CHUNLI ORTHOPEDICS GLOBAL INTELLIGENCE

CHUNLI

Beijing Chunlizhengda Medical Instruments Co., Ltd

2007 Gaohelanfeng Plaza, No.98 South of East 3rd Ring Road, Chaoyang Dist. Beijing (100021)

Mobile Hotline:

+86 13810479615 (English)
+86 18516853658 (Spanish)
+86 13520826455 (Russian)

www.clzd.com

Company Wechat

CHUNLI

XA Primary Knee Joint System

Surgical technique

Beijing Chunlizhengda Medical Instruments Co., Ltd

CONTENTS

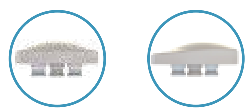
I

Product Introduction

Designed jointly by Professor wangkunzheng, Professor zhouyonggang and the company's R & D team, the product absorbs the suggestions of many top domestic knee joint experts and combines the Chinese bone measurement data to develop a knee joint product suitable for Chinese bone characteristics and conducive to deep bending and squatting.

NEWLY GRADIENT RADIUS DESIGN

Avoid instability resulted from sudden changes of radius in middle flexion; Guarantee the stability during squatting, and provide safe ebough contact area when reaching high flexion of 150°.



Patella replacement is one of the necessary part to achieve deep flexion and squatting.

PS POST COLUMN

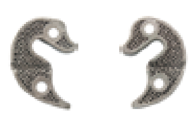
Post column moves backward design, and posterosuperior part of the column lengthened.

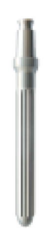
Ti-6Al-4V material, good tenacity;High-polished surface between tibial tray and inferior insert reduce wear and osteolysis rate.

Based on typical locking system, anti rotation locking is added to reduce slight motion, tibial insert wear and reduce osteolysis rate.

ANATOMICAL TIBIAL PLATEAU DESIGN

The first anatomically designed tibial plateau in China can obtain the maximum coverage of the tibial osteotomy surface, make the pressure evenly distributed in the proximal tibia, reduce the irritation of the tibial bracket to the surrounding soft tissue, reduce postoperative pain and facilitate deep bending and squatting.





Femoral and tibial prosthesis can be matched with cemented stems with distal tridentate structure, different wedges.

II

Indications

XA total knee system is mainly suitable for:

- 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

Patients shall be warned by the following contraindications, including:

- Apparent infection;
- Distant infected lesions (may cause blood-borne transmission to the prosth -esis);
- Manifested by obvious joint collapse or bone resorption under X-ray fluoros -copy due to rapid development of disease;
- Patients with immature skeletal structure;
- Cases of neuromuscular insufficiency (eg, poliomyelitis, abductor insufficie -ncy and/or fusion), poor bone mass, or low skin coverage around joints that are not suitable for surgery.

IV

Preoperative Preparation

- Full-length standing X-ray film of the lower limbs. The line passing through the center of the femoral medullary cavity and the midpoint of the knee joint is the anatomical axis of the femur; the line passing through the center of the femoral head and the midpoint of the knee joint is the mechanical axis. The angle between these two axes is the valgus angle.
- The valgus angle of both knees must be measured. The valgus angle is usually between 3°-8°. Therefore, for specific cases, the most appropriate valgus osteotomy angle should be determined before the distal femoral osteotomy, which is generally 5°-7°.
- Before operation, with the aid of the prosthetic template, the model of each component and the thickness of the osteotomy are measured.

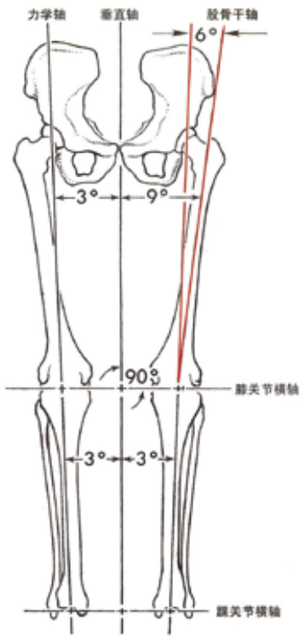


Fig. 1

V

Surgical steps

01.

PROXIMAL TIBIAL OSTEOTOMY

- Supine posture is generally adopted.
- Standard midline knee incision can be selected. If there is an old incision locally,the original incision can be used, or the old incision can be extended further to reduce the risk of skin peeling.
- A medial parapatella approach is used for opening sac.

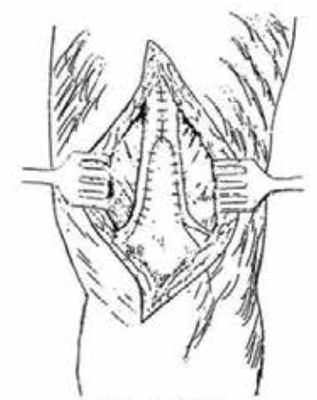


Fig. 2

02.

TIBIA ALIGNMENT AND OSTEOTOMY

- Extramedullary force line positioning-provide two force line positioning methods(fixed and movable).
- There are four extramedullary tibial osteotomy components: tibial osteotomy plate, tibial marrow external force line rod, tibial marrow external force line sleeve, and ankle attaching device.
  XA tibia osteotomy module selection.

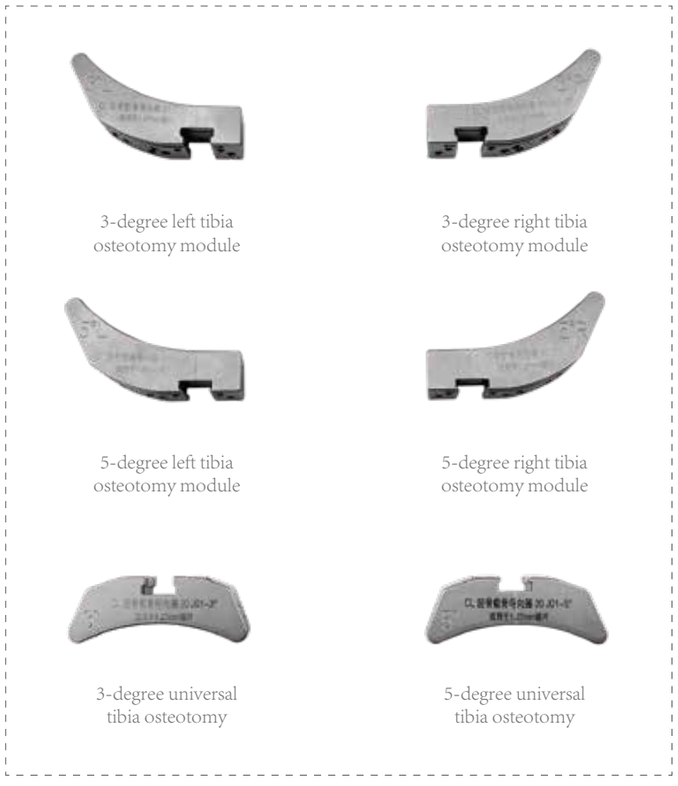


Fig. 3

Fig. 4

- After knee joint is flexed, the tibial extramedullary positioning device can be assembled and installed on the tibia. Please make sure to choose the right or left tibia osteotomy plate correctly.

- Fixed type: Firstly drive the posterior fixed nail into the highest point of tibial spine or refer to the inner third of the tibial tubercle. After the line of force andangle are confirmed to be correct, drive the anterior movable nail into the tibial spine. (See Fig. 4)

- Movable type: Place the tibial osteotomy module close to the proximal tibia. (See Fig. 5)

- Fix the ankle attaching device at the center of the ankle joint, loosen the knob nut at the distal end of the tibial bone marrow external force line sleeve, and adjust the forward and backward inclination angle. When the long axis of the proximal end of the extramedullary positioning rod is parallel to the center of the tibial coronal plane, the correct anteroposterior alignment is made. Loosen the knob of the distal end of ankle attaching device to allow the distal component to slide inside and outside on the attaching device to adjust the varus and valgus alignment until the extramedullary positioning rod has aligned with the center of the tibia. After the three-axis alignments have done, tighten the knob on the ankle attaching device. Under normal circumstances, the center of the ankle joint shall be flush with the second metatarsal bone. It is best to mark the second metatarsal, midline of the tibia, and tibial tubercle to ensure the correct line of force.

Fig. 5

Fig. 6

Fig. 7

- Connect the tibial osteotomy probe to the tibial osteotomy plate (the tibial osteotomy probe to provide 2mm and 10mm osteotomy planes). Remarks:a. The lowest point of the probe marked "10" on the outside of the tibial plateau is the reference point, meaning the thickness of the tibial osteotomy of 10mm. b. The end marked "2" on the probe is placed at the lowest point on the inner side of the tibial plateau as the reference point, meaning the thickness of the tibial osteotomy of 2mm.

- After using the sickle blade to determine the amount of osteotomy, lock the nut under the tibial osteotomy plate, and screw two fixed nails into the "0" hole to fix the tibial osteotomy plate on the tibia. Install the forceline measuring frame on the tibial osteotomy plate, and pass the lower limb force line measuring rod through the hole on the force line measuring frame to check the condition of the lower limb force line.

- Re-determine the thickness of the osteotomy with sickle blade (if necessary, adjust the amount of osteotomy through the adjustment hole), and implanta pin to fix the osteotomy plate, and use a 1.25mm saw blade for tibial osteotomy.

Fig. 8

03.

INTRAMEDULLARY POSITION -ING ANDDISTAL FEMORAL OSTEOTOMY

- Locate the Intramedullary point, usually 8mm-10mm in front of the cruciate ligament stop point. Open the femoral medullary cavity with an 8mm femoral drill.

Fig. 9

Fig. 10

Fig. 11

- The intramedullary locator is suitable for both the left and right sides. According to the interpretation of the X-ray film before operation, adjust the knob on the intramedullary locator, select the appropriate femoral valgus angle, and slowly insert the medullary needle until the femoral medullary cavity At the narrow part, push the intramedullary locator to make the plane close to the inner and outer condyle surface of the distal femur, and turn the locking knob to fix the position of the intramedullary locator.

Note:Check the "R" and "L" positions, usually the valgus angle is set to 5°-7°.

- Choose the appropriate amount of osteotomy of the distal femur, pay attention to the value on the osteotomy plate and confirm it with the sickle Screw 2 headless fixation spikes into the "0" position of the distal osteotomy plate to fix them on the femur.

Note:The amount of osteotomy that completely fits the distal femur should be at least 9mm, and the osteotomy adjustment knob can be sued for adjusting the degree of osteotomy.

- Press the locking latch of distal osteotomy and pull the entire instrument to the distal end to separate the intramedullary locator from the distal osteotomy plate.

- Install the force line corrector and force line rod to measure the force line of the lower limbs. The force ling rod should point to the center of the femoral head. Use a sickle blade to determine the amount of osteotomy at the distal femur again, and implant an oblique nail to fix the distal osteotomy guide, and perform the osteotomy with a 1.0mm-1.25mm saw blade.

Note:If the amount of osteotomy needs to be adjusted, it can adjustedwith the position of the nail hole of "plus or minus 2mm". Pay attention to protect the tibial plateau from damage during osteotomy.

Fig. 12

- Perform the osteotomy of distal femur. Remove the distal osteotomy plate. According to doctor's request, the pin can be removed or retained for use in re-osteotomy.

04.

STRAIGHTENING GAP MEASUREMENT

- Use the gap measuring board to measure the gap in the straight position, and use the force line rod to measure the force line of the lower limbs. If the osteotomy gap is ideal, remove the tibia and femur tailless fixed nails with nail.

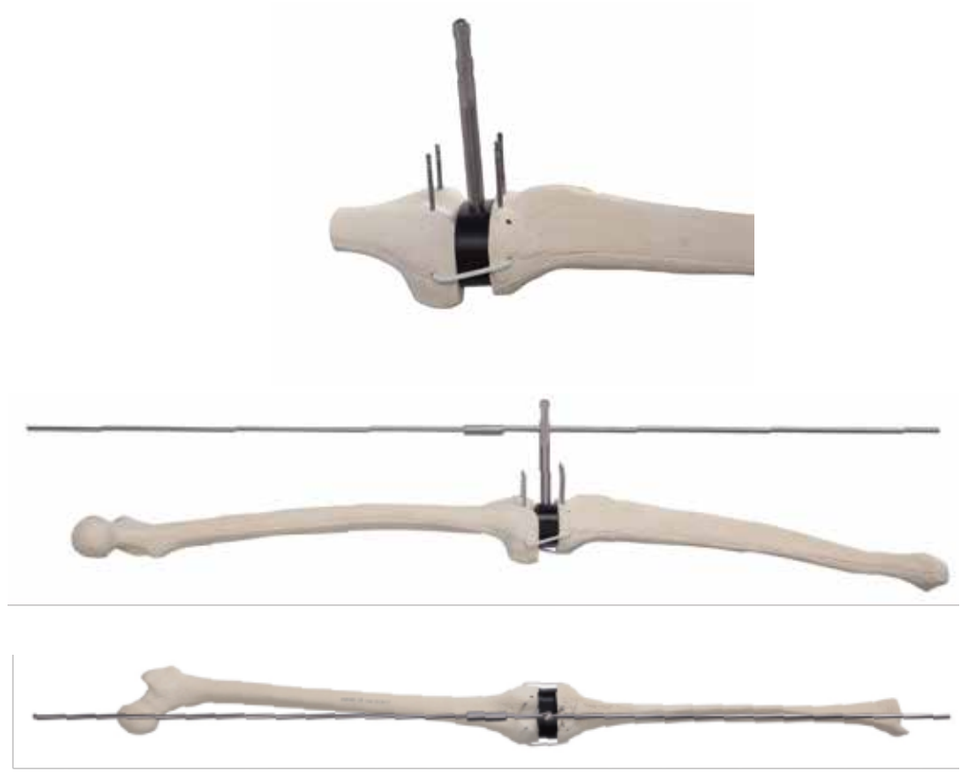


Fig. 13

05.

FEMUR MEASUREMENT

- This system provides two modes: front reference and back reference.
- Front reference:
  To avoid multiple resection of the anterior cortex leading to Notching, and better reconstruct the patellar joint space;
  The variability of posterior resection, pay attention to adjusting the flexion gap to avoid excessive flexion;
  More flexibility than less: avoid too tight flexion and reduce mobility.
- Back reference:
  Advantages: The flexion gap can be equal to the straightening gap;
  Disadvantages: the anterior cortex is easy to excessively resected;
  The prosthesis is too small to cause Notching in the front;
  The prosthesis is too large to cause patellofemoral joint being too tight.

Refer to the Insall line and Whiteside line to determine the femoral external rotation angle, and select the corresponding external rotation angle block (optional angles of 0°, 3°, 5° and 7°, pay attention to the left and right sides), and connect it to the femoral size measuring device (usually rotating externally by 3° is recommended). Place the femoral size measuring device close to the osteotomy surface of the distal femur, and hook the posterior condyle of the femur with the two wings.

Fig. 14

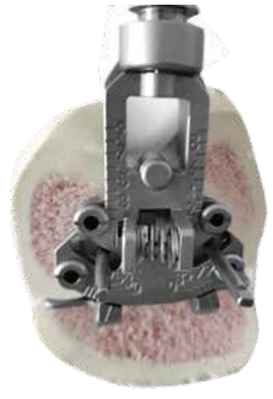


Fig. 15

- Place the measuring positioner against the osteotomy surface of the distal femur, and the back base of the measuring positioner should be closely attached to the posterior condyle of the femur. The pin can be driven into the fixing hole (as shown in the Figure) to ensure that the measuring positioner is stable. Pinch the button, rotate the measuring positioner, and adjust the external rotation angle to make it parallel to the condyle line and perpendicular to the Whiteside line.

Fig. 16

- Move the measuring probe installed on the size measuring device and adjust the length of the sliding probe appropriately until it touches the highest point of the anterior femoral cortex. Determine the size of the femoral prosthesis model according to the readings shown on the measuring device. After determining the external rotation angle, drive 2 fixed nails into the nail hole and remove the femoral size measuring device.

06.

FOUR-IN-ONE OSTEOTOMY

- Choose a suitable four-in-one femoral osteotomy plate, pass the nail hole marked with "0" through the two pins, place the osteotomy plate and fix it with a pin. If the position of osteotomy plate (forward or backward) needs to be adjusted, it can be made by adjusting the holes on the four-sided osteotomy plate (hole distance 1mm); perform osteotomy sequentially from the anterior condyle, posterior condyle and anterior oblique to posterior oblique. After the osteotomy of the anterior and posterior condyles has completed, and the 2 long nails can be removed.

Fig. 17

- Clean the bone tissue and install the CR trial condyle and perform perforated osteotomy (reserving theposterior cruciate ligament femoral prosthesis).

Fig. 18

Fig. 19

Fig. 20

07.

INTERCONDYLAR OSTEOTOMY

- Install the trial condyle of the same model as the four- in-one osteotomy plate, connect the condyle holderwith quick-change handle to install the trial condyle, adjust the appropriate position, fix it with a long nail, install the intercondylar osteotome on the quick connect handle, and then drive the intercondylar bone knife into the osteotomy slot above the trial condyle,or use a reciprocating saw, and perform the fossa intercondyloidea osteotomy with bone knife parallel to the intercondylar guide plate or the pendulum saw close to the inner wall of the trial condyle. Use the quick-change handle to connect the arc bone knife or the rongeur to clean the residual bone in the intercondylar fossa, and then use the intercondylar densifier to shape the intercondylar fossa.

- Drill two positioning holes on the trial condyle with a 6mm depth-limiting drill bit to install the trial intercondyloid notch.

08.

TIBIA PROSTHESIS SIZE DETERMINATION

- Choose the tibial plateau tray of the same model as the femoral trial condyle (the tibial plateau support specimen can be adjusted according to the type of tibial coverage) and the corresponding tibial plateau cushion specimen, and repeat the flexion and extension for three to four times after assembly to evaluate the gap between the extension and flexion zone, the matching of the prosthesis, and the stability of the ligament. At the same time, the lower limb line of force shall be measured. Remove the tibial plateau trial model, and use the condyle holder to remove the femoral condyle trial model.

Fig. 21

Fig. 22

Fig. 23

Fig. 24

09.

TIBIA FORMING

- Place the tibial plateau trial model according to the tibial mark previously determined, install the tibial force line handle and force line rod to determine the lower limb force line, and use the positioning pin A to fix it on the tibia; install the tibial cavity drill guide to the tibial tray and use a tibial drill to drill the tibial medullary cavity.

- Remove the tibial medullary drill and medullary cavity drill guide, and connect the quick-connect handle with corresponding type of tibial medullary cavity file to shape the proximal medullary cavity of the tibia.

10.

PROSTHESIS FITTING

- Assemble the femoral condyle products with column wrench to lock the femoral column.

Fig. 25

- Place the tibial plateau on the driving washer, use the quick-change handle to connect the plug driver to drive the plug to lock the taper; and tighten the fastening screw with quick-change handle and box spanner.

Fig. 26

- Fill the tibial medullary cavity with bone cement, use a tibial plateau driver to drive the cement into thetibial plateau tray, and quickly remove excess bone cement with cement scraper.

Fig. 27

Fig. 28

Fig. 29

Fig. 30

Fig. 31

- Apply bone cement to the femoral condyle prosthesis completely or evenly spread the bone cement on the osteotomy surface of the femur, and use the femoral condyle driver to press and compact it by aiming at the positioning hole. Clean the bone cement with bone cement scraper. When it is not solidified, follow the tibial plateau pad and reset to do flexion and extension exercises two to three times, then straighten the knee joint to give a certain strength,and wait for the cement to solidify.

- Have final confirmation on the knee joint gap and stability with tibial plateau pad and select the appropriate tibial plateau pad prosthesis, and use the tibial plateau pad to drive it in. (Pay attention to the angle when driving in)

- Apply bone cement on the patella and install the patella prosthesis, ensuring that the pins are alignedwith the corresponding pin holes. Fix the patellaprosthesis with patella forceps At the same time,remove the squeezed bone cement and wait for the bone cement to solidify before removing the patella forceps.

11.

INCISION SUTURING

- After the bone cement has cured and all excess bone cement has been removed,the joint shall be rinsed thoroughly. Close the soft tissues in a normal layered manner.

VI

Rehabilitation training guidance program after total knee arthroplasty

The recovery of the function of the affected limb after joint prosthesis arthroplasty depends not only on the success of the operation, but also on postoperative rehabilitation exercise. The time for postoperative rehabilitation exercise starts on the day after the operation and lasts for half a year after the operation. It is generally consists of five phases:

PHASE I

0-2/3 days after operation, patients only need to stay in bed or get up to just do the foot back extension exercise for 6-8 hours a day, about 15 minutes per hour.

PHASE II

The formal rehabilitation exercise shall start after the drainage tube was pulled out 2/3 days after the operation, the sutures were removed and discharged from the hospital 2 weeks after the operation.

- Firstly, stand on the ground with crutches, and walk with crutches after the head feels no dizzy. The patient is only allowed to bear part of the weight, and the intensity of exercise is limited to going to the bathroom every day, and walking on the ground shall do as little as possible in the remaining time.
- CPM exercise: Starting with knee flexion at 40°, and increasing knee flexion by 10° every day until it reaches 120°.
- Another 5 movements are required to be started 3 days after the operation (the second phase). In the second phase, the frequency and intensity of the exercise should be gradually increased according to the specific situation, and it is best to meet the requirement for phase 3 exercise when exiting the hospital.

PHASE III

6 weeks after operation and discharged from hospital.

- In this phase, patient is only allowed to walk on the ground with crutches, and the affected limb can be loaded with weight. The intensity of daily exercise is determined by being able to walk to bathroom as a limit, and walking on the ground shall do as little as possible in the remaining time.

- There are five exercise methods. The first three are exercises to straighten the knee joint, which is the most important; and another two are to practice the flexion and extension of knee joint, which is also very important. The first movement: Lie on the bed and lift your feet straight up, lasting for 10 seconds a day. A total of 100 time of such exercise shall be performed with one leg a day. The second movement: Life up lower leg on the edge of the bed. Lasting for 10 seconds a day. A total of 100 time of such exercise shall be performed with one leg a day. The third movement: push down to passively straighten knee joint on bed: the heel is padded up about 5cm away, and the knee joint is continuously pressed for 3-5 minutes with 3-5 kg of force or an object of equal weight each time, 10 times a day for one leg. The fourth movement: hold the lower leg on bed to flex the knee joint to the maximum pain that can be endured, lasting 3-5 minutes a day, a total of 10 times a day on one leg. The fifth movement: press the lower leg on the side of bed to flex the knee joint. Flex the knee joint to the maximum pain that can be endured, lasting 3-5 minutes a day, 10 times a day on one leg.

- Such 5 movements are required to be started 3 days after the operation (the second phase). In the second phase, the frequency and intensity of the exercise should be gradually increased according to the specific situation, and it is best to meet the aforementioned intensity and frequency for phase 3 exercise when exiting the hospital.

- In this phase, patient is only allowed to walk on the ground with crutches, and the affected limb can be loaded with weight. The intensity of daily exercise is determined by being able to walk to bathroom as a limit, and walking on the ground shall do as little as possible in the remaining time. In the second and third phases of exercise, knee pain must occur mainly caused by muscle and ligament pain during exercise, especially at night. So there is no need to be excessively nervous, and be sure to apply an appropriate amount of painkillers. The combination of two drugs is recommended, the "Indomethacin suppository", taking one or half to plug into anal a day, its effect is mainly to prevent knee joint adhesion and heterotopic ossification in addition to analgesia, anti-inflammatory and antipyretic; the other is oral anti-inflammatory analgesics, such as "Celebrex", "Voltaren", "Fenbid", and "Tramadol", either one of them can be used together with "Indomethacin suppository".

- In week 6 after surgery, it is recommended to find the surgeon for a review. According to the rehabilitation of the affected knee, the method, intensity and frequency of exercise will be further scheduled. If it is inconvenient for patients to see a doctor, please communicate with the surgeon on the phone about the exercise status.

PHASE IV

6 weeks to 3 months after surgery.

- The exercise is still of the five movements in the third phase, the intensity and frequent are the same as those in the third phase, and patients are allowed to walk on the ground with the aid of crutches.
- The affected limb can be fully weight-bearing, just make sure the intensity of exercise are adequate and appropriate.
- Reexamination by surgeon must be conducted after 3 months. If the function recovery is not as desired, there is still a chance to get good functions through methods such as massages. Otherwise, there will be no chance for improvement after more than 4 months.

PHASE V

3 months to 6 months after surgery.

- The exercise method is still of the five movements in the third phase. The intensity and frequency can be appropriately reduced but it is best not to be less than half of the intensity and frequency in the third and fourth phases, for which purpose is to maintain and consolidate the rehabilitation effect.

- otherwise, the recovery effect will be reversed in the sixth month after surgery. 6 months after the surgery, the effect obtained through the above rehabilitation will remain stable until the end of life, and there is no need for any other systematic rehabilitation exercise.

Wish all patients a speedy recovery

VII

Technical Parameters

Femoral condyle (unit: mm)

Model	1#	2#	3#N	3#	4#N	4#	5#N	5#	6#N	6#	7#N	7#	8#	9#
AP	48	50.5	53	53	55.5	55.5	58.5	58.5	61.5	61.5	65	65	68	71
ML	55	58	58	61	61	64	64	67	67	70	70	73	76	79

Tibia plateau pad (unit: mm)

Model									
	1#-10	2#-10	3#-10	4#-10	5#-10	6#-10	7#-10	8#-10	9#-10
	1#-11	2#-11	3#-11	4#-11	5#-11	6#-11	7#-11	8#-11	9#-11
	1#-12	2#-12	3#-12	4#-12	5#-12	6#-12	7#-12	8#-12	9#-12
	1#-13	2#-13	3#-13	4#-13	5#-13	6#-13	7#-13	8#-13	9#-13
	1#-14	2#-14	3#-14	4#-14	5#-14	6#-14	7#-14	8#-14	9#-14
AP	37	38.3	40.3	41.3	43.6	45.8	47.2	49	51.4
ML	58	60	63	65	69	72	75	78	81

Tibia plateau tray (unit: mm)

Model	1#	2#	3#	4#	5#	6#	7#	8#	9#
AP	40.5	42	43.5	45	47	49	51	54	57
ML	60	63	66	69	72	75	78	81	84

Patella (unit: mm)

Model	26	28	30	32
Length	26	28	30	32