CONFORMIS® | iTotal® IDENTITY

CR SURGICAL TECHNIQUE

Patient-Conforming **Cruciate Retaining** Knee Replacement System

MEASURED RESECTION AND GAP BALANCING

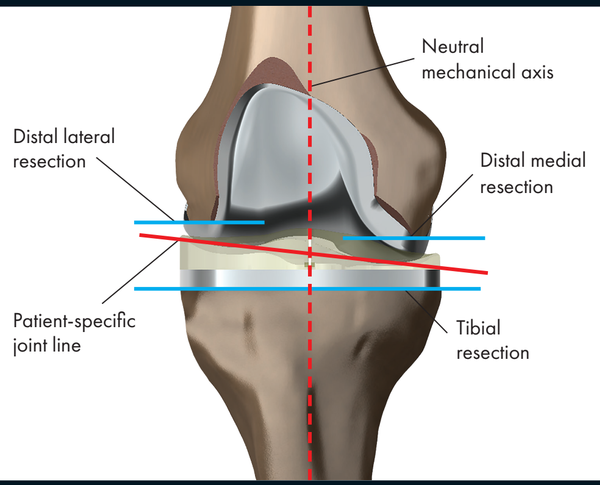
The Conformis **Advantage**

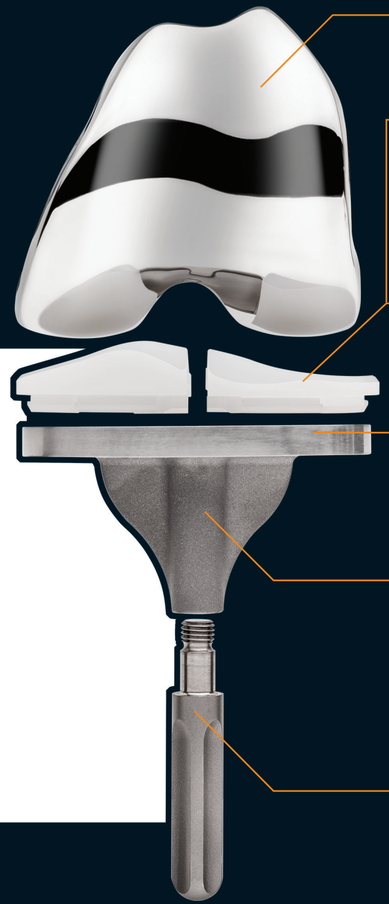
When it comes to total knee arthroplasty, off-the-shelf implants force compromises between sizing and coverage. Variations in anatomy make it virtually impossible for off-the-shelf designs to fit the femur.

This less than perfect fit can present several challenges for patients after surgery such as residual pain, functional limitations and early implant failure. That's why Conformis believes that the best solution is using an implant that's as close to the patient's original anatomy as possible. Using our proprietary 3D imaging process we can match the original anatomy, leading to better patient outcomes.

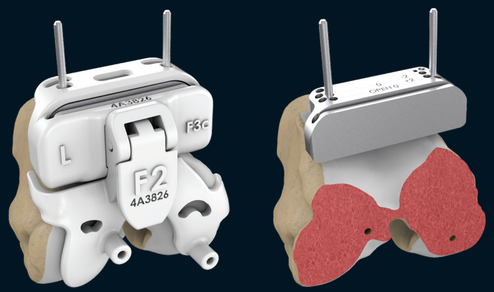
Design Philosophy

- Patient's natural articulating geometry extracted from 3D femoral anatomy
- J-curves are corrected for deformity and then used as the basis for femoral implant design
- Personalized fit helps to eliminate the sizing compromises typical in traditional TKA
- Implants have a patient-specific joint line replicating the distal and posterior femoral offsets
- Distal femoral and tibial resections are perpendicular to the neutral mechanical axis





iTotal® IDENTITY



Metal cut guides and refined iJigs® for a more traditional bone cutting experience

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Surgeon Design Team

iTotal Identity CR Surgical Technique was developed in collaboration with:

Henry Clarke, MD
Mayo Clinic
Phoenix, AZ

Wolfgang Fitz, M.D.
Brigham and Women's
Faulkner Hospital
Boston, MA

William Kurtz, M.D.
Tennessee Orthopedic Alliance
Nashville, TN

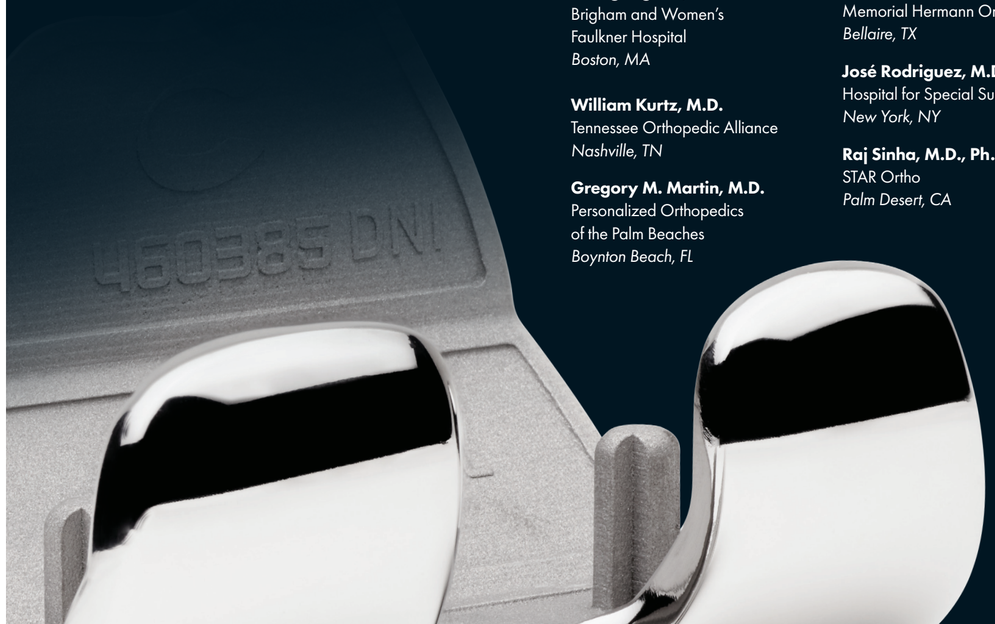
Gregory M. Martin, M.D.
Personalized Orthopedics
of the Palm Beaches
Boynton Beach, FL

Thomas Minas, M.D.
Paley Orthopedic & Spine Institute
West Palm Beach, FL

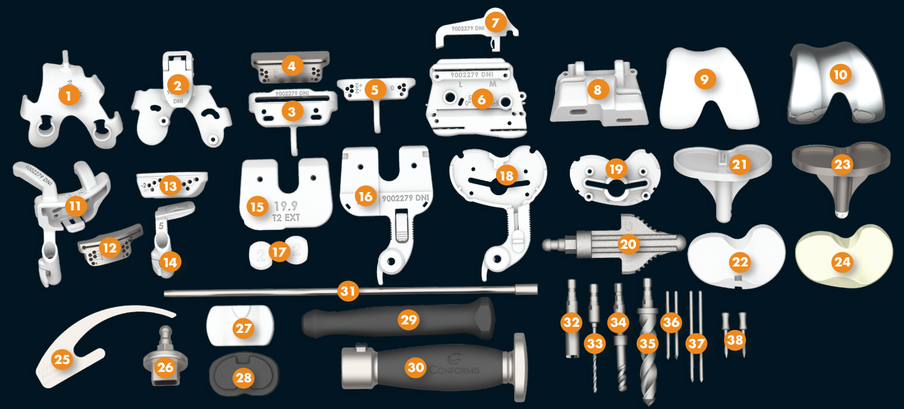
Brian Parsley, M.D.
Memorial Hermann Orthopedic and Spine Hospital
Bellaire, TX

José Rodriguez, M.D.
Hospital for Special Surgery
New York, NY

Raj Sinha, M.D., Ph.D.
STAR Ortho
Palm Desert, CA



iTotal Identity CR Sample OR Layout



Shown Above:

1. F1, Positioning iJig
2. F2, Alignment iJig
3. F3, Distal Resection Cutting Guide Casing
4. Metal Distal Femoral Cut Guide
5. F3u, Uncaptured Distal Resection iJig
6. F4, A-P Resection iJig
7. F4a, A-P iJig Stylus
8. F5, Chamfer iJig
9. Femoral Trial
10. Femoral Implant
11. T1, Tibial Resection iJig
12. Proximal Tibial Metal Cut Guide
13. T1u, Uncaptured Tibial Resection iJig
14. Down Rod Adaptor
15. T2, Extension Spacer iJig
16. T3, Flexion Spacer iJig
17. Shims
18. T4, Tibial Preparation and Trialing Baseplate iJig
19. T4a, Modular Drill Tower and Keel Punch iJig
20. Keel Punch
21. Tibial Tray Trial
22. Tibial Insert Trial
23. Tibial Tray Implant
24. Polyethylene Insert
25. Angel Wing
26. Impactor Tip Adaptor
27. Femoral Impactor iJig
28. Tibial Tray Impactor
29. Poly Insert Impactor
30. Impactor Handle
31. Alignment Rod
32. Coring Tool
33. 3mm Drill Bit
34. Femoral Drill Bit
35. Tibial Stem Drill Bit
36. 60mm Steinmann Pins
37. 80mm Steinmann Pins
38. Tack Pins

Not Pictured

- F3c, Step Cut Distal Femoral Captured iJig
- Femoral Plugs
- Patellar Osteotomy Guide
- Modular Patella Sizing Heads
- Patella Sizer Handle
- Patella Clamp
- Stem Extension Drill Bit
- Stem Extension Trial
- Tibial Extension Box Wrench
- Tibial Extension Handle

Suggested Surgical Instruments (not included in system)

- Laminar Spreader
- Quick Connect Drill Chucks (2)
- Pin Driver
- PCL Retractor
- Hohmann Retractors
- Z Retractors

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. When using a plastic iJig with a captured slot, 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
	ConMed - Linvatec	TN190-127-05	105	19	1.27

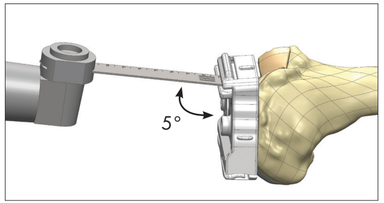


Image 1: Saw blade entering Captured iJig

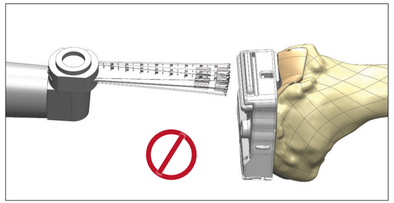


Image 2: Do not turn on the saw blade before touching bone

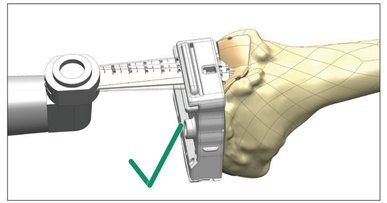
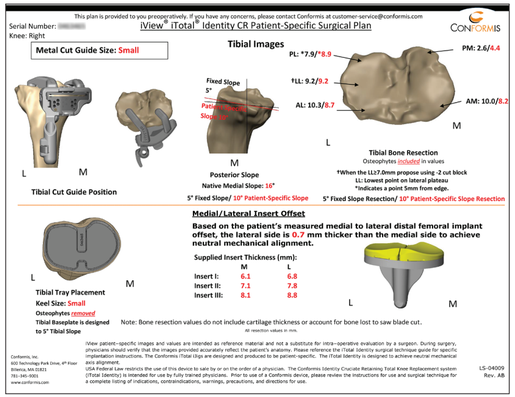


Image 3: Make sure that the saw blade is touching bone before initiating resection

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.



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

Serial Number: [redacted]
Knee: Right

iView® iTotal® Identity CR Patient-Specific Surgical Plan

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Metal Cut Guide Size: Small

Tibial Images

PL: *7.9/*8.9
PM: 2.6/4.4
†LL: 9.2/9.2
AL: 10.3/8.7
AM: 10.0/8.2
Fixed Slope 5°
Patient-Specific Slope
M
L

Tibial Cut Guide Position

Posterior Slope
Native Medial Slope: 16°
5° Fixed Slope/ 10° Patient-Specific Slope

Tibial Bone Resection
Osteophytes Included in values
*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/ 10° Patient-Specific Slope Resection

Medial/Lateral Insert Offset

Based on the patient's measured medial to lateral distal femoral implant offset, the lateral side is 0.7 mm thicker than the medial side to achieve neutral mechanical alignment.

Supplied Insert Thickness (mm):

	M	L
Insert I:	6.1	6.8
Insert II:	7.1	7.8
Insert III:	8.1	8.8

All resection values in mm.

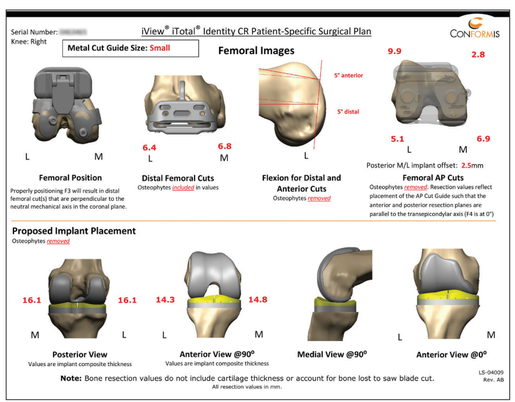
Tibial Tray Placement
Keel Size: Small
Osteophytes removed
Tibial Baseplate is designed to 5° Tibial Slope

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

Conformis, Inc.
600 Technology Park Drive, 4th Floor
Billerica, MA 01821
781-345-9001
www.conformis.com

iView 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 iTotal Identity surgical technique guide for specific implantation instructions. The Conformis iTotal iJigs are designed and produced to be patient-specific. The iTotal Identity 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 Identity Cruciate Retaining Total Knee Replacement system (iTotal Identity) 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-04009
Rev. AB



Serial Number: [redacted]
Knee: Right

iView® iTotal® Identity CR Patient-Specific Surgical Plan

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Metal Cut Guide Size: Small

Femoral Images

5° anterior
5° distal
9.9
2.8
5.1
6.9
6.4
6.8
L
M

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

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°)

Posterior M/L implant offset: 2.5mm

Proposed Implant Placement
Osteophytes removed

16.1
16.1
14.3
14.8

Posterior View
Values are implant composite thickness

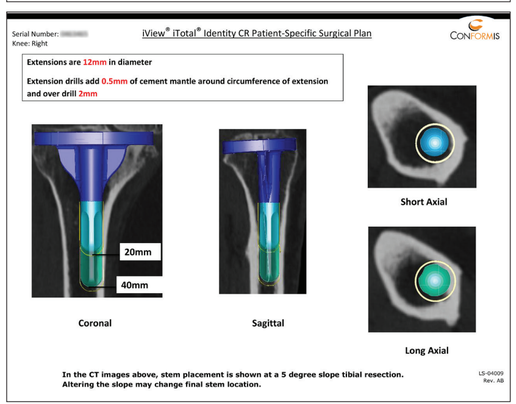
Anterior View @90°
Values are implant composite thickness

Medial 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-04009
Rev. AB



Serial Number: [redacted]
Knee: Right

iView® iTotal® Identity CR Patient-Specific Surgical Plan

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Extensions are 12mm in diameter

Extension drills add 0.5mm of cement mantle around circumference of extension and over drill 2mm

20mm
40mm

Coronal

Sagittal

Short Axial

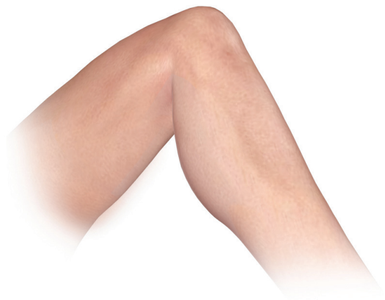
Long Axial

In the CT images above, stem placement is shown at a 5 degree slope tibial resection. Altering the slope may change final stem location.

LS-04009
Rev. AB

FEMORAL PREPARATION

Points of emphasis highlighted in orange



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) at this time.

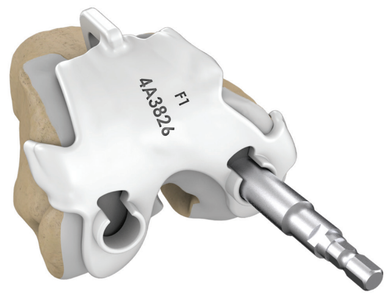
Do not remove osteophytes at this point.

It is recommended to defer standard releases (e.g. releasing the medial collateral ligament (MCL), posterior capsular release) until later in the procedure after assessment using the Extension Spacer iJig, T2, and the Flexion Spacer iJig, T3, or Final Trialing with the Femoral Trial and Tibial Preparation iJig, T4.

2.1 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.

F1 may be optional. If F1 is not preferred, skip to step 3 to begin femoral preparation.

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.



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

3.1 The distal femoral resection may or may not have a step cut depending on which resection preserves the most bone. The following steps are applicable to flat distal femoral resections only. If distal resection has a step cut, see step 3.2 for technique modifications.

Hold the Distal Resection Cutting Guide Casing, F3, upside down and insert the Distal Femoral Metal Cut Guide such that the laser etch is facing downward. Connect the F3 assembly to the Alignment iJig, F2, and close the anterior latch. This will lock metal cut guide securely into F3.

The Distal Femoral Metal Cut Guide is available in two sizes. The appropriate size for each case will be designated on the iView. The casing will also be marked "S" or "L" for either the small or large metal cut guide.

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.

Place the F2/F3 iJig assembly onto the femur. F2 has two round protrusions on the underside of the jig that are intended to sit on subchondral bone. Refer to the iView patient-specific planning images for proper placement of the F2 iJig on the femur. If F1 has been utilized, 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.

If F1 has not been utilized:

Mark the bottoms of the two references of the F2 iJig with a marker before placing it on the femur. Remove the cartilage and any residual tissue within the marked locations using a curette or a scalpel. This will allow the F2 iJig to sit flush on the subchondral bone.

Once alignment of the assembly is confirmed, drill and place a Steinmann Pin into each of the planned level or zero holes to set the distal resection depth per the surgical plan.

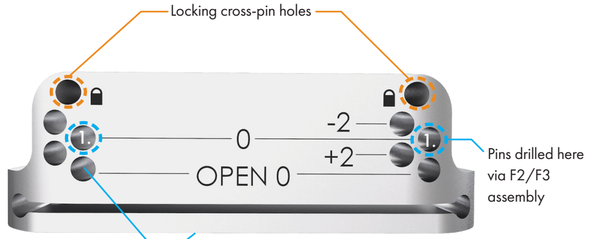
If desired, the Distal Femoral Metal Cut Guide may be stabilized by drilling one of the available cross pin holes (noted with a lock symbol). The cutting guide may also be stabilized by attaching a kocher to one of the Steinmann Pins.

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, during femoral preparation. Do not place Steinmann pins into these holes.

This step may be performed after the distal resection to allow the Steinmann pins to be drilled on a flat, even surface for improved accuracy. This can be accomplished by replacing F3 iJig over the metal cut guide and reattaching F2.

Optional: F2 and F3 may be removed before making distal resection for increased visibility. To remove the F2 iJig, disengage the latch and pull the F2 away from the F3, then slide the casing off the metal guide.

Optional Uncaptured Guide



For a more conservative initial distal femoral resection, a -2 distal cut option is available. For additional distal femoral resection, a +2 distal cut optional is available. To perform -2 or +2 distal resections, F2 and F3 must be removed. Remove the locking cross pin to remove the metal cut guide and place over the two vertical pins in the -2 or +2 locations. Cross pin may be re-drilled for additional stability once metal cut guide is replaced.

In some situations (e.g. significant flexion contracture), the +2 distal cut option may be performed as the primary distal femoral cut.

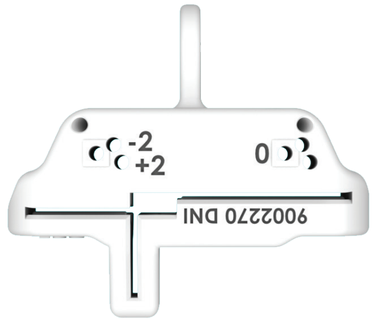
In other situations (e.g. excessive laxity and/or medial-lateral translation of the femur and tibia identified at initial exposure), the -2 distal cut option may be performed as the primary distal cut.

The top surface of the metal cut guide may also be used as an uncaptured guide for the planned '0' cut by repositioning the guide over the pin holes marked "OPEN 0". An optional uncaptured version of the Distal Resection iJig, F3u, is available. If selected, F3 must be used first in order to set the anterior pins. Once F3 is pinned in place on the femur, remove F2, F3, and the metal cut guide. Place the F3u iJig on the anterior pin holes and insert at least one cross pin for additional stability.

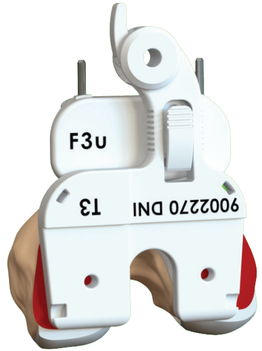
The two distal holes made with the F2 iJig may be marked with ink to help locate them after the distal femoral resection is made. One way this can be completed is by removing the tip from a sterile marker, attaching it to a kocher, and then inserting it into the drill holes.

Perform the distal femoral resection with the desired distal femoral cut guide.

Be sure to remove the metal cut guide from the iJig before discarding. Metal cut guides are not single use.



Step Cut Distal Femoral Captured iJig, F3c
(+2, 0, -2 options)



Checking flatness with Flexion
Spacer iJig, T3, and F3u

3.2 The following technique modifications should be made for a stepped distal resection.

Stepped femoral resections may not be completed with a metal cut guide. Instead, a Distal Femoral Captured iJig, F3c, will be utilized.

Connect F3c to the Alignment iJig, F2 and close the anterior latch. This will lock F2 and F3c together.

F2 must be removed from F3c before making the distal resection.

The step cut location will shift medially, away from the femoral implant step, if a -2 or +2 resection is made.

It is recommended to establish the step cut at the planned position before utilizing the -2 or +2 distal resection options.

4 Reviewing the distal cuts:
Once the distal femoral resection is complete, check to be sure the cut bone surface is even and there are no raised spots along the posterior edges of the condyles or trochlea.

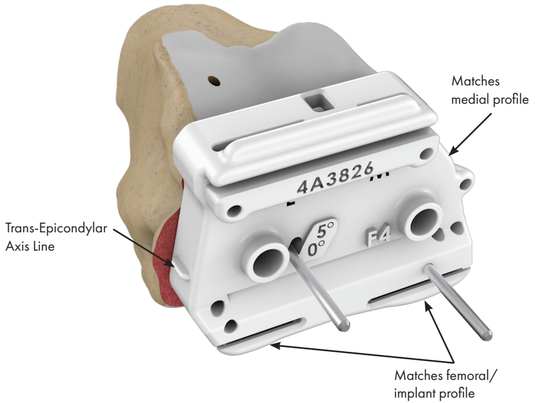
Optionally, flatness can be further assessed using the Flexion Spacer iJig, T3, with the Uncaptured Distal Resection iJig, F3u, placed on the bone at the chosen resection depth.

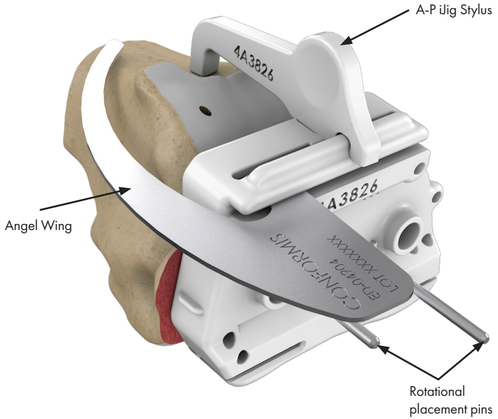
Place T3 on the cut distal femur such that the flat bottom is against the resected bone to confirm the resection is planar. If T3 does not sit flat against the bone and F3u, revisit the resection as needed. Remove the Steinmann Pins and the F3u iJig.

If distal femoral resection is stepped, the Extension Spacer iJig, T2, must be assembled onto T3 to review the distal cuts. Place the T2/T3 assembly onto the cut bone such that the stepped T3 face is against the stepped bone.

See step 8.1 for T2/T3 assembly

If a gap balancing approach is preferred, skip to Step 7 on page 14 for tibial preparation.





5.1 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. 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, aids in proper A-P placement of F4 and may be attached to the top of the F4 iJig prior to positioning.

The Flexion Spacer iJig, T3, may be left in place to aid in assessing the f lexion gaps and rotation of the F4 iJig. 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 (stylus) may be removed.

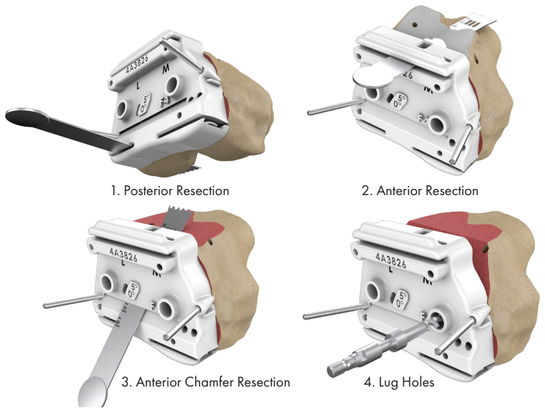
5.2 Using the supplied Angel Wing, confirm the anterior resection will not notch the femur. Reposition if required. When the desired position is set, drill and pin the F4 iJig into place through the cross pin holes and insert Steinmann Pins. Remove the initial two Steinmann Pins that were used for rotational placement.

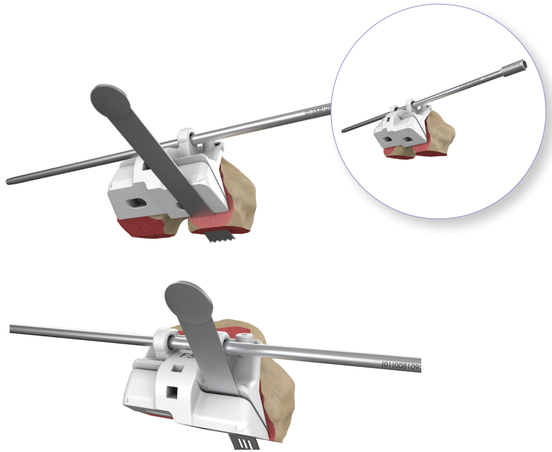
Confirm positioning of the F4 iJig against the target anterior and posterior condylar resection values on the iView patient-specific planning images prior to performing resections. Reposition and re-pin if needed.

In the instance the F4 iJig is repositioned, additional 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.

In very small patients, additional cross pin holes may not be present.

FEMORAL PREPARATION





5.3 Proceed with the anterior and posterior femoral resections followed by the anterior chamfer resection using the F4 iJig. 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.

6 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 pressed onto the femur by hand, or if needed, by lightly tapping with a mallet, on the impaction surface. DO NOT IMPACT THE CUTTING SURFACE.

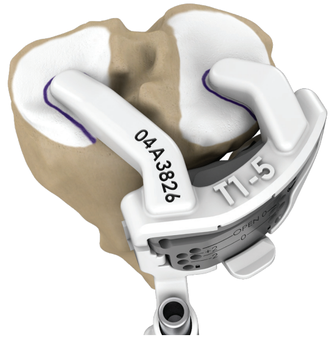
For smaller anatomies, there may not be an impaction surface present on F5. If not, press-fit the F5 iJig into place.

F5 may be held in place via cross pins or by sliding the Alignment Rod through the two anterior eyelets.

Complete the bottom (open) posterior chamfer resection first, then perform the top (captured) 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 selected Distal Resection iJig, F3, at the original position. See Appendix A for more details.

TIBIAL PREPARATION



7.1 The Tibial Resection iJig, T1, is designed to resect 3mm below the lowest point on the medial tibial plateau.

There are four Proximal Tibial Metal Cut Guides (small, large, left, right) available. The appropriate guide for each case will be designated on the iView.

There are two T1s available – a standard 5-degree slope T1 and an optional patient specific T1 matching patient's native slope between 5 and 10 degrees.

If choosing to use a stem extension, the 5-degree slope T1 is recommended as this is the slope utilized in the design and properative planning of all stem extensions. The iView stem extension plan depicts the expected stem extension location with a standard 5-degree slope only.

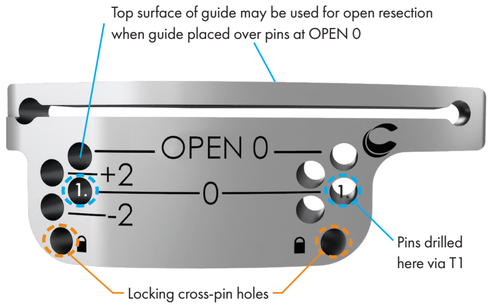
Before utilizing the T1 iJig, place the Proximal Tibial Metal Cut Guide into T1 such that the laser etch is facing outward. Push the metal cut guide into T1 until the anterior tab is engaged, locking the metal cut guide into the iJig.

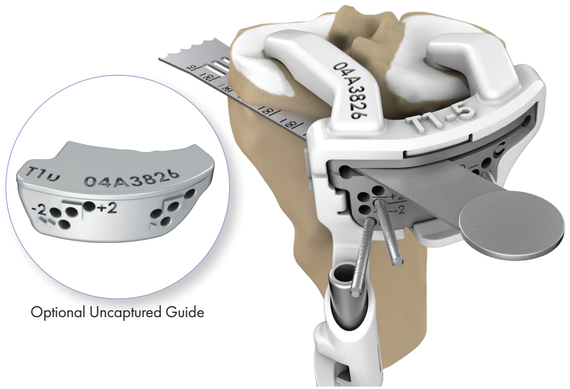
T1 has two subchondral bone references on the proximal tibia and one bone reference on the anterior tibia towards the tubercle. Refer to the iView patient-specific planning images for proper placement of the T1 iJig on the tibia. Mark the bottoms of the three references on the T1 iJig with a marker before placing it on the tibia. Remove the cartilage and any residual tissue within the marked locations using a curette or a scalpel. This will allow the T1 iJig to sit flush on subchondral bone.

7.2 Secure the T1 iJig into place and insert the Alignment Rod into the iJig to assess alignment. To lock the Alignment Rod into position, engage the clamp lever. The Alignment Rod should point distally towards the ankle and it should be parallel with the tibial mechanical axis in the coronal and sagittal planes. This will result in achieving the planned sagittal slope as noted on the iView.

Drill through the two parallel holes marked "0" on the metal cut guide portion of the T1 iJig on the anterior proximal tibia. If desired, the Proximal Tibial Metal Cut Guide may be stabilized by drilling one of the available cross pin holes (noted with a lock symbol). The cutting guide may also be stabilized by attaching a Kocher to one of the Steinmann Pins.

TIBIAL PREPARATION





For a more conservative initial tibial resection, a -2 cut option is available. When the -2 setting us used, 2mm less bone will be removed off the tibia. For additional tibial resection, a +2 cut option is available. When the +2 setting is used, an additional 2mm of bone will be removed off the tibia.

To perform -2 or +2 proximal resections, T1 must be removed. If a locking cross pin was inserted, remove it in order to remove the metal cut guide and reposition the guide over the two vertical pins in the -2 or +2 locations. Cross pin may be re-drilled for additional stability once metal cut guide is replaced.

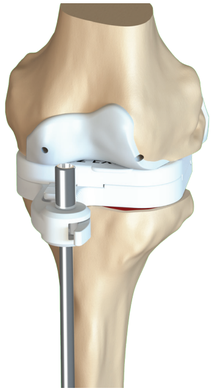
The metal cut guide may also be used as an uncaptured guide by placing it over the pin holes marked "OPEN 0". In this case, the top of the metal cut guide may be used as an open cutting surface.

An optional Uncaptured Tibial Resection iJig, T1u, is available. If selected, T1 must be used first in order to set the anterior pins. Once T1 is pinned in place on the tibia, remove T1 and the metal cut guide. Place the T1u iJig on the anterior pin holes and insert at least one cross pin for additional stability. A Down Rod Adaptor iJig is available to connect to the bottom of T1u if desired.

Perform the proximal tibial resection with the desired tibial cut guide.

Be sure to remove the metal cut guide from the iJig before discarding. Metal cut guides are not single use.

GAP BALANCING



8.1 Remove all peripheral tibial and femoral osteophytes including those along the posterior femoral condyles and in the intercondylar notch. In addition, remove any remaining ACL fibers and attached tissue.

The Extension Spacer iJig, T2, is modular and must be assembled onto the Flexion Spacer iJig, T3, before use.

With the knee in approximately 5-15° of extension, insert T2 between the cut femur and the cut tibia. The thickness of the T2 iJig is equivalent to the thickness of the Tibial Tray with the 6mm Poly Insert plus the thickness of the distal portion of the Femoral Implant.

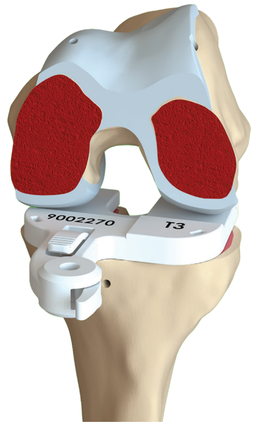
Assess the knee for appropriate balance by applying varus/valgus stress. The joint space should open approximately 1-2mm medially and laterally with the application of stress.

If desired, insert the Alignment Rod into the anterior hole on the T2 iJig. To lock the Alignment Rod into position, engage the clamp lever. The Alignment Rod should point distally towards the ankle and it should parallel with the tibial mechanical axis in the coronal plane and perpendicular to the tibial cut in the sagittal plane. Confirm full extension.

If the knee is tight in this position, consider completing Step 9.2 to confirm flexion balancing prior to completing additional resections. If checking flexion balance immediately after extension, be sure to disconnect the modular T2 iJig from T3.

If the knee is loose in this position, Shims are provided in different thicknesses that snap onto the surface of the T2 iJig to confirm whether alternative poly thicknesses will provide adequate balancing.

GAP BALANCING



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

8.2 Bring the knee into 90° of flexion, then place the Flexion Spacer iJig, T3, on the cut tibial plateau. The femoral condyles should sit posteriorly on the T3 iJig. The T3 iJig accounts for the presence of 3mm of posterior condylar cartilage. If there is posterior condylar cartilage loss, utilize the shims that snap onto the superior surface of the T3 iJig. If there is lateral laxity, the shims may aid in determining if external rotation of the femoral cuts is required.

If desired, insert the Alignment Rod into the anterior hole on the T3 iJig. To lock the Alignment Rod into position, engage the clamp lever. The Alignment Rod should point distally towards the ankle and it should parallel with the tibial mechanical axis in the coronal and sagittal planes.

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 required, the following steps can be taken:

- Additional distal femur can be resected as outlined previously using the Distal Femoral Metal Cut Guide or the Uncaptured Distal Resection iJig, F3u

The Distal Femoral Metal Cut Guide may be used as a recut guide without assembling into the Distal Femoral iJig, F3

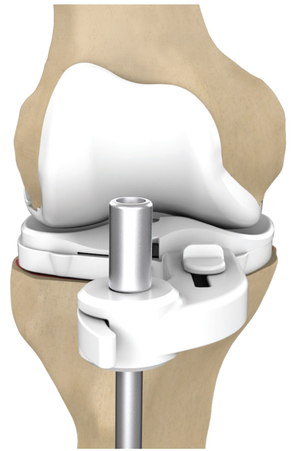
- Additional proximal tibia can be resected as outlined previously using the Proximal Tibial Metal Cut Guide or the Uncaptured Tibial Resection iJig, T1u

The Proximal Tibial Metal Cut Guide may be used as a recut guide without assembling into the Tibial Resection iJig, T1.

- The degree of flexion laxity can be modified by adjusting the position of the A-P Resection iJig, F4 as outlined below

- Ligament releases can be performed

TRIALING AND IMPLANT PREPARATION



9.1 Assemble the Impactor Tip Adaptor onto the Impactor Handle. Then connect the Femoral Impactor onto the Impactor Tip Adaptor.

9.2 Place the Femoral Trial on the femur and impact it into place using the Femoral Impactor. 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 flexion.

9.3 Single or dual piece inserts are available as part of the iTotal Identity CR Knee Replacement System (KRS). The trial inserts available will match the inserts polyethylene inserts that have been ordered.

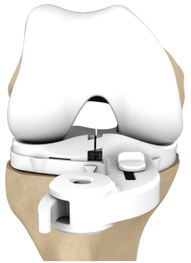
The Tibial Preparation and Trialing Baseplate iJig, T4, is a modular jig. If using dual piece implants, assemble the dual piece trials together. The trial is then assembled onto T4. To lock the trials into place, engage the sliding lock by pushing towards the trials. Ensure Trials are locked onto T4 before using.

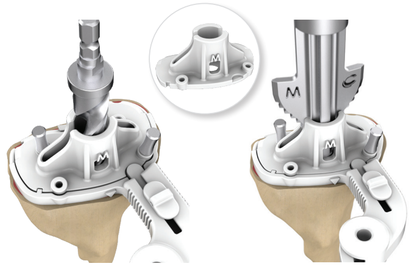
With the Femoral Trial in place, confirm peripheral tibial osteophytes have been removed and place the T4 and trial assembly on the cut proximal tibial surface.

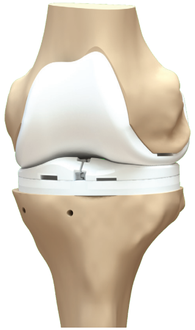
The T4 iJig has the same profile as the Tibial Tray. The profile of the Tibial Tray is designed such that the tray may be rotated up to 5° if necessary without overhanging the bone.

If desired, insert the Alignment Rod into the anterior hole on the T4 iJig to check coronal alignment. To lock the Alignment Rod into position, engage the clamp lever. The Alignment Rod should point distally towards the ankle and it should parallel with the tibial mechanical axis in the coronal plane and perpendicular to the tibial cut in the sagittal plane.

TRIALING AND IMPLANT PREPARATION







9.4 Bring the joint through the range of motion and assess balance and ligament tensioning using the 6mm Insert Trials assembled onto T4. If a thicker tibial assembly is desired, repeat with a thicker Insert Trial.

Perform the POLO test (Pull Out, Lift Off) in order to evaluate the tightness of the join 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 and disassemble the Trials Inserts from T4. T4 will now be used for tibial preparation.

10 Assemble the Modular Drill Tower and Keel Punch iJig, T4a, onto T4. To lock the T4a into place, engage the sliding lock by pushing towards T4a. Ensure T4a is locked onto T4 before using. The T4a iJig must be fully seated to allow for the proper drill angle and depth.

Adjust the placement of T4 for proper rotational alignment and for optimal plateau coverage. There are two posterior cutouts to aid in visualizing the alignment of T4 to the posterior rim of the bone. Stabilize the T4 iJig by inserting the Tack Pins into place on the proximal surface of the iJig, paying attention not to perforate the cortex of the tibia. In smaller cases, there may only be one anterior pin hole. Using the 15mm drill bit, drill the stem hole through the T4a iJig until the drill's collar is flush with the top of the drill/keel punch guide.

If using a Stem Extension, use the appropriate Stem Extension Drill Bit before preparing the keel. See Appendix B for further instructions on using the Stem Extensions.

Assemble the appropriate size Keel Punch (noted on the iView patient-specific planning images) onto the Impactor Handle. Impact through the keel slot on the T4a iJig using a mallet until the keel punch's collar is flush with the top of the drill/keel punch guide.

The keel punch is slightly oversized to leave approximately 0.5mm cement mantle around the implant keel and compress bone distally to the implant keel.

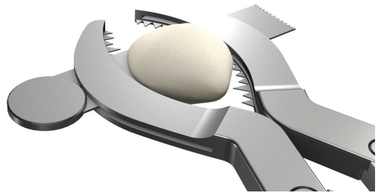
11 Prior to cementing, an additional trialing step can be performed using the Femoral Trial in conjunction with the Trial Inserts and the Tibial Tray Trial. If using Stem Extensions, the Stem Extension Trial may be assembled onto the Tibial Tray Trial as well.

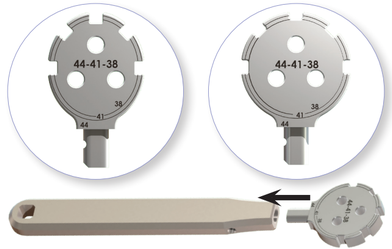
Install the Tibial Tray Trial by manually inserting it and then gently impacting it into place using the Tibial Tray Impactor Tip. Using the Femoral Impactor Tip, impact the Femoral Trial on the femur. Insert the selected Trial Insert into the Tibial Tray Trial. If needed, rotate the foot to expose the joint space to facilitate insertion.

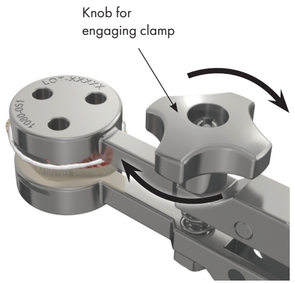
Evaluate kinematics and ligament balancing throughout the range of motion as described in Step 8.2. If optimal balancing and tensioning have been achieved, proceed to the next step. If they have not been achieved, revisit steps as outlined previously.

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

PATELLA PREPARATION







12.1 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.

Patella Size	Implant Thickness (mm)	
	Round	Oval
29	6	7
32	6	8
35	7	9
38	8.5	9
41	10	10
44	12	11

12.2 Determine the Patellar Implant diameter using the Patella Sizers. Patella Sizers are modular and there are a variety of round and oval heads available mirroring the available Patella Implants. Each modular Patella Sizer Heads represent three different implant diameters. The three diameters are noted by the outside edge of the head, a laser marked line, and the inside of the peripheral cutouts. The desired modular Patella Sizer Head should be assembled onto the Patella Sizer Handle before use.

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 midialized. The Patella Clamp may be used to prepare the three holes if desired.

12.3 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.

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

14 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 Tip Adaptor onto the Impactor Handle. Then connect the Tibial Tray Impactor onto the Impactor Tip Adaptor.

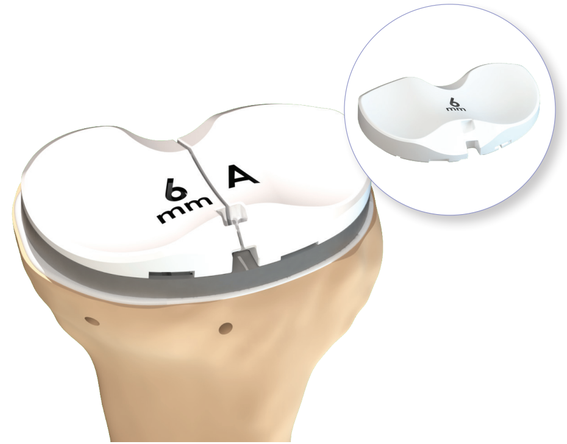
Impact the Tibial Tray. Remove any residually extruded cement from around the Tibial Tray with consideration for any cement that may have extruded posteriorly.

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

15 Apply a layer of cement to the femur, 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.

Assemble the Femoral Impactor iJig to the Impactor Tip Adaptor and Impactor Handle assembly. Impact the Femoral Implant.

Remove any residually extruded cement from around the Femoral Implant.



16.1 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. If using Dual Piece Inserts, the lateral insert is representative of the 6mm insert plus the distal femoral offset and increases in 1mm increments for each additional lateral insert.

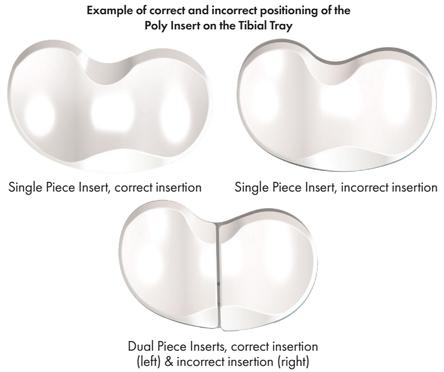
Insert the selected Trial Insert into the Tibial Tray. If needed, rotate the foot to expose the joint space to facilitate insertion.

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.



16.2 Align the Poly Insert by verifying the profile of the Poly Insert is directly on top of the profile of the Tibial Tray. DO NOT impact the Poly Insert if the profile of the insert is overhanging the profile of the Tibial Tray.

Slide the Poly Insert into the Tibial Tray to engage the posterior locking mechanism. If using Dual Piece Inserts, begin with the lateral insert. If needed, rotate the foot to expose the joint space to facilitate insertion.

Ensure the Poly Insert is fully seated posteriorly before impacting the insert. When the Poly Insert is fully seated, it will be at a 3-5° angle to the Tibial Tray, with no more than a 2-3mm gap anteriorly.

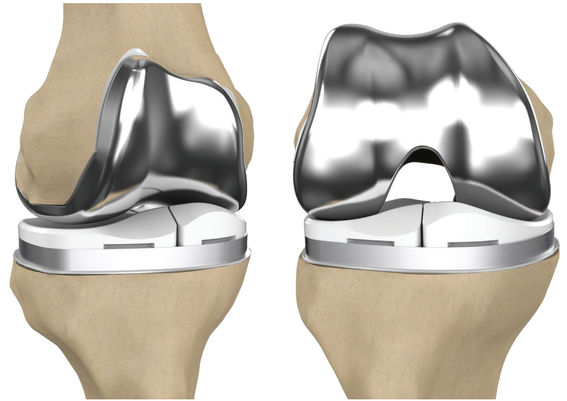
Ensure the Poly Insert is fully seated posteriorly within the Tibial Tray before tapping down.

16.3 Place the distal end of the Poly Insert Impactor onto the anterior Poly Insert and impact the 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.

If implanting a Single Piece Poly, ensure impaction is on middle of the Poly Insert and straight back to ensure the Poly Insert does not start to rotate. If implanting Dual Piece Poly Inserts, ensure impaction is in the middle of each individual insert.

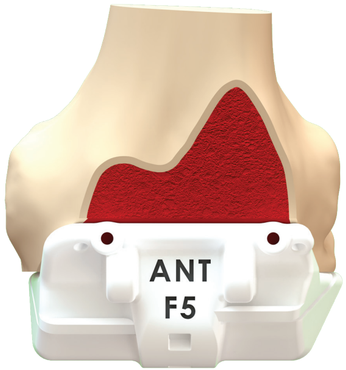
16.4 Visually confirm that the Poly Insert is locked into place within the Tibial Tray. There should be no gap between the Poly Insert and the Tibial Tray.

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.



17 After implantation of the iTotal Identity CR System is complete, closure is performed in layers according to standard protocol.

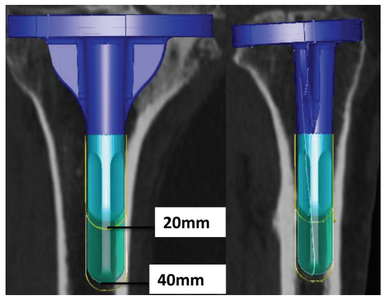
APPENDIX A - REVISITING DISTAL FEMORAL CUT AFTER FINAL TRIALING



The following steps can be taken if additional Distal Femur 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
- Place the desired distal femoral cut guide over the Steinmann pins through the +2mm pin holes
- Repeat steps as previously outlined to recut the following resections
- F4 – lug holes, anterior cut, and anterior chamfer only
- F5 – both chamfer cuts
- Repeat Final Trialing with the Femoral Trial and Tibial Preparation iJig, T4

APPENDIX B - STEM EXTESIONS



Two Stem Extensions are available if desired – 20mm and 40mm in length.

The iView displays an image of each Stem Extension in its planned position compared to the CT scan.

The Stem Extension placement is designed to the standard 5-degree slope. Therefore, it is recommended that the standard 5-degree Tibial Resection Guide, T1, is used when a Stem Extension is desired.

Due to varying patient anatomy, all available Stem Extensions may not be appropriate for use in every patient. Refer to the iView before preparing the tibia for a Stem Extension.

Tray trial assembly

As noted in Step 9.3, select the appropriate Stem Extension Drill Bit and drill through the T4a iJig until the drill's collar is flush with the top of the drill/keel punch guide. Stop drilling if excessive contact with the bone cortex is occurring. Remove the drill and the T4 guide assembly.

Assemble the corresponding Stem Extension Trial onto the Tray Trial and place onto bone to assess drilled Stem Extension depth. If the desired Stem Extension Trial is causing the Tibial Tray Trial to sit proud on the bone, consider down-sizing the Stem Extension or consider not using a Stem Extension for this case.

Once the tibial bone has been adequately prepared for the Stem Extension, continue through the remaining surgical technique guide steps until Tibial Implantation.

Tibial Tray with polyethelene cap

Each Tibial Tray Implant has a Polyethylene Cap assembled to the distal end of the implant stem. To attach a Stem Extension to the Tibial Tray Implant, first remove the cap by unscrewing in a counter-clockwise direction.

APPENDIX B - STEM EXTESIONS

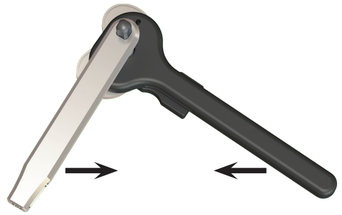
Assembling Tibial Tray into
Tibial Extension Handle

Place the Tibial Tray into the Tibial Extension Handle such that the stem and keel fit through the designated slot. Slide the latch toward the Tibial Tray to secure the implant onto the handle. Be sure that the implant is secured firmly onto the handle before proceeding.

The Tibial Extension Handle and Tibial Tray may be either placed on the back table such that the keel is facing upwards or may be held in the users' non-dominant hand while attaching the Stem Extension. If holding the implants during assembly, be sure the components are not dropped out of the sterile field.

Assembling Stem Extension
onto Tibial Tray

Screw the desired Stem Extension onto the Tibial Tray in a clockwise direction to hand tighten the extension onto the tray stem until secure. To achieve the final torque necessary to secure the Stem Extension, place the Tibial Extension Box Wrench over the distal end of the Stem Extension such that the Extension Handle and Box Wrench are forming a "V" shape.



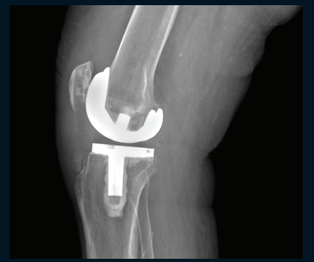
Assembling Stem Extension
onto Tibial Tray continued

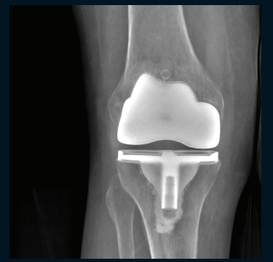
Push the Extension Handle and Box Wrench toward each other such that a clockwise torque is applied to the Stem Extension. Repeat this process until the Stem Extension is securely connected to the Tibial Tray and is unable to be torqued further.

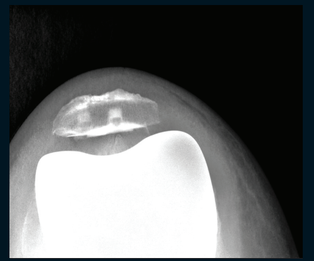
The Stem Extension is intended to be cemented. The stem extension drill is 1mm larger in diameter leaving a 0.5mm cement mantle around the stem extension. Once the extension has been adequately assembled onto the tray, follow the final implantation directions outlined in Step 13.

Do not implant Tibial Tray and Stem Extension without securely attaching the Stem Extension per the previous directions.

POSTOPERATIVE VIEWS







Indications for Use

The iTotal CR Knee Replacement System 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 bicompartmental prosthesis

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, or osteonecrosis of the knee
- Posttraumatic 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 unicondylar, patellofemoral or bicompartmental 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 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)
- Severe instability due to advanced loss of osteochondral structure or the absence of collateral ligament integrity
- Severe (>15º) fixed valgus or varus deformity
- Metal sensitivity (e.g., nickel)

Conformis, Inc.
600 Technology Park Drive
Billerica, MA 01821
781.345.9001
www.conformis.com

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