



iTotal[®] CR

SURGICAL TECHNIQUE GUIDE

Patient-specific CRUCIATE-RETAINING knee replacement system

GAP BALANCING

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Introduction

The iTotal® CR Cruciate Retaining 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.

1. Distal Femoral Resection
2. Tibial Resection
3. Femoral Preparation
4. Tibial Preparation
5. Patella Preparation (optional)
6. Final Trialing and Cementing Implants

iTotal CR

CRUCIATE-RETAINING

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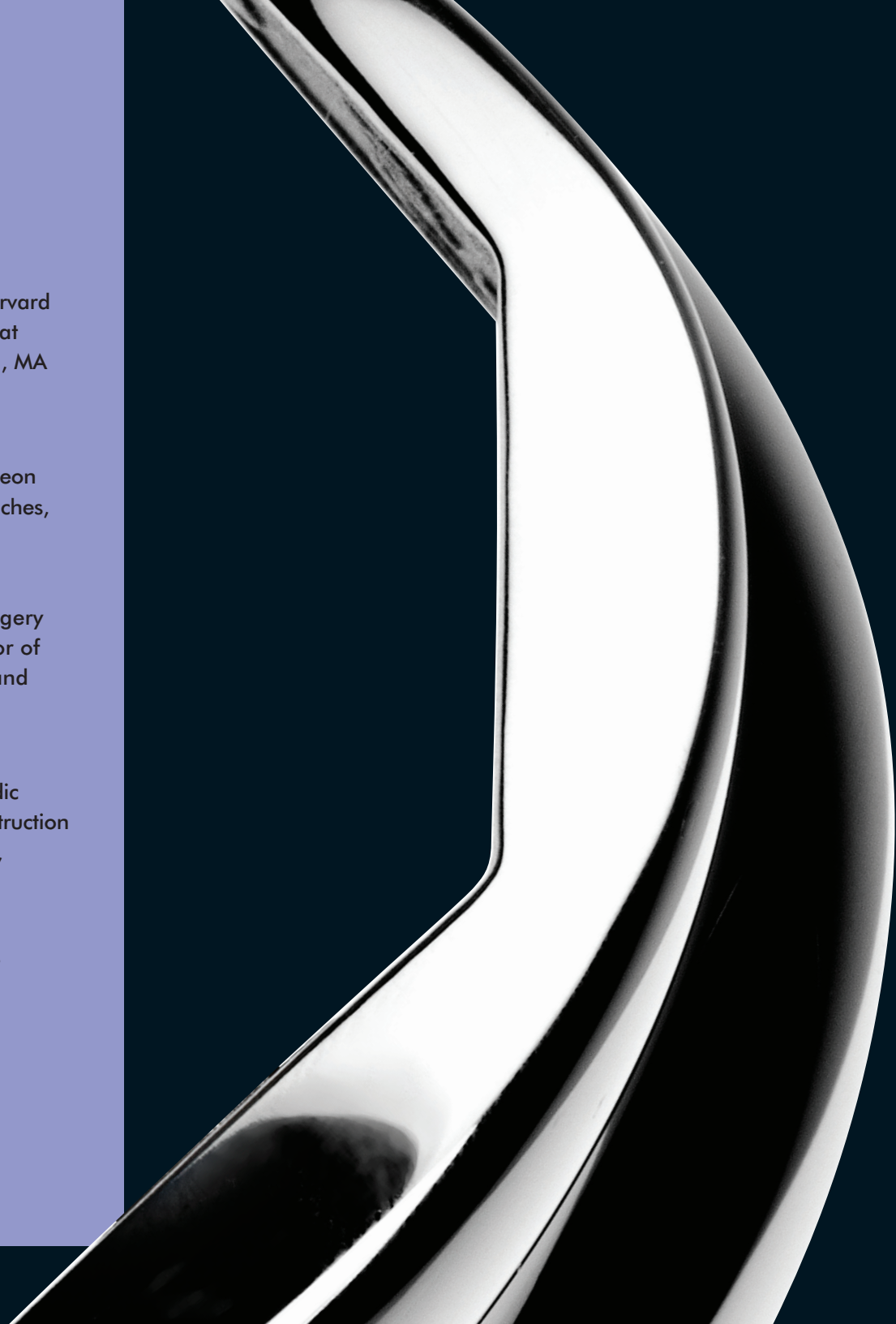
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iTotal CR Sample OR Layout



iJigs and Implants:

1. F1, Positioning iJig
2. F2, Alignment iJig
3. F3c, Distal Resection iJig (captured)
4. T1-5°, 5° Slope Tibial Resection iJig
5. T2, Extension Spacer iJig
6. T3, Flexion Spacer iJig
7. Shims - 2mm and 3mm
8. F4, A-P Resection iJig
9. F4a, A-P iJig Stylus
10. F5, Chamfer iJig
11. T4, Tibial Preparation iJig, 6A with T4a Tibial Preparation Drill Tower
12. A1, Alignment Rod Adaptor
13. T5, Tibial Template iJig
14. Femoral Trial
15. Femoral Impactor Tip
16. Femoral Implant
17. Tibial Tray
18. Trial Inserts

Reusable Instruments:

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

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 (Image 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
	ConMed - Linvatec	TN190-127-05	105	19	1.27

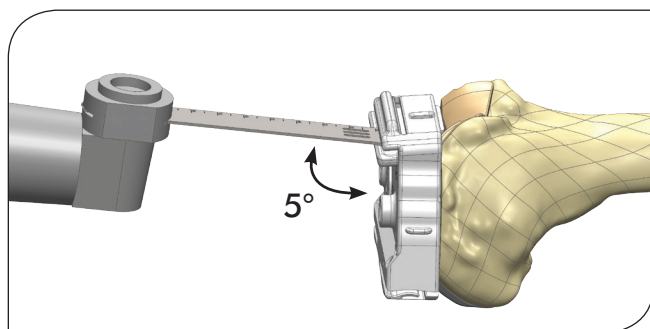


Image 1: Saw blade entering Captured iJig

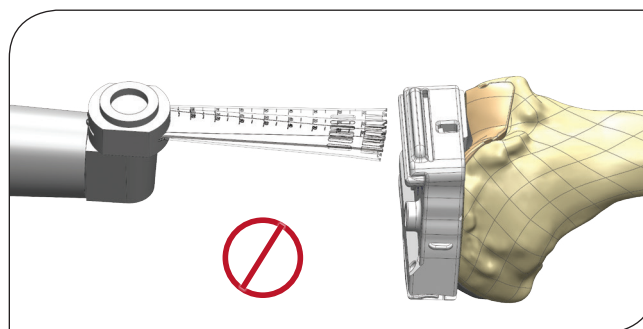


Image 2: Do not turn on the saw blade before touching bone

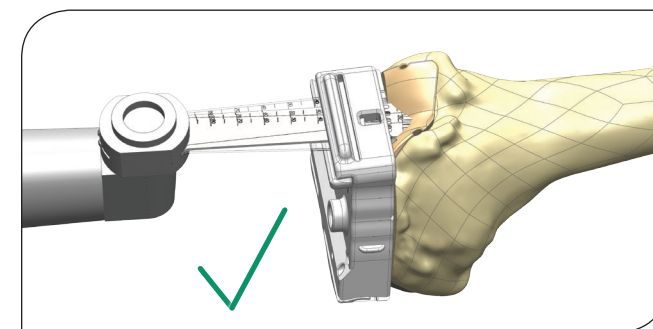


Image 3: Make sure that the saw blade is touching bone before initiating resection

Preoperative Image Review

This plan is provided to you preoperatively. If you have any concerns, please contact ConforMIS at customer-service@conformis.com

Serial Number: XXXXXXXX
Knee: Left

iView® iTTotal® G2 Patient-Specific Surgical Plan

CONFORMIS

Tibial Images

Posterior Slope
Native medial slope: 7°
Fixed slope: 5° Patient-specific slope: 7°

Tibial Bone Resection
*When the LL:7.0mm propose using -2 cut block
LL: Lowest point on lateral plateau
*Indicates a point 5mm from edge.
5° fixed slope resection/7° patient-specific resection

Medial/Lateral Insert Offset

Based on the patient's measured medial to lateral distal femoral implant offset, the lateral insert is **2.0mm** thicker than the medial insert to achieve neutral mechanical alignment.

Supplied Lateral Insert Thickness (mm):
Lateral Insert A: **8.1**
Lateral Insert B: **9.1**
Lateral Insert C: **10.1**

Tibial Tray Placement

Stem Drill & Keel Size (mm): **12**
Osteophytes Removed
Tibial Baseplate is designed to 5° Tibial Slope

Note: Bone resection values do not include cartilage thickness or account for bone lost to saw blade cut.
All resection values in mm.

View patient-specific images and values are intended as reference material and not a substitute for intra-operative evaluation by a surgeon. During surgery, physicians should verify that the images provided accurately reflect the patient's anatomy. Please reference the iTTotal G2 surgical technique guide for specific implantation instructions. The ConforMIS iTTotal G2 liggs are designed and produced to be patient-specific. The iTTotal G2 is designed to achieve neutral mechanical axis alignment. USA Federal Law restricts the use of this device to sale by or on the order of a physician. The ConforMIS G2 Cruciate Retaining Total Knee Replacement system (iTTotal G2) is intended for use 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.

LS-03057
Rev. AB
iTTotal iView v2.0

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 CR

CRUCIATE-RETAINING

Serial Number: XXXXXXXX
Knee: Left

iView® iTTotal® G2 Patient-Specific Surgical Plan

CONFORMIS

Femoral Images

Femoral Position
Properly positioning F3 will result in distal femoral cut(s) that are perpendicular to the neutral mechanical axis in the coronal plane.

Distal Femoral Cuts
Osteophytes included in values

Flexion for Distal and Anterior Cuts
Osteophytes removed

Posterior M/L Implant offset: **2.8mm**
Femoral AP Cuts
Osteophytes removed. Resection values reflect placement of the AP Cut Guide such that the anterior and posterior resection planes are parallel to the transepicondylar axis (F4 is at 0°)

Proposed Implant Placement

Osteophytes removed

Posterior View
Anterior View @90°
Anterior View @0°

Note: Bone resection values do not include cartilage thickness or account for bone lost to saw blade cut.
All resection values in mm.

LS-03057
Rev. AB
iTTotal iView v2.0

Step 1 DISTAL FEMORAL RESECTION



- 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 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.

Do not remove osteophytes or perform ligament releases at this point.



- 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.



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

Drill and pin the two anterior parallel holes and at least one of the cross pin holes of F3c using a 3mm Drill Bit and Steinmann Pins.

Drill through the two distal holes of F2. These holes will be used later as reference for the rotation of the A-P Resection iJig, F4. Do **not** place Steinmann Pins into these holes. Remove F2, by squeezing the release tabs on F2. Use a surgical marker to mark the two distal holes.

For a more conservative initial distal femoral resection, a -2mm distal resection option is available. For additional distal femoral resection, a +2mm distal resection option is available. To perform the ± 2 mm distal resections, remove the F3c iJig, slide F3a within the F3c iJig to the selected resection level and slide the iJig assembly onto the existing anterior parallel Steinmann Pins.

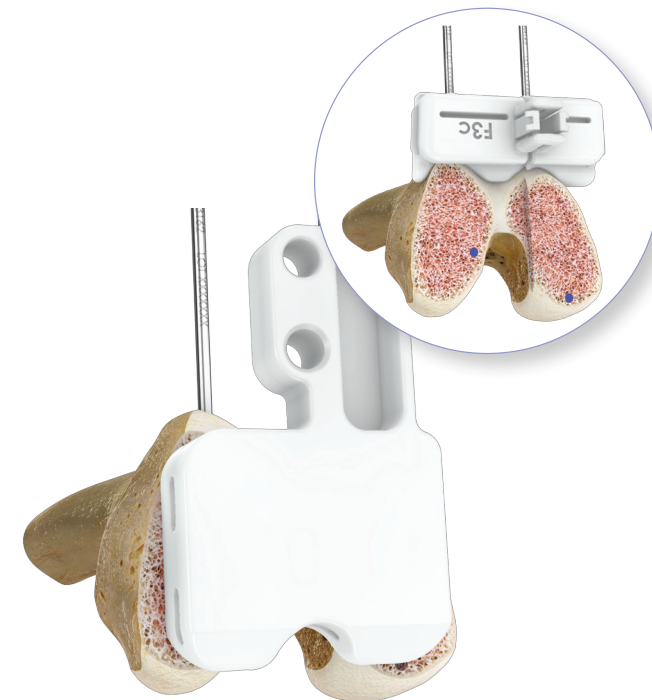
The patient specific surface is designed to the 0 position. When using ± 2 positions, the stylus may not touch on the bony surface. Do not push down on the stylus of as it may result in a resection that is in extension or flexion.



1.5 The F3c iJig has a patient-specific surface that extends over the trochlea and may or may not have a step cut. The distal resection offset (DRO) or step cut will be patient-specific in cases where it is greater than 2mm. In cases where it is less than 2mm, the DRO will either be a 2mm or a flat cut, depending on which option preserves the most bone. The DRO may not be equivalent to the distal implant offset.

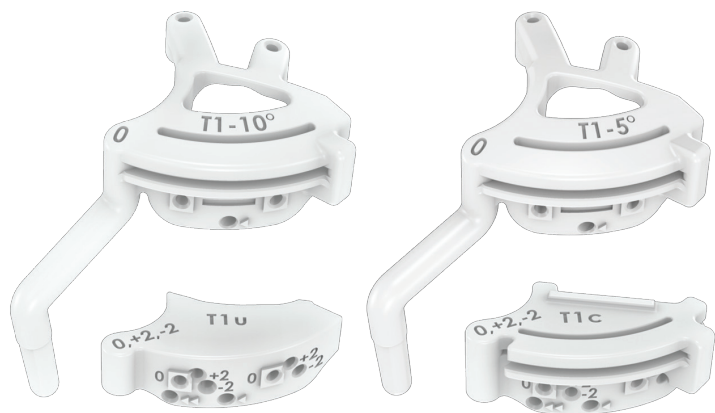
If F3c has a step cut, use a reciprocating saw blade along the step. Next, use the oscillating saw blade to complete the distal femoral resection.

An uncaptured version of the Distal Resection iJig, F3u, is available per surgeon preference. If selected, F3c will need to be used to set the anterior parallel and distal pin holes first before proceeding with the distal resection with F3u.



1.6 Remove the cross pin(s) and F3c or F3u. Place the Extension Spacer iJig, T2, onto the cut distal femur to confirm the resections are planar. If T2 does not sit flat, revisit the resections as needed. Remove the anterior parallel Steinmann Pins.

Step 2 TIBIAL RESECTION



2.1 Two primary Tibial Resection iJigs are provided based on surgeon preference. T1-5° is set to a fixed 5° tibial slope. T1-#° is set to the patient's native slope ranging from 5°-10° as indicated on the iJig. Both T1's are set to a resection plane 2mm below the lowest point on the medial tibial plateau. T1-5° and T1-#° are primary resection iJigs and **cannot** be interchanged. Therefore a specific T1 must be selected before drilling and inserting the Steinmann Pins.

The Tibial Tray is designed to match the 5° tibial slope value and position.

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 pin hole positions. If an additional 2mm of bone needs to be removed from the tibia, use the +2 pin hole position. If a more conservative tibial resection is desired, use the -2 pin hole position.



2.2 The T1 iJigs have two projections with distal tips that match the subchondral bone surface of the anterior tibial plateau. Place the selected T1 onto the tibia and mark the boundaries of the projections on the proximal tibia using a surgical marker. Remove the cartilage and any residual tissue within the marked lines using a curette or a scalpel. This will allow the T1 iJig to sit flush on subchondral bone.

An alternative to removing cartilage manually is available if desired. Once T1 is in the correct position, drill through the holes on the two distal tips of T1 using the 3mm Drill Bit. Remove T1 and place two Steinmann Pins into the holes. Place the Coring Tool over the pins and remove cartilage down to subchondral bone.

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

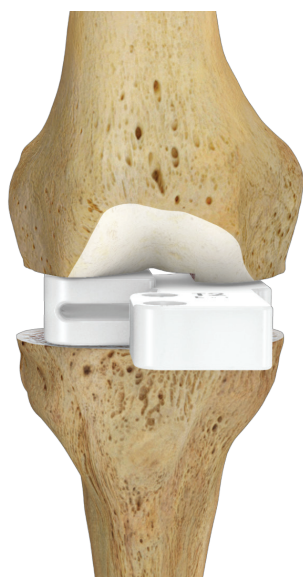


2.3 Secure the selected T1 iJig into place and attach an Alignment Rod to the iJig to assess alignment. The Alignment Rod should point distally to the center of the malleoli and it should be in line with the tibial mechanical axis in the coronal plane as well as parallel to tibial mechanical axis in the sagittal plane. Once T1 is in proper alignment, drill and pin T1 into place through the two parallel holes and the cross pin hole. Complete the tibial resection using the selected Tibial Resection iJig.

To use either of the Recut iJigs, the previously selected T1-5° or T1-#° must be used initially to set the pin placement. Once the pins have been drilled and pinned, slide T1c or T1u over the pins at the desired resection level and cross pin for additional stability. Verify alignment of the Recut iJigs by selecting the Tibial Recut Alignment Arm (A2-5° or A2-#°) that corresponds to the primary T1 iJig that was used. The alignment should be the same as it is with the primary T1 iJig.

In some situations (e.g. excessive wear on the medial tibial plateau) the planned resection could result in an aggressive lateral resection (greater than 7mm). These cases will typically have a varus deformity greater than 10°. The lateral tibial resection value is provided on the iView patient-specific planning images and if this value is greater than 7mm, the -2 position on the T1u or T1c iJig is recommended as the primary cut. Refer to the iView for more details.

Step 3 FEMORAL PREPARATION



- 3.1** Remove all peripheral tibial and femoral osteophytes. With the knee in extension, place the Extension Spacer iJig, T2, between the cut distal femur and the cut proximal tibia.

The thickness of T2 is equivalent to the thickness of the Tibial Tray with a 6mm medial Poly Insert, an A lateral Poly Insert, plus the thickness of the distal portion of the Femoral Implant.

Assess the knee for appropriate balance by applying varus/valgus stress. The joint space should open approximately 1-2mm medially and laterally with the application of stress.

Attach an Alignment Rod to the anterior hole on T2 pointing proximally towards the femoral head and an Alignment Rod to the posterior hole pointing distally towards the center of the malleoli, and assess the coronal alignment of the knee. Confirm full extension.

If it is challenging to insert T2, place the knee in slight flexion until the cut distal femur is parallel with the cut proximal tibia (this will occur between 5-15° of flexion). If the knee is still too tight in this position, consider completing Step 3.2 to confirm flexion balancing prior to completing additional resections. If the knee is too loose, shims of 2mm or 3mm thicknesses can be snapped onto the posterior surface of T2 to confirm whether alternative poly thicknesses will provide adequate balancing.



- 3.2** Bring the knee into approximately 95° of flexion, then place the Flexion Spacer iJig, T3, onto the cut proximal tibia. The femoral condyles should sit posteriorly on T3. The T3 iJig accounts for the presence of 3mm of posterior condylar cartilage. If there is posterior condylar cartilage loss, 2mm and 3mm Shims can be snapped onto the posterior surface of T3. If there is lateral laxity, the Shims may aid in determining if external rotation of the femoral cuts is required.

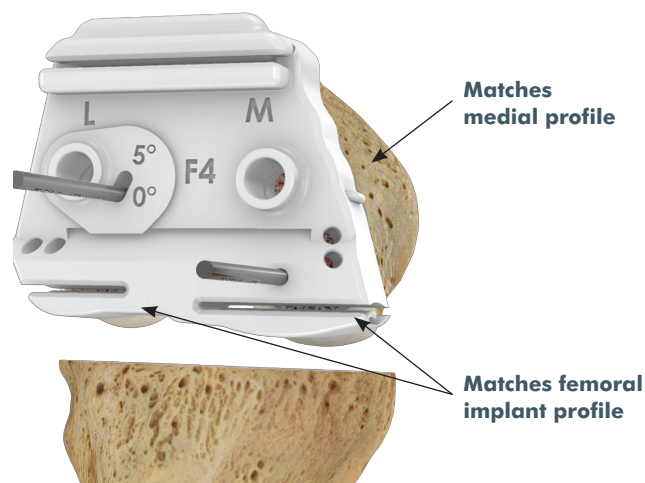
Assess the knee for appropriate balance by applying varus/valgus stress. The joint space should open approximately 1-2mm medially and laterally with the application of stress. If the knee is appropriately balanced and aligned, proceed to the next step.

If the knee is balanced in flexion but tight in extension, use the +2 position of either F3c or F3u to remove an additional 2mm of bone from the femur. If the knee is tight in flexion and extension, consider removing an additional 2mm from the Proximal Tibia by using the +2 pin position of either T1c or T1u. If the knee is balanced in extension and tight in flexion, check for any osteophytes that may be impinging on the PCL, then consider adding slope to the proximal tibia, and/or recess or lengthen the PCL. If additional slope is desired, a manual cut will have to be performed. Refer to Table 1 for balancing tips.

BALANCING TIPS	BALANCED IN EXTENSION	TIGHT IN EXTENSION
BALANCED IN FLEXION	Proceed with Femoral Preparation	Remove 2mm from the Distal Femur
TIGHT IN FLEXION	Add Slope to the Tibial Cut	Remove 2mm from the Proximal Tibia

Table 1: Balancing Tips

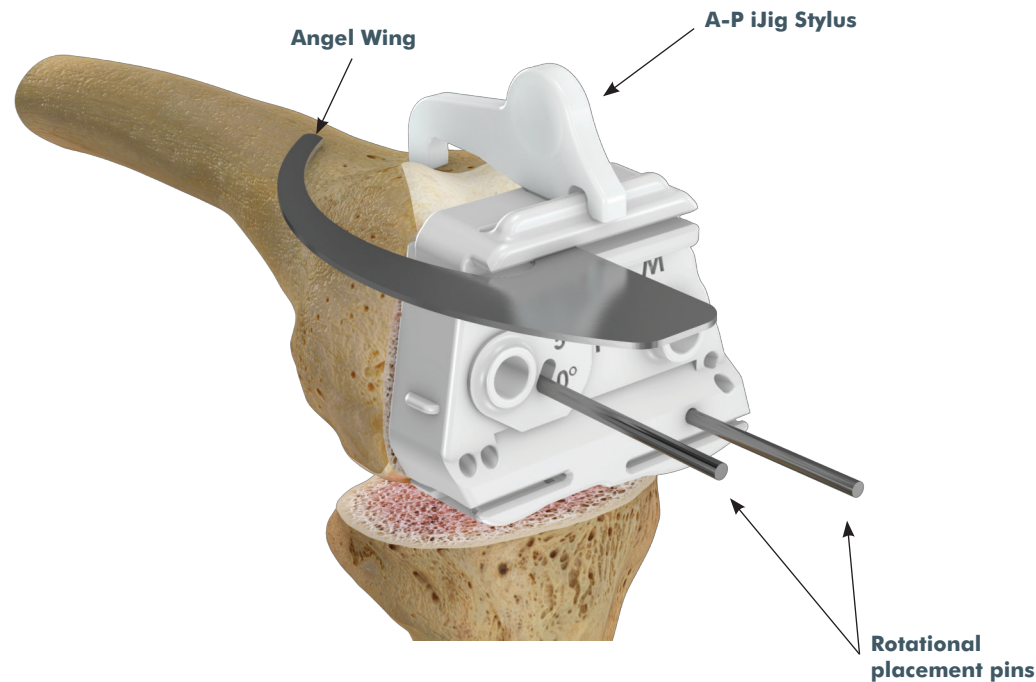
Step 3 FEMORAL PREPARATION



- 3.3** 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 F4 will match the medial profile of the cut distal femur. Confirm that 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, can be attached to F4 to aid in proper A-P placement of F4.

The Flexion Spacer iJig, T3, may be left in place to aid in assessing the flexion gaps and rotation of F4. Up to 5° of external rotation may be added by rotating the F4 iJig around the medial pin. When the pin is aligned with the 0 mark, the cuts will be parallel to the transepicondylar axis.



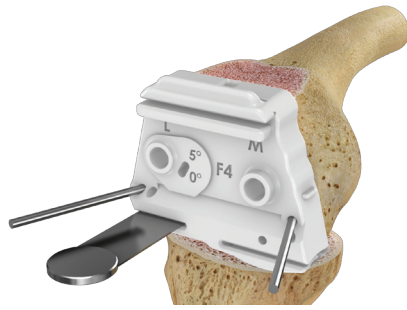
- 3.4** Use the Angel Wing to confirm the anterior resection will not notch the femur. When the desired rotation is set, drill and pin F4 into place through the cross pin holes and insert Steinmann Pins. In smaller anatomies, additional cross pin holes may not be present. Remove the initial two Steinmann Pins that were used for rotational placement.

In the instance F4 is repositioned, additional cross pin holes are available. 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.

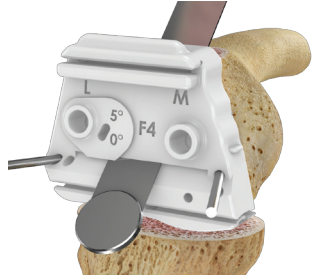
1. Anterior Resection



2. Posterior Resection



3. Anterior Chamfer Resection



4. Lug Holes



3.5 Proceed with the anterior and posterior femoral resections followed by the anterior chamfer resection. Drill the two lug holes of F4 using the 8mm Drill Bit. Remove the Steinmann Pins and F4.



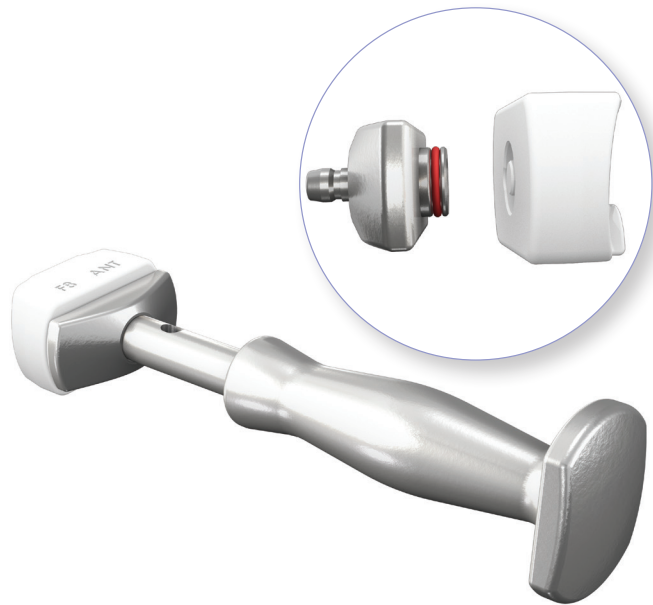
3.6 Place the Chamfer iJig, F5, onto the distal femur so the pegs fit into the previously drilled lug holes. F5 can be impacted by hand, or if needed by lightly tapping with a mallet, on the impaction surface. **Do not impact the cutting surface.**

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

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

Complete the open chamfer resection first then complete the captured chamfer resection using an oscillating saw blade.

Step 3 FEMORAL PREPARATION



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



3.8 Place the Femoral Trial onto the femur and impact into place. Remove any remaining osteophytes or bone in the transition area between the Femoral Trial and the posterior condyles. This is important for achieving increased flexion.

Step 4 TIBIAL PREPARATION



4.1 Confirm peripheral tibial osteophytes have been removed and place the Tibial Preparation iJig, T4, onto the cut proximal tibial surface. Multiple thicknesses of the T4 iJig are provided that are equivalent to the thickness of the Tibial Tray plus the thickness of the Poly Inserts.

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

Confirm alignment by attaching the Alignment Rod Adaptor, A1, to the handle of T4 and snap an Alignment Rod onto A1. In the coronal view, the Alignment Rod will be parallel to the mechanical axis. In the sagittal view, the Alignment Rod will be perpendicular to the tibial slope.

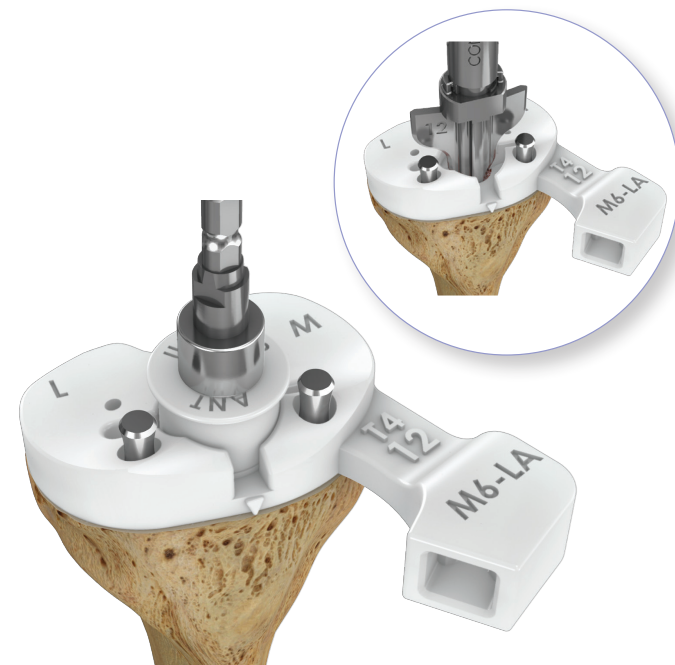


4.2 Bring the joint through the range of motion and assess balance and ligament tensioning using the selected T4 iJig.

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 thicker Poly Inserts. If the T4 iJig lifts off anteriorly in flexion, the joint may be too tight. Consider adding posterior slope to the tibia, and/or recess or lengthen the PCL.

Remove the Femoral Trial.

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



4.3 Insert the Tibial Preparation Drill Tower, T4a, onto the selected T4 iJig. T4a must be fully seated to allow for the proper drill angle and depth. Adjust the placement of T4 for proper rotational alignment. T4 should be positioned for optimal plateau coverage while keeping to the posterolateral corner of the proximal tibia.

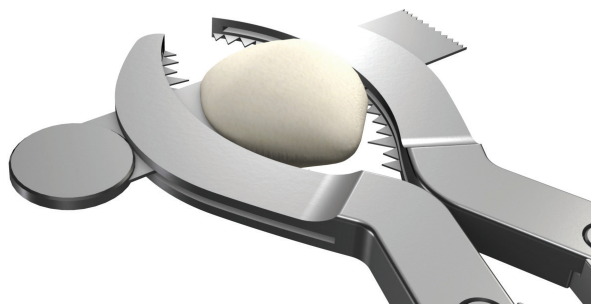
Stabilize T4 by impacting the Tack Pins into place on the proximal surface of the iJig. If additional stabilization is needed, drill and insert Steinmann Pins into the posterior stabilization holes using the 3mm Drill Bit.

Using the appropriate size Drill Bit (marked on the handle of T4 and on the iView) drill the stem hole through T4 down to the physical stop. Remove the T4a Drill Tower.

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

Remove the pins and the T4 iJig.

Step 5 PATELLA PREPARATION (OPTIONAL)

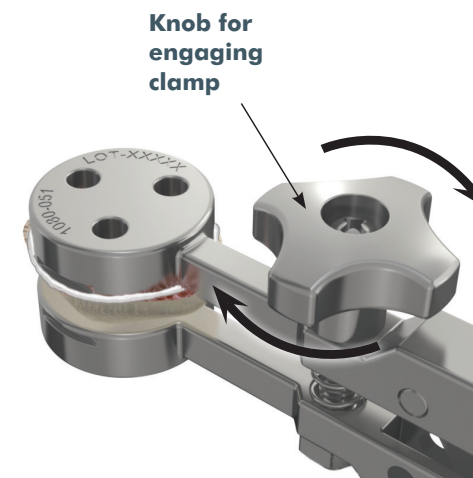


5.1 The patella can be prepared after tibial and femoral resections or just after the arthrotomy in order to facilitate exposure. Measure the patella thickness using a Caliper and make the desired cut. A Patella Osteotomy Guide is provided with graduations that indicate the thickness of the bone that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



5.2 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.



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

Step 6 FINAL TRIALING AND CEMENTING THE IMPLANTS



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

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

The Femoral Implant may be inserted and cemented prior to inserting the Poly Inserts. See Appendix A.

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

Assemble the Impactor Head onto the Impactor Handle and connect the Tibial Impactor Tip onto the Impactor Head.

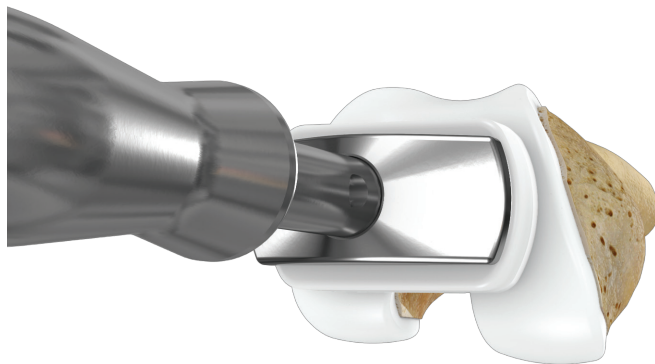
Using the Impactor assembly and a mallet, impact the Tibial Tray. Remove any residually extruded cement from around the Tibial Tray with consideration for any cement that may have extruded posteriorly.

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

6.3 Insert the A lateral Trial Insert first and then the 6mm medial Trial Insert. Additional Trial Inserts are provided with the system for proper balancing of the knee as needed (B and C lateral Trial Inserts and 7mm and 8mm medial Trial Inserts).

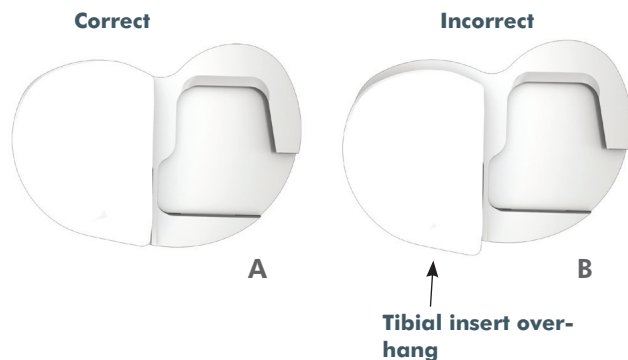
The A lateral Trial Insert measures 6mm plus the distal femoral implant offset which can be found on the iView. The B and C Trial Inserts increase by 1mm in thickness respectively. The thicknesses of the Poly Inserts are determined by the distal femoral implant offset to achieve neutral mechanical alignment.

Step 6 FINAL TRIALING AND CEMENTING THE IMPLANTS



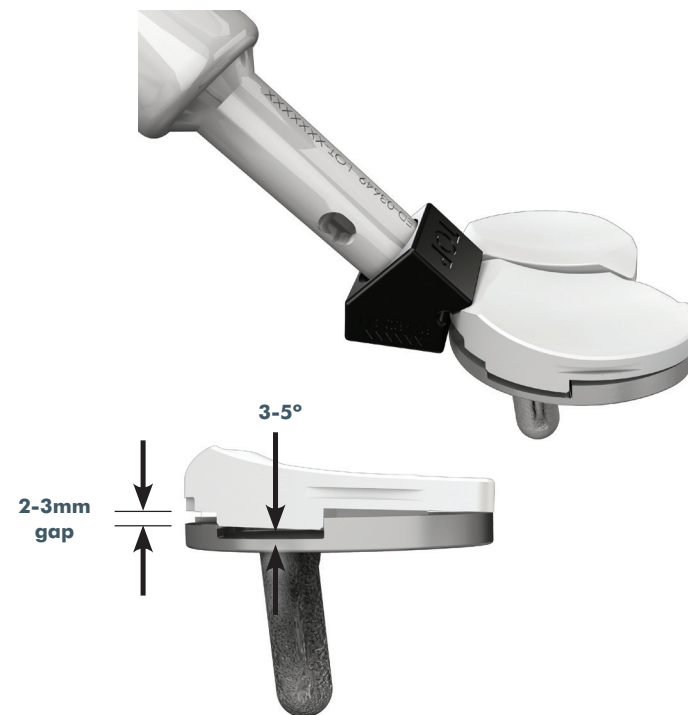
6.4 Assemble the Impactor Head onto the Impactor Handle and connect the Femoral Impactor Tip onto the Impactor Head. Then place the Femoral Trial onto the femur and impact into place using a mallet.

Evaluate kinematics and ligament balancing throughout the range of motion. Use thicker medial or lateral Trial Inserts 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 Femoral Trial and both Trial Inserts.



6.5.1 Align and slide the lateral Poly Insert into the Tibial Tray to engage the Tray's lateral posterior locking mechanism. Verify 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 Poly Insert is overhanging the profile of the Tibial Tray (Image B).

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



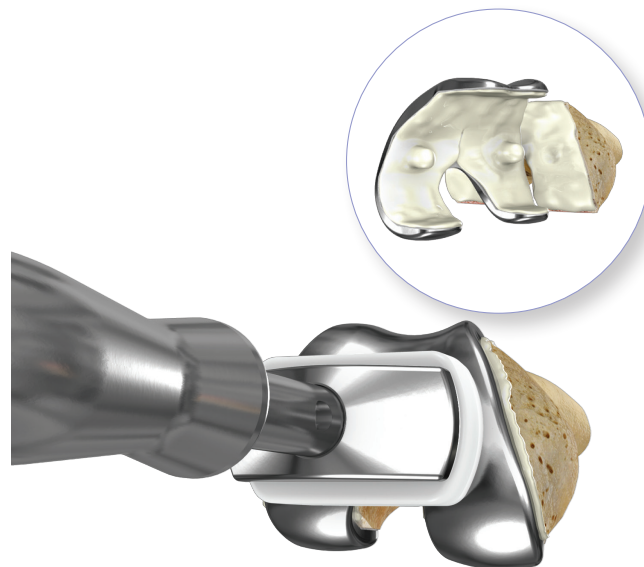
6.5.2 Assemble the Poly Impactor Tip onto the Impactor Handle. Place the Impactor Tip onto the anterior mating surface of the Poly Insert and impact the Impactor Handle with a mallet with a posterior projection (45-60° angle). The Poly Insert will be at a 3-5° angle to the Tibial Tray with no more than a 2-3mm gap anteriorly. Then impact the Poly Insert down. A snap sensation should be felt as the Poly Insert locks into place.



6.5.3 Visually confirm that the Poly Inserts are locked into place within the Tibial Tray. There should be no gapping between the Poly Inserts and the Tibial Tray.

Repeat steps 6.5.1 to 6.5.3 for the medial Poly Insert.

To remove the Poly Inserts, use a small osteotome in the anterior slot and lift the Poly Insert up to disengage the locking tab.



6.6 Apply a layer of cement to the femoral bone, filling holes and covering the 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. Assemble the Femoral Impactor Tip onto the Impactor Head and Impactor Handle. Using the Impactor assembly and a mallet, impact the Femoral Implant. Remove any residually extruded cement from around the Implant.

The Poly Inserts will be locked into place prior to cementing the femur. It is important to follow a cementing technique that allows for minimal cement extrusion while maximizing fixation.



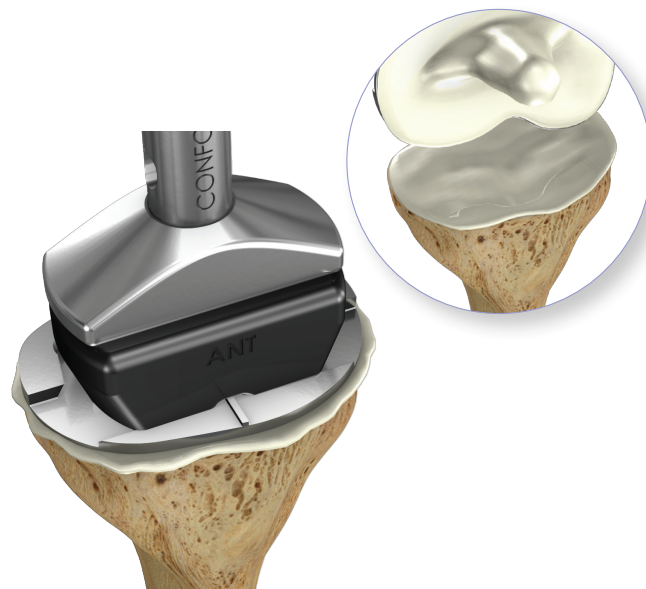
6.7 After implantation of the iTOTAL Femoral and Tibial Implants is complete, closure is performed in layers according to standard protocol.

Appendix A OPTIONAL CEMENTING ORDER



A.1 Thoroughly wash (using pulse lavage, if available) and dry the bone prior to applying cement.

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

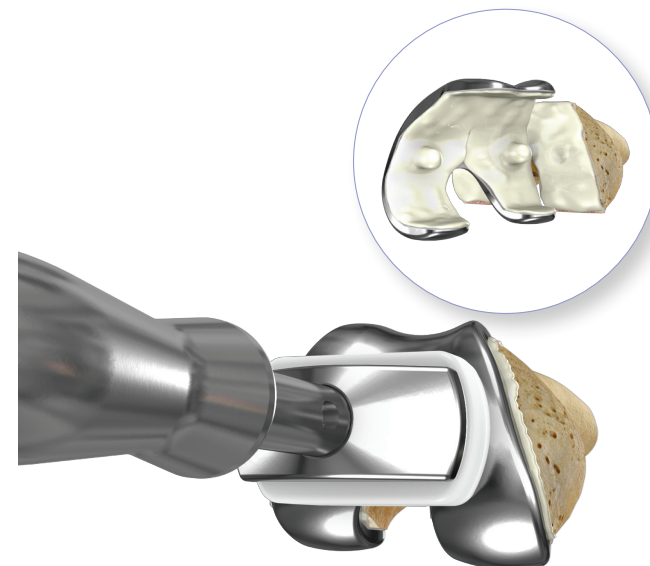


A.2 Apply a layer of cement (less cement posteriorly) to the Tibial Tray and the tibia, filling holes (especially the stem hole) and covering the bone surface.

Assemble the Impactor Head onto the Impactor Handle and connect the Tibial 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 Implant 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.



A.3 Apply a layer of cement to the femur, filling holes and covering the 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. Assemble the Femoral Impactor Tip onto the Impactor Head and Impactor Handle. Using the Impactor assembly and a mallet, impact the Femoral Implant. Remove any residually extruded cement from around the implant.

It is important to follow a cementing technique that allows for minimal cement extrusion while maximizing fixation.

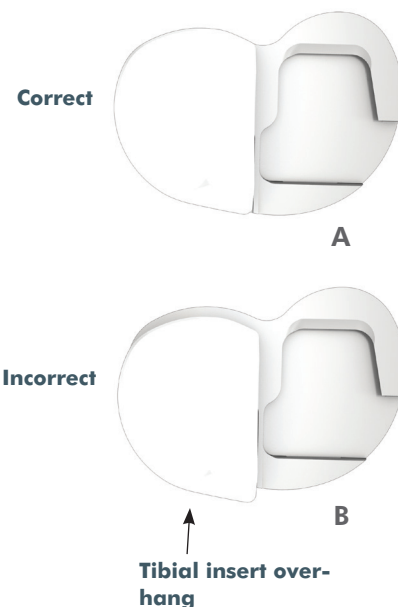


A.4 Rotate the foot to expose the joint space to insert the Trial Inserts. Insert the A lateral Trial Insert first and then the 6mm medial Trial Insert. Additional Trial Inserts are provided with the system for proper balancing of the knee as needed (B and C lateral Trial Inserts and 7mm and 8mm medial Trial Inserts).

The A lateral Trial Insert measures 6mm plus the distal femoral implant offset which can be found on the iView. The B and C trials increase by 1mm in thickness respectively. The thicknesses of the Poly Inserts are determined by the distal femoral implant offset to achieve neutral mechanical alignment.

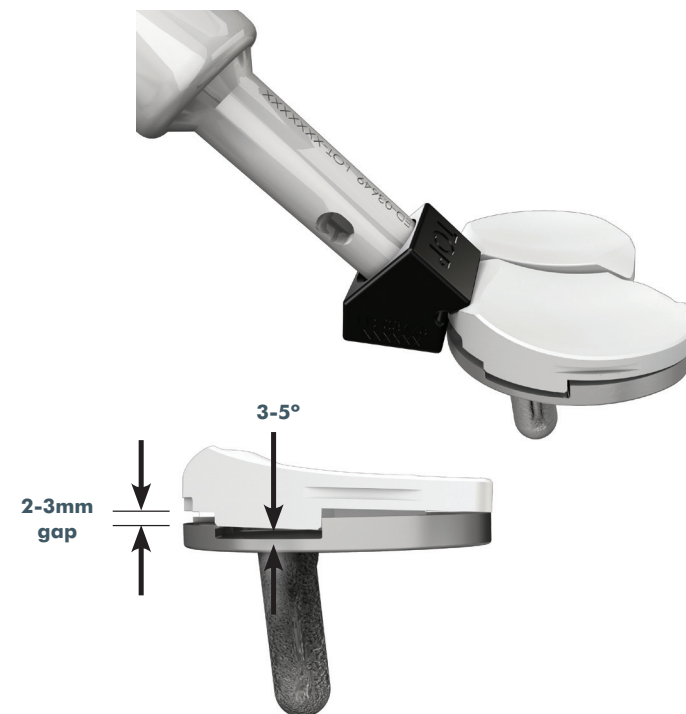
Bring the joint through the range of motion to evaluate kinematics and ligament balance. Use thicker medial or lateral Trial Inserts to achieve desired balancing and alignment. In the event soft tissue balance or joint alignment cannot be achieved, ligament balancing using standard soft-tissue releases may be considered. Remove the Trial Inserts.

As an alternative to the impaction method, a compression method may be effective with the Trial Inserts in place. Avoid hyperflexion of the knee while cement is hardening.



A.5.1 Align and slide the lateral Poly Insert into the Tibial Tray to engage the Tray's lateral posterior locking mechanism. Verify 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 Poly Insert is overhanging the profile of the Tibial Tray (Image B).

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



A.5.2 Assemble the Poly Impactor Tip onto the Impactor Handle. Place the Impactor Tip onto the anterior mating surface of the Poly Insert and impact the Impactor Handle with a mallet with a posterior projection (45-60° angle). The Poly Insert will be at a 3-5° angle to the Tibial Tray with no more than a 2-3mm gap anteriorly. Then, impact the Poly Insert down. A snap sensation should be felt as the Poly Insert locks into place.

Appendix A OPTIONAL CEMENTING ORDER



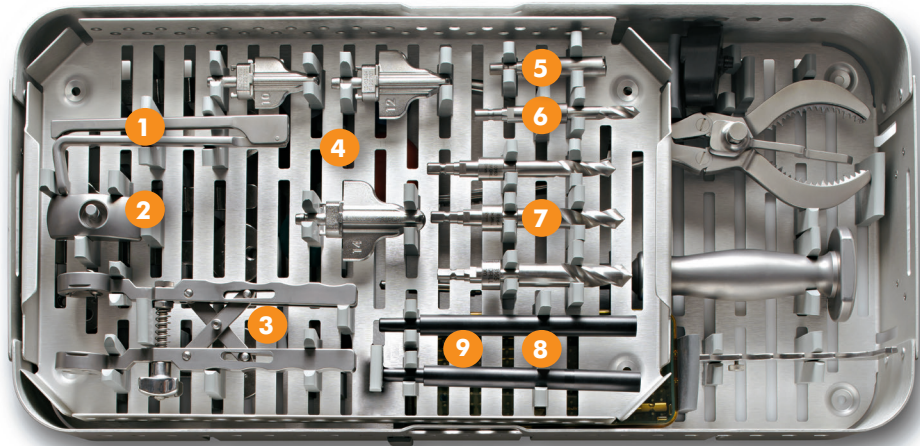
A.5.3 Visually confirm that the Poly Inserts are locked into place. There should be no gapping between the Poly Inserts and the Tibial Tray.

Repeat steps A.5.1 to A.5.3 for the medial Poly Insert.

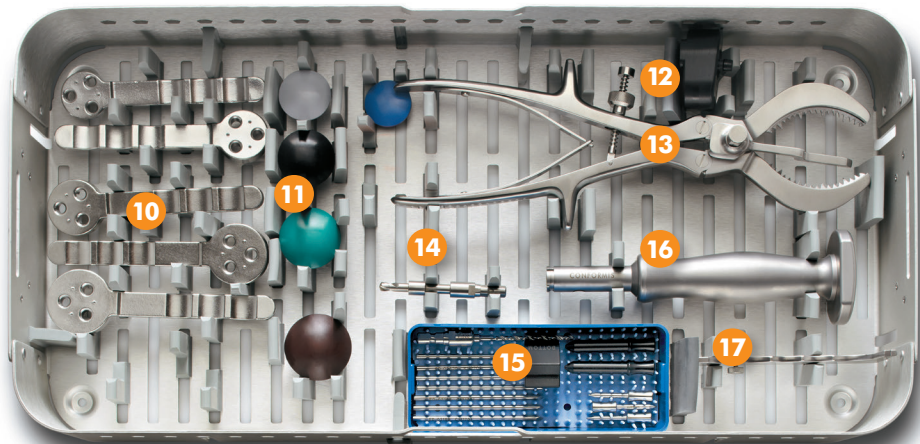
To remove the Poly Inserts, use a small osteotome in the anterior slot and lift the Poly Insert up to disengage the locking tab.



A.6 After implantation of the iTOTAL Femoral and Tibial Implants is complete, closure is performed in layers according to standard protocol.



- 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.

Postoperative Views



AP X-ray



Lateral X-ray



Sunrise X-ray

Indications for Use

The iTotal CR 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 unicompartmental, patello-femoral or bicompartamental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicompartmental, 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 cruciate retaining total knee repair.

- 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).
- Severe instability due to advanced loss of osteochondral structure or the absence of collateral ligament integrity.
- Severe ($> 15^\circ$) fixed valgus or varus deformity.
- Metal sensitivity (e.g., nickel).

Magnetic Resonance (MR) Environment

ConforMIS, Inc. iTTotal CR (Cruciate Retaining) KRS (Knee Replacement System) implants are manufactured of non-ferromagnetic materials such as, cobalt-chromium-molybdenum alloy (Co-Cr-Mo) 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 iTTotal CR 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 iTTotal CR KRS produced a temperature rise of less than 1.0°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 iTTotal CR KRS produced a temperature rise of less than 3.0°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 iTTotal CR KRS. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size extends approximately 7.8cm 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.



iTotal CR

CRUCIATE-RETAINING



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CAUTION: USA federal law restricts this device to sale by or on the order of a physician. The ConforMIS Cruciate Retaining Total Knee Replacement

System (iTotal CR) 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.

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