Unity Knee™

Difficult primary indications
Surgical technique

Corin
Connected Orthopaedic Insight

Think **isometry** Feel **balance**

Contents

Unity Knee™

Think **isometry** Feel **balance**

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 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.

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.

Instrumentation rationale

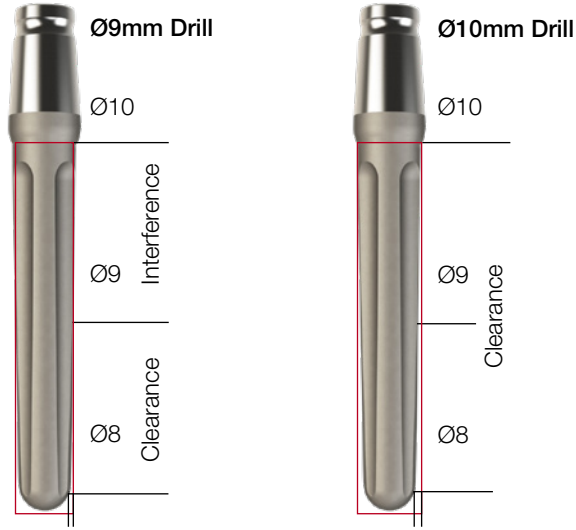
The surgical objective of the Unity Knee™ instrumentation for total knee arthroplasty is to place the prosthetic components in an anatomical and neutral position with respect to the mechanical axis of the knee joint, whilst maintaining stability throughout the full range of knee flexion.

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.

Surgical philosophy

The Unity Knee offers universal stem extensions for use on both the tibia and PS femur in 10 and 14mm diameter and 30, 60 and 100mm length. Both diameter stems are tapered by 2mm from proximal to distal which is demonstrated for the 10mm diameter stem in the image below.



2 x 0.5mm radial clearance = 1mm diametric clearance

2 x 1mm radial clearance = 2mm diametric clearance

Cylindrical drills are available to prepare for stem extension. The drills available for the 10mm diameter stem are the 9 and 10mm diameter and the drills available for the 14mm diameter stem are the 13 and 14mm diameter. The two drill sizes of the two stem diameters allow the surgeon to choose between a slight proximal press fit with distal cement mantle or a cement mantle over the full length of stem. The stem drills available for the 14mm diameter are the 13 and 14mm allowing the same flexibility.

Each drill has 30, 60 and 100mm depth markings for the selected stem extension length.

The table below provides details of the overall length of the stem extension in the sagittal plane when assembled with the PS femur and tibial tray. These measurements are taken from the resected tibial plateau to the tip of the stem extension on the tibia and from the resected distal femoral face to the tip of the stem extension.

	30mm Stem extension	60mm Stem extension	100mm Stem extension
Tibia	53.50mm	83.50mm	123.50mm
Femur	52.37mm	82.26mm	112.11mm

When using a posterior stabilised (PS) prosthesis, a 3° tibial slope should be maintained and if the slope is altered, the surgeon should be mindful of the stem position.

When the stem extension is assembled with the femoral component it will be positioned in 5° valgus in order to match as close as possible the anatomic angle of the femur.

Augments are available in two thicknesses (5 & 10mm) for the distal and posterior femur as well as the proximal tibia. Femoral augments may be used medially or laterally and have been designed to allow a slight ML shift and rotation relative to the femoral implant. The flexibility in femoral augment positioning allows for alignment to the outer, cortical edge of the bone for cortical support.

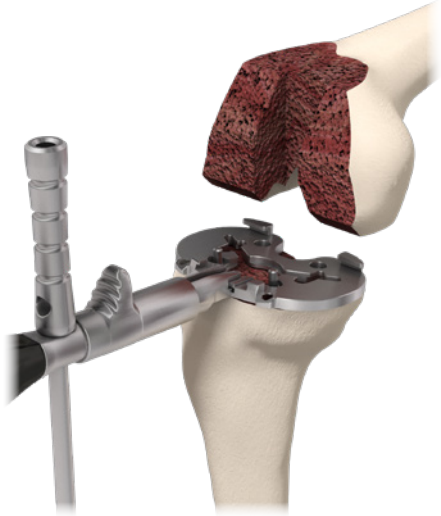
Tibial augments are only available in 5mm thicknesses but may combine with another tibial augment of the next smaller size to create a combined, 10mm augment. For example, a Size 4 tibial tray may be combined with a Size 4 tibial augment stacked with a Size 3 tibial augment.

Tibial augments are specifically identified as Right-Medial/Left-Lateral or Right-Lateral/Left-Medial. The outer profile of the tibial augments has a slight taper to account for the narrowing of the proximal tibial as the resection depth is increased.

Screws are provided with the augments for fixation to the implant. A separate 10mm-length screw must be used when combining two tibial augments into a 10mm construct.

Upon each patient pathology and surgeon necessities, either femur and or tibia can receive stem (several length and diameter available) or augments (5 or 10mm).

(I1136 Surgical Technique should be followed to Step 9)

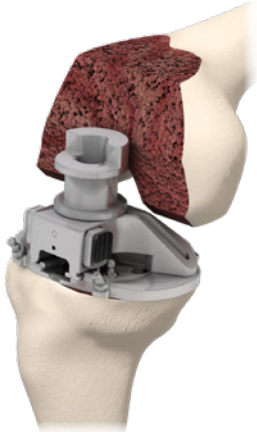


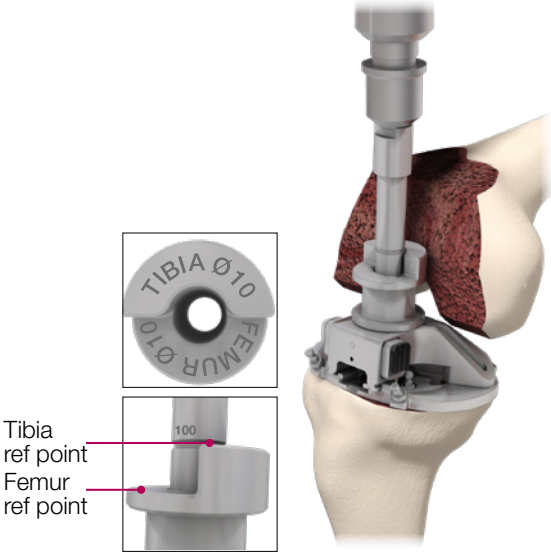
1. Tibial stem preparation

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 one up, one downsizing 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.





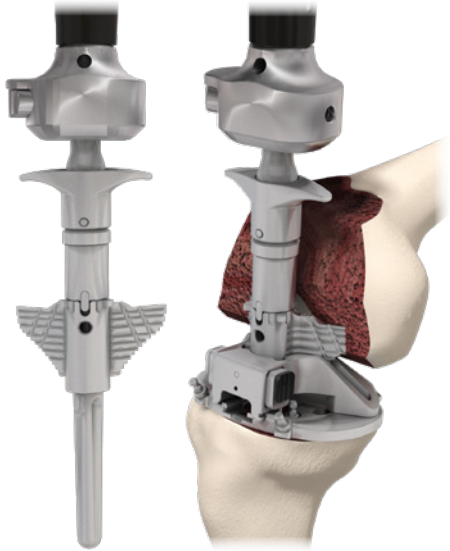
The tibial template is secured in place using two collared pins. The anterior pin holes on the tibial template can be used to secure the template should the surgeon wish to do so whilst the trial insert is *in situ*.

The tibial keel punch guide is assembled onto the secured tibial template. The tibial stem drill should be used conservatively to create the initial stem hole and not to full depth as the 175mm tibial stem plug is removed from the keel punch for stem assembly. The required diameter drill guide is assembled onto the keel punch guide.

The drill guides are used for both tibial and femoral stem preparation. The upper surface marked is used to indicate the drill depth when preparing the tibia and the lower surface marked is used to indicate the drill depth when preparing the femur.

The required diameter stem drill is selected and used to fully prepare for the stem extension. The depth marking on the drill is aligned with the upper surface of the drill guide marked 'tibia' to create the required depth.

The stem drills have depth markings at 30, 60 and 100mm and the required depth is aligned with the upper surface of the drill guide when preparing the tibia.

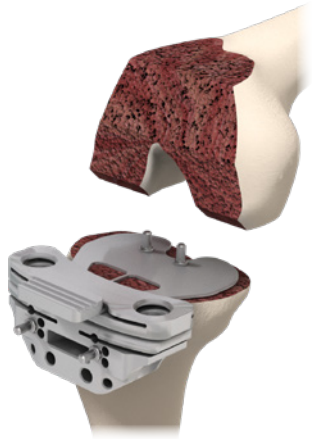


2. Tibial stem trial

The drill guide is removed leaving the keel punch guide assembled with the tibial template. The tibial stem plug is disassembled from the keel punch and the appropriate diameter and stem length tibial trial is assembled via the threaded feature and inserted using the keel punch connector and modular handle.

⚠ Ensure the tibial trial stem engraved with a "T" has been connected and thoroughly hand tightened to the keel punch before inserting.

Note: If the trial stem extension does not sit adequately when impacted, remove the trial assembly and re-drill the correct depth using the drill option one diameter size up before re-trialling. e.g. If the 9mm diameter drill was initially used, re-drill using the 10mm diameter drill.



3. Tibial augment preparation

Preparation for tibial augmentation can be performed with two options. Option one allows the resection to be performed with the tibial augment resection block attached to the standard extra-medullary tibial alignment guide. 5 or 10mm resections can be performed medially or laterally through the slots indicated.

Alternatively, the same cut block may be repositioned on the initial tibial resection surface with the tibial repositioning guide. The guide is designed to match the profile of the smallest Unity tibial component and includes an indicator for the tibial AP axis to help with rotational alignment. The tibial augment cut block is attached to the bone through the holes provided and the necessary 5 or 10mm augment resections are performed.

Additional fixation of the tibial repositioning guide can be achieved by driving collared pins through the posterior holes provided.

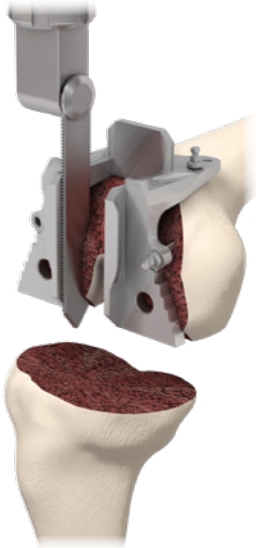
4. Tibial augment trial

After preparation of the tibia for the necessary augments, trial augment components may be attached to the ligament balancer and the tibial templates. The size of the 5mm augments must match the corresponding tibial size and is keyed such that the ML profile will match the tibial trial.

A 10mm augment may be trialed by attaching the next smaller size tibial augment to the distal face of the previous augment. Augments are magnetically secured and have additional markings of RM-LL (right medial – left lateral) or RL-LM (right lateral – left medal) to indicate the correct position on the tibial trial.

Preparation of the tibial stem and keel may be performed as described above with the tibial augment trials in place.

NOTE: Tibial augment trials are color-coded to match the corresponding insert sizes. They have also been designed to attach to the distal face of the tibial paddles and used with the ligament balancer.



5. Femoral stem preparation

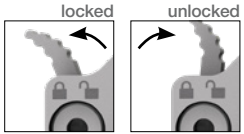
Note: Unity Knee™ difficult primary instrumentation allows the PS box preparation to be conducted before or after confirming and fixing stem positioning. The PS box saw resection guide should not be repositioned once fixing either the box or stem position.

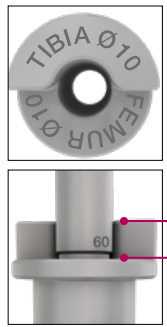
The appropriate sized PS box saw resection guide is selected and positioned onto the resected femur. Utilise the medio-lateral wings to centralise the guide on the distal femur. These medio-lateral wings represent the width of the femur at that position for each size.

When pinning the box resection guide in place, first two short collared pins should be used anteriorly followed by one short collared pin distally to ensure adequate stability of the guide. Femoral box resection is conducted with either a reciprocating or narrow sawblade resting flush against the guide walls.

Note: If the box preparation has been performed using the 'ream and chisel' technique, the PS box saw resection guide should be aligned with the resected box and pinned in place.

The femoral stem size adjustment dial is assembled with the reversible DPI femoral drill guide body for left and right femurs and inserted onto the PS box saw resection guide. The locking cam lever should be moved to the locked position once in place to secure the guide. The required diameter DPI drill guide is selected and assembled to complete the femoral drill guide. The universal spacer can be used to compensate for any distal gap for distal augments.





Tibia ref point

Femur ref point

The reversible femoral drill guide is used for left and right femurs and confirms the correct medio-lateral positioning of the stem. It is crucial the bushing is inserted in the correct orientation so as the proximal surface displays the correct limb e.g for a right knee the bushing will read 'RIGHT' with the arrow pointing to the anterior femur.

The size adjustment dial is set and locked to the appropriate femoral size to confirm anterior-posterior stem position.

Ensure the size adjustment dial is aligned on the correct femoral size.

The required diameter drill is selected and used to fully prepare for the stem extension. The depth marking on the drill is aligned with the lower surface of the drill guide marked 'femur' to create the required depth.

The stem drills have depth markings at 30, 60 and 100mm and the required depth is aligned with the lower surface of the drill guide when preparing the femur.

6. Femoral stem trial

Unity Knee™ incorporates both A) modular and B) monoblock femoral trials.

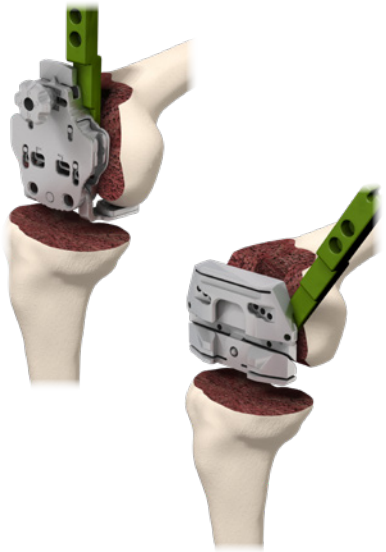
Note: When assembling the trial stem with the modular PS femoral component, it is recommended to attach the stem to the PS attachment first before assembling the attachment to the trial body.

The appropriate diameter and stem length femoral trial engraved with an “F” is assembled via the threaded feature with the appropriate size PS femoral component.

Ensure the trial stem has been thoroughly hand tightened to the femoral trial before inserting.

7. Distal femoral augment preparation

The distal femoral augment cutting block has been designed to attach to the current femoral valgus guide. If the need for a distal femoral augment is anticipated at this stage of the operation, the 5 or 10mm cutting slot should be used to guide the preparation of the bone. Alternatively, since the pin holes in the distal augment cutting block align with the pin holes from the standard Unity distal cutting block, the augment cutting block may be repositioned by referencing the original pins.

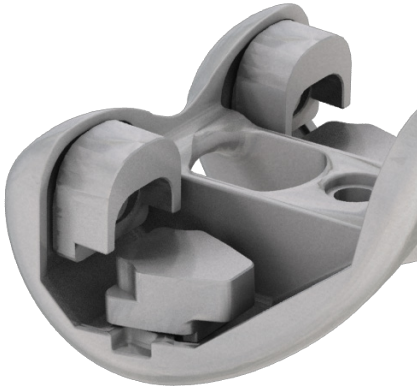


Note: The universal spacer has 2 tips: 5 and 10mm, and may be used at any stage of the operation when a fixed gap of 5 or 10mm should be considered. For example, If the medial, distal femoral bone is prepared for a 5mm augment prior to placement of the 4-in-1 guide, the universal spacer may be positioned between the bone and the 4-in-1 guide to ensure the correct position of the 4-in-1 guide.

8. Posterior femoral augment preparation

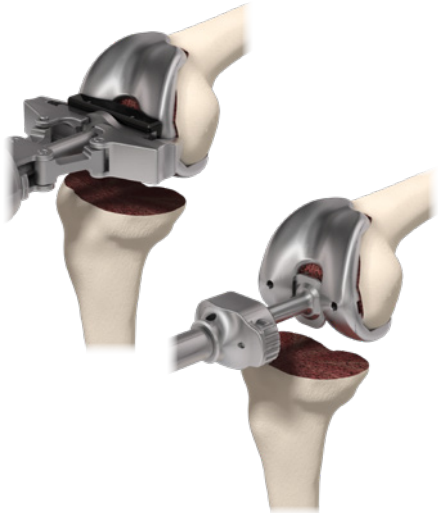
After the 4-in-1 resections have been performed any need for posterior femoral augments may be addressed by referencing the posterior femoral augment cutting jig on the posterior cut surface. Shims can be attached to the paddle to compensate bone defects. Oblique pins should be used to secure the jig to the bone prior to resecting bone for a 5 or 10mm augment in the slots indicated.

Note: 3 and 4mm spacer shims are available to attach to the feet of the femoral rotation guide and should be used prior to preparation for any posterior augments when there is a defect of 3 or 4mm. The shims, including the 1 and 2mm shims in the standard instrument set, may also be used in combination with the universal spacer to address any defect between 1 and 10mm.



9. Femoral augment trials

Distal femoral augment trials are designed to clip into the through-hole on the distal femoral component. Trials that are 5mm thick match the profile of the smallest 5mm augments available (Size 1&2), whereas the profile of the 10mm thick augments match the Size 3/4 augments. Sizing of the posterior femoral augment trials is the same, however they attach to the femoral trial with a captured screw.

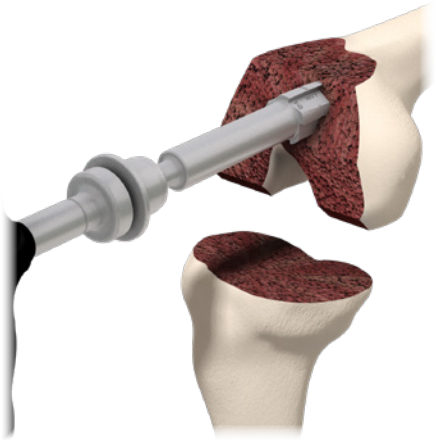


10. Complete trial reduction

The trial is assembled and impacted onto the resected femur using the dedicated femoral introducer for accurate positioning.

Note: If the trial stem extension does not sit adequately when impacting, remove the trial assembly and re-drill the correct depth using the thicker drill option before re-trialling. e.g. If the 9mm diameter drill was initially used, re-drill using the 10mm diameter drill.

If using a monoblock femoral trial, for trial removal the femoral trial extraction tool should be assembled with the slap hammer and slid onto the grooves on the femoral component. The femoral trial extraction tool should not be used to introduce or re-position the monoblock femoral trial.



In some instances it may be necessary to widen the femoral hole to create clearance for the femoral trial to clear the posterior bone resections. Where this is required the femoral stem reamer should be assembled with the T-handle and inserted into the hole and rotated clockwise by hand until the required depth marking is achieved. Another trial reduction should be conducted to reassess the posterior condyle clearance.

11. Stem implant assembly

To stem the tibial tray, the 3.5mm hex attachment is connected to the T-handle in the primary Unity Knee™ set and the tibial keel extension is removed from the tibial tray. To assemble the appropriate size stem extension to the tibial tray or PS femur, the component needs to be placed on the implant stem assembly plate. The latter is positioned on the plate in the identified orientation so as to stabilise the component during assembly.

The stem extension is positioned into the taper and the appropriate diameter impaction cap placed over the stem tip prior to impaction to engage the taper connection. It is recommended that the surgeon impacts the stem three times with a 0.6kg hammer from a swing distance of 0.5m to get optimum taper engagement.

⚠ The Unity Knee™ stem extension implant range is intended for single use. If a stem extension has been disassembled from the tibial tray or femoral component, then the stem extension and fixation screw need to be disposed of and cannot be re-used with any other tibial tray or femoral component. Both the femoral component and/or tibial tray cannot be re-used with a further stem extension and a new component will be required if a different stem extension has to be implanted. The tibial tray (following removal of an assembled stem extension) can only be re-used after being reassembled with the original tibial stem plug using the 3.5mm hex attachment and the T-handle.

A torque driver with a 2.5mm hex connection is then used to tighten the grub screw until the torque driver slips with an audible click. At this point a visual check should be made to ensure the stem and grub screw are fully connected and correctly positioned.

Note: When tightening the grub screw on the femoral component, the torque driver and hex should be slightly angled towards the anterior face for full engagement.

⚠ Only the torque limiting driver and 2.5mm hex attachment should be used to assemble and tighten the taper grub screw.

12. Augment implant assembly

To augment the femoral or tibial implant, first position the chosen augment within the corresponding cement pocket as illustrated. Insert the screw provided through the augment hole and into the threaded hole on the femoral or tibial implant. Carefully begin to thread the screw with the hex driver while ensuring not to cross-thread or strip the threads. Hold the augment in the desired position while applying the final turns until secure. Continue in the same way for any remaining augment components. The order of assembly is independent as clearance is provided for the hex driver and screws.

The Unity Knee augmentation implant range is intended for single use however the components may be re-used within the same operation if adjustments need to be made such that the augments are attached and detached.

All augments are attached via a screw with a 2.5mm hex connection. A 2.5mm torque driver shall be used to tighten the screw of tibia or femoral distal augments, until the torque driver slips with an audible click. For femoral posterior augments, the torque indicator should be used to tighten the screw: use the Allen key to make the assembly into the femoral component and insert the torque indicator on the Allen key. Use the assembly to complete the thightenning until the automatic declutch. At this point a visual check should be made to ensure the augment is fully connected and correctly positioned. Only these controlled torque instruments should be used to assemble and tighten the augment screws.

⚠ Ensure that the device is in the default position (all of the components in line) before use.

Beware that when the torque limit is reached, the device will suddenly snap into the “angled” position. Ensure your hand is appropriately positioned to avoid injury.

Ordering information

Femoral component PS Left

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

112.001.66	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

112.040.04	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 PS size 2

112.016.22	9mm thickness
112.016.23	10mm thickness
112.016.24	11mm thickness
112.016.25	12mm thickness
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

112.016.42	9mm thickness
112.016.43	10mm thickness
112.016.44	11mm thickness
112.016.45	12mm thickness
112.016.46	14mm thickness
112.016.47	16mm thickness
112.016.48	18mm thickness
112.016.49	20mm thickness

Tibial insert PS size 4

112.016.62	9mm thickness
112.016.63	10mm thickness
112.016.64	11mm thickness
112.016.65	12mm thickness
112.016.66	14mm thickness
112.016.67	16mm thickness
112.016.68	18mm thickness
112.016.69	20mm thickness

Tibial insert PS size 5

112.016.82	9mm thickness
112.016.83	10mm thickness
112.016.84	11mm thickness
112.016.85	12mm thickness
112.016.86	14mm thickness
112.016.87	16mm thickness
112.016.88	18mm thickness
112.016.89	20mm thickness

Tibial insert PS size 6

112.017.02	9mm thickness
112.017.03	10mm thickness
112.017.04	11mm thickness
112.017.05	12mm thickness
112.017.06	14mm thickness
112.017.07	16mm thickness
112.017.08	18mm thickness
112.017.09	20mm thickness

Tibial insert PS size 7

112.017.22	9mm thickness
112.017.23	10mm thickness
112.017.24	11mm thickness
112.017.25	12mm thickness
112.017.26	14mm thickness
112.017.27	16mm thickness
112.017.28	18mm thickness
112.017.29	20mm thickness

Tibial insert PS size 8

112.017.42	9mm thickness
112.017.43	10mm thickness
112.017.44	11mm thickness
112.017.45	12mm thickness
112.017.46	14mm thickness
112.017.47	16mm thickness
112.017.48	18mm thickness
112.017.49	20mm thickness

Tibial insert PS size 9

112.017.62	9mm thickness
112.017.63	10mm thickness
112.017.64	11mm thickness
112.017.65	12mm thickness
112.017.66	14mm thickness
112.017.67	16mm thickness
112.017.68	18mm thickness
112.017.69	20mm thickness

Dome patella

112.018.02	Size 1	7.5mm thickness
112.018.04	Size 2	8.0mm thickness
112.018.06	Size 3	8.5mm thickness
112.018.08	Size 4	9.0mm thickness
112.018.10	Size 5	9.5mm thickness

Offset dome patella

112.018.42	Size 1	8.0mm thickness
112.018.46	Size 2	8.5mm thickness
112.018.52	Size 3	9.0mm thickness
112.018.56	Size 4	9.5mm thickness

Distal Femoral Augments

1122306	Size 3/4	5mm thickness
1122310	Size 5/6/7	5mm thickness
1122316	Size 8/9	5mm thickness
1122346	Size 3/4	10mm thickness
1122350	Size 5/6/7	10mm thickness
1122356	Size 8/9	10mm thickness

Posterior Femoral Augments

1122326	Size 3/4	5mm thickness
1122330	Size 5/6/7	5mm thickness
1122336	Size 8/9	5mm thickness
1122366	Size 3/4	10mm thickness
1122370	Size 5/6/7	10mm thickness
1122376	Size 8/9	10mm thickness

Unity Knee™ Universal Stem extension implants

112.060.42	Stem extension cem ø10 length 30 mm
112.060.44	Stem extension cem ø14 length 30 mm
112.060.02	Stem extension cem ø10 length 60 mm
112.060.04	Stem extension cem ø14 length 60 mm
112.060.22	Stem extension cem ø10 length 100 mm
112.060.24	Stem extension cem ø14 length 100 mm

Tibial Augments – Size (5mm only)
Right Medial/Left Lateral

1123202	RM/LL – Size 1
1123204	RM/LL – Size 2
1123206	RM/LL – Size 3
1123208	RM/LL – Size 4
1123210	RM/LL – Size 5
1123212	RM/LL – Size 6
1123214	RM/LL – Size 7
1123216	RM/LL – Size 8
1123218	RM/LL – Size 9

Right Lateral/Left Medial

1123222	RL/LM – Size 1
1123224	RL/LM – Size 2
1123226	RL/LM – Size 3
1123228	RL/LM – Size 4
1123230	RL/LM – Size 5
1123232	RL/LM – Size 6
1123234	RL/LM – Size 7
1123236	RL/LM – Size 8
1123238	RL/LM – Size 9

Replacement Screws

1124302 Single Tibial Augment Screw, 10mm

112.054.92 Pack-of-5 Grub Screw

1122305 Pack-of-5 Augment Screw, 5mm

Indications

General total knee arthroplasty indications include:

- 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 stabilized 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.
* Indications are not CE marked

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

The Unity Knee™ is a fixed bearing total knee replacement system that consists of a Cobalt Chromium Alloy (CoCr) femoral component, a UHMWPE polyethylene tibial insert, a Cobalt Chromium Alloy (CoCr) tibial tray with a Titanium Alloy keel extension and all-polyethylene patellar component for use in primary and revision total knee arthroplasty. The Unity Knee™ femoral component is provided in two variants, cruciate retaining (CR) and posterior stabilized (PS).

- The Unity Knee™ CR femoral component is intended for use in conjunction with the CR tibial insert where the posterior cruciate ligament (PCL) is functional or in conjunction with a Unity Knee™ CS tibial insert* only where the PCL is present but is lax or non-functioning or when the PCL is absent.
- The Unity Knee™ PS femoral component and tibial insert variant is indicated for use where the posterior cruciate ligament is non-functioning or absent, resulting in joint instability.

The Unity Knee™ patellar component is optional for use with either the CR or PS variant and is indicated for use where replacement of the articular surface of the patella is required. The system also provides Titanium Alloy augment components including femoral augments, tibial augments and stem extensions.

The 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.

It is possible to use a size N tibial insert with a size N-1, N or N+1 femoral implant. The tibial insert must be the same size as the tibial.

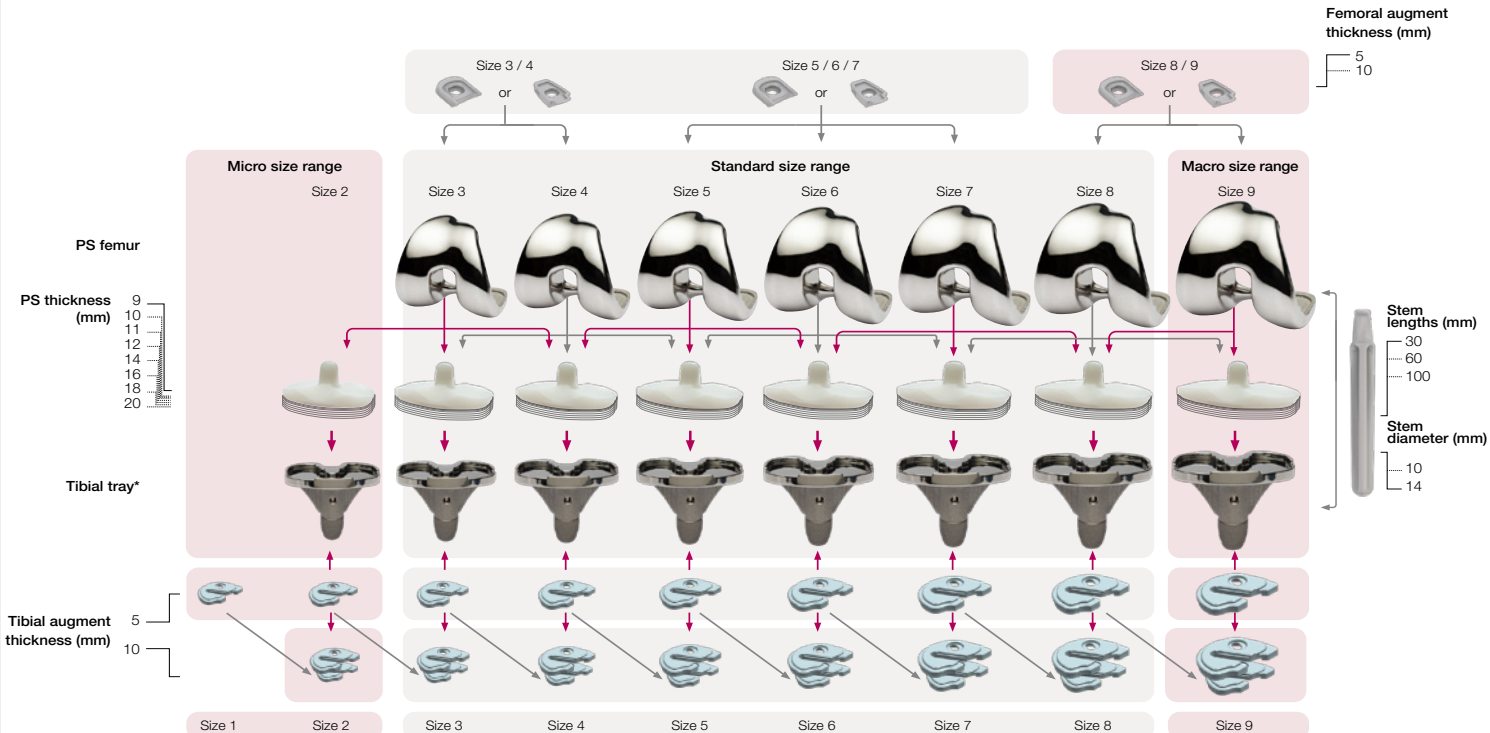
Tibial augments (only available in 5mm thicknesses) can be combined with another tibial augment of a consecutively smaller size to create a combined, 10mm augment. E.g. a size N tibial tray may be combined with a size N tibial augment stacked with a size N-1 tibial augment.

Femoral augments must be used with the corresponding size femoral implant.

For more details regarding the compatibility between implants, please contact your Corin representative or you could find more details on the following link www.coringroup.com/compatibility.

*The Unity CS tibial insert is not CE Marked

Compatibility chart



Size			1	2	3	4	5
Offset dome patella	Diameter (mm)		25	28	31	34	n/a
	Thickness (mm)		8	8.5	9	9.5	n/a
Centred dome patella	Diameter (mm)		26	29	32	35	39
	Thickness (mm)		7.5	8	8.5	9	9.5

*Tibial tray is compatible with stem and tibial augments regardless of CR or PS insert variants

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