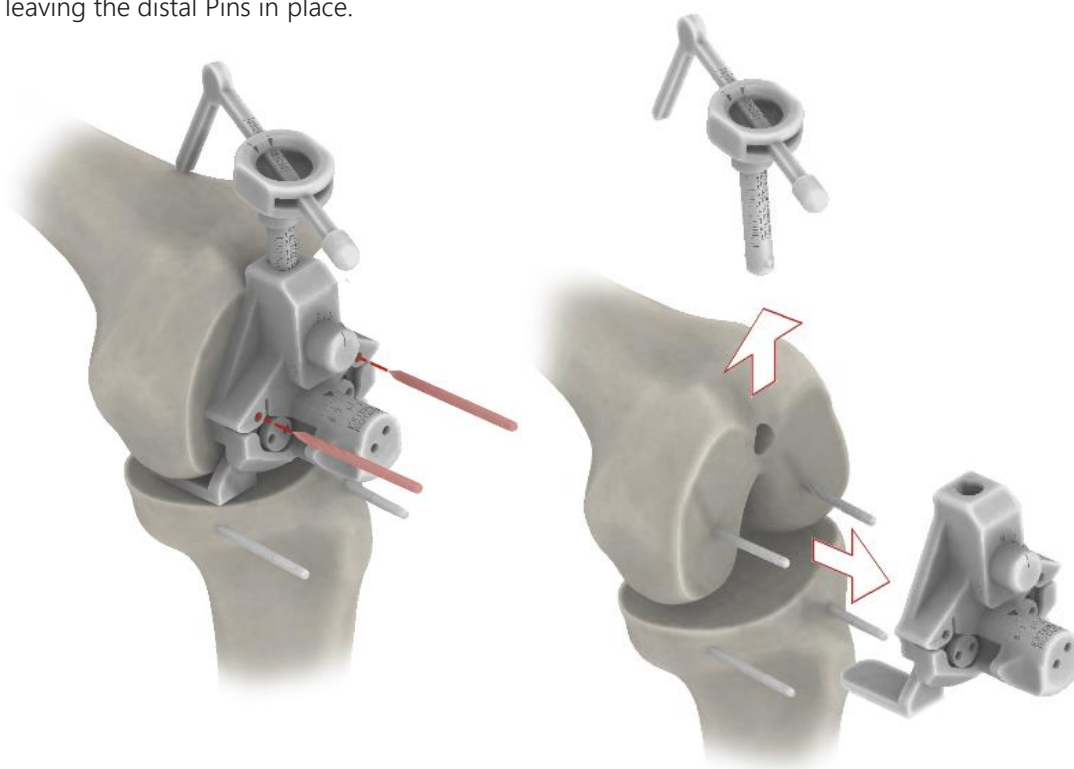
The value indicated by the centre dial indicates the additional posterior resection (mm) that will result.

Step 16

Set Multicut Block Position

Insert two Long Pins into the pin holes of the Femoral Sizing Jig central body.

Remove the jig, leaving the distal Pins in place.



Step 17

Position Multicut Block

Slide the Multicut Block onto the positioning Pins through the central (neutral) pin holes until it lies flush with the distal femur cut.

Check the anterior cut position with the Femoral Angel Wing.

If required to refine the anterior cut, the Multicut Block can be repositioned 1mm anterior or 1mm posterior from the neutral position by replacing the block on the Pins via the adjacent holes.

Secure the Multicut Block with medial and lateral Pins.

Remove the positioning Pins.

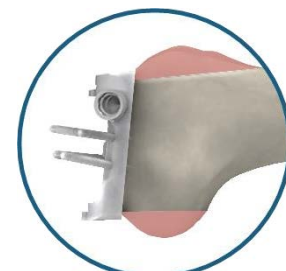
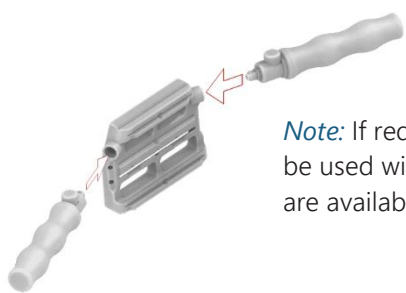
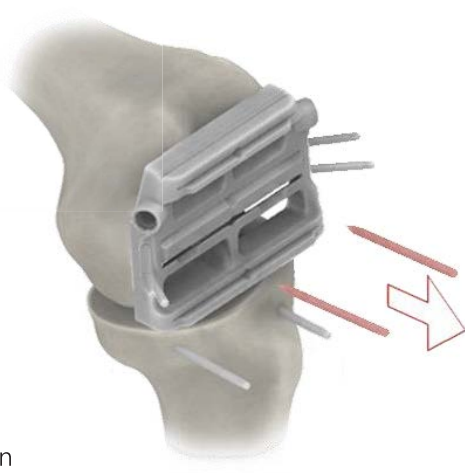
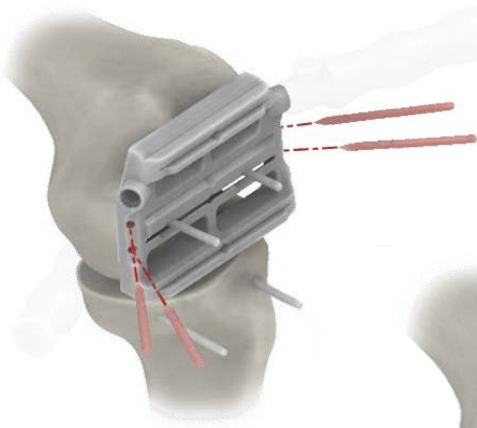
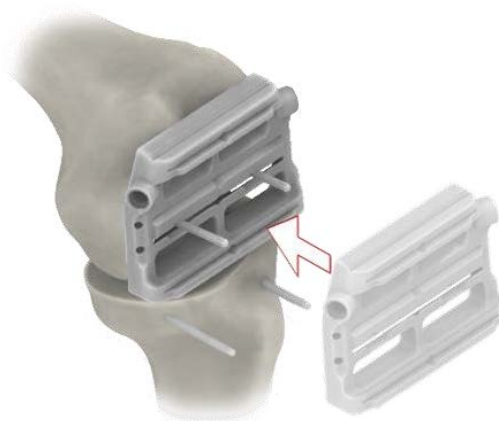
Note: If required, the optional Small Handles can be used with the Multicut block. Small Handles are available on request, shown on page 57.

Step 18

Resect the Anterior and Posterior Condyles

Resect the anterior and posterior condyles.

Remove the Multicut Block. Clear away posterior osteophyte, loose bodies, or meniscal remnant.



Step 19

Assess Joint Space using Dual-Ended Spacers

With the leg in flexion, insert the Tibial Spacer used in Step 7 with the relevant Femoral Spacer attached, which is determined by the Femoral Component size (refer to the Implant Sizing Chart on page 60). Check laxity by manipulating tibia between varus and valgus. If the joint exhibits excessive laxity, increase the size of Tibial Spacer.

If the minimum thickness of Tibial Spacer is tight in flexion, resect more tibia.

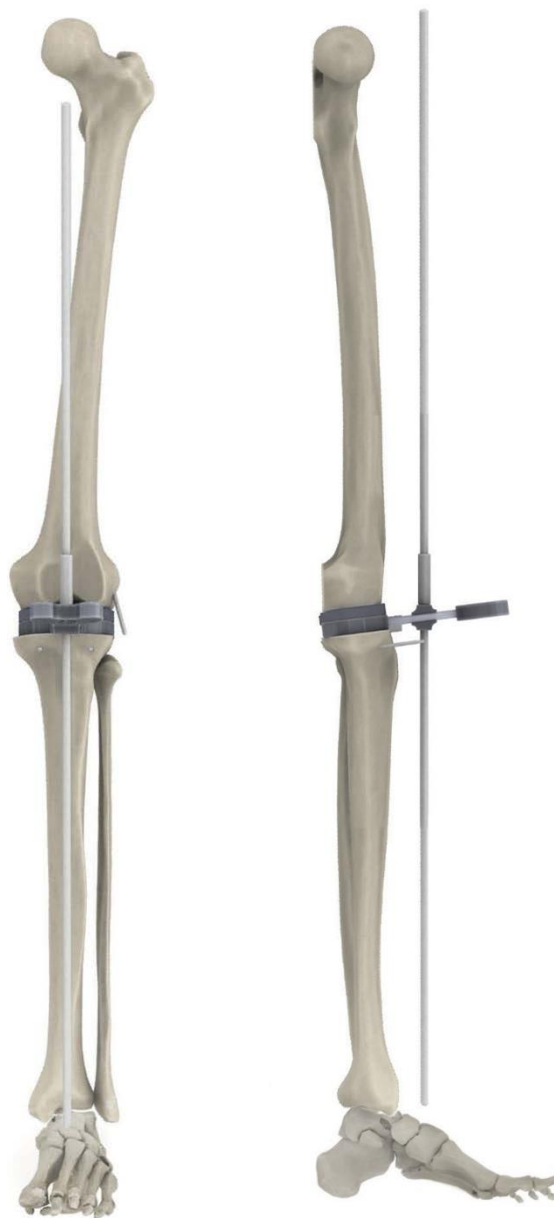
Extend the leg and insert the same Tibial Spacer with Femoral Spacer attached.



Check alignment (using the External Alignment Rod) and that the leg fully extends. If the knee cannot be fully extended, release any posterior adhesions.

If, following soft tissue releases, the knee cannot be fully extended, further distal femur resection will be required.

If an imbalance is observed in laxity between flexion and extension, such that the joint is tight in flexion, pack the distal cut.



Optional: Assess Joint Space using the Magic Spacer

Note: This step requires use of the optional Magic Spacer instrument shown on page 59.

With the paddles closed, the thickness represented is 10mm, equivalent to the minimum tibial resection. Each click of the trigger on the Magic Spacer represents a 2mm increase, relating to each tibial Bearing thickness. To assess the gap after femoral resection, secure the appropriate Femoral Spacer to the paddles.

Use in flexion first and distract the joint to achieve stability but not a tight space. Observe the thickness indicated.

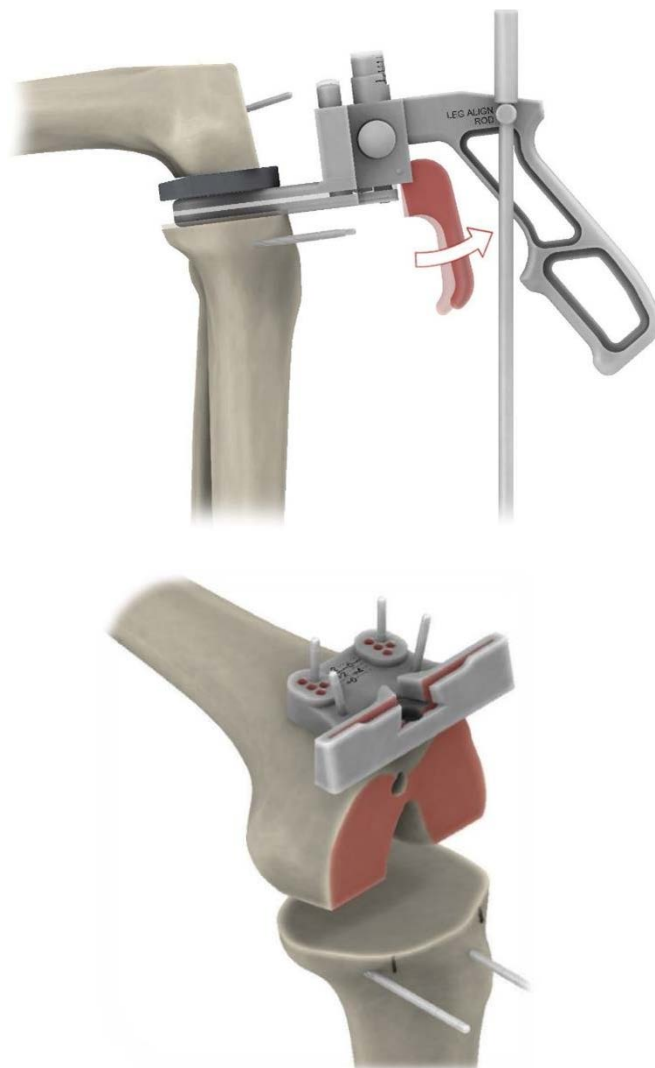
If the minimum available thickness (paddles closed) is tight in flexion, resect more tibia.

Release the spacer and check in extension to a relatively tight space. Check for stability in varus/valgus and release the tight side if necessary.

Check the leg alignment with the External Alignment Rod.

If satisfied with tension, stability, and alignment, observe the Tibial Bearing size on the scale. Any imbalance between flexion and extension spaces will be indicated by the difference in millimetres between measurements.

Refer to Implant Sizing Chart on page 60 for available thicknesses.

**Additional Distal Femur Resection (If Required)**

If additional resection is required, replace the Distal Cutting Guide on the two anterior Pins at the -2mm or -4mm position depending on the additional resection required.

Resect the distal femur.

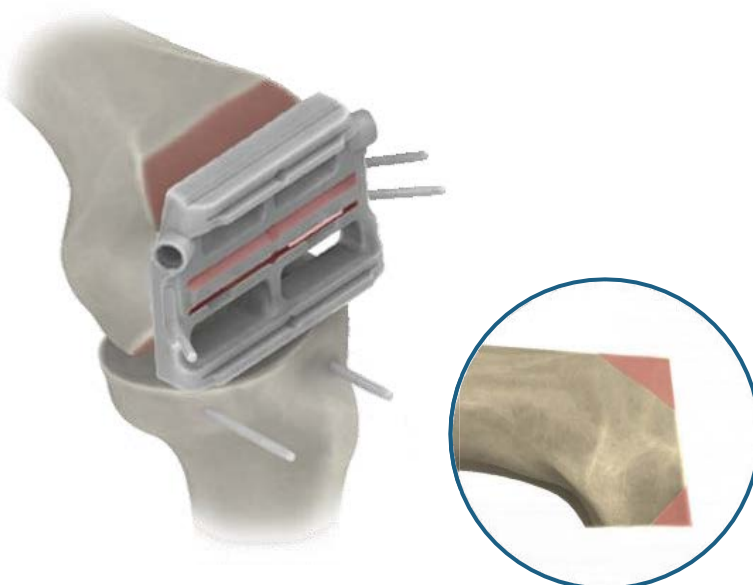
Recheck the knee in flexion and extension with the assembled Tibial Spacer and Femoral Spacer or with the assembled Magic Spacer and Femoral Spacer.

Step 20**Complete Chamfer Cuts**

Replace the Multicut Block using the securing Pins. Use the Anterior Reference Plate or an Angel Wing to ensure that it lies flush with the anterior and distal femur cuts.

Resect the posterior chamfer followed by anterior chamfer.

If any additional distal resection was performed following joint space assessment, repeat the posterior cut to ensure a good fit.



Section 4 | Trial Reduction

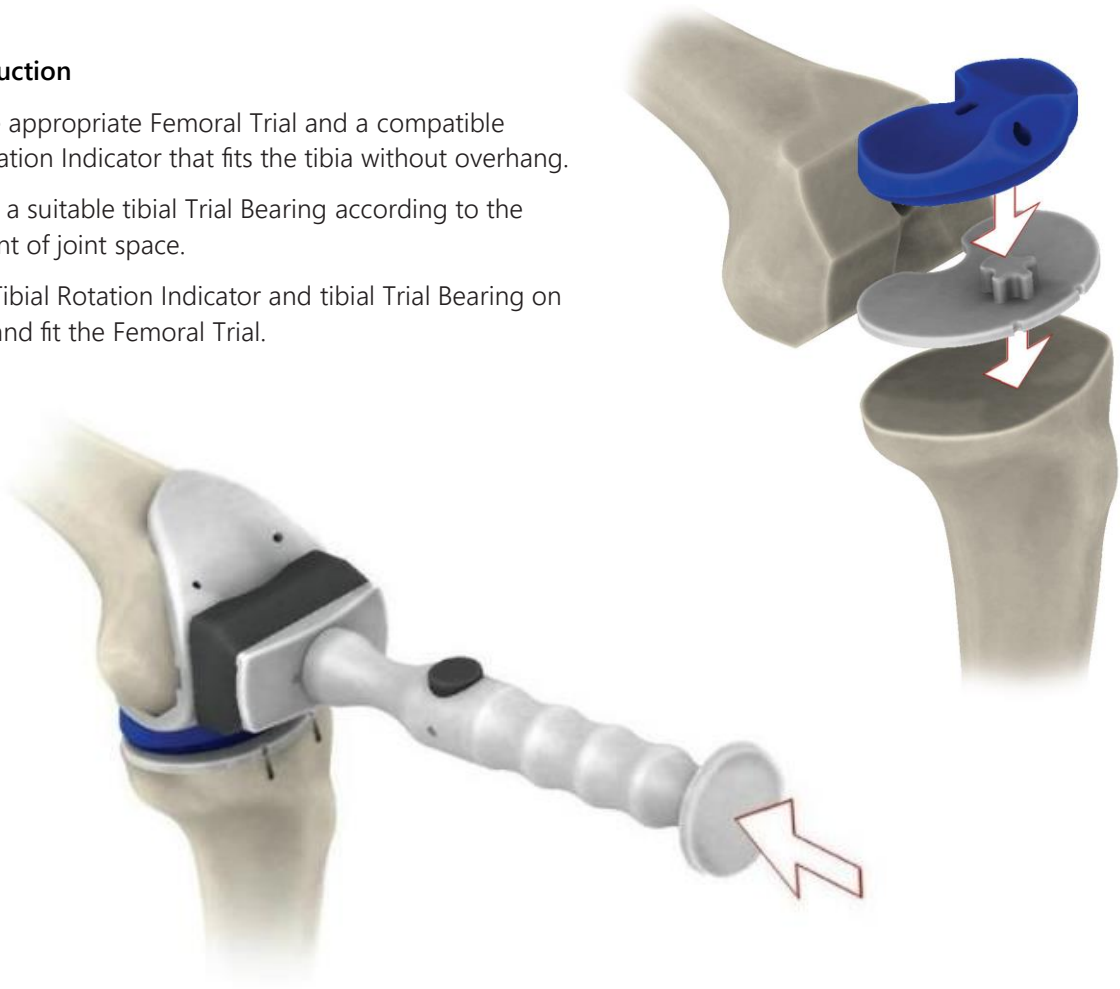
Step 21

Trial Reduction

Select the appropriate Femoral Trial and a compatible Tibial Rotation Indicator that fits the tibia without overhang.

Assemble a suitable tibial Trial Bearing according to the assessment of joint space.

Rest the Tibial Rotation Indicator and tibial Trial Bearing on the tibia and fit the Femoral Trial.



Check the fit and ML position of the Femoral Trial.

Test for extension and flexion with the patella reduced. The knee should be stable and have only limited laxity in flexion.

If excessive laxity is observed, remove the tibial Trial Bearing. Replace it with a thicker tibial Trial Bearing and recheck stability.

The tibial Trial Bearing should find its “best fit” position on the tibia.

Optionally, using a diathermy, make location marks on the tibia to aid positioning of the Tibial Template.

Note: Refer to the Implant Sizing Chart on page 60 for available thicknesses.

Section 5 | Finishing

Step 22

Femoral Finishing

Once satisfied with the position of the Femoral Trial, using the Peg Drill, drill the medial and lateral femoral peg holes.

Remove trial components.

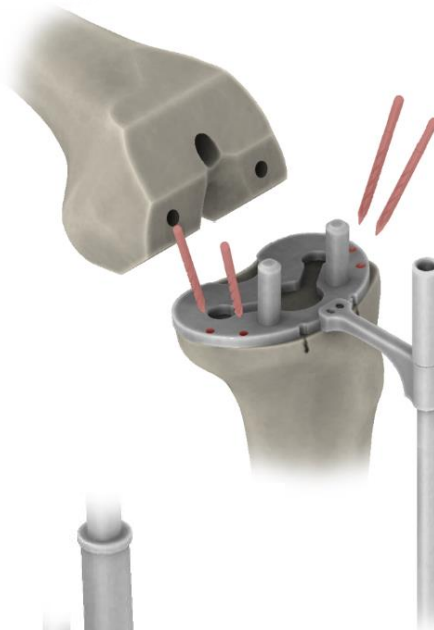


Step 23

Tibial Finishing

Select the appropriate Tibial Template and position on the tibial plateau, using the rotation mark if required. Optionally, use the External Alignment Rod to assess rotation. Ensure that there is no overhang.

Once satisfied with the position, secure with a minimum of two Short Pins.



Step 24

Prepare Stem and Pegs

Assemble with the appropriate Tibial Drill Guide.

Select the appropriate Stem Drill for the Tibial Drill Guide size. The Drills are clearly marked to indicate the correct size.

Drill the stem.

Uncouple the Stem Drill and leave in place.

Using the Peg Drill, drill the two pegs until the engraved mark meets the Tibial Drill Guide.

Remove the Tibial Drill, Peg Drill and Tibial Drill Guide.



Step 25

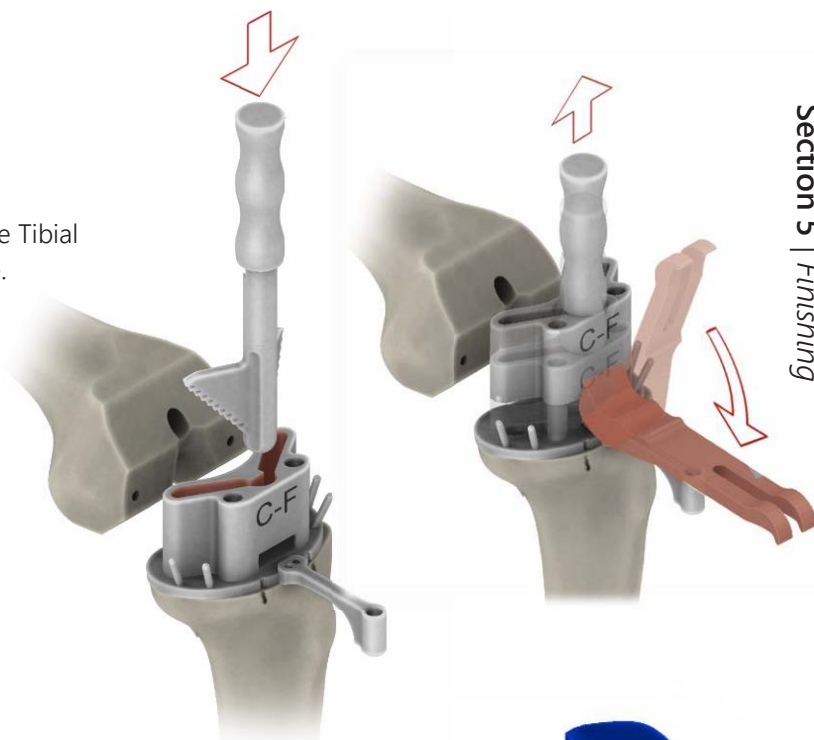
Prepare Tibial Webs

Prepare the tibial webs using the appropriate size Tibial Chisel, guided by the slot in the Tibial Drill Guide.

Assemble the appropriate Tibial Chisel Guide. The Tibial Chisel Guides are clearly marked to indicate the correct Tibial Template.

Impact the appropriate size Tibial Chisel until it reaches its end point.

Using the Extractor Lever, remove the Tibial Chisel and Guide.



Step 26

Final Trial Reduction

Select the appropriate Femoral Trial, Tibial Trial and Trial Bearing.

Note: Optionally, tibial trials with peg and stem can be used. Long stemmed Tibial Position Guides are shown on page 59 and are available on request, including a Tibial Trial Removal Tool.

Assemble the Tibial Trial and Trial Bearing first, then assemble the Femoral Trial using the Femoral Impactor.

Check that the joint is stable in flexion and extension.

If excessive laxity is observed, remove the Trial Bearing with the Insert Trial Remover. Replace with a thicker Trial Bearing and recheck stability.

Note: Refer to the Implant Sizing Chart on page 60 for available thicknesses.



Patellar resurfacing

If, following assessment of the patella, patellar resurfacing is required, it is recommended that this is done while the femoral and tibial trials are in place. Please refer to:

- page 23 for Patellar resurfacing: Cemented Patella;
- page 25 for Patellar resurfacing: Cementless Patella.

Section 6 | Implantation

Step 27

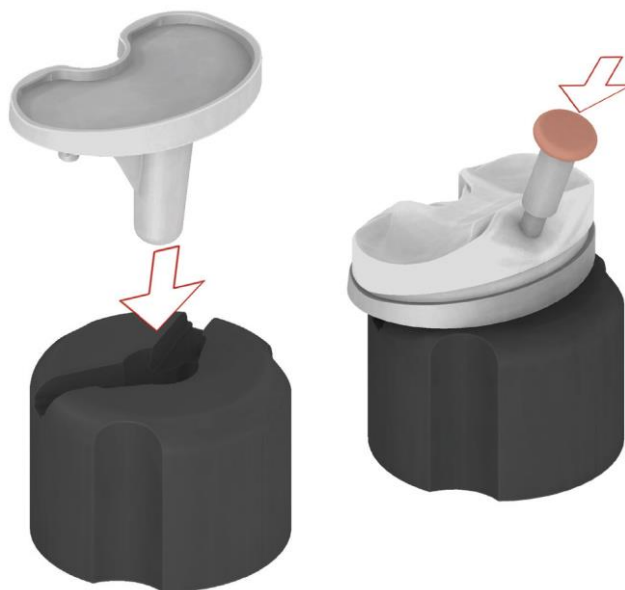
Tibial Component Assembly

Locate the Tibial Assembly Tool on a sterile, stable surface. Place the Tibial Tray component in the Tibial Assembly Tool. Insert the Tibial Bearing by locating the posterior feet into the posterior undercuts of the Tibial Tray. Push the Bearing Impactor Pin into the hole on the anterior aspect of the Tibial Bearing.

Hold the Assembly Tool and implant and strike the Bearing Impactor Pin with a hammer so that the bearing is fully seated in the Tibial Tray.

Remove the Bearing Impactor Pin from the Tibial Bearing. The combined Tibial Tray and Bearing assembly is now ready for implantation.

Note: A small gap of approximately 1mm will remain between the top of the tray and the Tibial Insert.



Step 28

Tibial Implantation

Clean the resected bone surface with a bone brush or pressurised lavage. Use suction to remove any debris and liquid. Dry thoroughly.

Place bone cement on the tibia, ideally with high viscosity cement or medium viscosity cement for syringe application. The Tibial Peg Plugs may be used to prevent cement seeping into the peg holes.

Note: It is recommended that the tibial stem, web and pegs are not cemented.

For Femoral Component sizes 1-4, assemble the Small Tibial Impactor with a Large Handle; for Femoral Component sizes 5-8, use the Large Tibial Impactor.

Insert the Tibial Tray and Bearing assembly carefully into the proximal tibia and impact.

Remove any excess cement that has been extruded around the Tibial Tray.



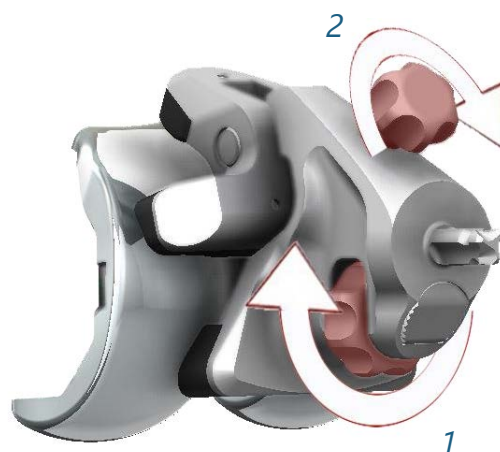
Step 29

Assemble Femoral Component

Connect the Femoral Introducer to a Quick Release Impaction Handle. Fully open the notch clamp and anterior lock by rotating all dials anticlockwise.

Assemble the Femoral Implant onto the introducer, ensuring that the notch clamp locates into the implant's intercondylar notch.

- 1 Secure the notch clamp by rotating the dial clockwise until hand tight.
- 2 Rotate the anterior dial clockwise to fully lock the implant to the introducer.



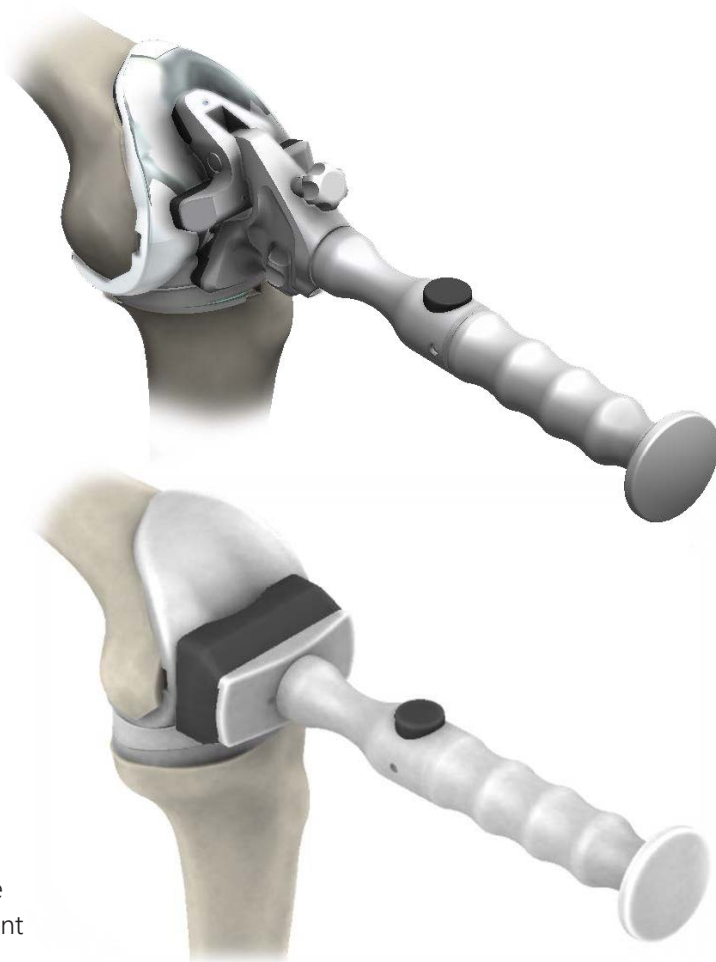
Step 30

Femoral Implantation

Place cement on the Femoral Component and push the implant firmly onto the femur in deep flexion. Extend the knee a few degrees as the component engages. Ensure the axis of the Large Handle is in line with the axis of the femoral shaft and impact.

Release the Femoral Introducer from the Femoral Component by rotating all dials anticlockwise.

Carefully extend the knee a little and fully impact the component into place using the Femoral Impactor assembled with a Large Handle.



Step 31

Final Seating

Place the knee carefully into full extension and elevate the patient's leg to fully seat the components and allow cement to set. Flex the knee again to remove all excess cement.

Step 32

Closure

Thoroughly irrigate the joint space. Achieve haemostasis and close the tissue in layers, according to standard procedure.

Optional: In-situ Tibial Trial and Final Assembly

If the desired thickness of Tibial Insert remains uncertain, it is possible to implant the Tibial Component and perform a further trial reduction with cemented implants.

Clean the resected bone surface with a bone brush or pressurised lavage. Use suction to remove any debris and liquid. Dry thoroughly.

Place bone cement on the tibia, ideally with high viscosity cement or medium viscosity cement for syringe application. The Tibial Peg Plugs may be used to prevent cement seeping into the peg holes.

Note: It is recommended that the tibial stem, web and pegs are not cemented.

Insert the Tibial Tray carefully using the Tibial Tray Impactor connected to the Quick Release Impactor Handle. Remove any excess cement that has been extruded around the Tibial Tray.

Implant the Femoral Component according to Step 29 and Step 30 (page 21).

Insert the appropriate Trial Bearing to perform a final trial reduction, seating the components while the cement goes off (Step 31, page 21). Take care not to damage any of the articulating surfaces when reducing the joint.

Once the cement has set, remove the Trial Bearing with the Trial Bearing Removal Tool.

Insert the definitive Tibial Bearing by locating the posterior feet into the posterior undercuts of the Tibial Tray. Connect a Quick Release Impaction Handle to the In-situ Bearing Impactor Drive and press into the hole on the anterior aspect of the tibial bearing. Strike the impaction handle with a sharp blow from a hammer so that the bearing is fully seated in the Tibial Tray.

Remove In-situ Bearing Impactor Drive. Optionally, ensure final seating by using the Tibial Impactor. Check for any extruded cement and remove if necessary.

Note: A small gap of approximately 1mm will remain between the top of the tray and the Tibial Insert.



Section 7 | Patella resurfacing: Cemented Patella

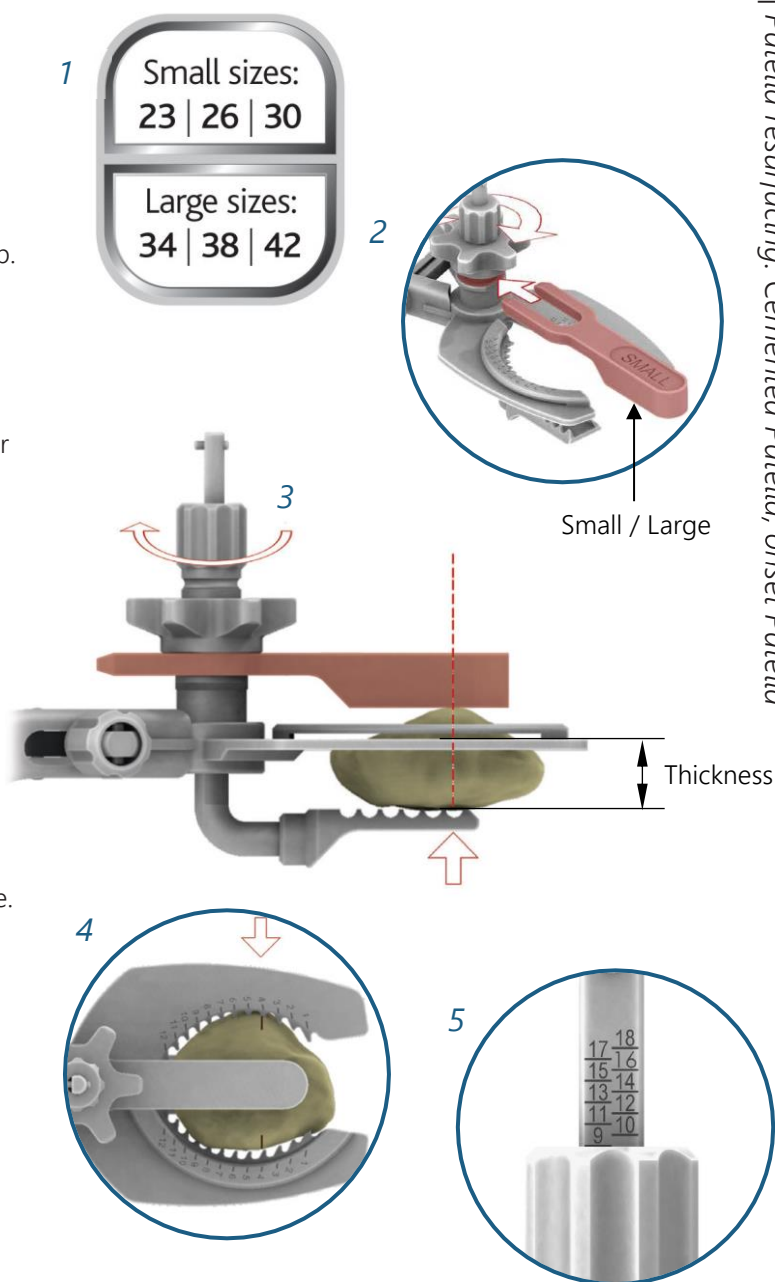
Note: Compatible with all sizes of Femur.

Step 33

Clamping

Trim the patella of any osteophytes and perform a trial reduction to assess if replacement and/or any release is indicated. The patella should be completely stable without stay sutures or finger help.

- 1 Determine the desired size by referring to the trial components.
- 2 Select the appropriate Cemented Patellar Feeler Arm: the Small Patellar Feeler Arm is used for Patella sizes 23 – 30; the Large Patellar Feeler Arm is used for Patella sizes 34 – 42.
- 3 Tighten the small wheel on the Cemented Patella Clamp until the patella is secured between the anterior referencing arm and the Cemented Patellar Feeler Arm.
- 4 Clamp the patella in line with the cartilage edge.
Note the offset of the patellar ridge and make a diathermy mark to reference the position of the Patellar Component.
- 5 Note the thickness of the remaining patellar bone stock using the clamp as shown. Check that the indicated value is at least 9mm.



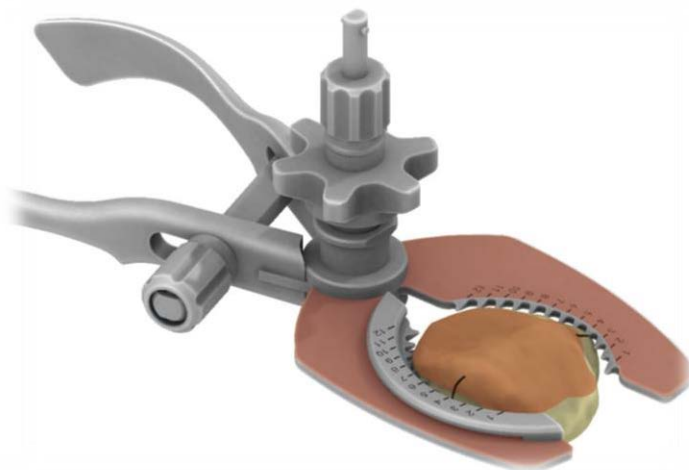
Step 34

Resection

Resect through the slotted guide.

Bone resection through the slot will ensure the original height of the patella is restored once the implant is in place.

The anterior reference arm may be retained in place to support the patella in the clamp during subsequent drilling operations.



Step 35

Drill Peg Holes

Attach the Patellar Peg Drill Guide to the Patellar Clamp and position the centre of the Patellar Peg Drill Guide with its centre offset to coincide with the offset noted for the native patellar ridge.

Clamp the Drill Guide using the large thumb wheel.

Create the three peg holes using the Cemented Patellar Peg Drill.



Step 36

Trial Reduction

Select Cemented Patellar Trial size for best coverage of the prepared patella.

Use the Cemented Patellar Trial to perform a trial reduction. Trim away any protruding bone edges.

Step 37

Implantation

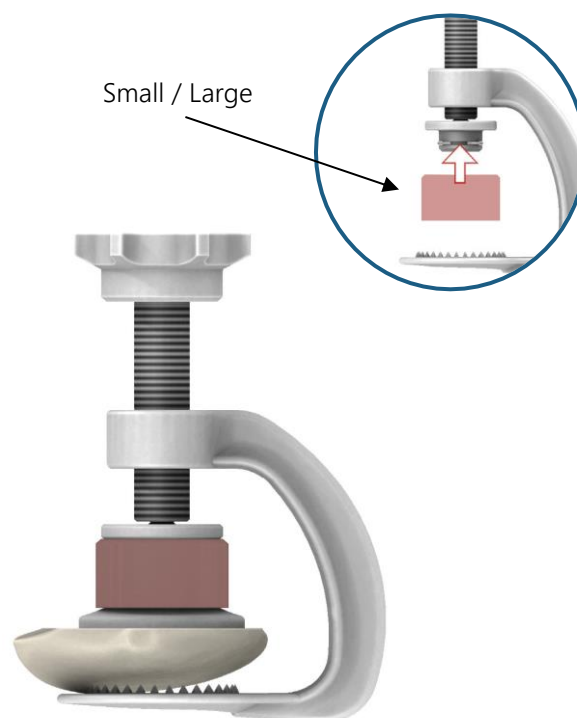
Note: Cement must be used with this implant; ideally high viscosity cement or medium viscosity for syringe application.

Assemble the appropriate Cemented Patellar Compressor Attachment for the Patellar Component size used.

The Large Patellar Compressor Attachment is used for Patellar Component sizes 34 – 42; the Small Patellar Compressor Attachment is used for Patellar Component sizes 23 – 30.

Place cement around the Patellar Component pegs. Place the Patellar Component on the prepared patella and compress using the Cemented Patellar Compressor.

Remove any residual bone cement and allow the cement to polymerise. Remove the Cemented Patellar Compressor.



Section 8 | Patella resurfacing: Cementless Patella

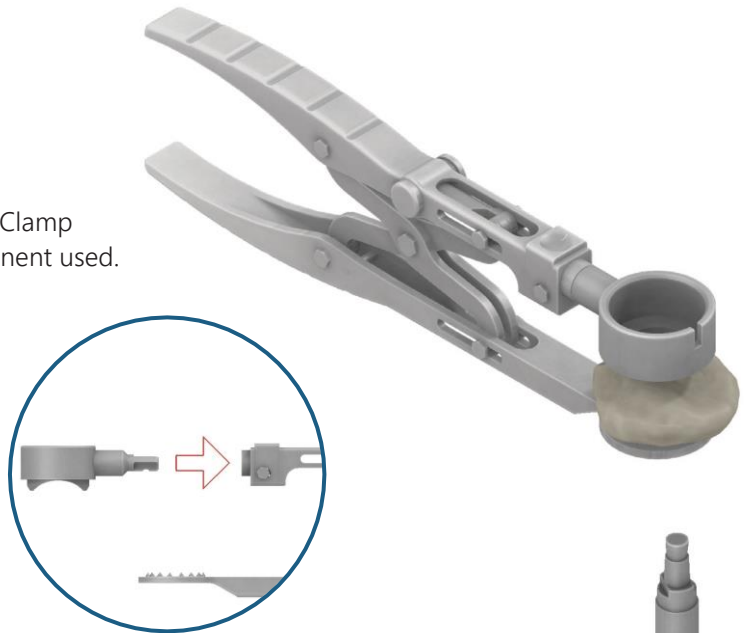
Note: Not available in the US.

Step 38

Assemble Clamp

Assemble the appropriate Cementless Patellar Clamp Collar according to the size of Femoral Component used.

Evert the patella laterally and position the clamp medially on the patella, seating the ridge of the Cementless Patellar Collar over the patellar ridge if available.



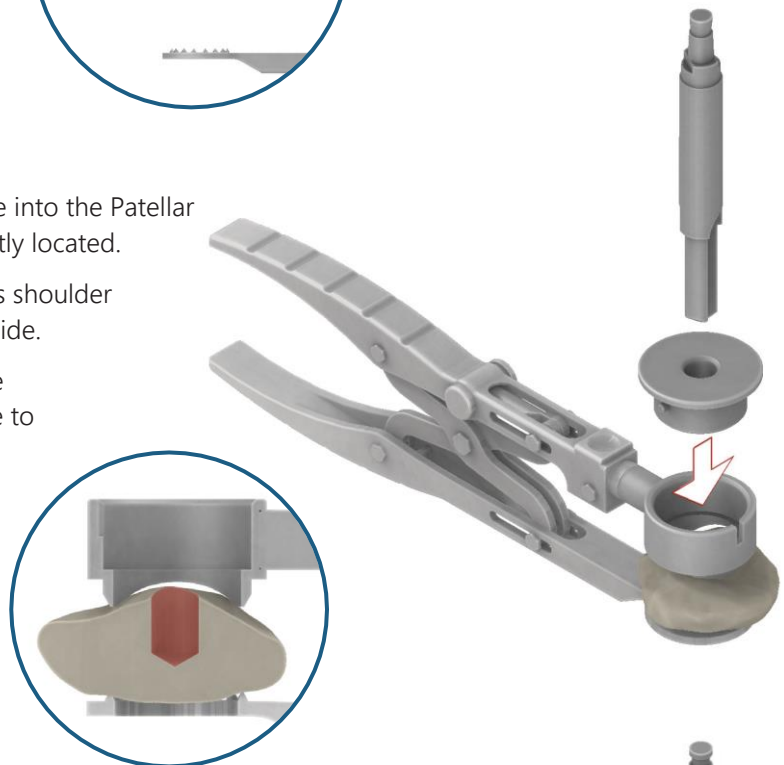
Step 39

Drill Peg Hole

Insert the Cementless Patellar Peg Drill Guide into the Patellar Collar, ensuring that the locator pin is correctly located.

Advance the Cementless Patellar Drill until its shoulder contacts the base of the Patellar Peg Drill Guide.

Note: The base of the peg hole is used in the following steps to define full depth: take care to remove all debris from the base of the hole.

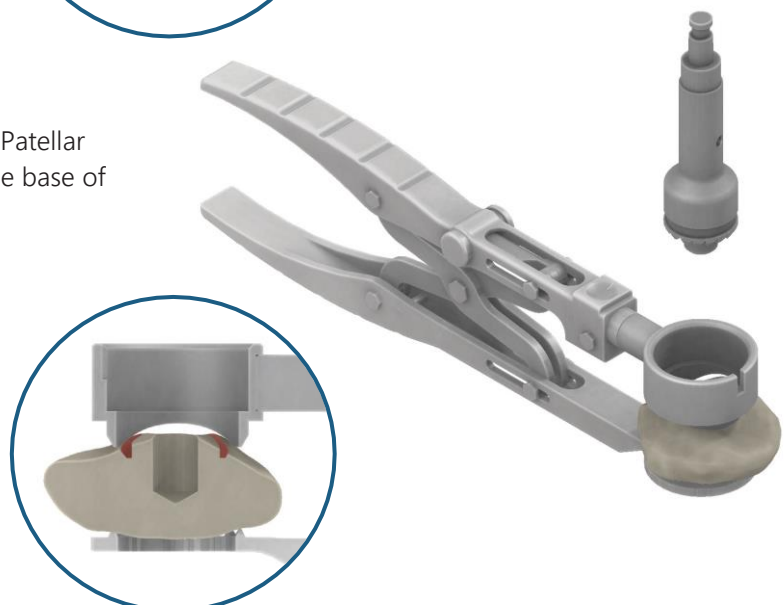


Step 40

Cut Bore Profile

Advance the appropriate size of Cementless Patellar Ring Cutter until the centre-guide reaches the base of the peg hole.

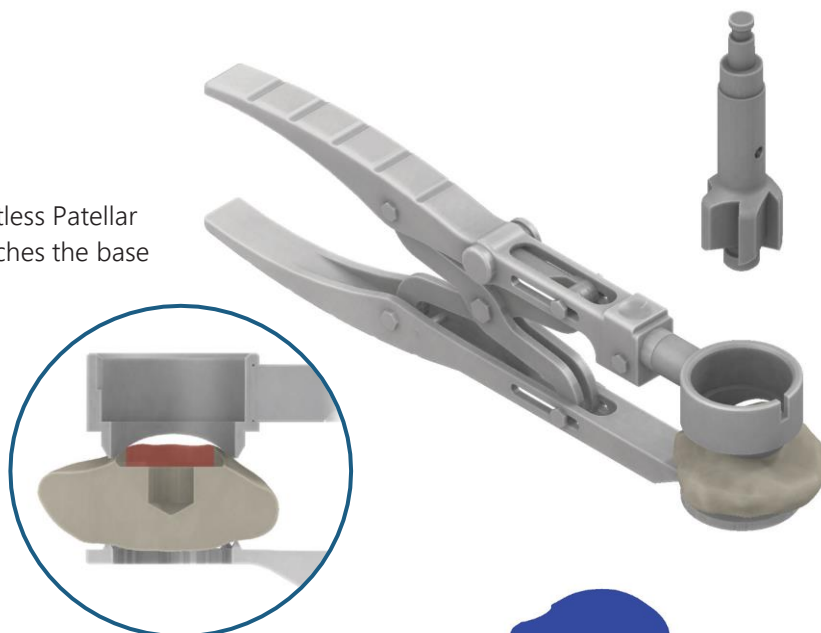
Note: This step is not required for the 16mm Cementless Patellar Component.



Step 41

Counter-bore Patella

Advance the appropriate size of Cementless Patellar Milling Cutter until the centre guide reaches the base of the peg hole.

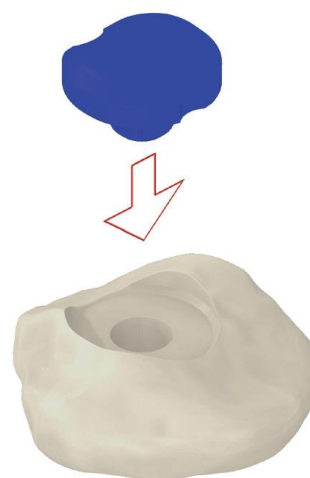


Step 42

Trial Reduction

Insert the Cementless Patellar Trial, with the notch approximately in line with the patellar tendon. Check that the articulating surface of the trial is level with, or slightly proud of the bone surface. The clamp can be removed once proper seating is confirmed.

Perform a trial reduction, checking patellar tracking and stability. The patella should be completely stable without the need for stay sutures or finger support.



Step 43

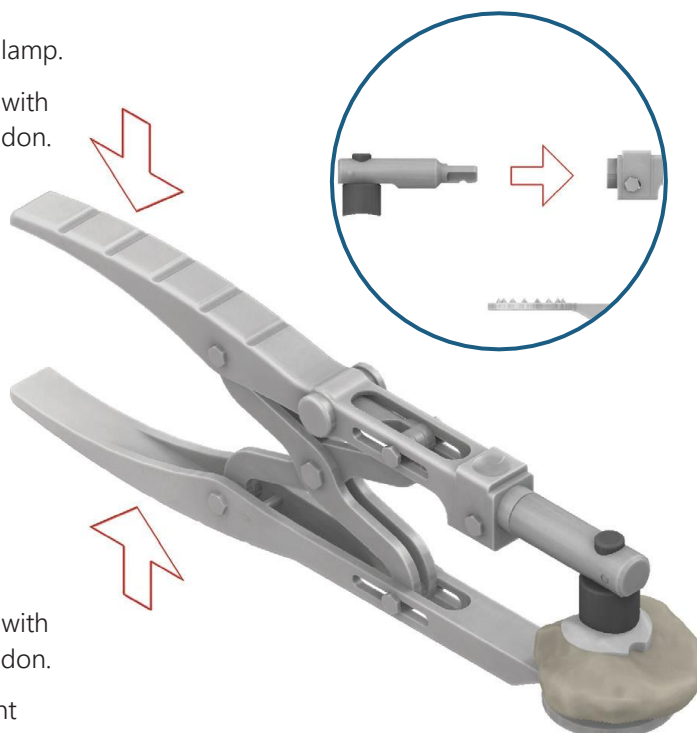
Implant Patellar Component

Assemble the Patellar Compressor with the Patellar Clamp.

Place the Cementless Patella into the prepared bone with the notch approximately aligned with the patellar tendon.

Position the Patellar Clamp over the Cementless Patella and squeeze firmly to fully seat the component.

Note: If the quality of prepared bone requires it, a small amount of cement can be added to the back of the Cementless Patella. If using cement, implant with the Patellar Compressor.



Alternative Method

Place the Cementless Patella into the prepared bone with the notch approximately aligned with the patellar tendon.

Reduce the patella and adjust the rotational alignment according to the femoral articulation. Manually (for example with the heel of the hand) impact the patella to fully seat the implant.

Appendices

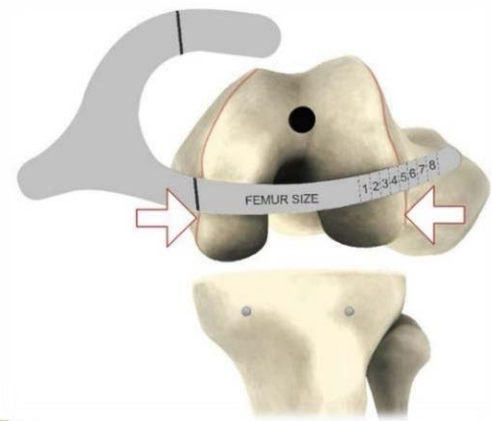
Appendix A | Anterior Cut First Technique

Note: The following steps are performed after tibial resection shown on pages 5-7.

Step A1

Sizing the femur

As a guide only, estimate the femur size according to its width at the widest point using the Femoral Angel Wing. Note the size indicated between the two adjacent lines that best fit the femur width.

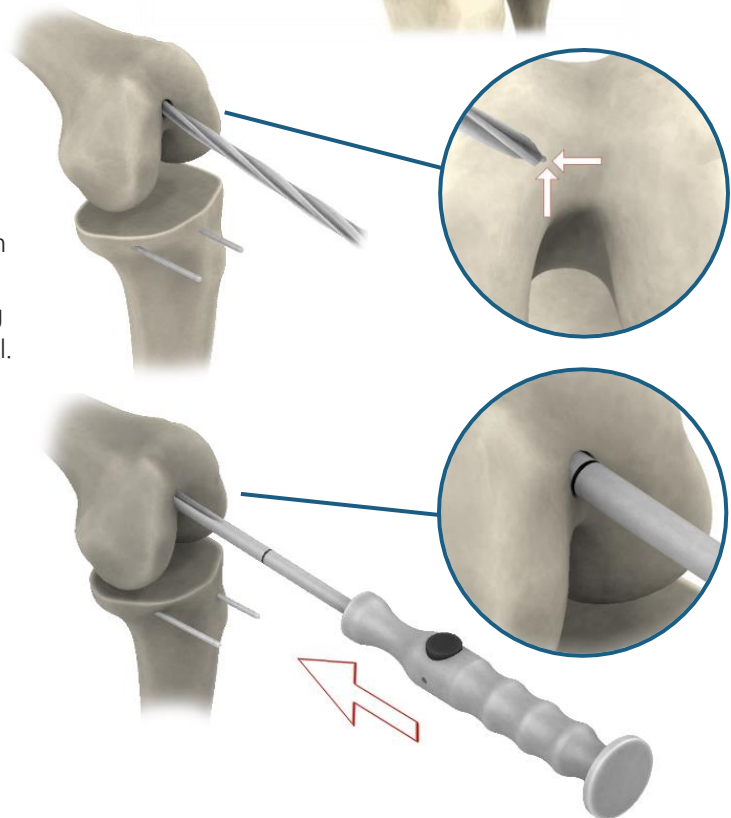


Step A2

Insert IM Rod

Position the tip of the Femoral IM Drill 5-10mm proximal to the intercondylar notch and 5-10mm medial to the midline. Advance the IM Drill until the depth reference line meets the femur, taking care to find the correct path of the femoral canal. Avoid rotating the IM Drill.

Insert the IM Rod until the depth reference line meets the femur. Remove the Large Handle.



Step A3

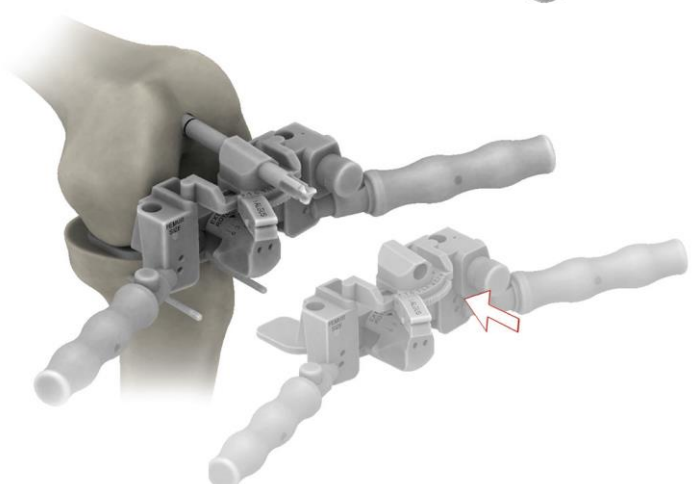
Assemble Anterior Femoral Alignment Guide

Note: Preparation of the Anterior Femoral Alignment Guide is shown on page 45.

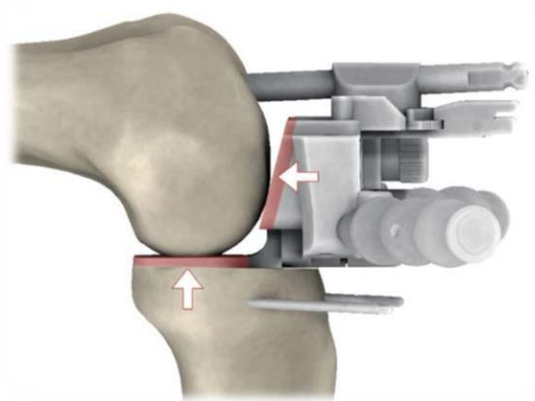
Set the external rotation to the desired angle for the left or right leg. An external rotation of 3° is the recommended default setting.

Set the valgus angle left or right as required. An angle between 5° and 7° is recommended.

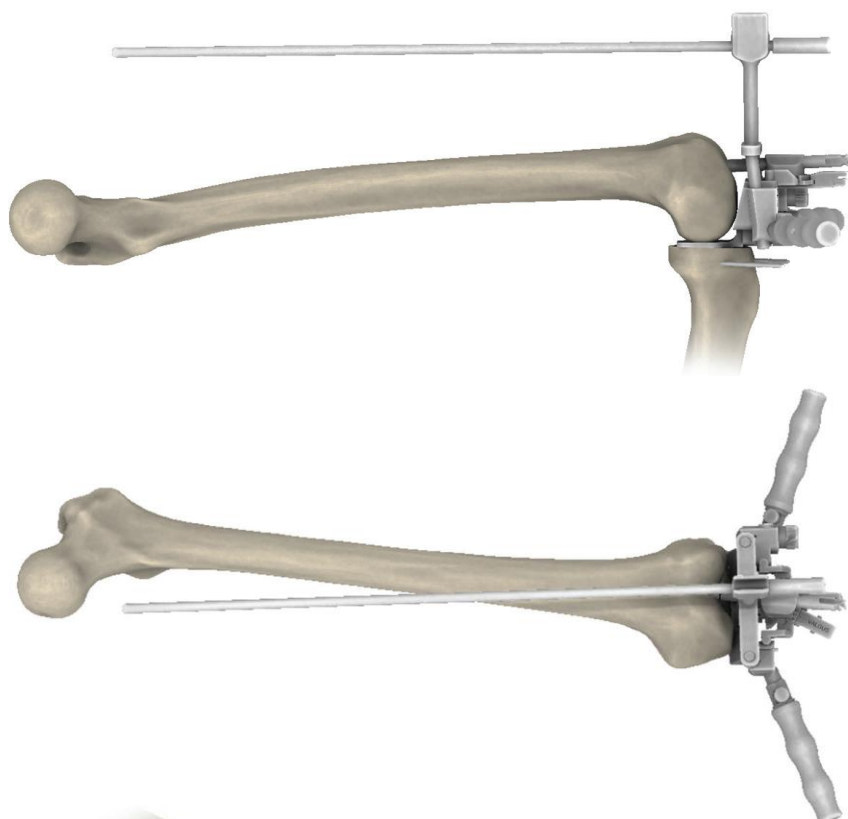
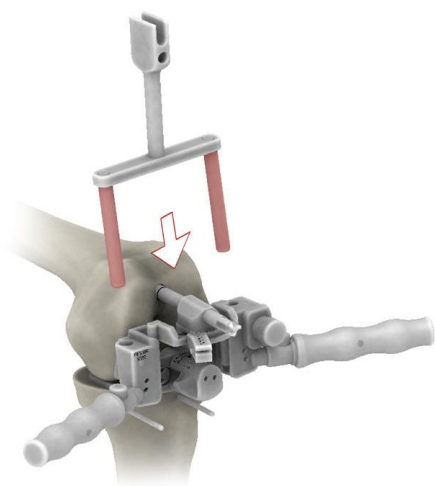
Slide the Femoral Alignment Guide over the IM Rod, through the hole of the Valgus Adjuster until the jig is positioned up against the distal femoral condyles.



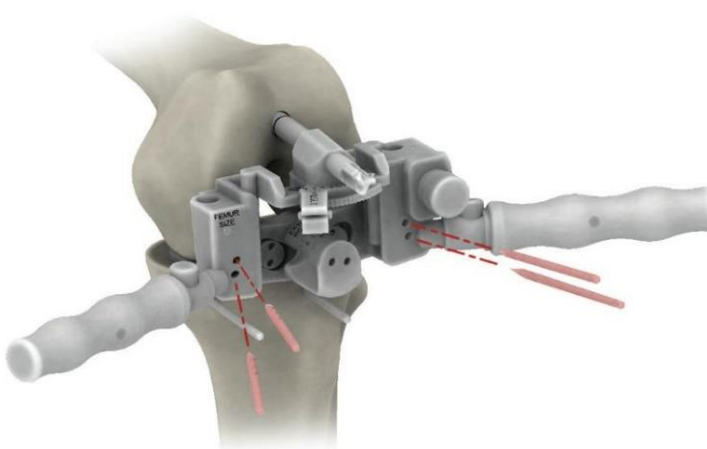
With the knee at 90° of flexion, allow the weight of the femur to sit down onto the posterior footplate and then cut tibia. Ensure that there is direct contact between the posterior femoral condyles and the footplate medially and laterally.



Optionally, check the femoral axis alignment using the External Alignment Rod Mount with the External Alignment Rod.



Secure the Femoral Alignment Guide with Long Pins.

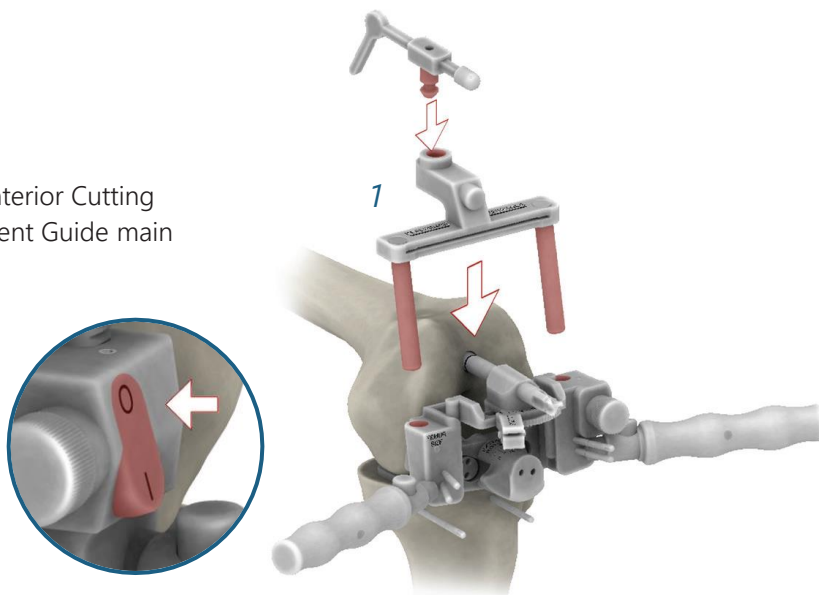


Step A4

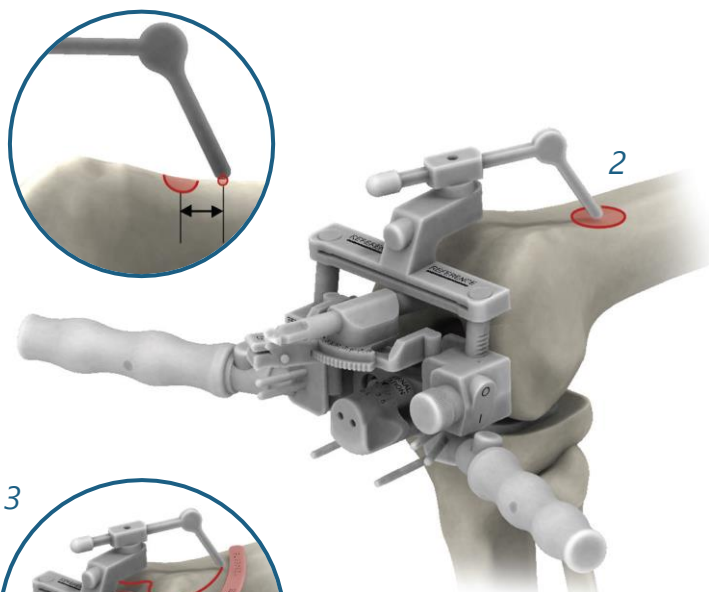
Set Anterior Cutting Guide

- 1 Assemble the Femoral Stylus and the Anterior Cutting Guide with the Anterior Femoral Alignment Guide main body.

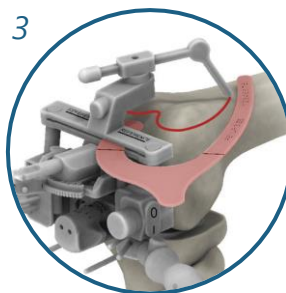
Check that the dial on the right side of the Femoral Guide is in the unlocked position (O - open; I - locked.).



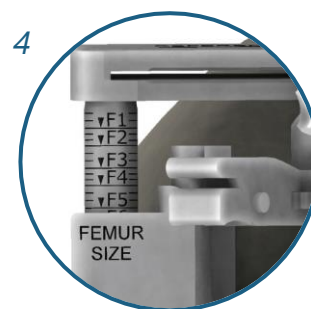
- 2 Locate the proximal extent of the anterior lateral femoral ridge. Lower the Femoral Stylus until its tip contacts the anterior femoral cortex 1cm proximal of the lateral femoral ridge.



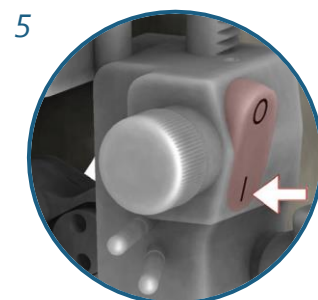
- 3 The Femoral Angel Wing can be used at any time to visualize the anterior cut plane and to check that the cut will not notch the femur.



- 4 Observe the indicated femoral size, shown at the intersection between the Anterior Cutting Guide and the Femoral Alignment Guide main body, on the left side.



- 5 When the appropriate anterior cut height has been established, lock the Anterior Cutting Guide in position. Record the femoral component size. Should an 'in-between' size be recorded, prepare the femur for the smaller of the two sizes.



Note: The anterior reference point for the SAIPH® Knee differs from other devices. Failure to position the stylus correctly can lead to an oversizing of the component.

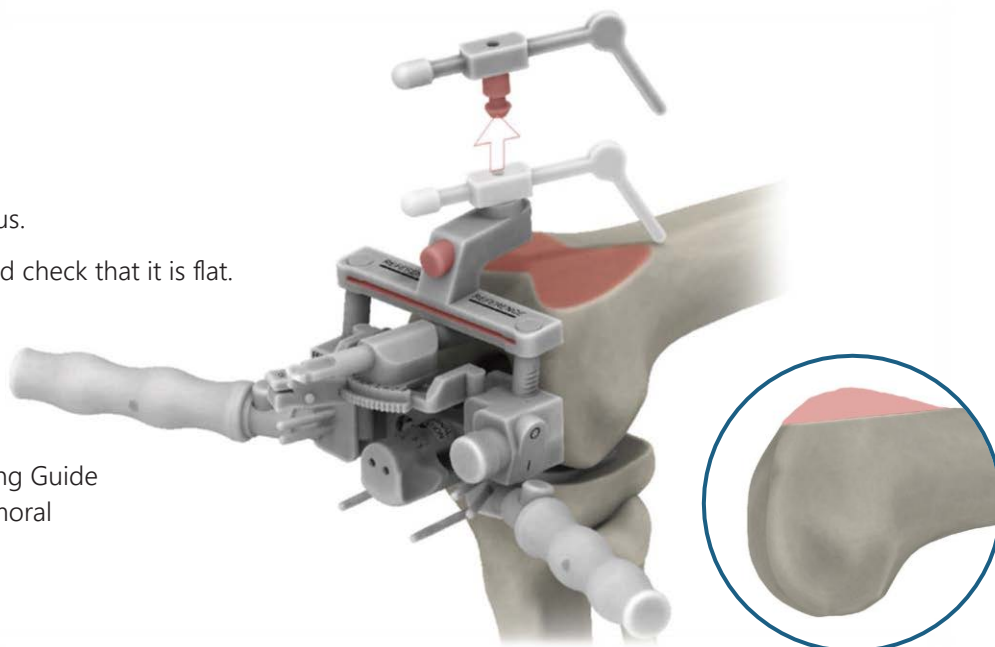
Step A5

Resect Anterior Femur

Remove the Femoral Stylus.

Cut the anterior femur and check that it is flat.

Unlock the Anterior Cutting Guide and remove from the Femoral Alignment Jig main body.



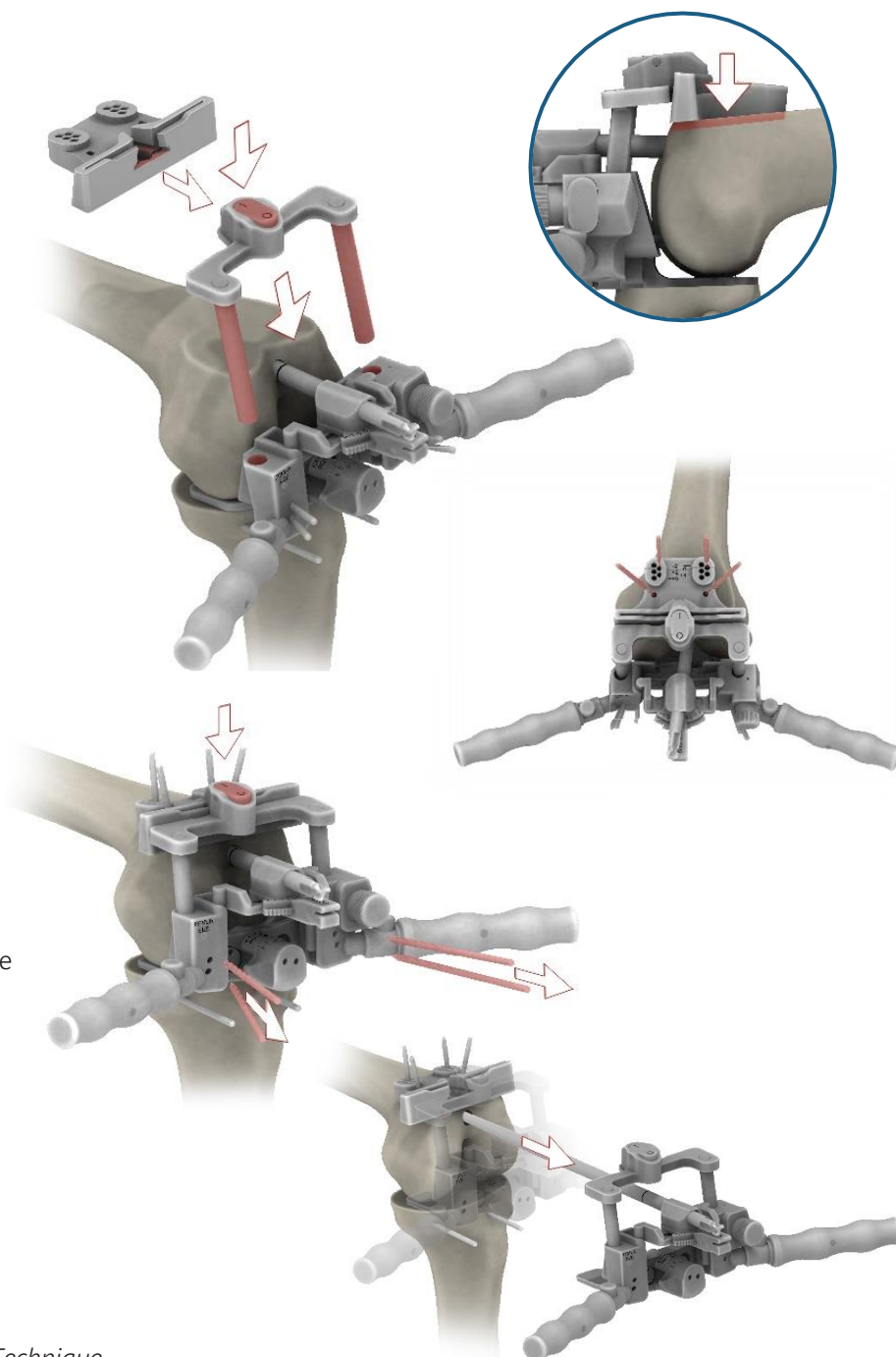
Step A6

Position Distal Cutting Guide

Attach the Distal Cutting Block to the Distal Cutting Block Mount and lock it in place.

Slide the Distal Cutting Block Mount onto the Anterior Femoral Alignment Guide main body so that the Distal Cutting Block rests flat on the anterior cut.

Pin the Distal Cutting Block through the pin holes (at the 0mm position). Add additional oblique Pins as required to ensure that the Distal Cutting Block is secure and in full contact with the bone.



Unlock the Distal Cutting Block Guide.

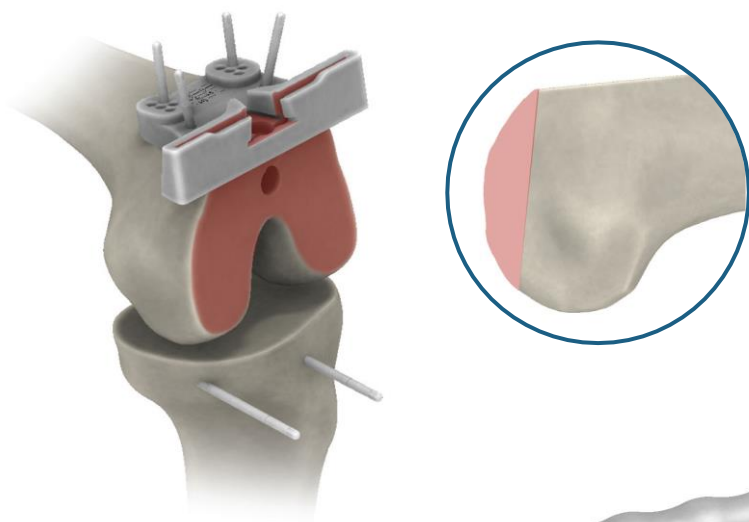
Remove the pins of the Femoral Alignment Guide and slide the jig off the femur with the IM Rod, leaving only the Distal Cutting Block for resection.

Step A7

Resect Distal Femur

Resect the distal femur.

After removing the bone, check that the cut is flat; to do this, the cut plane can be 'sighted' with the use of an Angel Wing.



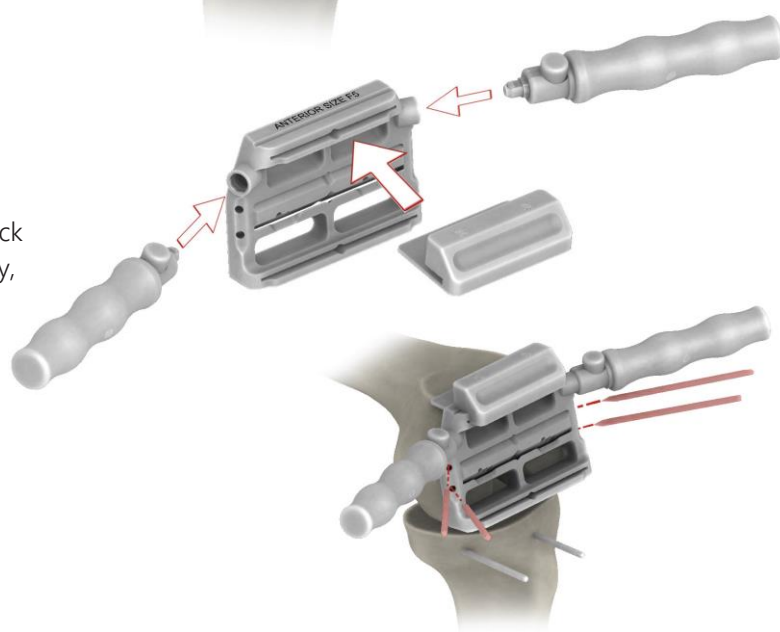
Step A8

Placing the Multicut Block

Assemble the relevant size femoral Multicut Block with the Anterior Reference Plate and, optionally, the Small Handles.

Place the Multicut Block so that it lies flush with the anterior and distal femur cuts.

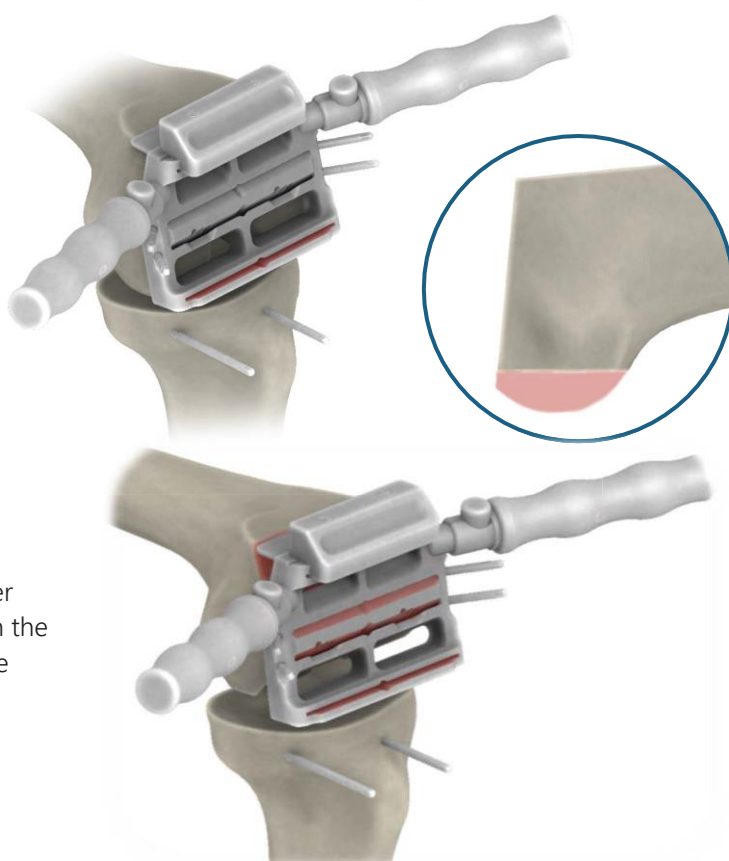
Secure the Multicut Block with medial and lateral Pins.



Step A9

Resect the Posterior Condyles

Remove the Multicut Block. Leave one of the fixation Pins in place to ease positioning of the Multicut Block for the chamfer cuts.



Return to Operative Technique Step 19, page 15.

Note: When completing Step 20 "Complete Chamfer Cuts", reposition the Multicut Block, assembled with the Anterior Reference Plate, so that it lies flush with the anterior and distal femur cuts.

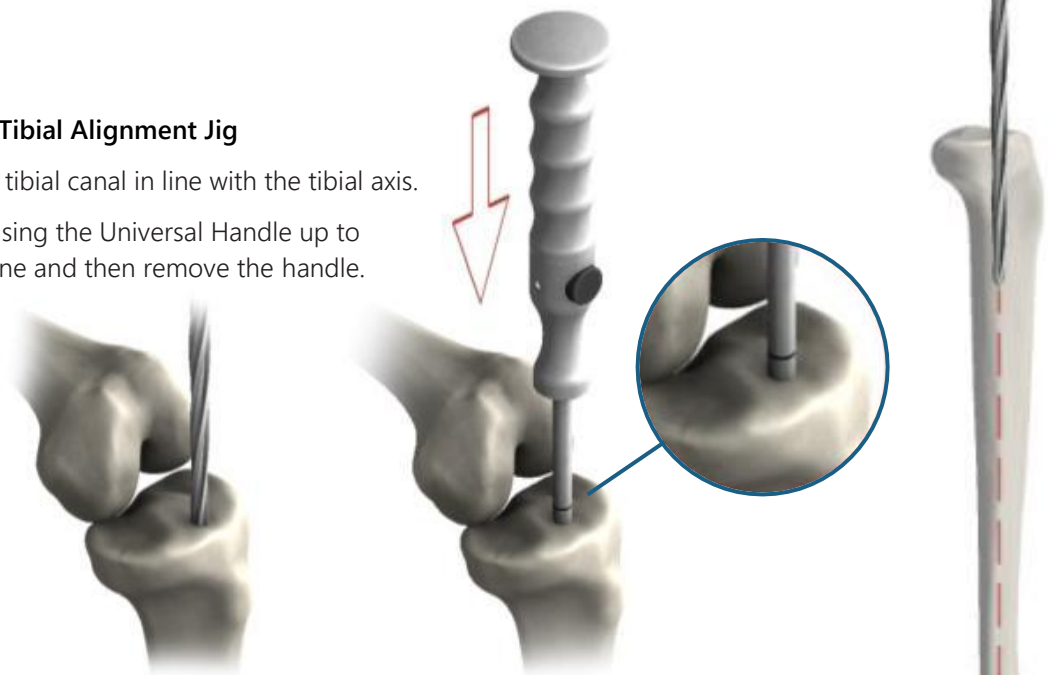
Appendix B | Tibial Preparation: Intra-medullary Alignment

Step B1

Assemble the IM Tibial Alignment Jig

Carefully ream the tibial canal in line with the tibial axis.

Insert the IM rod using the Universal Handle up to the laser marked line and then remove the handle.



Attach the tibial cutting block to the IM Tibial Alignment Jig swing arm and place the IM jig over the IM rod.

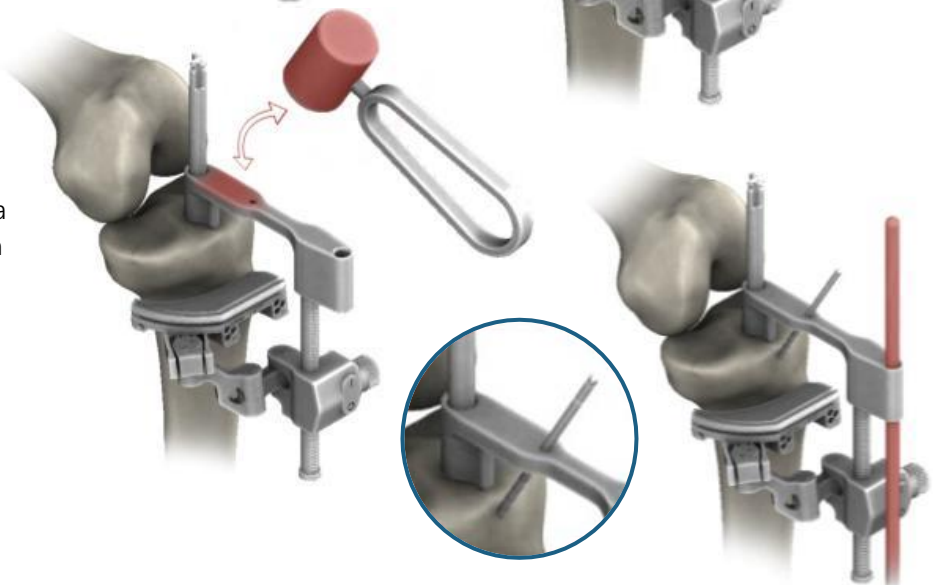
Note: Ensure that the IM rod is not pushed into the tibia.



Once the jig is positioned in the preferred position, hammer the flat area located anterior to the IM rod.

If extra fixation is required, insert a standard long pin through the pin hole as shown.

Optionally, check the tibial axis alignment using the External Alignment Rod.



Step B2

Follow steps as shown in the standard operative technique.

When removing the guide after performing the tibial cut, ensure that the swing arm clip is removed from the tibial cutting block first.

Ensure that the IM Rod is removed before performing the tibial cut.

Appendix C | BESPOKE™ Instrumentation

Introduction to the BESPOKE™ instrumentation

The BESPOKE™ instruments provide an alternative method to achieve tibial and femoral alignment without the need for intramedullary instruments. BESPOKE™ preoperative planning may also help to define optimum surgical parameters for complex cases.

The BESPOKE™ instruments comprise one femoral and one tibial phantom, for help in visualising positioning and resections, and one tibial and one femoral positioning and cutting guide. They are provided supplementary to the standard instrumentation which is required for all bony preparation and trialling steps according to the standard operative technique.



Figure 1 BESPOKE™ Instruments: box contents

Training Requirements

The surgeon is responsible for checking the alignment of all guides before cutting. Checking instruments are provided with the standard instrumentation and their use is described in this technique. If suitable positioning of the BESPOKE™ instruments is not possible, the standard alignment instruments must be used. Full training and familiarity of the standard operative technique, provided by a representative or agent of MatOrtho®, is a prerequisite to the use of BESPOKE™ instruments.

Training on the BESPOKE™ process, preoperative planning and use of BESPOKE™ instruments is provided by OneFIT Medical.

BESPOKE™ instruments and planning services are manufactured and supplied by OneFIT Medical: 18 rue Alain Savary | 25 000 | Besançon | France | +33 (0)3 81 25 24 27 | contact@onefit-medical.com.

Use of the BESPOKE™ instrumentation

Indications

To be used for preparation of the femur and tibia for total knee arthroplasty using the SAIPH® Knee System. Uniquely templated BESPOKE™ Instruments include reference guides and are used in conjunction with standard instruments.

Warnings

Check that the patient identification details shown on the label are correct before use.

Check all packaging for any signs of damage. If the sterile barrier packaging or templates appear to be damaged, do not use.

BESPOKE™ Instruments are single-use and are not for implantation. They should be disposed of after use following internal biological waste procedures.

The surgeon is responsible for checking the alignment of all guides before cutting. Checking instruments are provided to do this and their use is described in this technique.

If suitable positioning of the BESPOKE™ Instruments is not possible, use the standard alignment instruments described in this Operative Technique, using the Distal Cut First femoral preparation method.

If the surgery has been excessively delayed, take into account any changes that may have occurred to periarticular geometry between CT-scan, preoperative plan and surgery.

Precautions

Follow the steps described in this document and ensure that BESPOKE™ Instruments are removed before the TKA device is implanted.

The planned femur size will be marked clearly on the template. A sizing chart indicating compatible component combinations is shown on page 64.

Materials

BESPOKE™ Instruments are made from Selected Laser Sintered (SLS) nylon PA12, suitable for short-term passive tissue contact. Ensure the templates are removed before implantation.

Nylon is not readily detectable using external imaging techniques.

Preoperative planning

The planning software, available online, is a platform designed for the management of orthopaedic operations handled via the dedicated preoperative planning process. It is available at <https://onefit-online.com>.

To create a new account, select the link 'New account' on the login page.

Further information can be found in the OneFIT User Manual provided with your training. All associated OneFIT manuals are available through the website.

The BESPOKE instruments process

The overview process for

- 1 Appointment for CT scan. Note that the OneFIT CT-scan imaging protocol (available at www.onefit-medical.com) must be complied with.
- 2 Upload the CT scan data to the planning software.
- 3 The surgeon will receive the planning proposal. Note that the proposal is generated automatically, based on standard value, and may not be suitable for the individual patient.
- 4 Surgeon modification or approval of the plan proposal.
- 5 Manufacture of the BESPOKE™ instruments
- 6 Delivery of the non-sterile BESPOKE™ instruments to the hospital.
- 7 Sterilisation.
- 8 Surgery.
- 9 Disposal.

BESPOKE™ Operative technique: *Tibial Preparation*

Step C1

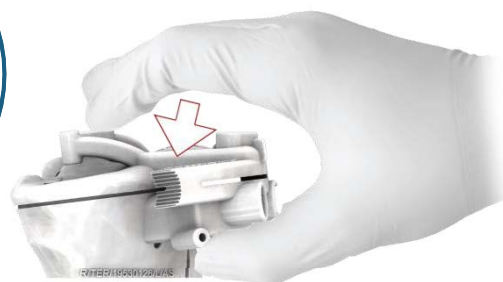
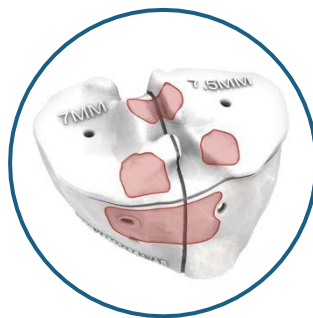
Exposure

Exposure of the joint is described in Section 1 | *General Preparation*, page 4.

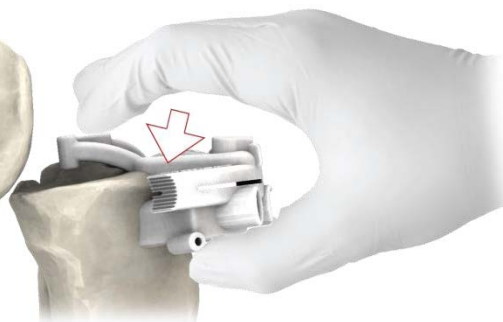
Step C2

Position BESPOKE™ Tibial Guide

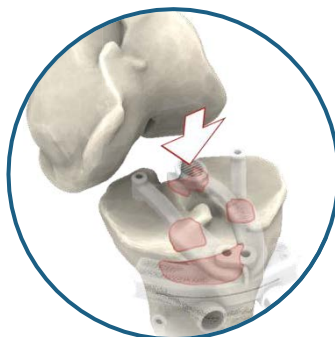
- 1 Observe the contact points identified in red (inset image) on the Reference Tibia Model. Assemble the BESPOKE™ Tibial Guide with the using thumb and index finger. Observe the fit and relative positioning.



- 2 Transfer the BESPOKE™ Tibial Guide to the native tibia, again using thumb and index finger, and observe fit and relative positioning.



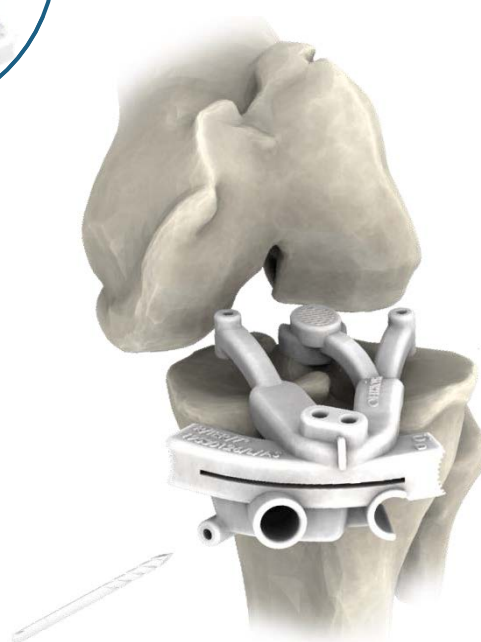
Check that the BESPOKE™ Tibial Guide contacts the native tibia in the same locations and that any soft tissue or other obstructive artefact is not preventing proper seating.



The template includes a button feature at the optimum position to apply pressure for the best stability. When in place, the template should be stable.

If it is necessary to trim obstructing soft tissues to achieve a stable fit, take care not to compromise ligamentous structures, or to remove underlying or surrounding hard bone.

- 3 While applying light pressure on the button feature, secure the BESPOKE™ Tibial Guide with a Short Pin, taking care not to alter the position of the template.



Step C3

Check Tibial Alignment

Check the tibial axis alignment using the Tibial Alignment Guide Mount and the Alignment Rod.



Step C4

Check Cut Position

Note the planned tibial cut plane shown on the reference tibia model.

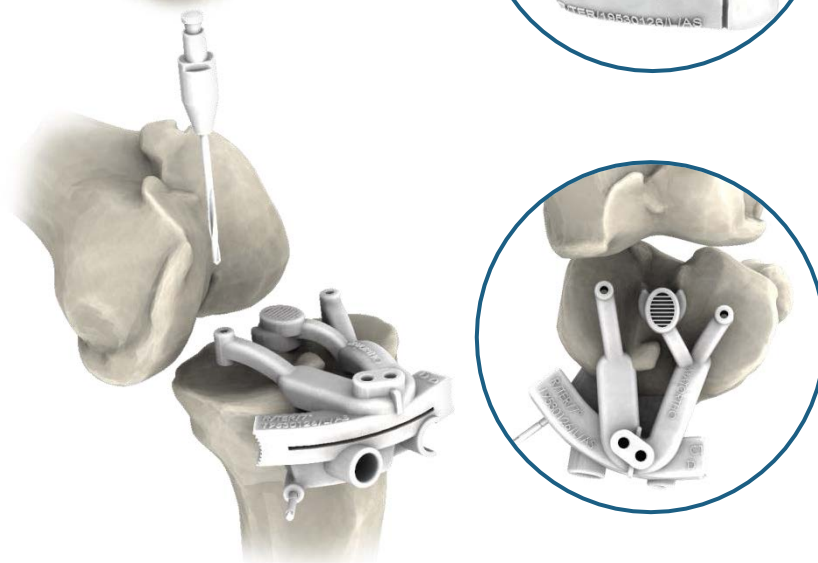
Using an Angel Wing, check the tibial cut plane.



Step C5

Mark Tibial Rotation

Mark tibial rotation using the Pin Drill, indicate tibial rotation with two small holes using the medial and lateral indication features.



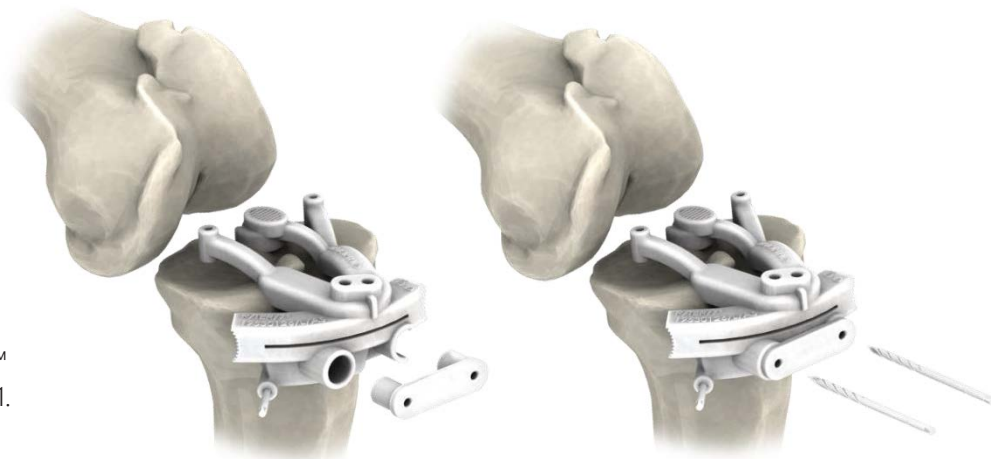
Step C6

Insert Cutting Guide Pins

Attach the Pin Guide to the BESPOKE™ Tibial Guide.

Using the Pin Driver or Pin Inserter/Extractor, insert two Long Pins through the Pin Guide.

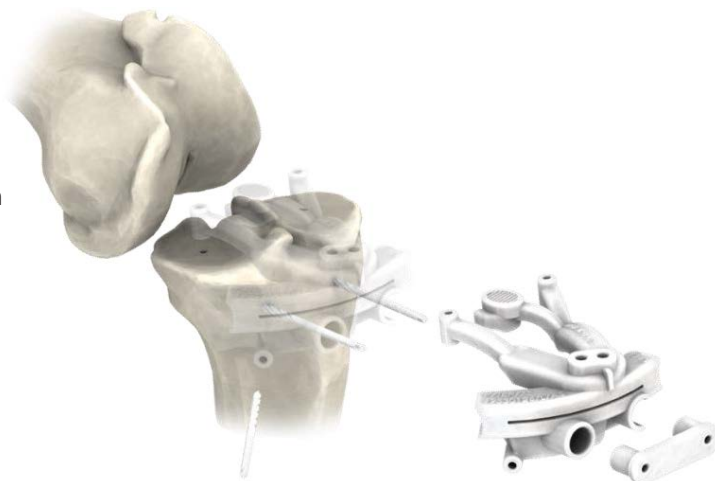
Note: 90mm Long Pins are recommended for use with BESPOKE™ instruments, pin pack number 255-301.



Step C7

Remove BESPOKE™ Guide

Leaving the two Long Pins in place, remove the Pin Guide, Short Pin and BESPOKE™ Tibial Guide.



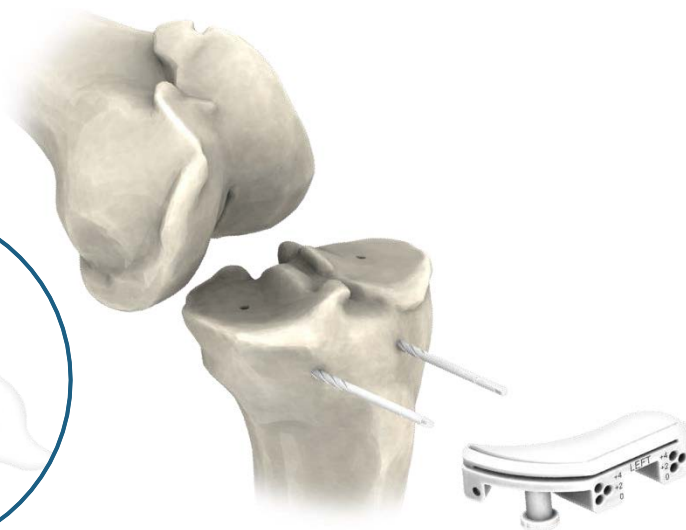
Step C8

Assemble Tibial Cutting Guide

Slide the Tibial Cutting Guide onto the two anterior Pins at the 0mm position (lowest holes).

Using an Angel Wing, check the tibial cut plane. Noting the planned tibial cut plane shown on the Reference Tibia Model.

When the Cutting Guide position is confirmed, insert a medial oblique Long Pin.



Step C9

Resect Tibia

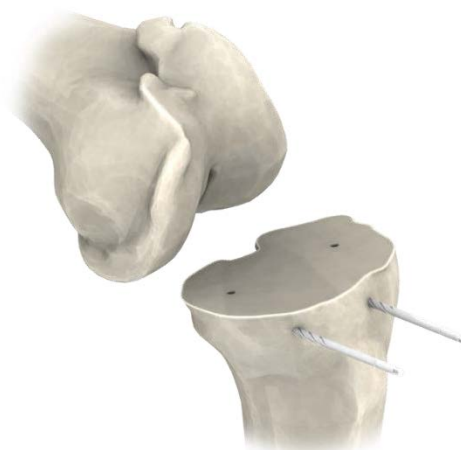
Resect the tibia with a 1.27mm thick saw blade.

Remove the medial oblique Pin and the Cutting Block, leaving the parallel anterior Pins in place in case additional resection is later required.



Check that the cut is complete and flat.

Remove any remaining tibial osteophytes.



Return to the Operative Technique Step 7, page 7.

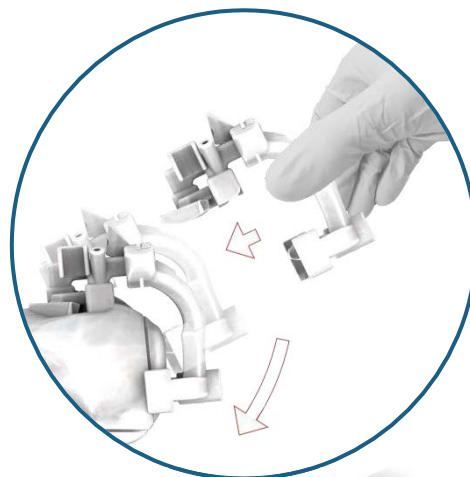
BESPOKE™ Operative technique: Femoral Preparation

Step C10

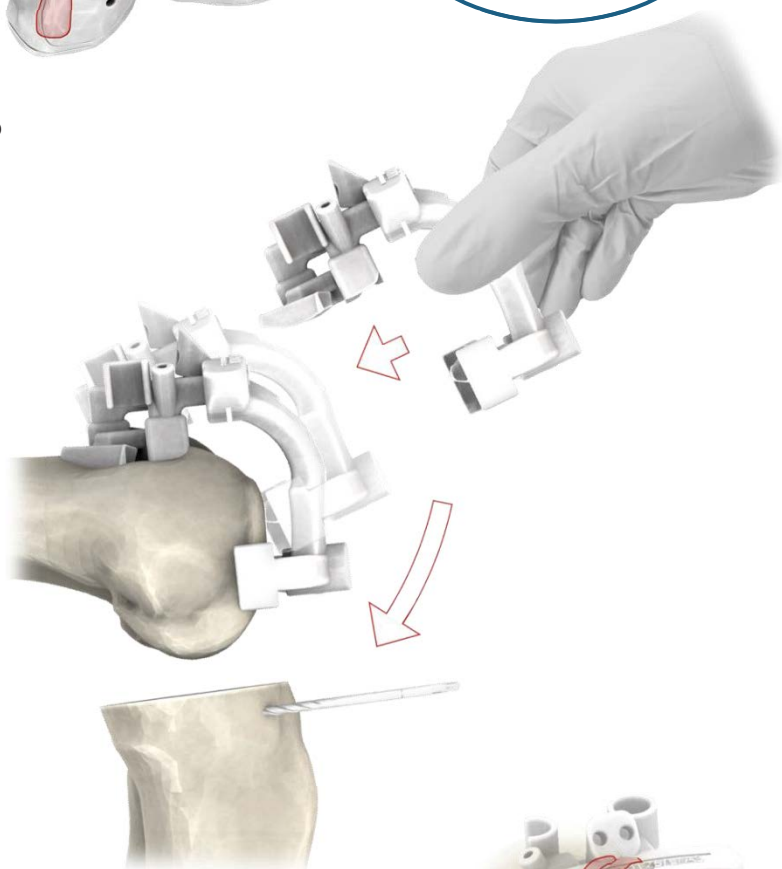
Position BESPOKE™ Femoral Guide

- 1 Observe the contact points identified in red on the Reference Tibia Model.

Assemble the BESPOKE™ Femoral Guide with the Reference Femur Model using thumb and index finger (inset). Observe the fit and relative positioning.



- 2 Transfer the BESPOKE™ Femoral Guide to the native femur, again using thumb and index finger, and observe fit and relative positioning.



- 3 Check that the BESPOKE™ Femoral Guide contacts the native femur in the same locations and that any soft tissue or other obstructive artefact is not preventing proper seating, in particular within the intercondylar notch.

The template includes one button area at the optimum position to apply pressure for best stability.

If necessary, trim obstructing soft tissues to achieve a stable fit, take care not to compromise ligamentous structures, or to remove underlying or surrounding hard bone.



Step C11

Insert Short Pin

Secure the BESPOKE™ Femoral Guide to the femur with a short pin, taking care not to alter the position of the BESPOKE™ Femoral Guide.

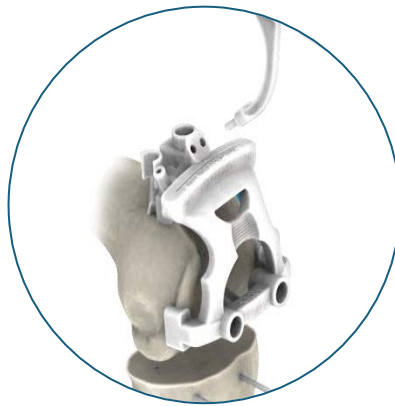


Step C12

Check Femoral Alignment

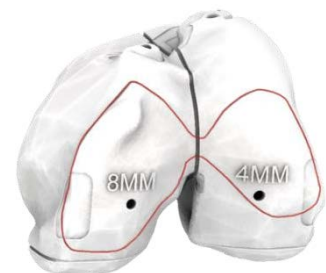
Assemble the Femoral Alignment Guide Mount and the Alignment Rod with the BESPOKE™ Femoral Guide.

Check femoral axis alignment.



Note the planned distal femur cut plane shown on the Reference Femur Model.

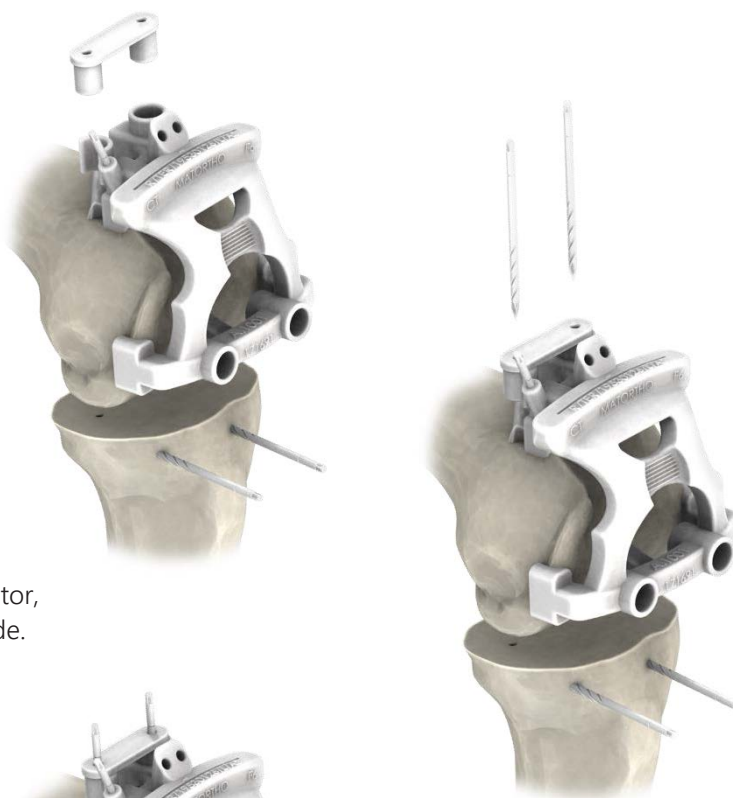
Using an Angel Wing, check the distal cut plane.



Step C13

Insert Cutting Guide Pins

Attach the Pin Guide to the BESPOKE™ Femoral Guide.

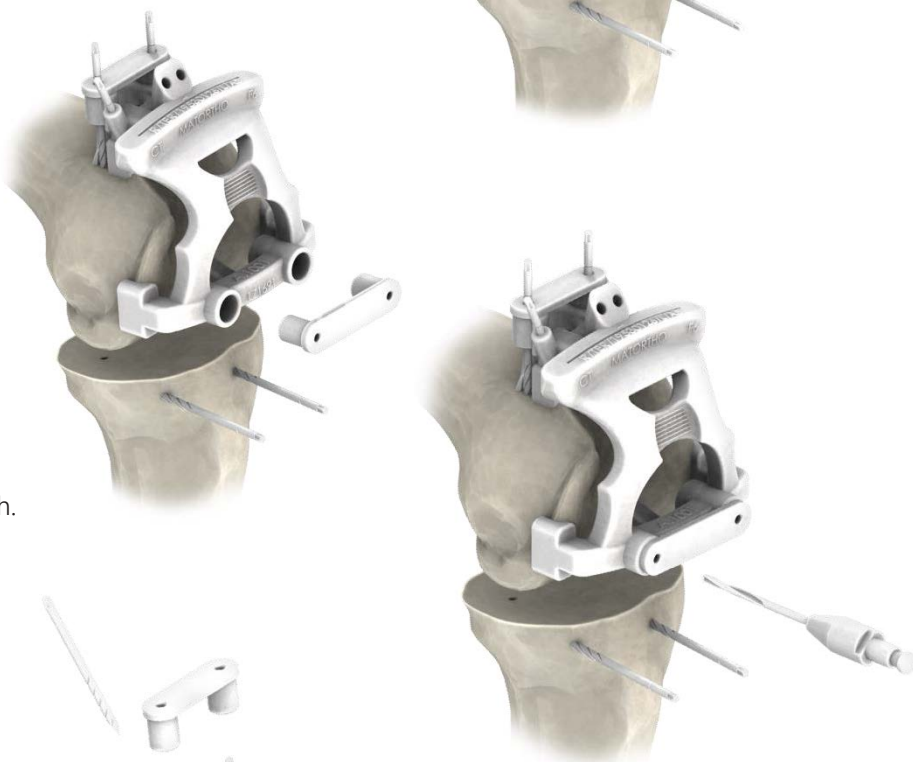


Using the Pin Driver or Pin Inserter/Extractor, insert two Long Pins through the Pin Guide.

Step C14

Drill Distal Pin Holes

Place the Distal Holes Pin Guide into the BESPOKE™ Femoral Guide.



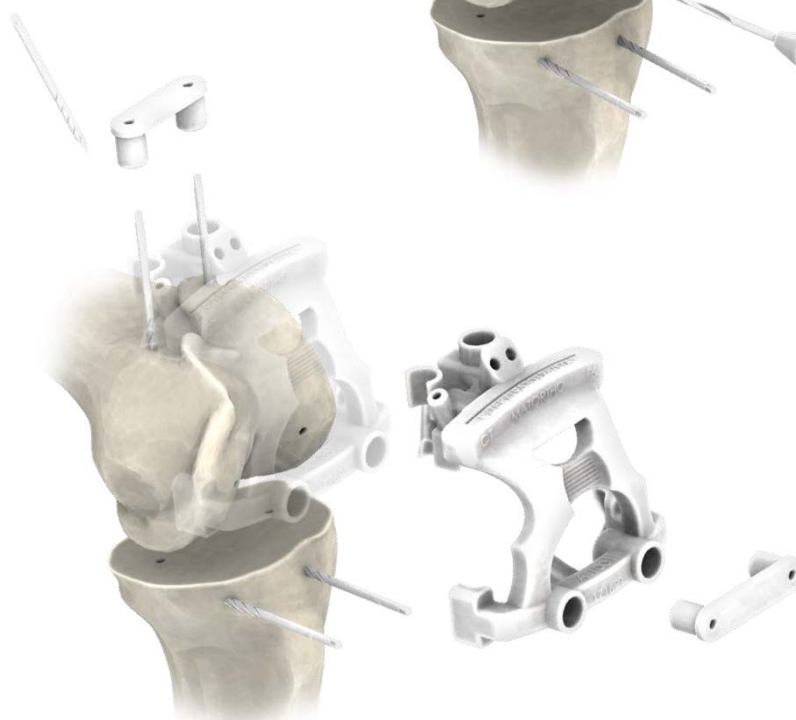
Using the Pin Drill, drill two holes to depth.

Step C15

Remove BESPOKE™ Guide

Leaving the two Long Pins in place, remove the Pin Guide, Short securing Pins, and BESPOKE™ Femoral Guide.

Optionally, mark the distal pin holes to locate them following distal femoral resection.

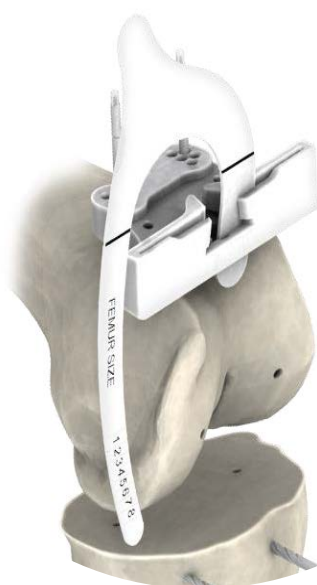


Step C16

Assemble Distal Cutting Block

Slide the Distal Cutting Block onto the 0mm position pin holes until it contacts the anterior femur.

Use an Angel Wing to check the distal cut plane and observe the prescribed plane shown on the Reference Femur Model.



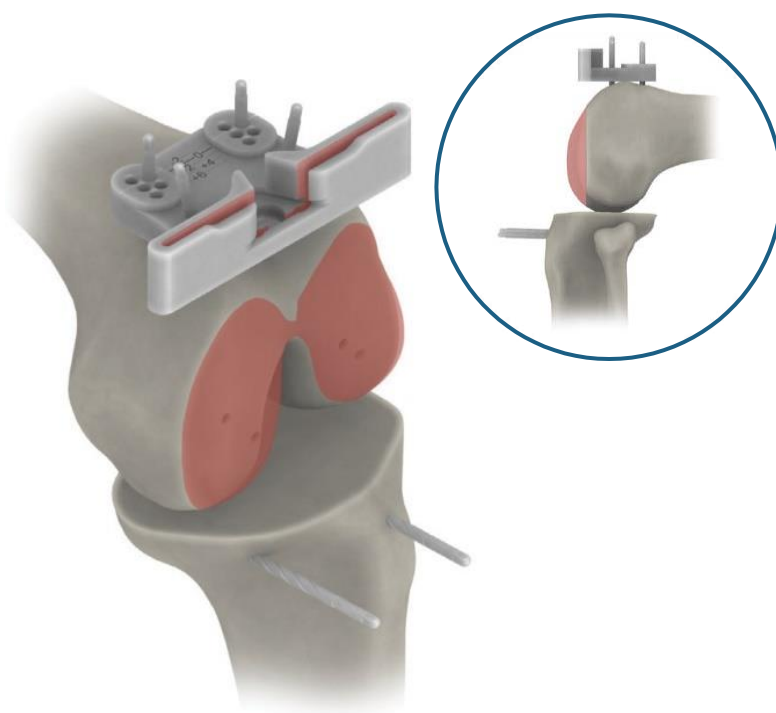
When the Cutting Guide position is confirmed, insert the medial and lateral oblique Long Pins.

Step C17

Resect Distal Femur

Cut the distal femur and check that it is flat.

Remove the oblique Pins and the Distal Cutting Block.



Step C18

Position Multicut Block

Insert two long precision pins into the pre-drilled pin holes in the distal femur.

Slide the Multicut Block onto the positioning Pins through the central (neutral) pin holes until it lies flush with the distal femur cut.

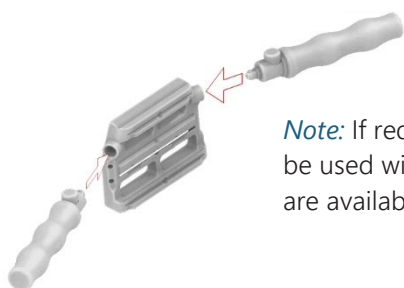
Check the anterior cut position with the Femoral Angel Wing.

If required to refine the anterior cut, the Multicut Block can be repositioned 1mm anterior or 1mm posterior from the neutral position by replacing the block on the Pins via the adjacent holes.

Secure the Multicut Block with medial and lateral Pins.

Remove the positioning Pins.

Note: If required, the optional Small Handles can be used with the Multicut block. Small Handles are available on request, shown on page 57.



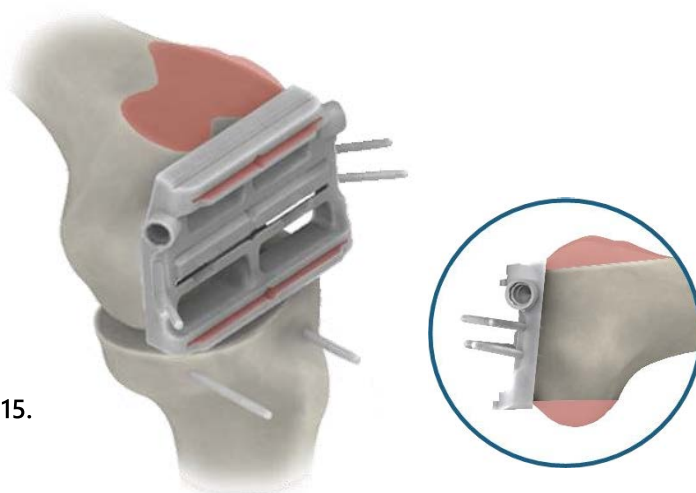
Step C19

Resect the Anterior and Posterior Condyles

Resect the anterior and posterior condyles.

Remove the Multicut Block. Clear away posterior osteophyte, loose bodies, or meniscal remnant.

Return to the Operative Technique Step 19, page 15.



Appendix D | In Case of Removal or Revision of a SAIPH® Knee Implant

Should one or more SAIPH® Knee System components require removal, do so with care to retain as much bone stock as possible and so that surrounding soft tissues and ligamentous structures are not compromised.

Special instrumentation is not provided by MatOrtho® for the removal of a failed implant. If a failed implant component has become loose, minimal force is typically required to remove the component. For a well-fixed implant the surgeon should use standard surgical practice and instrumentation to free the implant-bone interface. Note that excessive force may lead to component fracture or removal of excessive bone stock. Remove any remaining particles using curettes, rongeurs or osteotomes. Ensure that no component or component part (for a broken component) remains in the joint space.

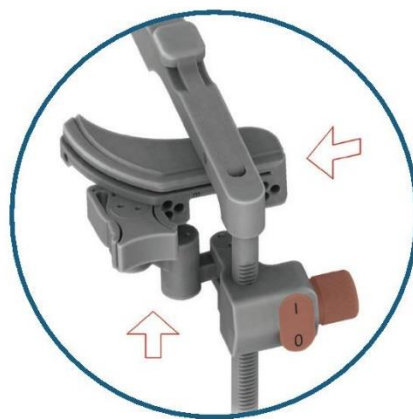
Do not attempt to alter, clean, resterilise or reuse any component. Even if the implant appears undamaged, the implant may have developed microscopic imperfections that could lead to implant failure. Dispose of single use devices using established hospital procedures. Thoroughly irrigate the joint space.

Appendix E | Preparation of Instruments

Tibial Alignment Guide Preparation

Assemble the Ankle Clamp with the Main Body, Left or Right Tibial Cutting Guide.

Position the Tibial Cutting Guide to the medial side and raise the Cutting Block Mount to sit directly beneath the Intercondylar Reference Arm. Switch the Cutting Guide Mount adjuster to the locked position.



Adjust the ML position at the ankle so that it is centralised. Switch the ML adjuster to the locked position.

Adjust the AP position at the ankle so that it is approximately midway between extents. Switch the AP adjuster to the locked position.



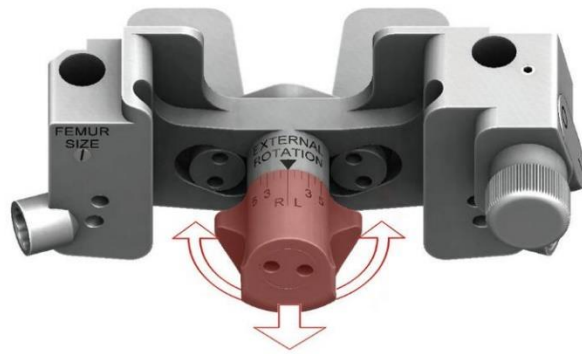
Open the arms of the Ankle Clamp fully.

Ensure the Main Body switch is in the unlocked position.

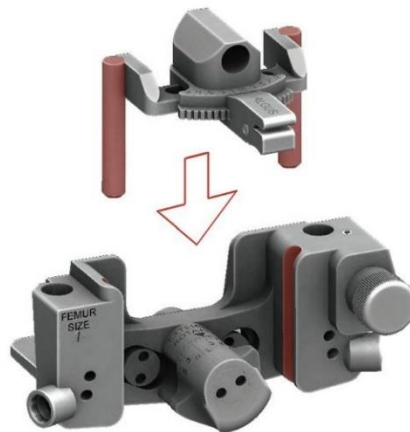


Anterior Femoral Alignment Jig Preparation

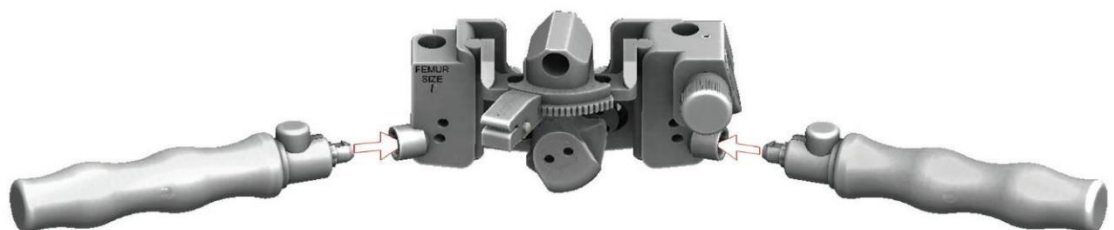
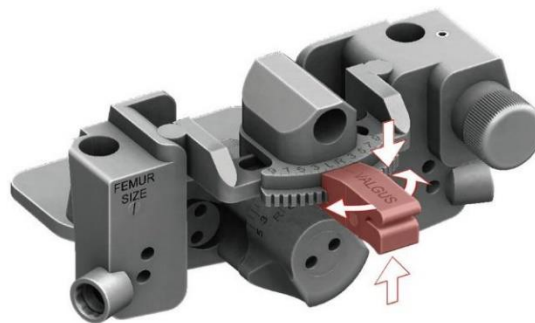
Set the external rotation of the main body and footplate to 3° to the left or right (external rotation) as required. The operating surgeon has the option to modify this setting for individual cases.



Assemble the Valgus Adjuster onto the main body. Set the valgus angle to 6° left or right as required. The operating surgeon has the option to modify this setting for individual cases.



If normally required by the operating surgeon, assemble with the two small handles.



Appendix F | *Cleaning Instructions*

All instruments are designed with consideration for cleaning and sterilising requirements.

All separable component parts are placed in the instrument trays as described in Appendix G | Instrument Tray Layouts. Assembly and disassembly of component parts before and after use is shown in the exploded views in Appendix E | Preparation of Instruments.



Do not disassemble any individual instrument or component part.

All screws are required for the permanent assembly of each instrument.

Never use any ancillary device including screwdrivers, including for repair.

If any device has missing or loose screws or appears faulty in any way contact MatOrtho® to arrange for return and repair or replacement.

Appendix G | Instrument Tray Layouts

The SAIPH® Knee instrument trays are laid out with usage and efficiency in mind.

It is advised that only the trays anticipated for a specific procedure are brought into the sterile area. Refer to the guide below according to requirements known preoperatively.

Note: It is anticipated that in some cases additional size-specific trays may be required until the required femoral size is established (Step 11, page 11).

Standard Trays

294-901	SAIPH® Core Instrument Set
294-902	SAIPH® Femoral and Tibial Alignment Instrument Set
294-903	SAIPH® Tibial Preparation Instrument Set
294-904	SAIPH® Core Trials Instrument Set
294-905	SAIPH® Small Trials Instrument Set
294-906	SAIPH® Large Trials Instrument Set

Patellar Resurfacing: Cemented or Cementless

294-908	SAIPH® Cemented Patella Instrument Set
294-909	SAIPH® Cementless Patella Instrument Set

Anterior Femur Cut First Technique (Appendix A)

294-910	SAIPH® Anterior Femoral Alignment Instrument Set
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Tibial Alignment: Intramedullary Alignment (Appendix B)

294-922	IM Tibial Alignment Instrument Set
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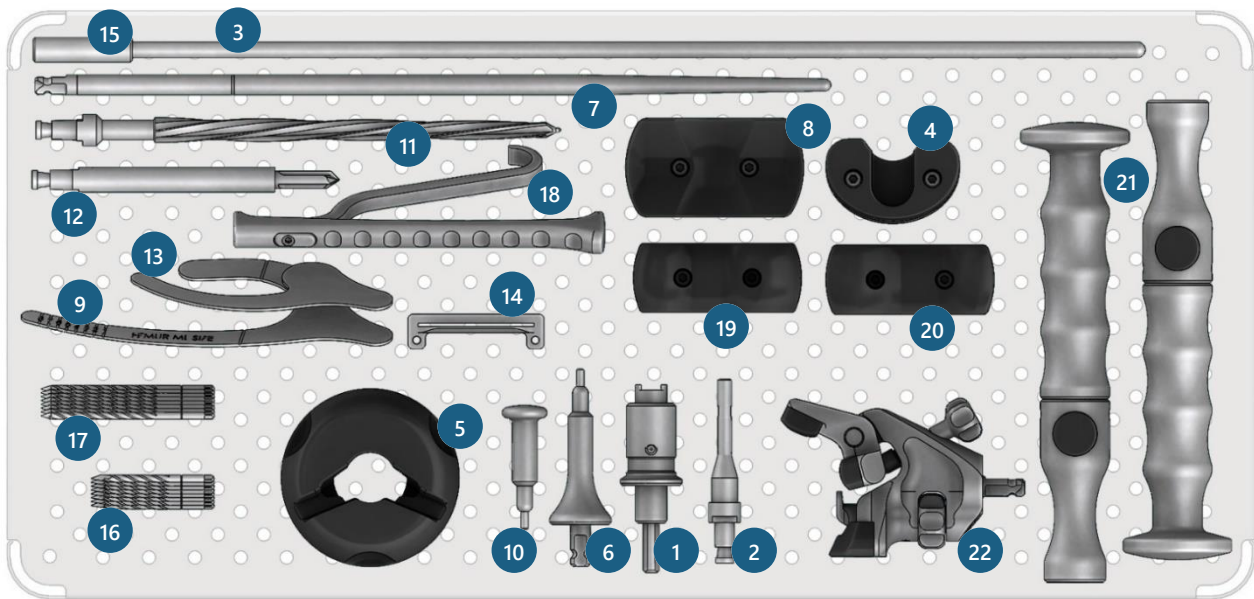
BESPOKE® Instruments (Appendix C)

294-921	PSI Instrument Set
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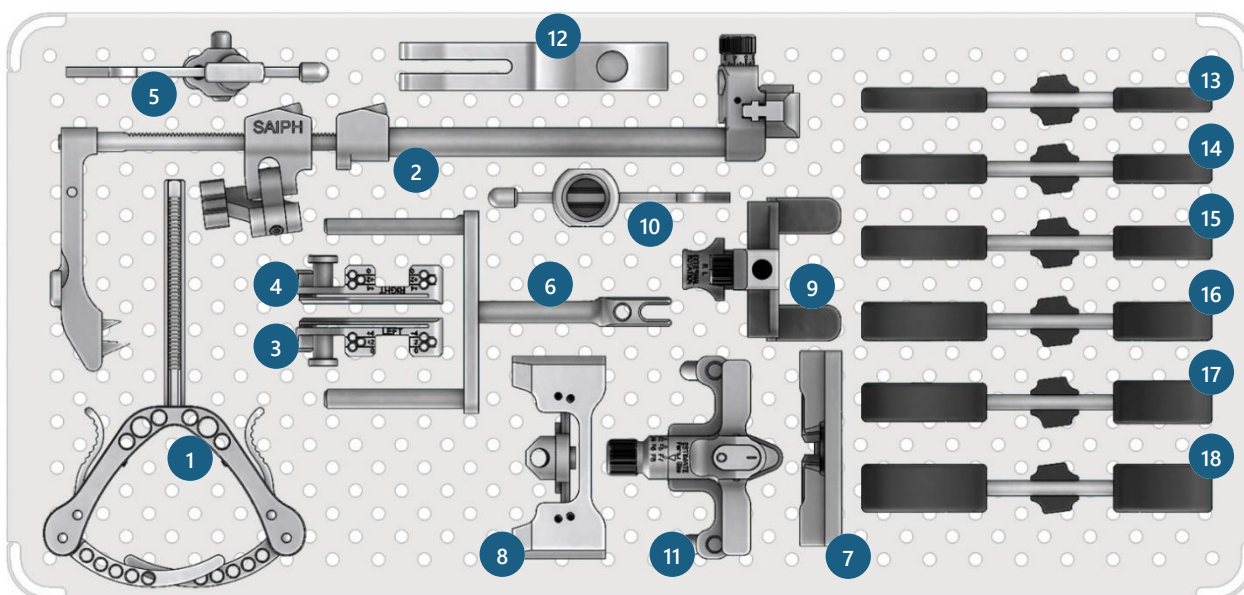
Optional Instruments

294-907	SAIPH® Thick Trials Instrument Set
294-923	Magic Spacer Instrument Set
294-924	Pegged and Stemmed Tibial Trials Instrument Set

294-901 SAIPH® Core Instrument Set



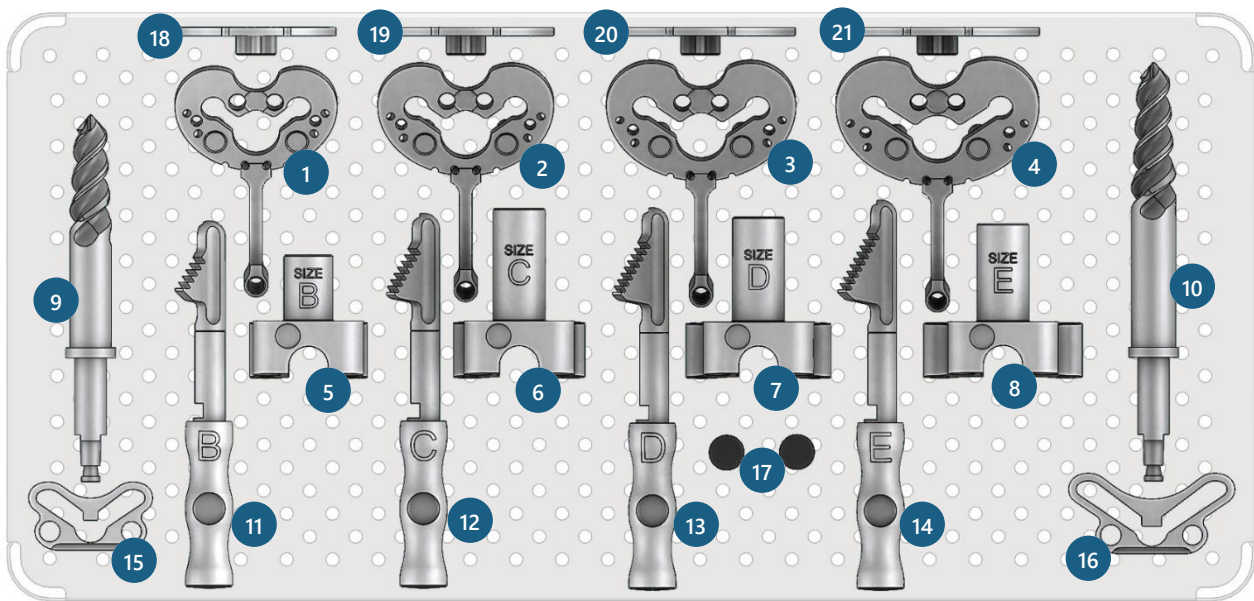
Item	Product Code	Item Description	Quantity
1	231-303	Jacobs/Hudson Adaptor	1
2	231-304	Pin Inserter/Extractor	1
3	256-462	Extended External Alignment Rod	1
4	293-202	Tibial Tray Impactor	1
5	293-251	Tibial Assembly Tool	1
6	293-262	In Situ Bearing Impactor Drive	1
7	293-265	IM Rod	1
8	293-270	Femoral Impactor	1
9	293-400	SAIPH® Femoral Angel Wing	1
10	293-405	Bearing Impactor Pin	1
11	293-427	SAIPH® IM Drill	1
12	293-429	Universal Peg Drill	1
13	293-516	Tibial Angel Wing	1
14	293-625	Re-Cutting Block 0°	1
15	293-284	SAIPH® Extended External Alignment Rod Extension	1
16	255-035	Short Pin - 50mm	8
17	255-036	Long Pin - 70mm	8
18	255-003	Pin Driver	1
19	293-285	Saiph® Tibial Impactor – Yellow and Red	1
20	293-286	Saiph® Tibial Impactor – Blue and Green	1
21	293-253	Quick Release Impaction Handle	2
22	293-653	Femoral Introducer	1



Item	Product Code	Item Description	Quantity
1	293-208	Tibial Alignment Guide Ankle Clamp	1
2	293-209	Tibial Alignment Guide Main Body	1
3	293-510	Tibial Cutting Block - Left	1
4	293-511	Tibial Cutting Block - Right	1
5	293-515	SAIPH® Tibial Stylus	1
6	293-291	SAIPH® External Alignment Rod Mount	1
7	293-294	SAIPH® Distal Cutting Block	1
8	293-297	SAIPH® Distal Femoral Alignment Guide	1
9	293-298	SAIPH® Femoral Sizing Jig	1
10	293-299	SAIPH® Femoral Stylus - Sizing Jig	1
11	293-289	SAIPH® Distal First Cutting Block Mount	1
12	293-210	Saiph® Extractor Lever	1
13	293-230	Dual Ended Tibial Spacer - 10mm	1
14	293-231	Dual Ended Tibial Spacer - 12mm	1
15	293-232	Dual Ended Tibial Spacer - 14mm	1
16	293-233	Dual Ended Tibial Spacer - 16mm	1
17	293-234	Dual Ended Tibial Spacer - 18mm	1
18	293-235	Dual Ended Tibial Spacer - 20mm	1

294-903

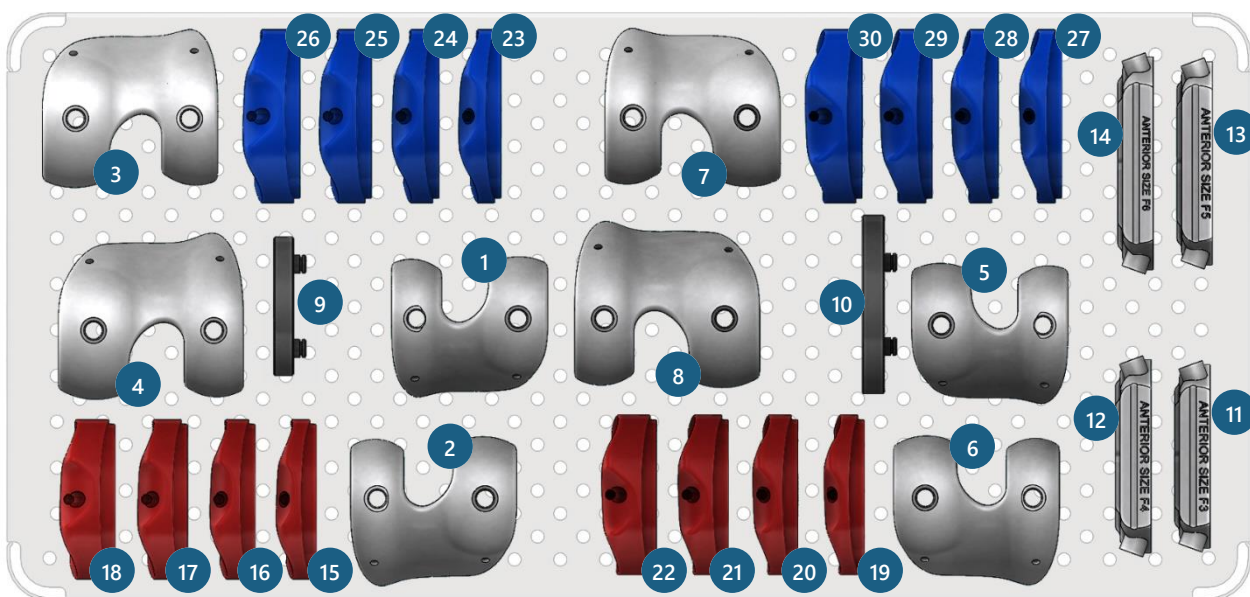
SAIPH® Tibial Preparation Instrument Set



Item	Product Code	Item Description	Quantity
1	293-187	Tibial Template - Size B	1
2	293-188	Tibial Template - Size C	1
3	293-189	Tibial Template - Size D	1
4	293-190	Tibial Template - Size E	1
5	293-223	Tibial Drill Guide Size B	1
6	293-224	Tibial Drill Guide Size C	1
7	293-225	Tibial Drill Guide Size D	1
8	293-226	Tibial Drill Guide Size E	1
9	293-228	Tibial Stem Drill Small, Sizes A-B	1
10	293-229	Tibial Stem Drill Large, Sizes C-F	1
11	293-272	Tibial Webbing Chisel Size B	1
12	293-273	Tibial Webbing Chisel Size C	1
13	293-274	Tibial Webbing Chisel Size D	1
14	293-275	Tibial Webbing Chisel Size E	1
15	293-282	Tibial Webbing Chisel Guide A to B	1
16	293-283	Tibial Webbing Chisel Guide C to F	1
17	293-568	SAIPH® Tibial Peg Plug	2
18	293-581	SAIPH® Tibial Rotation Indicator - Size B	1
19	293-582	SAIPH® Tibial Rotation Indicator - Size C	1
20	293-583	SAIPH® Tibial Rotation Indicator - Size D	1
21	293-584	SAIPH® Tibial Rotation Indicator - Size E	1

294-904

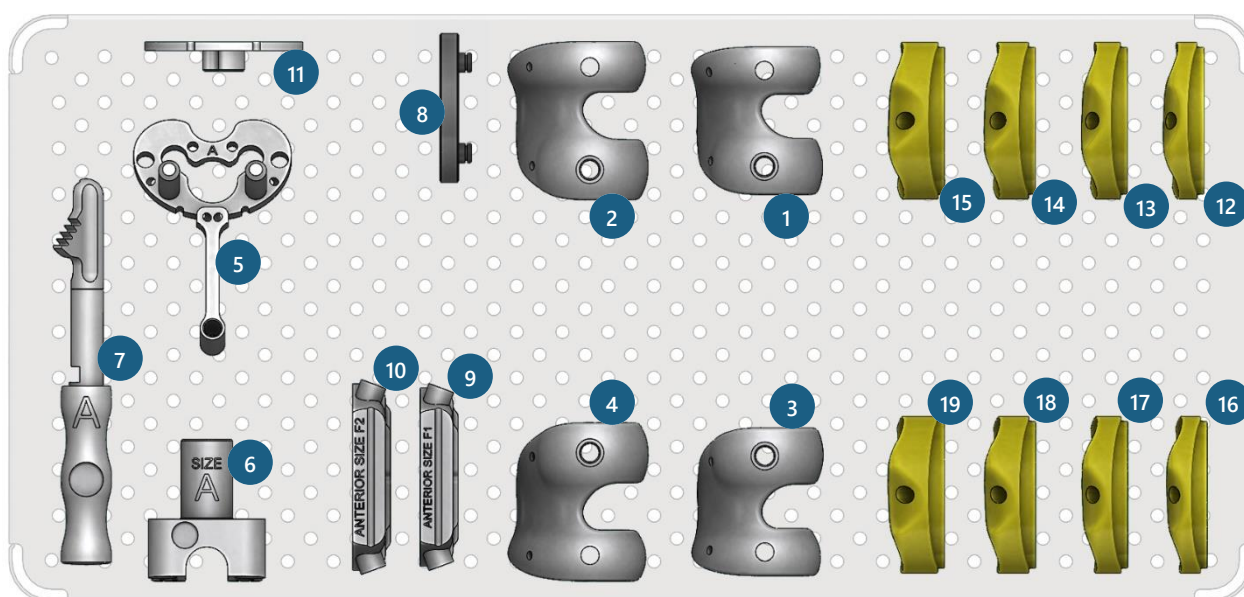
SAIPH® Core Trials Instrument Set



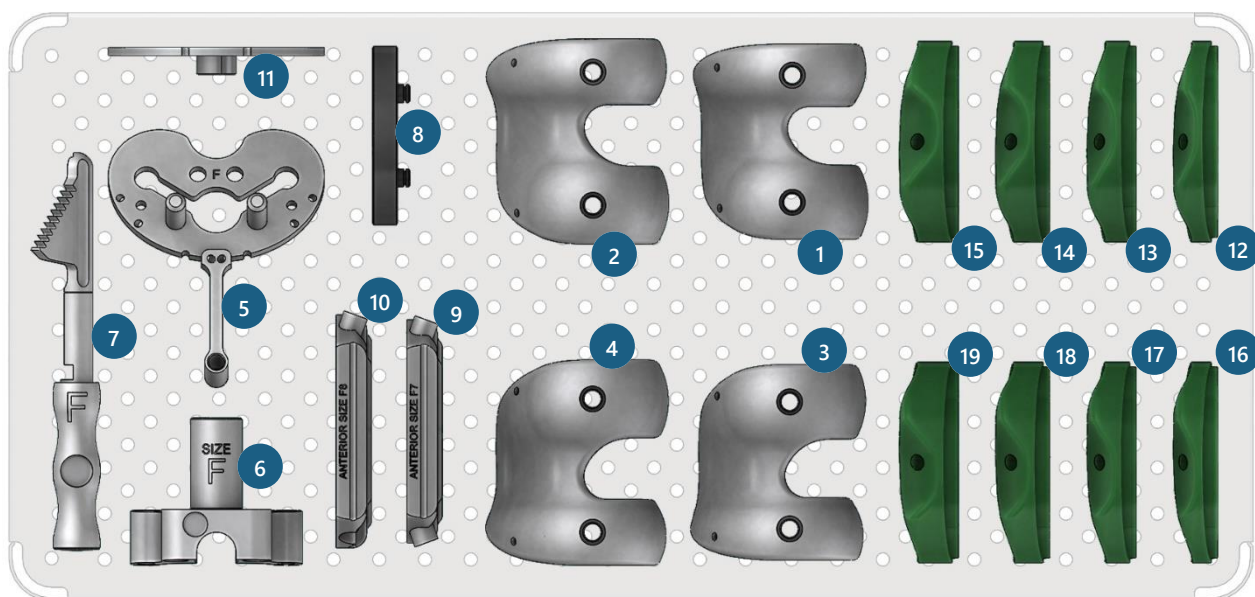
Item	Product Code	Item Description	Quantity
1	293-002	Femoral Trial Left, Size 3	1
2	293-003	Femoral Trial Left, Size 4	1
3	293-004	Femoral Trial Left, Size 5	1
4	293-005	Femoral Trial Left, Size 6	1
5	293-027	Femoral Trial Right, Size 3	1
6	293-028	Femoral Trial Right, Size 4	1
7	293-029	Femoral Trial Right, Size 5	1
8	293-030	Femoral Trial Right, Size 6	1
9	293-347	Femoral Spacer - Red	1
10	293-348	Femoral Spacer - Blue	1
11	293-444	Femoral Multicut Block Size 3	1
12	293-445	Femoral Multicut Block Size 4	1
13	293-446	Femoral Multicut Block Size 5	1
14	293-447	Femoral Multicut Block Size 6	1
15	293-724	SAIPH® Trial Bearing Red. Left.10mm	1
16	293-725	SAIPH® Trial Bearing Red. Left.12mm	1
17	293-726	SAIPH® Trial Bearing Red. Left.14mm	1
18	293-727	SAIPH® Trial Bearing Red. Left.16mm	1
19	293-730	SAIPH® Trial Bearing Red. Right.10mm	1
20	293-731	SAIPH® Trial Bearing Red. Right.12mm	1
21	293-732	SAIPH® Trial Bearing Red. Right.14mm	1
22	293-733	SAIPH® Trial Bearing Red. Right.16mm	1
23	293-748	SAIPH® Trial Bearing Blue. Left.10mm	1
24	293-749	SAIPH® Trial Bearing Blue. Left.12mm	1
25	293-750	SAIPH® Trial Bearing Blue. Left.14mm	1
26	293-751	SAIPH® Trial Bearing Blue. Left.16mm	1
27	293-754	SAIPH® Trial Bearing Blue. Right.10mm	1
28	293-755	SAIPH® Trial Bearing Blue. Right.12mm	1
29	293-756	SAIPH® Trial Bearing Blue. Right.14mm	1
30	293-757	SAIPH® Trial Bearing Blue. Right.16mm	1

294-905

SAIPH® Small Trials Instrument Set

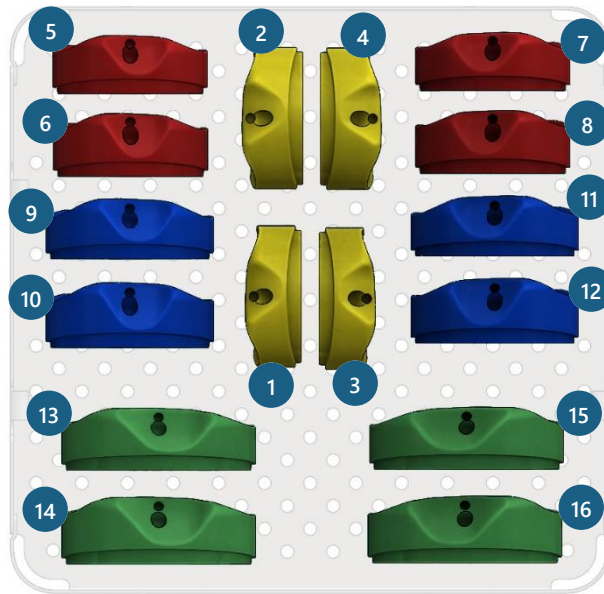


Item	Product Code	Item Description	Quantity
1	293-000	Femoral Trial Left, Size 1	1
2	293-001	Femoral Trial Left, Size 2	1
3	293-025	Femoral Trial Right, Size 1	1
4	293-026	Femoral Trial Right, Size 2	1
5	293-186	Tibial Template - Size A	1
6	293-222	Tibial Drill Guide Size A	1
7	293-271	Tibial Webbing Chisel Size A	1
8	293-346	Femoral Spacer - Yellow	1
9	293-442	Femoral Multicut Block Size 1	1
10	293-443	Femoral Multicut Block Size 2	1
11	293-580	SAIPH® Tibial Rotation Indicator - Size A	1
12	293-700	SAIPH® Trial Bearing Yellow. Left.10mm	1
13	293-701	SAIPH® Trial Bearing Yellow. Left.12mm	1
14	293-702	SAIPH® Trial Bearing Yellow. Left.14mm	1
15	293-703	SAIPH® Trial Bearing Yellow. Left.16mm	1
16	293-706	SAIPH® Trial Bearing Yellow. Right.10mm	1
17	293-707	SAIPH® Trial Bearing Yellow. Right.12mm	1
18	293-708	SAIPH® Trial Bearing Yellow. Right.14mm	1
19	293-709	SAIPH® Trial Bearing Yellow. Right.16mm	1



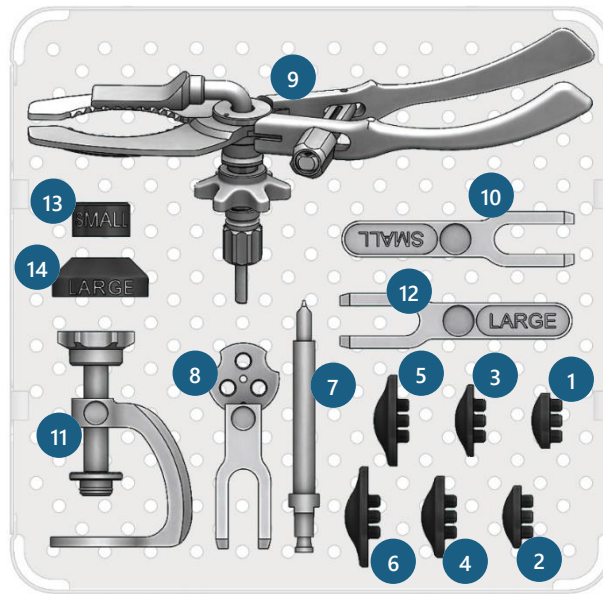
Item	Product Code	Item Description	Quantity
1	293-006	Femoral Trial Left, Size 7	1
2	293-007	Femoral Trial Left, Size 8	1
3	293-031	Femoral Trial Right, Size 7	1
4	293-032	Femoral Trial Right, Size 8	1
5	293-191	Tibial Template - Size F	1
6	293-227	Tibial Drill Guide Size F	1
7	293-276	Tibial Webbing Chisel Size F	1
8	293-349	Femoral Spacer - Green	1
9	293-448	Femoral Multicut Block Size 7	1
10	293-449	Femoral Multicut Block Size 8	1
11	293-585	SAIPH® Tibial Rotation Indicator - Size F	1
12	293-796	SAIPH® Trial Bearing Green. Left.10mm	1
13	293-797	SAIPH® Trial Bearing Green. Left.12mm	1
14	293-798	SAIPH® Trial Bearing Green. Left.14mm	1
15	293-799	SAIPH® Trial Bearing Green. Left.16mm	1
16	293-802	SAIPH® Trial Bearing Green. Right.10mm	1
17	293-803	SAIPH® Trial Bearing Green. Right.12mm	1
18	293-804	SAIPH® Trial Bearing Green. Right.14mm	1
19	293-805	SAIPH® Trial Bearing Green. Right.16mm	1

294-907

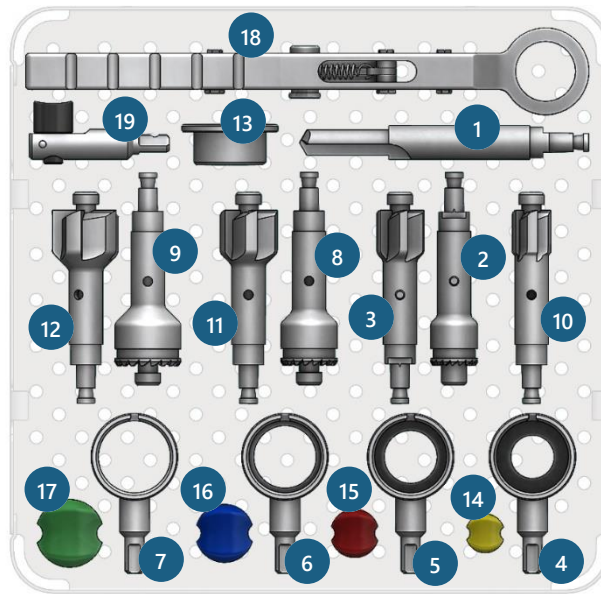
SAIPH® Thick Trials Instrument Set

Item	Product Code	Item Description	Quantity
1	293-704	SAIPH® Trial Bearing Yellow. Left.18mm	1
2	293-705	SAIPH® Trial Bearing Yellow. Left.20mm	1
3	293-710	SAIPH® Trial Bearing Yellow. Right.18mm	1
4	293-711	SAIPH® Trial Bearing Yellow. Right.20mm	1
5	293-728	SAIPH® Trial Bearing Red. Left.18mm	1
6	293-729	SAIPH® Trial Bearing Red. Left.20mm	1
7	293-734	SAIPH® Trial Bearing Red. Right.18mm	1
8	293-735	SAIPH® Trial Bearing Red. Right.20mm	1
9	293-752	SAIPH® Trial Bearing Blue. Left.18mm	1
10	293-753	SAIPH® Trial Bearing Blue. Left.20mm	1
11	293-758	SAIPH® Trial Bearing Blue. Right.18mm	1
12	293-759	SAIPH® Trial Bearing Blue. Right.20mm	1
13	293-800	SAIPH® Trial Bearing Green. Left.18mm	1
14	293-801	SAIPH® Trial Bearing Green. Left.20mm	1
15	293-806	SAIPH® Trial Bearing Green. Right.18mm	1
16	293-807	SAIPH® Trial Bearing Green. Right.20mm	1

294-908

SAIPH® Cemented Patella Instrument Set

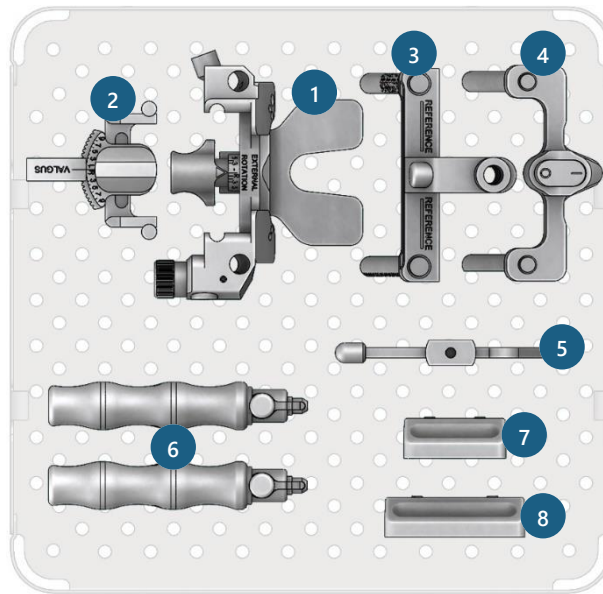
Item	Product Code	Item Description	Quantity
1	290-160	Cemented Patellar Trial 23mm	1
2	290-161	Cemented Patellar Trial 26mm	1
3	290-162	Cemented Patellar Trial 30mm	1
4	290-163	Cemented Patellar Trial 34mm	1
5	290-164	Cemented Patellar Trial 38mm	1
6	290-165	Cemented Patellar Trial 42mm	1
7	290-180	Cemented Patellar Peg Drill	1
8	290-181	Cemented Patellar Peg Drill Guide	1
9	290-182	Cemented Patellar Clamp	1
10	290-183	Cemented Patellar Feeler Arm Small	1
11	290-184	Cemented Patellar Compressor	1
12	290-191	Cemented Patellar Feeler Arm Large	1
13	290-192	Cemented Patellar Compressor Attachment Small	1
14	290-193	Cemented Patellar Compressor Attachment Large	1



Item	Product Code	Item Description	Quantity
1	256-430	Cementless Patellar Drill	1
2	256-431	Cementless Patellar Ring Cutter 20mm	1
3	256-433	Cementless Patellar Milling Cutter 20mm	1
4	290-000	Cementless Patellar Collar Yellow 16mm	1
5	290-001	Cementless Patellar Collar Red 20mm	1
6	290-002	Cementless Patellar Collar Blue 24mm	1
7	290-003	Cementless Patella Collar Green 28mm	1
8	290-012	Cementless Patellar Ring Cutter 24mm	1
9	290-013	Cementless Patellar Ring Cutter 28mm	1
10	290-020	Cementless Patellar Milling Cutter 16mm	1
11	290-022	Cementless Patellar Milling Cutter 24mm	1
12	290-023	Cementless Patellar Milling Cutter 28mm	1
13	290-030	Cementless Patellar Peg Drill Guide	1
14	290-050	Cementless Patellar Trial Yellow 16mm	1
15	290-051	Cementless Patellar Trial Red 20mm	1
16	290-052	Cementless Patellar Trial Blue 24mm	1
17	290-053	Cementless Patellar Trial Green 28mm	1
18	290-200	Patellar Clamp	1
19	290-202	Patellar Compressor	1

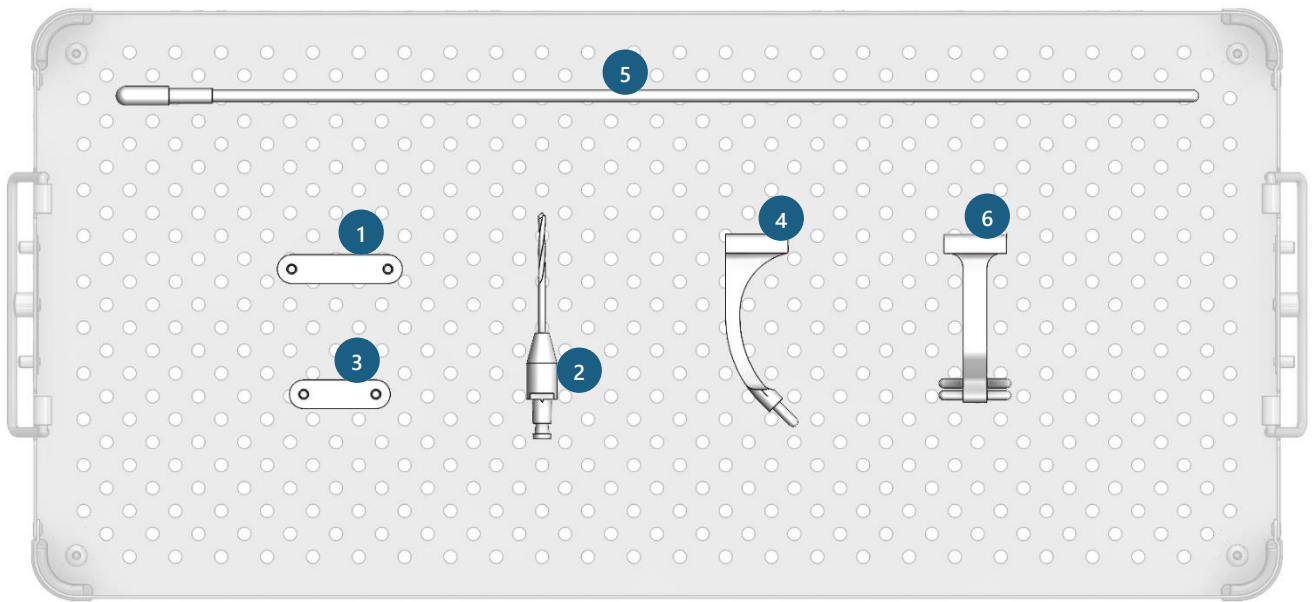
294-910

SAIPH® Anterior Femoral Alignment Instrument Set



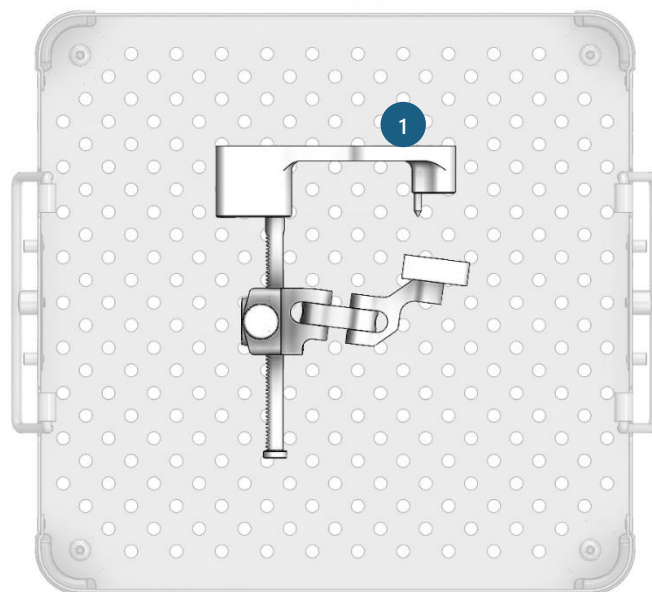
Item	Product Code	Item Description	Quantity
1	293-288	SAIPH® Anterior Femoral Alignment Guide	1
2	255-043	Valgus Adjuster	1
3	293-292	SAIPH® Anterior Cutting Guide	1
4	293-295	SAIPH® Distal Cutting Block Mount	1
5	293-293	SAIPH® Femoral Stylus	1
6	293-242	Universal Small Handle	2
7	255-008	Anterior Reference Plate Standard	1
8	293-278	Anterior Reference Plate Large	1

294-921 PSI Instrument Set



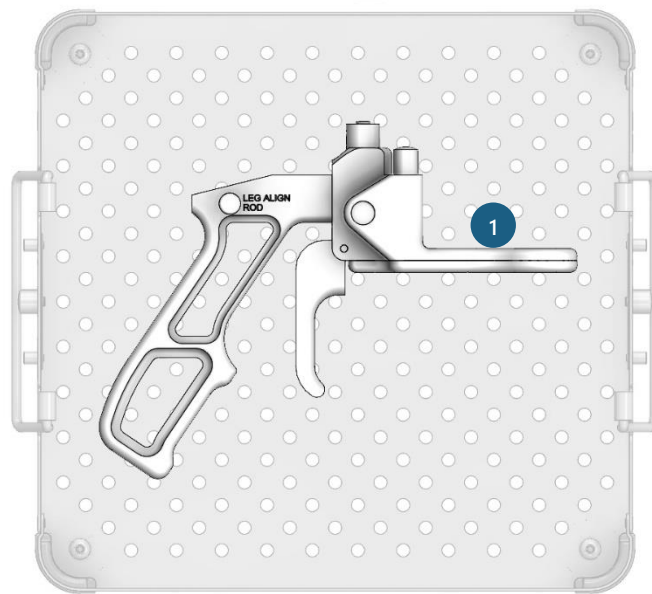
Item	Product Code	Item Description	Quantity
1	255-032	Pin Guide Distal Holes	1
2	255-033	Pin Drill Short Version	1
3	256-302	Pin Guide 30mm	1
4	293-303	Femoral Alignment Guide mount	1
5	293-304	Alignment Rod Ø5	1
6	293-305	Tibial Alignment Guide Mount	1

294-922 IM Tibial Alignment Instrument Set



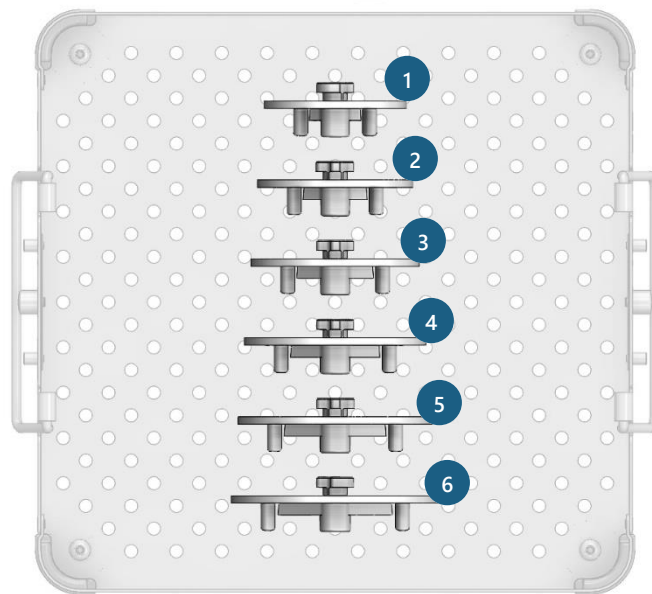
Item	Product Code	Item Description	Quantity
1	293-532	Intramedullary Tibial Alignment Jig	1

294-923 Magic Spacer Instrument Set



Item	Product Code	Item Description	Quantity
1	293-499	Magic Spacer	1

294-924 Pegged and Stemmed Tibial Trials Instrument Set



Item	Product Code	Item Description	Quantity
1	293-016	Long Stemmed Tibial Position Guide - Size A	1
2	293-017	Long Stemmed Tibial Position Guide - Size B	1
3	293-018	Long Stemmed Tibial Position Guide - Size C	1
4	293-019	Long Stemmed Tibial Position Guide - Size D	1
5	293-020	Long Stemmed Tibial Position Guide - Size E	1
6	293-021	Long Stemmed Tibial Position Guide - Size F	1

Appendix H | Implant Sizing Chart

Primary size should be taken from the femur measurement: Step 15, page 12 for the Distal Cut First method; Step A4, page 29 for the Anterior Cut First method; or during BESPOKE™ Preoperative Planning, page 34.

Femoral Component



Sided: LEFT or RIGHT

Tibial Component



Tibial Insert



Sided: CHECK compatibility with Femur

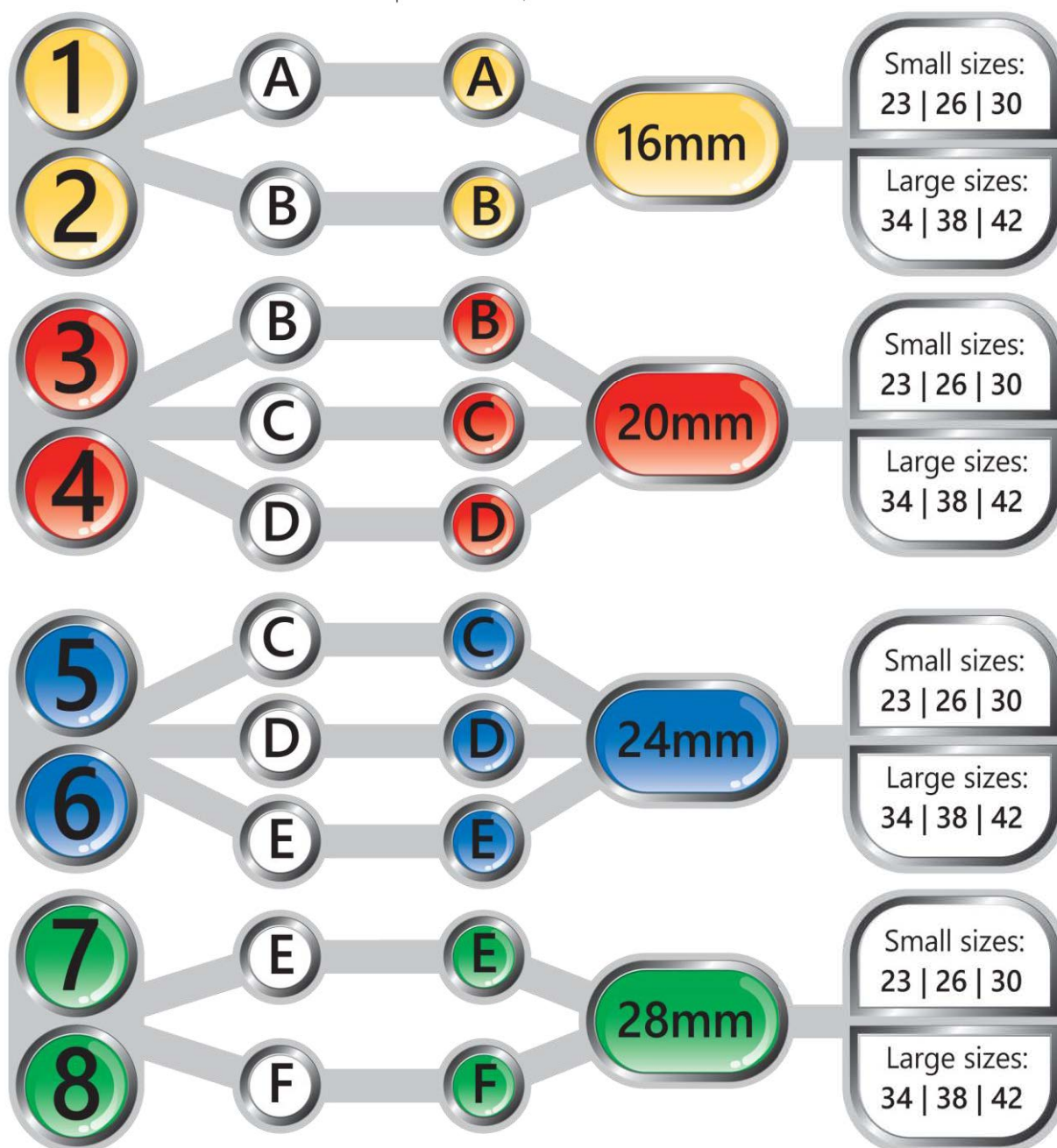
Thicknesses: 10mm, 12mm, 14mm, 16mm.
Optional: 18mm, 20mm.

Cementless Patella*



*Not Available in the US

Cemented Patella





Forever **Active**