



iTotal[®]PS

SURGICAL TECHNIQUE GUIDE

Patient-specific POSTERIOR-STABILIZING knee replacement system

MEASURED RESECTION

Table of Contents

Introduction	page 2
Sample OR Layout.....	page 3
Saw Blade Recommendations	page 4
Preoperative Image Review.....	page 5
Step 1: Femoral Preparation	page 6
Step 2: Tibial Resection	page 9
Step 3: Tibial Preparation	page 11
Step 4: Patella Preparation (optional)	page 16
Step 5: Final Trialing and Cementing the Implants	page 17
Appendix A: Revisiting Distal Femoral Cut after Trialing	page 21
Indications for use	page 23
Magnetic Resonance (MR) Environment	page 24

Introduction

The iTotal® Posterior Stabilized (PS) Total Knee Replacement System is a patient-specific tricompartmental knee replacement system composed of personalized implants and disposable instrumentation. The product design incorporates a bone preserving approach for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. By utilizing proprietary iFit® image-to-implant technology and data from a patient's CT scan, implants are personalized for each patient. This personalized approach enables a fit so precise that it virtually eliminates the sizing compromises common with traditional total knee replacements. The implant is designed to restore the natural articulating geometry of the knee. The accompanying patient-specific, disposable iJig® instrumentation is employed in this surgical technique guide.

iTotal PS

POSTERIOR-STABILIZING

Surgeon Design Team

iTotal® PS Surgical Technique was developed in collaboration with:

Henry Clarke, MD

Orthopaedic surgeon at Mayo Clinic Hospital, Phoenix AZ

Wolfgang Fitz, MD

Instructor of Orthopaedic Surgery at Harvard Medical School and Attending Surgeon at Brigham and Women's Hospital, Boston, MA

William Kurtz, MD

Chief of Orthopedics of Baptist Hospital, Nashville, TN

José Rodriguez, MD

Chief of Reconstruction Arthroplasty and Director of Arthroplasty Fellowship Program at Lenox Hill Hospital, New York, NY

Raj Sinha, MD, PhD

Director of the Bone and Joint Institute at JFK Memorial Hospital, Indio, CA

The Measured Resection variation was developed in collaboration with:

Vivek Neginhal MD

Orthopedic Surgeon at Scott Orthopedic Center, Huntington, WV

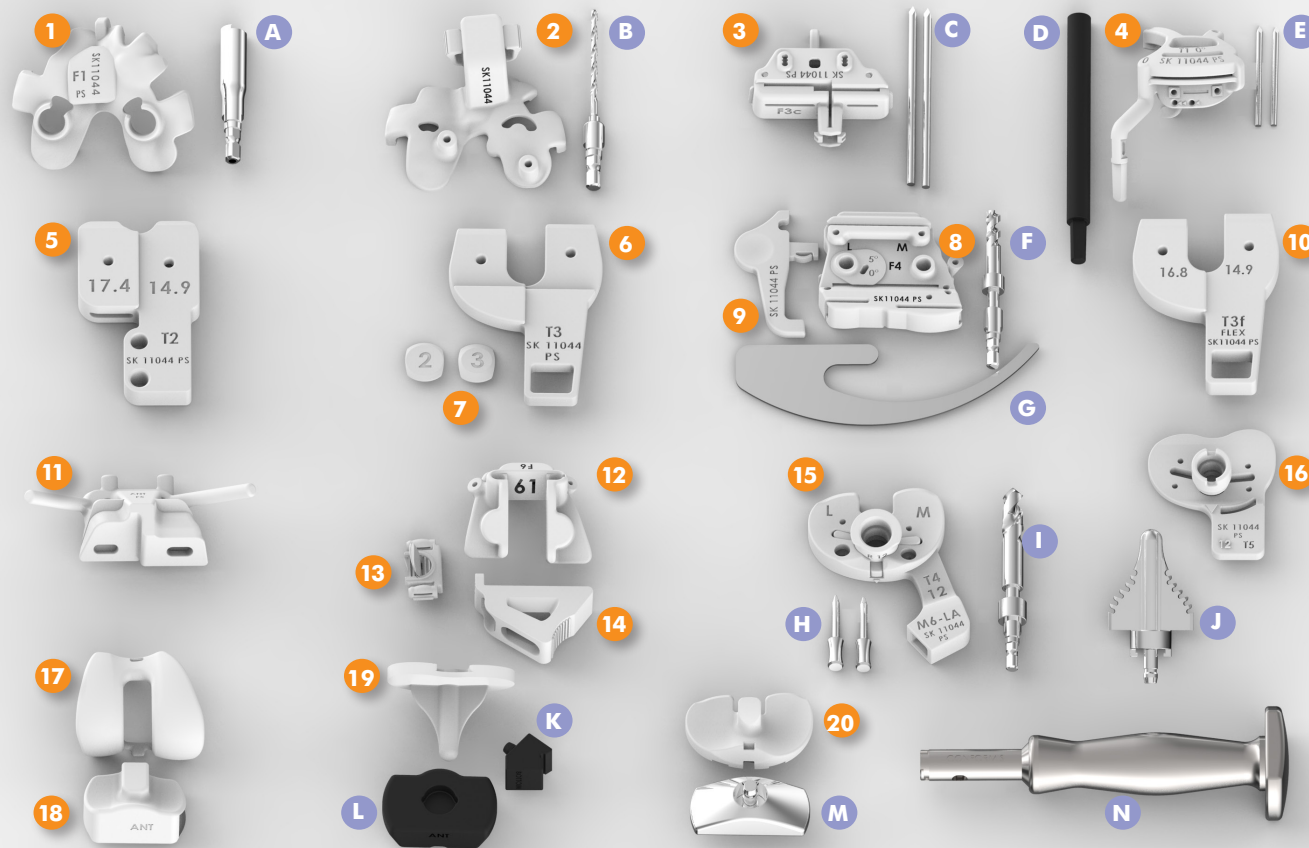
Derek Johnson, MD

Director of Orthopedics and Joint Replacement, Parker Adventist Hospital, Denver, CO

Bryan Huber, MD

Chair, Mansfield Orthopaedics, Division of Sports Medicine and Arthroplasty at Copley Hospital, Morrisville, VT

iTotal PS Sample OR Layout



Disposable iJigs:

1. F1, Positioning iJig
2. F2, Alignment iJig
3. F3c, Distal Resection iJig (captured)
4. T1-0°, 0° Slope Tibial Resection iJig
5. T2, Extension Spacer iJig
6. T3, Flexion Spacer iJig
7. Shims - 2, 3, 4, 5 mm
8. F4, A-P Resection iJig
9. F4a, A-P iJig Stylus
10. T3f, Post Resection Flexion Spacer iJig
11. F5, Chamfer iJig
12. F6, Box Cutting iJig
13. F6a, Drill Card iJig
14. F6b, Box Gauge iJig
15. T4, Tibial Preparation iJig
16. T5, Tibial Template iJig
17. Femoral Trial
18. Femoral Impactor
19. Tibial Tray Trial
20. Trial Instert (1 of 4)

Reusable Instruments:

- | | | |
|------------------------|--------------------------|-----------------------------|
| A. Coring Tool | F. Femoral Drill Bit | K. Poly Impactor Tip |
| B. 3mm Drill Bit | G. Angel Wing | L. Tibial Tray Impactor Tip |
| C. 80mm Steinmann Pins | H. Tack Pins | M. Impactor Head |
| D. Alignment Rod | I. Tibial Stem Drill Bit | N. Impactor Handle |
| E. 60mm Steinmann Pins | J. Keel Punch Tip | |

Suggested Ancillary Surgical Instruments

(not included in set)

- Laminar Spreader
- Quick Connect Drill Chucks (x2)
- Pin Driver
- PCL Retractor
- Hohmann Retractors
- Z Retractors
- Curved Osteotome
- Ring Curette

Saw Blade Recommendations

The captured iTotal iJigs are designed to accommodate a standard saw blade thickness. The captured slots are intended to minimize skiving and maximize the accuracy of the bone resection relative to the cutting plane, based on pre-navigated values.

The saw blade must enter the iJig at approximately a 5° angle (Image 1). The saw blade must touch bone **prior** to initiation of the saw blade (Images 2 and 3).

Recommended Saw Blades		Product Code	Length (mm)	Width (mm)	Thickness (mm)
Reciprocating	Stryker	277-96-325	77.5	11.18	0.76
	ConMed - Linvatec	5052-179	76	12.5	0.90
Wide Oscillating	Stryker	4125-127-100	100	25	1.27
	Stryker ("Precision")	6525-127-105	105	25	1.27
	ConMed - Linvatec	TN250-127-90	90	25	1.27
Narrow Oscillating	Stryker	6118-119-110	110	18	1.19
	Stryker	4118-127-100	100	18	1.27
	Stryker	2108-158-000	81.50	12.5	1.27
	ConMed - Linvatec	TN190-127-05	105	19	1.27

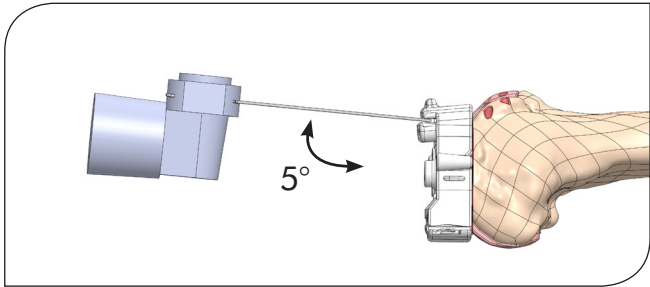


Image 1: Saw blade entering Captured iJig

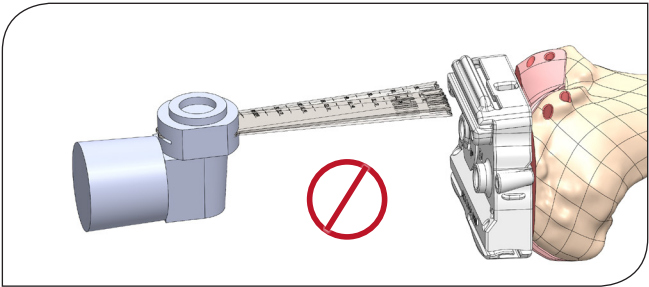


Image 2: Do not turn on the saw blade before touching bone

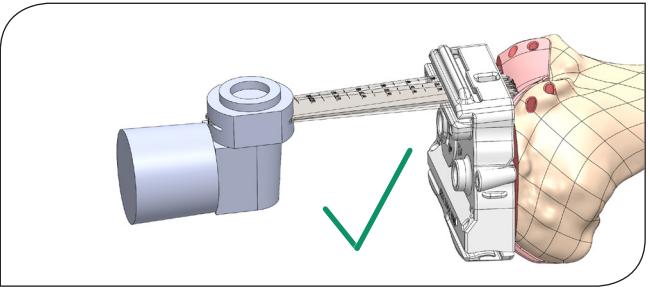
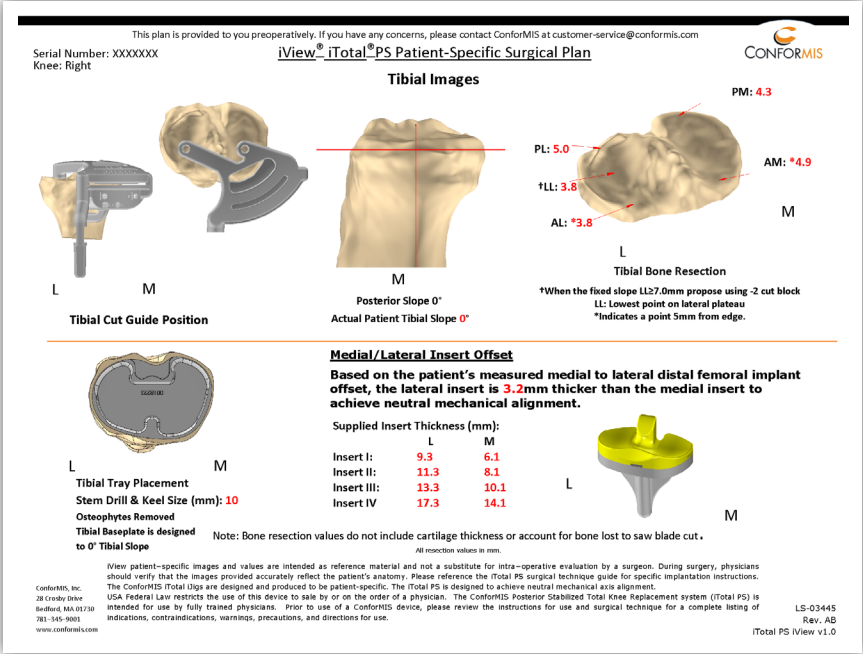


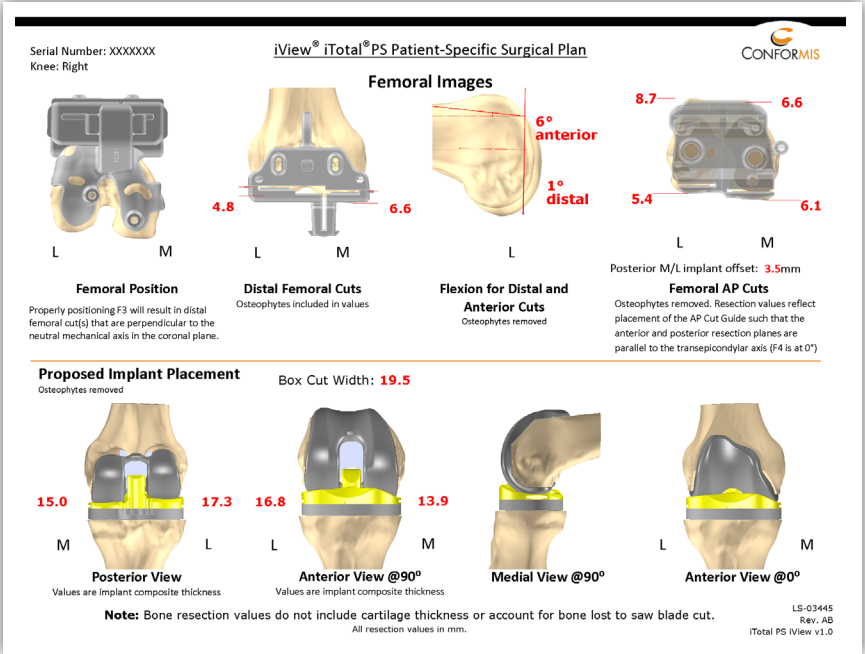
Image 3: Make sure that the saw blade is touching bone before initiating resection

Preoperative Image Review



iView® patient-specific planning images are included with each implant and are also available preoperatively from ConforMIS (visit orders.conformis.com). The images provide patient-specific tibial and femoral resection values, iJig placement, and final implant positioning information.

iView patient-specific planning images are intended as reference material and not a substitute for intraoperative evaluation by a surgeon. During surgery, physicians should verify that the images provided accurately reflect the patient's anatomy.



iTotal PS

POSTERIOR-STABILIZING

Step 1 FEMORAL PREPARATION



- 1.1** Position the patient on an operating table with the leg resting on a foot support at approximately 90° of flexion. Make a straight midline skin incision 2-4cm above the patella and down to the tibial tubercle. Make a medial parapatellar arthrotomy through the retinaculum, the synovium, and the capsule. The arthrotomy should begin proximal to the patella, continue distally around the medial aspect of the patella, and stop medial to the tibial tubercle. A subvastus or midvastus approach may also be utilized if desired.

Resect the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) at this time.

It is recommended to defer standard releases (e.g. releasing the Medial Collateral Ligament (MCL), posterior capsular release) until later in the procedure after Final Trialing with the Femoral Trial and Tibial Preparation iJig, T4.



- 1.2** Place the Positioning iJig, F1, onto the femur so it finds its natural conforming location. This iJig is designed to reference osteophytes and will secure firmly onto the femur. The anterior stylus will reference the anterior cortex.

In rare instances, the F1 iJig may not secure firmly into place. This could be due to osteophytes that were not recognized from the CT scan and are interfering with the iJig placement. Reference the iView patient-specific planning images for proper iJig placement and remove only those interfering osteophytes.

There may be space between the F1 iJig and the femur where there has been cartilage loss. The F1 iJig is designed to fit over 3mm of cartilage.

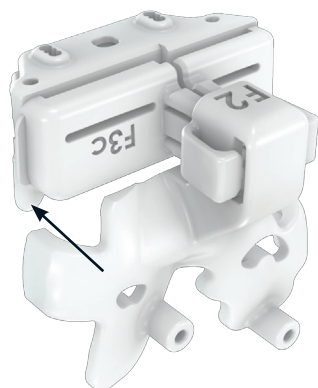


- 1.3** Using the Coring Tool, core through the two distal holes of the F1 iJig down to subchondral bone. Take care **not** to drill through subchondral bone. Remove the F1 iJig. A curette or rongeur will facilitate the removal of any residual cartilage within the cored holes.

Do not remove osteophytes.

Points of emphasis highlighted in purple.

Step 1 FEMORAL PREPARATION



1.4.1 Attach the Alignment iJig, F2, to the captured Distal Resection iJig, F3c. Ensure the Distal Resection Key iJig, F3a, is properly positioned within the F3c iJig to the 0 position. Place the iJig assembly onto the femur. The two round protrusions on the undersurface of the F2 iJig should seat into the cartilage voids created by the Coring Tool on the distal femur.



1.4.2 Once alignment of the assembly is confirmed, drill and place a Steinmann Pin into one of the crosspin holes of the F3c iJig using the 3mm drill bit. Drill the two anterior holes of the F3c iJig. Insert Steinmann Pins in the two anterior holes, impacting them through the iJig to allow complete resection during the distal cut.

Drill through the two distal holes of the F2 iJig. These holes will be used later as a reference for the rotation of the A-P Resection iJig, F4. Do not place Steinmann pins into these holes. Remove the F2 iJig by squeezing the finger positions and keep the F3c iJig, the anterior crosspin, and the two anterior Steinmann Pins in place.

An uncaptured version of the Distal Resection iJig, F3u, is available per surgeon preference. If selected, F3c must be used **first** in order to set the anterior pins. Once F3c is pinned in place on the femur, remove F2 and F3c. Slide the F3a into the F3u iJig to the 0 position for the initial planned resection based on the patient-specific surface of the F2/F3 iJig assembly. Place the F3u iJig on the anterior pin holes and insert at least one crosspin for additional stability.

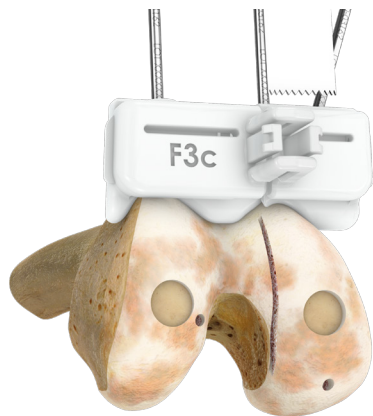


1.4.3 Both F3u and F3c have the ability to cut at 0, +2, and -2mm resection levels. When the +2 setting is used, an additional 2mm will be removed off the distal femur, raising the resection plane by 2mm. When the -2 setting is used, 2mm less will be removed off the femur, lowering the resection plane by 2mm. To perform -2 or +2 distal femoral resections, slide the Distal Resection Key, F3a, within the F3c iJig to the elected resection level as marked on the F3c iJig. Slide the iJig assembly onto the previously pinned anterior Steinmann pins.

In some situations (e.g. significant flexion contracture), the +2mm distal cut option may be performed as the primary distal femoral cut or after trialing with the Femoral Trial and Tibial Preparation iJig, T4, using steps outlined in Appendix A – Revisiting Distal Femoral Cut after Final Trialing. In other situations (e.g. excessive laxity and/or medial-lateral translation of the femur and tibia identified at initial exposure) the -2 distal cut option may be performed as the primary distal cut.

The two distal holes made with the F2 iJig may be marked with ink to help locate them after the distal femoral resection is made. One way this can be completed is by removing the tip from a sterile marker, attaching it to a kocher, and then inserting it into the drill holes.

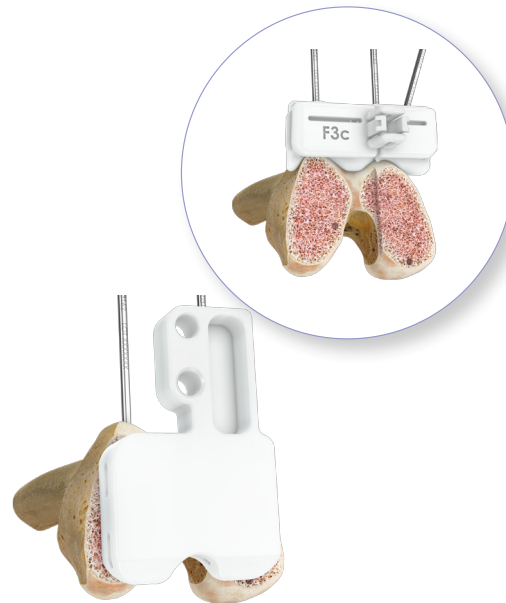
Step 1 FEMORAL PREPARATION



- 1.5** Both captured and uncaptured versions of the F3 iJig have a patient-specific surface that extends over the trochlea and may or may not have a step cut depending on which option preserves the most bone. The distal resection offset may not be equivalent to the distal implant offset.

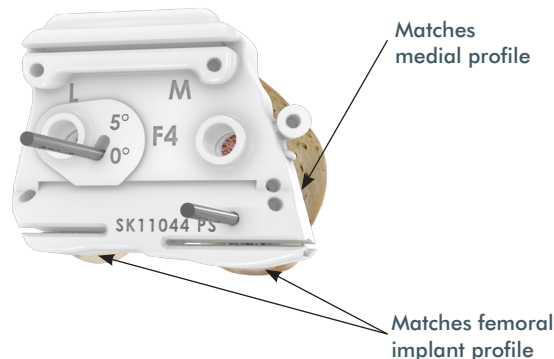
A Kocher can be attached to one of the Steinmann Pins to further stabilize the selected F3 iJig while the distal femoral resections are made.

Perform the distal femoral resection. If the selected F3 iJig has a step transition zone, use a reciprocating saw blade along the step. Then, using an oscillating saw blade, complete the distal femoral resection(s) by cutting across the flat surface(s) of the chosen F3 iJig.



- 1.6** Use a surgical marker to mark the holes on the cut distal femur for reference with the F4 iJig. Place the Extension Spacer iJig, T2, onto the cut distal femur to confirm the cuts are planar. If the T2 iJig does not sit flat, revisit the cuts as needed. Remove the Steinmann Pins and the selected F3 iJig.

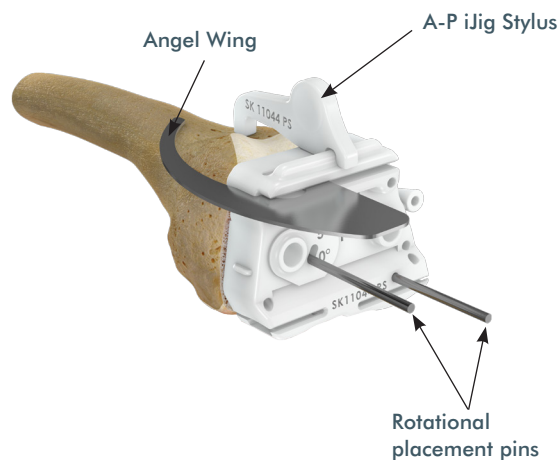
Step 1 FEMORAL PREPARATION



- 1.7** Place two Steinmann Pins into the previously marked holes on the distal femur. Place the A-P Resection iJig, F4, over the Steinmann Pins to sit flush against the surface of the cut distal femur.

The medial side of the F4 iJig will match the medial profile of the cut distal femur, excluding the profile of the medial offset crosspin hole. Confirm that the profile of F4 does not overhang the cut distal femur medially or laterally and is centered on the cut surface. The posterior profile of F4 represents the profile of the Femoral Implant. The A-P iJig Stylus, F4a, aids in proper placement of F4 and may be attached to the top of the F4 iJig prior to positioning.

External rotation may be added by rotating the F4 iJig around the medial pin. The cuts can be rotated up to 5° by rotating about the medial pin. To facilitate adjustments needed in F4, the F4a iJig may be removed.

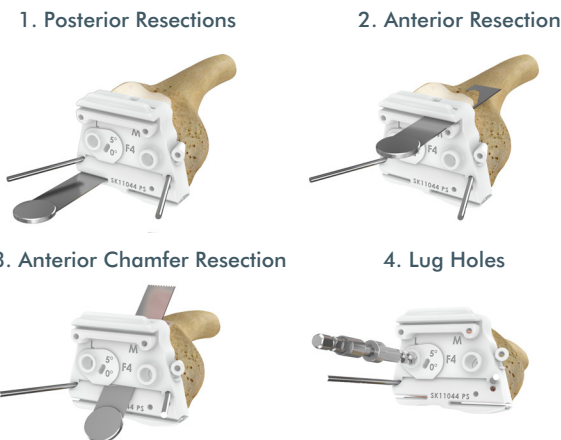


- 1.8** Use the supplied Angel Wing to confirm the anterior resection will not notch the femur. Reposition if required.

When the desired position is set, drill and pin the F4 iJig into place through any of the posterior crosspin holes and insert Steinmann Pins. Anterior crosspin holes and a medial offset crosspin hole are provided to allow for additional stabilization of the F4 iJig. Remove the initial two Steinmann Pins that were used for rotational placement.

Confirm positioning of the F4 iJig against the target anterior and posterior condylar resection values on the iView patient-specific planning images prior to performing resections. Reposition and re-pin if needed. In the instance the F4 iJig is repositioned, additional stabilization pin holes are available. In very small patients, additional stabilization pin holes may not be present.

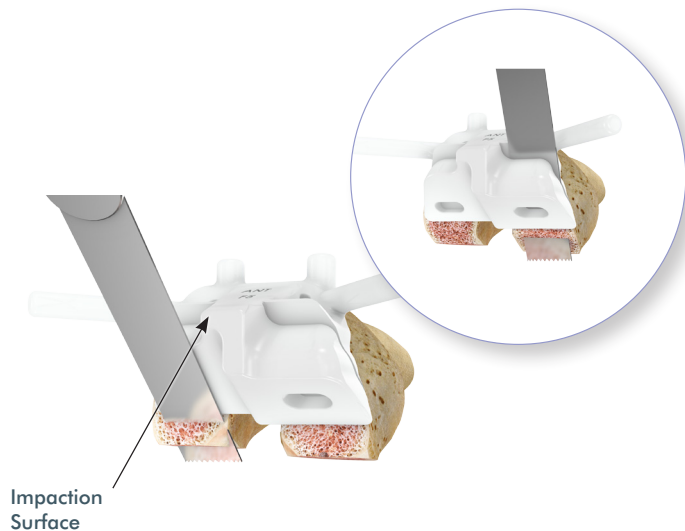
iView values may not match if F4 is adjusted. If F4 is externally rotated, use the Angel Wing to confirm the anterior resection will not notch the femur.



- 1.9** Proceed with the posterior and anterior femoral resections followed by the anterior chamfer resection using the F4 iJig. If either of the anterior crosspin holes were used to stabilize the F4 iJig, remove them before completing the anterior chamfer resection. Once completed, drill through the two lug holes of the F4 iJig using the 8mm drill bit. Remove the Steinmann pins and the F4 iJig.

Ensure the F4 iJig is pressed tightly against the resected distal femoral surface while performing all resections. Two black pegs can be used to help stabilize F4 by drilling the lug holes first and inserting the pegs into the holes.

Step 1 FEMORAL PREPARATION



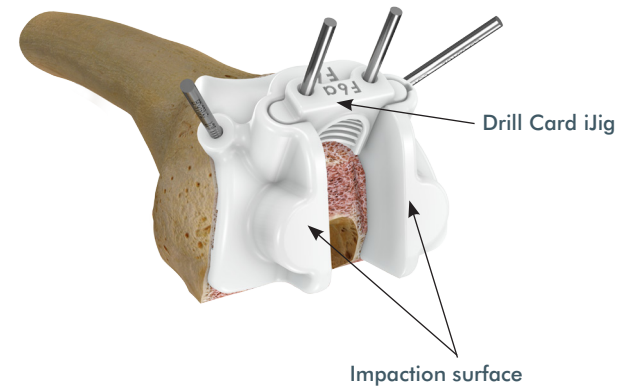
- 1.10** Place the Chamfer iJig, F5, on the distal femur so the pegs on the F5 iJig fit into the peg holes on the distal femur. The letters A-N-T are marked on the anterior surface of the F5 iJig. F5 can be impacted by hand, or if needed, by lightly tapping with a mallet, on the impaction surface. **DO NOT IMPACT THE CUTTING SURFACE.**

The F5 iJig can be stabilized using the handles on the medial and lateral edges or the iJig can be pinned into place on the anterior surface using Steinmann pins.

Complete the bottom posterior chamfer resection first then perform the top posterior chamfer resection.

If additional resection of the distal femur is required at any point after the posterior chamfer resections are completed, there are anterior pin holes on the F5 iJig that represent the nominal position of the pins set by the F3 iJig, at the original position. See Appendix A for more details.

For smaller anatomies, there may not be an impaction surface present on F5. If not, press-fit the F5 iJig into place.



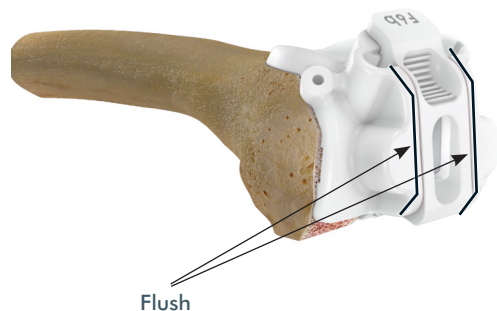
- 1.11.1** Place the Box Cutting iJig, F6, into position on the femur and fully seat it by gently impacting the two small distal surfaces using a mallet. Confirm proper femoral fit of the F6 iJig. If necessary, revisit the previously completed resections to improve fit. When in final position, the F6 iJig should sit flush in the prepared lug holes and around the femoral bone surfaces.

Stabilize the F6 iJig in its final position by drilling and inserting Steinmann Pins into the provided crosspin holes. The value provided on the anterior cutting surface of the F6 iJig represents the depth the sawblade must plunge to complete the box resection. This measurement is made from the top of the F6 iJig to the bottom of the box resection.

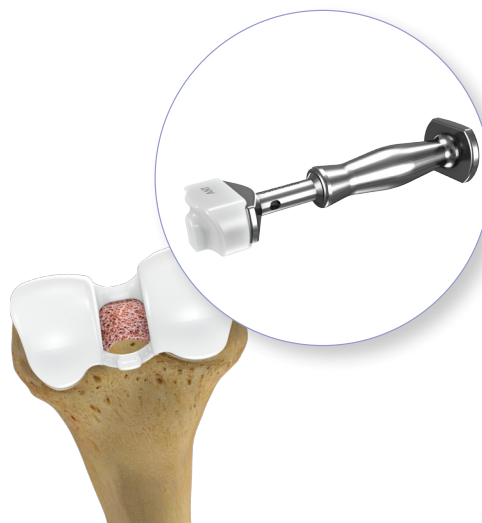
Create the box resection by cutting vertically downward with the edge of the saw blade set flush against the iJig surface around the three sides of the F6 iJig. Remove the Steinmann Pins and the F6 iJig from the femur.

An optional iJig, F6a, the Drill Card iJig, can be used with the F6 iJig. Insert the F6a into the F6 iJig, drill and insert Steinmann Pins into the pin holes within the F6a iJig. Remove the F6a iJig. The Steinmann Pins previously pinned through the F6a iJig can be left in the femur at the surgeon's discretion.

Step 1 FEMORAL PREPARATION



1.11.2 The Box Gauge iJig, F6b, can also be used with the F6 iJig after the box resection is made. Place the F6b iJig in the box of the F6 iJig. If the F6b iJig does not seat flush with the F6 iJig, remove the F6b iJig and check for any leftover bone or soft tissue that may be preventing the F6b iJig from sitting flush within the F6 iJig. Do not impact the F6b iJig into the F6 iJig.



1.12 Assemble the Impactor Head onto the Impactor Handle by connecting the two pieces at the mating surfaces. Then connect the Femoral Impactor onto the Impactor Head.

Place the Femoral Trial on the femur and impact it into place. Confirm proper femoral fit. If necessary, revisit completed resections to improve fit.

Visually inspect for and remove osteophytes on the posterior femoral condyles and posterior intercondylar notch, as well as bone in the transition area between the Femoral Trial and the posterior condyles. This is important for achieving increased flexion.

Step 2 TIBIAL RESECTION



- 2.1** The Tibial Resection iJig, T1, is designed to resect below the lowest point on the medial tibial plateau. Alternative resection blocks are also available as needed.

A captured Tibial Recut iJig, T1c, and an uncaptured Tibial Recut iJig, T1u, are available per surgeon preference. Both recut iJigs have 0, +2, and -2 pinhole positions. When the +2 setting is used, an additional 2mm will be removed off the tibia lowering the resection plane by 2mm. When the -2 setting is used, 2mm less will be removed off the tibia, raising the resection plane by 2mm. Both T1c and T1u have these ± 2 mm options. Refer to Step 2.3 on how to use these Recut iJigs.

In some situations (e.g. excessive wear on the medial tibial plateau) the planned resection could result in an aggressive lateral resection (≥ 7 mm). These cases will typically have a varus deformity. The lateral tibial resection value is provided on the iView patient-specific planning images and if this value is ≥ 7 mm, the -2 tibial cut guide is recommended for the primary cut. Refer to the iView patient-specific planning images for more details. In other situations (e.g. if the native tibial slope is less than 5° or if there is a significant anterior resection value of ≥ 10 mm on the anterior of the tibia as noted in the iView patient-specific planning image) the -2 tibial cut guide may be used to reduce the tibial resection.



- 2.2** The T1 iJig has two projections that match the subchondral bone surface of the proximal tibial plateau and one projection that matches the subchondral bone surface on the anterior tibia. Refer to the iView patient-specific planning images for proper placement of the T1 iJig on the tibia. Once positioned, mark the boundaries of the T1 iJig on the proximal and anterior tibia using a surgical marker. Remove the cartilage and any residual tissue within the marked line using a curette or a scalpel. This will allow the T1 iJig to sit flush on subchondral bone.

Marking the bottoms of the three projections on the T1 iJig with a marker before placing it on the tibia can facilitate locating the areas on the proximal tibia to scrape.

An alternative to removing cartilage manually is available per surgeon preference. Start with the T1 iJig in the correct position and drill through the holes on the two projections. Remove T1 and insert two short Steinman pins into the holes. Use the Coring Tool to remove cartilage down to subchondral bone. Take care not to drill through the subchondral bone. Remove pins.

Avoid over-coring to ensure proper varus/valgus alignment and resection depth.



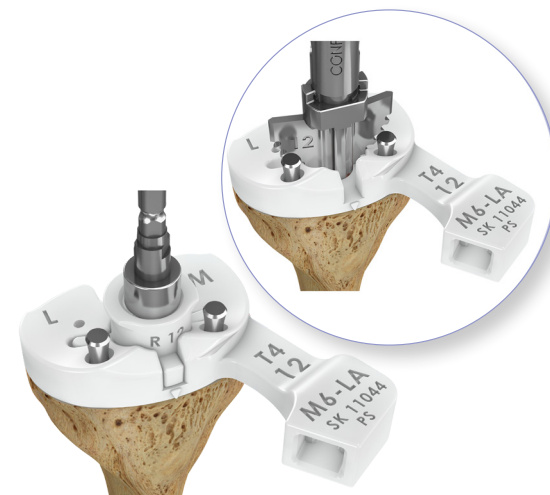
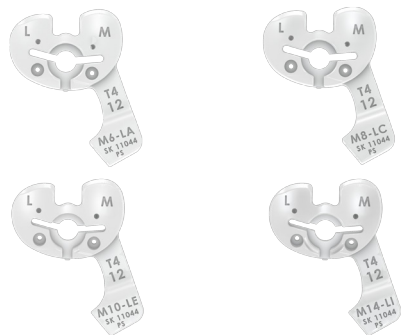
- 2.3** Secure the T1 iJig into place and attach an Alignment Rod to the iJig to assess alignment. The Alignment Rod should point distally to the center of the malleoli and it should be in-line with the tibial mechanical axis in the coronal plane as well as parallel to the tibial mechanical axis in the sagittal plane. This will result in achieving the planned sagittal slope as noted on the iView.

Drill through the two parallel holes and the crosspin holes of the T1 iJig on the anterior proximal tibia. Place short Steinmann Pins into the two parallel holes and long Steinmann Pins into the crosspin holes to secure the iJig firmly into place.

Complete the tibial resection using the selected Tibial Resection iJig.

To use the alternative Recut iJigs, the T1 iJig must be used **first** in order to set the anterior tibial pin locations. Once set, remove the pins and the T1 iJig. Replace the two parallel Steinmann Pins, slide the desired cut block over the parallel pins at the selected resection level, and insert the crosspin. A Tibial Recut Alignment Arm, A2, is provided to confirm axial alignment and mates with the projection on any of the Tibial Recut iJigs.

Step 3 TIBIAL PREPARATION



3.1 With the Femoral Trial in place, confirm peripheral tibial osteophytes have been removed and the ACL and PCL have been fully excised. Place the Tibial Preparation iJig, T4, on the cut proximal tibial surface. Multiple thicknesses of the T4 iJig are provided that are equivalent to the thickness of the Tibial Tray and the thickness of the Tibial Poly Inserts.

The T4 iJig has the same profile as the Tibial Tray. There is approximately 1mm of clearance around the T4 iJig to allow for intraoperative flexibility in rotational positioning.

Coronal alignment can be confirmed by attaching the Alignment Rod Adaptor, A1, into the rectangular slot on the handle of T4 and an Alignment Rod Assembly to the A1.

3.2 Bring the joint through the range of motion and assess balance and ligament tensioning using the selected T4 iJig. If a thicker tibial assembly is desired, repeat with a larger T4 iJig.

Perform the POLO test (Pull Out, Lift Off) in order to evaluate the tightness of the joint space. If the T4 iJig pulls out easily in flexion, the joint may be too loose. Consider using a thicker Poly Insert. If the T4 iJig lifts off anteriorly in flexion, the joint may be too tight. Consider revisiting the options provided previously if the knee is tight in flexion.

Once optimal balancing and ligament tensioning is confirmed, remove the Femoral Trial.

In the event the trialing versions of the T4 iJig are difficult to insert, a thinner option is provided for tibial preparation, the Tibial Template iJig, T5. The T5 iJig is not to be used for trialing and therefore, the Femoral Trial should be removed when using the T5 iJig. The T5 iJig has a drill tower that can be disassembled after drilling to facilitate keel preparation.

3.3 If using the T4 iJig for tibial preparation, insert the Tibial Preparation Drill Tower, T4a, and push down until it is fully bottomed out within the T4. The T4a iJig must be fully seated to allow for the proper drill angle and depth. Adjust the placement of T4 iJig for proper rotational alignment. The T4 iJig should be positioned for optimal plateau coverage while keeping to the posterolateral corner of the proximal tibia.

Stabilize the T4 iJig by impacting the Tack Pins into place on the proximal surface of the iJig. Using the appropriate size drill bit (marked on the handle portion of the T4 iJig and on the iView patient-specific planning images) drill the stem hole through the T4 iJig down to the physical stop. Remove the Tibial Preparation Drill Tower iJig.

Assemble the appropriate size Keel Punch (marked on the handle portion of the T4 iJig and on the iView patient-specific planning images) and attach it to the mating surface of the Impactor Handle and turn clockwise to lock in place. Impact through the keel slot on the T4 iJig using a mallet down to the physical stop.

If using the thinner T5 iJig for tibial preparation, confirm its final position and stabilize it by impacting the Tack Pins into place. Drill the stem hole and impact the Keel Punch as previously outlined using the appropriate sizes (marked on the handle portion of T5 iJig and on the iView).

Use a marker or a bovie to mark along the anterior tibia under the small, triangular projection on the T5 to make re-aligning it to the same position easier.

Step 4 PATELLA PREPARATION (OPTIONAL)

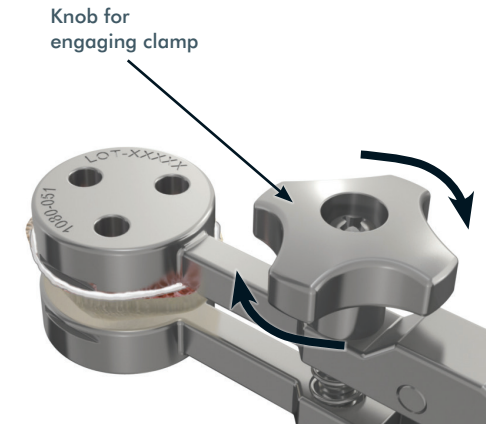


4.1 The patella can be prepared after tibial and femoral resections or just after the arthrotomy in order to facilitate exposure. Measure the patella thickness using a Caliper and make the desired cut. A Patella Osteotomy Guide is provided with graduations that indicate the thickness of the bone that will be resected.



4.2 Determine the Patellar Implant diameter using the Patella Sizers. Using a mallet, impact the Sizer (with the spikes facing down) onto the cut patellar surface. Drill through the three holes of the Sizer down to the physical stop using the provided patella drill bit.

It is suggested that the patella be medialized. The Patella Clamp may be used to prepare the three holes if desired.



4.3 Insert the Patella Trial corresponding to the size determined by the Patella Sizers. Remove the Patellar Trial. Apply a layer of cement to the patella, filling holes and covering the bone surface. Add a layer of cement to the Patella Implant. Insert the Patella Implant and clamp the patella and the Implant. Turn the knob in a clockwise direction to engage the Clamp. Remove any extruded cement from around the Implant.

Step 5 FINAL TRIALING AND CEMENTING THE IMPLANTS



5.1 Prior to cementing, an additional trialing step can be performed using the Femoral Trial in conjunction with the Trial Inserts and the Tibial Tray Trial. Install the Tibial Tray Trial by manually inserting it and then gently impacting it into place using the Tibial Tray Impactor Tip. Using the Femoral Impactor Tip, impact the Femoral Trial on the femur. Insert the selected Trial Insert by sliding the Trial Insert's spine underneath the box and up and against the cam mechanism of the Femoral Trial. Push the Trial Insert into the Tibial Tray Trial. Rotate the foot to expose the joint space to facilitate insertion.

If optimal balancing and tensioning have been achieved, proceed to the next step. If they have not been achieved, revisit steps as outlined previously.

Trials may be removed by gently prying them off of the femur and tibia using an osteotome if needed.

Do not use the metal Femoral Implant or Tibial Tray when trialing.



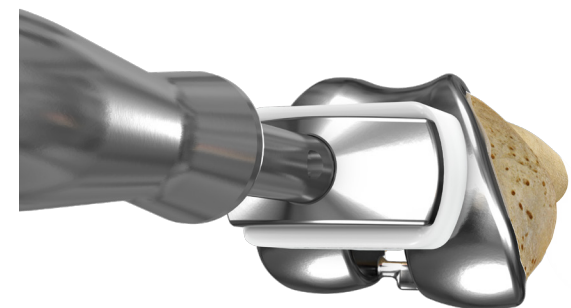
5.2 Thoroughly wash (using pulse lavage, if available) and dry the bone prior to applying cement.

Apply a layer of cement (less cement posteriorly) to the Tibial Tray and to the tibia, filling holes (especially the stem hole) and covering the bone surface.

Assemble the Impactor Head onto the Impactor Handle by connecting the two pieces at the mating surfaces. Connect the Tibial Tray Impactor Tip onto the Impactor Head.

Using the Impactor assembly and a mallet, impact the Tibial Tray. Remove any residually extruded cement from around the Tibial Tray with consideration for any cement that may have extruded posteriorly.

The patient-specific profile of the Tibial Tray is designed to be supported by the cortical rim.



5.3 Apply a layer of cement to the femoral bone, filling holes and covering bone surface while taking care not to apply cement on the posterior condyles. Add a layer of cement to the Femoral Implant applying less cement posteriorly. This will aid in preventing posterior cement extrusion. Using the Femoral Impactor iJig, Impactor Head, and Impactor Handle, impact the Femoral Implant. Remove any residually extruded cement from around the Femoral Implant.

Step 5 FINAL TRIALING AND CEMENTING THE IMPLANTS



5.4.1 Select the appropriate Trial Insert. Multiple Trial Inserts are provided to facilitate proper balancing of the knee. Successive Trial Inserts increase in thickness while maintaining the distal femoral offset, which is provided on the iView patient-specific planning images. The thickness of the Trial Inserts is determined by the patient's distal femoral offset to achieve neutral mechanical alignment.

Insert the selected Trial Insert into the Tibial Tray by sliding the Trial Insert's spine underneath the box and up and against the cam mechanism of the Femoral Implant. Push the Trial Insert into the Tibial Tray. Rotate the foot to expose the joint space to facilitate insertion.

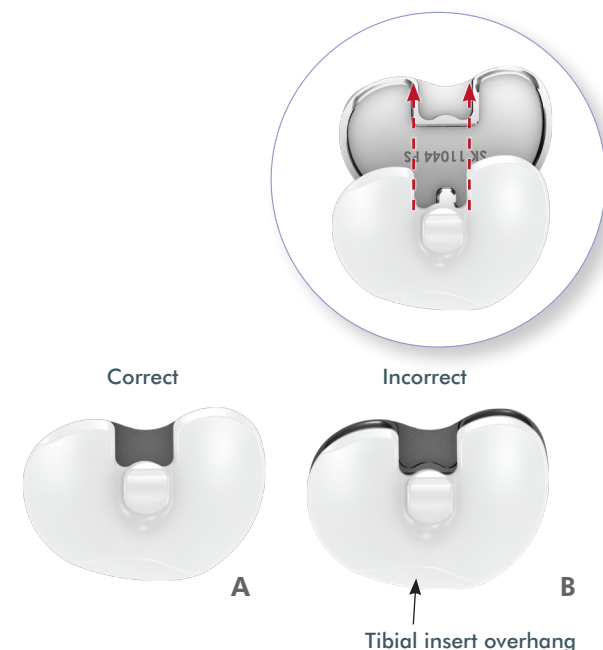


5.4.2 Bring the joint through the range of motion to evaluate kinematics and ligament balance. Use different Trial Insert thicknesses to achieve desired balancing and alignment. In the event soft tissue balance or joint alignment cannot be achieved, ligament balancing using standard soft-tissue releases may be considered.

Remove the Trial Insert.

As an alternative to the above-mentioned impaction method, a compression method may be effective with the Trial Insert in place as well.

Avoid hyper-flexion of the knee while the cement is hardening.



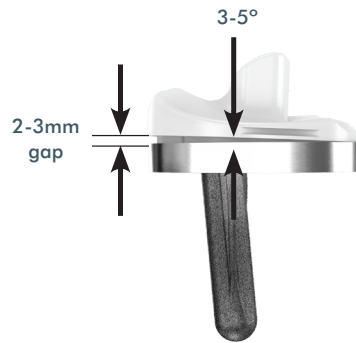
5.5.1 Align the Poly Insert by verifying the profile of the Poly Insert is directly on top of the profile of the Tibial Tray (Image A). **Do not** impact the Poly Insert if the profile of the Insert is overhanging the profile of the Tibial Tray (Image B).

Insert the Poly Insert by sliding the Poly Insert's spine underneath the box and up and against the cam mechanism of the Femoral Implant. Push the Poly Insert into the back of the Tibial Tray. Rotate the foot to expose the joint space to facilitate insertion.

Aligning the cut-out on the Poly Insert with the cut-out on the Tibial Tray during insertion will help ensure proper positioning (Inset).

Impacting a Poly Insert that is improperly placed on the Tibial Tray may damage the locking mechanism of the Poly Insert.

Step 5 FINAL TRIALING AND CEMENTING THE IMPLANTS



5.5.2 Tap the Poly Insert back and into place with a posterior projection impaction. Once properly in place, the Poly Insert will be at a 3-5° angle to the Tibial Tray, with no more than a 2-3mm gap anteriorly.

Ensure the Poly Insert is fully seated posteriorly within the Tibial Tray before tapping down.



5.5.3 Assemble the Tibial Poly Impactor Tip onto the Impactor Handle.

Place the Tibial Impactor Tip onto the anterior mating surface of the Poly Insert and impact the head of the Impactor Handle with a mallet. The force should impact the Poly Insert at a 45-60° angle and will produce a snap sensation as the Poly Insert locks into place.

Ensure impaction is on the middle of the Poly Insert and straight back to ensure the Poly Insert does not start to rotate.



5.5.4 Visually confirm that the Poly Insert is locked into place within the Tibial Tray. There should be no gapping between the Poly Insert and the Tibial Tray.

To remove the Poly Insert, insert a small osteotome into the anterior slot of the Poly Insert and lift it up to disengage the locking tab.

Step 5 FINAL TRIALING AND CEMENTING THE IMPLANTS



5.6 After implantation of the iTotal PS System is complete, closure is performed in layers according to standard protocol.

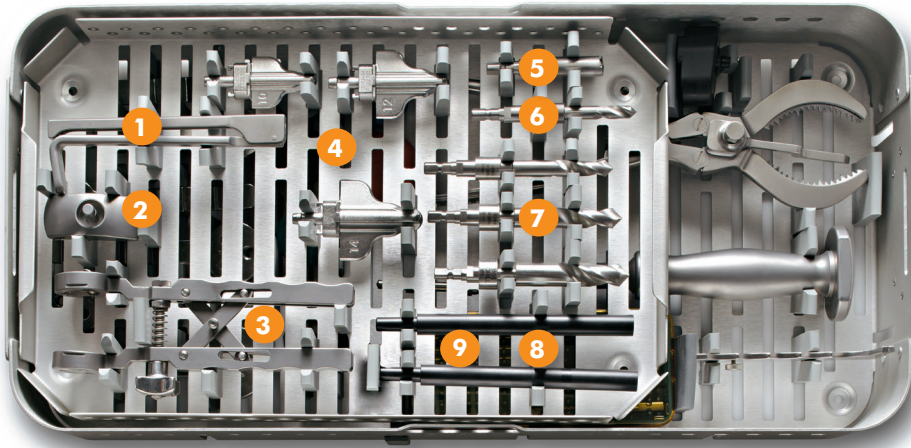
Appendix A REVISITING DISTAL FEMORAL CUT AFTER FINAL TRIALING



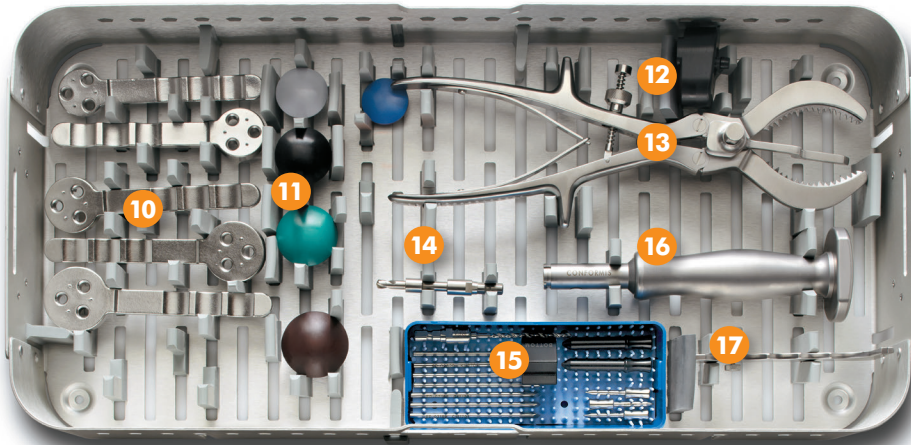
A.1 If additional distal femoral resection is required after trialing with the Femoral Trial and Tibial Preparation iJig, T4, place the Chamfer iJig, F5, on the resected femur and secure into place. Use the anterior drill holes on F5 to reestablish nominal drill holes initially placed with F3, then reinsert Steinmann pins. Reset the Distal Resection Key iJig, F3a, within the selected Distal Resection iJig (either the captured version, F3c, or uncaptured version F3u) to a +2mm setting. Place the F3/F3a assembly back over the pins and take the additional 2mm off the distal femur.

Repeat steps as previously outlined to recut the anterior resection, anterior chamfer resection, lug holes, both chamfer resections, and the box cut.

Repeat Final Trialing with the Femoral Trial and Tibial Preparation iJig, T4.



- 1. Pin Puller:**
Is used to remove Steinmann Pins.
- 2. Impactor Head:**
Mates with the patient-specific Femoral Impactor Tip, Tibial Impactor Tip, and Impactor Handle.
- 3. Patella Clamp:**
Clamps onto the patella and patella implant while the cement is setting. Can also be used to prepare patella fixation holes.
- 4. Keel Punch Tips:**
Are attached to the Impactor Handle and used to prepare the cavity for the keel of the Tibial Tray.
- 5. Coring Tool:**
Is used to remove tibial and femoral cartilage in order for iJigs to reference off subchondral bone.
- 6. Femoral Drill Bit:**
Is used to drill the femoral fixation lugs.
- 7. Tibial Stem Drill Bits:**
Are used to prepare the central portion of the tibial fixation keel.
- 8. Alignment Rods:**
Are assembled to either T1, T2 and either the Tibial Recut iJigs or T4.
- 9. Angel Wing:**
Used to confirm the anterior resection will not notch the femur.



- 10. Patella Sizers:**
Are used to select the patella size and serve as a drill guide to prepare the patella holes.
- 11. Patella Trials:**
Are provided to trial the selected patella size.
- 12. Tibial Impactor Tip:**
Used to impact the Tibial Tray onto the tibia and mates with the Impactor Handle.
- 13. Patella Osteotomy Guide:**
Is used to clamp onto the patella to make the resection.
- 14. Patella Drill Bit:**
Is used to prepare the patella holes.
- 15. Drill Bit, Pins and Poly Impactor Tip:**
The small blue tray contains a 3mm Drill Bit used for drilling the holes for placement of Steinmann Pins, four 80mm Steinmann Pins, three 60mm Steinmann Pins, two black pegs used with A-P Resection iJig (F4), Poly Impactor Tip that attaches to the Impactor Handle, and two tack pins used with T4, or T5.
- 16. Impactor Handle:**
Mates with the Keel Punch Tips, Impactor Head, and Poly Impactor Tip.
- 17. Caliper:**
Is used to measure the patella in preparation for patella resection and sizing.

Indications for Use

The iTotal PS Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral, or bicompartamental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, or osteonecrosis of the knee
- Post traumatic loss of joint function
- Moderate varus, valgus or flexion deformity
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartamental implants
- Revision procedures, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

This implant is intended for cemented use only.

Contraindications

The following conditions are absolute contraindications for posterior stabilized total knee replacement:

- Active or recent local or systemic infection
- Insufficient bone stock on the femoral or tibial surfaces
- Skeletal immaturity
- Loss of bone or musculature, osteoporosis, neuromuscular or vascular compromise in the area of the joint to be operated to an extent that the procedure is unjustifiable (e.g., absence of musculoligamentous-supporting structures, joint neuropathy)
- Metal sensitivity (e.g., nickel)

Magnetic Resonance (MR) Environment

ConforMIS, Inc., iTotal PS (Posterior Stabilized) KRS (Knee Replacement System) implants are manufactured of non-ferromagnetic materials such as, cobalt-chromium-molybdenum alloy (CoCrMo) and ultra-high molecular weight polyethylene (iPoly) or highly cross-linked ultra-high molecular weight Vitamin E enriched polyethylene (iPoly XE).

Non-clinical testing demonstrated that the iTotal PS KRS is MR Conditional. A patient with this device can be scanned safely, immediately after placement, under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) and 3.0-Tesla (3.0T)
- Maximum spatial gradient magnetic field of 3000 Gauss/cm (30T/m) or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg
- Normal operating mode of the MR system

The effects of MRI procedures using MR systems and conditions above these levels have not been determined.

In non-clinical testing, the iTotal PS KRS produced a temperature rise of less than 2.0°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 1.5-Tesla (Siemens Espree, Siemens, Erlangen, Germany, SYNGO MR B17 software) MR scanner.

In non-clinical testing, the iTotal PS KRS produced a temperature rise of less than 5.0°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3.0-Tesla (Siemens Trio, Siemens, Erlangen, Germany, SYNGO MR A35 4VA35A software) MR scanner.

Image Artifact

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the iTotal PS KRS. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size extends approximately 8.5cm relative to the size and shape of this implant in image distortion tests using spin-echo pulse sequences as defined in ASTM F2119 in a 3.0T MR system.

Notes



iTotal PS

POSTERIOR-STABILIZING



ConforMIS, Inc. • 28 Crosby Drive • Bedford, MA 01730, USA • Phone: 781.345.9001 • Fax: 781.345.0147

www.conformis.com

iTotal, iJig, iView and ConforMIS are registered trademarks of ConforMIS.
CAUTION: USA federal law restricts this device to sale by or on the order of a physician. The ConforMIS Posterior Stabilizing Total Knee Replacement System (iTotal PS) is intended for use only by fully trained physicians. Prior to use of a ConforMIS device, please review the instructions for use and surgical technique for a complete listing of indications, contraindications, warnings, precautions, and directions for use.

MK-03026-AA 4/16 | © 2016. ConforMIS, Inc.