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Total
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stryker Total Knee Smart Robotics Instruction Manual

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Specifications

- CT-based planning
- Dynamic joint balancing
- AccuStop™ haptic technology

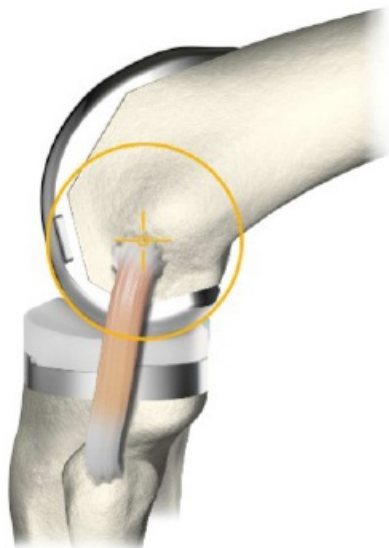
Product Information

The Mako Total Knee SmartRobotics™ with Functional Knee Positioning™ utilizes 3D CT-based planning and AccuStop™ haptic technology to assist surgeons in achieving optimal component positioning for knee replacement procedures. This technology allows for intraoperative assessment of soft tissue laxities and adjustments to implant placement before making cuts, ensuring precise final positioning.

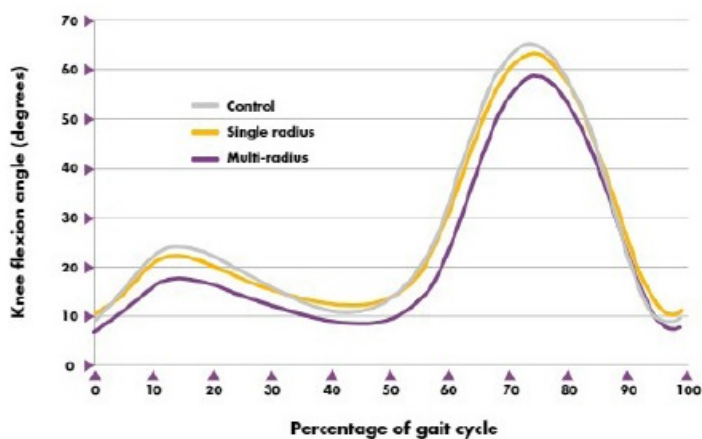
Mako Total Knee and Triathlon®

Triathlon is designed to work with the body and remaining soft tissues to achieve stability.

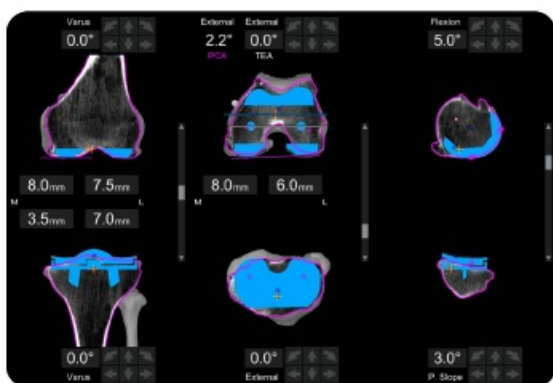
- Triathlon features a single radius throughout the arc of active flexion that is designed to align with curvature of the patient's native femur.¹⁻³ This assists in restoring the knee's single center of rotation and allows for constant ligament tension and stability in flexion.⁴⁻⁶
- Gait reviews comparing patients with a single or multi-radius knee implant showed that patients with a single radius knee implant experienced gait patterns that more closely mimicked that of the non-diseased control group.⁶
- Additionally, a fluoroscopic study on 20 Triathlon TKAs showed the femoral component was kinematically stabilized in mid-flexion ranges, and posterior femoral rollback occurred in deeper knee flexion with this knee design.⁵



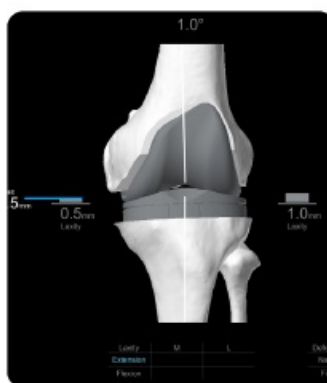
Gait data: flexion one year after TKA



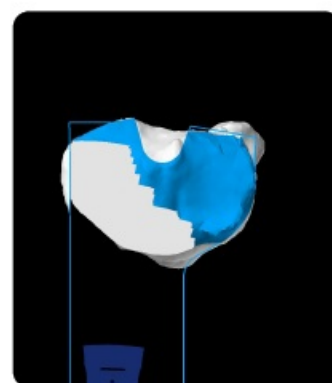
- Informed by over 500,000 global Mako Total Knee procedures, Mako Total Knee 2.0 is built on the legacy of Mako SmartRobotics™ – 3D CT-based planning and AccuStop™ haptic technology.
- Mako Total Knee 2.0 drives Functional Knee Positioning through a customizable step-by-step workflow that includes a new Digital Tensioner allowing for independent medial and lateral laxity assessments, fine tune balancing to the half millimeter, a trialing page and more.



CT-based planning



Dynamic joint balancing

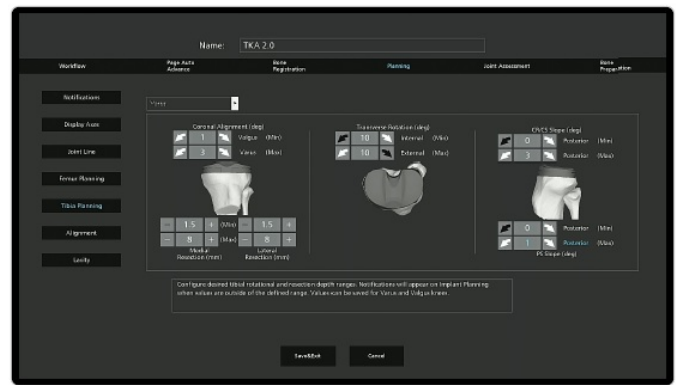
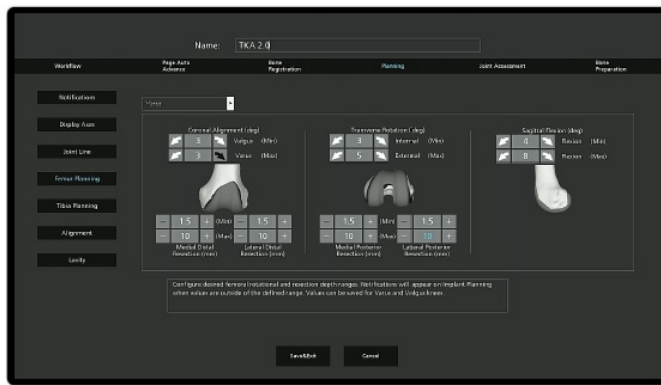


AccuStop™ haptic technology

Functional planning

Planning Triathlon with functional planning guidelines

- Surgeons can set personalized intraoperative planning parameters using the surgeon preferences feature. When adjusting the implant plan, if any value exceeds these limits, a notification is provided to the surgeon.
- The Mako Total Knee goalposts, seen in the images below, provide guidance when making intraoperative adjustments and serve as a recommendation for most cases.



The goalposts – in conjunction with the functional planning guidelines – are designed to help optimize Triathlon component positioning and enhance functional outcomes.⁷

Femoral component rotations

- Varus/valgus alignment Femoral mechanical axis 3° varus – 3° valgus
- External rotation Transepicondylar axis (TEA) 5° external – 3° internal
- Femoral flexion Femoral sagittal alignment 4° – 8° flexion*

Tibial component rotations

- Varus/valgus alignment Tibial mechanical axis 3° varus – 1° valgus
- Posterior slope Tibial sagittal alignment CR: 3° | PS: 0-1°*

Combined component position

- Overall limb alignment Femoral + tibial coronal alignment 5° varus – 3° valgus
- Combined tibiofemoral flexion
- Femoral flexion + tibial slope Tibia size ≥ femur size, Max = 10°
- Tibia size < femur size, Max = 8°

Component resections

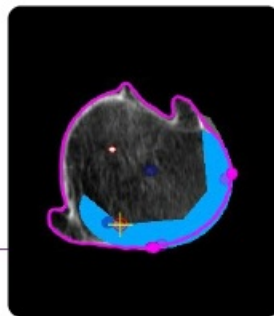
- Distal and posterior medial femur Maximum: 10mm
- Lateral tibia Maximum: 8mm

Mako's 3D CT-based planning is designed to help surgeons achieve their desired Triathlon component positioning in the coronal, transverse and sagittal planes. The functional planning guidelines enable the surgeon to prioritize the attributes of the knee that have the most impact of function, before and after assessing the soft tissue laxities.

Follow the counterclockwise sequence on the implant planning screen to complete the functional planning guidelines assessment.

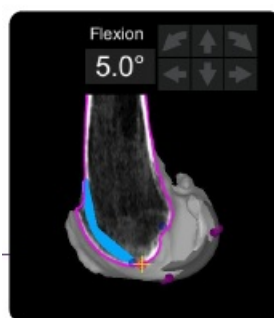


Step 1 Medial concentricity



- Triathlon's single radius design matches the curvature of the native femur 1-3 to help achieve concentricity and stability throughout the active flexion arc 4-6
- Ensure that the femoral component's medial condyle is concentric with the native condyle preoperatively and after making implant adjustments.
- The magenta line of native bone should match the blue of the implant.

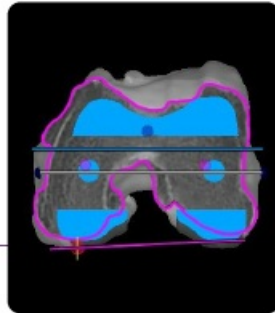
Step 2 Mid-trochlea flexion



- The unique 7° anterior flange design of Triathlon is designed to avoid the occurrence of notching.
- Scroll through the CT slices to ensure implant anterior runoff.
- The surgeon has the ability to anchor at the flexion radius center to flex the component and optimize femoral size while maintaining medial femoral concentricity.

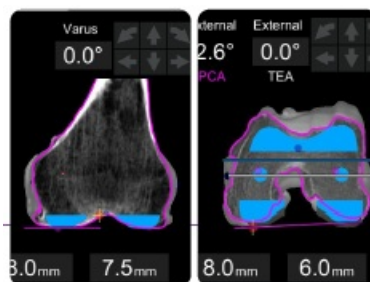
- Evaluate femoral flexion and size in comparison to the tibia. Typically, the femur is the same size or one size smaller than the tibia. Use the anchor point to flex the component accordingly.
- Assess the volume of the anterior flange proximal to native trochlea and anterior to anterior cortex.

Step 3 Trochlea groove



- Triathlon's deepened trochlear groove is designed to help relax the extensor mechanism, enable deeper flexion and reduce contact stresses exerted across the patella. Triathlon incorporates the same patellofemoral design as Duracon, which demonstrated <1% patella- femoral complication rates in multiple studies.⁸⁻⁹
- Use transverse CT Slicer view to confirm the femoral component does not overstuff the patellofemoral compartment.
- Set the component to the desired size, and center the component between the resected medial and lateral cortical edges, so that there is no overhang ML.
- Position the component ML to reproduce the patient's native trochlea position, resulting in symmetrical ML trochlea resection.
- When making intraoperative adjustments, note the amount of external rotation that is added to the femoral component as this can disrupt the medial concentricity.

Step 4 Lateral column



- In the coronal view, ensure that the lateral side of the component is not adding excessive tension to the lateral side in extension and flexion.
- Greater laxity laterally in both extension and flexion may be desirable.
- To avoid over lengthening the lateral column, the surgeon may modulate femoral valgus and lateral laxity in extension.
- Modulate femoral IE rotation and lateral laxity in flexion
 - Reduced resections laterally will likely add more tension to the lateral slide.
 - Balance and position respecting the medial role of MCL and the PCL and the lateral role of the LCL.

Step 5 Tibia varus



- Confirm that the tibial resection landmarks are positioned 2/3 posterior and default lateral resection value is 7mm.
- Medial tightness is more predictable to change by adjusting tibial varus and with a lateral pivot point than adjusting tibial slope.
- With medial bony erosion, the medial resection may be less than 7mm.
- The surgeon can accommodate for medial tibial bony erosion:
 - As a starting point, pin the tibia lateral and drop the medial side into varus to coronally orient the tibia to reflect the estimated pre-diseased joint orientation.

Step 6 Tibial posterior slope

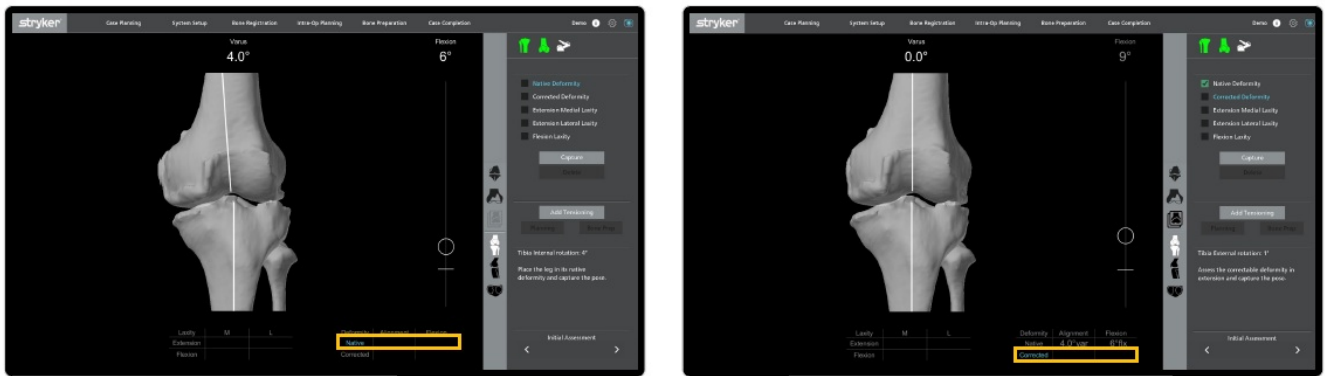


- Triathlon CR tibial posterior slope is set between 0 – 3°, as Triathlon's shortened, flared posterior condyles are designed to facilitate the relaxation of the soft tissues to enable deep flexion without excessive slope.¹⁰
- The reduced slope guidance is designed to enhance rotary and AP stability when there is no ACL and no meniscus.
- Triathlon's short flared condyles take tension out of the flexion space beyond 110° and allow for stability at 90° with minimal slope.
- Excessive slope may:
 - Result in PCL laxity in mid-flexion with the potential for inconsistent femoral translation
 - Cause the femur to ride posterior in or block extension.
- Excessive roll back laterally is undesirable in TKA as the popliteus lateral meniscus mechanism is disrupted when the lateral meniscus is removed.

Intraoperative assessment

- Native deformity
- Corrected deformity

- Extension medial laxity
- Extension lateral laxity
- Flexion laxity



Assess native deformity

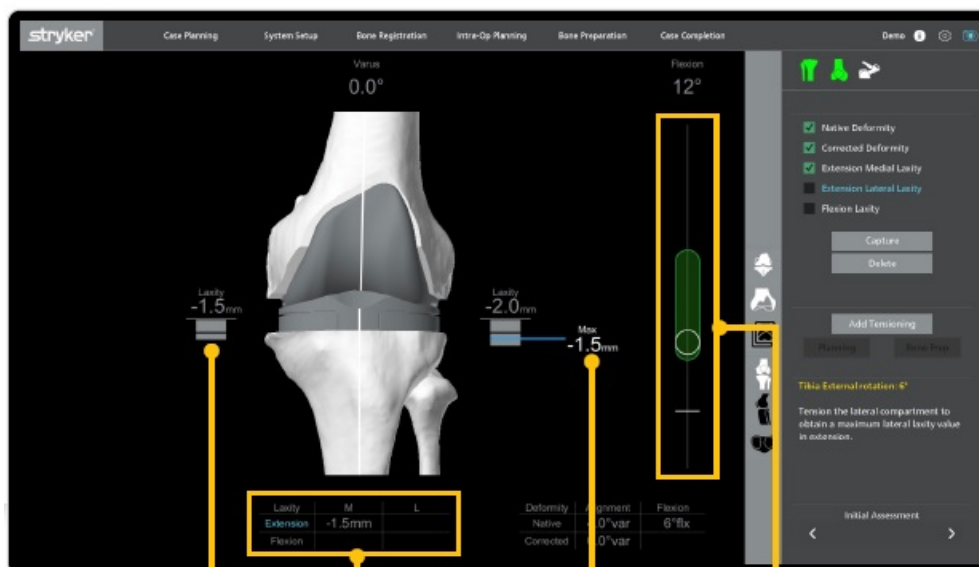
- The goal of the native deformity is to assess the leg's presented deformity in both the coronal and sagittal planes.
- The surgeon should hold the ankle and let the joint sit freely.

Assess corrected deformity

- The goal of the corrected deformity is to assess whether the patient's leg is correctable and to what degree of correction is achievable.
- The surgeon should slightly flex the joint 5-10° from the native deformity to disengage the posterior capsule and apply a corrective force.

Intraoperative assessment: Digital Tensioner

The Digital Tensioner is used to capture the medial and lateral laxities in both flexion and extension. This does not require any additional instrumentation or hardware. Medial and lateral compartment laxity in both flexion and extension can be captured independently and is measured by the half millimeter.



Live
laxity
value

Laxity
table

Maximum
laxity
value

Extension
capturable
range

1. As the surgeon applies tension to the ligaments and opens each compartment, an audible and visual cue will be provided every 0.5 millimeters.
2. As the surgeon opens a compartment, they may reference the audible cues. Once the surgeon finds the end stop of the ligament, by referencing the plateau of the stress/strain curve, the audible and visual feedback will start to slow and eventually stop. Once it stops, the surgeon is ready to capture the laxity value.
3. The system will temporarily store the maximum laxity value assessed, after which the value can be captured into the laxity table by the Mako Product Specialist. Once captured, the surgeon can move onto the next compartment.

It is recommended that the surgeon captures the extension poses at the bottom of the capturable range to relax the posterior capsule and remove the knee from screw home in order to better assess the ligaments, without going into mid-flexion.

Using the Digital Tensioner, the surgeon will:



Assess medial extension laxity

The goal is to assess the medial ligament laxity in extension. Apply a valgus stress to the joint, while listening to the Digital Tensioner's audible cues. Once the surgeon has reached the end stop of the ligament, they can release the tension and capture the pose.

Assess lateral extension laxity

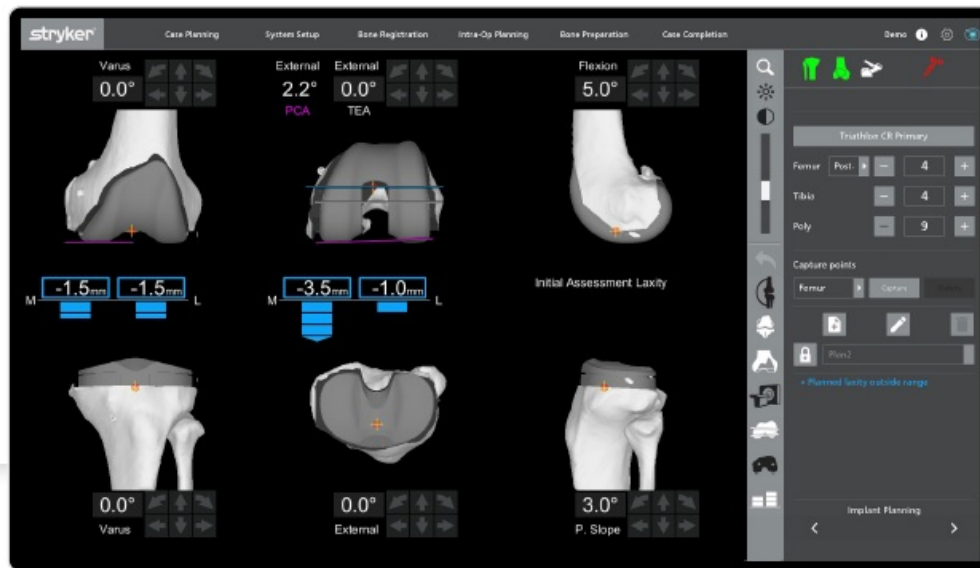
The goal is to assess the lateral ligament laxity in extension. Apply a varus stress to the joint while listening to the Digital Tensioner's audible cues. Once the surgeon has reached the end stop of the ligament, they can release the tension and capture the pose.

Assess flexion laxity

The surgeon can take the medial and lateral compartments simultaneously. Using a tool, like Mako spoons or osteotomes, the surgeon can apply tension to the joint and capture the laxity pose with the Digital Tensioner.

Intraoperative planning

Mako allows the surgeon to make virtual adjustments to the position of the implants before making cuts. The surgeon can select specific pivot points for rotational adjustments which are in half-millimeter increments.



When assessing the laxities of the knee, the surgeon can take into consideration the following implant positioning to help minimize soft tissue releases:

Femoral and tibia varus/valgus

Consider tibial adjustments first, as to preserve femur bony adjustments and maintain the posterior condylar offset.

- **Symmetric extension gaps** – Surgeon could consider adding varus to the tibia then valgus to the femur to maintain extension gaps
- **Asymmetric extension gaps** – Surgeon could consider adding varus to the tibia

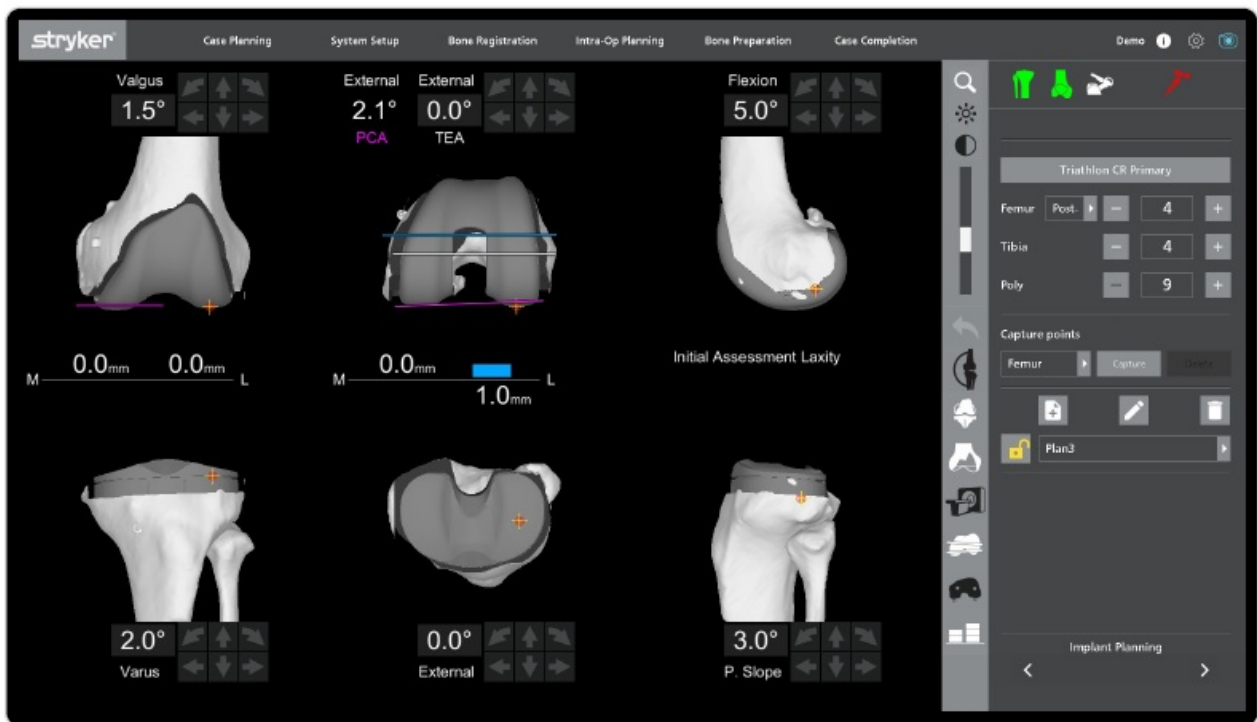
Femoral internal/external rotation

Surgeon could consider adding femoral rotation, as needed, to balance flexion gaps.

Intraoperative planning: planned target laxities

In order to achieve Functional Knee Positioning at the end of the case, consider adjusting the position of the implants to:

1. Reduce the planned laxities on the medial side in flexion and extension.
2. Slightly increase the planned laxity laterally in flexion to accommodate natural rollback.



Consider the following target laxities

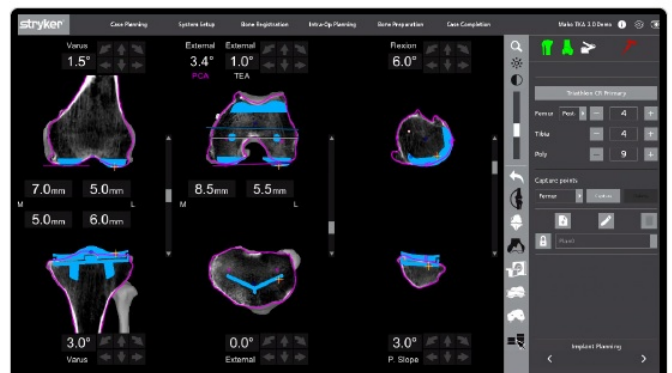
- Extension medial: 0 to 0.5mm
- Extension lateral: 0 to 0.5mm
- Flexion medial: 0 to 0.5mm
- Flexion lateral: 0.5 to 1.0mm

Review the final plan

Final step in intraoperative planning

Review the final plan and confirm the functional planning guidelines are met. Refer to pages 7 and 8 and follow steps 1 through 6 for more details.

- Final implant position is within the surgeon preferences
- Medial concentricity
- Lateral condyle resection
- Trochlea groove

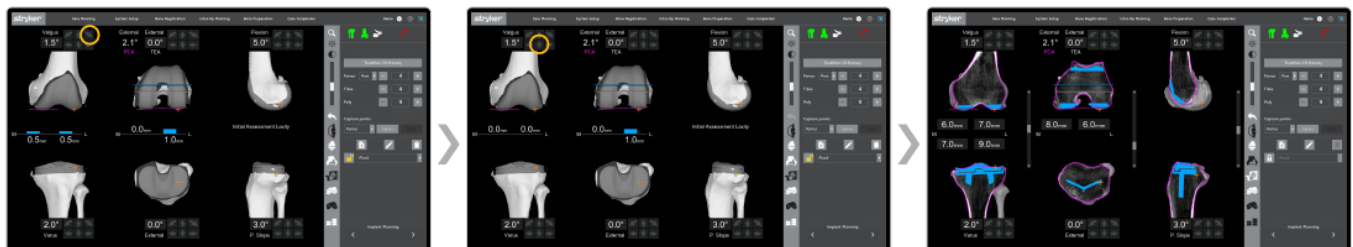


Intraoperative planning: Varus knee guide | Balancing symmetric extension gaps

1. The extension gaps are symmetric and the flexion gaps are asymmetric.
2. Move the tibial component distal 1.5mm.
3. Add 2.0° of varus to the tibial component.

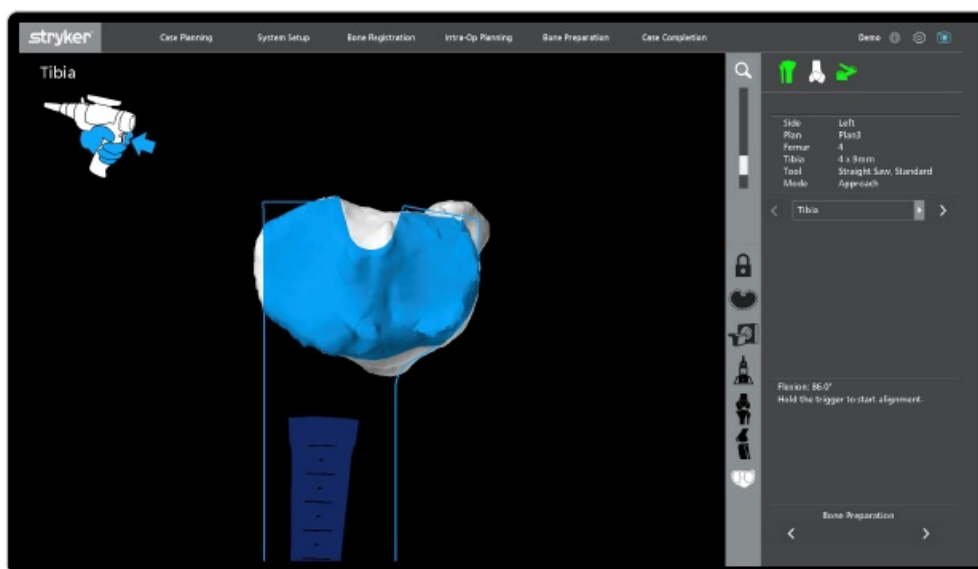


4. Add 1.5° of valgus to the femoral component.
5. Move the femoral component distal 0.5mm to achieve symmetric extension gaps and flexion laxities are all balanced within 1.0mm.
6. Check resection depths, PF joint and posterior medial condyle in CT Slicer view to confirm proper fit of components.



AccuStop™ haptic technology

Mako's CT-based pre-planning enables AccuStop™ haptic technology, allowing the surgeon to execute their plan with precision and accuracy.^{11, 12}



Mako's AccuStop™ haptic technology

- Constrains the saw within the virtual boundary that is established by the surgeon's patient-specific plan¹³
- The surgeon is no longer limited by cutting blocks and manual techniques
- Allows the surgeon to execute more pristine bone resections,¹⁴ with less soft tissue damage¹⁴ and greater bone preservation when compared to manual cutting blocks¹⁵
- The surgeon can advance through their cut sequence by double clicking the MICS trigger

The powerful combination of Mako and Triathlon Cementless

- Triathlon Cementless TKA has demonstrated excellent clinical outcomes with five-year follow-up.¹⁶
- Triathlon Cementless implants make up over half of the Mako Total Knees implanted¹⁷ in the U.S.

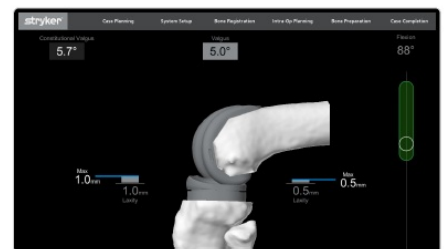
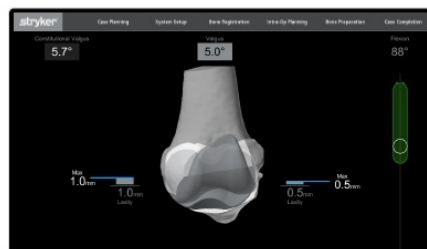


Mako Park

Ensures that the Mako System is positioned into the most optimal spot for cutting. This will allow the surgeon to access each cut with ease and complete bone prep efficiently.

Trailing

Once all bone cuts have been made using the AccuStop™ haptic technology, assess the joint on the Trialing page.



On this page, the surgeon can assess:

- Final limb alignment
 - Final compartment laxities, throughout the range of motion
 - Medial and lateral translations, throughout the range of motion
 - AP drawer tests to confirm AP stability, throughout the range of motion
1. The surgeon can utilize the sagittal and transverse preset views to ensure the medial and lateral translations and drawer test
 2. With the sagittal preset view on, and the lateral side visible, complete AP drawer tests at the following intervals: 15-20°, 45°, 60-70°, 90°
 3. During AP drawer test, the surgeon may notice that the medial side doesn't move but the lateral side rolls back

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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FAQ


What is Functional Knee Positioning?

Functional Knee Positioning is achieved by use of the 3D CT-based preoperative plan based on the patient's bony anatomy and acknowledging proxies for knee function. Intraoperatively, the surgeon has the ability to assess soft tissue laxities and adjust the placement of implants to achieve the final position before cuts are made using AccuStop™ haptic technology.

Documents / Resources

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References

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