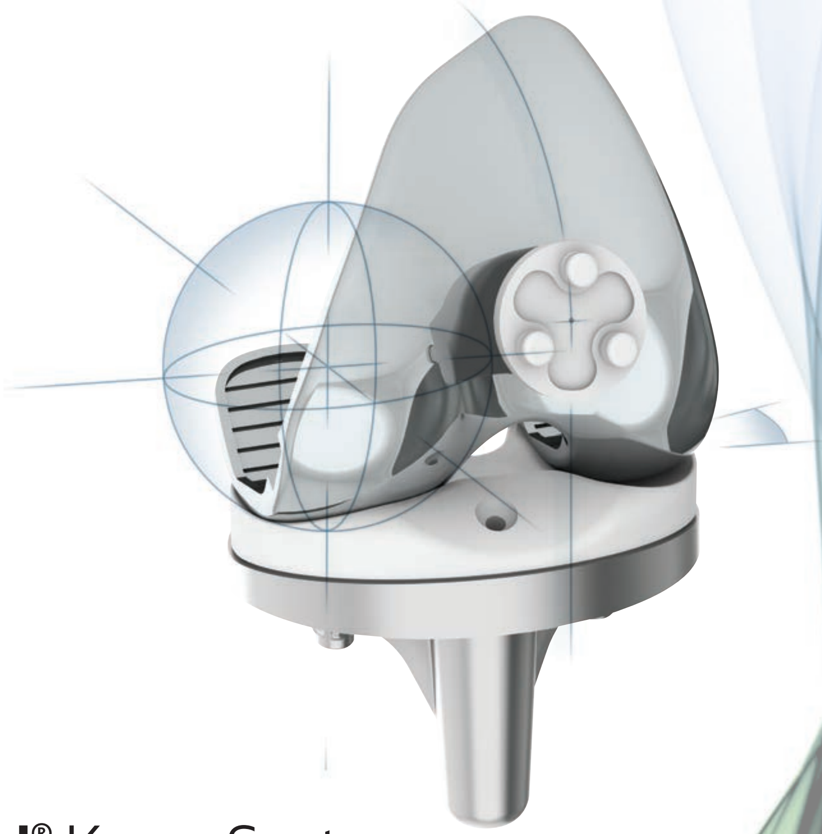


SAIPH® Knee System

Anterior Cut First
Operative Technique

Physiological Stability and
Mobility for the Active Knee
Without Compromise

Forever **Active**

Contents

Patents

EP1329205 / US6869448

GB2306653 / US5800438

Manufactured by Mat**Ortho** Limited

13 Mole Business Park | Randalls Road | Leatherhead | Surrey | KT22 7BA | United Kingdom

T: +44 (0)1372 224 200 | info@Mat**Ortho**.com

For more information visit: www.Mat**Ortho**.com

Developed in collaboration with an international surgical team

Professor Justin P Cobb
Chair in Orthopaedic Surgery
Imperial College Hospital, London

Professor Fares S Haddad
Director, Institute of Sport and Surgical Specialties
University College London Hospitals, London

Dr Andrew J Shimmin
Specialist Hip and Knee Surgeon
Melbourne Orthopaedic Group, Melbourne

Mr Adrian Fairbank
Consultant Orthopaedic Surgeon
Parkside Hospital, Wimbledon

Mr Gilbert T Railton
Consultant Orthopaedic Surgeon
The Elective Orthopaedic Centre, Epsom

Associate Professor William L Walter
Chairman Department Orthopaedic Surgery
Mater Hospital, Sydney

Further acknowledgement to

Professor Piers J Yates
Fremantle Hospital and University of Western Australia

Introduction

The SAIPH® Knee System was developed in collaboration with an international panel of surgeons with the aim of improving patient outcomes and satisfaction. It is the latest in a series that has evolved over 40 years, using clinical experience gained since 1968 with the first condylar knee replacement at the Royal London Hospital[1,2].

The tibiofemoral bearing design is based on **the principle of medial rotation**, which mimics the function of the normal healthy knee[3,4]. It comprises a prominent spherical medial condyle, similar to a ball-and-socket joint, which stabilises the medial condyle throughout flexion. The lateral side is a conforming cylinder that permits some laxity and can be thought of as a stabilising 'outrigger'.

More normal patellar tracking is achieved throughout flexion with a lateralised trochlea and offset patella button[5,6]. The deep trochlear groove and smooth single radius allow for increased conformity and stability of the patella throughout flexion.

This combination of asymmetric tibiofemoral and patellofemoral articulations provides optimal knee kinematics, whilst maintaining intrinsic stability throughout the functional flexion range. This superior combination of stability and mobility is associated with improved high-end function and low revision rates[7,8].

The SAIPH® Knee instruments are intended for use 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 user instructions (part no. 400-480) before using the SAIPH® Knee implants.

References

1. Freeman and Swanson (1972) JBJS; 54-B(1): 170-171
2. Freeman *et al.* (1978) JBJS; 60-B(3): 339-344
3. Iwaki *et al.* (2000) JBJS; 82-B: 1189-1195
4. Shimmin *et al.* (2015) The Knee; 22 (6): 522-526
5. Iranpour *et al.* (2010) CORR; 468: 782-788
6. Rhee *et al.* (2012) JBJS; 94-B (SUPP IX): 90
7. Hossain *et al.* (2011) CORR; 469: 55-63
8. Medial Rotation Knee™ in the NJR for England, Wales, Northern Ireland and Isle of Man, 12th Annual Report (2015)

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 41) for suitably-paired components.

The appropriate size components are confirmed intraoperatively.

Step 2

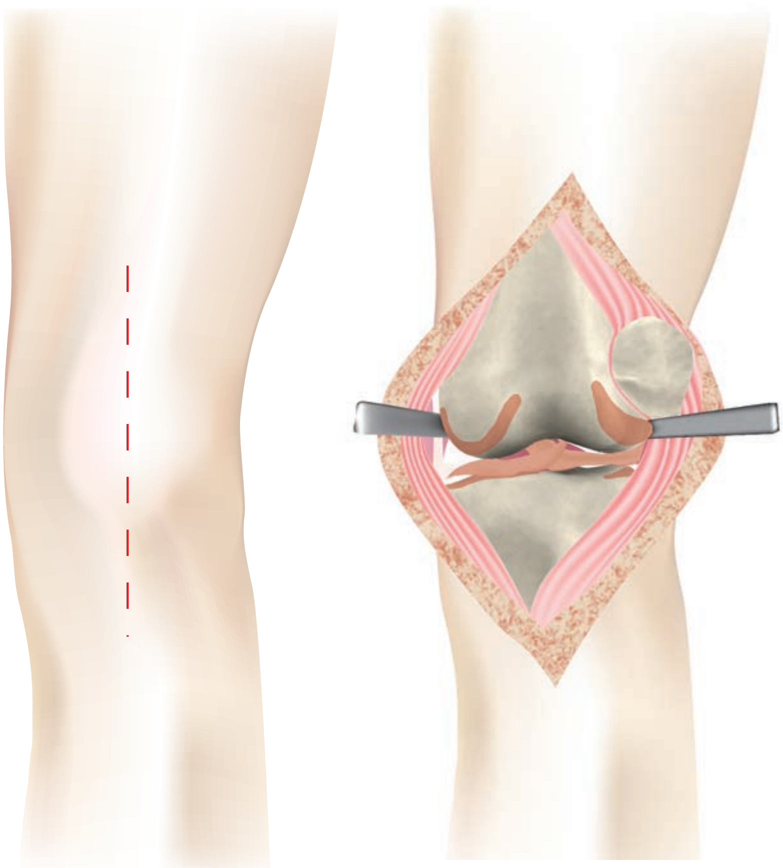
Exposure

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.

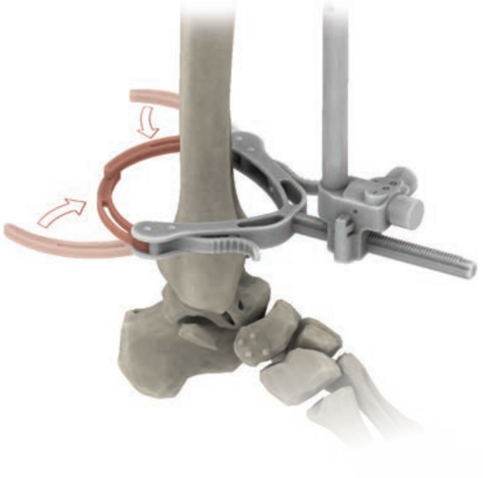


Step 3

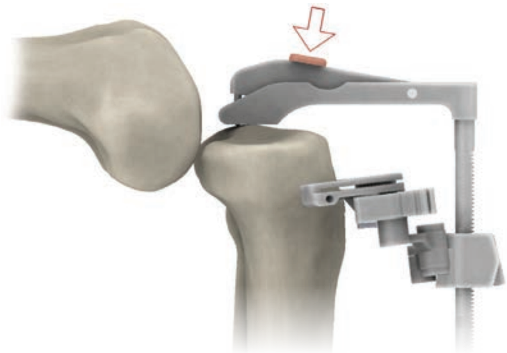
Note: Preparation of the Tibial Alignment Guide is shown on page 28.

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.

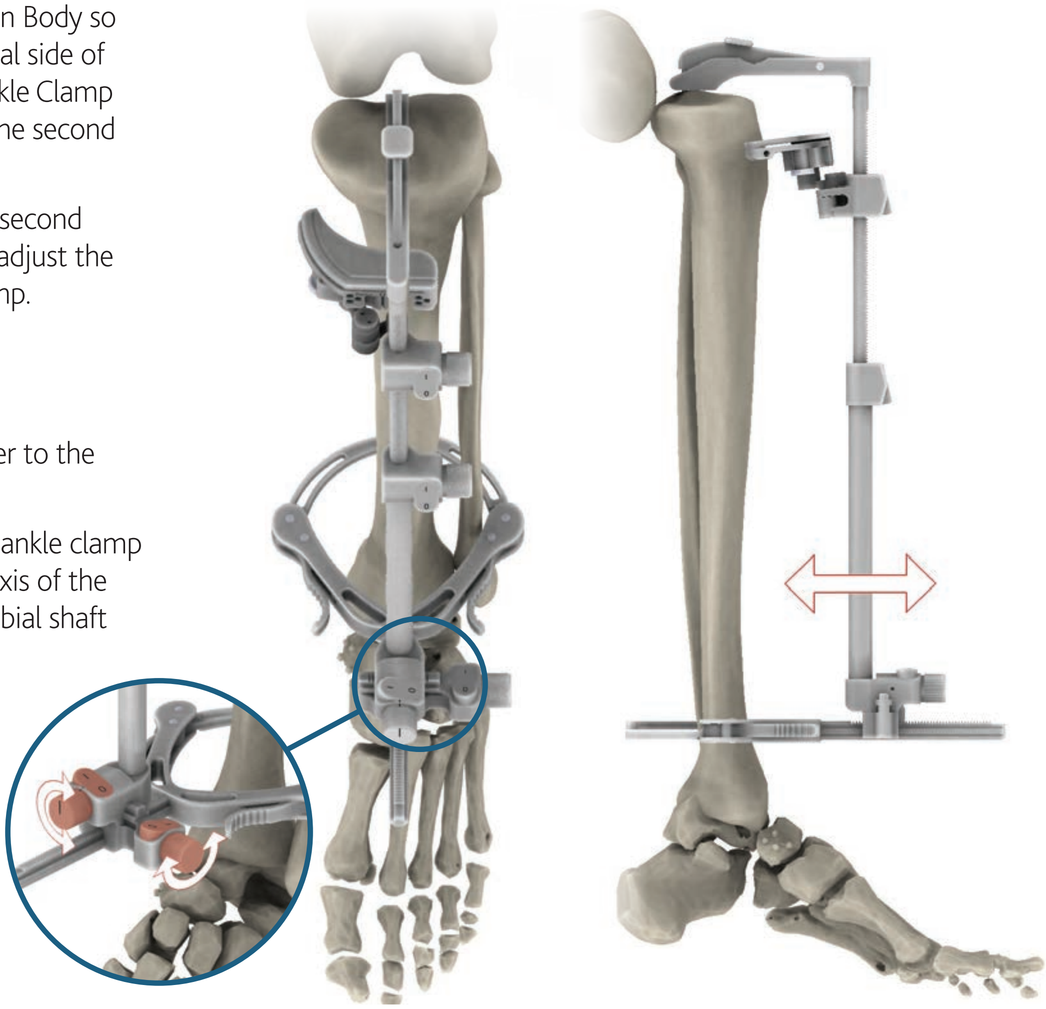


Align the long axis of the Main Body so that it is centred on the medial side of the tibial tubercle and the Ankle Clamp rail points approximately to the second metatarsal.

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.

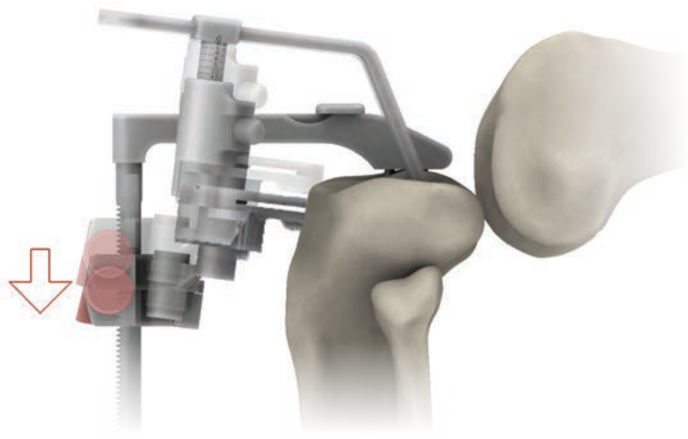
Adjust the AP position at the ankle clamp as required so that the long axis of the Main Body is parallel to the tibial shaft when viewed laterally.



Step 4

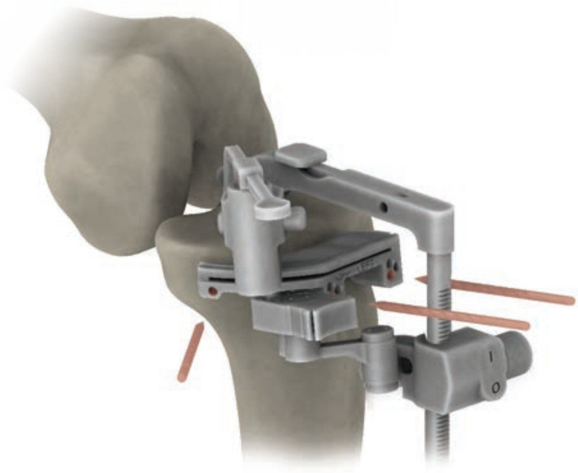
Position Tibial Cutting Block

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.

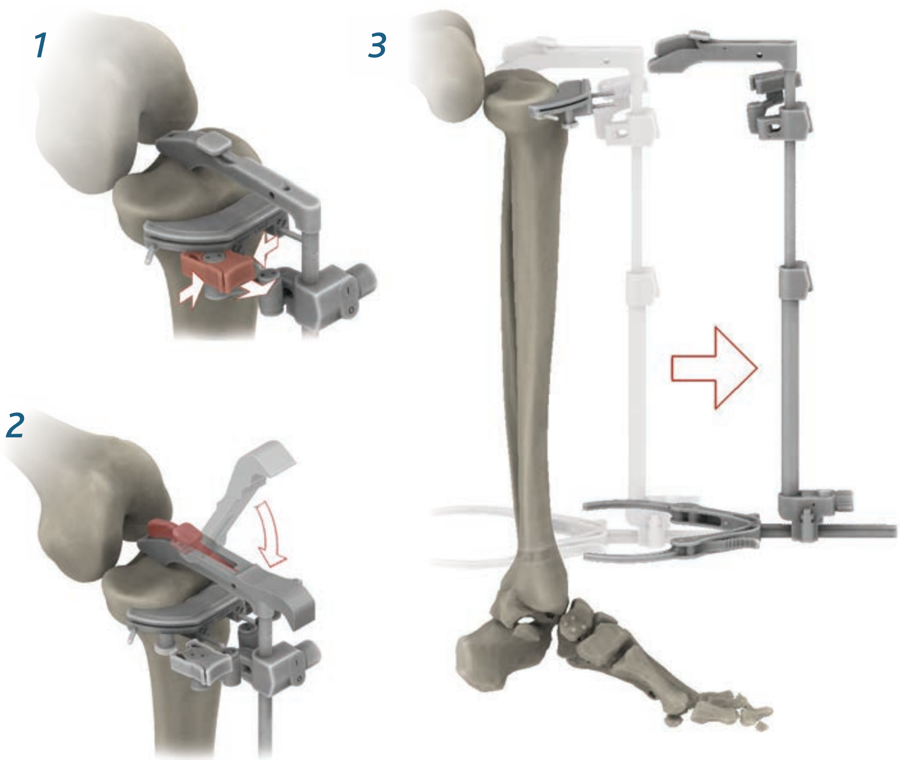
When the appropriate tibial resection height is obtained, switch the Tibial Cutting Block adjuster to the locked position.

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 visualise the tibial resection.

Step 7

Check tibial resection

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 size compatibility chart on page 41 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).

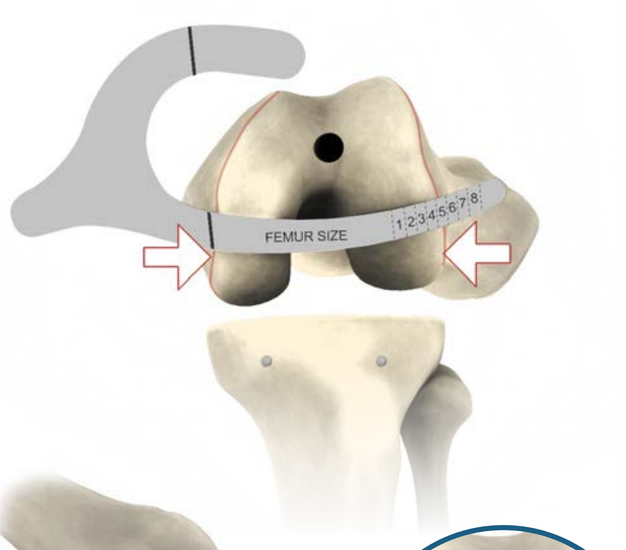
Adjust the alignment of the Main Body as required.

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.

Step 8

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.

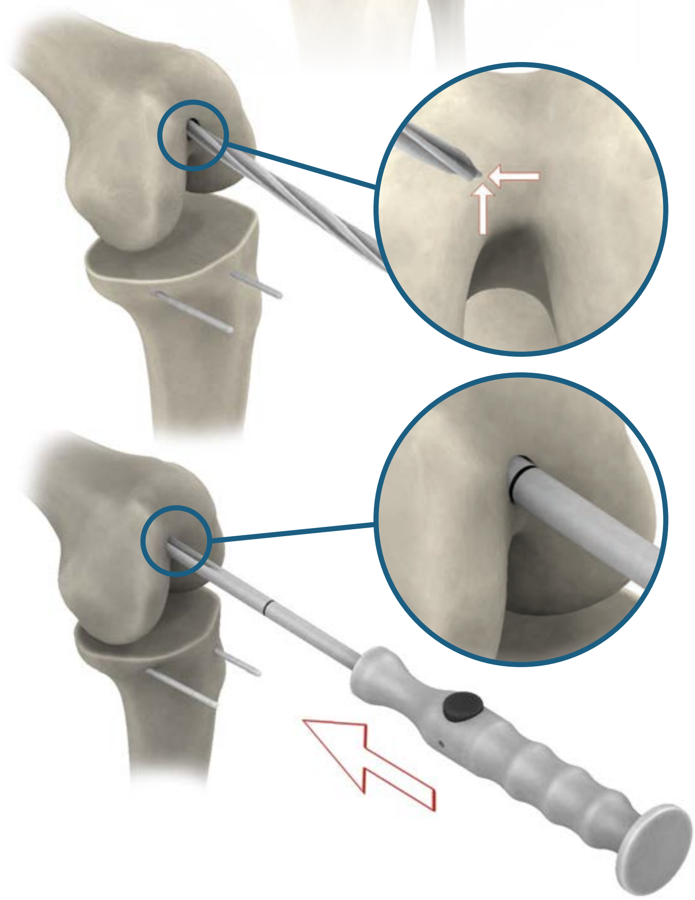


Step 9

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.

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



Step 10

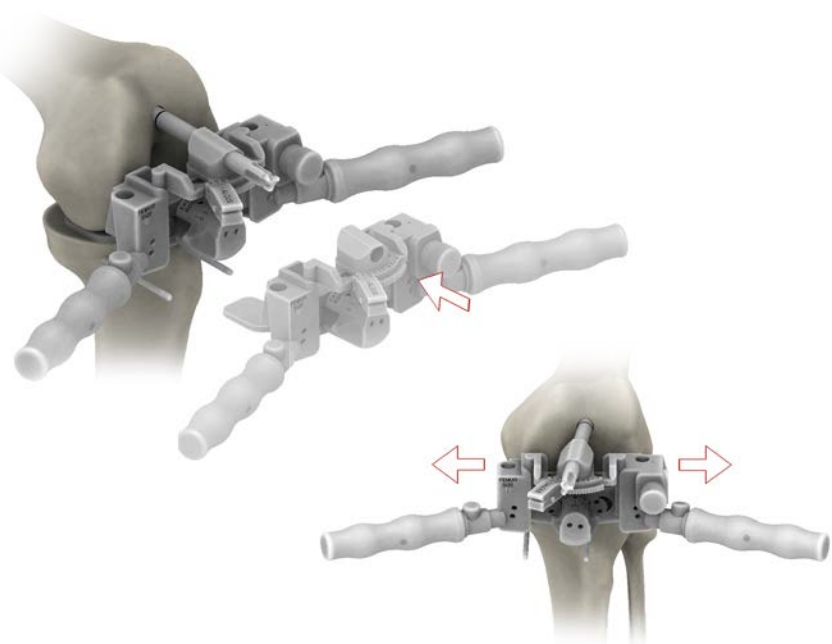
Assemble Anterior Femoral Alignment Guide

Note: Preparation of the Anterior Femoral Alignment Guide is shown on page 29.

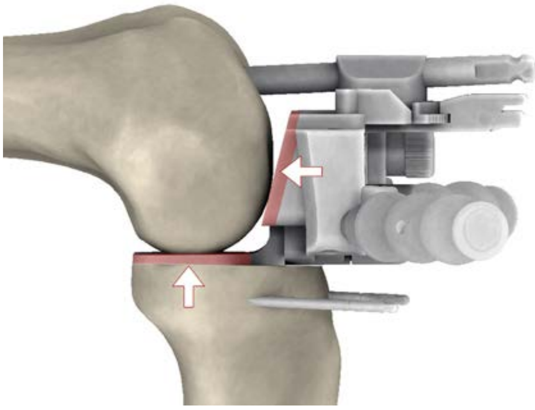
Set the external rotation to the desired angle for the left or right leg. An external rotation of 3° is the recommended default setting.

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

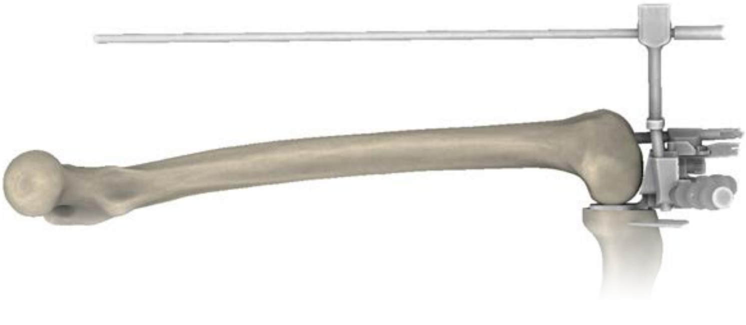
Slide the Femoral Alignment Guide over the IM Rod, through the hole of the Valgus Adjuster until the jig is positioned up against the distal femoral condyles.

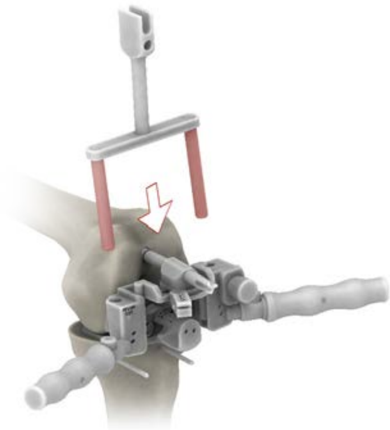


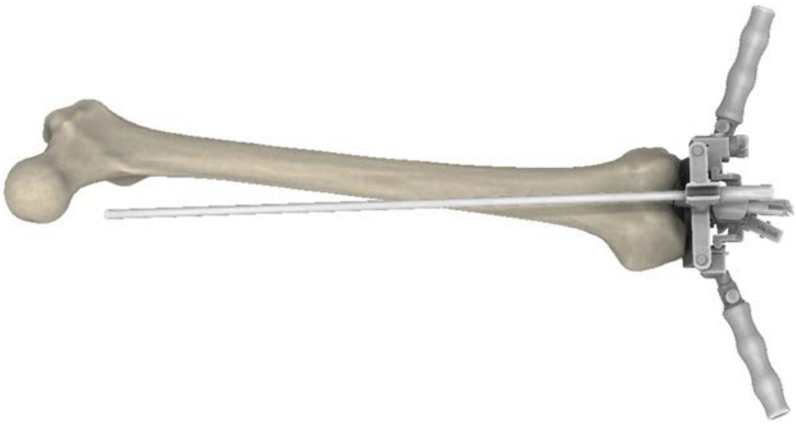
With the knee at 90° of flexion, allow the weight of the femur to sit down onto the posterior footplate and the cut tibia. Ensure that there is direct contact between the posterior femoral condyles and the footplate medially and laterally.



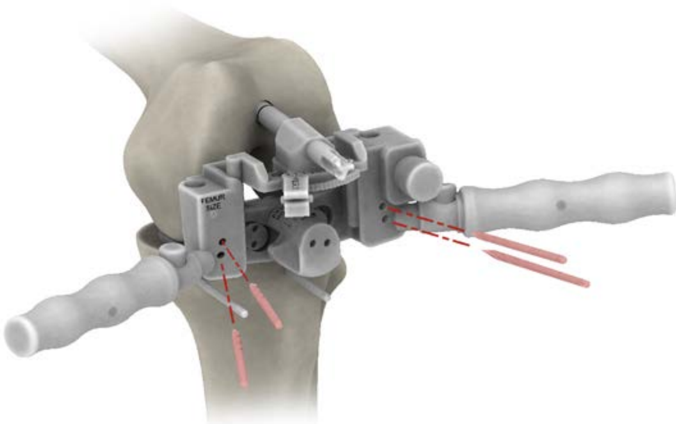
Optionally, check the femoral axis alignment using the External Alignment Rod Mount with the External Alignment Rod.





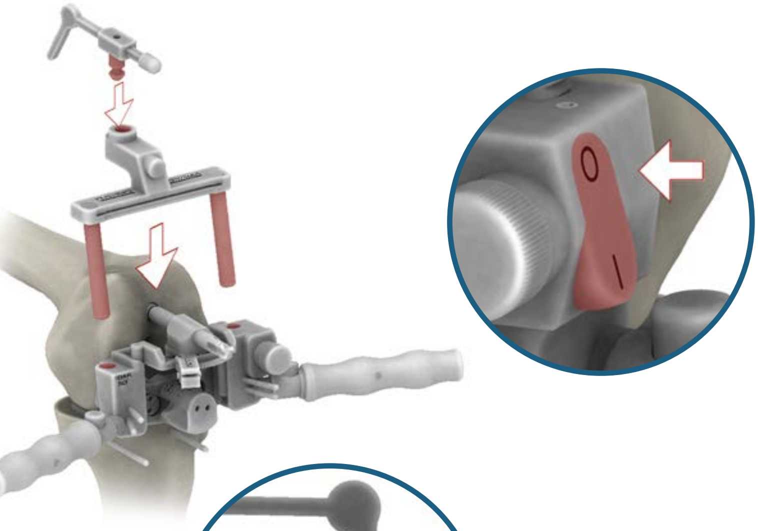


Secure the Femoral Alignment Guide with Long Pins.

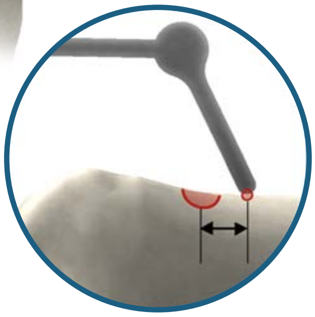


Step 11

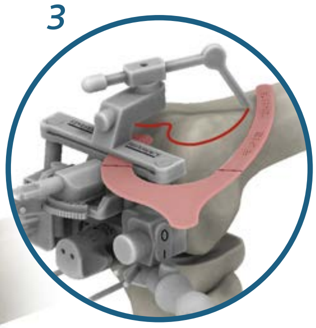
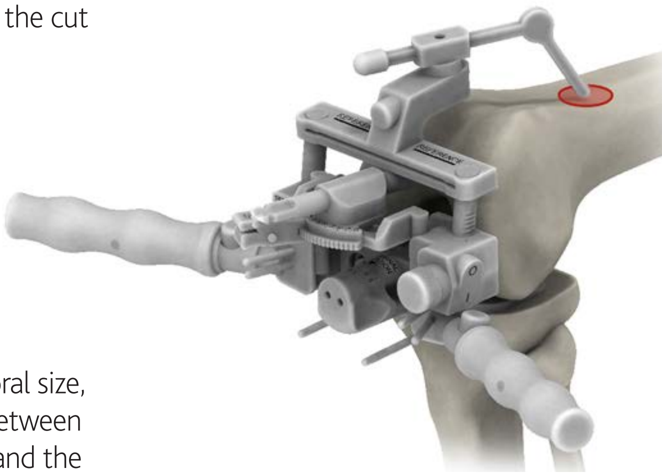
Set Anterior Cutting Guide

1


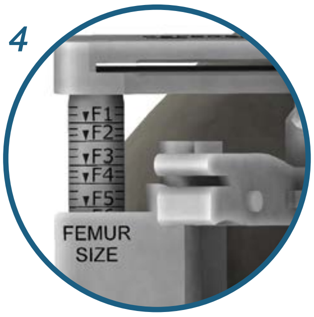
1. Assemble the Femoral Stylus and the Anterior Cutting Guide with the Anterior Femoral Alignment Guide main body. Check that the dial on the right side of the Femoral Guide is in the unlocked position (O - open; I - locked.).

2


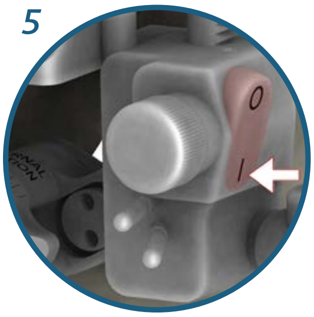
2. Locate the proximal extent of the anterior lateral femoral ridge. Lower the Femoral Stylus until its tip contacts the anterior femoral cortex 1cm proximal of the lateral femoral ridge.

3



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

4


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


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.

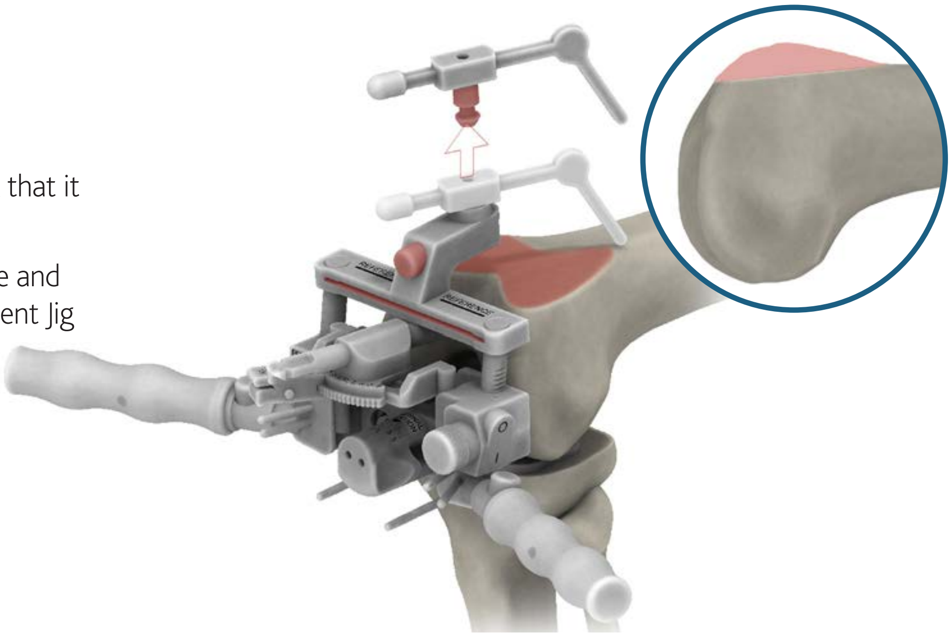
Step 12

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.



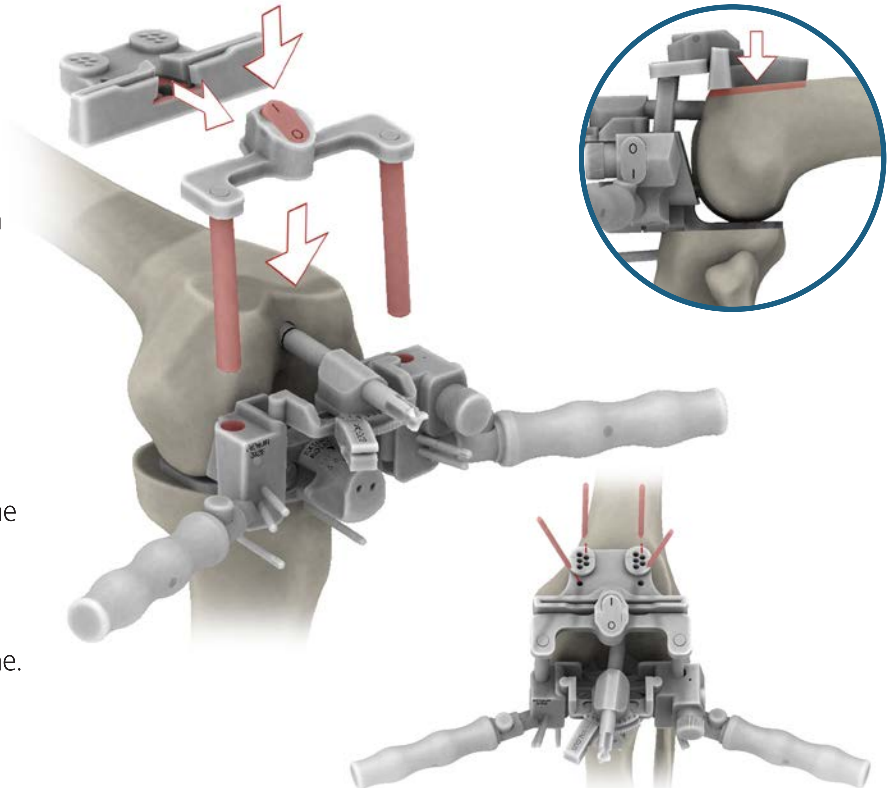
Step 13

Position Distal Cutting Block

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

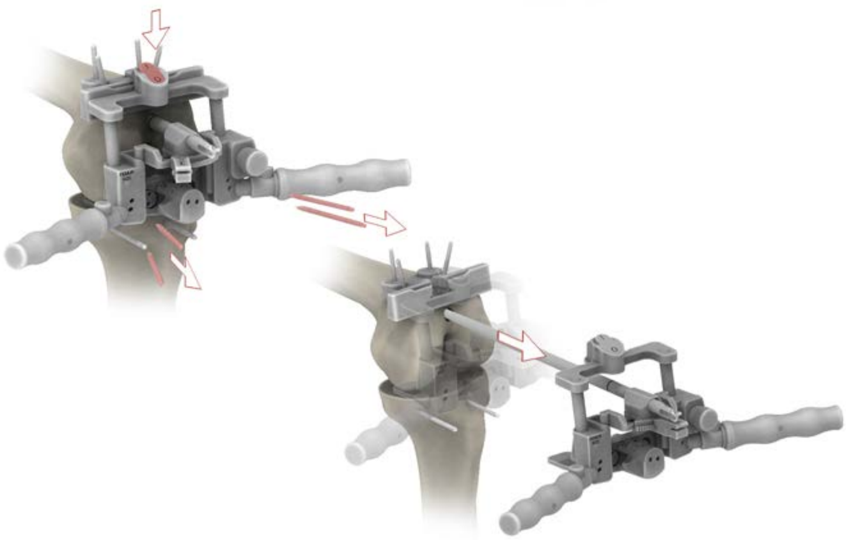
Slide the Distal Cutting Block Mount onto the Anterior Femoral Alignment Guide main body so that the Distal Cutting Block rests flat on the anterior cut.

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.

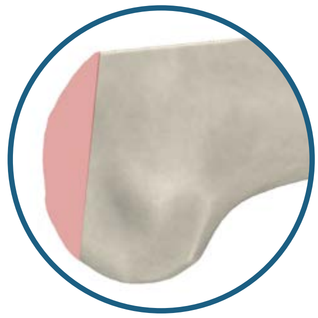


Step 14

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.



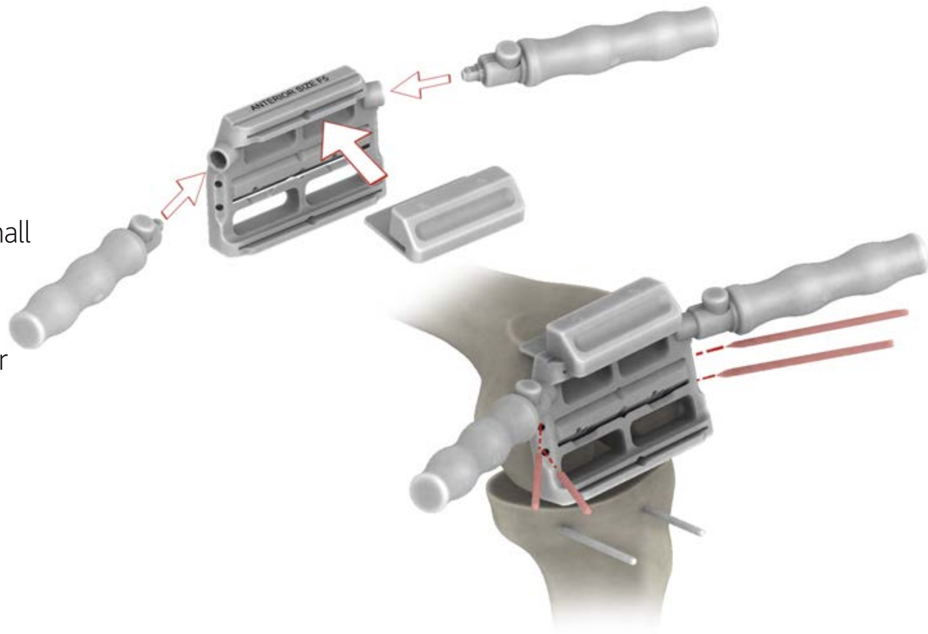
Step 15

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.

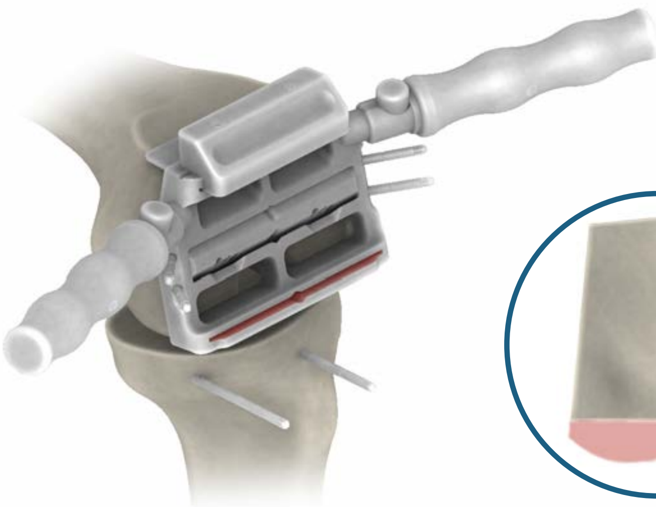
Secure the Multicut Block with medial and lateral Pins.

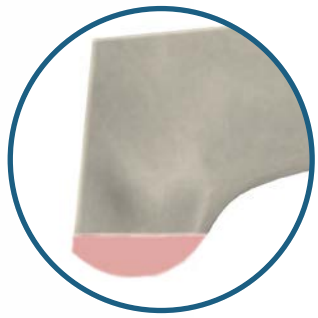


Step 16

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.





Step 17

Assess joint space using Tibial 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 size compatibility chart on page 41). 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.

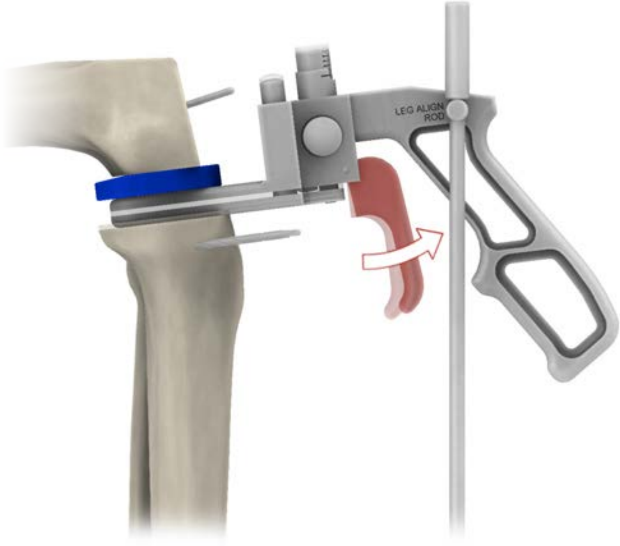
Check alignment (using the External Alignment Rod) and that the leg fully extends. If the knee cannot be fully extended, release any posterior adhesions.

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.

Assess joint space using the Magic Spacer

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.

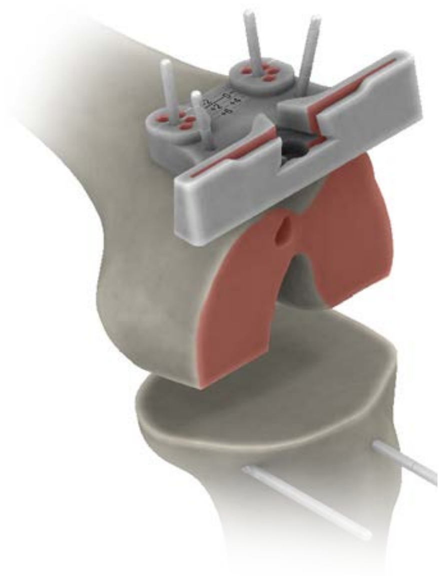
If the minimum available thickness (paddles closed) is tight in flexion, resect more tibia.

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 size compatibility chart on page 41 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 positions 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.

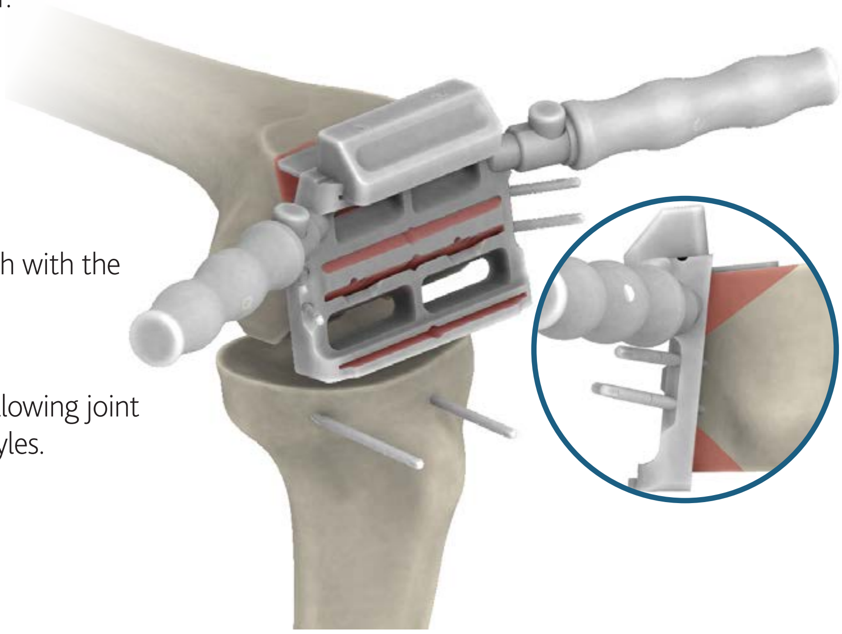
Step 18

Complete chamfer cuts

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

Resect posterior and anterior chamfers.

If any additional resection was performed following joint space assessment, re-cut the posterior condyles.



Step 19

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 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 size compatibility chart on page 41 for available thicknesses.

Step 20

Femoral finishing

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

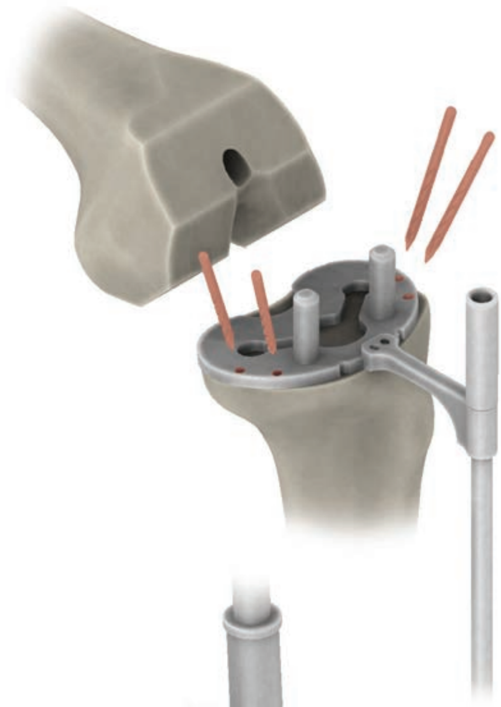
Remove trial components.

Step 21

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 22

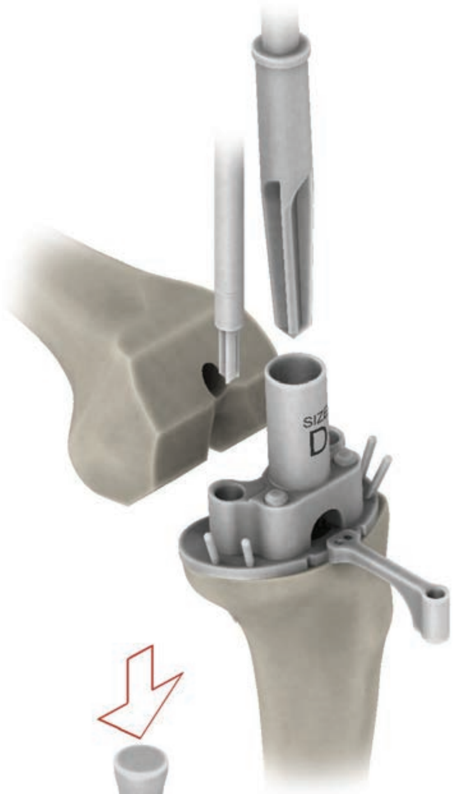
Assemble with the appropriate Tibial Drill Guide.

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.



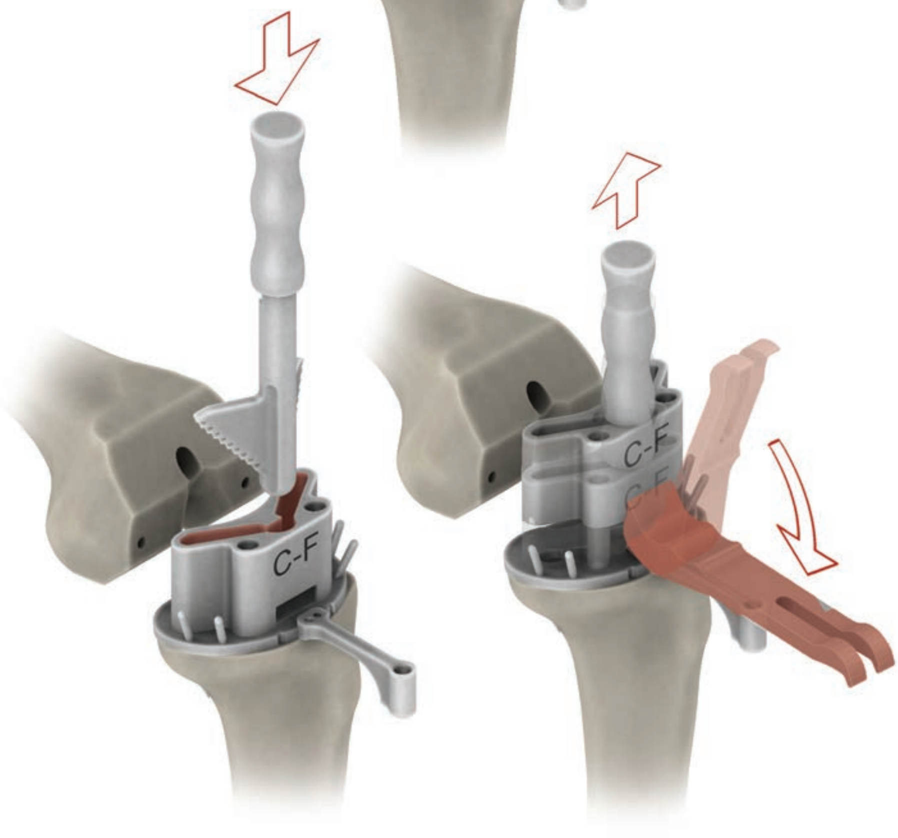
Step 23

Prepare the tibial webs using the appropriate size Tibial Chisel, guided by the prepared stem and slots 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 24

Final trial reduction

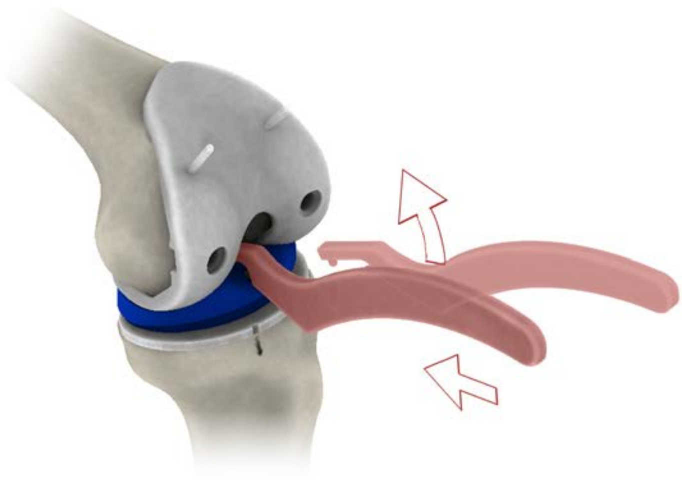
Select the appropriate Femoral Trial, Tibial Trial and Trial Bearing.

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.

Refer to size compatibility chart on page 41 for available thicknesses.



Patellar resurfacing

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

- page 22 for Patellar resurfacing: Cementless Patella,
- page 24 for Patellar resurfacing: Cemented Patella, onset Patella,
- page 26 for Patellar resurfacing: Cemented Patella, Iinset Patella.

Step 25

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 26

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.

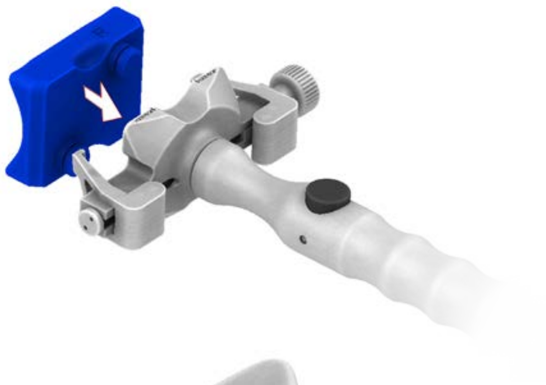
Insert the Tibial Tray and Bearing assembly carefully into the proximal tibia and impact.

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

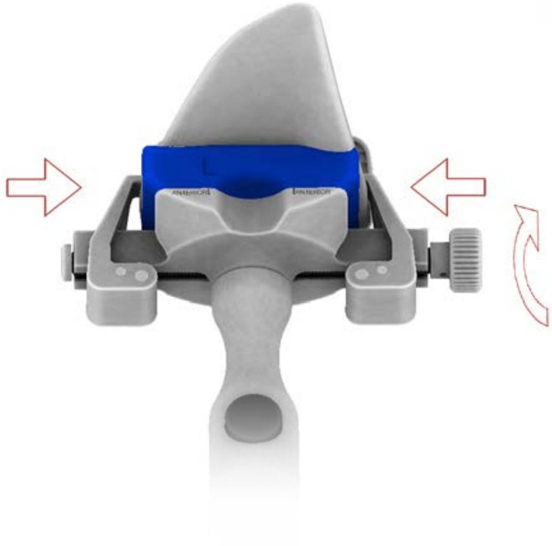
Step 27

Assemble Femoral Component

Assemble the Femoral Component Inserter with the appropriate support, ensuring that it is correctly oriented for the left or right. Connect the Femoral Component Inserter to a Quick Release Impaction Handle. Retract the clamp arms by rotating the adjuster anticlockwise.



Assemble the Femoral Component with the Inserter, ensuring that the arms of the Inserter locate into the notches on either side of the Femoral Component. Secure by rotating the knob clockwise until hand-tight.



Step 28

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 Component Inserter from the Femoral Component by rotating the knob anticlockwise.

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

Step 29

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 30

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 27 and Step 28 (page 20).

Insert the appropriate Trial Bearing to perform a final trial reduction, seating the components while the cement goes off (Step 29, page 20). 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.

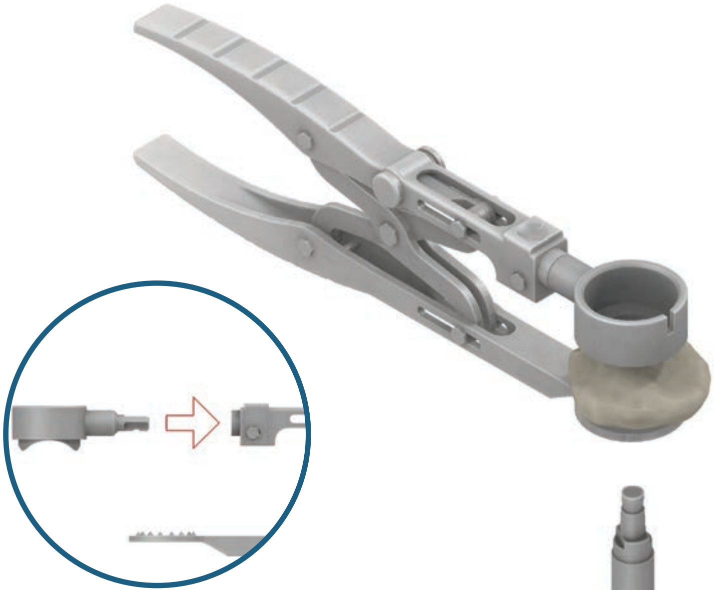
Patellar resurfacing: Cementless Patella

Step 1

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.



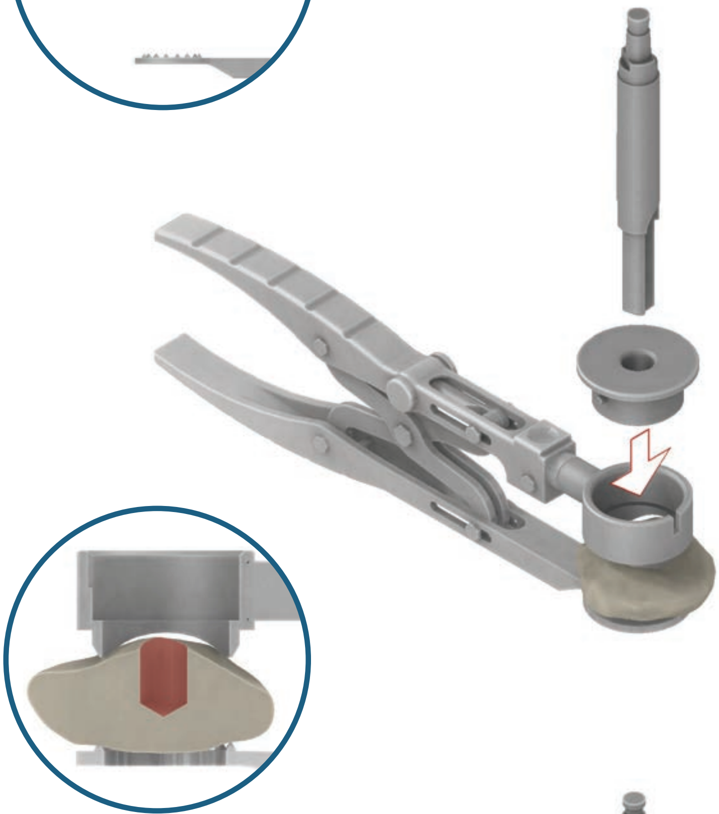
Step 2

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.

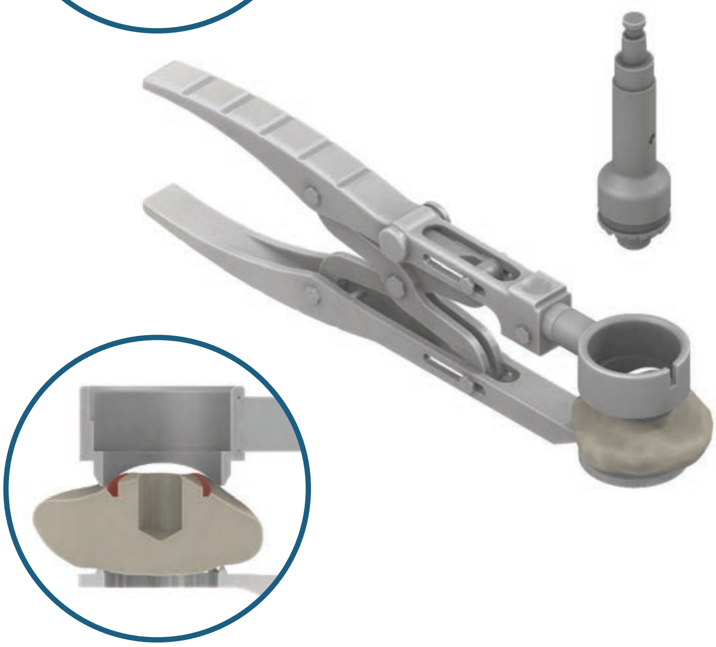


Step 3

Cut bore profile

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

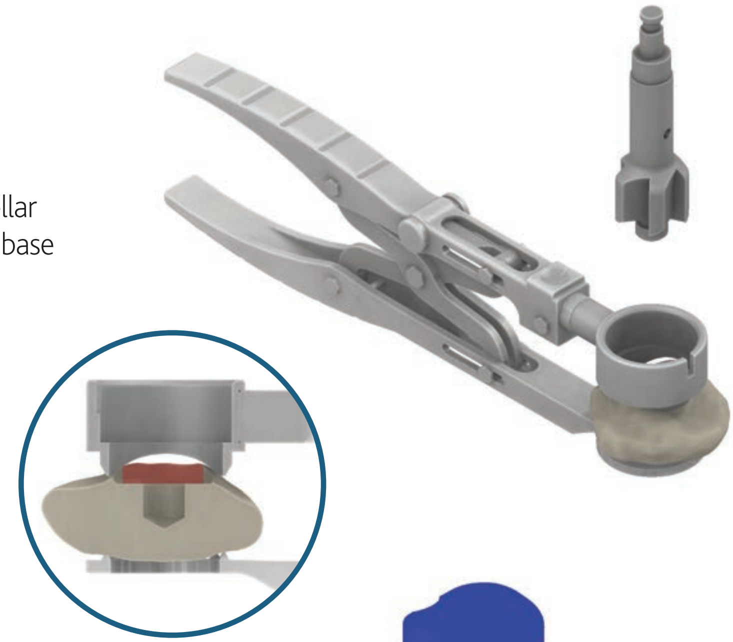
Note: This step is not required for the 16mm Cementless Patellar Component.



Step 4

Counter-bore Patella

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

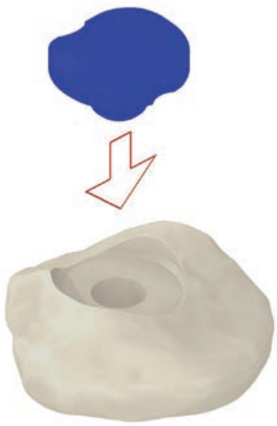


Step 5

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 6

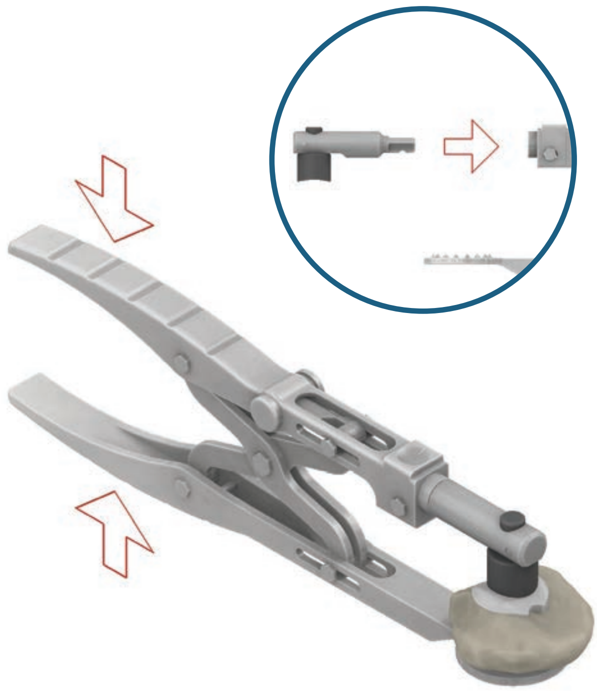
Implant Patellar Component

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.



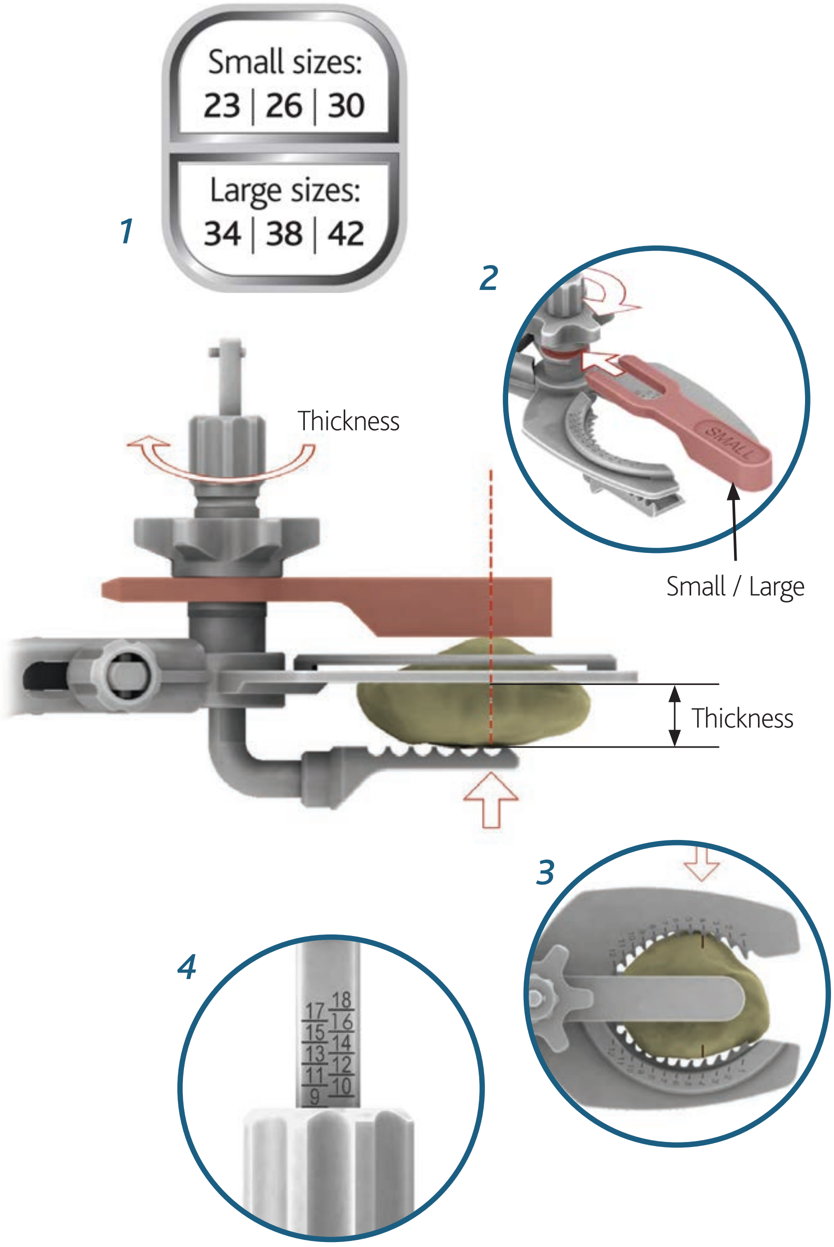
Alternative method

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.

Patellar resurfacing: Cemented Patella, onset Patella

Note: Compatible with all sizes of patella.



Step 1

Clamping

1. 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.

   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.

   The patella should be advanced using the anterior referencing arm until it touches the Cemented Patellar Feeler Arm and then clamped in line with the cartilage edge.

3. Once the Cemented Patellar Clamp is in place, note the offset of the patellar ridge and make a diathermy mark to reference the position of the Patellar Component.

4. Note the thickness of the remaining patellar bone stock using the clamp as shown. Check that the indicated value is at least 9mm.

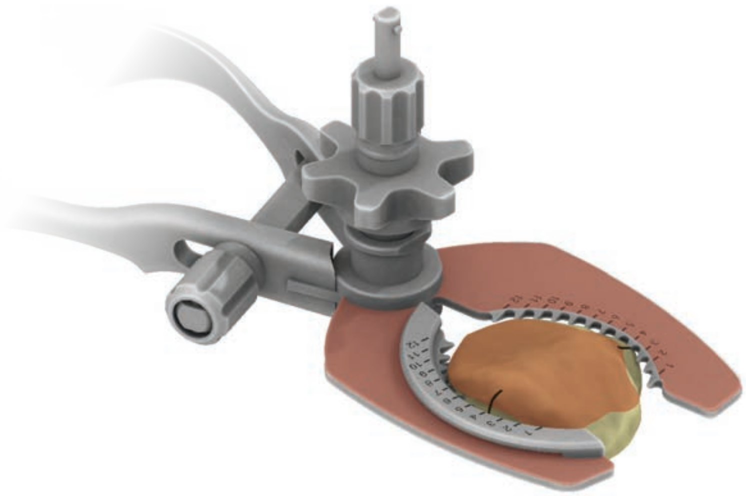
Step 2

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.

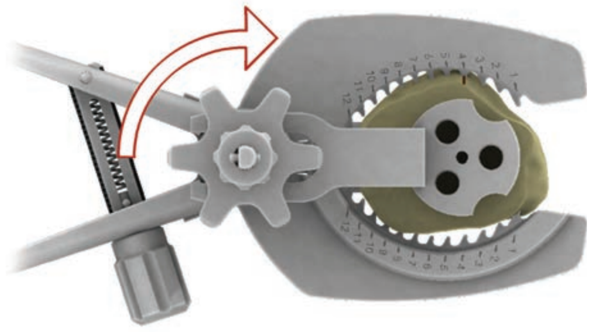


Step 3

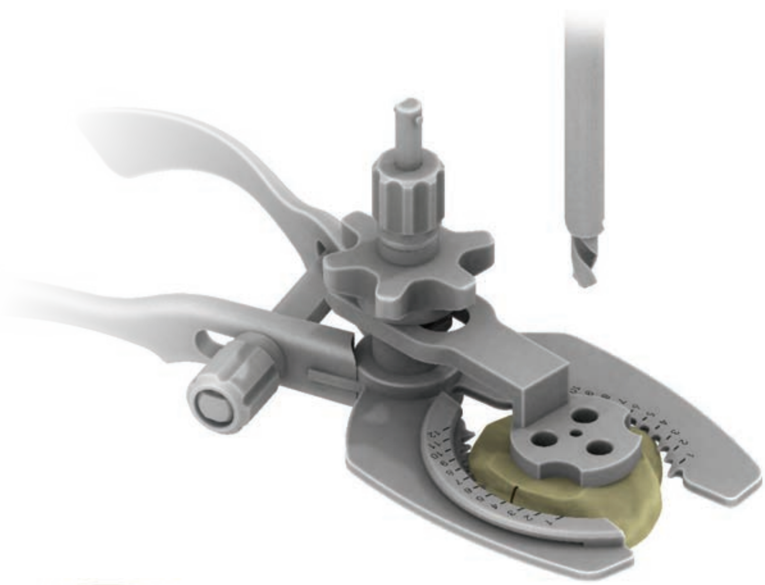
Drill peg holes

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 4

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 5

Implantation

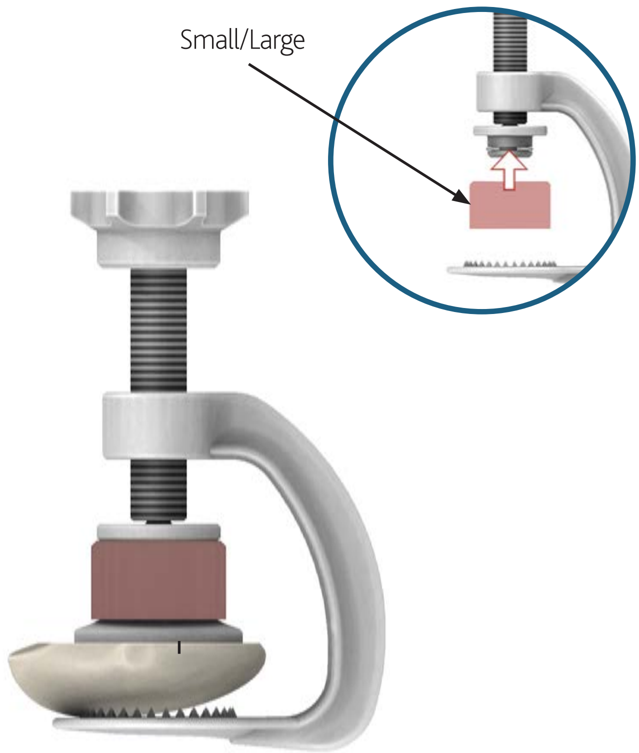
Note: Cement must be used with this implant; ideally high viscosity cement or medium viscosity for syringe application.

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.



Patellar resurfacing: Cemented Patella, inset Patella

Note: Only compatible with small sizes (23 – 30).

Step 1

Clamping

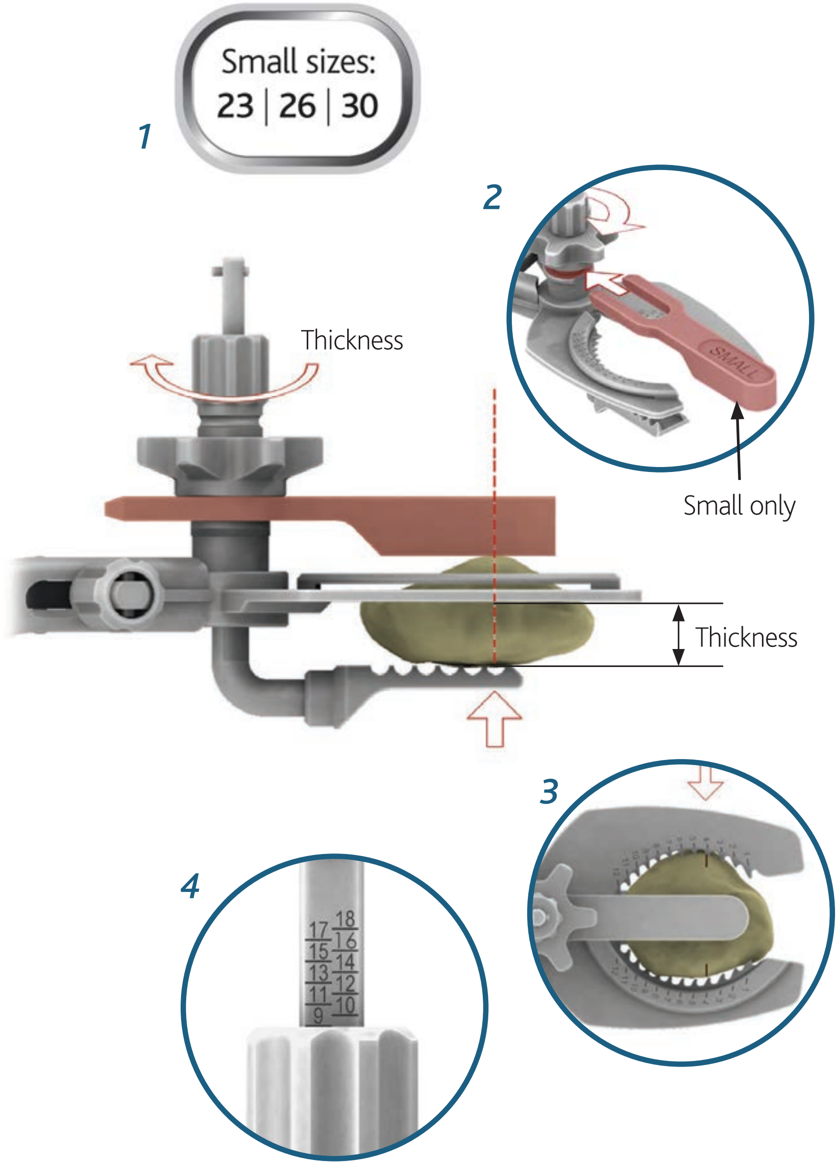
1. Trim the patella of any osteophytes and perform a trial reduction to assess if replacement and/or any release is indicated. The patella should be completely stable without stay sutures or finger help.

   Determine the desired size by referring to the trial components.

2. Reference from the articular surface using the Small Patellar Feeler Arm. The patella should be advanced using the anterior referencing arm until it touches the Patellar Feeler Arm and then clamped in line with the cartilage edge.

3. Once the Cemented Patellar Clamp is in place, note the offset of the patellar ridge and make a diathermy mark to reference the position of the Patellar Component.

4. Note the thickness of the remaining patellar bone stock using the clamp as shown. Check that the indicated value is at least 9mm.



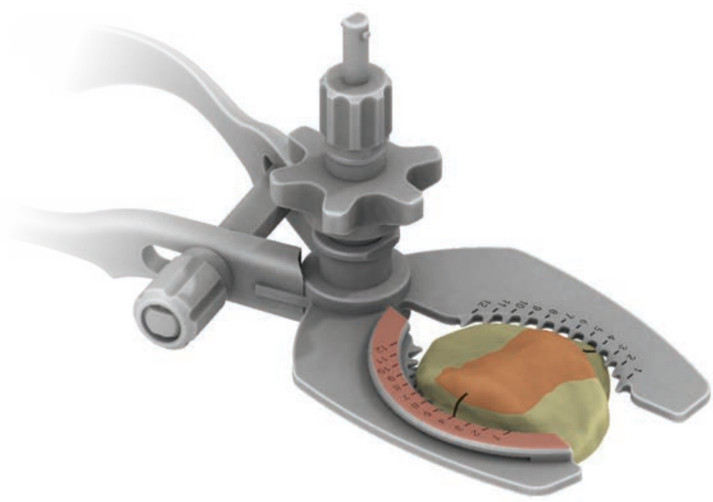
Step 2

Resection

Resect above the slotted guide.

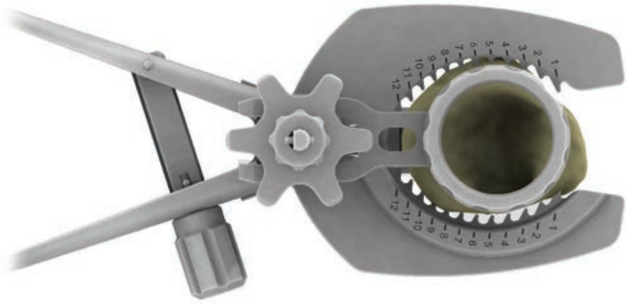
Bone resection above the slot will ensure the original height of the patella is restored once the implant has been inset into place.

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



Step 3

Counterbore patella



Determine the Patellar Component size that best fits the resected area.

Attach the Cemented Inset Drill Guide to the Cemented Patellar Clamp with its centre offset to coincide with the offset noted for the native patellar ridge.

Clamp the Inset Drill Guide using the large thumb wheel and screw the Threaded Collar of the Inset Drill Guide to contact the bone surface.

Choose the appropriate diameter Cemented Patellar Inset Drill and drill through the guide to the full depth.

Step 4

Drill peg holes

Place the Patellar Inset Peg Drill Guide at the bottom of the Inset Patellar Drill Guide and create the three peg holes using the Cemented Patellar Peg Drill.

Step 5

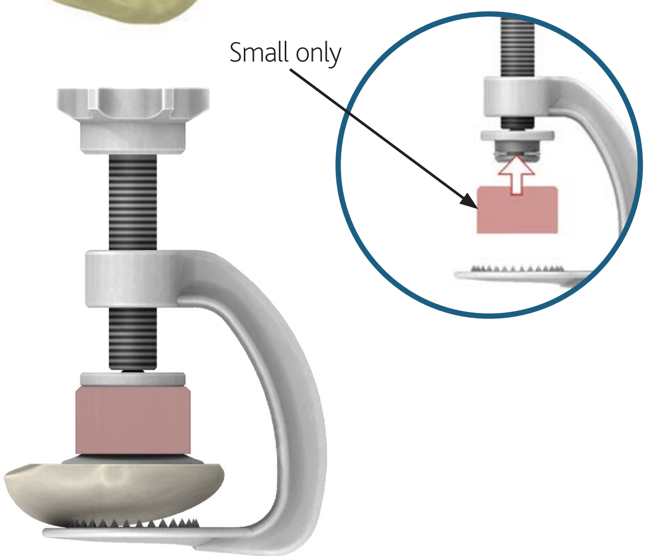
Trial reduction

Select the appropriate Cemented Patellar Trial size and perform a trial reduction.

Trim away any protruding bone edges.

Step 6

Implantation



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

Place cement around the Patellar Component Pegs. Place the Patellar Component on the prepared patella using the Cemented Patellar Compressor.

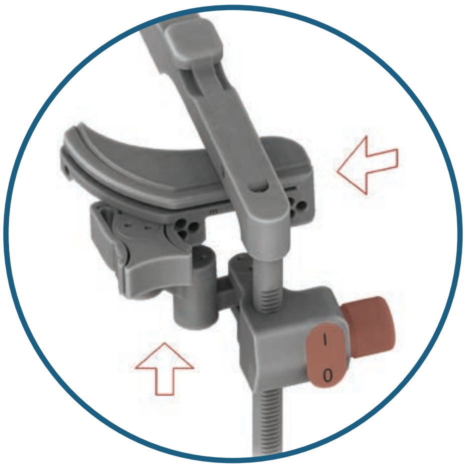
Remove any residual bone cement and allow the cement to polymerise. Remove the Cemented Patellar Compressor.

Preparation of instruments

Tibial Alignment Guide preparation

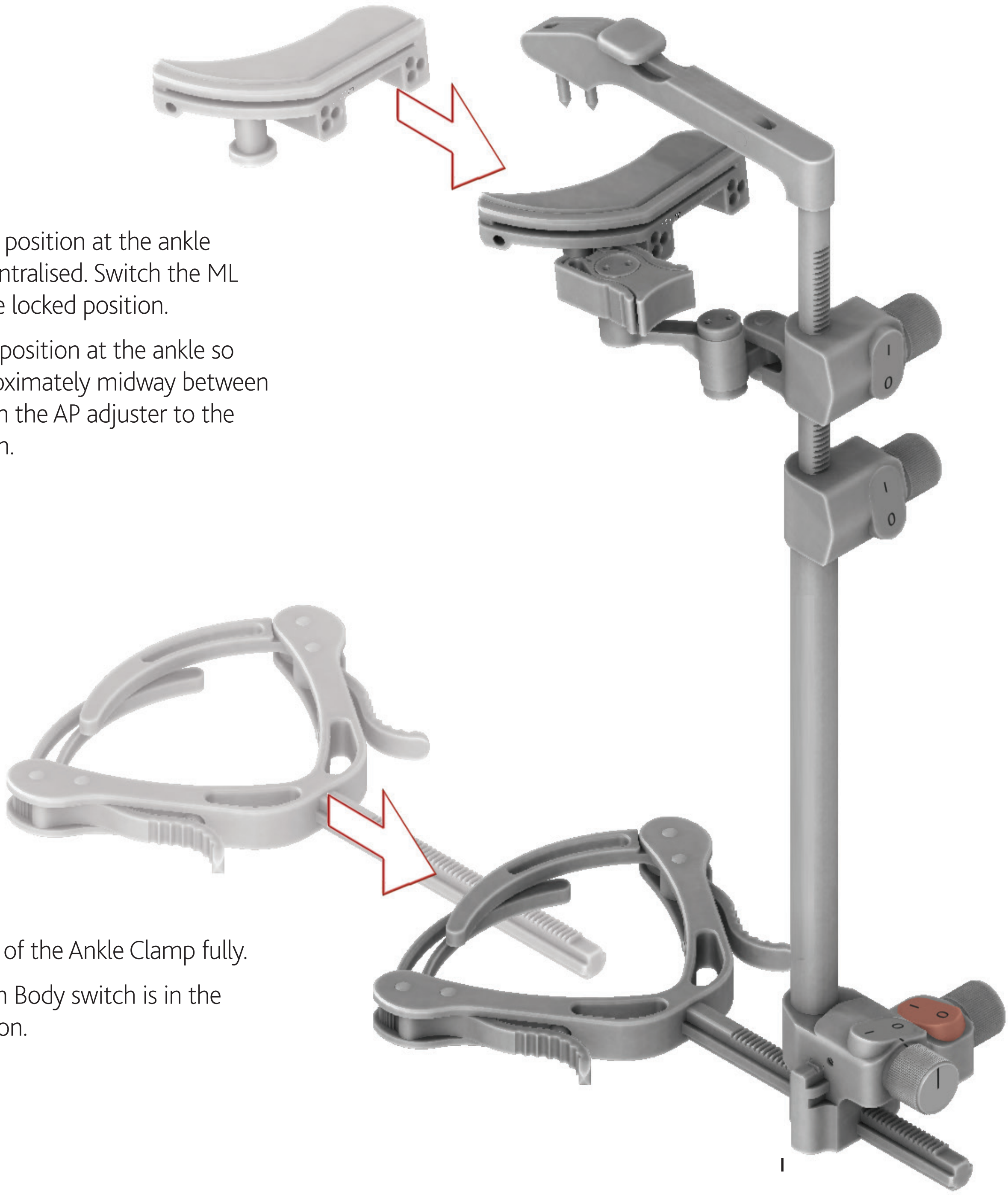
Assemble the Ankle Clamp with the Main Body, Left or Right Tibial Cutting Guide.

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.

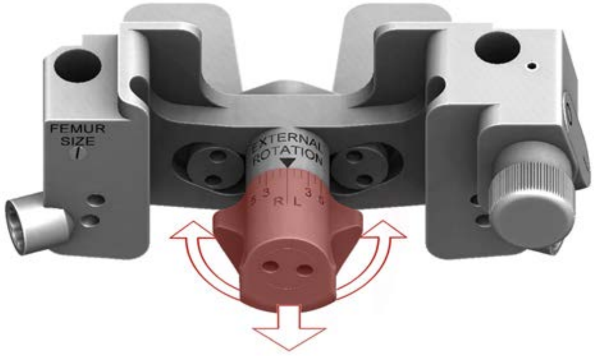


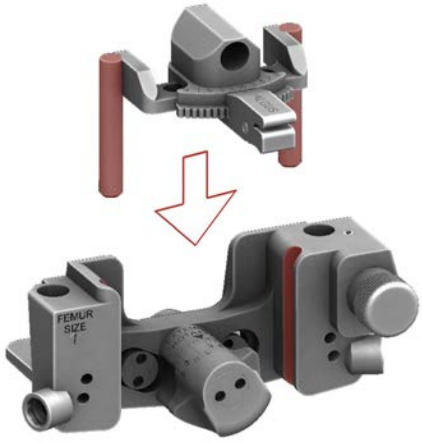
Open the arms of the Ankle Clamp fully.

Ensure the Main Body switch is in the unlocked position.

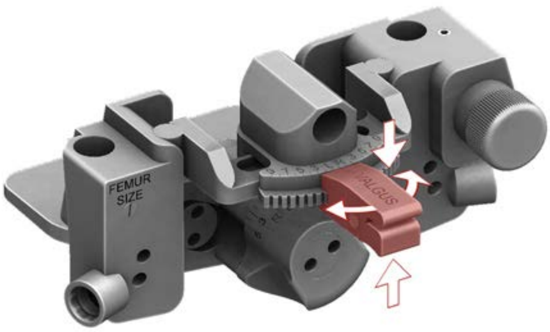
Anterior Femoral Alignment Guide preparation

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.

Instrument tray layout

The SAIPH® Knee instrument trays are laid out with usage in mind. There are a total of 10 trays, which together include all instruments required for the:

- Anterior First technique,
- Cementless Patella and
- Cemented Patella.

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 both large and small trials for the relevant side may be required until the required femoral size is established (Step 11, page 11).

Anterior First instrumentation without patellar resurfacing

5 trays

Tray 1	Core instruments
Tray 2	Femoral and tibial alignment
Tray 3	Balancing
Tray 4	Tibial preparation
Tray 5-8	Trials

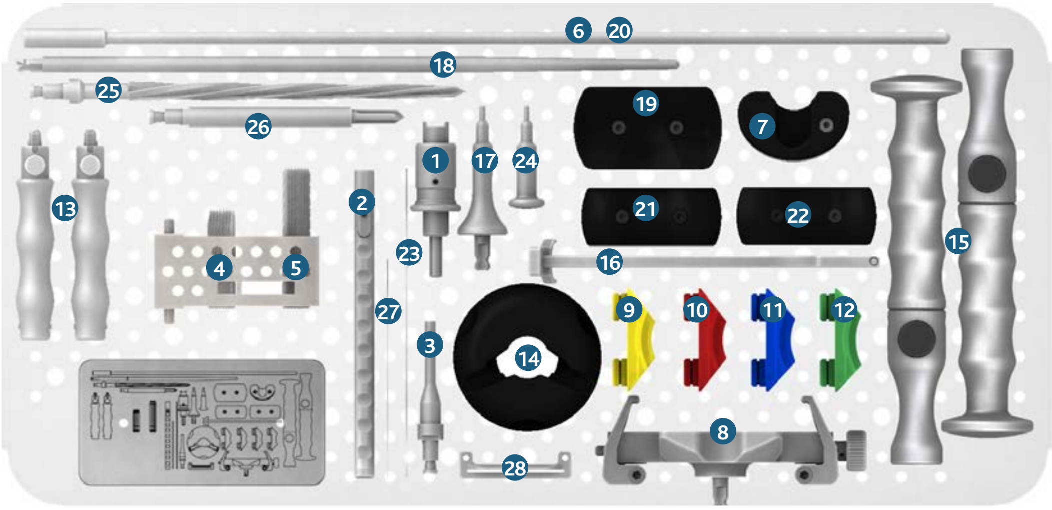
With patellar resurfacing, add

1 tray

Tray 9-10	Patellar instruments

Tray 1

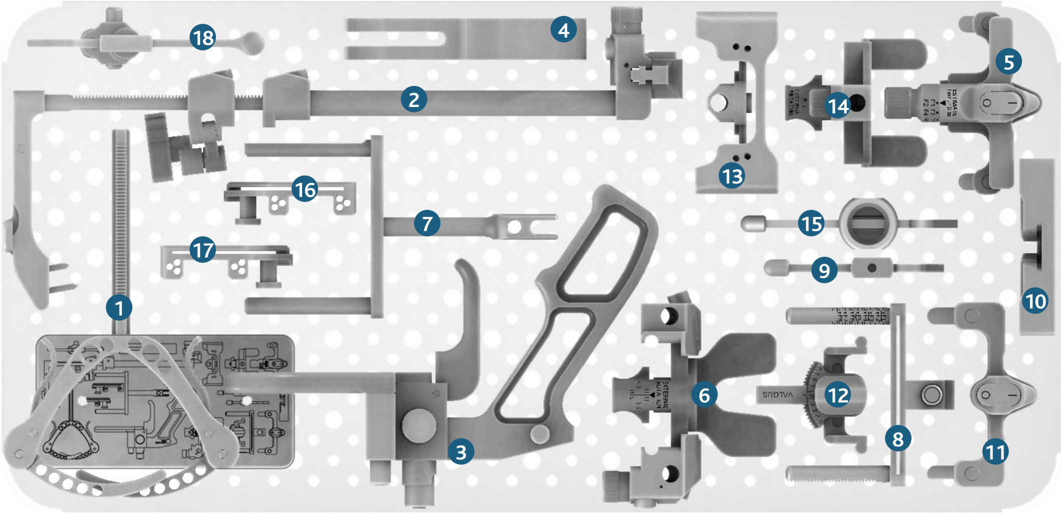
Core Instruments



Item	Part No.	Description	Qty
1	231-303	Jacobs/Hudson Adaptor	1
2	231-304	Pin Inserter/Extractor	1
3	255-003	Pin Driver	1
4	255-035	Short Pin - 50mm	8
5	255-036	Long Pin - 70mm	8
6	256-462	Extended External Alignment Rod	1
7	293-202	Tibial Tray Impactor	1
8	293-203	Femoral Component Inserter / Remover	1
9	293-204	Femoral Component Inserter / Remover Support - Yellow	1
10	293-205	Femoral Component Inserter / Remover Support - Red	1
11	293-206	Femoral Component Inserter / Remover Support - Blue	1
12	293-207	Femoral Component Inserter / Remover Support - Green	1
13	293-242	Universal Small Handle	2
14	293-251	Tibial Assembly Tool	1
15	293-253	Quick Release Impaction Handle	2
16	293-259	Tibial Trial Removal Tool	1
17	293-262	In-Situ Bearing Impactor Drive	1
18	293-265	IM Rod	1
19	293-270	Femoral Impactor	1
20	293-284	Extended External Alignment Rod Extension	1
21	293-285	Tibial Impactor - Yellow and Red	1
22	293-286	Tibial Impactor - Blue and Green	1
23	293-400	Femoral Angel Wing	1
24	293-405	Bearing Impactor Pin	1
25	293-427	IM Drill	1
26	293-429	Universal Peg Drill	1
27	293-516	Tibial Angel Wing	1
28	293-625	Re-Cutting Block 0°	1

Tray 2

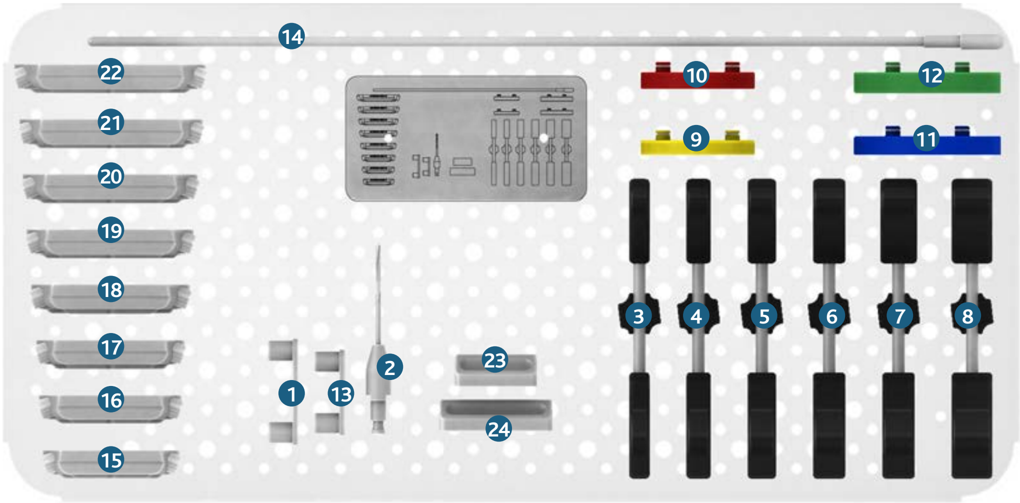
Femoral and Tibial Alignment



Item	Part No.	Description	Qty
1	293-208	Tibial Alignment Guide Ankle Clamp	1
2	293-209	Tibial Alignment Guide Main Body	1
3	293-279	Magic Spacer	1
4	293-210	Extractor Lever	1
5	293-289	Distal First Cutting Block Mount	1
6	293-288	Anterior Femoral Alignment Guide	1
7	293-291	External Alignment Rod Mount	1
8	293-292	Anterior Cutting Guide	1
9	293-293	Femoral Stylus	1
10	293-294	Distal Cutting Block	1
11	293-295	Distal Cutting Block Mount	1
12	255-043	Valgus Adjuster	1
13	293-297	Distal Femoral Alignment Guide	1
14	293-298	Femoral Sizing Jig	1
15	293-299	Femoral Stylus - Sizing Jig	1
16	293-510	Tibial Cutting Block - Left	1
17	293-511	Tibial Cutting Block - Right	1
18	293-515	Tibial Stylus	1

Tray 3

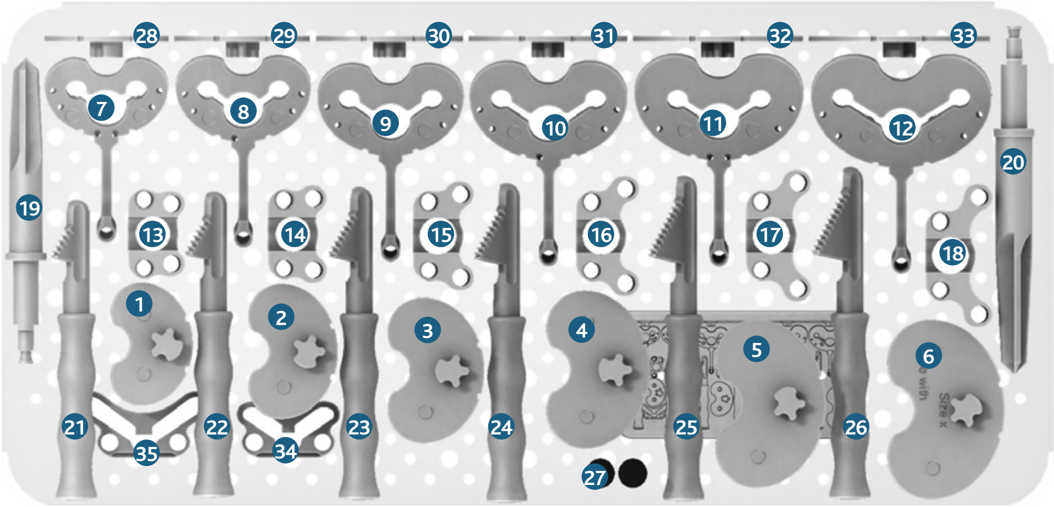
Balancing and BESPOKE™ Instruments



Item	Part No.	Description	Qty
1	255-032	Pin Guide - Distal Holes	1
2	255-033	Pin Drill - Short Version	1
3	293-230	Dual Ended Tibial Spacer - 10mm	1
4	293-231	Dual Ended Tibial Spacer - 12mm	1
5	293-232	Dual Ended Tibial Spacer - 14mm	1
6	293-233	Dual Ended Tibial Spacer - 16mm	1
7	293-234	Dual Ended Tibial Spacer - 18mm	1
8	293-235	Dual Ended Tibial Spacer - 20mm	1
9	293-266	Femoral Spacer. Yellow	1
10	293-267	Femoral Spacer. Red	1
11	293-268	Femoral Spacer. Blue	1
12	293-269	Femoral Spacer. Green	1
13	293-302	Pin Guide, 30mm	1
14	293-304	Alignment Rod Ø5	1
15	293-321	Multicut Block Size 1	1
16	293-322	Multicut Block Size 2	1
17	293-323	Multicut Block Size 3	1
18	293-324	Multicut Block Size 4	1
19	293-325	Multicut Block Size 5	1
20	293-326	Multicut Block Size 6	1
21	293-327	Multicut Block Size 7	1
22	293-328	Multicut Block Size 8	1
23	255-008	Anterior Reference Plate Standard	1
24	293-278	Anterior Reference Plate Large	1

Tray 4

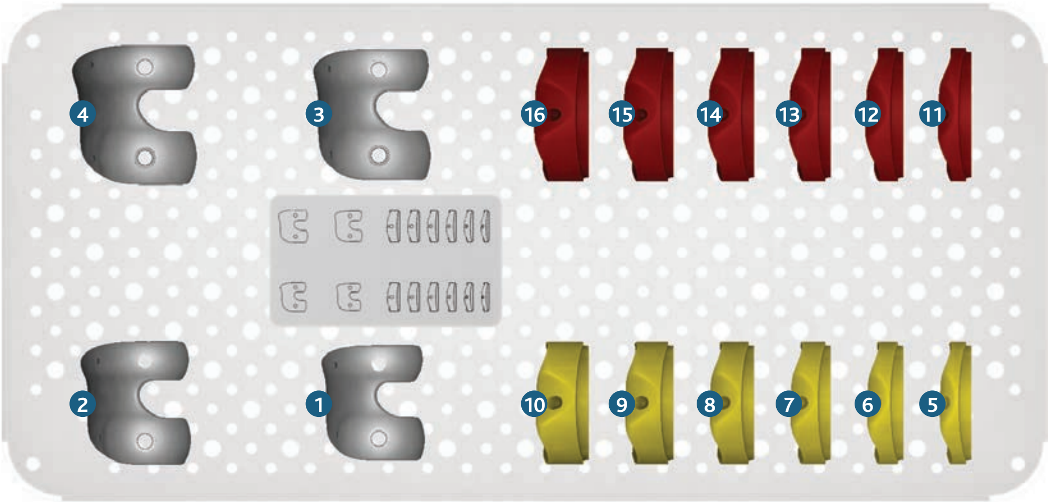
Tibial Preparation



Item	Part No.	Description	Qty
1	293-110	Tibial Trial Size A	1
2	293-111	Tibial Trial Size B	1
3	293-112	Tibial Trial Size C	1
4	293-113	Tibial Trial Size D	1
5	293-114	Tibial Trial Size E	1
6	293-115	Tibial Trial Size F	1
7	293-216	Tibial Template - Size A	1
8	293-217	Tibial Template - Size B	1
9	293-218	Tibial Template - Size C	1
10	293-219	Tibial Template - Size D	1
11	293-220	Tibial Template - Size E	1
12	293-221	Tibial Template - Size F	1
13	293-222	Tibial Drill Guide Size A	1
14	293-223	Tibial Drill Guide Size B	1
15	293-224	Tibial Drill Guide Size C	1
16	293-225	Tibial Drill Guide Size D	1
17	293-226	Tibial Drill Guide Size E	1
18	293-227	Tibial Drill Guide Size F	1
19	293-228	Tibial Stem Drill Small, Sizes A-B	1
20	293-229	Tibial Stem Drill Large, Sizes C-F	1
21	293-271	Tibial Webbing Chisel Size A	1
22	293-272	Tibial Webbing Chisel Size B	1
23	293-273	Tibial Webbing Chisel Size C	1
24	293-274	Tibial Webbing Chisel Size D	1
25	293-275	Tibial Webbing Chisel Size E	1
26	293-276	Tibial Webbing Chisel Size F	1
27	293-568	Tibial Peg Plug	2
28	293-580	Tibial Rotation Indicator - Size A	1
29	293-581	Tibial Rotation Indicator - Size B	1
30	293-582	Tibial Rotation Indicator - Size C	1
31	293-583	Tibial Rotation Indicator - Size D	1
32	293-584	Tibial Rotation Indicator - Size E	1
33	293-585	Tibial Rotation Indicator - Size F	1
34	293-282	Tibial Webbing Chisel Guide A to B	1
35	293-283	Tibial Webbing Chisel Guide C to F	1

Tray 5

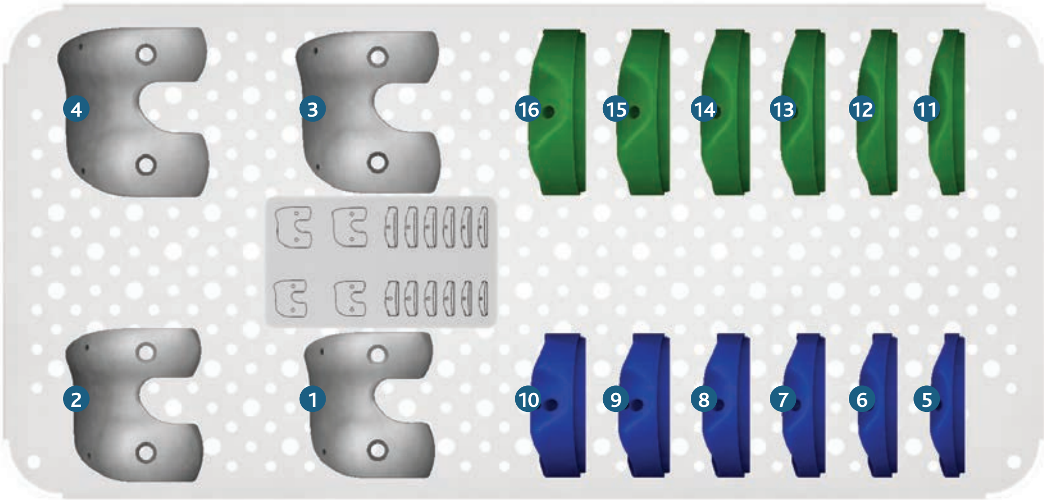
Small Left Trials



Item	Part No.	Description	Qty
1	293000	Femoral Trial Left, Size 1	1
2	293001	Femoral Trial Left, Size 2	1
3	293002	Femoral Trial Left, Size 3	1
4	293003	Femoral Trial Left, Size 4	1
5	293700	Trial Bearing Yellow. Left.10mm	1
6	293701	Trial Bearing Yellow. Left.12mm	1
7	293702	Trial Bearing Yellow. Left.14mm	1
8	293703	Trial Bearing Yellow. Left.16mm	1
9	293704	Trial Bearing Yellow. Left.18mm	1
10	293705	Trial Bearing Yellow. Left. 20mm	1
11	293724	Trial Bearing Red. Left.10mm	1
12	293725	Trial Bearing Red. Left.12mm	1
13	293726	Trial Bearing Red. Left.14mm	1
14	293727	Trial Bearing Red. Left.16mm	1
15	293728	Trial Bearing Red. Left.18mm	1
16	293729	Trial Bearing Red. Left. 20mm	1

Tray 6

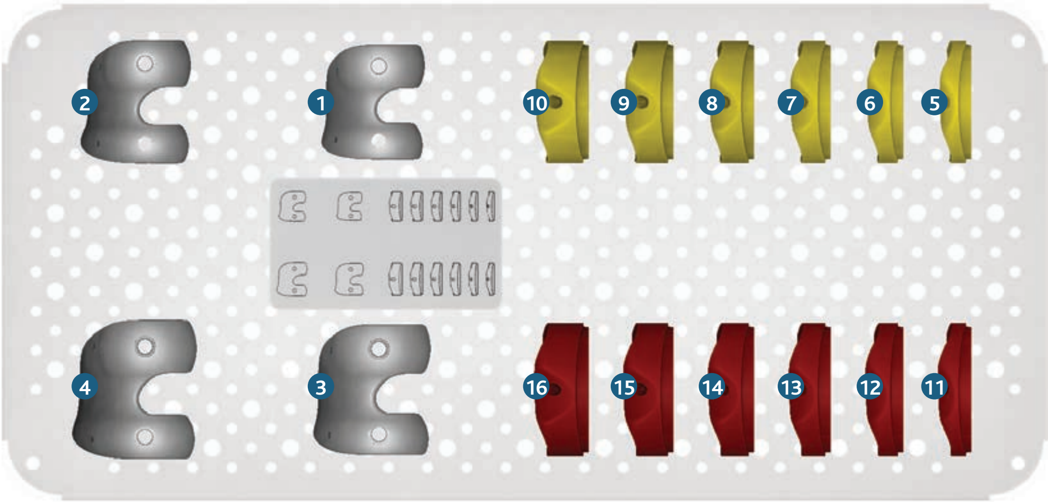
Large Left Trials



Item	Part No.	Description	Qty
1	293004	Femoral Trial Left, Size 5	1
2	293005	Femoral Trial Left, Size 6	1
3	293006	Femoral Trial Left, Size 7	1
4	293007	Femoral Trial Left, Size 8	1
5	293748	Trial Bearing Blue. Left.10mm	1
6	293749	Trial Bearing Blue. Left.12mm	1
7	293750	Trial Bearing Blue. Left.14mm	1
8	293751	Trial Bearing Blue. Left.16mm	1
9	293752	Trial Bearing Blue. Left.18mm	1
10	293753	Trial Bearing Blue. Left. 20mm	1
11	293796	Trial Bearing Green. Left.10mm	1
12	293797	Trial Bearing Green. Left.12mm	1
13	293798	Trial Bearing Green. Left.14mm	1
14	293799	Trial Bearing Green. Left.16mm	1
15	293800	Trial Bearing Green. Left.18mm	1
16	293801	Trial Bearing Green. Left. 20mm	1

Tray 7

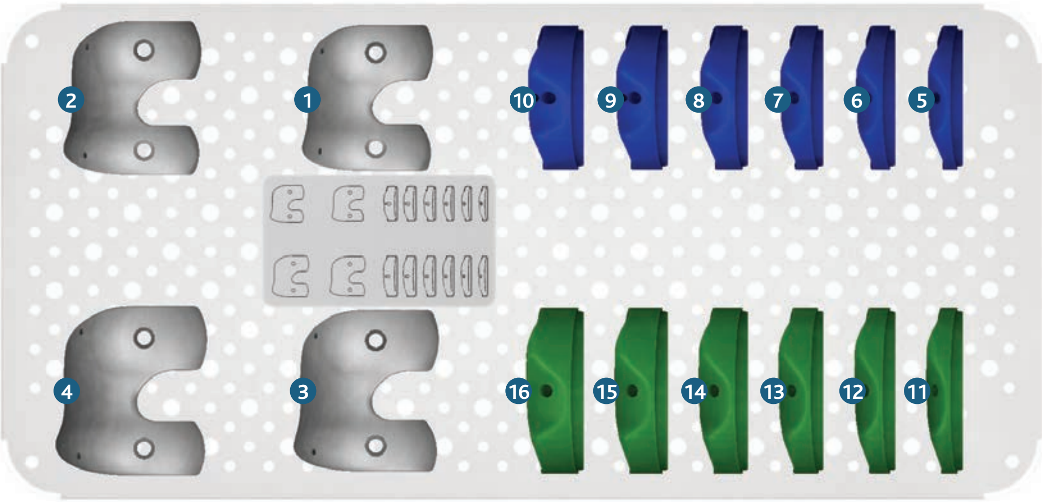
Small Right Trials



Item	Part No.	Description	Qty
1	293025	Femoral Trial Right, Size 1	1
2	293026	Femoral Trial Right, Size 2	1
3	293027	Femoral Trial Right, Size 3	1
4	293028	Femoral Trial Right, Size 4	1
5	293706	Trial Bearing Yellow. Right.10mm	1
6	293707	Trial Bearing Yellow. Right.12mm	1
7	293708	Trial Bearing Yellow. Right.14mm	1
8	293709	Trial Bearing Yellow. Right.16mm	1
9	293710	Trial Bearing Yellow. Right.18mm	1
10	293711	Trial Bearing Yellow. Right. 20mm	1
11	293730	Trial Bearing Red. Right.10mm	1
12	293731	Trial Bearing Red. Right.12mm	1
13	293732	Trial Bearing Red. Right.14mm	1
14	293733	Trial Bearing Red. Right.16mm	1
15	293734	Trial Bearing Red. Right.18mm	1
16	293735	Trial Bearing Red. Right. 20mm	1

Tray 8

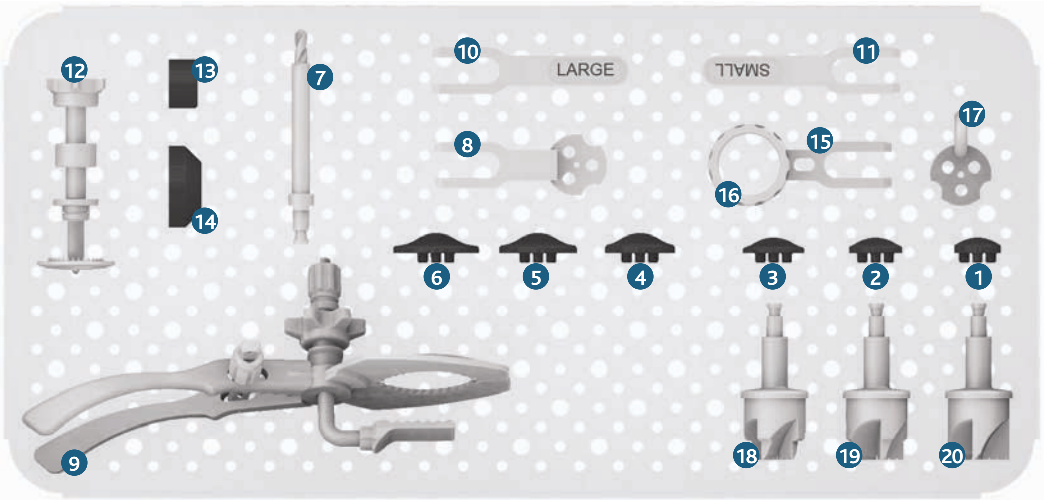
Large Right Trials



Item	Part No.	Description	Qty
1	293029	Femoral Trial Right, Size 5	1
2	293030	Femoral Trial Right, Size 6	1
3	293031	Femoral Trial Right, Size 7	1
4	293032	Femoral Trial Right, Size 8	1
5	293754	Trial Bearing Blue. Right.10mm	1
6	293755	Trial Bearing Blue. Right.12mm	1
7	293756	Trial Bearing Blue. Right.14mm	1
8	293757	Trial Bearing Blue. Right.16mm	1
9	293758	Trial Bearing Blue. Right.18mm	1
10	293759	Trial Bearing Blue. Right. 20mm	1
11	293802	Trial Bearing Green. Right.10mm	1
12	293803	Trial Bearing Green. Right.12mm	1
13	293804	Trial Bearing Green. Right.14mm	1
14	293805	Trial Bearing Green. Right.16mm	1
15	293806	Trial Bearing Green. Right.18mm	1
16	293807	Trial Bearing Green. Right. 20mm	1

Tray 9

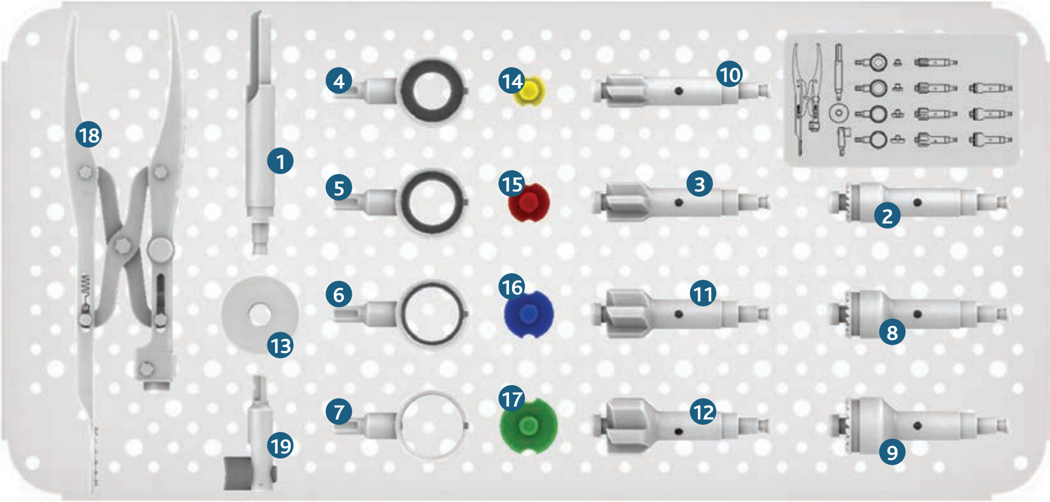
Cemented Patellar Instruments



Item	Part No.	Description	Qty
1	290160	Cemented Patellar Trial 23mm	1
2	290161	Cemented Patellar Trial 26mm	1
3	290162	Cemented Patellar Trial 30mm	1
4	290163	Cemented Patellar Trial 34mm	1
5	290164	Cemented Patellar Trial 38mm	1
6	290165	Cemented Patellar Trial 42mm	1
7	290180	Cemented Patellar Peg Drill	1
8	290181	Cemented Patellar Peg Drill Guide	1
9	290182	Cemented Patellar Clamp	1
10	290183	Cemented Patellar Feeler Arm, Small	1
11	290191	Cemented Patellar Feeler Arm, Large	1
12	290184	Cemented Patellar Compressor	1
13	290192	Cemented Patellar Compressor Attachment, Small	1
14	290193	Cemented Patellar Compressor Attachment, Large	1
15	290185	Cemented Patellar Inset Drill Guide	1
16	290186	Cemented Patellar Inset Drill Guide Threaded Collar	1
17	290187	Cemented Patellar Inset Peg Drill Guide	1
18	290188	Cemented Patellar Inset Drill 23mm	1
19	290189	Cemented Patellar Inset Drill 26mm	1
20	290190	Cemented Patellar Inset Drill 30mm	1

Tray 10

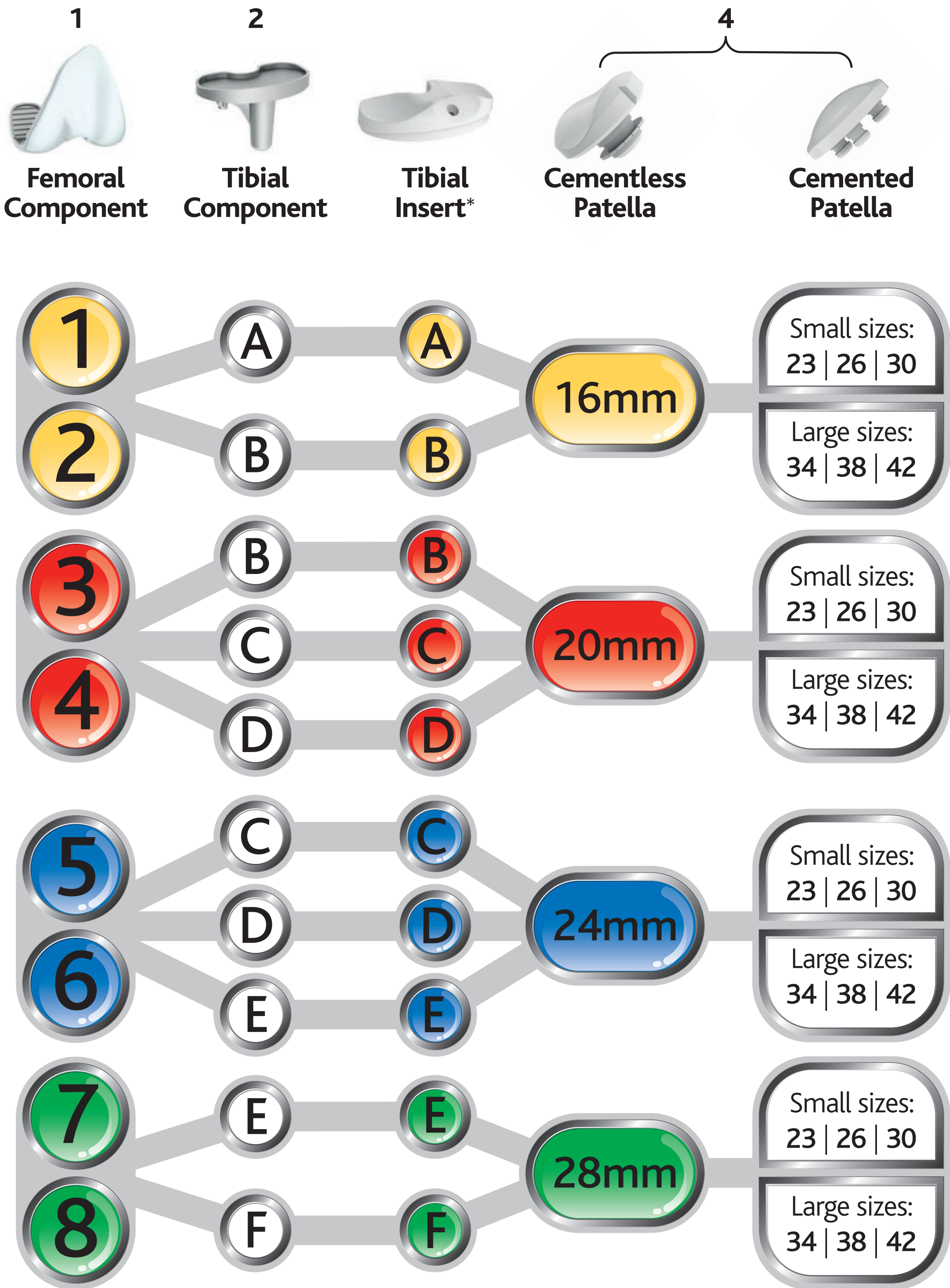
Cementless Patellar Instruments



Item	Part No.	Description	Qty
1	256430	Cementless Patellar Drill	1
2	256431	Cementless Patellar Ring Cutter 20mm	1
3	256433	Cementless Patellar Milling Cutter 20mm	1
4	290000	Cementless Patellar Collar Yellow 16mm	1
5	290001	Cementless Patellar Collar Red 20mm	1
6	290002	Cementless Patellar Collar Blue 24mm	1
7	290003	Cementless Patellar Collar Green 28mm	1
8	290012	Cementless Patellar Ring Cutter 24mm	1
9	290013	Cementless Patellar Ring Cutter 28mm	1
10	290020	Cementless Patellar Milling Cutter 16mm	1
11	290022	Cementless Patellar Milling Cutter 24mm	1
12	290023	Cementless Patellar Milling Cutter 28mm	1
13	290030	Cementless Patellar Peg Drill Guide	1
14	290050	Cementless Patellar Trial Yellow, 16mm	1
15	290051	Cementless Patellar Trial Red, 20mm	1
16	290052	Cementless Patellar Trial Blue, 24mm	1
17	290053	Cementless Patellar Trial Green, 28mm	1
18	290200	Patellar Clamp	1
19	290202	Patellar Compressor	1

Size compatibility chart

Primary size should be taken from the femur measurement (Step 11, page 11).



**18/20mm optional*

Notes

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