CHUNLI ORTHOPEDICS GLOBAL INTELLIGENCE

XG UNI-KNEE

SURGICAL TECHNIQUE

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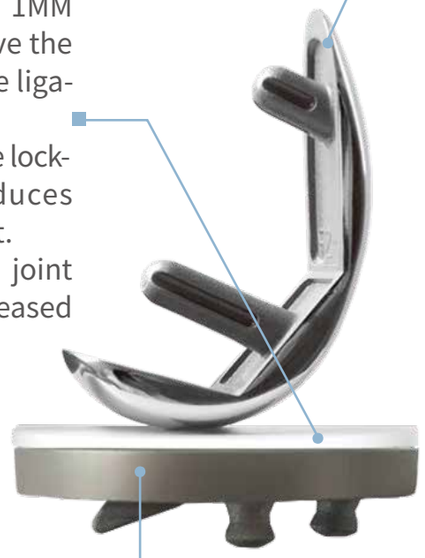
I

Product Introduction

Tibial plateau pad

- The tibial plateau pad is fine-tuned in 1MM increments to give the most appropriate ligament tension.
- Precise and stable locking design reduces Micro-movement.
- Low restrictive joint surface for increased joint mobility.



Femoral condyles

- Multi-curvature radius design, smooth and stable curved surface, 15° design of double column and posterior femoral condyle plane, making the prosthesis more firmly fixed and less likely to loosen.
- The femoral condyle extends posteriorly, allowing high knee flexion up to 155°.
- The bionic structure is designed to restore and replicate the natural knee anatomy.

Tibial platform brace

- The tibial plateau double column combined with fin design effectively prevents the tibial plateau from moving laterally and longitudinally, increases the stability of the prosthesis, and reduces the loosening of the tibial plateau after surgery.
- It is designed according to the national bone characteristics to achieve excellent bone coverage.

II

Indications

- Persons with osteoarthritis, rheumatoid arthritis, or disability.
- Inversion, ectropion or traumatic deformity correction.
- Patients with previous femoral condyle or tibial plateau fractures with anatomic or functional loss.

III

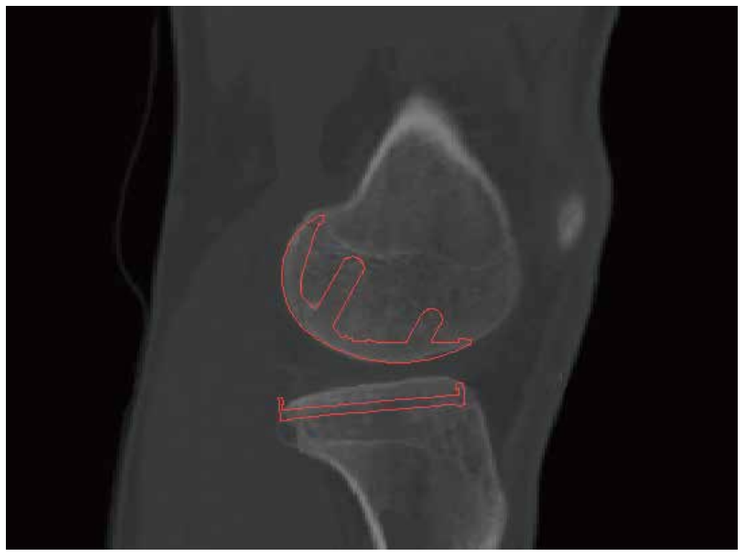
Contraindications

- Persons with acute or underlying infection, overall or localized.
- Persons with particularly osteoporotic bone, poor bone quality, insufficient bone mass on the surface of the femur or tibia, and skeletal dysplasia.
- Excessively obese persons (body mass index BMI > 30).
- Insufficiency of the lateral and anterior and posterior cruciate ligaments that prevent the stability of the mounted prosthesis.
- Those whose function is affected by other diseases after surgery.
- Metabolic diseases that can affect bone formation.
- Chondromalacia or damage to the articular cartilage of the contralateral joint capsule.
- Rapidly progressive disease evident on X-ray as joint destruction, bone loss or bone resorption.
- Vascular insufficiency, muscle atrophy or neuromuscular disease.
- Inversion/extrusion deformity of more than 15 degrees.
- Allergic reaction to the material.

IV

Pre-operative X-ray Template Measurement

- A preoperative template can be placed on radiographs for comparison prior to surgery, and the type of femoral condyle, tibial plateau brace and tibial plateau pad can be initially selected in preparation for the later surgery.



V

Surgical Procedure

• The XG fixed unicondylar procedure uses a gap block to position the osteotomy. After the tibial osteotomy, a gap block of appropriate thickness is inserted into the joint space according to the thickness of the tibial osteotomy, and a distal femoral osteotomy guide for joint osteotomy is attached to the gap block to help ensure that the proximal tibial osteotomy surface is parallel to the distal femoral osteotomy surface.

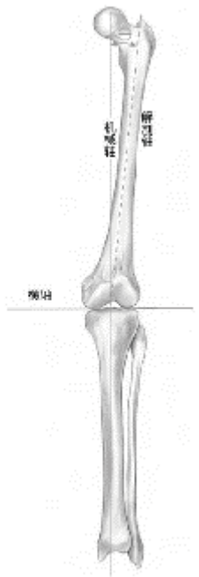


Figure 1

PRE-OPERATIVE PLANNING

- For the gap pad positioning method, the tibial osteotomy must be performed first, as the tibial osteotomy surface is used as the base for positioning to complete the distal femoral osteotomy.
- AP and lateral radiographs of the knee with the patient upright and weight-bearing, as well as a tangential radiograph of the patella, are taken. An upright long A/P radiograph is then taken to show the center of the femoral head, the knee joint and, if possible, the tibia (preferably including the ankle).

- The distal femoral osteotomy component is designed with reference to the anatomical axis of the femur. On the radiograph, a straight line is drawn from the center of the femoral head toward the center of the distal femur at the knee joint. This line represents the mechanical axis of the femur. A second straight line is drawn down through the center of the distal femoral stem (Figure 1). The angle between the mechanical and anatomic axes of the femur determines the distal femoral condyle osteotomy, which is usually 6°.

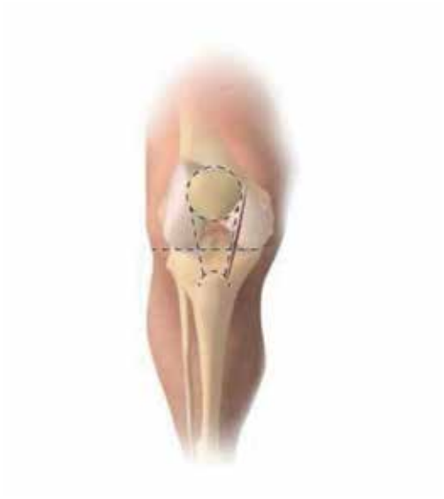


Figure 2

PRE-OPERATIVE PREPARATION

- Depending on individual preference, the incision can be made with the lower extremity in the flexed or extended position, with a medial patellar skin incision made from the medial edge of the patella to 2-4 cm below the joint line (Figure 2).

- The joint capsule is incised through the skin incision. The upper end of the capsule incision should be extended 2 cm proximally into the medial femoral muscle. The joint capsule incision then extends downward along the medial edge of the patella to the medial patellar ligament.

- The lower part of the incision exposes the tibial tuberosity to the anteromedial edge of the tibial plateau. Remove as much of the medial meniscus as possible. Do not perform a release of the lateral collateral ligament; surgeons in the learning process should widen the surgical incision for better visualization. The patella should be semi-dislocated, not fully dislocated.

- A portion of the posterior patellar fat pad is excised, and then a pulling hook is inserted into the synovial cavity to check the integrity of the ACL. (Functional ACL deficiency is a surgical contraindication, and if this is found, unicondylar knee arthroplasty should be discontinued in favor of total knee arthroplasty).

(01)

PROXIMAL TIBIAL OSTEOTOMY

- The XG Fixed Unicondylar Knee System is designed for a posteriorly inclined 5° anatomic position and is capable of performing precise osteotomies of the proximal tibia. The extramedullary force line positioning device is composed of the tibial osteotomy guide, the ankle hugger body, the extramedullary force line adjustment bar and the extramedullary force line guide bar.The positioning of the tibial force line is critical.

- Assemble the extramedullary force line positioning device according to Figure 3 (note that there are two sizes of tibial osteotomy guide, left: LM/RL and right: RM/LL, choose the corresponding model according to the actual needs). Adjust the knobs so that the tibial osteotomy guide is at the proximal end of the tibial tuberosity and the osteotomy guide groove is near the ideal osteotomy level.

Figure 3

Figure 4

Figure 5

- While keeping the proximal portion of the extramedullary force line positioning device in the proper position, loosen the knob on the distal end that can be adjusted medially and laterally, adjust the distal end so that the extramedullary force line positioning device is positioned just above the tibial crest (Figure 4), and then fully tighten the knob to hold it in place. This helps to ensure that the proximal portion of the guide is parallel to the mechanical axis of the tibia. It can also be adjusted medially and laterally at the proximal end, but the proximal portion must be parallel to the distal portion and thus parallel to the mechanical axis of the tibia.

- Adjust the position of the tibial osteotomy guide so that it is just medial to the midpoint of the tibial tuberosity and in a straight line with the center of the intercondylar augmentation (Figure 5). In the sagittal plane, it is placed parallel to the front of the tibial tuberosity and the knob is tightened for alignment.

- After completion of adjustment, the proximal tibia was initially fixed with a captive screw/pin for the extramedullary force line positioning device (Figure 6).

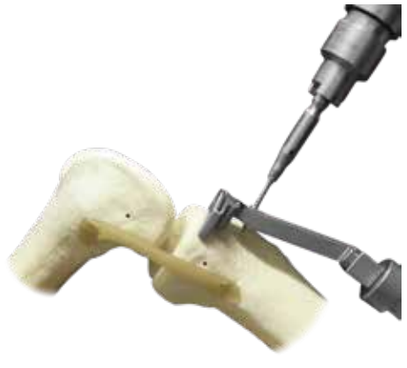


Figure 6

- An accurate tibial osteotomy thickness is achieved by using a depth finder with an extramedullary force line positioning device. The depth finder is inserted into the hole at the top of the tibial osteotomy guide, and the 2 mm tip of the depth finder should be located at the most concave part of the tibial defect (Figure 7), which indicates that the osteotomy will remove 2 mm of bone tissue below the tip of the depth finder. If necessary, the height of the tibial osteotome guide can be adjusted by adjusting the butterfly knob of the tibial osteotome guide.

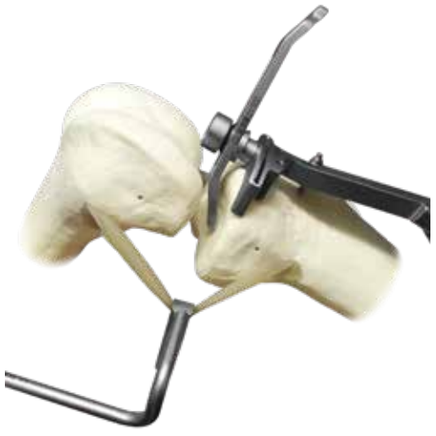


Figure 7

Note:If the 4mm tip of the tibial depth osteotome is used, the osteotomy will remove 4nm of tibial tissue below the tip of the depth gauge.

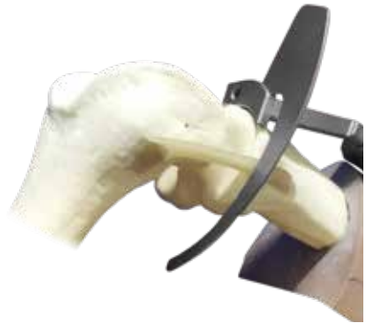


Figure 8

- After the tibial osteotomy guide is adjusted, the tibial osteotomy guide is fixed to the proximal tibia by inserting a captive screw through the nail hole in the tibial osteotomy guide. If needed, the depth of the osteotomy can be confirmed by inserting a condylar plane gauge (Figure 8).

Figure 9

- The reciprocating saw is brought to the base of the tibial intercondylar augmentation and parallel to the augmentation in the A/P plane, using the reciprocating saw to cut down along the ACL to the transverse osteotomy plane but not beyond the intended transverse osteotomy plane (Figure 9), and then the transverse osteotomy is completed along the osteotomy guide slot of the tibial osteotomy guide using a swing saw with a 1.27 mm blade.

- After the tibial osteotomy is completed, the position of the scale above the butterfly knob is recorded (Figure 10), the tibial osteotomy guide is removed by rotating the butterfly knob, and then the thin end of the gap test pad is used to measure the gap in flexion (Figure 11) and the gap pad is used to measure the gap in extension (Figure 12).

Note:

1.The thickness of the gap test pad and gap pad of the same mark is different,the gap test pad will be 2mm thinner than the gap pad, for example: the actual thickness of the gap test pad of 8mm mark is 6mm, while the actual thickness of the gap pad is 8mm.

2.If the 8 mm gap pad does not fit just into the joint, the tibial osteotomy guide is reinstalled, the butterfly knob is adjusted to lower the osteotomy slot by 2 scales (Figure 13),a screw is driven into the other nail hole of the tibial osteotomy guide to fix it (Figure 14), and the proximal tibia is resected by an additional 2 mm.

3.The depth of the osteotomy can be determined by the graduated line on the saw blade.

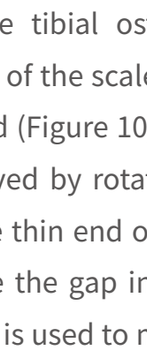


Figure 13

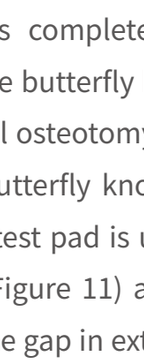


Figure 14

Figure 10

Figure 11

Figure 12

Figure 15

Figure 16

- The bone fragments cut from the tibia were compared with the trial rests in the instrument box to initially determine the specifications of the tibial platform rest (Figure 15).

(02)

DISTAL FEMORAL OSTEOTOMY

- After completing the proximal tibial osteotomy, the knee is placed in an extended position. The gap pad is inserted into the joint space until the anterior block contacts the anterior tibia (Figure 16). The gap block must be fully inserted and placed smoothly on the tibial osteotomy surface, thus ensuring the amount of osteotomy at the distal end of the cut femur.

Note:If the gap spacer is too loose, use a thicker gap spacer.

- After the gap pad is placed in place, the gap pad is secured to the tibia with a captive screw (Figure 17).

Figure 17

- Connect the force line adapter to the handle of the spacer, insert the force line rod A and B through the force line adapter, and then perform the force line alignment (Figure 18).

Figure 18

- The tibial portion of the XG Fixed Unicondylar Knee System has a 5° posterior tilt and the handle of the gap pad has a 5° angle with respect to the gap pad, which ensures that the distal femur can be osteotomized perpendicular to the long axis of the femur.

Figure 19

- The distal femoral osteotomy guide is mounted on the handle of the gap pad (Figure 19), and the distal femoral osteotomy guide is secured to the femur with a captive screw (Figure 20). The distal femur is osteotomized with a swing saw equipped with a 1.27 mm thick saw blade (Figure 21).

Figure 20

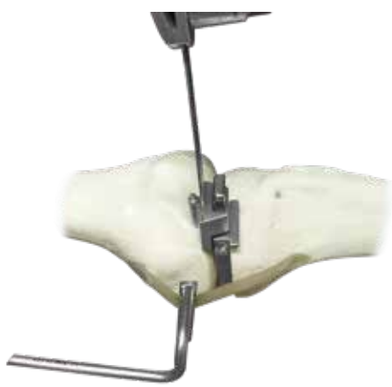


Figure 21

(03)

CHECK FLEXION/EXTENSION GAP

- When evaluating the flexion/extension gap, a gap test pad corresponding to the thickness of the tibial plateau can be used to examine the flexion/extension gap. The thick end of each gap test pad simulates the combined thickness of the corresponding tibial and femoral components in extension, and the thin end of each gap test pad simulates the thickness of the tibial component in flexion.

- The extension gap is checked using the thick end of the gap test pad inserted into the joint (Figure 22).

- Remove the gap test pad. Flex the knee joint and insert the thin end of the selected gap test pad into the joint to check the flexion gap (Figure 23).

- If the joint gaps in flexion and extension are too tight for insertion of the 8 mm gap test pad, then more of the tibia must be removed. These gaps are then rechecked with the gap test pad.

Figure 22

Figure 23

- If the joint gap is too loose in flexion and extension, insert thicker gap test pads in sequence and recheck the gap.

- If the extension position is tense and the flexion position meets the requirements, 2 methods are available.

Note:

1) Recutting of the proximal tibia with a smaller tibial inclination
2) After re-truncating 1mm-2mm off the distal femur to adjust the flexion gap or extension gap, the flexion/extension gap is re-checked with a gap trial pad. Confirming the gap at this stage of the procedure reduces the possibility of gap imbalance during trial repositioning.

(04)

DETERMINING FEMUR SIZE

- To determine the femur size, 11 sizes of femoral implants and corresponding sizes of femoral osteotomy guides are available. The lateral profile of the femoral osteotomy guide is matched to the profile of the corresponding implant.

- The trial condylar grip is attached to the femoral osteotomy guide, and then the knob on the end of the handle is tightened so that it is securely assembled (Figure 24).

Figure 24

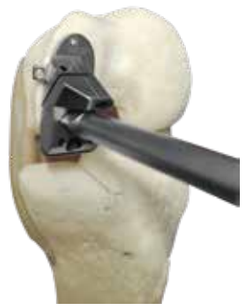


Figure 25

- Insert the foot of the femoral osteotomy guide into the joint and place the plane against the distal femoral osteotomy surface after osteotomy. Pull the foot of the femoral osteotomy guide forward until it contacts the cartilage/bone tissue of the posterior femoral ankle. 2mm-3mm of bone tissue should be exposed above the anterior edge of the femoral osteotomy guide (Figure 25). If the selected size is not appropriate, repeat the procedure with another guide until the appropriate size is selected. If the femoral condyle is between the two sizes, choose the smaller size. This helps prevent the patella from impinging on the prosthesis.

Note:There must be no soft tissue or remnants of bone between the femoral osteotomy guide and the distal femoral condyle. It is important that the femoral osteotomy guide be installed flush with the bone. Any gap between the femoral osteotomy guide and the bone will destroy the accuracy of the osteotomy surface and thus the retention of the component. Do not allow the patella to cause the guide to misalign. In the medial UKA, the patella can cause the femoral osteotomy guide to move inward.

(05)

COMPLETION OF THE FEMUR

It is recommended that the femoral osteotomy guide be used in the following order so that maximum stability and retention can be achieved and help ensure accurate femoral osteotomy and drilling.

1. Place the appropriately sized femoral osteotomy guide in the appropriate position on the femur and secure the femoral osteotomy guide to the femur with a captive screw (Figure 26). The guide is rotated on the screw until the posterior edge of the guide is parallel to the osteotomy surface of the tibia (Figure 27), ensuring that the bones on either side of the guide are exposed and that the femoral osteotomy guide is not protruding.

2. A captive screw is inserted into the anteverted locating pin hole parallel to the notched osteotomy (Figure 28). For optimal retention, the screw needs to be slowly screwed in, which is sufficient to stabilize the femoral guide for completion of the femur. For additional stability, the fixation pin can be pre-drilled and inserted into the intermediate hole closest to the intercondylar notch. If this hole is occupied, the femoral osteotomy guide must be removed prior to completing the femoral osteotomy.

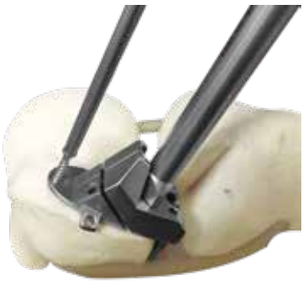


Figure 26

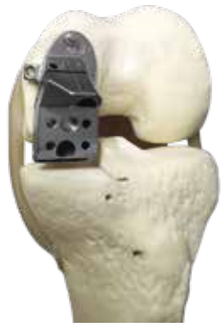


Figure 27

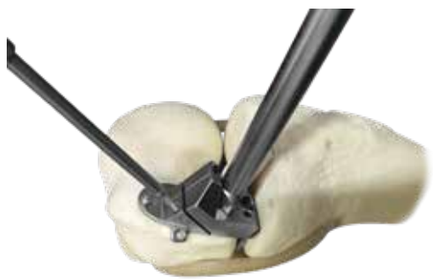


Figure 28

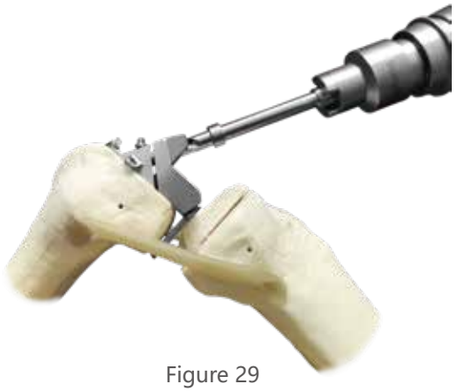


Figure 29

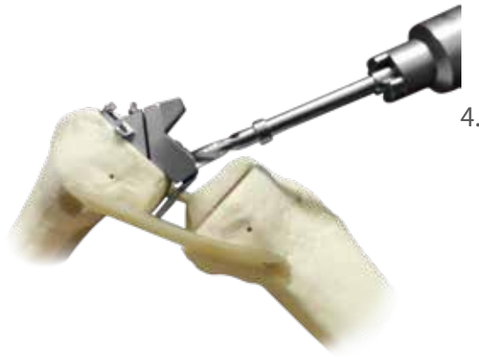


Figure 30

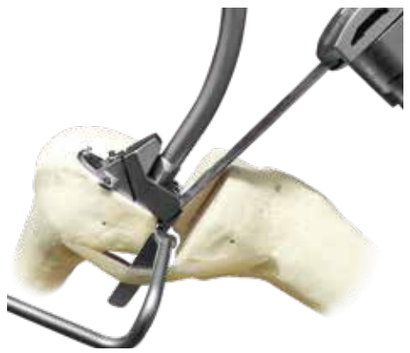


Figure 31

3. Insert the ϕ7 drill bit into the front post hole and position it to the proper angle (Figure 29). After proper alignment, drill the front post hole and do not try to insert or align the drill bit while the ϕ7 drill is turning.

4. Drill the rear pillar hole in the same way. This hole is at the same angle as the front post hole (Figure 30). If necessary, a retaining pin can be inserted in the front post hole to improve stability.

5. The posterior femoral condyle is osteotomized by inserting a fixation pin in the anterior post hole and passing it through the guide slot in the femoral osteotomy guide (Figure 31). If the fixation pin has already been inserted in the anterior post hole during the previous drilling of the post hole, the posterior femoral condyle can be osteotomized directly.

6. Remove the fixation pins and complete all outstanding osteotomies of the femur along the osteotomy guide groove of the femoral osteotomy guide (Figure 32).

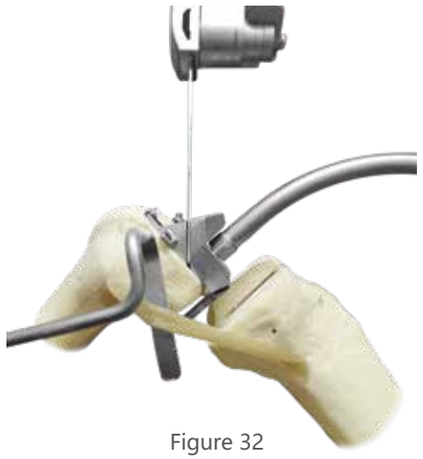


Figure 32

7. Make sure all surfaces are flat. Remove all protrusions The bone tissue that is divided or has hairy edges.

(06)

DETERMINING FEMUR SIZE

Removal of the remaining meniscus and removal of all bone fragments, especially those interfering with the collateral ligament.

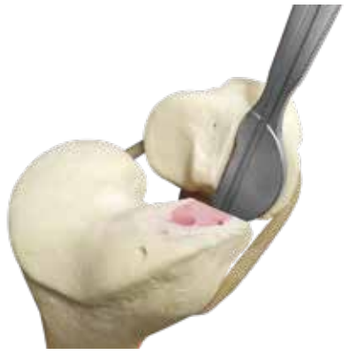


Figure 33

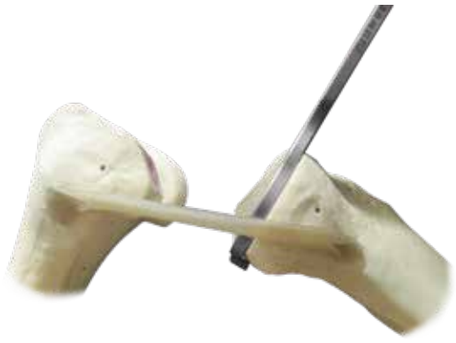


Figure 34

- Place the head of the tibial plateau gauge on the osteotomy surface of the tibia so that the straight edge rests on the surface formed by the sagittal osteotomy. Determine the proper rotation of the sagittal osteotomy in the transverse plane. Appropriate rotation is indicated when the sizer handle is at a 90° angle to the coronal plane (Figure 33). Select a tibial plateau sizer that optimally covers the tibial osteotomy surface in both the A/P and M/L positions.

- A depth gauge on the tibial plateau gauge can be used to measure the A/P position. Be sure to attach the head of the tibial plateau gauge to the dense bone near the cortical edge throughout the periphery, being sure not to make it protrude. Pull the tibial plateau gauge forward until the hooks of the depth gauge touch the posterior edge of the tibia (Figure 34).

- There are a number of scale symbols on the tibial plateau gauge. If the tibial plateau gauge is not used with a depth gauge, the scales 1 to 8 on the tibial plateau gauge indicate the A/P length of the corresponding implant. If the tibial plateau gauge is used with a depth gauge, the A/P length is indicated on the handle of the tibial plateau gauge (Figure 35). In addition, the straight medial recess of the tibial plateau gauge is a guide slot for keel shaping.

Figure 35

- The tibial plateau gauge was removed. All soft tissue debris is then removed from the carpel fossa area. The appropriate size tibial plateau test rest is placed on the osteotomy surface of the tibia. The keel of the tibial plateau test rest is placed in the groove of the tibial osteotomy and driven into place with the tibial plateau pounder so that the central fissure keel is fixed to the tibial bone and the tibial plateau test rest will sit flat on the tibial osteotomy (Figure 36).

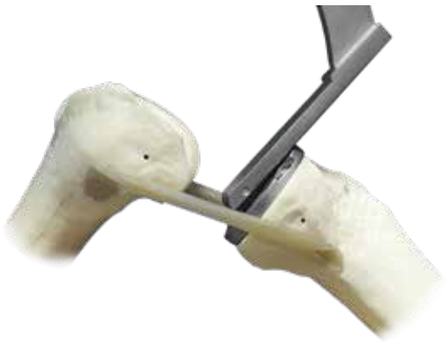


Figure 36

Figure 37

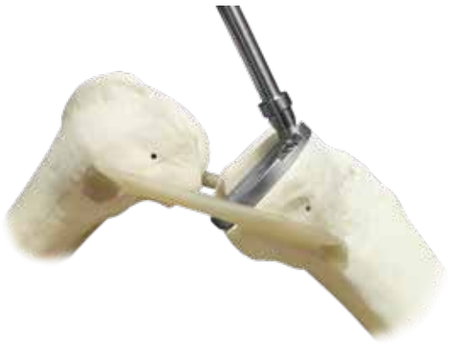


Figure 38

- Pre-drill and insert a short-headed, capped pin into the front retaining hole (Figure 37).

- Two tibial fixation peg holes were drilled with a ϕ9 drill along the drill guide holes of the tibial plateau trial bracket (Figure 38).

(07)

PERFORM A TEST RESET

- After completion of the tibial osteotomy and femoral osteotomy, trial resetting is performed with the appropriately sized trial condyles, tibial plateau trial brackets, and tibial plateau trial pads.

- Firstly, insert the two parallel posts on the test die holder into the matching holes on the test condyles (Figure 39), and then turn the knob on the test die holder to make it firmly connected with the test condyles.

Figure 39

- To facilitate the installation of the trial condyle, the lower extremity can be placed in a deep flexion position to begin the installation. The long post is first inserted, then the lower extremity is adjusted to intermediate flexion, the condyle is rotated around and behind the patella, the lower extremity is repositioned in deep flexion, and the condyle is mounted on the femur with a bone hammer (Figure 40).

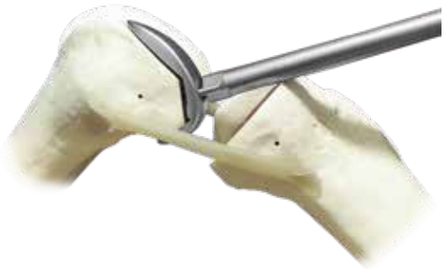


Figure 40

Figure 41

- Slide the slide on the bottom of the tibial platform trial pad into the groove on the tibial platform trial rest (Figure 41).

- Finally, a 2MM tensiometer was used to check for proper soft tissue tension in extension and flexion (Figure 42).

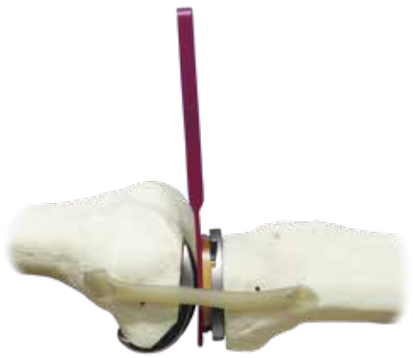


Figure 42

(08)

IMPLANTATION OF PROSTHESIS

- **Tibial plateau brace**
  To facilitate insertion of the tibial plateau brace, the knee can be placed in a flexed position with the tibia externally rotated. If necessary, an open, slightly moistened sterile gauze sheet is placed behind the tibia to absorb the cement of the excess bone posterior to the tibia prior to implantation of the tibial plateau brace.

- Bone cement is applied and the tibial plateau rest is implanted into the tibia using a tibial plateau punch. The posterior part of the tibial plateau rest is first placed and pressed down, then the anterior part of the tibial plateau rest is pressed down using a bone hammer with the tibial plateau punch to squeeze out the excess cement anteriorly, and finally the sterile gauze sheet is slowly removed from the posterior part of the joint and all the excess cement is removed from the tibia using a cement removal tool.

- **Femoral condyles**
  The lower extremity is placed in deep flexion, cement is applied and the femoral condyles are implanted using a femoral condyle punch. The lower extremity is first adjusted to intermediate flexion by inserting a long stem, rotating the femoral condyle around and posterior to the patella, then resetting the lower extremity in deep flexion and using the femoral condyle penetrator to place the femoral condyle in place (Figure 43), and removing all excess cement from the femur with a cement removal tool.

Figure 43

Figure 44

- **Tibial plateau pad**
  After the cement holding the tibial plateau bracket has set, the tibial plateau pad and tibial plateau bracket are locked together using the tibial plateau pad indenter.

  First place the tibial plateau pad with the engraved text side down, slide the edge of the tibial plateau pad over the posterior edge of the tibial plateau rest notch, then insert the metal head portion of the tibial plateau pad indenter into the notch on the front of the tibial plateau rest, use the portion with the paraformaldehyde spacer to contact the upper articular surface of the tibial plateau pad, and finally squeeze the handle of the tibial plateau pad indenter in the together direction until the tibial plateau pad snaps into place (Figure 44).

- **Closure of the operative area**
  The knee is finally flushed and the opening in the operative area is sutured. The incision is covered with a sterile dressing and secured with an elastic bandage.

VI

Technical parameters

(citing product specifications on the product promotional leaflet)
Femoral condyles XG-GG（Unit：mm）

Femoral condyles	0#	1#	2#	3#	4#	5#	6#	7#	8#	9#	10#	Illustrations
ML	17	18	19	19.5	20.3	20.8	21.6	21.6	22.5	22.5	24	
AP	37	40	43	45	46.5	48	50	51.5	53.5	55.5	58	

Tibial platform pad XG-JDG（Unit：mm）

Tibial plateau pad	0#	1#	2#	3#	4#	5#	6#	7#	8#	9#	10#	Illustrations
ML	20	23	25	26	27	28	29	31	33	35	37	
AP	38	41	44	46	47	48	50	53	56	58	60	

Tibial platform rest XG-JTG（Unit：mm）

Femoral condyles	0#	1#	2#	3#	4#	5#	6#	7#	8#	9#	10#	Illustrations
ML	20	23	25	26	27	28	29	31	33	35	37	
AP	38	41	44	46	47	48	50	53	56	58	60	

Note: Femoral condyles, tibial plateau pads, and tibial plateau rests are divided into left medial right lateral knee (LM/RL); right medial left lateral knee (RM/LL).

VII

Sterilization

• Prosthetic injections

The prosthetic implants described in this manual have been sterilized and do not require further sterilization prior to surgery.

• Surgical instruments

Surgical instruments are non-sterile and must be sterilized prior to surgery in accordance with the laws and regulations of the country in which they are used, industry regulations and the system of the hospital in which they are used.

VIII

Surgical tools