Surgical technique
Ligament balancing approach

Think isometry Feel balance
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical philosophy</td>
<td>4</td>
</tr>
<tr>
<td>Pre-operative assessment</td>
<td>5</td>
</tr>
<tr>
<td>Operative technique</td>
<td>6</td>
</tr>
<tr>
<td>1. Approach</td>
<td>6</td>
</tr>
<tr>
<td>2. Initial tibial preparation</td>
<td>6</td>
</tr>
<tr>
<td>3. Tibial resection</td>
<td>8</td>
</tr>
<tr>
<td>4. Initial femoral preparation</td>
<td>9</td>
</tr>
<tr>
<td>5. Varus/valgus alignment</td>
<td>9</td>
</tr>
<tr>
<td>Option A Anatomic alignment technique</td>
<td>10</td>
</tr>
<tr>
<td>6a. Distal femoral resection</td>
<td>10</td>
</tr>
<tr>
<td>7a. Soft tissue balance and final femoral resection</td>
<td>11</td>
</tr>
<tr>
<td>Option B Mechanical alignment</td>
<td>13</td>
</tr>
<tr>
<td>6b Distal femoral resection</td>
<td>13</td>
</tr>
<tr>
<td>7b Soft tissue balance</td>
<td>14</td>
</tr>
<tr>
<td>8. Extension gap confirmation</td>
<td>15</td>
</tr>
<tr>
<td>9. Rotational alignment and femoral sizing</td>
<td>15</td>
</tr>
<tr>
<td>10. Flexion gap confirmation</td>
<td>17</td>
</tr>
<tr>
<td>11. Flexion-extension gap balance</td>
<td>18</td>
</tr>
<tr>
<td>12. 4-in-1 femoral resection</td>
<td>19</td>
</tr>
<tr>
<td>13. Initial femoral trial</td>
<td>20</td>
</tr>
<tr>
<td>14. Final tibial preparation</td>
<td>22</td>
</tr>
<tr>
<td>15. Final femoral preparation</td>
<td>23</td>
</tr>
<tr>
<td>16. Patella resection</td>
<td>23</td>
</tr>
<tr>
<td>17. Patella sizing</td>
<td>24</td>
</tr>
<tr>
<td>18. Patella drill</td>
<td>24</td>
</tr>
<tr>
<td>19. Patella trial</td>
<td>24</td>
</tr>
<tr>
<td>20. Trial reduction</td>
<td>24</td>
</tr>
<tr>
<td>21. Insertion of definitive implants</td>
<td>25</td>
</tr>
<tr>
<td>Ordering information</td>
<td>26</td>
</tr>
<tr>
<td>Sizing guide</td>
<td>29</td>
</tr>
<tr>
<td>Unity Knee™ femoral sizing chart</td>
<td>30</td>
</tr>
<tr>
<td>Indications</td>
<td>30</td>
</tr>
<tr>
<td>Contraindications</td>
<td>30</td>
</tr>
<tr>
<td>Device description</td>
<td>31</td>
</tr>
<tr>
<td>Notes</td>
<td>31</td>
</tr>
</tbody>
</table>

Corin would like to thank Professor J Bellemans, Dr S Kreuzer, Dr T Paszicsnyek, Mr A Toms, Professor J Victor and Professor R Wittenberg for their contribution to this surgical technique.
Surgical philosophy

Modern research has shown that function of the soft tissue envelope goes beyond structural and mechanical support, playing an important proprioceptive role in maintaining knee joint stability and minimising sense of pain post knee arthroplasty\(^1\). In addition, several studies have demonstrated that anatomic landmarks, particularly in defining rotation, have a large inter- as well as intra-observer variability, making it difficult to ensure an accurate alignment confirmation intra-operatively\(^2\).

To avoid sensory disturbances that occur due to ligament releases during total knee surgery, and to minimise the effect of inaccuracy in identification of anatomic landmarks, the Unity Knee™ implant design, combined with EquiBalance™ instrumentation, is designed to facilitate ligament balancing and MCL isometry throughout range of motion.

The EquiBalance™ instrument platform is designed to allow intra-operative confirmation of medio-lateral and flexion-extension soft tissue balance, as well as correction of both distal and posterior femoral resections, to facilitate soft tissue balance without the need to make ligamentous releases.

Recent publications on native knee alignment have demonstrated that over 32% of men and 17% of women have a natural alignment of 3° varus or more with their joint-line remaining parallel to the ground\(^3,4\). Leaving these patients in mild varus significantly improved their functional and clinical outcomes compared with those patients restored to neutral alignment\(^5\). Restoring these patients to neutral mechanical alignment may be unnatural leading to reduced patient satisfaction\(^3\).

Therefore, in addition to neutral mechanical alignment, EquiBalance™ offers one of the first comprehensive balancer systems designed to accommodate anatomic alignment principles, whilst maintaining neutral tibial resection, with the aim to avoid long-term issues noted with varus tibiae\(^3,6\). The EquiBalance™ Extension Balancer allows up to 3° alignment correction in extension, thereby facilitating anatomic alignment for patients who are in natural or constitutional varus/valgus.

Important: The Unity EquiBalance™ platform does not eliminate need for soft tissue release in severe varus/valgus and fixed flexion deformities. It is the responsibility of the surgeon to correct post-arthritis deformities during surgery. The aim of the EquiBalance™ platform is to provide an intra-operative adjustment tool to fine-tune alignment in both extension and flexion so as to suit individual patient anatomy.
Pre-operative assessment

Pre-operative long leg standing radiographs are recommended to determine both the mechanical and anatomical axes of the limb. It is generally recognised that in order to achieve mechanical alignment (HKA angle = 180°) the joint is reconstructed with a standing knee valgus of between 5° and 9°, and the tibial component at 90° to the anatomic axis in the coronal plane. Recent anatomic studies have demonstrated that approximately 30% of the human population are in constitutional varus\(^3\). In order to restore anatomic alignment in these patients, the Unity Knee™ instrument platform allows valgus adjustments between 2° and 8° (±3° from mechanical alignment). Please refer to Option A for anatomic alignment technique.

Radiographic templates can also be used to get an indication of the probable implant size and to determine whether additional bone support is required in the form of bone grafts. A lateral template should be used to give an indication of femoral sizing. The A-P size is critical to the restoration of normal knee kinematics and quadriceps function. The A-P template can be overlaid on the A-P radiograph to check adequate coverage of the medial and lateral condyles and the probable size of the femoral prosthesis.

It is important that a 1.27mm saw blade is utilised with this system, as the use of thinner blades will compromise the accuracy of the cuts.

Note: The minimum recommended thickness of insert is the 9mm tibial bearing which has a minimum thickness of 6mm in the load bearing area as per BS EN ISO 21536:2009.
1. Approach

A standard medial parapatellar approach can be used in the majority of cases. Prepare and drape the limb to allow the centre of the ankle and hip to be palpated during the course of the procedure as this may be necessary when using EM alignment instrumentation. A thigh tourniquet may be used but is not mandatory. Dissect soft tissues until the quadriceps and patella tendon are clearly exposed. Dislocate or evert the patella for complete exposure of the joint.

2. Initial tibial preparation

With the knee in 90° of flexion or more, the ankle clamp arms of the EM tibial alignment guide are opened and placed around the ankle. The ankle clamp can be locked into an open position for ease of placement and released by depressing the quick release button. Flexion-extension axis is considered to be correct when the long axis of the assembly is parallel to the mid-coronal plane of the tibia. At this setting a 3° slope is built into the tibial cutting block. To adjust the tibial slope further, the EM guide can be shifted on the AP arm of the ankle clamp by using the cam lock lever. For varus/valgus alignment the medial/lateral offset can be adjusted by depressing the ML button and shifting the assembly until the shaft is pointing towards the medial third of the tibial tuberosity.
Usually if the foot is in neutral at this position, the anterior tongue of the ankle clamp points to the centre of the ankle joint which is generally in line with the second metatarsal.

Once the flexion-extension and varus/valgus settings are achieved, the first proximal spike is tapped into the tibial spine to provide varus/valgus and anterior/posterior stability, whilst still allowing rotational correction of the jig. The left or right tibial resection block is located against the tibial plateau by adjusting the AP button on the proximal tibial spike arm. Once the rotational alignment is confirmed, the second spike is engaged to lock in the correct position of the tibial jig. The EM tibial jig has both macro and micro adjustment features to allow for accurate resection depth. The micro-adjustment feature operates at 1mm increments allowing for small adjustments to tibial resection levels.

Note: The EM tibial spike is modular and can be removed should the surgeon want to use the guide without the spike. See Figure A and B (page 6 and 7)

An adjustable stylus is also provided which allows resection levels from 2-10mm depending on whether the reference point is the most worn or least worn condyle. This stylus is positioned into the superior hole on the tibial resection block and the tip of the stylus allowed to rest in the deepest point of the tibial plateau. Once the position of the tibial cutting block and the resection level are confirmed, the cutting block is fixed into position.

Note: The minimum polyethylene and tibial tray combined thickness of the Unity Knee is 9mm.
3. Tibial resection

The tibial resection block is pinned to the proximal tibia with two collarless pins located in ‘0’ holes positioned along the same line. This will allow for resection level adjustment if necessary. As an additional check, the EM reference guide can be placed within the distal holes of the tibial block and EM alignment rod to verify alignment.

Once the tibial alignment checks are complete, collared pins are inserted into the angled holes to secure the guide in place for the saw cut. The angel wing can be used to assess the tibial resection depth and slope.

The tibia is now resected through the tibial guide slot.

**Note:** Should the surgeon prefer to use non-slotted resection, the proximal surface of the tibial block allows 3mm less resection.

⚠️ When using a Cruciate Retaining (CR) prosthesis it is recommended that the EM tibial guide arm is adjusted to maintain an anatomic posterior tibial slope. When using a Posterior Stabilised (PS) prosthesis, a 3° tibial slope can be maintained by ensuring the tibial guide arm is parallel to the tibial shaft in the sagittal plane.

The resected tibia should be checked to confirm that the cut is flat and that an accurate posterior slope has been achieved. If the surgeon chooses to retain the posterior cruciate ligament, care should be taken when resecting the proximal tibia to preserve the PCL attachment.
4. Initial femoral preparation
The IM canal drill is used to penetrate the cortex of the distal femur. This drill includes a sharp proximal tip for improved accuracy of femoral canal alignment. The correct entry point is in line with the medullary canal, medial to the mid point between the distal condyles and 10mm anterior to the origin of the posterior cruciate ligament.
The IM rod is assembled with the T-handle by pulling the locking collar towards the handle. The assembly is then pushed into the canal only as far as the fluted section. The T-handle is removed.

5. Varus/valgus alignment
The valgus angle to be created to achieve mechanical alignment is determined from pre-operative templating. The femoral distal alignment jig has varus/valgus settings from 0-9°. The appropriate varus/valgus setting is chosen, and the IM femoral jig is locked to the IM rod using the cam lock.

⚠️ To ensure medial joint-line preservation, it is recommended that any bone loss be taken into account with adjustments in resection depth prior to locking the distal block in situ.

*Should the surgeon want to follow Anatomical alignment principles please see Option A.*
*If the surgeon would prefer to restore mechanical alignment please see Option B.*
Option A Anatomic alignment technique

The distal femoral alignment jig is completely removed by rotating the locking knob to the ‘unlocked’ setting and pulling the resection depth adjustment drum assembly anteriorly.

To confirm IM alignment, the EM alignment guide and rods can be used connecting to the distal holes of the distal femoral resection block.

Once the surgeon is satisfied with the position and orientation of the distal resection block, collared pins can be used in the angled holes to secure the block and distal resection can be conducted to make a 5mm pre-cut on the distal femur.

6a. Distal femoral resection

The distal femoral resection block attaches to the distal femoral alignment jig via the resection depth adjustment drum. For a standard distal femoral resection the drum should be set at ‘-4’, which equates to a 5mm pre-cut on the distal femur. Once the varus/valgus setting and depth of resection is confirmed, the distal femoral alignment jig is slid onto the IM rod until the distal plate rests against one or both distal femoral condyles. The distal resection block assembly can then be adjusted in an AP direction so that the resection block rests against the anterior femoral cortex.

Once the varus/valgus setting and resection depth are confirmed, the distal femoral cutting block can be pinned onto the anterior cortex of the femur with two collarless pins in the ‘0’ hole position.
7a. Soft tissue balance and final femoral resection

Once both distal femoral (pre-cut) and tibial resections are completed, assemble the EquiBalance™ ligament tensioner with the tensioner extension paddle and the EquiBalance™ extension balancer and insert within the joint.

**Note:** To better stabilise the extension balancer, use collared pins in the angled fixation holes.

Squeeze the handles of the tensioner to achieve adequate tension between the paddle and the extension balancer feet; check angular reading on the extension balancer.

⚠️ Avoid over-tensioning the device. If the reading is in extreme varus/valgus, it may be due to over-tensioning. In this case release the tension and repeat.

---

**Scenario 1. If the reading displays 0°:**

If the reading on the extension balancer is at 0° the mediolateral gaps are balanced. In this case re-pin the extension balancer at the 0° setting using two non-collared pins. Remove the EquiBalance™ tensioner and extension balancer, re-insert the distal femoral cutting block onto the two non-collared pins at the 0 setting of the cutting block and resect an additional 4mm of distal femur. This will allow for 9mm of distal femoral resection from the native medial condyle which equates to the thickness of the femoral component. The pre-determined (Step 6a) valgus angulation will be maintained.
Scenario 2. If the reading displays 1-3°:
If the extension balancer reading is between 1-3°, this implies that the mediolateral gaps are not balanced. In this case, two non-collared pins should be used to pin the extension attachment at the holes corresponding to the amount of imbalance, e.g. 3° holes for a 3° imbalance.

Remove the tensioner and extension balancer, re-insert the distal femoral cutting block onto the two non-collared pins at 0 and resect an additional 4mm of distal femur. This will adjust the varus/valgus angle (within a ±3° envelope depending on the amount of imbalance) to allow for a balanced mediolateral gap, whilst removing a total of 9mm distal femoral resection from the native medial condyle, which equates to the thickness of the femoral component.

Scenario 3. If the reading displays >±3° of medio-lateral imbalance:
Soft tissue releases may be required to reduce this imbalance to within ±3° prior to following the above steps for anatomic alignment. This is to ensure that the overall patient alignment in extension does not deviate more than ±3° from mechanical alignment.

⚠️ For a PS knee, if posterior releases are made after 4-in-1 resection, this may affect the alignment and balance in extension, therefore the mechanical alignment technique should be followed in this case. Alternatively, posterior capsular releases should be made prior to extension alignment confirmation and correction.
Option B Mechanical alignment

6b Distal femoral resection
The distal femoral resection block attaches to the distal femoral alignment jig via the resection depth adjustment drum. For a standard distal femoral resection the drum should be set at ‘0’, which equates to the thickness of the femoral implant (9mm). Once the varus/valgus setting and depth of resection is confirmed, the distal femoral alignment jig is slid onto the IM rod until the distal plate rests against one or both distal femoral condyles. The distal resection block assembly is shifted in an AP direction so that the resection block rests against the anterior femoral cortex.

Once the varus/valgus setting and resection depth are confirmed, the distal femoral cutting block can be pinned onto the anterior cortex of the femur with two collarless pins in the ‘0’ hole position. The distal femoral alignment jig is completely removed by rotating the locking knob to the ‘unlocked’ setting and pulling the resection depth adjustment drum assembly anteriorly, disengaging the distal femoral alignment jig from the distal femoral block. The T-handle can then be used to remove the distal femoral alignment jig and the IM rod.
7b Soft tissue balance

Once both distal femoral and tibial resection are completed, assemble the EquiBalance™ ligament tensioner with the tensioner extension paddle and the extension balancer and insert within the joint.

Note: To better stabilise the extension balancer, use collared pins in the angled fixation holes.

Squeeze the handles of the tensioner to achieve adequate tension between the paddle and the extension balancer feet; check angular reading on the extension balancer. If the reading on the extension balancer is at ‘0’ the mediolateral gaps are balanced.

Avoid over-tensioning the device. If the reading is in extreme varus/valgus, it may be due to over-tensioning. In this case release the tension and repeat.

Note: If the reading is not on ‘0’ appropriate ligament releases are required to ensure mediolateral gap balance.

Gap space reading should be a minimum of 18mm (9mm tibial resection +9mm distal resection)
8. Extension gap confirmation

The final mediolateral balance and extension gap space can be confirmed using the EquiBalance™ extension balancer and the graduations on the tensioner. A minimum gap of 18mm (9mm tibial resection plus 9mm distal femoral resection) should be achieved. If the gap space is less than 18mm additional resection can be made after flexion gap confirmation so as to determine whether further tibial or distal resection is necessary.

9. Rotational alignment and femoral sizing

The Unity Knee™ femoral sizer together with the EquiBalance™ tensioner allows for rotational alignment in flexion via the proximal angular settings. The femoral sizer also allows femoral sizing in conjunction with the femoral stylus.

⚠️ Unity Knee™ is a posterior referencing system allowing for 9mm bone resection from the medial posterior femoral condyles at all angular settings in the sizer. This facilitates preservation of the natural joint-line and providing medial collateral isometry post surgery.
Femoral external rotation angles are set relative to the medial posterior condyle using the femoral sizer, set at unlocked position, in conjunction with the tensioner. As the tensioner is compressed, the femoral sizer dial will find its most appropriate rotation angle to give a balanced mediolateral flexion gap.

⚠️ In instances of severe posterior condylar wear and/or hypoplasia, care should be taken when determining femoral rotation. The 1mm and 2mm femoral shims should be used to adjust for deformities and accommodate restoration of the natural joint-line.

The rotation angle identified should be checked against the surgical transepicondylar axis using the ML width-checker/alignment guide to avoid any large deviations from the patient’s natural functional (flexion) axis, as this may occur in instances of severe deformities and soft tissue contracture. In the latter case, soft tissue releases should be made to correct deformities.

Note: Should the surgeon wish to stabilise the sizer prior to femoral sizing, two collared pins can be used through the distal drill holes, instead of the drill, after rotation has been set to stabilise the jig against the distal femoral bone.

To size the femur, the femoral stylus clicks into the medial hole of the femoral sizer and provides an indication of optimal femoral size for the patient. It is recommended that the femoral stylus be positioned so that it contacts the lateral ridge of the anterior cortex where the anterior flange ends.

⚠️ It is essential that the stylus is connected to the medial hole of the femoral sizer as connection to the lateral hole will give an incorrect size reading.

Gap space reading should be a minimum of 9mm based on tibial resection.
If the femoral sizer was not stabilised with collared pins during sizing, once the optimal rotational alignment has been confirmed and the femoral size determined, the 4-in-1 peg drill can be used instead to drill two holes in the distal femur for the 4-in-1 cutting blocks.

**Note:** As Unity Knee™ is a posterior and medial referencing system, the position of the 4-in-1 peg holes are only dependent on the rotational angle chosen and not the femoral size. Therefore the femoral sizing can be determined after positioning of the 4-in-1 peg holes.

⚠️ Avoid over-tensioning the device. If the reading is in extreme external rotation, it may be due to over-tensioning. In this case release the tension, repeat and perform further checks against the transepicondylar axis so as to not vary from the patients anatomy.

10. Flexion gap confirmation

The final flexion gap space can be confirmed using the graduations on the EquiBalance™ tensioner. A minimum gap of 9mm (9mm tibial resection) should be achieved. If the gap space is less than 9mm checks should be made to determine any soft tissue contracture and/or whether the initial tibial/distal femoral cuts have removed adequate bone. It may be that soft tissue releases, additional posterior tibial slope and/or additional tibial resection is required to bring the flexion gap space to 9mm.
11. Flexion-extension gap balance

Both flexion and extension gap spaces can now be compared to confirm the gaps are balanced at this stage.

⚠️ As the distal femoral resection has been completed but the posterior femoral resection has not been completed, an 18mm extension joint space will be equal to a 9mm flexion joint space i.e. extension joint space – 9mm = flexion joint space (= 9mm minimum)

In instances where the flexion-extension gaps are not balanced, the following may be necessary to consider to allow for a balanced knee joint:

1. Tight extension gap: Soft tissue releases and/or additional distal resection to accommodate the appropriate size of tibial insert.

2. Tight flexion gap: Soft tissue releases, additional posterior tibial slope and/or further osteophyte removal to accommodate the appropriate size of tibial insert.

The 4-in-1 cutting block height adjustment button may also be used in this instance to balance the flexion/extension gaps.

⚠️ Caution should be taken when using this technique as it will result in a shift of posterior femoral joint-line.

When the knee is balanced to the surgeon's satisfaction, the final femoral and tibial preparation is conducted. An EM alignment check hole is included in the EquiBalance™ tensioner for a secondary alignment confirmation.
12. 4-in-1 femoral resection

The appropriate size 4-in-1 femoral cutting block is positioned onto the distal femur using the 4-in-1 block impactor. The angel wing can be used at this point to confirm anterior and posterior resection levels. In instances where further stability of the 4-in-1 block is required, collared pins can be used to secure the block in situ. The angel wing can also be used to confirm depth of resection.

⚠️ A posterior referencing philosophy is recommended to confirm preservation of posterior condylar offset. For this it is crucial that the 4-in-1 block button is maintained at the '0' setting as this will result in a consistent 9mm posterior bone resection from the posterior medial femoral condyle. Shifting the button to the '+1' or '+2' setting results in a 1 or 2mm anterior shift of the flexion joint-line, whilst shifting the button to the '-1' or '-2' setting will result in a 1 or 2mm posterior shift of the flexion joint-line.

The femoral cuts are now performed through the 4-in-1 block slots in the following order:
1. Anterior/posterior femoral resection
2. Anterior chamfer
3. Posterior chamfer

At this stage it may be necessary to clear behind the posterior condyles, especially in larger knees, to remove any condyle bone remnants or osteophytes which could restrict flexion.
13. Initial femoral trial

Unity Knee™ incorporates modular femoral trials to allow the surgeon to easily move from a CR to a PS knee without the need for additional instrument boxes. Modular CR and PS attachments connect to a universal trial body to allow intra-operative flexibility.

In instances where the posterior cruciate ligament is retained, the CR femoral trial is assembled and impacted onto the resected femur to confirm femoral component positioning. The dedicated femoral introducer should be used for accurate positioning of the femoral trial.

Note: A trial reduction can be conducted at this point with the tibial template and inserted in situ to determine optimal alignment. In a CR knee replacement, mediolateral positioning need not be fixed until after trial reduction.

Assembly

push here to lock

Monoblock femoral trials also available see I1136 for technique

Note: If the femoral size reading is in between the recommended Unity Knee™ sizes, the preference should be to down-size the component to avoid over-stuffing the patella-femoral joint. The Unity Knee™ femur includes a 7° anterior flange which is intended to reduce the risk of notching when downsizing.

Should there be any concerns on sizing once the smaller 4-in-1 block is in position, the top surface (non-slotted) of the block will allow for the same anterior cut as a size above – e.g. the top surface of a size 4 cutting block creates the same anterior cut as a size 5 cutting block. This allows the surgeon to verify if the larger size is the better option and change the cutting block prior to resecting through the slots of a smaller block.

Top surface = anterior cut of size above
When using a PS knee, the femoral chain drill guide is assembled with the box resection guide and the femoral trial once the latter has been positioned in situ. The assembly should be pinned in place with collared pins using the anterior pin holes on the femoral trial to stabilise the assembly during the box resection step. The chain drill should be used first. The drill guide should then be disconnected from the box resection guide and the box chisel used to clear any final remnants of bone around the PS box, taking care to ensure the PS femoral attachment is seated fully against the resected femur.

⚠️ The femoral trial assembly should be pinned in place prior to box resection to enable accurate bone resection.

⚠️ The most lateral and distal pin holes should be used if possible to pin the trial assembly.

⚠️ Confirm the PS box cut guide is assembled in the correct orientation and fully seated against the femoral trial.

Once the PS box resection has been completed, the PS box resection guide is removed and the modular PS trial attachment is connected to the femoral trial to confirm femoral component seating.

A monobloc PS box resection saw guide is also available on request should the surgeon wish to adopt this approach. In this case the mediolateral wings on the guide allow centralisation of the guide to accommodate accurate box resection.
14. Final tibial preparation

The tibial template which conforms optimally to the resected proximal tibia should be chosen and assembled with the tibial template handle.

**Note:** Unity Knee™ allows for 1 up, 1 down sizing across its range – e.g. for a size 4 femur, sizes 3, 4 or 5 tibial trays may be used. However, the tibial insert must be specific to the size of the tibial tray chosen.

Alignment of the tibial template assembly is made by placing it so that the central handle is aligned with the medial third of the tibial tuberosity. Using the EM rod, an extramedullary alignment check may be made ensuring that the rod is parallel to the long axis of the tibia.

The tibial template is secured in place using two collared pins. The anterior pin holes on the tibial template can be used to secure the template should the surgeon wish to do so whilst the trial insert is in situ.

The tibial keel punch guide is assembled onto the secured tibial template and tibial stem drill used to create the initial tibial stem hole. The tibial keel punch should be used next for accurate bone removal.

Should the surgeon wish to finalise tibial rotation after trial positioning, a tibial keel plug is available which allows rotational adjustment of the template during trial.

The keel punch handle is then disassembled from the tibial keel punch and the latter left in situ with the tibial template as the tibial tray trial.
15. Final femoral preparation
The CR or PS trial femur of appropriate size and trial tibial insert of appropriate size (corresponding to the tibial template size) and thickness are inserted into the joint and trial reduction is conducted.
In instances where the CR femur and insert are being used, the mediolateral position of the femoral implant can be confirmed at this stage and the peg drill used to drill through the two holes in the condyles of the CR femoral trial.
⚠️ In instances where the PS implant is being used femoral holes do not need to be drilled as the PS femoral implant does not have pegs.

16. Patella resection
The patella should be firmly grasped with the patella resection guide and the instrument locked in position. The patella depth gauge measures the thickness of patella retained. It is recommended that a minimum of 12mm of bony patella be preserved to facilitate sufficient peg fixation.
Patella callipers have also been provided to confirm thickness of the natural patella and resected patella surfaces.
The patella is resected via the slot in the patella resection guide taking care not to damage the femoral and patella ligaments.

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17. Patella sizing
To size the patella, peg drill guides are placed on the resected surface and the appropriate size chosen.

**Note:** The peg locations in the dome patellas and offset dome patellas have been designed to allow for fine tuning of patella size and type based on thickness and improved patella tracking. Please see table above for size compatibility between the two patella types.

18. Patella drill
Once the correct peg drill guide has been chosen, it is inserted into the drill guide handle and placed on the patella in the orientation shown. The patella drill is then passed through each hole.

19. Patella trial
Remove the patella peg drill guide and place the appropriate trial patella 3-peg dome or 3-peg offset/asymmetric dome patella trial onto the bony surface.

20. Trial reduction
A trial reduction in flexion and extension is performed to confirm that correct balancing of the knee joint has been achieved.
The CR tibial insert trials include a modular PS post which should be clicked into place prior to introducing into the joint space. A post removal tool has been provided to support disassembly after surgery.

21. Insertion of definitive implants
Remove all trial components from each of the bones and prepare the bony surfaces for cement. Insert the definitive femoral and tibial tray components. The trial tibial insert should be used to pressurise the cement prior to insertion of the definitive tibial insert. The tibial insert impactor should be used to impact the tibial insert at an approximate 70° angle onto the tibial tray, ensuring secure engagement of the tibial insert.

Note: Particular attention should be paid to clearing cement posteriorly from both the tibia and femur, in the intercondylar area of the femur, and around the patella implant.

To cement the patella, pressure can be applied using the patella pressurisation clamp.

⚠ Care should be taken when handling the definitive implants and all polished surfaces should be protected.

The wound is closed according to the surgeon’s usual practice.
### Ordering information

**Femoral component CR Left**
- 112.001.02  Size 1*
- 112.001.04  Size 2*
- 112.001.06  Size 3
- 112.001.08  Size 4
- 112.001.10  Size 5
- 112.001.12  Size 6
- 112.001.14  Size 7
- 112.001.16  Size 8
- 112.001.18  Size 9

**Femoral component CR Right**
- 112.001.22  Size 1*
- 112.001.24  Size 2*
- 112.001.26  Size 3
- 112.001.28  Size 4
- 112.001.30  Size 5
- 112.001.32  Size 6
- 112.001.34  Size 7
- 112.001.36  Size 8
- 112.001.38  Size 9

**Femoral component PS Left**
- 112.001.42  Size 1*
- 112.001.44  Size 2*
- 112.001.46  Size 3
- 112.001.48  Size 4
- 112.001.50  Size 5
- 112.001.52  Size 6
- 112.001.54  Size 7
- 112.001.56  Size 8
- 112.001.58  Size 9

**Femoral component PS Right**
- 112.001.62  Size 1*
- 112.001.64  Size 2*
- 112.001.66  Size 3
- 112.001.68  Size 4
- 112.001.70  Size 5
- 112.001.72  Size 6
- 112.001.74  Size 7
- 112.001.76  Size 8
- 112.001.78  Size 9

**Tibial component**
- 112.040.02  Size 1*
- 112.040.04  Size 2*
- 112.040.06  Size 3
- 112.040.08  Size 4
- 112.040.10  Size 5
- 112.040.12  Size 6
- 112.040.14  Size 7
- 112.040.16  Size 8
- 112.040.18  Size 9

**Tibial insert CR size 2**
- 112.014.22  9mm thickness
- 112.014.23  10mm thickness
- 112.014.24  11mm thickness
- 112.014.25  12mm thickness
- 112.014.26  14mm thickness
- 112.014.27  16mm thickness
- 112.014.28  18mm thickness
- 112.014.29  20mm thickness

**Tibial insert CR size 3**
- 112.014.42  9mm thickness
- 112.014.43  10mm thickness
- 112.014.44  11mm thickness
- 112.014.45  12mm thickness
- 112.014.46  14mm thickness
- 112.014.47  16mm thickness
- 112.014.48  18mm thickness
- 112.014.49  20mm thickness

**Tibial insert CR size 4**
- 112.014.62  9mm thickness
- 112.014.63  10mm thickness
- 112.014.64  11mm thickness
- 112.014.65  12mm thickness
- 112.014.66  14mm thickness
- 112.014.67  16mm thickness
- 112.014.68  18mm thickness
- 112.014.69  20mm thickness

*Not currently available*
Tibial insert CR size 5
112.014.82 9mm thickness
112.014.83 10mm thickness
112.014.84 11mm thickness
112.014.85 12mm thickness
112.014.86 14mm thickness
112.014.87 16mm thickness
112.014.88 18mm thickness
112.014.89 20mm thickness

Tibial insert CR size 8
112.015.42 9mm thickness
112.015.43 10mm thickness
112.015.44 11mm thickness
112.015.45 12mm thickness
112.015.46 14mm thickness
112.015.47 16mm thickness
112.015.48 18mm thickness
112.015.49 20mm thickness

Tibial insert CR size 9
112.015.62 9mm thickness
112.015.63 10mm thickness
112.015.64 11mm thickness
112.015.65 12mm thickness
112.015.66 14mm thickness
112.015.67 16mm thickness
112.015.68 18mm thickness
112.015.69 20mm thickness

Tibial insert PS size 1*
112.016.02 9mm thickness
112.016.03 10mm thickness
112.016.04 11mm thickness
112.016.05 12mm thickness
112.016.06 14mm thickness
112.016.07 16mm thickness
112.016.08 18mm thickness
112.016.09 20mm thickness

Tibial insert PS size 2*
112.016.22 9mm thickness
112.016.23 10mm thickness
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112.016.26 14mm thickness
112.016.27 16mm thickness
112.016.28 18mm thickness
112.016.29 20mm thickness

Tibial insert PS size 3
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112.016.43 10mm thickness
112.016.44 11mm thickness
112.016.45 12mm thickness
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112.016.47 16mm thickness
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112.016.49 20mm thickness

Tibial insert PS size 4
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112.016.63 10mm thickness
112.016.64 11mm thickness
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112.016.67 16mm thickness
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112.016.69 20mm thickness
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<td>112.018.56 Size 4 9.5mm thickness</td>
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Sizing guide

**Micro size range**
- Size 1
- Size 2

**Standard size range**
- Size 3
- Size 4
- Size 5
- Size 6
- Size 7
- Size 8

**Macro size range**
- Size 9

**PS thickness (mm)**
- 9
- 10
- 11
- 12
- 14
- 16
- 18
- 20

**CR thickness (mm)**
- 9
- 10
- 11
- 14
- 16
- 18
- 20

**Patella options**
- Offset dome patella: 8.0mm, 8.5mm, 9.0mm, 9.5mm, n/a
- Centred dome patella: 7.5mm, 8.0mm, 8.5mm, 9.0mm, 9.5mm
Unity Knee™ femoral sizing chart

<table>
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<th>Size</th>
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<th>ML (mm)</th>
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</table>

Whilst it is paramount that both anteroposterior and mediolateral dimensions are optimised for each individual patient, Unity Knee™ incorporates a varying femoral aspect ratio maximising mediolateral coverage and minimising overhang for each femoral size available. This allows the surgeon to optimise femoral size based on the anteroposterior dimension so as to maintain both posterior condylar and patellofemoral offsets.

**Indications**

General total knee arthroplasty indications including:
- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function
- Revision of previous unsuccessful knee replacement or other procedure, where soft tissue stability is adequate
- Fracture of the distal femur and/or proximal tibia that cannot be stabilised by standard fracture management techniques
- The posterior stabilised variant is also indicated for PCL instability requiring implant bearing surface geometries with increased anterior-posterior constraint and absent or non-functioning posterior cruciate ligament

The Unity Knee™ is intended for cemented use, single use only.

**Contraindications**

- Severe instability secondary to advanced loss of osteochondral structure or the absence of collateral ligament integrity
- Infection/distant foci of infections
- Osteomyelitis, osteoporosis, osteomalacia
- Marked bone loss or bone resorption
- Metabolic disorders which may impair bone formation
- Vascular insufficiency
- Muscular atrophy or neuromuscular disease
- Allergy to implant material
- Severe deformity
Device description

Unity Knee™ is a fixed bearing total knee replacement system that consists of a femoral component, tibial insert, tibial tray and all-polyethylene patellar component for use in primary total knee arthroplasty. The Unity Knee™ is provided in two variants, Cruciate Retaining (CR) and Posterior Stabilised (PS). The Unity Knee™ CR variant is intended for use in instances where the Posterior Cruciate Ligament (PCL) is functional. The Unity Knee™ PS variant is utilised when a total knee replacement is indicated and the PCL is non-functioning or absent, resulting in joint instability. The Unity Knee™ patellar component is optional and is used in situations where replacement of the articular surface of the patella is required. The system also provides augment components including femoral augments, tibial augments, stem extensions and offset connections.

Unity Knee™ is intended for use in total knee arthroplasty in skeletally mature patients, to provide increased mobility and reduce pain by replacing the damaged knee joint articulation where there is evidence of sufficient sound bone to seat and support the components.
References:


