





SKI PS High Flexion Total Knee System

Surgical technique

JUST KNEE True knee set sail



KNEE STEPWISE SURGICAL SOLUTIONS



Dynamic fatigue tests after 10 million cycles in the international CNAS laboratory shows excellent results and no risk of fracture. Dynamic wear tests after 5 million cycles in the international Endolab® laboratory in Germany shows excellent wear resistance.

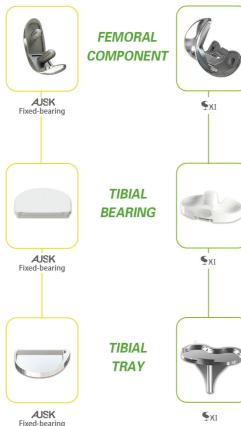


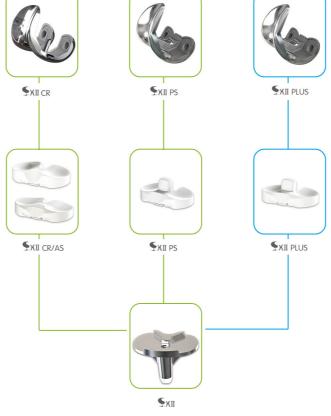


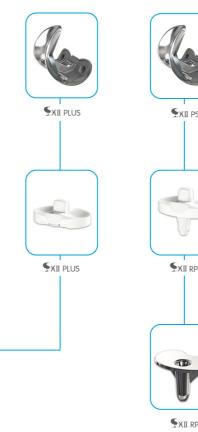


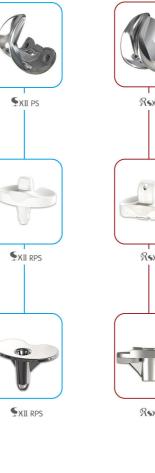


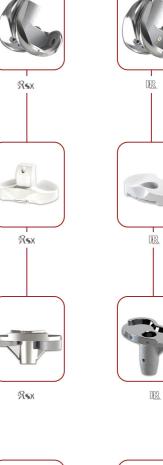






















































PRIMARY -

CUSTOMIZED ____ REVISION ———

Imported Raw Materials

All raw material of UHMWPE inserts were manufactured in Germany, meeting the technical requirements in ISO 5834 part 2 and ASTM F648.





Precise Processing







Strict Inspection

JUST MEDICAL Inspection Center





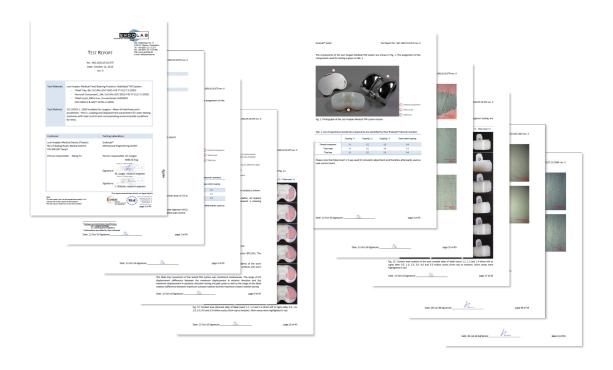


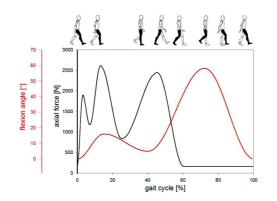
Wear Test in EndoLab®

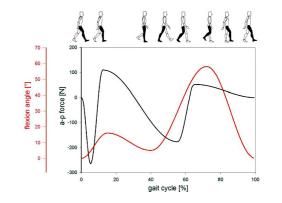
EndoLab® GmbH offers a variety of technological implant testingservices to develop and certify medical products.

EndoLab® is an accredited (DAkkS O-PL-18838-02-00) and certified (ZLG-P-944.98.07) test laboratory according to DIN EN ISO/IEC 17025 and 93/42/EWG.

The company is a spin-off from the Technical University of Munich and is closely connected to several national and international research departments.

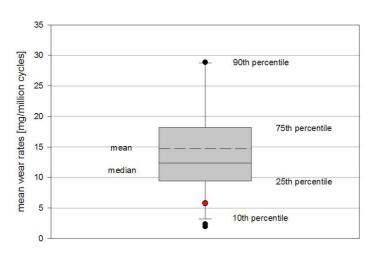






本实验旨在测试嘉思特医疗固定平台后稳定型全膝关节系统的磨损表现。

SKI PS High Flexion Total Knee System



经过500万次模拟人体正常运动的活动周期后,测得嘉思特医疗全膝关节系统的平均磨损率为5.79 mg/百万次。与EndoLab®数据库比较,嘉思特医疗全膝关节产品的平均磨损率低于EndoLab®,目前测得的平均值14.73mg/百万次。

▲ 嘉思特膝关节系统的数据为红色标记

专利证书

专利名: 一种改良滑车沟型股骨髁假体专利号: ZL 2015 2 0299126.3专利名: 一种可调型股骨远端截骨导向器专利号: ZL 2015 2 0253076.5专利名: 一种可调节 膝关节股骨外旋角度装置专利号: ZL 2016 2 1010838.X



SK1 high flexion PS knee prosthesis meets the requirements of different sex and figure's patients who need to have total knee joint replacement

♦ Design Features

- 1. Optimized patellofemoral articular surface: deeper, extended, swept-back, wider trochlear groove:
- ■2. Extended cam and heightened PS post;
- 3. Maximized preservation of bone stock;
- 4. Sizing;
- 5. Effective reduction of postoperative wear.



Rounded Sagittal Profile

Two distinct femoral designs: Anatomic (box-like) femoral profile and swept-back (rounder) femoral profile. Rounded sagittal profile, as founded in the SK1 knee, allows for greater range of motion and may be more forgiving to the retinaculum by not over tensioning the soft tissues.



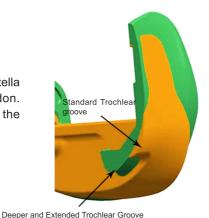
Anatomic (Green) vs. Swept-back Sagittal Profile (Gray)

Deeper/swept-back Trochlear Groove

The trochlear groove is a critical design feature for patella performance. Translation of the trochlear groove posteriorward in the femur has shown to resist patella crepitus and clunk. The SK1 trochlear groove has been designed to sweep back posteriorly for better patellar performance.

Extended Trochlear Groove

The trochlear groove has been lengthened to further support the patella in deep flexion and provide more support of the quadriceps tendon. The junction of the trochlear groove and PS box articulates with the quadriceps tendon at 105-120 degrees of flexion.





Wider Proximal Trochlear Goove

Patellar capture during flexion must be balanced with the need for less patellar constraint in extension. The trochlear floor of the SK1 knee has been widened to reduce the constraining forces in extension. The patella track provides a 6.5 degree valgus angulation and a 2mm lateralized trochlear groove. "Valgus angulation has been shown to reduce the patellar shear stresses."

Except the wider trochlear groove, SK1 knee system provides a set of plan to accords with the biomechanics of patellofemoral joint, including loosening of femoral retinaculum, more lateral trochlear and clinically proven good effect circular patella. To sum up the above total features, the wider proximal trochlear groove offers excellent patellar tracking (within 0-15 degrees of valgus) regardless of the patient's Q-angle. The loosening of femoral retinaculum will decrease effectively the tensile force of soft tissue to reduce the potential need to the loosening of lateral accessory ligament.

To solve the problem of rim overhang, SK1 knee system designs the femoral rim with round corner. The patient in small figure, especially the female patient, the top element about overhang is that the femur is good match or not.

6



Tibial-Femoral Contact

To increase contact area with axial rotation, the SK1 knee features a rotated articulation bearing surface. As compared to a linear articulation, a rotated articulation increases the contact area by 13 percent.



Rotated Articulation Bearing Surface



The coronal geometry features softened intercondylar M/L edges. This radius enhancement provides increased contact area when the patella articulates on the condyles in flexion. A Finite Element Analysis has demonstrated a 25 percent reduction in patella contact pressure compared to a conventional total knee.

SK1 knee system provides a fully congruent

(coronally), moderately dished articulation to reduce

Coronal Features

polyethylene stresses.





High Flexion Patellar Tendon Rei

Increased Range of Motion

SK1 knee system has been designed to allow up to 145 degrees without additional posterior condyle resection. The SK1 tibial bearings have a deep anterior relief to accommodate the patella tendon during high flexion.

PS Proportional Intercondylar Resection

PS intercondylar resection becomes proportional larger increasing with the size. This design helps to improve the bone coverage; for the smaller femur, decrease the flexion gap resulting from the excessive resection; for the larger femur, avoid effectively that the hypocondylar box is too small. Excellent hypocondylar coverage helps to reach the high flexion and reconstruct the femoral offset. Optimize the hypocondylar shape, provide the larger contact area when flexion. Larger contact area will disperse the stress more effectively.

New Femoral Sizes

SK1 knee system offers nine femoral sizes and seven tibial sizes and increases the flexibility intraoperatively, at the same time maintaining the ability to complete the inter-change. No matter femur and tibia that is good enough for solving the special anatomic profile for different patients. SK1 total knee system is the most flexible in the Chinese market and specifically designed for optimal bone coverage of all patient populations.



9 Femoral Sizes

Posterior Stabilized Design Features

The SK1 PS femoral component has been specifically designed to enhance performance. Key elements design includes:

Cam and Post Engagement

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The cam, of the SK1 PS femoral component, is designed to engage the post of the tibial bearing at 45 degrees of flexion. Gait analysis demonstrates that the weight bearing phase occurs from 0-45 degrees. After weight bearing phase occurs, the cam engages the post to provide stability and increase quadriceps efficiency, specifically during activities such as ascending and descending stairs. Mid-flexion cam engagement avoids cam and post contact during cycle activities but provides for stability during load activities.

PS Plus Bearing Design

The prominent anterior lip of the PS plus bearing helps resist paradoxical anterior femoral slide during gait phase. This cradling effect controls the femoral component on the articulating surface without sacrificing freedom of rotation. The combination of 45 degrees cam engagement with a prominent anterior lip limits premature wear of the tibial post and provides mid-flexion stability.



Prominent Anterior Lip

45° 60° 775° 90° 17.3

Height The normal programment relatively law on the tiblical beauting post

Lower Cam Engagement Position/High Dislocation

The cam engagement relatively low on the tibial bearing post and remains low throughout full range of motion. The forces at the tibial bone interface and locking mechanism are decreased, while maintaining a high bearing dislocation height. The dislocation height of the SK1 PS is never less than 17.3mm at 90 degrees of flexion or greater. The SK1 PS component allows for 10 degrees of hyperextension before anterior post impingement.



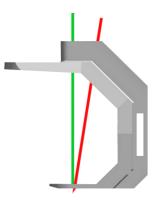
PS Bearing Design

PS post geometry is rounded to minimize forces on the post due to femoral rotation. According to a mechanical wear simulation test, the SK1 PS bearing had a 71 percent reduction in gravimetric wear at 5.5 million cycles, as compared to standard square post design geometry.



SK1 knee system offers an open box femoral component.

The open box design allows for additional preservation of distal bone. Utilizing the bone conserving resection with the open box design is made for closed box design. The open box femoral component can be implanted utilized either the open box or the bone conserving resection level.

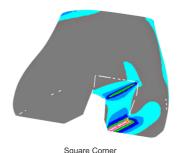




Milled Intercondylar Notch

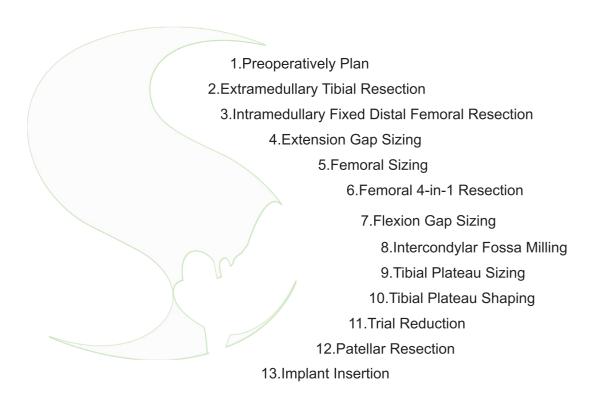
resection.

Instrumentation system specifically offers the milling PS resection instrument. Retain the PS box bone amount around the corner by milling and additionally preserve five percent intercondylar resection.



Round Corner

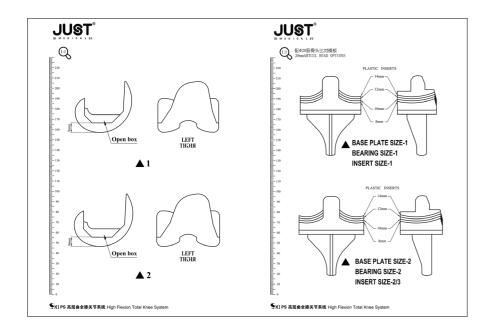
A Finite Element Analysis demonstrated the lower stress concentration in intercondylar resection corner

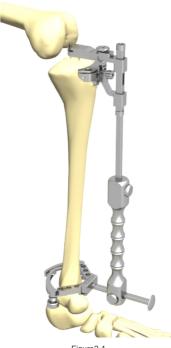


I. Preoperatively Plan

In order to assess bone stock, potential ligament instability and the anatomical axis, a long standing A/P X-ray is recommended. Determine the angle between the anatomic and mechanical axis, assuring the distal femoral cut is perpendicular to the mechanical axis. Estimate femoral component size preoperatively by using lateral view X-ray and radiographic templates. Confirmation of the appropriate size component intraoperatively is critical for normal kinematics.

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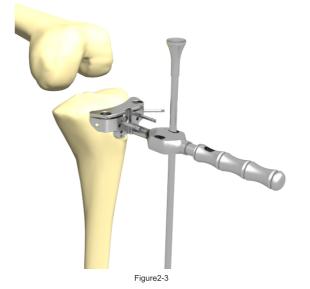
II.Extramedullary Tibial Resection

With the knee flexed, placed the spring loaded arm of the ankle clip around the distal tibia just above the malleoli. Press the silver button on the body of the tibial resection to change the height of the tibial cutting block. Place the tibial cutting block against the proximal tibia.(Figure 2-1).

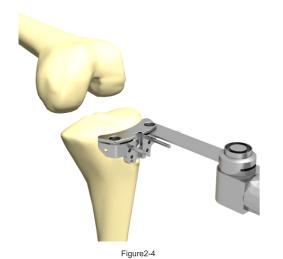
Figure2-1

Set the stylus to read 10mm. From the sagittal view, depress the side of the EM guide along the perpendicular shaft of the guide bottom until the tubular body is parallel with the shaft of the tibia. Once the adjustment of the resector axis is correct in the M/L view, rotate the resector until the shaft of resector is just medial to the tibial tubercle. Push the gold button on the top of the stylus to release the stylus locking mechanism and snap the stylus into the top of the tibial cutting locking.Set the stylus to read 2mm when referencing the most affected condylar.(Figure 2-2)





To confirm alignment, an power line calibrator can be placed on the tibial cutting block and a 6.4mm alignment rod can be inserted into the lateral hole of the power line calibrator.(Figure 2-3)



Resect the proximal tibia, using a sawblade(Figure 2-4).

III.Intramedullary Fixed Distal Femoral

Utilize the intramedullary taphole drill to penetrate the femoral canal to a depth of approximately 3.5-5 cm. Place the canal entry location 1cm above the insertion of the posterior ligament and slightly medial in the

Resection

intercondylar notch (Figure 3-1).



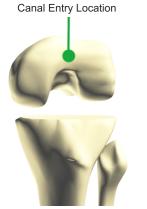


Figure3-1

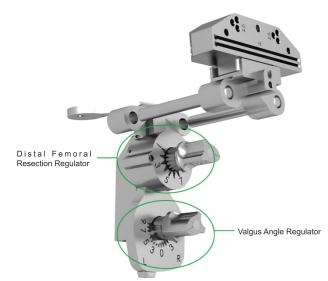


Figure3-2

Set the adjustable distal femoral osteotomy guide to the desired valgus angle by pressing and turning the valgus angle dial. A valgus angle setting of 5 to 7 degrees is available. Select the depth of 9mm of distal resection by turning the resection level dial (Figure 3-2).

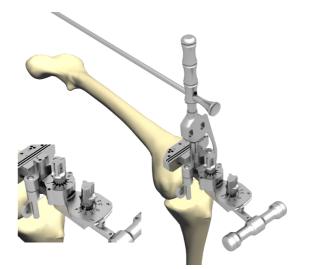
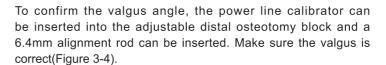


Figure3-3

Attach the adjustable distal femoral osteotomy module connector and distal femoral osteotomy block to the adjustable femoral resection guide by sliding the two legs on the connector through the anterior holes of the osteotomy guide. Attach the distal femoral osteotomy block to the distal osteotomy guide. Continue sliding the connector until the block is sitting against the anterior cortex. Pin the osteotomy block into place (Figure 3-3).



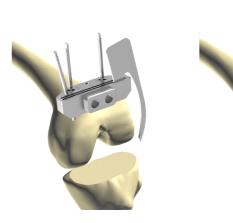


Figure3-5

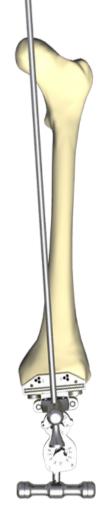
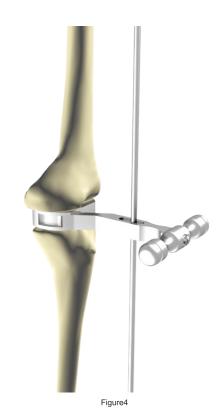


Figure3-4

The two resection slots of 0 and +3mm are available for the distal resection. The 0mm slot will resect 9mm from the most prominent part of the contacting distal condyle. If additional distal resection is required, the +3mm slot will resect 12mm. If additional distal resection is required beyond the +3mm slot, shift the rosteotomy module connector proximal by utilizing the +2 or +4mm pin holes (Figure 3-5).

B



IV.Extension Gap Sizing

Combine the gap measurer with the different thickness of gap measurer insert and insert the 6.4mm alignment rod at the same time, extending the knee, which is good for making sure the thickness of the insert and confirming the alignment (Figure 4).



Place the adjustable A/P measuring device against the resected distal surface with the feet in contact with posterior condyles of the femur. Three options are available feet: 3 degree external rotation (left and

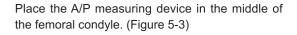
V. Femoral Sizing

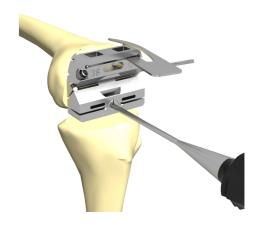
14

right) and neutral (Figure 5-1).

VI. Femoral 4-in-1 Resection

Choose the slotted femoral 4-in-1cutting block that matches the selected size on the A/P measuring device and place it into the holes drilled into the distal femur. Handles can be attached into the sides of the femoral 4-in-1 block. Ensure the A/ P block is sitting flush against the distal femur (Figure 6-1).





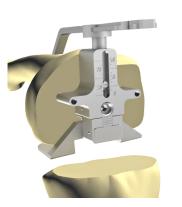
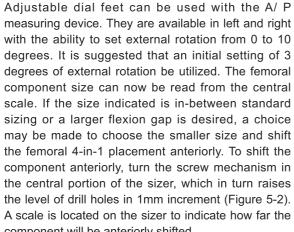
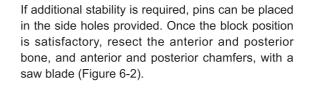


Figure5-1

measuring device. They are available in left and right with the ability to set external rotation from 0 to 10 degrees. It is suggested that an initial setting of 3 degrees of external rotation be utilized. The femoral component size can now be read from the central scale. If the size indicated is in-between standard sizing or a larger flexion gap is desired, a choice may be made to choose the smaller size and shift the femoral 4-in-1 placement anteriorly. To shift the component anteriorly, turn the screw mechanism in the central portion of the sizer, which in turn raises the level of drill holes in 1mm increment (Figure 5-2). A scale is located on the sizer to indicate how far the component will be anteriorly shifted.







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VII. Flexion Gap Sizing

Combine the gap measurer with the different thickness of gap measuring insert and insert the 6.4mm alignment rod at the same time, flexing the knee, which is good for making sure the thickness of the insert and confirming the alignment (Figure 7).



Figure6-2

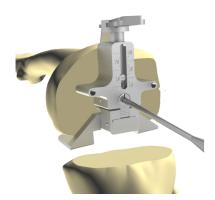


Figure5-2

VIII. Intercondylar Fossa Milling

Impact the size-specific box resection mill guide on the prepared distal femur.

Note: The M/L width of the standard PS intercondylar cutting block and mill PS box guides mimic the dimension of the final implant. Take care to position the guide to avoid overhang.

Secure the PS intercondylar cutting block with two drill pins through the holes located in the anterior flange.

Insert the appropriate size grinding drill into a power drill. Insert the tip of the grinding drill into the central hole in the posterior axle of the PS intercondylar cutting block. Under power, rotate the grinding drill around the axle anteriorly into the box guide. To guard against potential damage to the grinding drill tip, ensure the grinding drill is fully seated on the PS box mill pivot and avoid applying excessive force when milling. Use only as much force as necessary to aid the reamer's advancement through the bone. Repeat this step with the reamer inserted in both the medial and lateral positions. If a bone conserving resection is desired, insert the appropriate magnet limiting block prior to reaming (Figure 8-1 and 8-2).

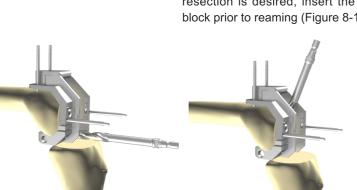


Figure8-2

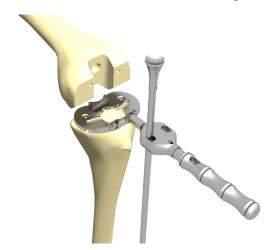
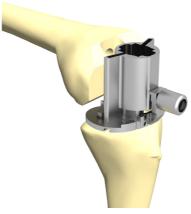


Figure8-1

Figure9

IX. Tibial Plateau Sizing

Slight external rotation is preferred to optimize patellofemoral tracking. Perform an initial trial reduction to confirm proper external rotation. When correct lateral rotation has been determined, mark the position by extending the anterior mark of the baseplate onto the anterior tibia with electrocautery and fix the tibial trial tray with the screws (Figure 9).







Introduce the primary reamer bore to provide an initial hole into the tibia. The primary reamer

bore should be fully engaged in the punch guide

before power is started (Figure 10-2).

Assemble the punch guide tower to the tibial tray

X. Tibial Plateau Shaping

(Figure 10-1).

After the punch is fully seated, press the button on top of the punch handle to release the punch head. The punch head sits in the tibial trial plate and acts as the trial stem.



Figure10-2

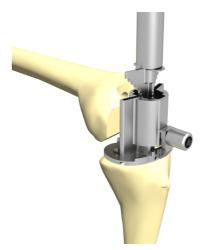


Figure10-3

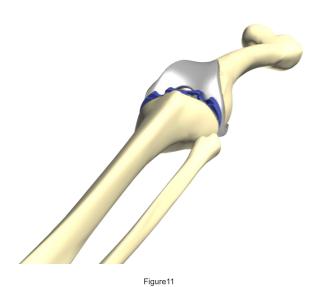
Carefully drive the trial punch into the guide until it mechanically stops (Figure 10-3).

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XI. Trial Reduction

Place the appropriate trial in the correct position. When the trial components are in place, check range-of-motion and stability of the knee (Figure 11).





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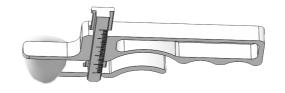


Figure12-1

XII. Patellar Resection

Tilt the patella to 90 degrees and remove the osteophytes and peripatellar tissues down to the level of the tendinous insertions of the quadriceps and patellar tendons. Determine the level of the cut through caliper measurement of the total patellar thickness (Figure 12-1).

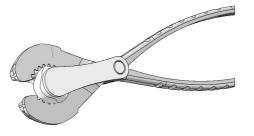


Figure12-2

Perform the initial patellar resection utilizing the patella clamp surface cut guide. Clamp the guide to perform a flat cut across the patella. A magnetic depth stylus may be utilized to determine the appropriate resection level. Select a trial patellar component to optimize coverage without increasing patellar thickness beyond preresection height (Figure 12-2).

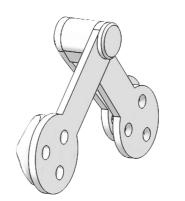


Figure12-3

Use the drill bit to make the central holes (Figure 12-3).

The insertion placement of patellar component is usually in the medial side of patellar center.

B



Figure13-1

XIII. Implant Insertion

1.Tibial Implant Insertion

Assemble the modular tibial component, by choosing the appropriate stem. Utilize the tibial impactor to firmly seat the component (Figure 13-1). Remove excess cement with a curette.



Figure13-2

2.PS Femoral Implant Insertion

Place the appropriate femoral component into position manually as far as possible.impacting with blow helps to pressurize the cement. Remove the extruded cement with a curette. The provisional bearing may be reinserted, and a trial reduction performed to confirm joint tension and stability. (Figure 13-2).



Figure13-3

3. Tibial Plateau Insert Insertion
Place the appropriate polyethylene bearing insert
on the tibial tray and make the final insertion

(Figure 13-3).

Parameter

Product name	REF No.	Specification (L/R)	A/P (mm)	M/L (mm)	Material	Product name	REF No.	Specification (L/R)	A/P(mm)	M/L(mm)	Material
	716008	1#(R)	55	59	C	Tibial Bearing	716026	1#×8	38	59	- PE
	716009	1#(L)					716027	1#×10			
	716010	2#(R)	57	61			716028	1#×12			
	716011	2#(L)					716029	1#×14			
	716012	3#(R)	59	64			716030	2#×8	41/43	63/67	
	716013	3#(L)					716031	2#×10			
	716014	4#(R)	61	66			716032	2#×12			
	716015	4#(L)					716033	2#×14			
Femoral	716016	5#(R)	63	68			716034	4#×8	46/48	71/75	
Condyle	716017	5#(L)					716035	4#×10			
	716018	6#(R)	66	71			716036	4#×12			
	716019	6#(L)					716037	4#×14			
	716020	7#(R)	68	73			716038	6#×8	51/53	79/83	
	716021	7#(L)					716039	6#×10			
	716022	8#(R)	70	75			716040	6#×12			
	716023	8#(L)					716041	6#×14			
	716024	9#(R)	72	78			716001	1#	38 41	59	
	716025	9#(L)					716002	2#		63	
Product				.	Material	Tibial Tray	716003	3#	43	67	С
name	F	REF No.	Specification				716004	4#	46	71	
		716042	28×	8			716005	5#	48	75	
Patella	-	16043 30		×9	PE		716006	6#	51 53	79	
		716044	34×9				716007	7#		83	

X ray film



Preoperative X-ray



Postoperative X-ray

JUST MEDICAL DEVICE(TIANJIN)CO.,LTD

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