gap balancing

Patient-specific POSTERIOR-STABILIZING knee replacement system

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

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Disposable iJigs:
1. F1, Positioning iJig
2. F2, Alignment iJig
3. F3c, Distal Resection iJig (captured)
4. T1-0°, 0° Slope Tibial Resection iJig
5. T2, Extension Spacer iJig
6. T3, Flexion Spacer iJig
7. Shims - 0.3, 0.4, 0.5 mm
8. F4, A-P Resection iJig
9. F4a, A-P iJig Stylus
10. T3f, Post Resection Flexion Spacer iJig
11. F5, Chamfer iJig
12. F6, Box Cutting iJig
13. F6a, Drill Card iJig
14. F6b, Box Gauge iJig
15. T4, Tibial Preparation iJig
16. T5, Tibial Template iJig
17. Femoral Trial
18. Femoral Impactor
19. Tibial Tray Trial
20. Trial Insert (1 of 4)

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

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

Suggested Ancillary Surgical Instruments
(Not included in set)
- Laminar Spreader
- Hohmann Retractors
- Quick Connect Drill Chucks (x2)
- Z Retractors
- Pin Driver
- Curved Osteotome
- PCL Retractor
- Ring Curette

Recommended Saw Blades

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<th>Saw Blade Recommendations</th>
<th>Product Code</th>
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Saw Blade Recommendations
New 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.

**Preoperative Image Review**

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

1.2 Resect the Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) at this time. It is recommended to defer standard releases (e.g., releasing the Medial Collateral Ligament (MCL), posterior capsular release) until later in the procedure after 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.

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 coral holes.

**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 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.

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.

Do not remove osteophytes.

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

1.4.2 Once alignment of the assembly is confirmed, drill
and place a Steinmann Pin into one of the crosspin
holes of the F3c Jig using the 3mm drill bit. Drill the
two anterior holes of the F3c Jig. Insert Steinmann
Pins in the two anterior holes, impacting them through
the Jig to allow complete resection during the distal
cut. Drill through the two distal holes of the F2 Jig.
These holes will be used later as a reference for the
rotation of the A-P Resection Jig, F4, during femoral
preparation. Do not place Steinmann pins into these
holes. Remove the F2 Jig by squeezing the finger
positions and keep the F3c Jig, the anterior cruciate,
and the two anterior Steinmann Pins in place.

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

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

In some situations (e.g. significant flexion contracture), the +2
distal cut option may be performed as the primary distal femoral
cut. The -2 distal cut option may also be performed after
assessment using the Extension Spacer Jig, T2, by reinserting
the anterior Steinmann Pins in place and the F3 Jig assembly
as previously outlined. In addition, the +2 distal cut option
may be performed after trialing with the Femoral Trial and
Tibial Preparation Jig, T4, using steps outlined in Appendix
A – Revisiting Distal Femoral Cut after Final Trialing. In other
situations (e.g. excessive laxity and/or medial-lateral translation
of the femur and tibia identified at initial exposure), the -2 distal
cut option may be performed as the primary distal cut.

This two distal holes made with the F2 Jig 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.
2.1 The Tibial Resection Jig, T1, is designed to resect below the lowest point on the medial tibial plateau. Alternative resection blocks are also available as needed. A captured Tibial Recut Jig, T1c, and an uncaptured Tibial Recut Jig, T1u, are available per surgeon preference. Both recut jigs have 0, +2, and -2 pinhole positions. When the +2 setting is used, an additional 2mm will be removed off the tibia lowering the resection plane by 2mm. When the -2 setting is used, 2mm less will be removed off the tibia, raising the resection plane by 2mm. Both T1c and T1u have these ±2mm options. Refer to Step 2.3 on how to use these Recut jigs.

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

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

An alternative to removing cartilage manually is available per surgeon preference. Start with the T1 jig in the correct position and drill through the holes on the two projections. Remove T1 and insert two short Steinman pins into the holes. Use the Coring Tool to remove cartilage down to subchondral bone. Take care not to drill through the subchondral bone. Remove pins. Avoid over-coring to ensure proper varus/valgus alignment and resection depth.

2.3 Secure the T1 jig into place and attach an Alignment Rod to the jig 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. This will result in achieving the planned sagittal slope as noted on the iView.

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

Complete the tibial resection using the selected Tibial Resection Jig.

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

Step 2  Tibial Resection

T1 Jig and T1c Jig in use

To View patient-specific planning images for proper placement of the T1 jig on the tibia. Once positioned, mark the boundaries of the T1 jig projections on the proximal and anterior tibia using a surgical marker.

Remove the cartilage and any residual tissue within the marked line using a curette or a scalpel. This will allow the T1 jig to sit flush on subchondral bone.

An alternative to removing cartilage manually is available per surgeon preference. Start with the T1 jig in the correct position and drill through the holes on the two projections. Remove T1 and insert two short Steinman pins into the holes. Use the Coring Tool to remove cartilage down to subchondral bone. Take care not to drill through the subchondral bone. Remove pins. Avoid over-coring to ensure proper varus/valgus alignment and resection depth.

2.3 Secure the T1 jig into place and attach an Alignment Rod to the jig 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. This will result in achieving the planned sagittal slope as noted on the iView.

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

Complete the tibial resection using the selected Tibial Resection Jig.

To use the alternative Recut jigs, the T1 jig must be used first in order to set the anterior tibial pin locations. Once set, remove the pins and the T1 jig. Replace the two parallel Steinmann Pins, slide the desired cut block over the parallel pins at the selected resection level, and insert the crosspin. A Tibial Recut Alignment Arm, A2, is provided to confirm axial alignment and mates with the projection on any of the Tibial Resect Jigs.
Step 3 FEMORAL PREPARATION

3.1 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 and PCL fibers and attached tissue. With the knee in extension, place the Extension Spacer iJig, T2, between the cut distal femur and the cut proximal tibia. The thickness of the T2 iJig is equivalent to the thickness of the Tibial Tray with the smallest Poly Insert size plus the thickness of the distal portion of the Femoral Implant.

3.2 Bring the lines 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 Shim that snap onto the superior surface of the T3 iJig. If there is lateral laxity, the Shim 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.

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 anterior edge of the F4 iJig will match the profile of the cut distal femur, excluding the profile of the medial offset crossover hole. Confirm that the profile of the F4 iJig does not overhang the cut distal femur medially or laterally and is centered on the cut surface.

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

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

3.5 Proceed with the posterior and anterior femoral reactions followed by the anterior chamfer femoral reaction using the F4 iJig. If either of the anterior crosspin holes were used to stabilize the F4 iJig, remove them before completing the anterior chamfer reaction. Once completed, drill through the two lug holes of the F4 iJig using the 8mm drill bit. Remove the Steinmann pins and the F4 iJig. Ensure the F4 iJig is pressed tightly against the resected distal femoral surface while performing all resections. Two black pegs can be used to help stabilize F4 by drilling the lug holes first and inserting the pegs into the holes.

3.6 Ligament releases may be considered.
3.6 With the knee in 90° of flexion, insert the Post Resection Spacer Jig, T3r, on the cut tibial plateau. The femoral condyles should sit posteriorly on the T3r Jig. The T3r Jig represents the thickness of the Tibial Tray with the smallest Poly Insert size plus the thickness of the posterior portion of the Femoral Implant.

3.7 Place the Chamfer Jig, F5, on the distal femur so the pegs on the F5 Jig fit into the peg holes on the distal femur. The letters A-N-T are marked on the anterior surface of the F5 Jig. 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.

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

3.9 Complete the bottom posterior chamfer resection first then perform the top posterior chamfer resection. If additional resection of the distal femur is required at any point after the posterior chamfer resections are completed, there are anterior pin holes on the F5 Jig that represent the nominal position of the pins set by the selected Distal Resection Jig, F3, at the original position. See Appendix A for more details.

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

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

3.11 The Box Gauge Jig, F6b, can be also used with the F6 Jig after the box cut is made. Place the F6a Jig in the box of the F6 Jig. If the F6a Jig does not sit flush with the F6 Jig, remove the F6a Jig and check for any leftover bone or soft tissue that may be preventing the F6a Jig from sitting flush within the F6 Jig. Do not impact the F6a Jig into the F6 Jig.

3.12 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. Place the Femoral Trial on the femur and impact it into place. Confirm proper femoral fit. If necessary, revisit completed resections to improve fit. Visually inspect for and remove osteophytes on the posterior femoral condyles and posterior intercondylar notch, as well as bone in the transition area between the Femoral Trial and the femoral condyles. This is important for achieving increased flexion.

3.13 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.

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

3.15 Visually inspect for and remove osteophytes on the posterior femoral condyles and posterior intercondylar notch, as well as bone in the transition area between the Femoral Trial and the posterior condyles. This is important for achieving increased flexion.
4.1 Confirm peripheral tibial osteophytes have been removed and place the Tibial Preparation jig, T4, on the cut proximal tibial surface. Multiple thicknesses of the T4 jig are provided that are equivalent to the thickness of the Tibial Tray and the thickness of the Tibial Poly Inserts.

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

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

4.2 Bring the joint through the range of motion and assess balance and ligament tensioning using the selected T4 jig. If a thicker tibial assembly is deemed, repeat with a larger T4 jig. Perform the POLO test (Pull Out, Lift Off) in order to evaluate the tightness of the joint space. If the T4 jig pulls out easily in flexion, the joint may be too loose. Consider using a thicker Poly Insert. If the T4 jig life off anteriorly in flexion, the joint may be too tight. Consider revisiting the options provided previously if the knee is tight in flexion.

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

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

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

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

Assemble the appropriate saw Keel Punch (marked on the handle portion of the T4 jig and on the iView patient-specific planning images) and drill the stem hole through the T4 jig using a mallet down to the physical stop. If using the thinner T5 jig for tibial preparation, confirm its final position and stabilize it by impacting the Tack Pins into place. Drill the stem hole and impact the Keel Punch as previously outlined using the appropriate size drill bit (marked on the handle portion of T5 jig and on the iView).

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

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 bones 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 desired size 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 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 knobs in a clockwise direction to engage the Clamp. Remove any extruded cement from around the Implant.
Prior to cementing, an additional trialing step can be performed using the Femoral Trial in conjunction with the Trial Inserts and the Tibial Tray Trial. Install the Tibial Tray Trial by manually inserting it and then gently impacting it into place using the Tibial Tray Impactor Tip. Using the Femoral Impactor Tip, impact the Femoral Trial on the femur. Insert the selected Trial Insert by sliding the Trial Insert’s spine underneath the box and up against the cam mechanism of the Femoral Trial. Push the Trial Insert into the Tibial Trial. Rotate the foot to expose the joint space to facilitate insertion.

If optimal balancing and tensioning have been achieved, proceed to the next step. If they have not been achieved, revisit steps as outlined previously. Trials may be removed by gently prying them off of the femur and tibia using an osteotome if needed. Do not use the metal Femoral Implant or Tibial Tray when trialing.

Thoroughly wash (using pulse lavage, if available) and dry the bone prior to applying cement. Apply a layer of cement (less cement posteriorly) to the Tibial Tray and to the tibia, filling holes (especially the stem hole) and covering the bone surfaces. Assemble the Impactor Head onto the Impactor Handle by connecting the two pieces at the mating surfaces. Connect the Tibial Tray Impactor Tip onto the Impactor Head. Using the Impactor assembly and a mallet, impact the Tibial Tray. Remove any residually extruded cement from around the Tibial Tray.

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

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

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

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

Aligning the cut-out on the Poly Insert with the cut-out on the Tibial Tray during insertion will help ensure proper positioning (Inset). Impacting a Poly Insert that is improperly placed on the Tibial Tray may damage the locking mechanism of the Poly Insert.
6.5.2 Tap the Poly Insert back and into place with a posterior projection impaction. Once properly in place, the Poly Insert will be at a 3-5° angle to the Tibial Tray, with no more than a 2-3mm gap anteriorly.

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

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

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

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

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

6.6 After implantation of the iTotal PS System is complete, closure is performed in layers according to standard protocol.
If additional distal femoral resection is required after trialing with the Femoral Trial and Tibial Preparation Jig, T4, place the Chamfer Jig, F5, on the resected femur and secure into place. Use the anterior drill holes on F5 to reestablish nominal drill holes initially placed with F3, then reinsert Steinmann pins. Reset the Distal Resection Key Jig, F3a, within the selected Distal Resection Jig (either the captured version, F3c, or uncaptured version F3u) to a +2mm setting. Place the F3/F3a assembly back over the pins and take the additional 2mm off the distal femur.

Repeat steps as previously outlined to recut the anterior resection, anterior chamfer resection, lug holes, both chamfer resections, and the box cut. Repeat Final Trialing with the Femoral Trial and Tibial Preparation Jig, T4.

1. Pin Puller: Is used to remove Steinmann Pins.
2. Impactor Head: Mates with the patient-specific Femoral Impactor Tip, Tibial Impactor Tip, and Impactor Handle.
3. Patella Clamp: Clamps onto the patella and patella implant while the cement is setting. Can also be used to prepare patella fixation holes.
4. Keel Punch Tips: Are attached to the Impactor Handle and used to prepare the entries for the keel of the Tibial Tray.
5. Coring Tool: Is used to remove tibial and femoral cartilages in order for lugs 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 Jigs 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: Is 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 Jig (PM), 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 Tip, Impactor Handle, and Poly Impactor Tip.
17. Caliper: Is used to measure the patella in preparation for patella resection and sizing.
Indications for Use

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

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis, polyarthritis, or osteonecrosis of the knee.
- Post traumatic loss of joint function.
- Moderate varus, valgus or flexion deformity.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or 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 posterior stabilized total knee replacement:

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

Magnetic Resonance (MR) Environment

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

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

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

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

In non-clinical testing, the iTotal PS KRS produced a temperature rise of less than 5.0°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg, as assessed by calorimetry for 15 minutes of MR scanning in a 3.0-Tesla (Siemens Trio, Siemens, Erlangen, Germany, SYNGO MRI A35 4VASSA 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 Total PS KRS. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size extends approximately 8.5cm relative to the size and shape of this implant in image distortion tests using spiral echo pulse sequences as defined in ASTM F2119 in a 3.0T MR system.
Notes