United®
Orthopedic Corporation

U2™ Knee

Surgical Protocol

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Preface

Throughout the evolution of total knee replacement science, significant improvements have been achieved to both implant design and implantation techniques, refining the procedure to routinely provide measurable improvements in clinical results. Amidst these advancements, the body of science continues to evolve, inspiring further refinements in both TKR implant and instrumentation design. At United Orthopedic Corporation, our research and development efforts have focused on a comprehensive review of the contemporary state of the art, an observance of time proven performance and design elements, and thoughtful analysis of those areas which may be improved through refined design elements. Our research areas included a scientific review of contemporary TKR designs and their associated clinical performance, along with a dimensional analysis of normal human knee anatomy, a study of motion patterns which achieve deep flexion, and key mechanisms of wear and failure in present designs. We then applied this data to evaluate ideal implant shape, size range, contact geography, durability, and increased functional range of motion. The result is a comprehensive design intended to enhance patient satisfaction. We invite you to reference the U2 Design Rationale documents for further information.

Among the major features of the U2 Knee design are:

- A science-based size range for improved implant fit and associated capsular / soft tissue interactions
- An interchangeable femorotibial articulation for essier size matching
- A refined PS Progressive Rollback Post and Cam mechanism to provide more effective anatomic rollback behavior for improved ROM potentials
- An improved Post and Cam jumping distance to reduce dislocation potential
- A multi radius femoral component curvature to encourage physiologic ligament tension relationships

The U2 Total Knee System Instrumentation key components include:

- Anterior Reference System to accurately position anterior flange blending
- Distal Femoral Valgus cutting guide in 1-degree increments
- PS Notch Cutting Guide with powered Reamer and Osteotomes for precise preparation
- Both Intramedullary and Extramedullary Tibial Alignment Guide Options
- Both Inset and Onset Patellar Cutting Guide Options to accurately prepare and restore the patellar thickness
- Femoral/Tibial Spacer Blocks to allow assessment of the extension and flexion gap balance
- Four compact sterilization trays to provide efficient instrument handling

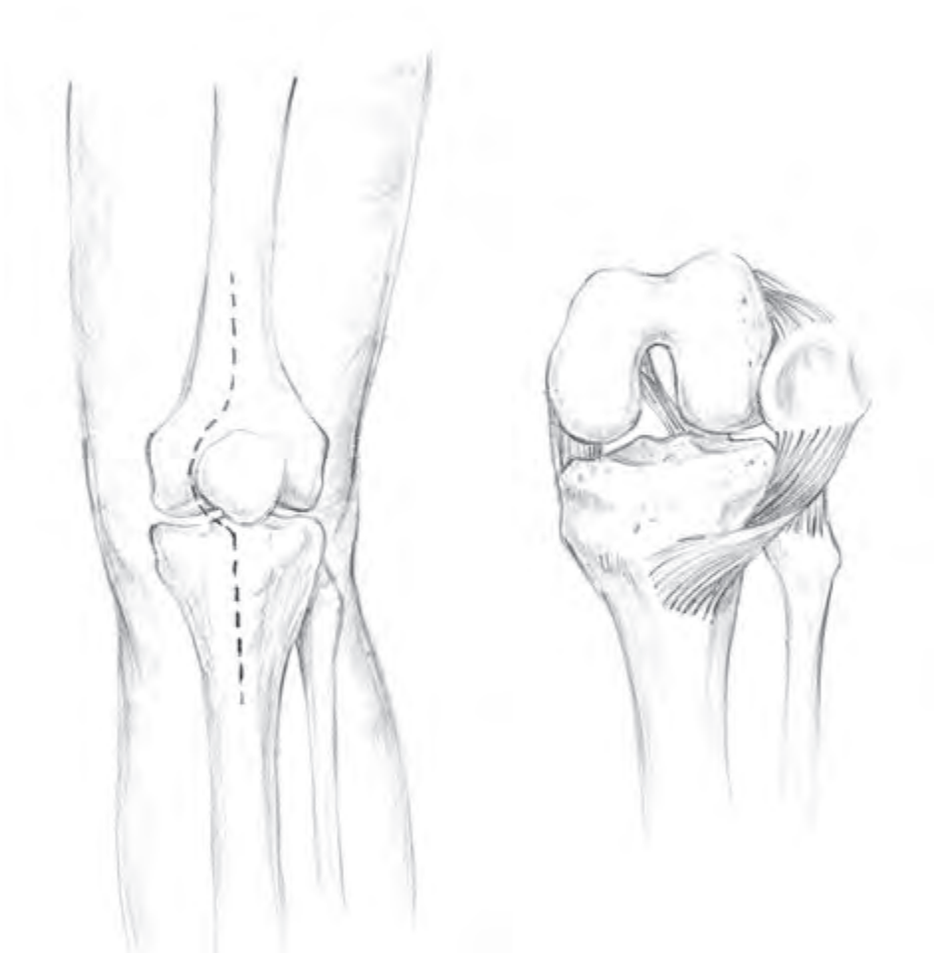
MIS options include minimal size instrumentation, a patented Distal Femoral Cutting Guide and Femoral Sizing Caliper to improve working within the spacial limitations of the incision.

CMA stem/augment options include instruments to allow adequate management of minor or moderate tibial defects with the use of augments and the extension stem.

Surgical Incision

The surgeon may select to use any standard exposure method to perform the skin and capsular incision. If the medial parapatellar approach is selected, a straight midline skin and capsular incisions, extending above and below the patella is applied to begin the exposure. The capsular exposure is then approached by utilizing a longitudinal medial parapatellar incision, typically extending upward to a level of one third of the rectus femoris or vastus medialis and downward to the medial side of the origin of patellar tendon on the tibial tuberosity.

Once the exposure is completed, the patella is everted in a standard fashion, and the knee joint is inspected under vision. Careful assessment and removal of the ostoephytes should be undertaken. In the meanwhile, ROM, patellar tracking, and soft tissue stability/instability should be evaluated again. It may be the preference of the surgeon to conduct a preliminary soft tissue release of the fixed contracted structures. Once completed, the knee is flexed to 90 degrees to perform the initial femoral pilot hole for the intramedullary alignment.



A. Femoral Preparation

A.1. Pilot Hole

1 Starter
9301-2101-RB

2 8mm Twist Drill
9301-3201

3 Alignment Rod
9403-2202

4 Femoral IM Rod
9303-3200,(400 mm)

5 T-Handle
9301-1100

With the ACL removed, the typical femoral entry hole location is thought to be slightly medial to the center of the intercondylar notch, and approximately 5 to 7 mm anterior to the anterior insertion of the PCL into the femur. Important note: As both varus and valgus deformities are commonly encountered in the Patient who receives Total knee arthroplasty, careful evaluation of the possible A-P and M-L curvature of the femoral shaft should be undertaken to consider shifting the initial entry hole to a more appropriate location for each patient.

A **Starter** [1] is used to mark the hole location, followed by the **8mm Twist Drill** [2] to create an opening in the femoral canal. The drill is typically inserted to a depth of approximately 100mm within the femoral canal.

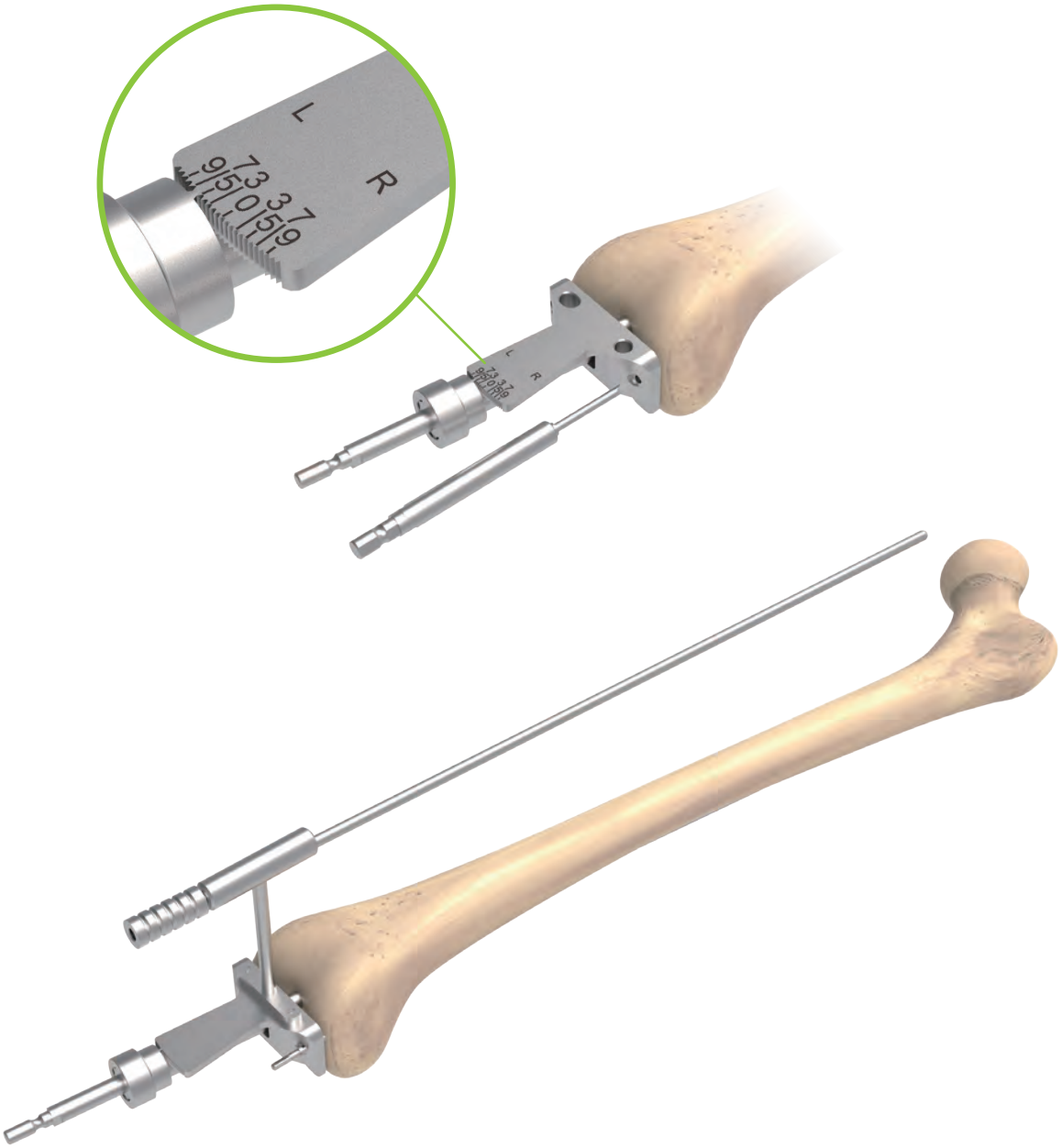
After removal of the drill, intramedullary fluid of the femur may be reduced by inserting the small diameter **Alignment Rod** [3] into the femoral shaft several times. This will also identify the femoral canal.

Once the canal is identified, the **Femoral IM Rod** [4] and **T-Handle** [5] is manually inserted into the femoral canal until the isthmus is engaged. Care should be taken when encountering the isthmus and make sure the rod can be completely pass through.
Please note: If the canal isthmus diameter is thought to be too narrow for standard passage of the rod, advancement is discontinued, and an intraoperative radiograph may be employed to access the appropriate location of the rod.

A. Femoral Preparation

A.2. Femoral Valgus Angle Confirmation

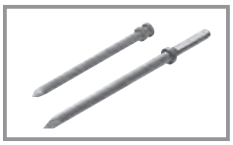
Take the **T-Handle** [5] off. Adjust the valgus angle (range: 0-11˚) on the **Femoral IM Alignment Guide** [6] to the pre-operative estimated angle. Slip the **Femoral IM Alignment Guide** [6] through the **Femoral IM Rod** [4]. Fix the **Femoral IM Alignment Guide** [6] with **Spikes** [8] to ensure the Guide is firmly contacted to the distal femur. The **Alignment Rod** [3] can be also attached to the **Extramedullary Alignment Tower** [7], following to the **Femoral IM Alignment Guide** [6] and directed towards to the center of the femoral head to confirm if the intended valgus angle is correct.



6 Femoral IM Alignment Guide
9303-2111-RA

7 Extramedullary Alignment Tower
9301-2282

8 Spike
9301-3207
9303-3201
9303-3202



A. Femoral Preparation

A.3. Distal Femur Cutting

Attach the **Distal Femoral Cutting Guide** [10] to the **Distal Femoral Alignment Guide** [9]. To secure the cutting guide, two **3.2 mm Twist Drills** [11] are drilled into the "0" hole site on the distal femoral cutting guide. Prior to cutting the distal femur, additional fixation may be achieved by utilizing the **Quick Pin Driver** [12] to place additional pins in the medial and lateral pin holes.

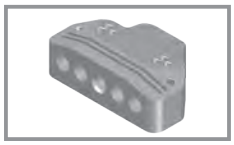
Once the instrument is secured, the resection is performed through the most distal slot in the instrument by using is a standard .050" (1.27 mm) thick saw blade.

NOTE : The +3 mm slot option may also be selected for use if the surgeon wishes to resect an extra 3 mm thick distal bone.

NOTE : +2 mm / +4 mm guide hole provides options to allow additional resection if desired at a later point in the procedure.

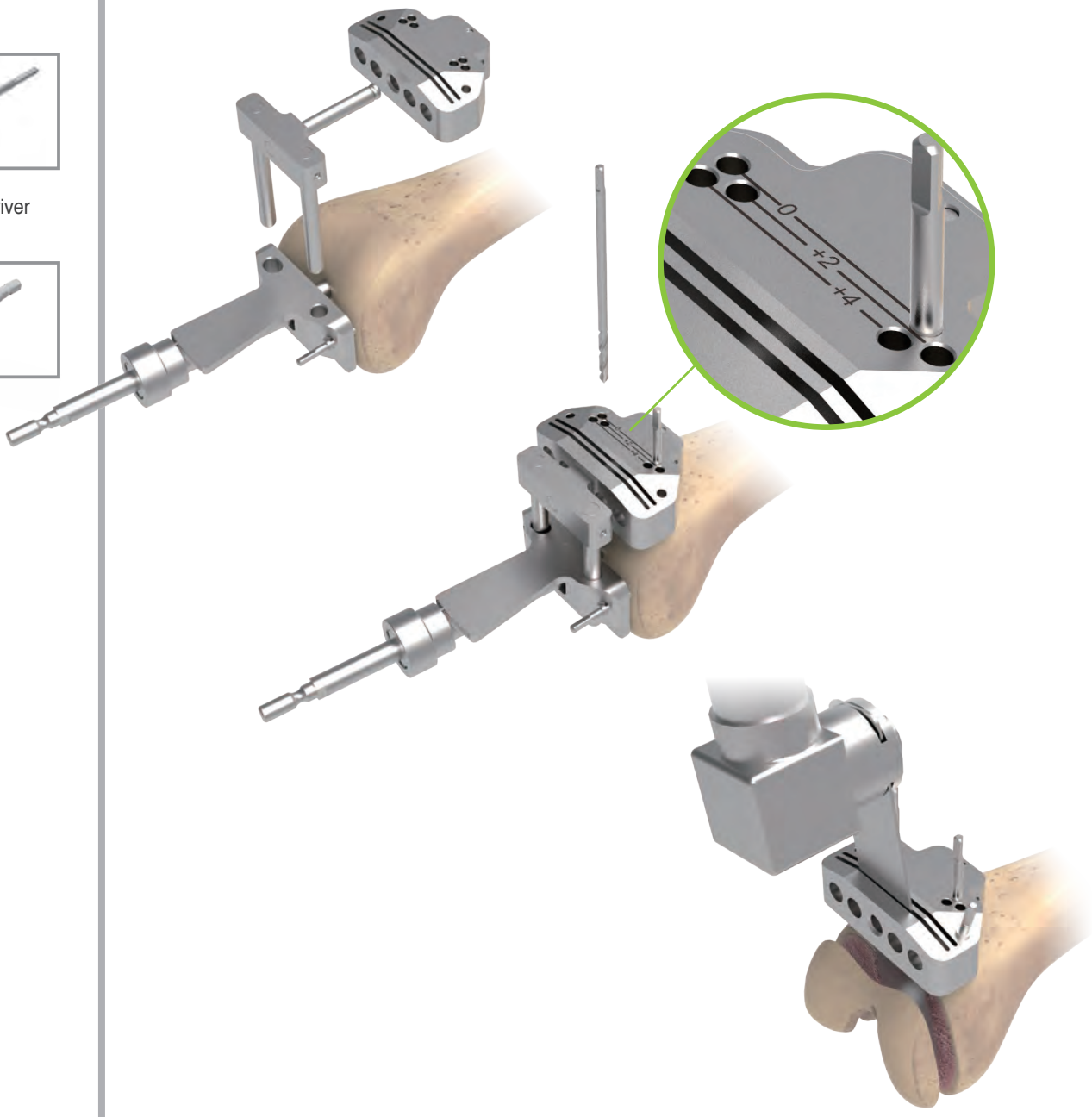
9 Distal Femoral Alignment Guide 9303-2102-RA

10 Distal Femoral Cutting Guide 9303-2103-RC



11 3.2mm Twist Drill 9303-3203 9303-3204

12 Quick Pin Driver 9304-5105

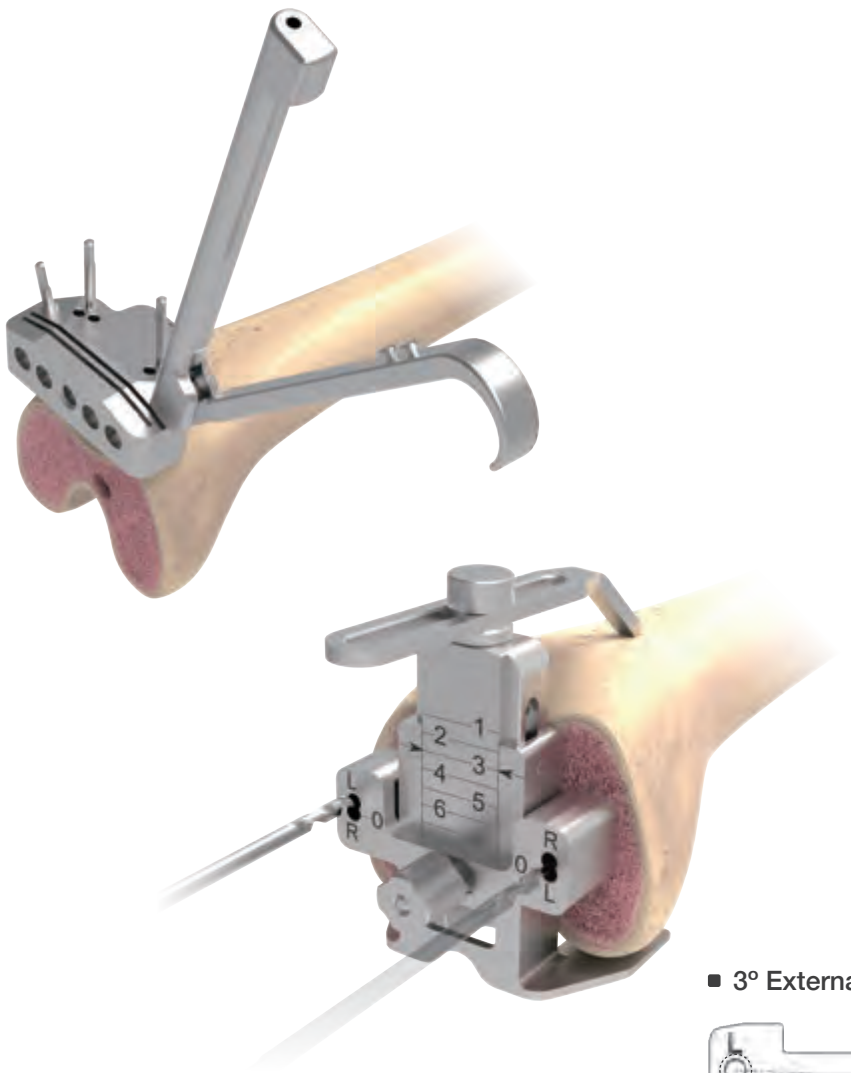


A. Femoral Preparation

A.4. Femoral Component Sizing

Extract the **3.2 mm Twist Drills** [11] and **Spikes** [8] with a **Pin Extractor** [13] and remove the **Distal Femoral Cutting Guide** [10] after resection. Place a **Femoral Sizer** [14] flush against the resected distal femur, with the two feet rested flat against the posterior femoral condyles and ensure its stylus touching the lowest point of the anterior femoral cortex. The estimated size is indicated on the front and tight the screw of the **Femoral Sizer** [14]. To estabilish a 3° external rotation, create the fixation pin holes with **3.2 mm Twist Drills** [11] through the holes that correspond to the affected knee (left or right) on the front of the **Femoral Sizer** [14]. The neutral position can simply be created by drilling the fixation pin holes through the drill holes labelled “0” on the front of the **Femoral Sizer** [14].

NOTE : The U2 Knee primary system is an anterior reference system. If the indicated size on the face of the guide is between two sizes, it is generally preferred to choose the smaller one. The additional bone resection will be removed from the posterior condyles.



- 3° External rotation

Left/Right

- No rotation

13 Pin Extractor
9303-5002

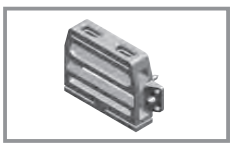
14 Femoral Sizer
Anterior Ref
9303-7101-RE

A. Femoral Preparation

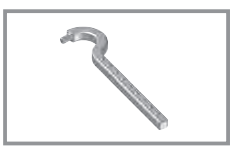
A.5. A-P Chamfer Cutting

Fix the chosen **Femoral A/P Chamfer Cutting Guide** [15] in the predrilled fixation pin holes (Note: it must be placed flush against the resected distal femur). Use **Spike** [8] or **Femoral A/P Chamfer Guide Handle** [16] to enhance the stability during resection and check resection thickness with the **Lower Point Gauge** [17]. Then, complete the four resection procedure with a 1.27 mm saw blade. At this point, the femoral preparation for posterior cruciate retaining femoral component is completed.

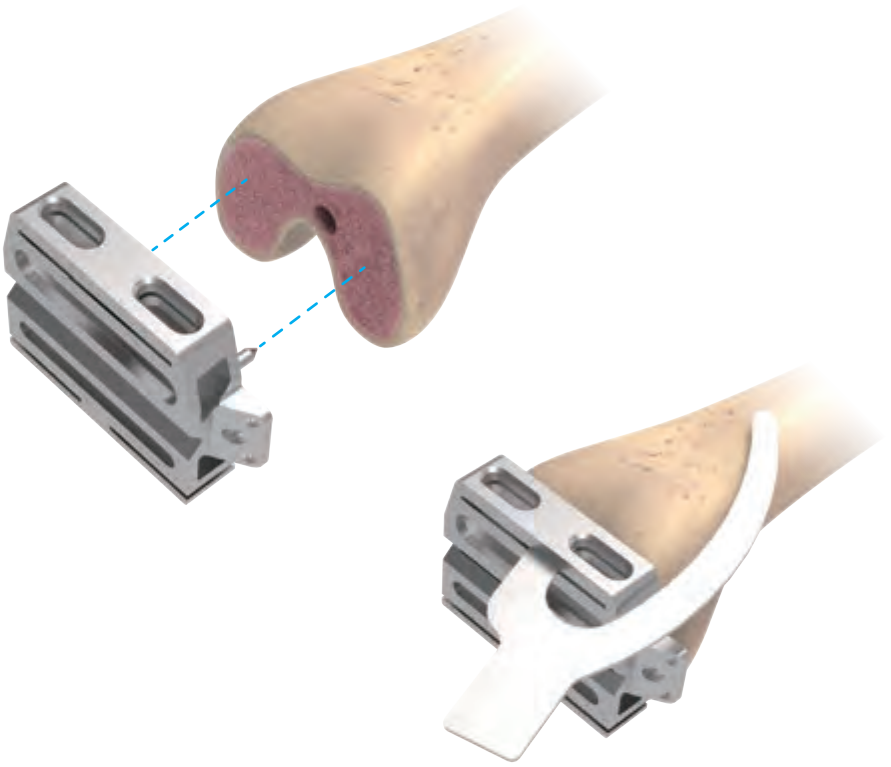
15 Femoral A/P Chamfer Cutting Guide
9303-2110-RC
9303-2120-RC
9303-2130-RC
9303-2140-RC
9303-2150-RC
9303-2160-RC

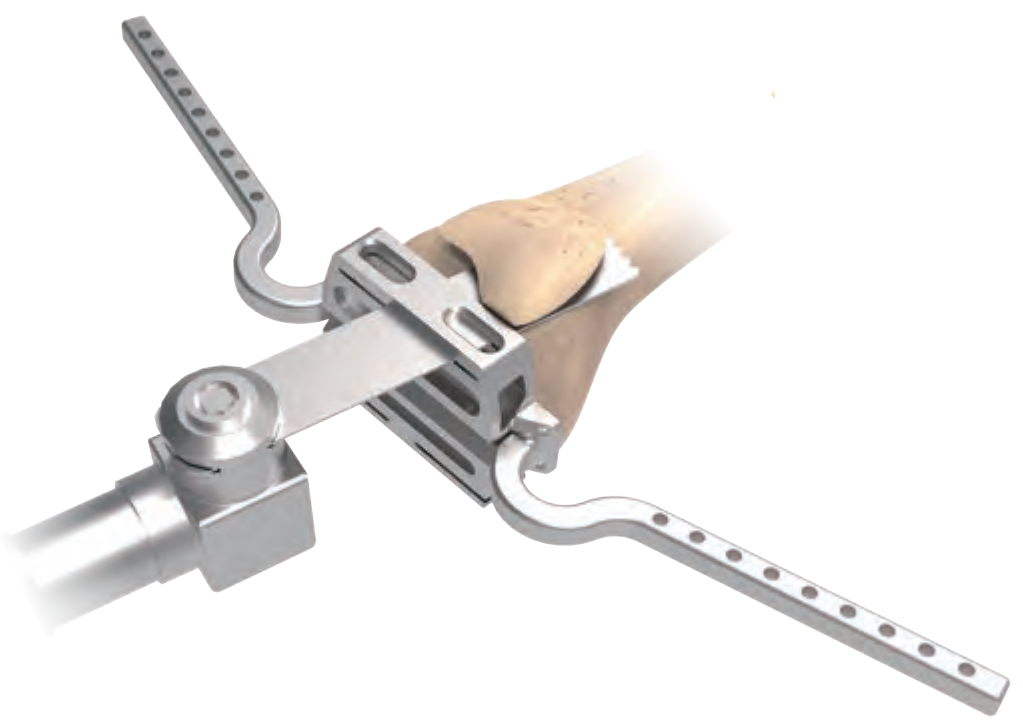


16 Femoral A/P Chamfer Guide Handle
9301-2291



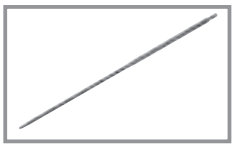
17 Lower Point Gauge, 1.3 mm
9301-2251





B. Tibial Preparation

18 Tibial IM Rod
9401-2203

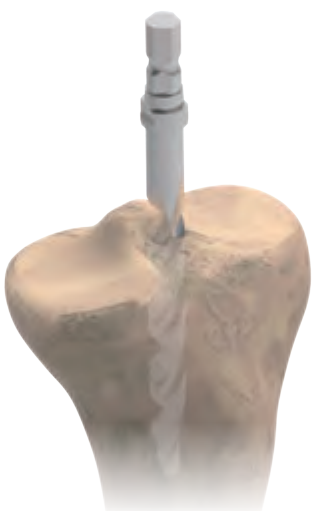


There are two options for preparing tibial platforms. One is the intramedullary alignment method, and the other is the extramedullary alignment method.

B.1. Tibial Intramedullary Alignment Method

B.1.1. Pilot Hole

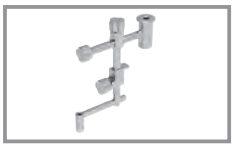
Flex the knee joint to the maximum angle and expose the whole tibial plateau by moving it anteriorly. Use the **Starter** [1] to create a pilot hole which is located at approximately 10 mm posterior to the origin of anterior cruciate ligament. Then, use an **8 mm Twist Drill** [2] to create canal with a depth of approximately 100 mm into the tibial. After taking out the drill, it is recommended to apply an **Alignment Rod** [3] into the marrow cavity several times to reduce the risk of fat embolism. Connect the **T-Handle** [5] to the **Tibial IM Rod** [18] and insert the assembly manually into tibial canal through the narrowest point inside. Then, remove the **T-Handle** [5]. If it is difficult to insert or align the **Tibial IM Rod** [18], enlarge the pilot hole with the **8 mm Twist Drill** [2] again.



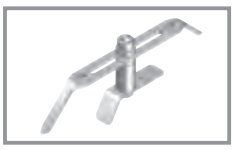
B. Tibial Preparation

B.1.2. Tibial Cutting Jig Positioning and Tibial Resection

19 Tibial IM Alignment Guide
9403-2103-RA



20 Tibial Stylus
9403-7101-RA



21 Tibial Cutting Jig
9403-2120-RE
9403-2220-RE

Position the **Tibial Cutting Jig** [21] onto the **Tibial IM Alignment Guide** [19]. With the thumb screw held loosely, the **Tibial Stylus** [20] may be used to establish the appropriate height position of the **Tibial Cutting Jig** [21].

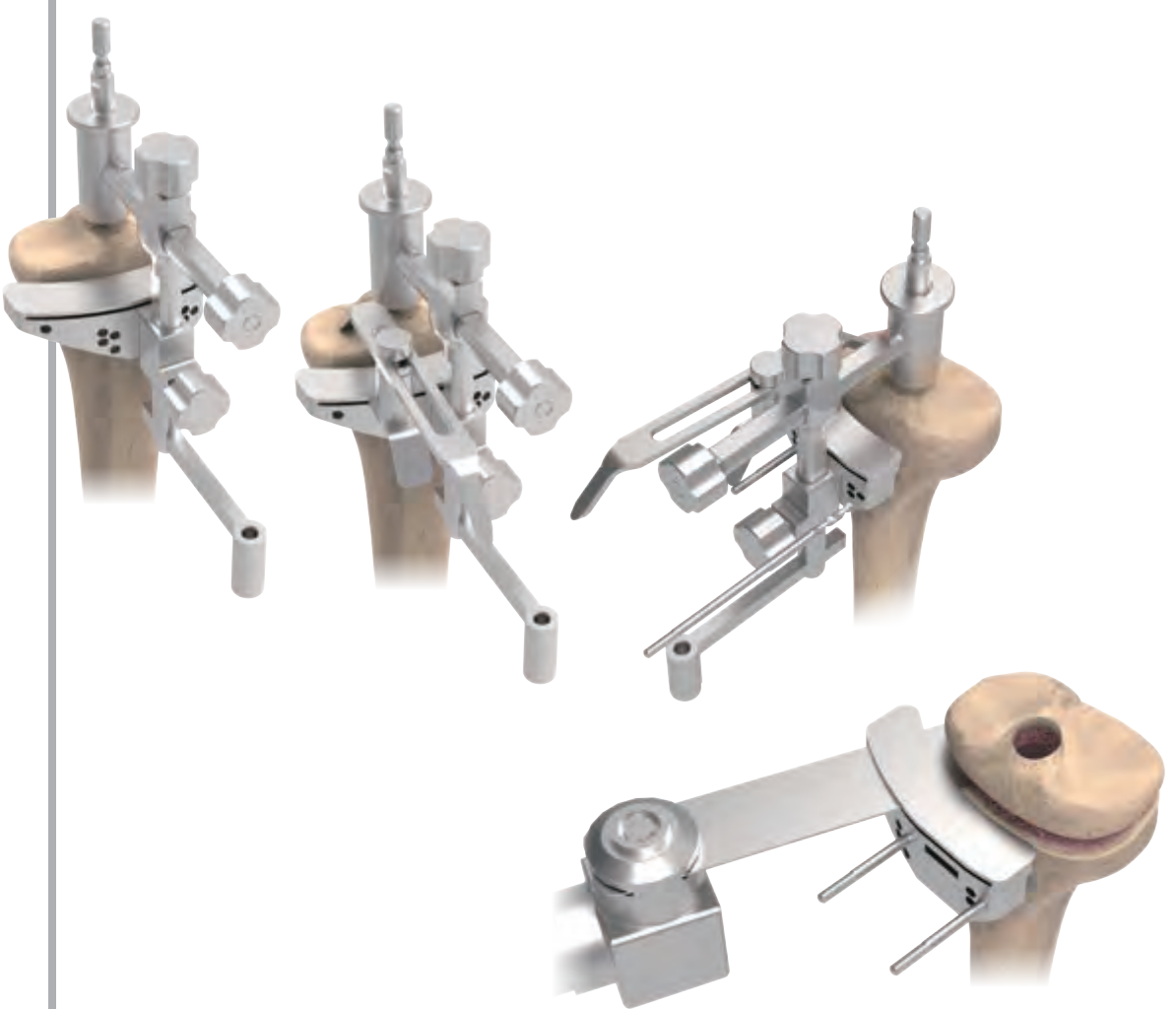
NOTE : The **Tibial Stylus** [20] allows two options to position the Cutting Guide: 2 mm or 9 mm cutting levels. When the **Tibial Stylus** [20] tip marked 2 mm is positioned on the low point of the tibial plateau, the bone resection will be 2 mm below the contact point of the stylus tip. If the 9 mm stylus tip is positioned on the high point of the tibial plateau, it will position the **Tibial Cutting Jig** [21] 9 mm below the contact point of the stylus tip.

With the **Tibial Cutting Jig** [21] properly positioned, two **3.2 mm Twist Drills** [11] are placed into the “0” hole locations. Additional **Drills** [11] may be used in the peripheral holes provided.

With the **Tibial Cutting Jig** [21] secured, the **T-Handle** [5] is re-assembled onto the **Tibial IM Rod** [18] for the removal of the **Tibial IM Rod** [18] and **Tibial IM Alignment Guide** [19]. The **Tibial Cutting Jig** [21] will stay in the position.

Now the proximal tibial resection may be performed utilizing a 1.27 mm saw blade. Once the resection is completed, the Cutting Guide and Pins may be removed for subsequent trial reduction.

NOTE : Prior to resection, if the surgeon wishes to increase or decrease the tibial resection thickness, the “+2” or “-2” hole locations may be utilized to re-position the **Tibial Cutting Jig** [21].



B. Tibial Preparation

B.2. Tibial Extramedullary Alignment Method

Assemble the **Tibial Cutting Jig** [21] to the selected **Tibial EM Alignment Guide** [22].

With the knee fully flexed, position the distal portion of the **Tibial EM Alignment Guide** [22] at the anterior ankle joint with the supramalleolar spring tabs. Position the proximal portion of the **Tibial EM Alignment Guide** [22] by impacting the spikes of the **Tibial EM Alignment Guide** [22] into the central portion of the proximal tibial plateau.

The cutting amount may be determined by inserting the **Tibial Stylus** [20] in the resection slot.

NOTE : The **Tibial Stylus** [20] allows two options for to position the Cutting Guide; 2 mm or 9 mm cutting levels. When the **Tibial Stylus** [20] tip marked 2 mm is positioned on the low point of the tibial plateau, the bone resection will occur 2 mm below the contact point of the stylus tip. If the 9 mm stylus tip is positioned on the high point of the tibial plateau, it will position the **Tibial Cutting Jig** [21] 9 mm below the contact point of the stylus tip.

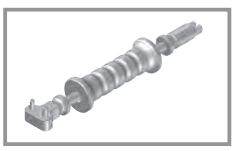
Once the elevation is chosen, the **3.2 mm Twist Drills** [11] are placed in the “0” hole option of the **Tibial Cutting Jig** [21]. Additional peripheral **Drills** [11] or **Spike** [8] may also be used to secure the **Tibial Cutting Jig** [21].

Once the **Tibial Cutting Jig** [21] is securely positioned, the **Tibial EM Alignment Guide** [22] may now be removed by utilizing the **Spike and Tibial EM Guide Extractor** [23]. Resection of the tibial plateau is now performed by using a 1.27 mm saw blade.

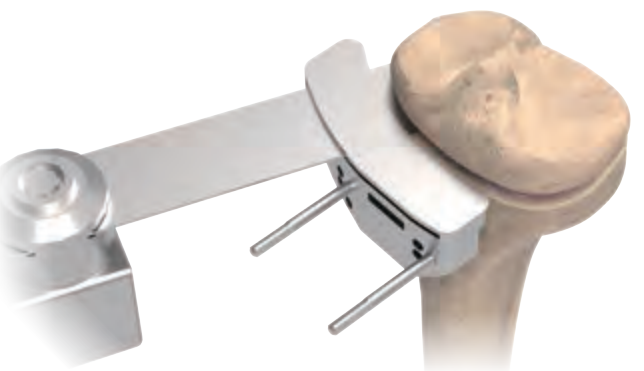
NOTE : Prior to resection, if the surgeon wishes to increase or decrease the tibial resection thickness, the “+2” or “-2” hole locations may be utilized to re-position the **Tibial Cutting Jig** [21].

22 Tibial EM Alignment Guide
9403-2104-RA

23 Spike and Tibial EM Guide Extractor
9303-5101



B. Tibial Preparation



B. Tibial Preparation

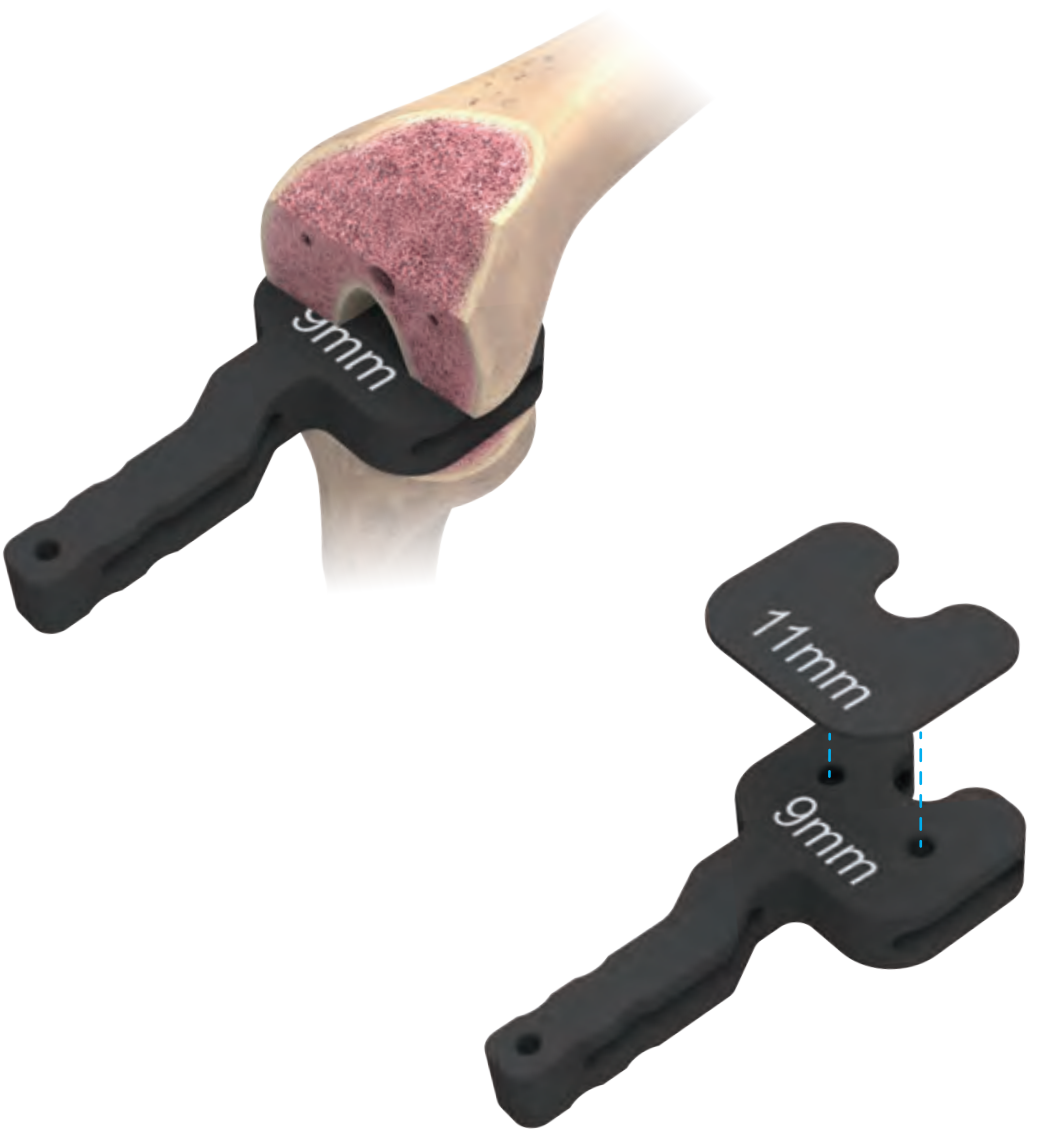
B.3. Extension and Flexion Gaps Confirmation

The extension and flexion joint gaps may be evaluated at this time with the **Gap Gauge** [24]. The 9 mm **Gap Gauge** [24] is initially selected to assess both the extension and flexion joint gaps.

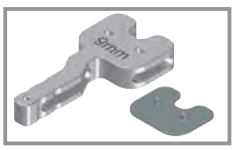
If a thicker gap is required, combine additional **Gap Gauge** [24] blocks with different thicknesses and test again. The range of thickness is from 9 mm to 18 mm.

If neither the extension and flexion gaps nor soft tissue tension shows any problem, insert the femoral and tibial trial to test the knee mobility and their relative positions.

NOTE : The **Alignment Rod** [3] may be inserted through the **Gap Gauge** [24] handle to assess the extramedullary alignment in both extension and flexion.



24 Gap Gauge
9403-7009
9403-7011
9403-7013
9403-7015
9403-7018



B. Tibial Preparation

If the flexion, extension, or both gaps and associated soft tissue tension appear to be unbalanced, the following techniques may be employed :

Tight Flexion - Tight Extension :
Resect Additional Bone from the Tibia

If the gap is deemed too tight in both flexion and extension, the surgeon may wish to remove additional bone from the tibia, as it is the common surface to both flexion and extension gaps. The surgeon may re-position the **Tibial Cutting Jig** [21] to perform this resection. The **Gap Gauge** [24] may then be utilized to re-access the newly established flexion/extension gap.

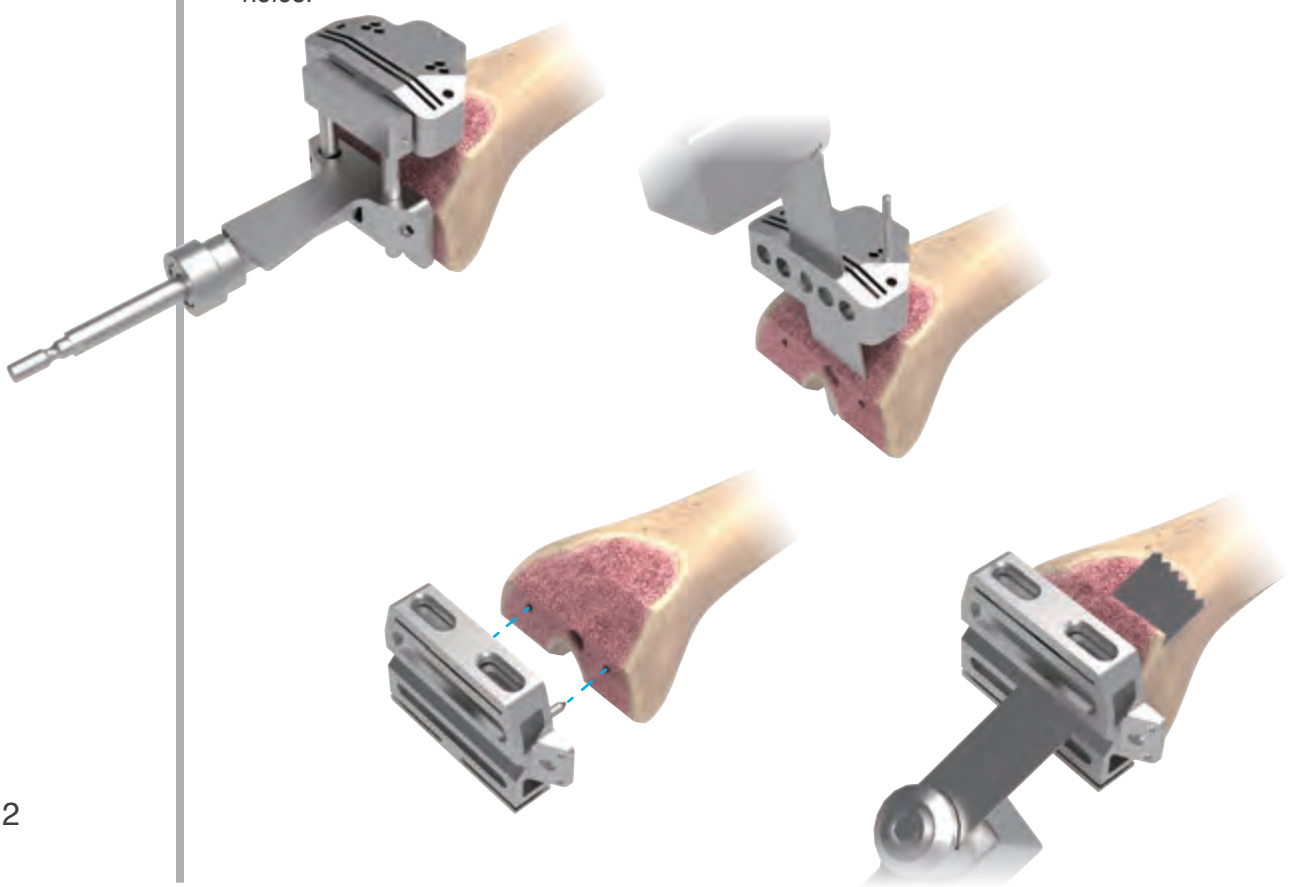
Balanced Flexion - Tight Extension :
Resect Additional Bone from the Distal Femur

If the gap is deemed too tight in extension only, the surgeon may wish to remove additional bone from the distal femur, as recutting this surface will only affect the extension gap only. The **Distal Femoral Cutting Guide** [10] may be repositioned on the femur to perform this resection. Then the **Gap Gauge** [24] may be utilized to re-access the flexion/extension gap.

NOTE : Following the distal femoral recuting, the **Femoral A/P Chamfer Cutting Guide** [15] is required to recreate the femoral chamfer cuts.

Tight Flexion - Balanced Extension :
Resect Additional Bone from the Posterior Femur

If the **Gap Gauge** [24] is too tight in flexion only, the surgeon may select to down-size the femoral component and thereby affect the associated flexion gap only. To down-size the femoral component, select an **Femoral A/P Chamfer Cutting Guide** [15] which is one size smaller than the originally used, and reposition the guide into the original distal femoral drill holes.



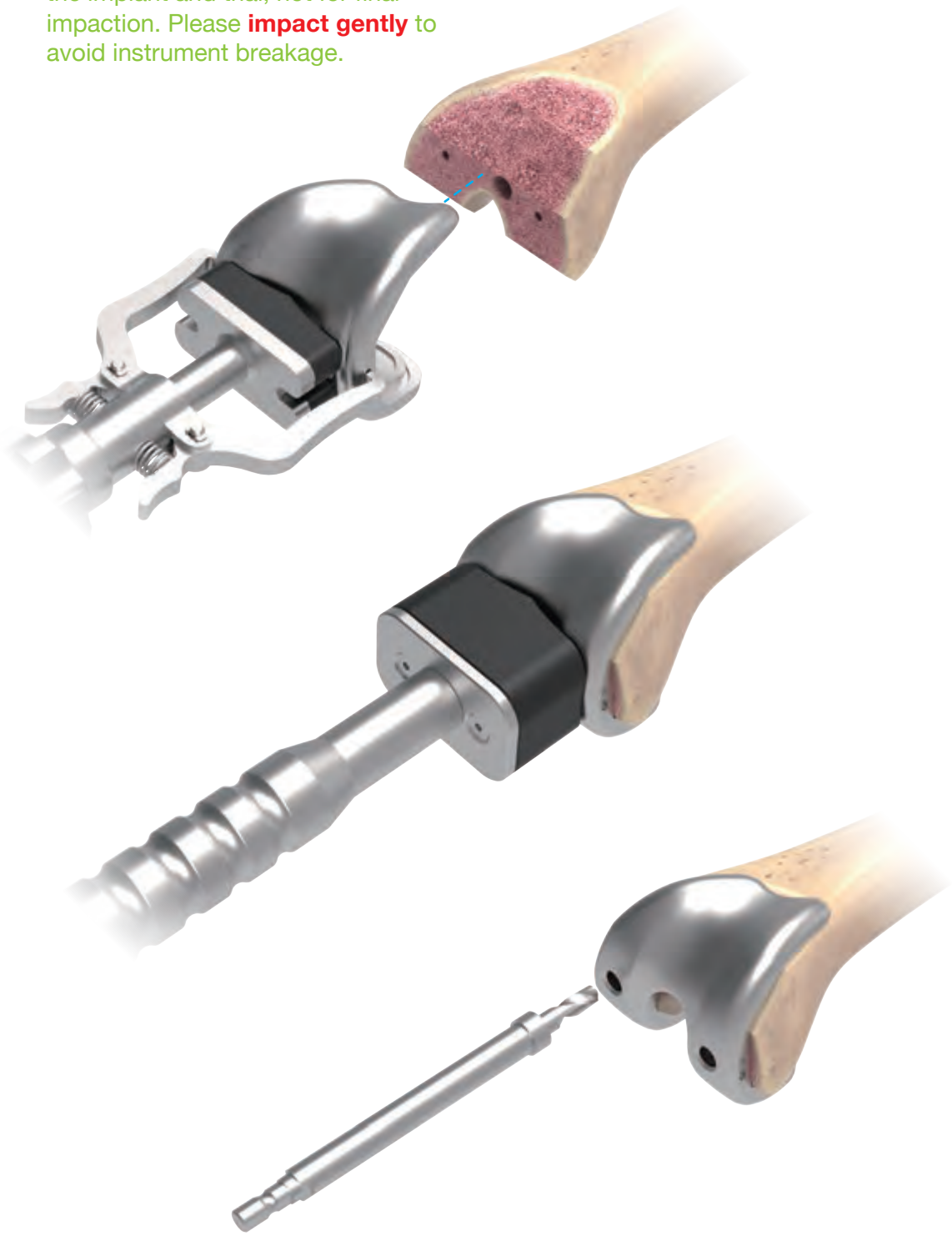
C. Trial Preparation

C.1. Initial Femoral Trial Insertion

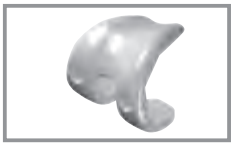
Assemble the **CR Femoral Trial** [25] to the **Femoral Driver** [26]. Center **CR Femoral Trial** [25] at the femoral intercondylar notch and hit it onto the resected femur with the **Femoral Impactor** [27]. Perform with great care and pay extra attention to make sure that it is aligned with the mechanical axis and rested flush against the bone cutting surface. Drill the fixation peg holes with the **Femoral Condyle Drill** [28] if preparing the CR femoral component.

-Caution:

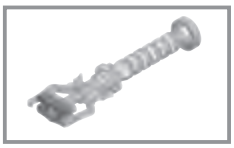
Femoral Driver is designed to position the implant and trial, not for final impaction. Please **impact gently** to avoid instrument breakage.



25 Femoral Trial, CR
C/N various by size

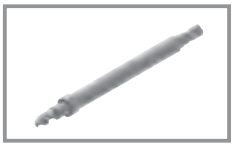


26 Femoral Driver
9303-5110-RD



27 Femoral Impactor
9303-5103-RB

28 Femoral Condyle Drill
9303-3206



C. Trial Preparation

C.2. Initial Tibial Baseplate Trial Insertion

As the U2 Knee system allows interchangeability of femoral and tibial implant sizes, attach the **Tibial Baseplate Trial Handle** [30] to the **Tibial Baseplate Trial** [29] that best provides maximum coverage of the proximal tibia.

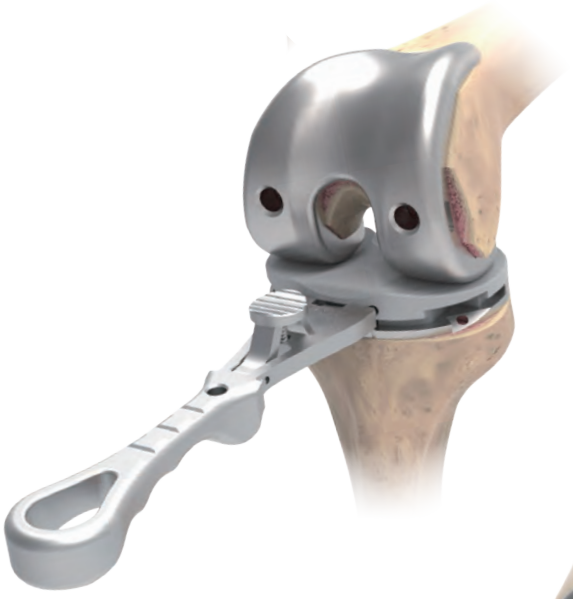
Once selected, remove the **Tibial Baseplate Trial Handle** [30] and insert a **CR Tibial Insert Trial** [31] of desired thickness with **Tibial Insert Trial Handle** [32].The **Alignment Rod** [3] may be inserted into the **Tibial Insert Trial Handle** [32] to re-check the alignment.

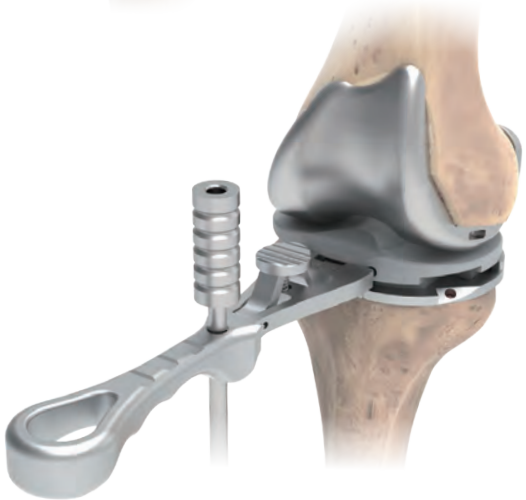
29 Tibial Baseplate Trial
2203-4000-RB
2203-4010-RB
2203-4020-RB
2203-4030-RB
2203-4040-RB
2203-4050-RB
2203-4060-RB
2203-4070-RB

30 Tibial Baseplate Trial Handle
9404-1102

31 Tibial Insert Trial, CR
C/N varies by size

32 Tibial Insert Trial Handle
9404-1103



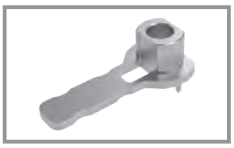


C. Trial Preparation

C.3. Creating Stem Space for Tibial Baseplate

Fix the **Tibial Baseplate Trial** [29] on the tibia with **Spikes** [7]. Attach the **Tibial Drill Guide** [33] to it and drill an opening with the **Tibial Drill** [34]. Choose a corresponding size **Cemented Tibial Punch** [36] and attach it to a **Tibial Punch Handle, CM** [35]. Position the Handle to the guide hole on the **Tibial Baseplate Trial** [29] and to ensure that the **Cemented Tibial Punch** [36] hits precisely and vertically into the tibial canal.

33 Tibial Drill Guide
9403-2105-RF



34 Tibial Drill
9403-3001

35 Tibial Punch
Handle, CM
9403-1101-RC

36 Cemented
Tibial Punch
9403-6010
9403-6020
9403-6030

D. Posterior Stabilized Femoral Component Preparation

37 PS Notch Cutting Jig
9303-2210-RC
9303-2220-RC
9303-2230-RC
9303-2240-RC
9303-2250-RC
9303-2260-RC
9303-2270-RC

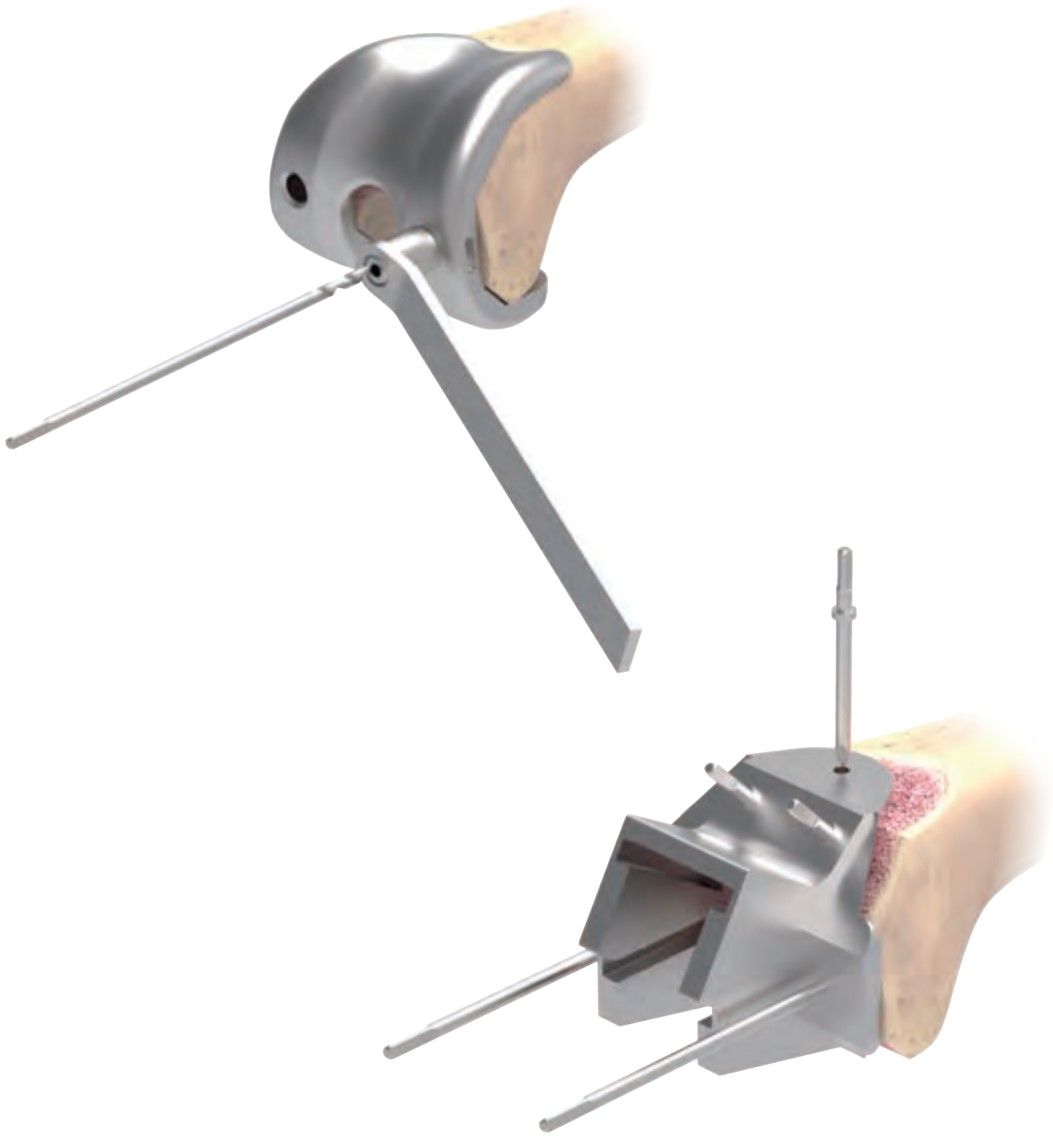
38 PS Cutting Jig
Drill Guide
9303-2104

D.1. PS Femoral Notch Guide Positioning

To utilize the PS Femoral system, the **CR Femoral Trial** [25] component is firstly used to position the hole locations for the **PS Notch Cutting Jig** [37].

The **CR Femoral Trial** [25] is positioned and carefully impacted as aforementioned. Locate the **PS Cutting Jig Drill Guide** [38] onto the **CR Femoral Trial** [25]. A **3.2 mm Twist Drill** [11] is now used, leaving the drills in place to position the **PS Notch Cutting Jig** [37].

Remove the **CR Femoral Trial** [25] and position the **PS Notch Cutting Jig** [37] onto the two drills. Additional **Spikes** [8] are now used to secure the Jig in position.

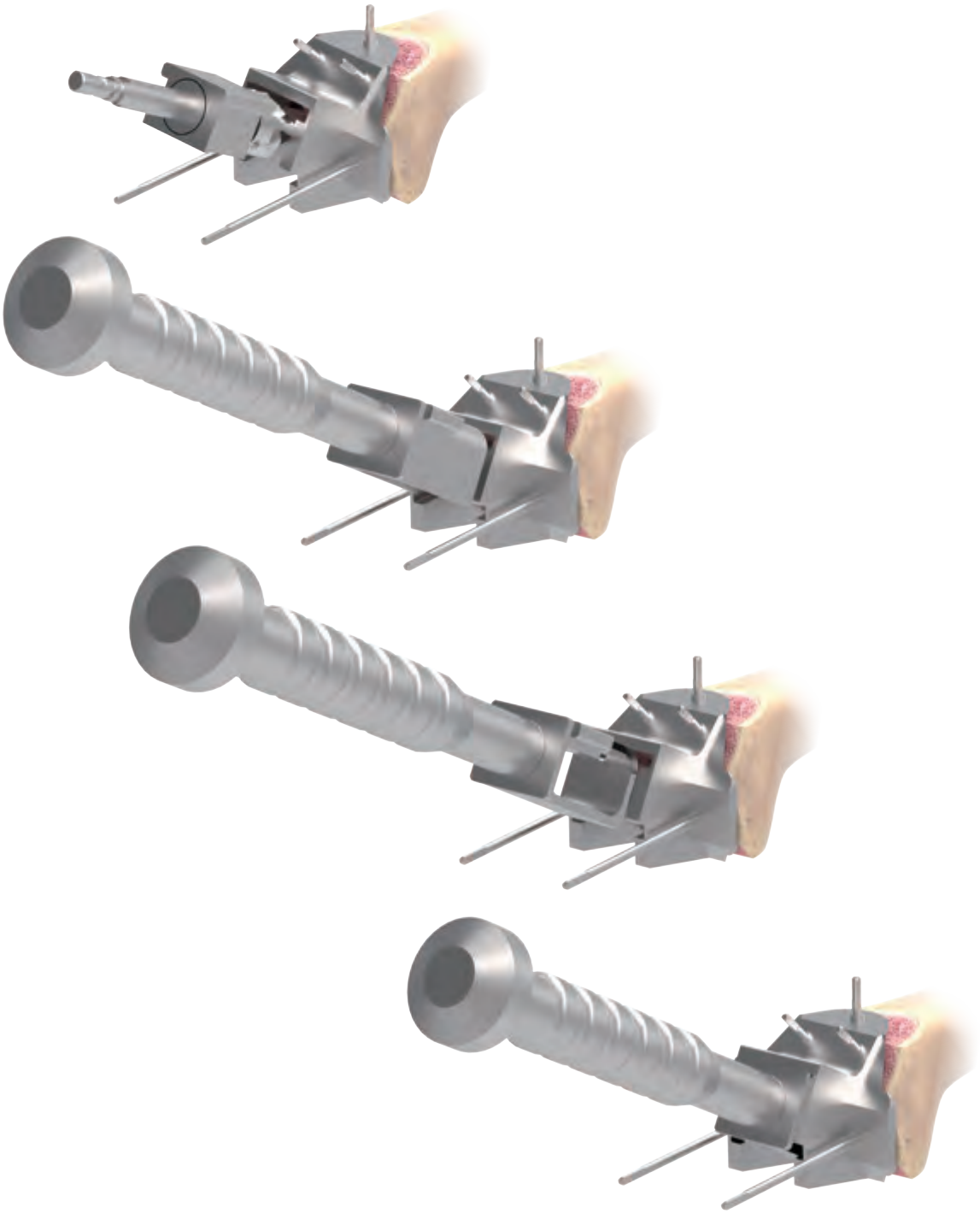


D. Posterior Stabilized Femoral Component Preparation

D.2. PS Intercondylar Notch Creation

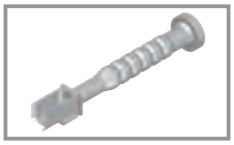
Insert the **PS Reamer** [39] first into the anterior guide slot in the **PS Notch Cutting Jig** [37]. Advance the **PS Reamer** [39] under drill power until it is seated flush with the **PS Notch Cutting Jig** [37]. The **PS Reamer** [39] is then inserted in the same manner into the posterior guide slot. A visual clearance of complete bone removal is advised.

The **PS Housing Punch** [40] is now inserted into both the anterior and posterior slots to complete all bone removal. The **PS Housing Impactor** [41] is now inserted to verify complete clearance of bone.

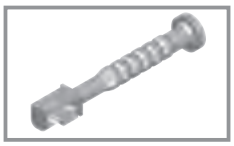


39 PS Reamer
9303-4101-RF

40 PS Housing Punch
9303-5104-RA



41 PS Housing Impactor
9303-5105-RA



D. Posterior Stabilized Femoral Component Preparation

42 Femoral Trial, PS
C/N varies by size

43 Tibial Insert Trial, PS
C/N varies by size

D.3. PS Femoral Trial Reduction

Introduce the **PS Femoral Trial** [42] onto the femur, carefully aligning the PS Housing of the Trial implant to the cut housing in the femoral bone. Advance the **PS Femoral Trial** [42] and **Femoral Driver** [26] carefully with a mallet until fully seated.

Insert an appropriate size and thickness of **PS Tibial Insert Trial** [43] onto the **Tibial Baseplate Trial** [29] and **PS Femoral Trial** [42] in a standard fashion. Once trialing is completed, the trials may be removed in a standard fashion.

E. Patellar Preparation

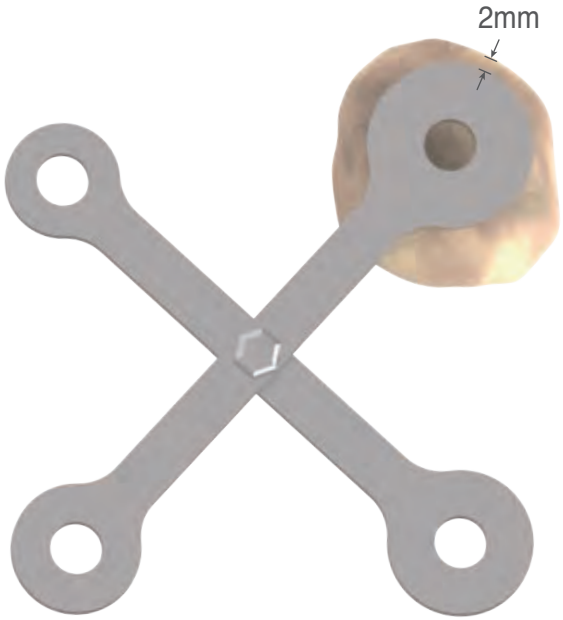
There are two options for patellar component: Inset and Onset.

E.1. Inset Patellar Component Preparation

Evert the patellar and remove excessive osteophytes. With a **Caliper** [44], measure and record the thickness of the A-P dimension of the patella.

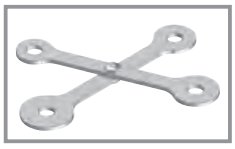
NOTE : In planning the resection thickness, it is recommended to retain a 10 mm minimal thickness of retained patella bone to support the implant structure.

The **Patellar Sizing Ring** [45] is used to determine the desired patellar diameter and positioning. Typically, the Ring is positioned over the highest point of the articulation and the center position is marked with a cautery or ink.



44 Caliper
9401-7012

45 Patellar Sizing Ring
9401-7002



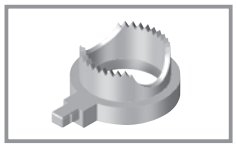
E. Patellar Preparation

E.1.1. Inset Patellar Reaming Depth and Pilot Hole

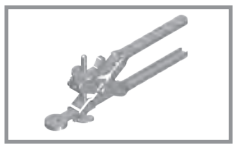
Attach the **Patellar Clamp Ring** [46] to the **Patellar Resection Clamp** [47] of the chosen size. Center the Ring at the highest position of the patella and clamp the patella for fixation. Place a **Patellar Drill Depth Sleeve** [48] on the clamp ring. Direct the **Patellar Reamer** [49] downwards into the Ring, with its tip touching the highest point of patellar. Place **Patellar Reamer Stopper** [50] level on the sleeve and tighten the stopper with a **Screw Driver** [51]. Make sure the drill depth of the reamer equals to the patellar component thickness. Remove the sleeve and insert a **Patellar Drill Guide** [52] of the same size. Next, use the **Patellar Drill** [53] to create the pilot hole for the **Patellar Reamer** [49]. Once the drilling is completed, the **Patellar Reamer** [49] is reintroduced into the **Patellar Clamp Ring** [46] for creating the inset patellar bed.

NOTE: If the thickness of patella is smaller than 20 mm, it will be necessary to adjust the stopper manually to the desired drill depth to retain at least 8 mm patellar thickness.

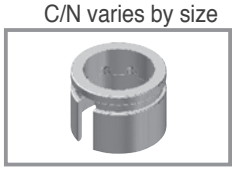
46 Patellar Clamp Ring
C/N varies by size



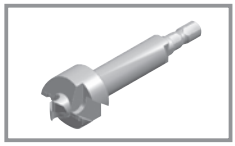
47 Patellar Resection Clamp
9401-5302-RB



48 Patellar Drill Depth Sleeve
C/N varies by size



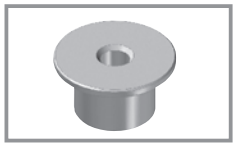
49 Patellar Reamer
C/N varies by size



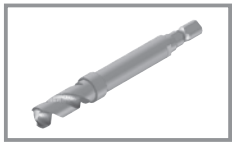
50 Patellar Reamer Stopper
9401-4205

51 Screw Driver
9404-1701

52 Patellar Drill Guide
C/N varies by size



53 Patellar Drill
9401-5121

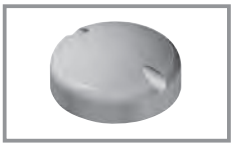


E. Patellar Preparation

E.1.2. Drill Hole Completion and Trial Installation

Now the **Patellar Resection Clamp** [47] is removed, and the **Inset Patellar Trial** [54] is in the position of the prepared bone bed. The peripheral bone shoulder surrounding the inset patellar trial is accessed, and may be trimmed to achieve a smooth blending of the implant periphery to the boney shoulder.

54 Patellar Trial, Inset
2401-2010
2401-2020
2401-2030
2401-2040



E. Patellar Preparation

E.2. Onset Patellar Component Preparation

When the Onset patellar component is choosed, assemble the **Onset Patellar Resection Guide** [55] to the **Patellar Resection Clamp** [47]. Use the stylus on the bottom of onset patellar resection guide to check if the remained patellar thickness exceeds 10 mm. If so, clamp the patella tight and place the saw blade into the slot of the clamp and resect the patella until the showing subchondral bone. Then choose the appropriate size **Onset Patellar Drill Guide** [56], and drill three round fixation peg holes with the **Onset Patellar Peg Drill** [57]. Now the preparation for onset patellar component is completed.

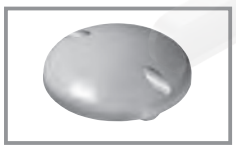
Now the **Onset Patellar Trial** [58] may be positioned. Assessing the contact and stability of the bone/implant couple. A thickness measurement of the implant/bone couple may be performed to assure the original patellar A-P thickness. Trialing is performed in a standard fashion.

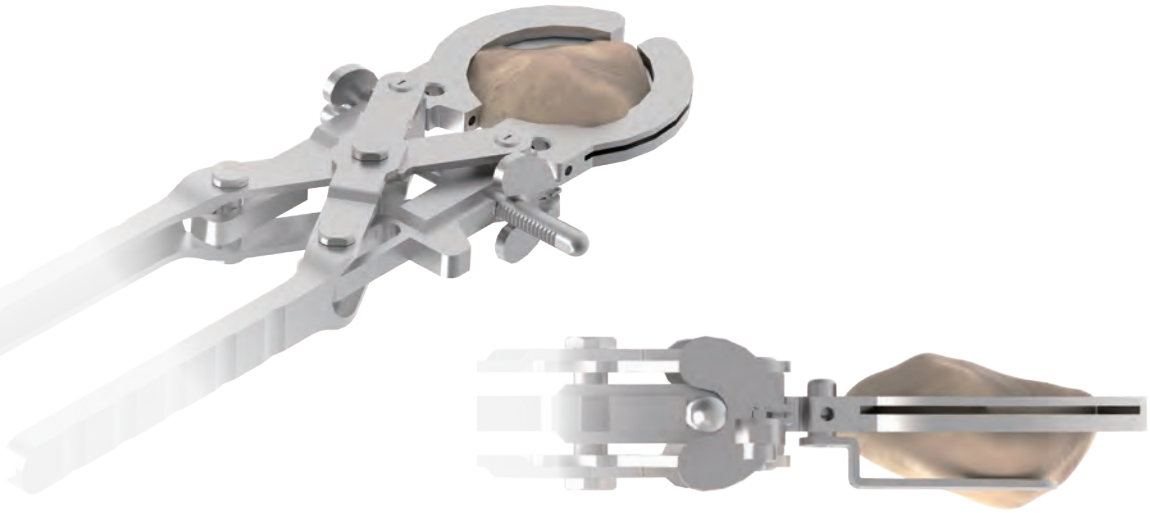
55 Onset Patellar Resection Guide 9403-5302-RB

56 Onset Patellar Drill Guide C/N varies by size

57 Onset Patellar Peg Drill 9404-3201

58 Patellar Trial, Onset C/N varies by size





F. Implant Fixation

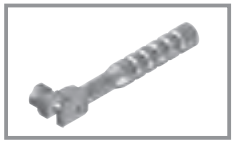
F.1. Final Trial Reduction

Apply the patellar trial, femoral trial, tibial baseplate trial, and tibial insert trial to the corresponding resected bony surfaces. Test for the joint laxity and range of motion, and observe how muscles and ligaments react at extension and flexion. If it is too loose or too tight, adjust the soft tissue tension to ensure both joint stability and mobility are ideal. After testing is done, remove all trials and clean the cutting surface.

F. Implant Fixation

F.2. Implant Fixation

59 Tibial Baseplate Driver
9403-5101-RC



60 Tibial Baseplate Impactor
9403-5102-RF

61 Patella Cement Clamp Adaptor
9401-5312-RD

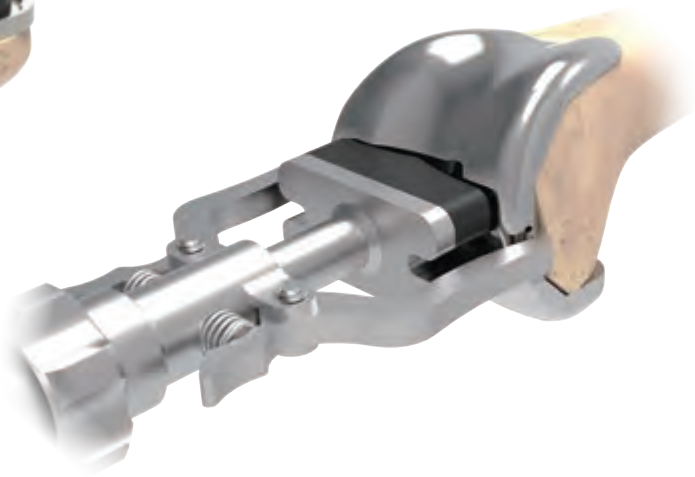
To impact the Tibial Baseplate, it is recommended to carefully introduce and align the stem of the implant into the prepared stem hole. The implant may be positioned by hand or by using the **Tibial Baseplate Driver** [59]. Once the Tibial Baseplate is advanced sufficiently, the **Tibal Baseplate Impactor** [60] may then be used to complete seating of the implant.

To impact the Femoral Implant, the **Femoral Driver** [26] is assembled onto the Femoral Implant. Carefully align the femoral implant with the distal femur to assure correct advancement and seating of the implant. The **Femoral Impactor** [27] may also be used for seating if desired.

The Patellar Implant is firstly seated by hand, carefully aligning the implant peg(s) with the prepared bone bed. The **Patellar Resection Clamp** [47] is equipped with the **Patella Cement Clamp Adaptor** [61]. This assembly is then used to fully seat the cemented implant in a standard fashion.

Femoral Tibial trialing may now be performed again if desired.

-Caution:
Femoral Driver is designed to position the implant and trial, not for final impaction. Please **impact gently** to avoid instrument breakage.

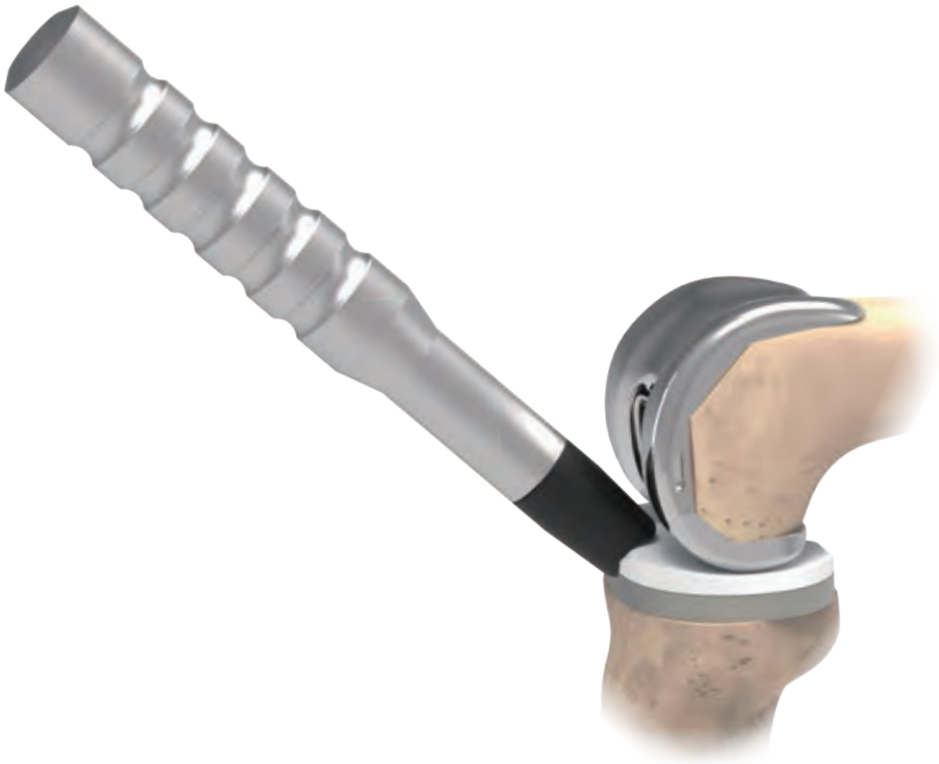


F. Implant Fixation

62 Universal Impactor
9303-5119-RD

Prior insertion of the final Tibial Insert, place the knee in a flexed position and be sure to adequately retract soft tissues to allow proper visualization of the peripheral locking detail.

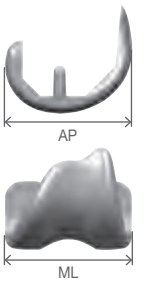
It is recommended to initially introduce the Tibial Insert by hand onto the Tibial Baseplate. Once initial engagement with the locking detail is verified, the grooved **Universal Impactor** [62] may be used to fully seat the Insert. All areas of the assembly are then visually assessed for complete seating and locking detail engagement.



Implant

Special Order Items

U2 Femoral Component



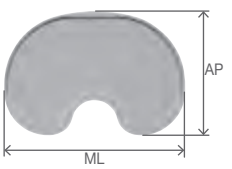
	CR		CR (Cementless)	
	Left	Right	Left	Right
#1	2103-1310	2103-1410	2103-1110	2103-1210
#2	2103-1320	2103-1420	2103-1120	2103-1220
#3	2103-1330	2103-1430	2103-1130	2103-1230
#4	2103-1340	2103-1440	2103-1140	2103-1240
#5	2103-1350	2103-1450	2103-1150	2103-1250
#6	2103-1360	2103-1460	2103-1160	2103-1260
#7	2103-1370	2103-1470	2103-1170	2103-1270

	PS	
	Left	Right
#1	2103-3110	2103-3210
#2	2103-3120	2103-3220
#3	2103-3130	2103-3230
#4	2103-3140	2103-3240
#5	2103-3150	2103-3250
#6	2103-3160	2103-3260
#7	2103-3170	2103-3270

Unit: mm

	AP	ML
#1	52	56
#2	56	60
#3	60	64
#4	64	68
#5	68	72
#6	72	76
#7	76	80

U2 Tibial Baseplate



	CMA
#0	2203-3200
#1	2203-3210
#2	2203-3220
#3	2203-3230
#4	2203-3240
#5	2203-3250
#6	2203-3260
#7	2203-3270

Unit: mm

	AP	ML
#0	39.5	60
#1	42	63
#2	44.5	66
#3	47	69
#4	49.5	72
#5	52.5	76
#6	55.5	80
#7	58.5	84

Special Order Items

Tibial Insert (CR)

CR		#0	#1	#2	#3	#4	#5	#6	#7
UHMWPE	9 mm	2303-1201	2303-1211	2303-1221	2303-1231	2303-1241	2303-1251	2303-1261	2303-1271
	11 mm	2303-1202	2303-1212	2303-1222	2303-1232	2303-1242	2303-1252	2303-1262	2303-1272
	13 mm	2303-1203	2303-1213	2303-1223	2303-1233	2303-1243	2303-1253	2303-1263	2303-1273
	15 mm	2303-1204	2303-1214	2303-1224	2303-1234	2303-1244	2303-1254	2303-1264	2303-1274
	18 mm	2303-1205	2303-1215	2303-1225	2303-1235	2303-1245	2303-1255	2303-1265	2303-1275

XCR		#0	#1	#2	#3	#4	#5	#6	#7
XPE	9 mm	2303-1601	2303-1611	2303-1621	2303-1631	2303-1641	2303-1651	2303-1661	2303-1671
	11 mm	2303-1602	2303-1612	2303-1622	2303-1632	2303-1642	2303-1652	2303-1662	2303-1672
	13 mm	2303-1603	2303-1613	2303-1623	2303-1633	2303-1643	2303-1653	2303-1663	2303-1673
	15 mm	2303-1604	2303-1614	2303-1624	2303-1634	2303-1644	2303-1654	2303-1664	2303-1674
	18 mm	2303-1605	2303-1615	2303-1625	2303-1635	2303-1645	2303-1655	2303-1665	2303-1675

E-XCR		#0	#1	#2	#3	#4	#5	#6	#7
E-XPE	9 mm	2303-1801	2303-1811	2303-1821	2303-1831	2303-1841	2303-1851	2303-1861	2303-1871
	11 mm	2303-1802	2303-1812	2303-1822	2303-1832	2303-1842	2303-1852	2303-1862	2303-1872
	13 mm	2303-1803	2303-1813	2303-1823	2303-1833	2303-1843	2303-1853	2303-1863	2303-1873
	15 mm	2303-1804	2303-1814	2303-1824	2303-1834	2303-1844	2303-1854	2303-1864	2303-1874
	18 mm	2303-1805	2303-1815	2303-1825	2303-1835	2303-1845	2303-1855	2303-1865	2303-1875

Implant

Special Order Items

Tibial Insert (UC)

XUC		#0	#1	#2	#3	#4	#5	#6	#7
XPE	9 mm	2303-1401	2303-1411	2303-1421	2303-1431	2303-1441	2303-1451	2303-1461	2303-1471
	11 mm	2303-1402	2303-1412	2303-1422	2303-1432	2303-1442	2303-1452	2303-1462	2303-1472
	13 mm	2303-1403	2303-1413	2303-1423	2303-1433	2303-1443	2303-1453	2303-1463	2303-1473
	15 mm	2303-1404	2303-1414	2303-1424	2303-1434	2303-1444	2303-1454	2303-1464	2303-1474
	18 mm	2303-1405	2303-1415	2303-1425	2303-1435	2303-1445	2303-1455	2303-1465	2303-1475

E-XUC		#0	#1	#2	#3	#4	#5	#6	#7
E-XPE	9 mm	2303-1701	2303-1711	2303-1721	2303-1731	2303-1741	2303-1751	2303-1761	2303-1771
	11 mm	2303-1702	2303-1712	2303-1722	2303-1732	2303-1742	2303-1752	2303-1762	2303-1772
	13 mm	2303-1703	2303-1713	2303-1723	2303-1733	2303-1743	2303-1753	2303-1763	2303-1773
	15 mm	2303-1704	2303-1714	2303-1724	2303-1734	2303-1744	2303-1754	2303-1764	2303-1774
	18 mm	2303-1705	2303-1715	2303-1725	2303-1735	2303-1745	2303-1755	2303-1765	2303-1775

Special Order Items

Tibial Insert (PS)

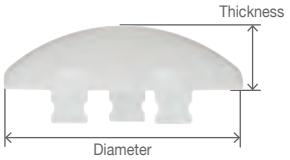
PS		#0	#1	#2	#3	#4	#5	#6	#7
UHMWPE	9 mm	2303-3001	2303-3011	2303-3021	2303-3031	2303-3041	2303-3051	2303-3061	2303-3071
	11 mm	2303-3002	2303-3012	2303-3022	2303-3032	2303-3042	2303-3052	2303-3062	2303-3072
	13 mm	2303-3003	2303-3013	2303-3023	2303-3033	2303-3043	2303-3053	2303-3063	2303-3073
	15 mm	2303-3004	2303-3014	2303-3024	2303-3034	2303-3044	2303-3054	2303-3064	2303-3074
	18 mm	N/A	2303-3015	2303-3025	2303-3035	2303-3045	2303-3055	2303-3065	2303-3075

XPS		#0	#1	#2	#3	#4	#5	#6	#7
XPE	9 mm	2303-3601	2303-3611	2303-3621	2303-3631	2303-3641	2303-3651	2303-3661	2303-3671
	11 mm	2303-3602	2303-3612	2303-3622	2303-3632	2303-3642	2303-3652	2303-3662	2303-3672
	13 mm	2303-3603	2303-3613	2303-3623	2303-3633	2303-3643	2303-3653	2303-3663	2303-3673
	15 mm	2303-3604	2303-3614	2303-3624	2303-3634	2303-3644	2303-3654	2303-3664	2303-3674
	18 mm	N/A	2303-3615	2303-3625	2303-3635	2303-3645	2303-3655	2303-3665	2303-3675

E-XPS		#0	#1	#2	#3	#4	#5	#6	#7
E-XPE	9 mm	2303-3801	2303-3811	2303-3821	2303-3831	2303-3841	2303-3851	2303-3861	2303-3871
	11 mm	2303-3802	2303-3812	2303-3822	2303-3832	2303-3842	2303-3852	2303-3862	2303-3872
	13 mm	2303-3803	2303-3813	2303-3823	2303-3833	2303-3843	2303-3853	2303-3863	2303-3873
	15 mm	2303-3804	2303-3814	2303-3824	2303-3834	2303-3844	2303-3854	2303-3864	2303-3874
	18 mm	N/A	2303-3815	2303-3825	2303-3835	2303-3845	2303-3855	2303-3865	2303-3875

Special Order Items

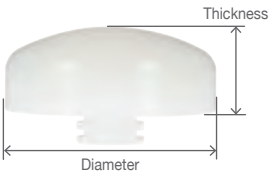
Patella Component



Onset Patella

	XS	S	M	L	XL	XXL	EL
UHMWPE	2403-1010	2403-1020	2403-1030	2403-1040	2403-1050	2403-1060	2403-1070
XPE	2403-3210	2403-3220	2403-3230	2403-3240	2403-3250	2403-3260	2403-3270
E-XPE	2403-5210	2403-5220	2403-5230	2403-5240	2403-5250	2403-5260	2403-5270

Thickness	7	8	8.5	9	9.5	10	10.5
Diameter	26	29	32	35	38	41	44



Inset Patella

	S	M	L	XL
UHMWPE	2401-1010	2401-1020	2401-1030	2401-1040
XPE	2403-3010	2403-3020	2403-3030	2403-3040
E-XPE	2403-5010	2403-5020	2403-5030	2403-5040

Unit: mm

Thickness	8	10	10	10
Diameter	22	25	28	32

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Each Step
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Instrument Catalog

Special Order Items

CR Femoral Trial

	#1	#2	#3	#4	#5	#6	#7
Left	2103-2110	2103-2120	2103-2130	2103-2140	2103-2150	2103-2160	2103-2170
Right	2103-2210	2103-2220	2103-2230	2103-2240	2103-2250	2103-2260	2103-2270

PS Femoral Trial

	#1	#2	#3	#4	#5	#6	#7
Left	2103-4110	2103-4120	2103-4130	2103-4140	2103-4150	2103-4160	2103-4170
Right	2103-4210	2103-4220	2103-4230	2103-4240	2103-4250	2103-4260	2103-4270

Tibial Baseplate Trial

#0	#1	#2	#3	#4	#5	#6	#7
2203-4000-RB	2203-4010-RB	2203-4020-RB	2203-4030-RB	2203-4040-RB	2203-4050-RB	2203-4060-RB	2203-4070-RB

Instrument Catalog

Special Order Items

CR Insert Trial

	#1	#2	#3	#4	#5	#6	#7
9 mm	2303-2211-RF	2303-2221-RF	2303-2231-RF	2303-2241-RF	2303-2251-RF	2303-2261-RF	2303-2271-RF
11 mm	2303-2212-RF	2303-2222-RF	2303-2232-RF	2303-2242-RF	2303-2252-RF	2303-2262-RF	2303-2272-RF
13 mm	2303-2213-RF	2303-2223-RF	2303-2233-RF	2303-2243-RF	2303-2253-RF	2303-2263-RF	2303-2273-RF
15 mm	2303-2214-RF	2303-2224-RF	2303-2234-RF	2303-2244-RF	2303-2254-RF	2303-2264-RF	2303-2274-RF
18 mm	2303-2215-RF	2303-2225-RF	2303-2235-RF	2303-2245-RF	2303-2255-RF	2303-2265-RF	2303-2275-RF

PS Insert Trial

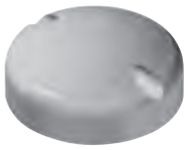
	#1	#2	#3	#4	#5	#6	#7
9 mm	2303-4011-RF	2303-4021-RF	2303-4031-RF	2303-4041-RF	2303-4051-RF	2303-4061-RF	2303-4071-RF
11 mm	2303-4012-RF	2303-4022-RF	2303-4032-RF	2303-4042-RF	2303-4052-RF	2303-4062-RF	2303-4072-RF
13 mm	2303-4013-RF	2303-4023-RF	2303-4033-RF	2303-4043-RF	2303-4053-RF	2303-4063-RF	2303-4073-RF
15 mm	2303-4014-RF	2303-4024-RF	2303-4034-RF	2303-4044-RF	2303-4054-RF	2303-4064-RF	2303-4074-RF
18 mm	2303-4015-RF	2303-4025-RF	2303-4035-RF	2303-4045-RF	2303-4055-RF	2303-4065-RF	2303-4075-RF

UC Insert Trial

	#1	#2	#3	#4	#5	#6	#7
9 mm	2303-2411-RF	2303-2421-RF	2303-2431-RF	2303-2441-RF	2303-2451-RF	2303-2461-RF	2303-2471-RF
11 mm	2303-2412-RF	2303-2422-RF	2303-2432-RF	2303-2442-RF	2303-2452-RF	2303-2462-RF	2303-2472-RF
13 mm	2303-2413-RF	2303-2423-RF	2303-2433-RF	2303-2443-RF	2303-2453-RF	2303-2463-RF	2303-2473-RF
15 mm	2303-2414-RF	2303-2424-RF	2303-2434-RF	2303-2444-RF	2303-2454-RF	2303-2464-RF	2303-2474-RF
18 mm	2303-2415-RF	2303-2425-RF	2303-2435-RF	2303-2445-RF	2303-2455-RF	2303-2465-RF	2303-2475-RF

Instrument Catalog

Special Order Items



Catalog Number	Description	
2401-2010	Patellar Trial, Inset, S	ø22 mm
2401-2020	Patellar Trial, Inset, M	ø25 mm
2401-2030	Patellar Trial, Inset, L	ø28 mm
2401-2040	Patellar Trial, Inset, XL	ø32 mm

Catalog Number	Description	
2403-2010	Patellar Trial, Onset, Size XS	ø26 mm
2403-2020	Patellar Trial, Onset, Size S	ø29 mm
2403-2030	Patellar Trial, Onset, Size M	ø32 mm
2403-2040	Patellar Trial, Onset, Size L	ø35 mm
2403-2050	Patellar Trial, Onset, Size XL	ø38 mm
2403-2060	Patellar Trial, Onset, Size XXL	ø41 mm
2403-2070	Patellar Trial, Onset, Size EL	ø44 mm

Catalog Number	Description
9301-1100	T-Handle

Catalog Number	Description
9301-2101-RB	Starter

Catalog Number	Description
9301-2251	Lower Point Gauge, 1.3 mm

Instrument Catalog

Catalog Number	Description
9301-2282	Extramedullary Alignment Tower

Catalog Number	Description
9301-2291	Femoral A/P Chamfer Guide Handle

Catalog Number	Description
9301-3201	Twist Drill, ø8 mm

Catalog Number	Description
9301-3207	Spike, Short

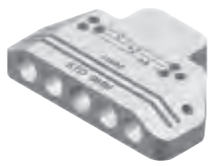
Catalog Number	Description
9301-6202	Bone File

Catalog Number	Description
9303-2111-RA	Femoral IM Alignment Guide

Instrument Catalog

Special Order Items

Catalog Number	Description
9303-2102-RA	Distal Femoral Alignment Guide



Catalog Number	Description
9303-2103-RC	Distal Femoral Cutting Guide

Catalog Number	Description
9303-2104	PS Cutting Jig Drill Guide

Catalog Number	Description
9303-2110-RC	Femoral A/P Chamfer Cutting Guide #1
9303-2120-RC	Femoral A/P Chamfer Cutting Guide #2
9303-2130-RC	Femoral A/P Chamfer Cutting Guide #3
9303-2140-RC	Femoral A/P Chamfer Cutting Guide #4
9303-2150-RC	Femoral A/P Chamfer Cutting Guide #5
9303-2160-RC	Femoral A/P Chamfer Cutting Guide #6
9303-2170-RC	Femoral A/P Chamfer Cutting Guide #7

Catalog Number	Description
9303-2210-RC	PS Notch Cutting Jig #1
9303-2220-RC	PS Notch Cutting Jig #2
9303-2230-RC	PS Notch Cutting Jig #3
9303-2240-RC	PS Notch Cutting Jig #4
9303-2250-RC	PS Notch Cutting Jig #5
9303-2260-RC	PS Notch Cutting Jig #6
9303-2270-RC	PS Notch Cutting Jig #7

Catalog Number	Description
9303-3200	Femoral IM Rod, 400 mm

Instrument Catalog

Special Order Items

Catalog Number	Description
9303-3201	Spike, Short
9303-3202	Spike, Long

Catalog Number	Description
9304-3003	Threaded Pin, 30 mm
9304-3004	Threaded Pin, 50 mm

Catalog Number	Description
9303-3203	Twist Drill, ø3.2 mm, Short
9303-3204	Twist Drill, ø3.2 mm, Long

Catalog Number	Description
9303-3205	Round Pin, ø3.2x120 mm

Catalog Number	Description
9303-3206	Femoral Condyle Drill

Catalog Number	Description
9303-4101-RF	PS Reamer

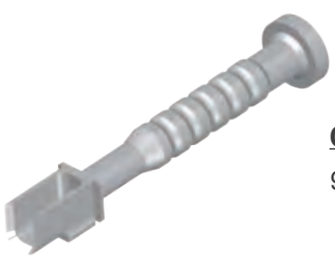
Catalog Number	Description
9304-5105	Quick Pin Driver

Instrument Catalog

Catalog Number	Description
9303-5002	Pin Extractor

Catalog Number	Description
9303-5101	Spike and Tibial EM Guide Extractor

Catalog Number	Description
9303-5103-RB	Femoral Impactor



Catalog Number	Description
9303-5104-RA	PS Housing Punch

Catalog Number	Description
9303-5105-RA	PS Housing Impactor

Catalog Number	Description
9303-5110-RD	Femoral Driver

Instrument Catalog

Special Order Items

Catalog Number	Description
9303-5119-RD	Universal Impactor

Catalog Number	Description
9303-7101-RE	Femoral Sizer, Anterior Ref.

Catalog Number	Description	
9303-8010	Tool Box	U2 Knee Case #1
9303-8020	Tool Box	U2 Knee Case #2
9303-8030-RA	Tool Box	U2 Knee Case #3
9303-8040-RA	Tool Box	U2 Knee Case #4
9303-8070	Tool Box	U2 Knee Case #7

Catalog Number	Description
9401-2203	Tibial IM Rod

Catalog Number	Description
9401-4201	Patellar Reamer, Size S
9401-4202	Patellar Reamer, Size M
9401-4203	Patellar Reamer, Size L
9401-4204	Patellar Reamer, Size XL

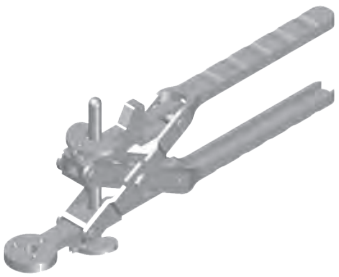
Catalog Number	Description
9404-1103	Tibial Insert Trial Handle

Instrument Catalog

Catalog Number	Description
9401-4205	Patellar Reamer Stopper

Catalog Number	Description
9401-5113	Patellar Drill Depth Sleeve, Size S
9401-5114	Patellar Drill Depth Sleeve, Size M
9401-5115	Patellar Drill Depth Sleeve, Size L
9401-5116	Patellar Drill Depth Sleeve, Size XL

Catalog Number	Description
9401-5121	Patellar Drill



Catalog Number	Description
9401-5302-RB	Patellar Resection Clamp

Catalog Number	Description
9401-5303-RA	Patellar Clamp Ring, Size S
9401-5304-RA	Patellar Clamp Ring, Size M
9401-5305-RA	Patellar Clamp Ring, Size L
9401-5306-RA	Patellar Clamp Ring, Size XL

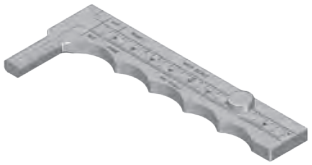
Catalog Number	Description
9404-1701	Screw Driver, HEX 5

Instrument Catalog

Catalog Number	Description
9401-5308	Patellar Drill Guide, Size S
9401-5309	Patellar Drill Guide, Size M
9401-5310	Patellar Drill Guide, Size L
9401-5311	Patellar Drill Guide, Size XL

Catalog Number	Description
9401-5312-RD	Patellar Cement Clamp Adapter

Catalog Number	Description
9401-7002	Patellar Sizing Ring



Catalog Number	Description
9401-7012	Caliper

Catalog Number	Description
9403-1101-RC	Tibial Punch Handle, CM

Catalog Number	Description
9404-1102	Tibial Baseplate Trial Handle

Instrument Catalog

Catalog Number	Description
9403-2103-RA	Tibial IM Alignment Guide

Catalog Number	Description
9403-2104-RA	Tibial EM Alignment Guide

Catalog Number	Description
9403-2105-RF	Tibial Drill Guide

Catalog Number	Description
9403-2120-RE	Tibial Cutting Jig, 0°(Left)
9403-2125-RE	Tibial Cutting Jig, 5°(Left)
9403-2220-RE	Tibial Cutting Jig, 0°(Right)
9403-2225-RE	Tibial Cutting Jig, 5°(Right)

Catalog Number	Description
9403-2202	Alignment Rod

Catalog Number	Description
9403-3001	Tibial Drill

Instrument Catalog

Catalog Number	Description
9404-3201	Onset Patellar Peg Drill

Catalog Number	Description
9403-5101-RC	Tibial Baseplate Driver

Catalog Number	Description
9403-5102-RF	Tibial Baseplate Impactor

Catalog Number	Description
9403-5104	Tibial Insert Extractor

Catalog Number	Description
9403-5106	EM Alignment Guide

Catalog Number	Description
9403-5302-RB	Onset Patellar Resection Guide

Instrument Catalog

Special Order Items

Catalog Number	Description
9403-5307-RA	Onset Patellar Drill Guide, ø26 mm
9403-5308-RA	Onset Patellar Drill Guide, ø29 mm
9403-5309-RA	Onset Patellar Drill Guide, ø32 mm
9403-5310-RA	Onset Patellar Drill Guide, ø35 mm
9403-5311-RA	Onset Patellar Drill Guide, ø38 mm
9403-5312-RA	Onset Patellar Drill Guide, ø41 mm
9403-5313-RA	Onset Patellar Drill Guide, ø44 mm

Catalog Number	Description
9403-6010	Cemented Tibial Punch, Size S
9403-6020	Cemented Tibial Punch, Size M
9403-6030	Cemented Tibial Punch, Size L

Catalog Number	Description
9403-7009	Gap Gauge, 9 mm
9403-7011	Gap Gauge, 11 mm
9403-7013	Gap Gauge, 13 mm
9403-7015	Gap Gauge, 15 mm
9403-7018	Gap Gauge, 18 mm

Catalog Number	Description
9403-7101-RA	Tibial Stylus

Safety Statement

INDICATIONS

The U2 Total Knee system is indicated in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery. This device system is intended for cemented use only in the U.S.A.

Please refer to the product-specific package inserts for important information, including indications, contraindications, warnings, precautions, and potential adverse effects.
For Reprocessing Instructions for Reusable Surgical Instruments, please check at www.uoc.com.tw

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