Reusable Instruments Surgical Technique

QUANTUM®
Total Ankle System

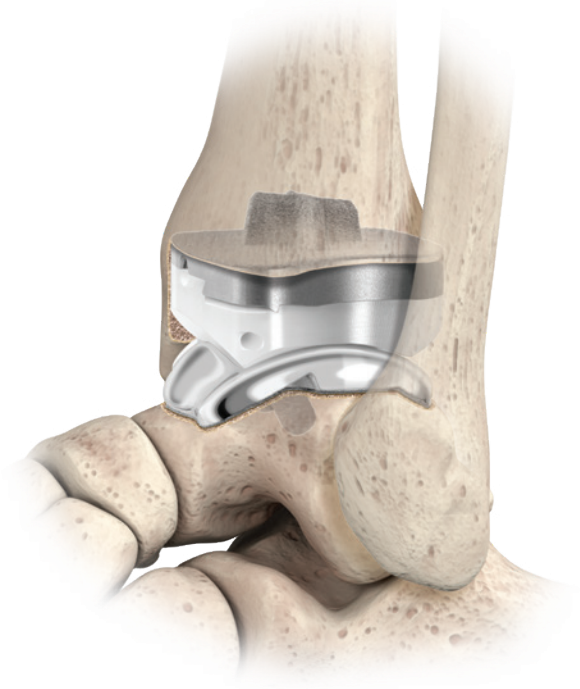

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Table of Contents

QUANTUM® Total Ankle System

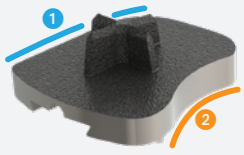
The QUANTUM® Total Ankle System is designed to address the complexity of TAR and allow reproducible outcomes for every surgeon.

Implants Designed to Increase Longevity:
- Favorable gravimetric wear rate compared to competitive systems*

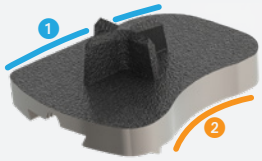
Intuitive Instrumentation:
- Two single-level trays for case execution
- Streamlined procedure and tray design intended to reduce the dependency on specialists

Tibial Components:
- Curved medial profile (1) and lateral fibular contour (2)
- Cross-shaped keel for rotational stability and direct axial loading
- Side-specific, Standard and Long versions, in sizes 2 through 6, to cater to patient anatomy
- Designed to rest on the cortical rim
- Titanium alloy with titanium porous coating

SIZE X or X+1



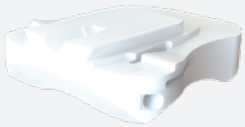
Standard Tibial Implant



Long Tibial Implant

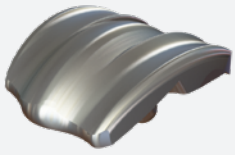
Tibial Inserts:
- Side-specific implants for sizes 2 through 6, in 8 thicknesses (5-15mm)
- Dovetail locking feature
- Vacuum sealed and gamma sterilized
- Ultra-high molecular weight polyethylene

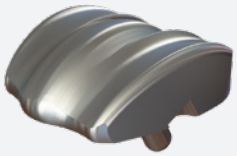
SIZE X


Tibial Insert

Talar Components:
- Side-specific, Standard and Flat-Cut varieties, in sizes 2 through 6
- Double radius of curvature, and tronconic shape, designed to replicate healthy ankle kinematics
- CoCr with titanium porous coating

SIZE X


Standard Talar Implant


Flat-Cut Talar Implant

*Data on file

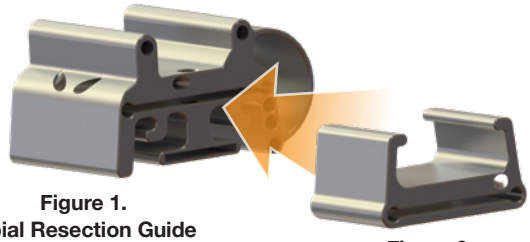


Figure 1.
Tibial Resection Guide

Figure 2.
Standard Talar Resection Guide

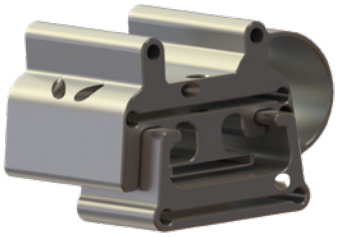


Figure 3. Assembled Resection Guides for Standard Talus

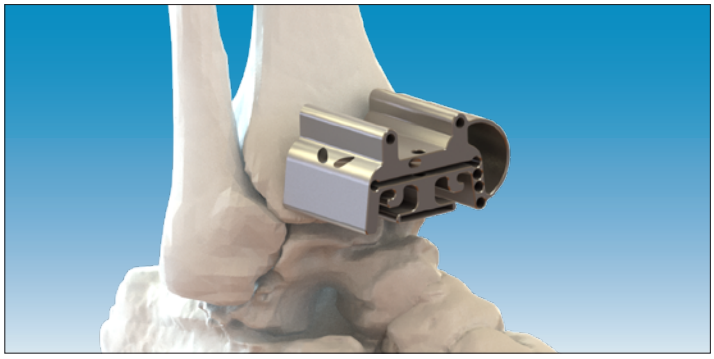


Figure 4. Initial Placement of Tibial Guide

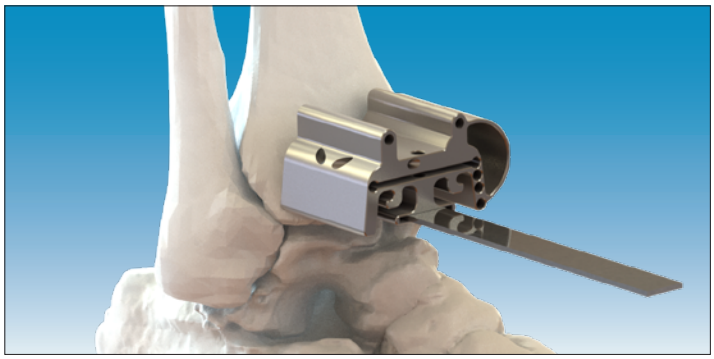


Figure 5. Insertion of Reference Saw Blade

1. Reusable Cutting Guide Introduction

The reusable cutting block is a two-piece assembly used to perform both tibial resections and the horizontal talar cut (**Figures 1 & 2**).

Both parts are assembled over the patient's anatomy by sliding the talar cutting block into the tibial cutting block (**Figure 3**).

Multiple features allow for the verification of axis alignment, anterior-posterior slope, mediolateral position, and the residual malleolar distance before performing any bone resection.

The cuts performed through these blocks represent the minimal bone resection necessary to implant the QUANTUM® Total Ankle construct.

2. Resection Guide Positioning

Tibial Resection Guide Positioning

Remove any anterior osteophytes and clear access to the tibial plafond ensuring ease of access to the distal tibia.

Position the Tibial Resection Guide over the patient's anterior tibia with the laser etching of the operative side facing toward the surgeon (**Figure 4**).

Note: *The Tibial Resection Guide is available in two sizes. Size 1 is used to prepare for implant sizes 2-3 while the Size 2 guide is used to prepare for implant sizes 4-6. Select the appropriately sized Guide based on the preoperative templating that was performed.*

Insert a 1.27mm narrow graduated saw blade into the dedicated area in the guide, extending the blade posteriorly to allow for insertion into the tibiotalar joint space (**Figure 5**).

Note: *Saw blades are not provided with the system. A blade that is 1.27mm thick and at least 80mm long must be used with the QUANTUM Resection Guides. It is recommended to have a maximum blade width of 13mm to allow for use when cutting and referencing the joint line.*

A 2.5mm K-wire may be placed in the medial malleolar gutter as an anatomic reference point based on surgeon preference.

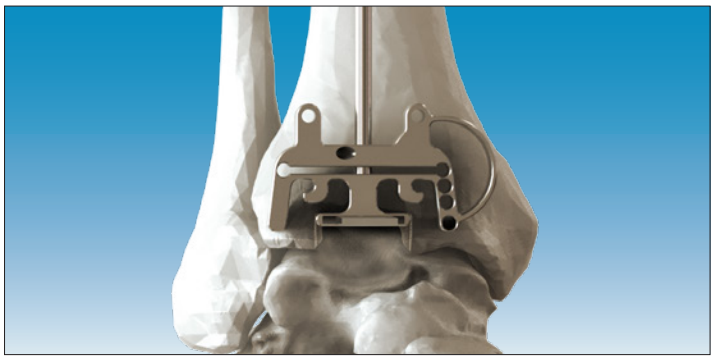


Figure 6. Tibial Axis Visualization and Alignment

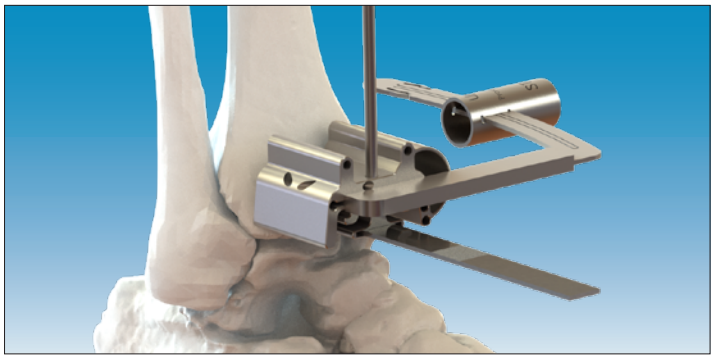


Figure 7. Assembly of Visualization Bow

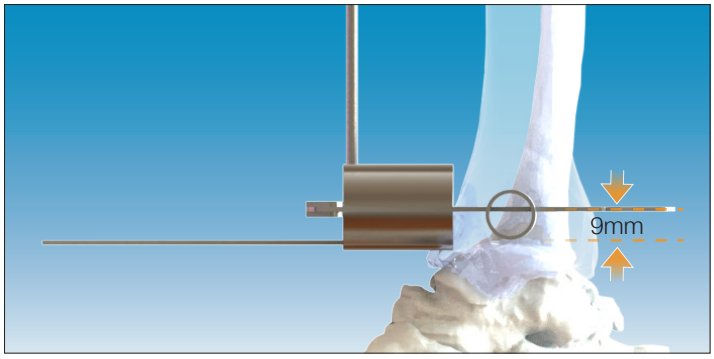


Figure 8. Tibial Cut Trajectory and Nominal Resection

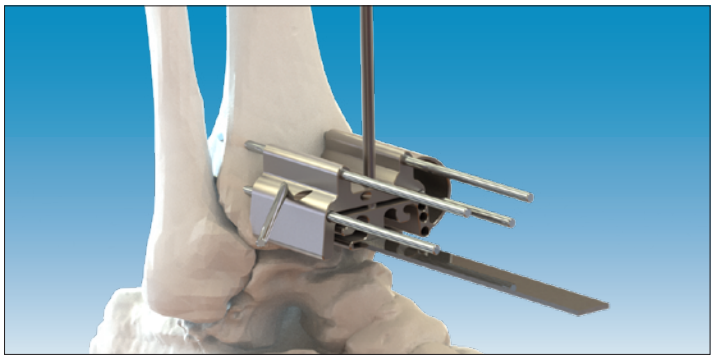


Figure 9. Tibial Resection Guide Fixation

Insert the Tibial Axis into the hole located on the Tibial Resection Guide's proximal surface and align the Guide with the tibial anatomic axis. A residual malleolar distance of 10mm is represented by the Resection Guide's medial arch (**Figure 6**).

Insert the Visualization Bow into the cutting slot of the Resection Guide (**Figure 7**).

Slide the Control Cylinder for Standard Cut onto the Visualization Bow with the "Up" inscription oriented proximally.

Confirm placement with fluoroscopic verification.

The visualization bow corresponds with the cut trajectory while the distal portion of the Control Cylinder for Standard Cut represents the 9mm nominal tibial resection.

Note: *Take care to check for proper alignment of the fluoroscopy arm during this step by confirming that the cylinder is a perfect circle on the lateral view (**Figure 8**).*

Adjust the position of the Tibial Resection Guide as needed based on anterior and lateral fluoroscopic views.

Once proper alignment has been obtained, secure the Tibial Resection Guide with two parallel 2.5mm K-wires located proximally. Remove the Visualization Bow.

Two additional 2.5mm K-wires are inserted into the cutting slot's medial and lateral boundaries as malleolar protection followed by a single oblique K-wire on the lateral aspect of the Guide (**Figure 9**).

Remove the saw blade and the Tibial Axis from the Resection Guide.

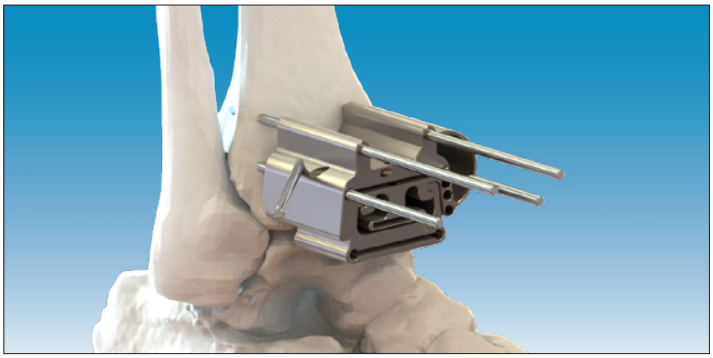


Figure 10. Assembly of Standard Talar Resection Guide

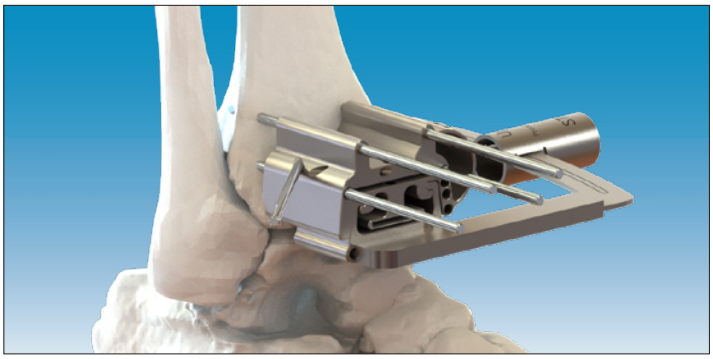


Figure 11. Assembly of Visualization Bow

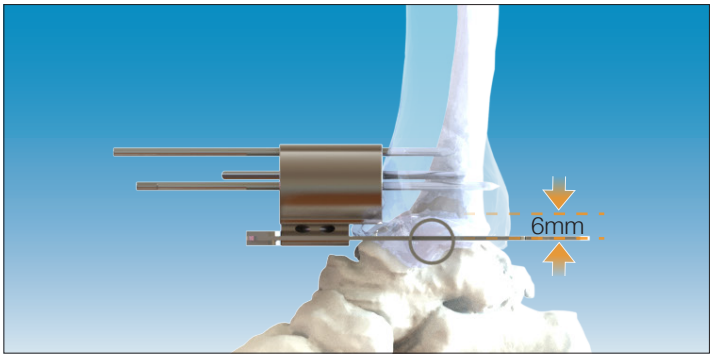


Figure 12. Talar Cut Trajectory and Nominal Resection

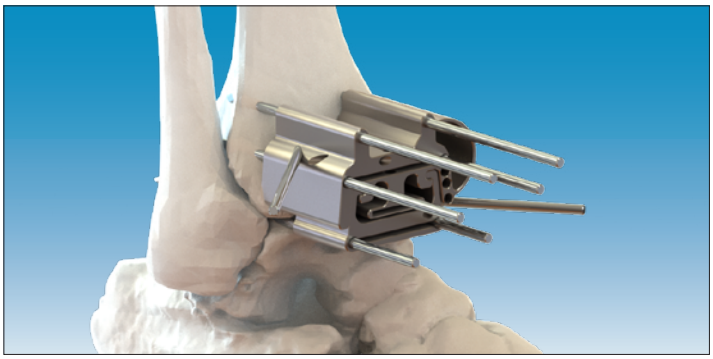


Figure 13. Standard Talar Resection Guide Fixation

Talar Resection Guide Positioning

Slide the Standard Talar Resection Guide into the Tibial Resection Guide until in contact with the talar neck with the ankle in a neutral position (**Figure 10**).

Insert the Visualization Bow into the cutting slot of the Talar Resection Guide (**Figure 11**).

Tip: *The Visualization Bow may be positioned medially or laterally based on surgeon preference and accessibility.*

Slide the Standard Cut Control Cylinder onto the Visualization Bow with the "Up" inscription oriented proximally.

Confirm placement with fluoroscopic verification.

With the ankle in a neutral position, the Visualization Bow corresponds with the cut trajectory. The proximal portion of the Standard Cut Control Cylinder represents the 6mm nominal talar resection.

Tip: *Take care to check for proper alignment of the fluoroscopy arm during this step by confirming that the cylinder is a perfect circle on the lateral view (**Figure 12**).*

Once the cut trajectory has been confirmed, secure the Standard Talar Resection Guide in place with two parallel 2.5mm K-wires and a third oblique K-wire to lock the Guide to the talus (**Figure 13**).

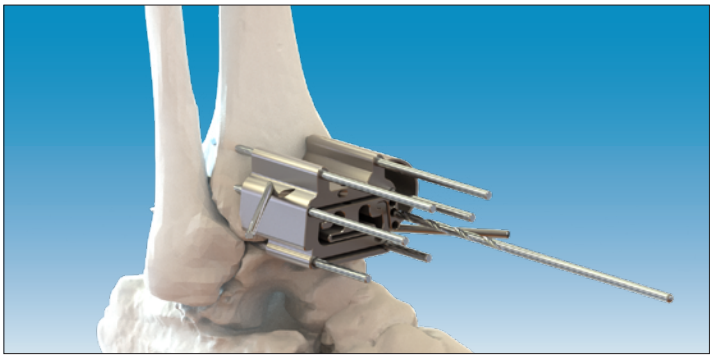


Figure 14. Tibial Stamping

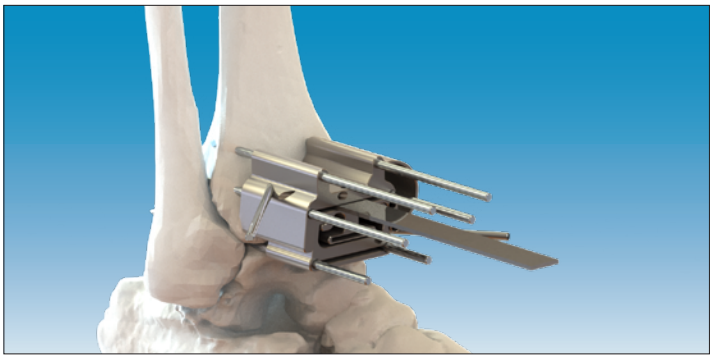


Figure 15. Tibial Resection

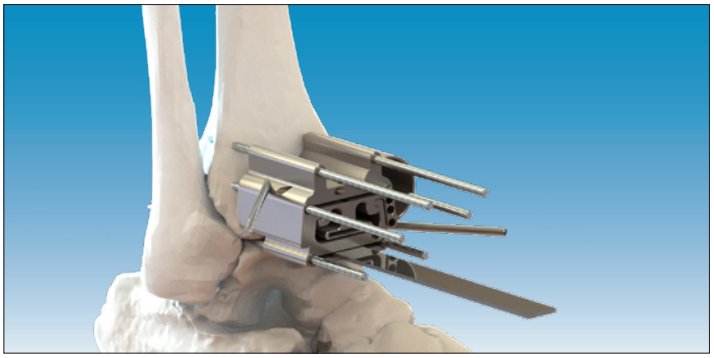


Figure 16. Standard Talar Resection

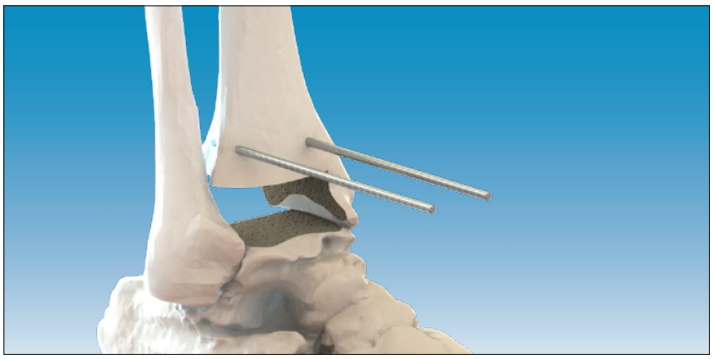


Figure 17. Resection Guide Removal

3. Initial Preparation

Tibial Cuts

The vertical tibial cut is created in a stamping fashion with the use of a 2.5mm drill.

Using a wire driver, insert and remove the 2.5mm drill through each of the medial holes in the Resection Guide starting with the most distal and proceeding proximally in sequence (**Figure 14**).

Complete the horizontal tibial cut through the cutting slot in the Tibial Resection Guide. A narrow graduated 1.27mm thick by 80mm long saw blade is used (**Figure 15**).

Tip: *Care should be taken to avoid damage to posterior soft tissues.*

Standard Talar Resection

Complete the horizontal talar cut through the cutting slot in the Standard Talar Resection Guide. A narrow graduated 1.27mm thick by 80mm long saw blade is used (**Figure 16**).

Tip: *Care should be taken to avoid damage to posterior soft tissues.*

Remove all K-wires from the Resection Guides except for the two most proximal wires in the Tibial Resection Guide. Remove the Resection Guides (**Figure 17**).

Refine the prepared cuts as needed taking care to avoid any modification to the alignment planes. Then clear the joint space of the resected bone. The Hockey Stick may be used to access and remove any posterior bone fragments.

Tip: *The Corner Chisel may be used to aid in connection of the vertical and horizontal tibial resections for bone removal. Upon reaching the posterior cortex, the estimated tibial implant size is indicated by the laser markings on the Corner Chisel.*

Figure 18. Gap Check for Standard Talus

Figure 19. Tibial Recut Block

Figure 20. Alignment of Standard Talar Template

Figure 21. K-Wire Fixation of Standard Talar Template

4. Resection Verification and Optional Recut

Insert the Gap Sizer into the prepared joint line with the laser marking reading "STD" facing the resected bone surface (**Figure 18**).

Note: *The Gap Sizer is used for Standard and Flat Cut operations. When the laser marking reading "STD" faces the resected bone surface, the minimum construct thickness with the Standard Talus is simulated.*

The Alignment Rod may be inserted into the holes on the handle of the Gap Sizer to allow for fluoroscopic verification of perpendicularity of the tibial and talar resections to the tibial mechanical axis.

If the Gap Sizer indicates that the existing resections will not accommodate the minimum construct thickness, the Resection Cut Adjustment Block shall be used.

Note: *The Resection Cut Adjustment Block may be used for tibial and talar recuts as indicated by the block's markings. Ensure the block is oriented correctly depending on the bone being addressed.*

To recut the tibia, take care to orient the Resection Cut Adjustment Block so that the side marked "Tibia" is facing anteriorly and slide the block over the two K-wires left in the anterior tibia at the corresponding recut height (**Figure 19**).

Insert two K-wires into the cutting slot holes as malleolar protection. Use a 1.27mm graduated saw blade to perform the cut.

Remove the K-Wires and Resection Cut Adjustment Block once the recut is complete.

5. Final Talar Preparation

Standard Talar Component Positioning

Place the Standard Talar Template onto the resected talar surface to establish proper sizing. Initally orient the handle of the Template with the 2nd digit of the operative foot. Refine the rotation as needed to allow for alignment of the talar flanges with the handle (**Figure 20**).

Confirm placement with fluoroscopic verification with a direct lateral view indicated by a perfect circle view of the thru-hole on the side of the Template.

Full contact between the Template and the talar resection should be obtained prior to moving to the next step.

Figure 22. Alignment of Talar Chamfer Resection Guide

Figure 23. K-Wire Fixation of Talar Chamfer Resection Guide

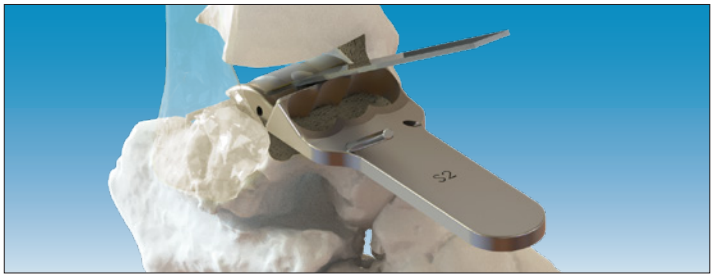


Figure 24. Posterior Chamfer Resection

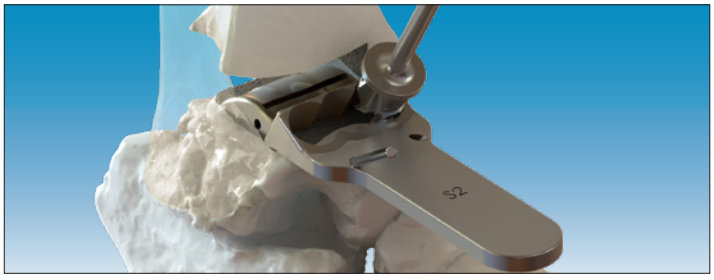


Figure 25. Anterior Chamfer Reaming

Figure 26. Placement of K-Wires and Peg Preparation

Upon confirmation of appropriate alignment, fix the Standard Talar Template to the talus using two 2.5mm K-wires. Stop when the K-wire contacts cortical bone on the distal side of the talus to avoid penetration of the subtalar joint (**Figure 21**).

Verify placement under fluoroscopy and remove the Template and K-wires.

Positioning of Talar Chamfer Resection Guide

Align the pegs of the Talar Chamfer Resection Guide with the holes previously prepared in the talus with K-wires (**Figure 22**) and secure it in place with one K-wire through the anterior hole on the guide (**Figure 23**).

Tip: *Prior to securing the Talar Chamfer Resection Guide, ensure full seating with the use of fluoroscopy. Incomplete seating of the Guide may result in incomplete bone preparation.*

Posterior Chamfer Preparation

Complete the posterior chamfer resection through the posterior slot of the Talar Chamfer Resection Guide (**Figure 24**).

Note: *Hold the guide firmly during this step to avoid any unintentional movements of the Talar Chamfer Resection Guide during the cutting process.*

Anterior Chamfer Preparation

Using the Talar Reamer, prepare the anterior chamfer by reaming within the holes in the anterior portion of the resection guide (**Figure 25**).

Note: *Hold the guide firmly during this step to avoid any unintentional movements of the Talar Chamfer Resection Guide during the drilling process.*

Remove the Talar Chamfer Resection Guide and the resected bone then clean all bone surfaces of debris.

Talar Pegs Preparation

Place two K-wires into the holes previously created through the Talar Template.

Tip: *Initial manual insertion of the K-wires is recommended to ensure proper alignment with the previously prepared holes.*

Using the 5mm Standard Peg Cannulated Drill, drill over the K-wires until the Drill's step meets the bone (**Figure 26**).

Remove both K-wires.

Figure 27. Impaction of Standard Talar Trial

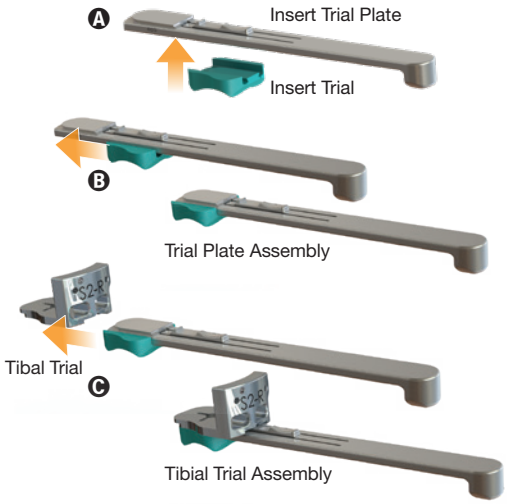


Figure 28. Tibial Trial Assembly

Ⓐ Insert Trial and Trial Plate
Ⓑ Assembly of Insert Trial and Trial Plate
Ⓒ Assembly of Tibial Trial to Trial Plate Sub-Assembly

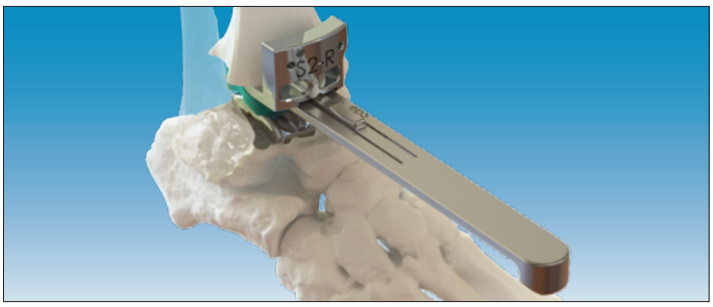


Figure 29. Alignment of Tibial Trial Assembly

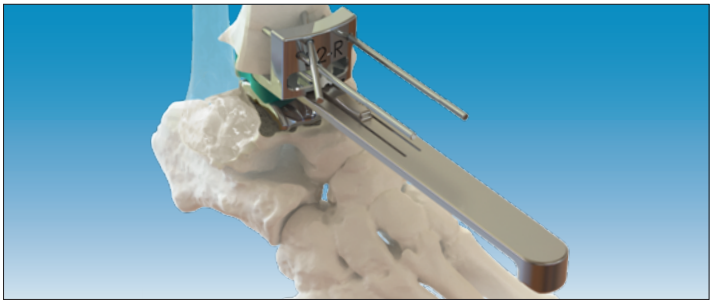


Figure 30. K-Wire Fixation of Tibial Trial Assembly

6. Trialing

Standard Talar Trial Positioning

Select the appropriate Standard Talar Trial, Implant Holder, and Talar Implant Impactor from the instrument tray.

Align the Standard Talar Trial with the prepared talar peg holes and impact it into place with the Talar Implant Impactor (**Figure 27**).

Confirm full seating of the Trial with fluoroscopic verification.

Tibial Trial Assembly

Select the appropriate Insert Trial Plate and Insert Trial from the instrument tray, ensuring size and side are correct (**Figure 28A**).

Note: *The Insert Trial size must be the same as the selected Talar Implant.*

Slide the Insert Trial Plate over the Insert Trial until the two components are clipped together (**Figure 28B**).

Select the appropriate Tibial Trial from the instrument set, ensuring size and side are correct.

Note: *The Tibial Implant size must be the same size or one size over the selected Talar Implant.*

Slide the Insert Trial Assembly into the Tibial Trial until the two components are clipped together (**Figure 28C**).

Tibial Trial Positioning

Insert the Tibial Trial Assembly into the prepared joint space and trial for fit and laxity. Mobilize the ankle to obtain desired positioning of the assembly over the Talar Trial Implant (**Figure 29**).

If increased construct height or reduced laxity is required, increase the Insert Trial thickness until the construct provides satisfactory results.

Fix the Tibial Trial Assembly to the tibia using two parallel and one oblique 2.5mm K-wires (**Figure 30**).

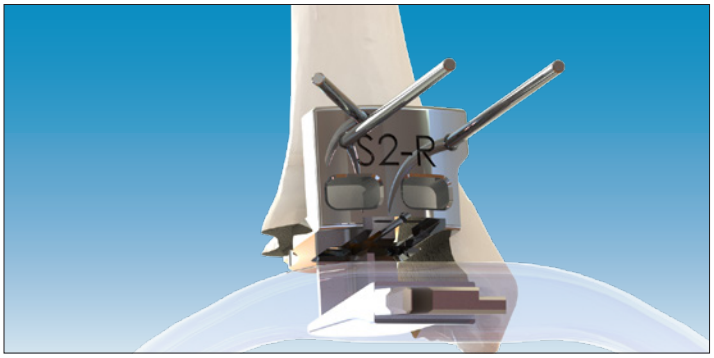


Figure 31. Alignment of Tibial Stem Shaper

Figure 32. Impaction of Tibial Stem Shaper

Figure 33. Assembly of Impaction Tip

Figure 34. Implanted Tibial Component

7. Tibial Stem Preparation

Remove the Insert Trial and Insert Trial Plate from the Tibial Trial Assembly, while leaving the Tibial Trial Implant in place on the tibia. Remove the Talar Trial Implant from the talus.

Thread the Handle into the Impaction Frame until in full contact with the Frame. Assemble the Tibial Stem Shaper to the Impaction Frame.

Slide the assembly into the prepared joint space while aligning the shaper with the Tibial Trial Implant's cross-shaped socket (**Figure 31**).

Prepare the tibial stem by striking the Impaction Frame Hitting Plate with an axial force to drive the Tibial Stem Shaper into the tibia until complete contact with the Tibial Trial Implant is obtained (**Figure 32**).

Remove the Impaction Frame and the Tibial Stem Shaper.

Remove the oblique K-wire from the tibia and slide the Tibial Trial Implant out of the joint space while leaving the two parallel K-wires in place.

8. Implantation

Final Tibial Implant Insertion

Obtain the appropriate Final Tibial Implant and assemble it to the Tibial Implant Holder.

Assemble the Tibial Implant Guide to the Tibial Implant Holder. Verify the Tibial Implant Guide's correct orientation by referencing the side-specific laser markings on the Guide.

Slide the Tibial Implant Guide Assembly over the parallel K-wires until complete contact with the anterior wall of the tibia is achieved.

Assemble the Impactor Tip to the Impaction Frame. Slide the Impactor Tip into the groove on the Tibial Implant Holder until it is nested with the impaction socket on the handle (**Figure 33**).

Strike the Impaction Frame Hitting Plate with an axial force to insert the Tibial Implant into the tibia until fully seated.

Note: *Take care to verify complete insertion of the Tibial Implant and full contact between the Tibial Tray and the tibia (**Figure 34**).*

Figure 35. Inserted Articular Surface Protector

Figure 36. Standard Talar Implant Insertion

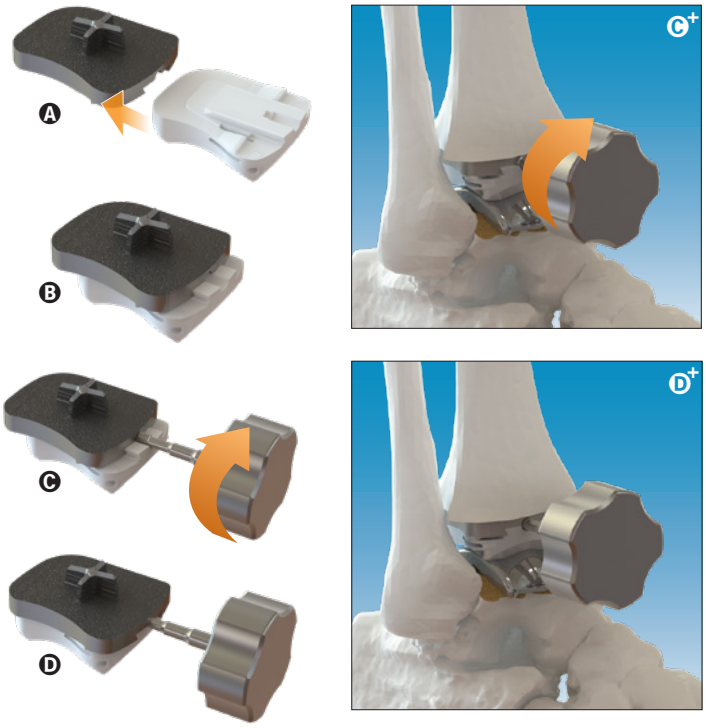


Figure 37. Tibial Insert Placement

Ⓐ Tibial Implant and Insert
Ⓑ Manual Assembly
Ⓒ Addition of Scroll Wheel (+ in-situ)
Ⓓ Final Seating of Insert (+ in-situ)

Figure 38. Final Standard Talus Construct

Remove all instrumentation and K-wires from the tibia while leaving the Tibial Implant in place.

Final Talar Implant Positioning and Insertion

Select the appropriately sized Articular Surface Protector (Sizes 2-3 or 4-6) and insert it into the dovetail groove of the Tibial Implant with hole located anteriorly (**Figure 35**).

Hold the final Talar Implant with the Implant Holder and align it with the prepared talar peg holes.

Insert the Final Talar Implant by striking the end of the Talar Implant Impactor until complete contact is achieved between the Implant and talus (**Figure 36**).

Remove the Articular Surface Protector from the Tibial Implant using the Hockey Stick to engage the anterior hole.

Note: *Take care to prevent damage or scratches to the Talar Implant's surface during implantation and impaction.*

Final Insert Assembly

Align the final Tibial Insert with the anterior portion of the implanted Tibial Implant (**Figure 37A**). Initiate insert placement by manually sliding it into the Tibial Implant's grooves until contacting the dovetail locking feature (**Figure 37B**).

Assemble the Scroll Wheel to the Tibial Implant and Tibial Insert assembly and turn the Scroll Wheel clockwise to initiate final seating of the Insert (**Figures 37C & 37C+**).

Continue turning the Scroll Wheel clockwise until the Tibial Insert is fully engaged with the Tibial Implant and the Wheel is unable to advance any further (**Figures 37D & 37D+**).

Note: *When pairing a Tibial Insert with a Tibial Implant that is one size larger (ex. Size 3 Tibia with Size 2 Talus and Insert), the final Insert location will be recessed relative to the anterior aspect of the Implant. Take care to confirm the Insert is fully engaged and locked in place.*

Remove the Scroll Wheel by turning counterclockwise.

Note: *Take care to prevent damage or scratches to the polished surface of the Talar Implant and articular surface of the Tibial Insert during implantation.*

Final Verification and Closure

Mobilize the ankle and confirm complete implant seating with fluoroscopic verification (**Figure 38**).

Close the surgical site per surgeon preference.

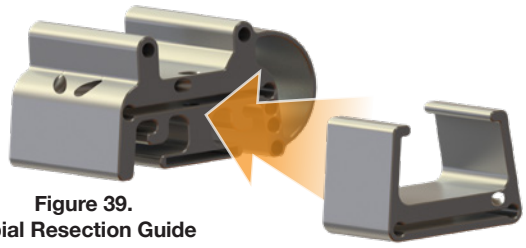


Figure 39.
Tibial Resection Guide

Figure 40.
Flat-Cut Talar Resection Guide

Figure 41. Assembled Resection Guides for Flat-Cut Talus

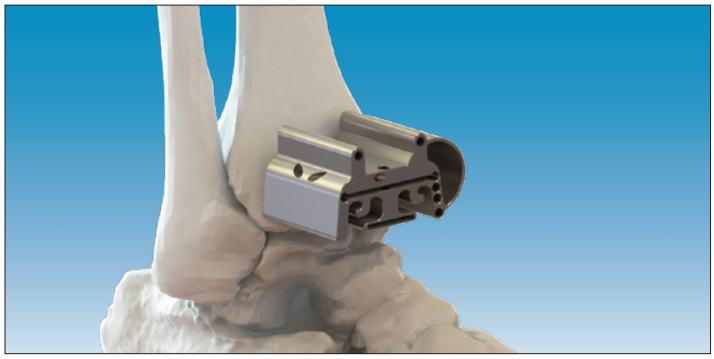


Figure 42. Initial Placement of Tibial Guide

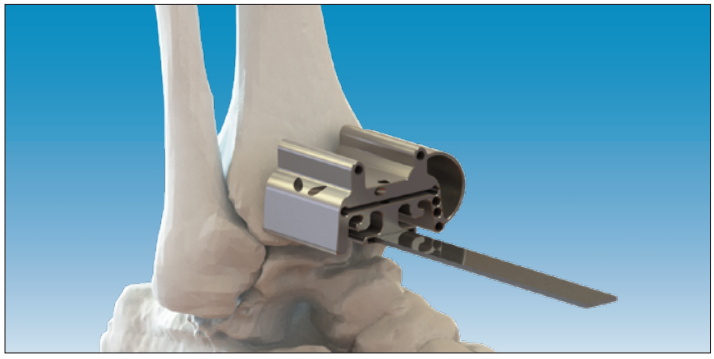


Figure 43. Insertion of Reference Saw Blade

1. Reusable Cutting Guide Introduction

The reusable cutting block is a two-piece assembly used to perform both tibial resections and the horizontal talar cut (**Figures 39 & 40**).

Both parts are assembled over the patient's anatomy by sliding the talar cutting block into the tibial cutting block (**Figure 41**).

Multiple features allow for the verification of axis alignment, anterior-posterior slope, mediolateral position, and the residual malleolar distance before performing any bone resection.

The cuts performed through these blocks represent the minimal bone resection necessary to implant the QUANTUM® Total Ankle construct.

2. Resection Guide Positioning

Tibial Resection Guide Positioning

Remove any anterior osteophytes and clear access to the tibial plafond ensuring ease of access to the distal tibia.

Position the Tibial Resection Guide over the patient's anterior tibia with the laser etching of the operative side facing toward the surgeon (**Figure 42**).

Note: *The Tibial Resection Guide is available in two sizes. Size 1 is used to prepare for implant sizes 2-3 while the Size 2 guide is used to prepare for implant sizes 4-6. Select the appropriately sized Guide based on the preoperative templating that was performed.*

Insert a 1.27mm narrow graduated saw blade into the dedicated area in the guide, extending the blade posteriorly to allow for insertion into the tibiotalar joint space (**Figure 43**).

Note: *Saw blades are not provided with the system. A blade that is 1.27mm thick and at least 80mm long must be used with the QUANTUM Resection Guides. It is recommended to have a maximum blade width of 13mm to allow for use when cutting and referencing the joint line.*

A 2.5mm K-wire may be placed in the medial malleolar gutter as an anatomic reference point based on surgeon preference.

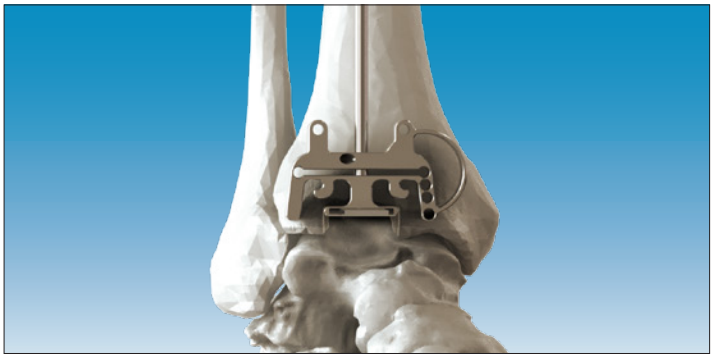


Figure 44. Tibial Axis Visualization and Alignment

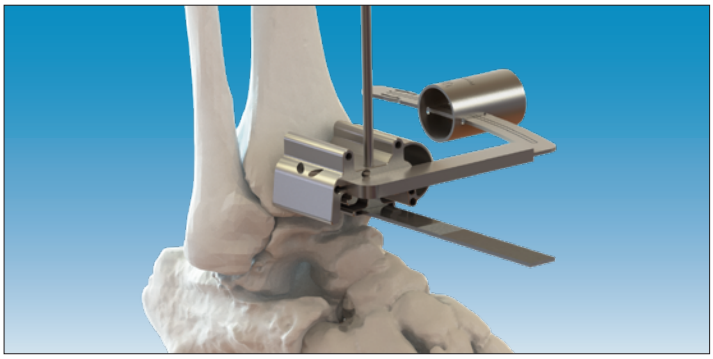


Figure 45. Assembly of Visualization Bow

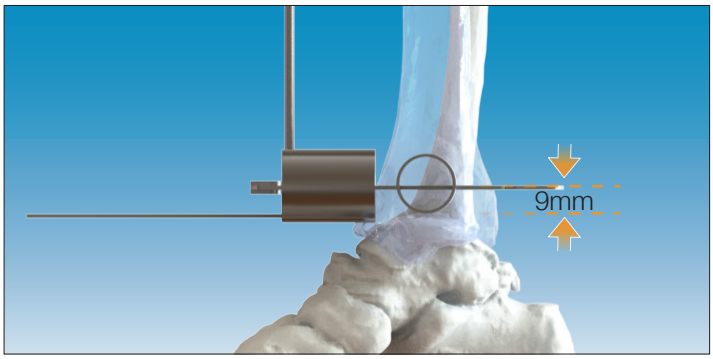


Figure 46. Tibial Cut Trajectory and Nominal Resection

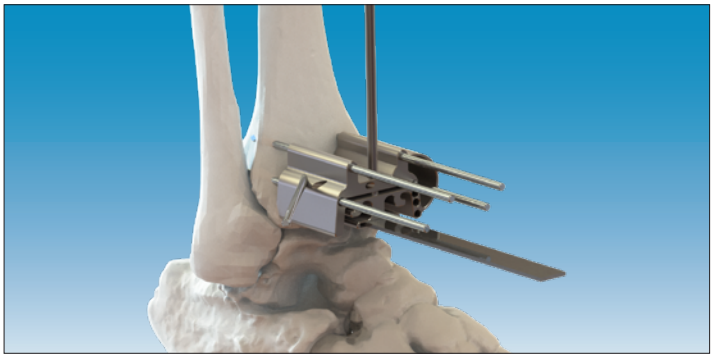


Figure 47. Tibial Resection Guide Fixation

Insert the Tibial Axis into the hole located on the Tibial Resection Guide's proximal surface and align the Guide with the tibial anatomic axis. A residual malleolar distance of 10mm is represented by the Resection Guide's medial arch (**Figure 44**).

Insert the Visualization Bow into the cutting slot of the Resection Guide (**Figure 45**).

Slide the Flat-Cut Control Cylinder onto the Visualization Bow with the "Up" inscription oriented proximally.

Confirm placement with fluoroscopic verification.

The visualization bow corresponds with the cut trajectory while the distal portion of the Flat-Cut Control Cylinder represents the 9mm nominal tibial resection.

Note: *Take care to check for proper alignment of the fluoroscopy arm during this step by confirming that the cylinder is a perfect circle on the lateral view (**Figure 46**).*

Adjust the position of the Tibial Resection Guide as needed based on anterior and lateral fluoroscopic views.

Once proper alignment has been obtained, secure the Tibial Resection Guide with two parallel 2.5mm K-wires located proximally. Remove the Visualization Bow.

Two additional 2.5mm K-wires are inserted into the cutting slot's medial and lateral boundaries as malleolar protection followed by a single oblique K-wire on the lateral aspect of the Guide (**Figure 47**).

Remove the saw blade and the Tibial Axis from the Resection Guide.

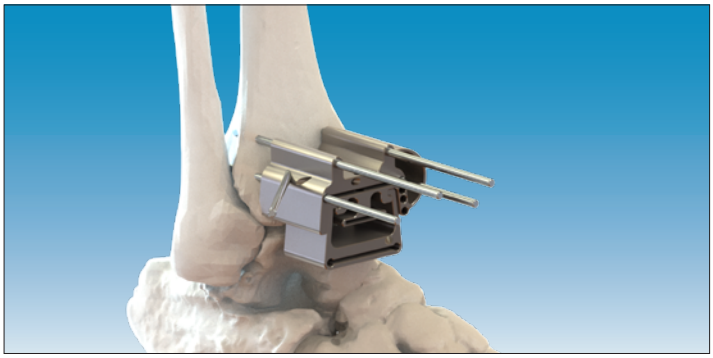


Figure 48. Assembly of Flat-Cut Talar Resection Guide

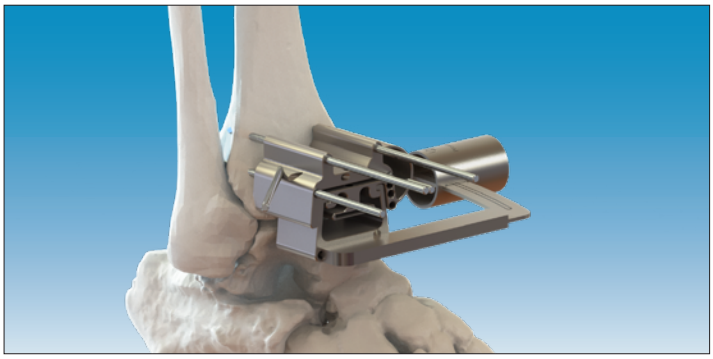


Figure 49. Assembly of Visualization Bow

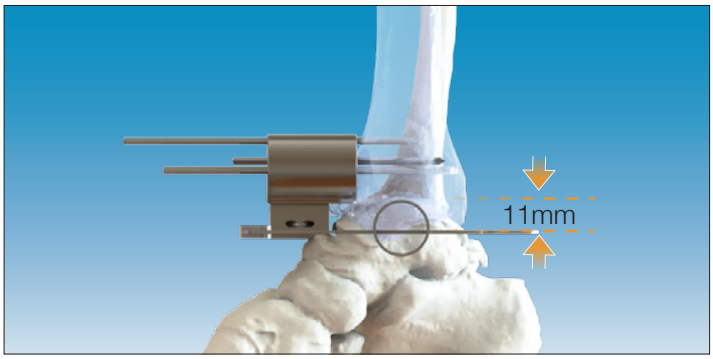


Figure 50. Talar Cut Trajectory and Nominal Resection

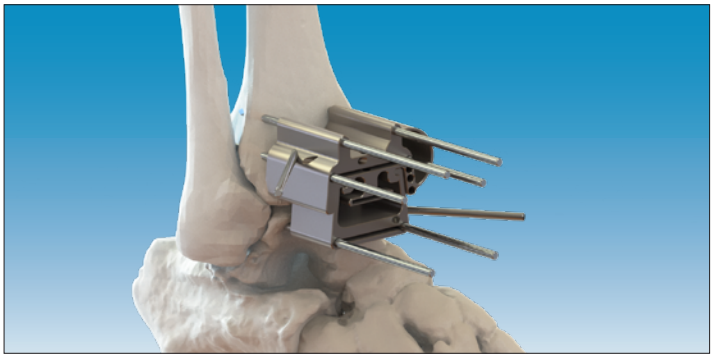


Figure 51. Flat-Cut Talar Resection Guide Fixation

Talar Resection Guide Positioning

Slide the Flat-Cut Talar Resection Guide into the Tibial Resection Guide until in contact with the talar neck with the ankle in a neutral position (**Figure 48**).

Insert the Visualization Bow into the cutting slot of the Talar Resection Guide (**Figure 49**).

Note: *The Visualization Bow may be positioned medially or laterally based on surgeon preference and accessibility.*

Slide the Flat-Cut Control Cylinder onto the Visualization Bow with the "Up" inscription oriented proximally.

Confirm placement with fluoroscopic verification.

With the ankle in a neutral position, the Visualization Bow corresponds with the cut trajectory. The proximal portion of the Flat-Cut Control Cylinder represents the 11mm nominal talar resection.

Note: *Take care to check for proper alignment of the fluoroscopy arm during this step by confirming that the cylinder is a perfect circle on the lateral view (**Figure 50**).*

Once the cut trajectory has been confirmed, secure the Flat-Cut Talar Resection Guide in place with two parallel 2.5mm K-wires and a third oblique K-wire to lock the Guide to the talus (**Figure 51**).

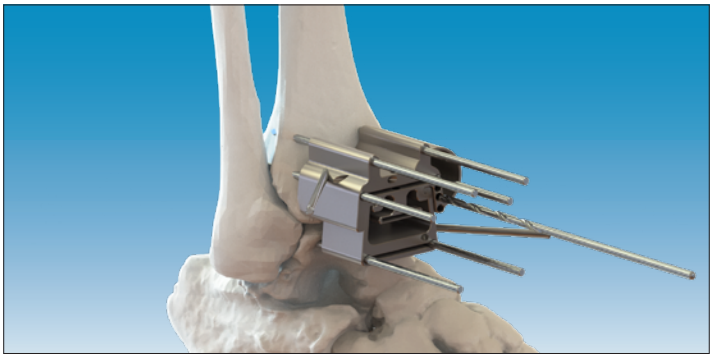


Figure 52. Tibial Stamping

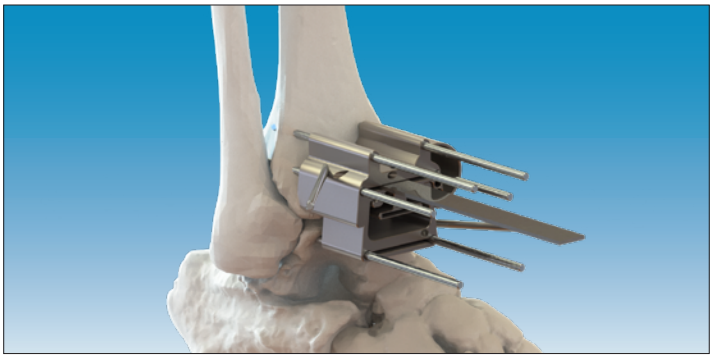


Figure 53. Tibial Resection

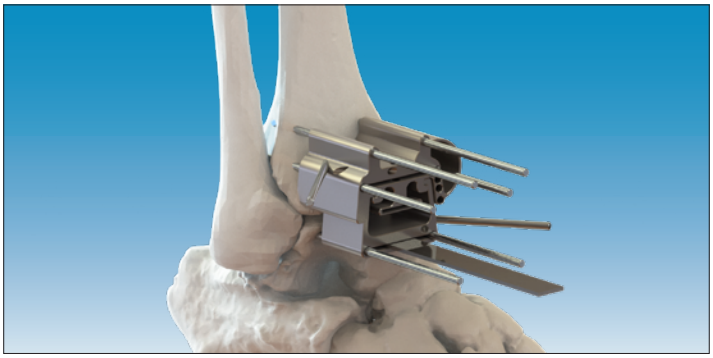


Figure 54. Flat-Cut Talar Resection

Figure 55. Resection Guide Removal

3. Initial Preparation

Tibial Cuts

The vertical tibial cut is created in a stamping fashion with the use of a 2.5mm drill.

Using a wire driver, insert and remove the 2.5mm drill through each of the medial holes in the Resection Guide starting with the most distal and proceeding proximally in sequence (**Figure 52**).

Complete the horizontal tibial cut through the cutting slot in the Tibial Resection Guide. A narrow graduated 1.27mm thick by 80mm long saw blade is used (**Figure 53**).

Note: *Care should be taken to avoid damage to posterior soft tissues.*

Talar Resection

Complete the horizontal talar cut through the cutting slot in the Flat-Cut Talar Resection Guide. A narrow graduated 1.27mm thick by 80mm long saw blade is used (**Figure 54**).

Note: *Care should be taken to avoid damage to posterior soft tissues.*

Remove all K-wires from the Resection Guides except for the two most proximal wires in the Tibial Resection Guide. Remove the Resection Guides (**Figure 55**).

Refine the prepared cuts as needed taking care to avoid any modification to the alignment planes. Then clear the joint space of the resected bone. The Hockey Stick may be used to access and remove any posterior bone fragments.

Note: *The Corner Chisel may be used to aid in connection of the vertical and horizontal tibial resections for bone removal. Upon reaching the posterior cortex, the estimated tibial implant size is indicated by the laser markings on the Corner Chisel.*

Figure 56. Gap Check for Flat-Cut Talus

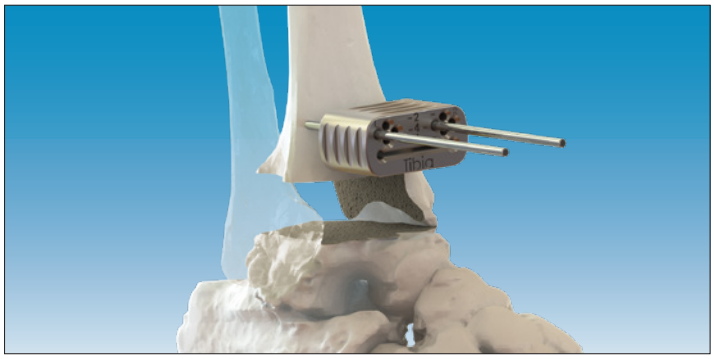


Figure 57. Tibial Recut Block

Figure 58. Alignment of Flat-Cut Talar Template

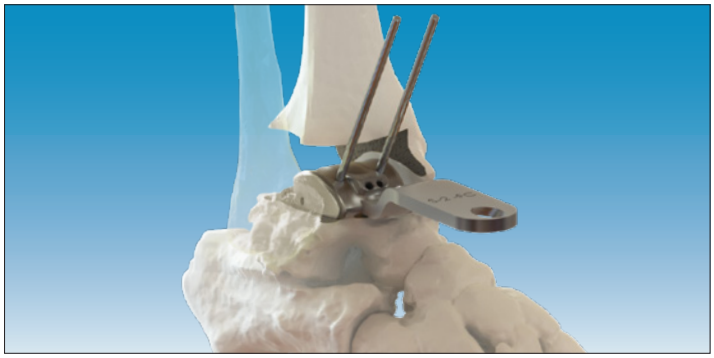


Figure 59. K-Wire Fixation of Flat-Cut Talar Template

4. Resection Verification and Optional Recut

Insert the Gap Sizer into the prepared joint line with the laser marking reading "FC" facing the resected bone surface (**Figure 56**).

Note: *The Gap Sizer is used for Standard and Flat Cut operations. When the laser marking reading "FC" faces the resected bone surface, the minimum construct thickness with the Flat-Cut Talus is simulated.*

The Alignment Rod may be inserted into the holes on the handle of the Gap Sizer to allow for fluoroscopic verifcation of perpendicularity of the tibial and talar resections to the tibial mechanical axis.

If the Gap Sizer indicates that the existing resections will not accommodate the minimum construct thickness, the Resection Cut Adjustment Block shall be used.

Note: *The Resection Cut Adjustment Block may be used for tibial and talar recuts as indicated by the block's markings. Ensure the block is oriented correctly depending on the bone being addressed.*

To recut the tibia, take care to orient the Resection Cut Adjustment Block so that the side marked "Tibia" is facing anteriorly and slide the block over the two K-wires left in the anterior tibia at the corresponding recut height (**Figure 57**).

Insert two K-wires into the cutting slot holes as malleolar protection. Use a 1.27mm graduated sawblade to perform the cut.

Remove the K-Wires and Resection Cut Adjustment Block once the recut is complete.

5. Final Talar Preparation

Flat-Cut Talar Component Positioning

Place the Flat-Cut Talar Template onto the resected talar surface to establish proper sizing. Initially orient the handle of the Template with the 2nd digit of the operative foot. Refine the rotation as needed to allow for alignment of the talar flanges with the handle (**Figure 58**).

Confirm placement with fluoroscopic verification with a direct lateral view indicated by a perfect circle view of the thru-hole on the side of the Template.

Full contact between the Template and the talar resection should be obtained prior to moving to the next step.

Figure 60. Placement of K-Wires and Lug Preparation

Figure 61. Impaction of Flat-Cut Talar Trial

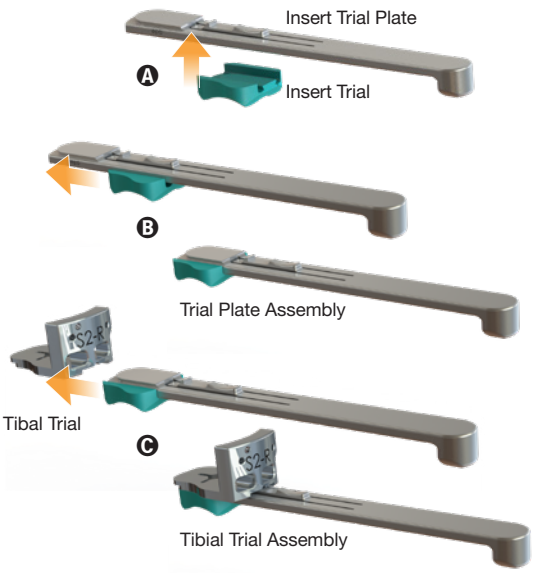


Figure 62. Tibial Trial Assembly

Ⓐ Insert Trial and Trial Plate
Ⓑ Assembly of Insert Trial and Trial Plate
Ⓒ Assembly of Tibial Trial to Trial Plate Assembly

Upon confirmation of appropriate alignment, fix the Flat-Cut Talar Template to the talus using two 2.5mm K-wires. Stop when the K-wire contacts cortical bone on the distal side of the talus to avoid penetration of the subtalar joint (**Figure 59**).

Verify placement with under fluoroscopy and remove the Template and K-wires.

Talar Pegs Preparation

Place two K-wires into the holes previously created through the Talar Template.

Tip: *Initial manual insertion of the K-wires is recommended to ensure proper alignment with the previously prepared holes.*

Using the 5mm Flat-Cut Peg Cannulated Drill, drill over the K-wires until the Drill's step meets the bone (**Figure 60**).

Remove both K-wires.

6. Trialing

Flat-Cut Talar Trial Positioning

Select the appropriate Flat-Cut Talar Trial, Implant Holder, and Talar Implant Impactor from the instrument tray.

Align the Flat-Cut Talar Trial with the prepared talar peg holes and impact it into place with the Talar Implant Impactor (**Figure 61**).

Confirm full seating of the trial with fluoroscopic verification.

Tibial Trial Assembly

Select the appropriate Insert Trial Plate and Insert Trial from the instrument tray, ensuring size and side are correct (**Figure 62A**).

Note: *The Insert Trial size must be the same as the selected Talar Implant.*

Slide the Insert Trial Plate over the Insert Trial until the two components are clipped together (**Figure 62B**).

Select the appropriate Tibial Trial from the instrument set, ensuring size and side are correct.

Note: *The Tibial Implant size must be the same size or one size over the selected Talar Implant.*

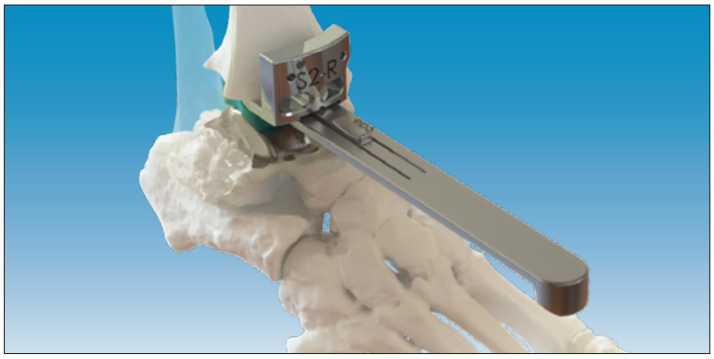


Figure 63. Alignment of Tibial Trial Assembly

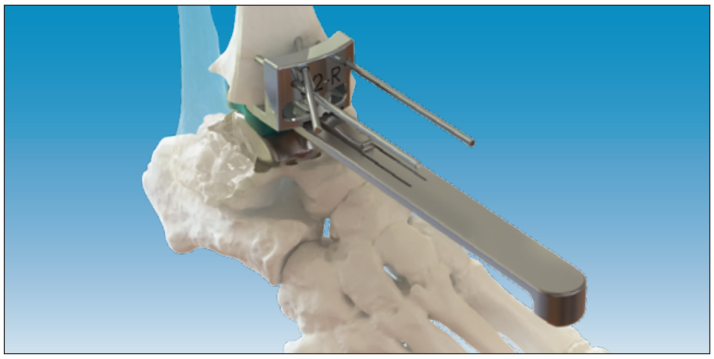


Figure 64. K-Wire Fixation of Tibial Trial Assembly

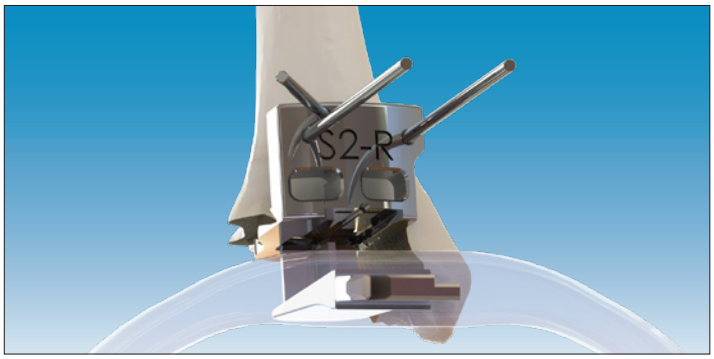


Figure 65. Alignment of Tibial Stem Shaper

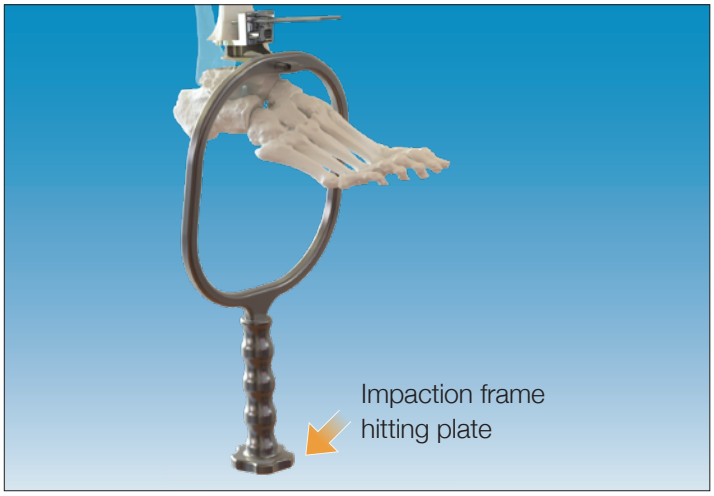


Figure 66. Impaction of Tibial Stem Shaper

Slide the Insert Trial Assembly into the Tibial Trial until the two components are clipped together (**Figure 62C**).

Tibial Trial Positioning

Insert the Tibial Trial Assembly into the prepared joint space and trial for fit and laxity. Mobilize the ankle to obtain desired positioning of the assembly over the Talar Trial Implant (**Figure 63**).

If increased construct height or reduced laxity is required, increase the Insert Trial thickness until the construct provides satisfactory results.

Fix the Tibial Trial Assembly to the tibia using two parallel and one oblique 2.5mm K-wires (**Figure 64**).

7. Tibial Stem Preparation

Remove the Insert Trial and Insert Trial Plate from the Tibial Trial Assembly while leaving the Tibial Trial Implant in place on the tibia. Remove the Talar Trial Implant from the talus.

Thread the Handle into the Impaction Frame until in full contact with the Frame. Assemble the Tibial Stem Shaper to the Impaction Frame.

Slide the assembly into the prepared joint space while aligning the shaper with the Tibial Trial Implant's cross-shaped socket (**Figure 65**).

Prepare the tibial stem by striking the Impaction Frame Hitting Plate with an axial force to drive the Tibial Stem Shaper into the tibia until complete contact with the Tibial Trial Implant is obtained (**Figure 66**).

Remove the Impaction Frame and the Tibial Stem Shaper.

Remove the oblique K-wire from the tibia and slide the Tibial Trial Implant out of the joint space while leaving the two parallel K-wires in place.

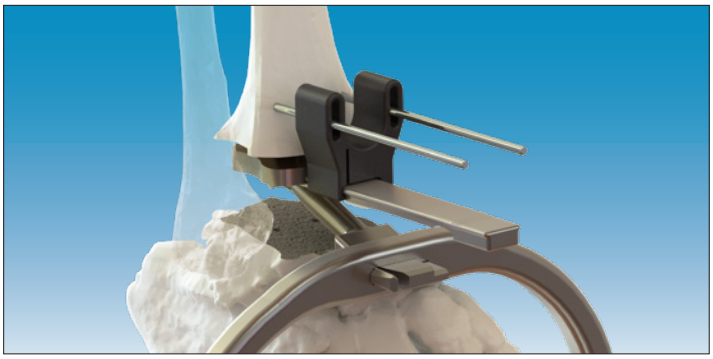


Figure 67. Assembly of Impaction Frame

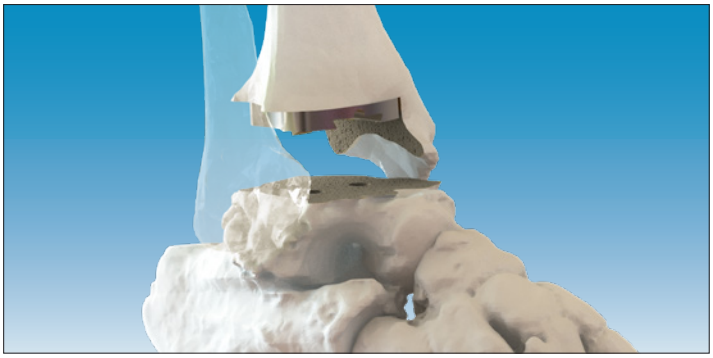


Figure 68. Implanted Tibial Component

Figure 69. Inserted Articular Surface Protector

Figure 70. Flat-Cut Talar Implant Insertion

8. Implantation

Final Tibial Implant Insertion

Obtain the appropriate Final Tibial Implant and assemble it to the Tibial Implant Holder.

Assemble the Tibial Implant Guide to the Tibial Implant Holder. Verify the Tibial Implant Guide's correct orientation by referencing the side-specific laser markings on the Guide.

Slide the Tibial Implant Guide Assembly over the parallel K-wires until complete contact with the anterior wall of the tibia is achieved.

Assemble the Impactor Tip to the Impaction Frame. Slide the Impactor Tip into the groove on the Tibial Implant Holder until it is nested with the impaction socket on the handle (**Figure 67**).

Strike the Impaction Frame Hitting Plate with an axial force to insert the Tibial Implant into the tibia until fully seated.

Note: *Take care to verify complete insertion of the Tibial Implant and full contact between the Tibial Tray and the tibia (**Figure 68**).*

Remove all instrumentation and K-wires from the tibia while leaving the Tibial Implant in place.

Final Talar Implant Positioning and Insertion

Select the appropriately sized Articular Surface Protector (Sizes 2-3 or 4-6) and insert it into the dovetail groove of the Tibial Implant with hole located anteriorly (**Figure 69**).

Hold the final Talar Implant with the Implant Holder and align it with the prepared talar peg holes.

Insert the Final Talar Implant by striking the end of the Talar Implant Impactor until complete contact is achieved between the Implant and talus (**Figure 70**).

Remove the Articular Surface Protector from the Tibial Implant using the Hockey Stick to engage the anterior hole.

Note: *Take care to prevent damage or scratches to the Talar Implant's surface during implantation and impaction.*

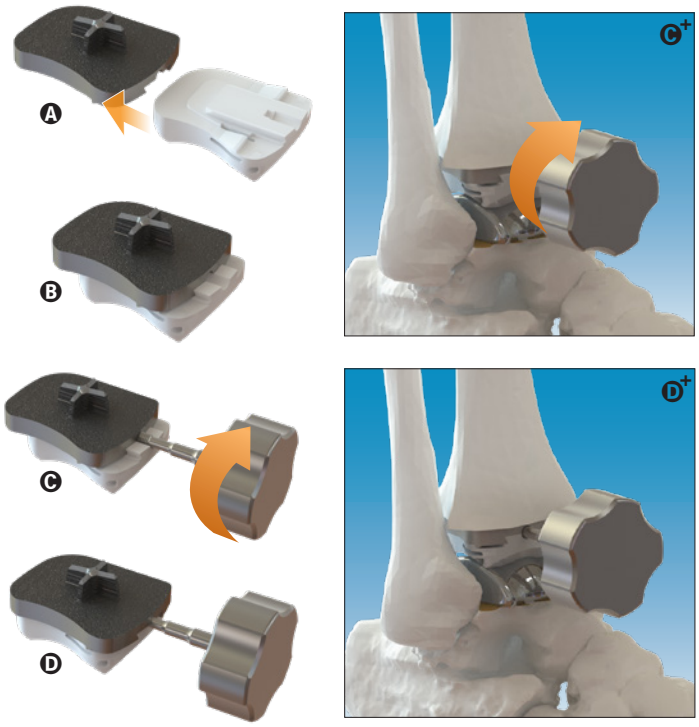


Figure 71. Tibial Insert Placement

Ⓐ Tibial Implant and Insert
Ⓑ Manual Assembly
Ⓒ Addition of Scroll Wheel (+ in-situ)
Ⓓ Final Seating of Insert (+ in-situ)

Figure 72. Final Flat-Cut Talus Construct

Final Insert Assembly

Align the final Tibial Insert with the anterior portion of the implanted Tibial Implant (**Figure 71A**). Initiate insert placement by manually sliding it into the Tibial Implant's grooves until contacting the dovetail locking feature (**Figure 71B**).

Assemble the Scroll Wheel to the Tibial Implant and Tibial Insert assembly and turn the Scroll Wheel clockwise to initiate final seating of the Insert (**Figures 71C & 71C+**).

Continue turning the Scroll Wheel clockwise until the Tibial Insert is fully engaged with the Tibial Implant and the Wheel is unable to advance any further (**Figures 71D & 71D+**).

Note: *When pairing a Tibial Insert with a Tibial Implant that is one size larger (ex. Size 3 Tibia with Size 2 Talus and Insert), the final Insert location will be recessed relative to the anterior aspect of the Implant. Take care to confirm the Insert is fully engaged and locked in place.*

Remove the Scroll Wheel by turning counterclockwise.

Note: *Take care to prevent damage or scratches to the polished surface of the Talar Implant and articular surface of the Tibial Insert during implantation.*

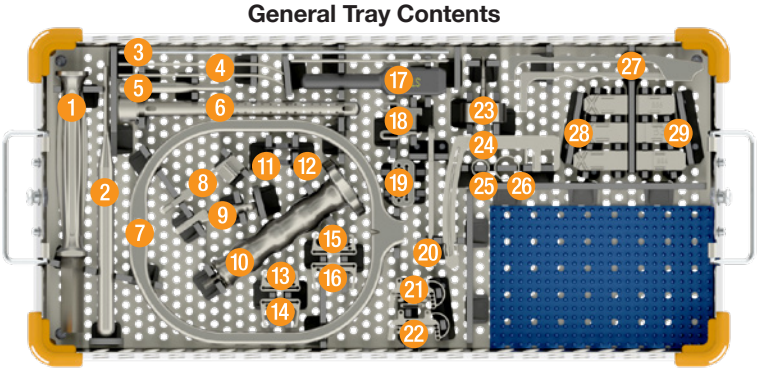
Final Verification and Closure

Mobilize the ankle and confirm complete implant seating with fluoroscopic verification (**Figure 72**).

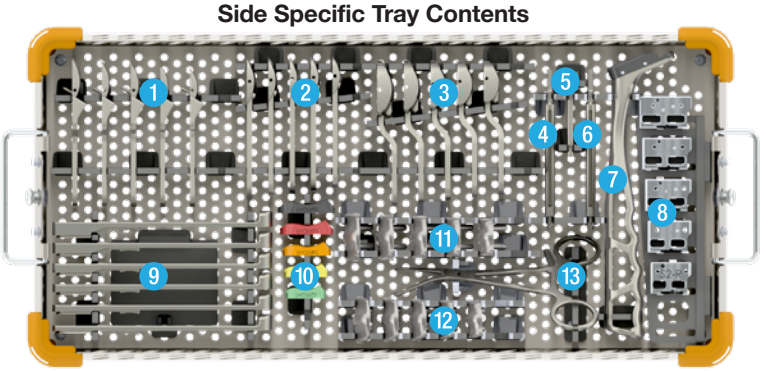
Close the surgical site per surgeon preference.

Instrumentation

General Tray Contents



Side Specific Tray Contents



General Tray Contents

1. Corner Chisel.....M05 01241
2. Hockey Stick.....M05 01251
3. Tibial Axis.....M05 00911
4. Insert Extractor (x2).....M05 01161
5. Pin Pusher.....M05 00971
6. K-Wire Storage Tube (x2).....G01 40021
7. Impaction Frame.....M05 00771
8. Tibial Stem Shaper.....M05 00801
9. Tibial Implant Impactor Tip.....M05 00761
10. Impaction Frame Handle.....M05 00791
11. Articular Surface Protector (Sizes 2-3).....M05 01301
12. Articular Surface Protector (Sizes 4-6).....M05 01311
13. Std Talar Resection Guide (Sizes 2-3).....M05 01191
14. Flat-Cut Talar Resection Guide (Sizes 2-3).....M05 01211
15. Std Talar Resection Guide (Sizes 4-6).....M05 01201
16. Flat-Cut Talar Resection Guide (Sizes 4-6).....M05 01221
17. Gap Sizer.....M05 00961
18. Tibial Implant Guide.....M05 00731
19. Recut Block.....M05 00881
20. Tibial Implant Holder.....M05 00721
21. Reusable Resection Guide (Sizes 2-3).....M05 00951
22. Reusable Resection Guide (Sizes 4-6).....M05 01181
23. Scroll Wheel.....M05 00811
24. Visualization Bow.....M05 00891
26. Control Cylinder for Standard Talus.....M05 00901
25. Control Cylinder for Flat-Cut Talus.....M05 01171
27. Pin Puller*.....D11288M
28. Resection Guides for Tibial PSI
    A12 – M05 00821, A34 – M05 00831, A56 – M05 00841
29. Resection Guides for Talar PSI
    B12 – M05 00851, B34 – M05 00861, B56 – M05 00871

Side Specific Tray Contents

1. Talar Chamfer Resection Guides

Size 2	M05 00991	Size 5	M05 01021
Size 3	M05 01001	Size 6	M05 01031
Size 4	M05 01011		

2. Standard Talar Templates

Size 2	M05 01051	Size 5	M05 01081
Size 3	M05 01061	Size 6	M05 01091
Size 4	M05 01071		

3. Flat-Cut Talar Templates

Size 2	M05 01111	Size 5	M05 01141
Size 3	M05 01121	Size 6	M05 01151
Size 4	M05 01131		

Side Specific Tray Contents Continued...

4. Cannulated Peg Drill (for Standard Talus).....M05 00661
5. Anterior Chamfer Reamer.....M05 00701
6. Cannulated Peg Drill (for Flat-Cut Talus).....M05 00671
7. Talar Implant Impactor.....M05 00751
8. Tibial Trials

Right:		Left:	
Size 2	M05 00022	Size 2	M05 00082
Size 3	M05 00032	Size 3	M05 00092
Size 4	M05 00042	Size 4	M05 00102
Size 5	M05 00052	Size 5	M05 00112
Size 6	M05 00062	Size 6	M05 00122

9. Insert Trial Plates

5mm	M05 00251	8mm	M05 00281
6mm	M05 00261	9mm	M05 00291
7mm	M05 00271	11mm	M05 01261

10. Insert Trials

Right:		Left:	
Size 2	M05 00141	Size 2	M05 00201
Size 3	M05 00151	Size 3	M05 00211
Size 4	M05 00161	Size 4	M05 00221
Size 5	M05 00171	Size 5	M05 00231
Size 6	M05 00181	Size 6	M05 00241

11. Flat-Cut Talar Trials

Right:		Left:	
Size 2	M05 00431	Size 2	M05 00491
Size 3	M05 00441	Size 3	M05 00501
Size 4	M05 00451	Size 4	M05 00511
Size 5	M05 00461	Size 5	M05 00521
Size 6	M05 00471	Size 6	M05 00531

12. Standard Talar Trials

Right:		Left:	
Size 2	M05 00311	Size 2	M05 00371
Size 3	M05 00321	Size 3	M05 00381
Size 4	M05 00331	Size 4	M05 00391
Size 5	M05 00341	Size 5	M05 00401
Size 6	M05 00351	Size 6	M05 00411

13. Implant and Trial Holder.....M05 00741

Drills and K-Wires

- 2.5x70mm K-wire.....K10 NS257
- 2.5x100mm K-wire.....K10 NS251
- 2.5mm Tibial Drill.....M05 00711
- 2.5x100mm Olive Wire.....M05 01231

*Manufactured by: Oury Guye & Fils, 31 rue Malaingre, 52800 Nogent - France. +33 3 25 31 81 04

General Information

The QUANTUM® Total Ankle System is a fixed-bearing semi-constrained ankle prosthesis comprised of two (2) components which are available in different sizes and configurations:

- A tibial component composed of a titanium (TA6V) metallic tibial tray implant fixed to a polymer (UHMWPE) insert
- A cobalt chrome (CoCr) metallic talar implant reproducing the talus dome anatomy.

Before surgery, the surgeon should utilize the provided implant sizing templates to identify the appropriate implant sizes for use during surgery.

Preoperative planning for the QUANTUM Total Ankle System is completed using three standard weight-bearing radiological views:

- Anterior view
- Anterior view with 30° internal rotation to expose the tibiofibular joint space
- Direct lateral view

Examination of the healthy side should be used for comparison.

Key planning elements defined from the anterior view:

- Implant size that does not impinge on the lateral malleolus
- Ideal joint line level that accounts for articular wear

Note: *Comparative images are often necessary to assess the prosthetic joint line at the theoretical anatomic joint line. The thickness of the tibial resection is governed by this determination.*

Key planning elements defined from the lateral view:

- Confirmation of implant size
- Evaluation of anterior osteophytic margin and assessment of the proposed bone resection necessary to expose the roof of the pilon
- Evaluation of the talar dome morphology, particularly the degree of convexity
- Evaluation of talar positioning, which may be centered or retroplaced beneath the pilon

Note: *The tibial component size is always the same or one size larger than the talar component.*

Note: *The polyethylene insert is always the same size as the talar component.*

Indications / Contraindications

INDICATIONS:

The QUANTUM total ankle prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Note: *In the United States, the ankle prosthesis is intended for cement use only.*

CONTRAINDICATIONS:

The QUANTUM Total Ankle Prosthesis is contraindicated for the following conditions:

- Sepsis, active / prior deep infection in ankle joint or adjacent bones, fever and/or local inflammation
- Avascular necrosis of the talus / tibia
- Osteoporosis / osteopenia
- Poor skin coverage / soft-tissue quality around the ankle joint that would make the procedure unjustifiable
- Inadequate or insufficient quality of bone stock, Important joint laxity, or tendon dysfunction
- Neuromuscular or mental disorders which might jeopardize fixation and post-operative care
- Neurobiological diseases
- Non-functional lower limb muscle / weakness
- Skeletal immaturity
- Known allergy to one of the materials
- Pregnancy / breast-feeding woman

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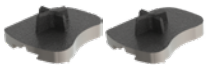
Ordering Information

QUANTUM® Tibial Implants



STANDARD

PART NUMBER	DESCRIPTION
M50 ST120	Tibial Implant, Standard, 2R
M50 ST130	Tibial Implant, Standard, 3R
M50 ST140	Tibial Implant, Standard, 4R
M50 ST150	Tibial Implant, Standard, 5R
M50 ST160	Tibial Implant, Standard, 6R
M50 ST220	Tibial Implant, Standard, 2L
M50 ST230	Tibial Implant, Standard, 3L
M50 ST240	Tibial Implant, Standard, 4L
M50 ST250	Tibial Implant, Standard, 5L
M50 ST260	Tibial Implant, Standard, 6L

LONG

PART NUMBER	DESCRIPTION
M50 ST121	Tibial Implant, Long, 2R
M50 ST131	Tibial Implant, Long, 3R
M50 ST141	Tibial Implant, Long, 4R
M50 ST151	Tibial Implant, Long, 5R
M50 ST161	Tibial Implant, Long, 6R
M50 ST221	Tibial Implant, Long, 2L
M50 ST231	Tibial Implant, Long, 3L
M50 ST241	Tibial Implant, Long, 4L
M50 ST251	Tibial Implant, Long, 5L
M50 ST261	Tibial Implant, Long, 6L

QUANTUM® Talar Implants

STANDARD

PART NUMBER	DESCRIPTION
M50 SC132	Talar Implant, Standard, 2R
M50 SC133	Talar Implant, Standard, 3R
M50 SC134	Talar Implant, Standard, 4R
M50 SC135	Talar Implant, Standard, 5R
M50 SC136	Talar Implant, Standard, 6R
M50 SC232	Talar Implant, Standard, 2L
M50 SC233	Talar Implant, Standard, 3L
M50 SC234	Talar Implant, Standard, 4L
M50 SC235	Talar Implant, Standard, 5L
M50 SC236	Talar Implant, Standard, 6L

FLAT-CUT

PART NUMBER	DESCRIPTION
M50 SC142	Talar Implant, Flat-Cut, 2R
M50 SC143	Talar Implant, Flat-Cut, 3R
M50 SC144	Talar Implant, Flat-Cut, 4R
M50 SC145	Talar Implant, Flat-Cut, 5R
M50 SC146	Talar Implant, Flat-Cut, 6R
M50 SC242	Talar Implant, Flat-Cut, 2L
M50 SC243	Talar Implant, Flat-Cut, 3L
M50 SC244	Talar Implant, Flat-Cut, 4L
M50 SC245	Talar Implant, Flat-Cut, 5L
M50 SC246	Talar Implant, Flat-Cut, 6L

QUANTUM® Tibial Fixed Inserts

SIZE 2

PART NUMBER	DESCRIPTION
M50 SU125	Fixed Insert, 2R, 5mm
M50 SU126	Fixed Insert, 2R, 6mm
M50 SU127	Fixed Insert, 2R, 7mm
M50 SU128	Fixed Insert, 2R, 8mm
M50 SU129	Fixed Insert, 2R, 9mm
M50 SU121	Fixed Insert, 2R, 11mm
M50 SU122	Fixed Insert, 2R, 13mm
M50 SU123	Fixed Insert, 2R, 15mm
M50 SU225	Fixed Insert, 2L, 5mm
M50 SU226	Fixed Insert, 2L, 6mm
M50 SU227	Fixed Insert, 2L, 7mm
M50 SU228	Fixed Insert, 2L, 8mm
M50 SU229	Fixed Insert, 2L, 9mm
M50 SU221	Fixed Insert, 2L, 11mm
M50 SU222	Fixed Insert, 2L, 13mm
M50 SU223	Fixed Insert, 2L, 15mm

SIZE 3

PART NUMBER	DESCRIPTION
M50 SU135	Fixed Insert, 3R, 5mm
M50 SU136	Fixed Insert, 3R, 6mm
M50 SU137	Fixed Insert, 3R, 7mm
M50 SU138	Fixed Insert, 3R, 8mm

SIZE 3 Continued

PART NUMBER	DESCRIPTION
M50 SU139	Fixed Insert, 3R, 9mm
M50 SU131	Fixed Insert, 3R, 11mm
M50 SU132	Fixed Insert, 3R, 13mm
M50 SU133	Fixed Insert, 3R, 15mm
M50 SU235	Fixed Insert, 3L, 5mm
M50 SU236	Fixed Insert, 3L, 6mm
M50 SU237	Fixed Insert, 3L, 7mm
M50 SU238	Fixed Insert, 3L, 8mm
M50 SU239	Fixed Insert, 3L, 9mm
M50 SU231	Fixed Insert, 3L, 11mm
M50 SU232	Fixed Insert, 3L, 13mm
M50 SU233	Fixed Insert, 3L, 15mm

SIZE 4

PART NUMBER	DESCRIPTION
M50 SU145	Fixed Insert, 4R, 5mm
M50 SU146	Fixed Insert, 4R, 6mm
M50 SU147	Fixed Insert, 4R, 7mm
M50 SU148	Fixed Insert, 4R, 8mm
M50 SU149	Fixed Insert, 4R, 9mm
M50 SU141	Fixed Insert, 4R, 11mm
M50 SU142	Fixed Insert, 4R, 13mm
M50 SU143	Fixed Insert, 4R, 15mm

SIZE 4 Continued

PART NUMBER	DESCRIPTION
M50 SU245	Fixed Insert, 4L, 5mm
M50 SU246	Fixed Insert, 4L, 6mm
M50 SU247	Fixed Insert, 4L, 7mm
M50 SU248	Fixed Insert, 4L, 8mm
M50 SU249	Fixed Insert, 4L, 9mm
M50 SU241	Fixed Insert, 4L, 11mm
M50 SU242	Fixed Insert, 4L, 13mm
M50 SU243	Fixed Insert, 4L, 15mm

SIZE 5

PART NUMBER	DESCRIPTION
M50 SU155	Fixed Insert, 5R, 5mm
M50 SU156	Fixed Insert, 5R, 6mm
M50 SU157	Fixed Insert, 5R, 7mm
M50 SU158	Fixed Insert, 5R, 8mm
M50 SU159	Fixed Insert, 5R, 9mm
M50 SU151	Fixed Insert, 5R, 11mm
M50 SU152	Fixed Insert, 5R, 13mm
M50 SU153	Fixed Insert, 5R, 15mm
M50 SU255	Fixed Insert, 5L, 5mm
M50 SU256	Fixed Insert, 5L, 6mm
M50 SU257	Fixed Insert, 5L, 7mm
M50 SU258	Fixed Insert, 5L, 8mm

SIZE 5 Continued

PART NUMBER	DESCRIPTION
M50 SU259	Fixed Insert, 5L, 9mm
M50 SU251	Fixed Insert, 5L, 11mm
M50 SU252	Fixed Insert, 5L, 13mm
M50 SU253	Fixed Insert, 5L, 15mm

SIZE 6

PART NUMBER	DESCRIPTION
M50 SU165	Fixed Insert, 6R, 5mm
M50 SU166	Fixed Insert, 6R, 6mm
M50 SU167	Fixed Insert, 6R, 7mm
M50 SU168	Fixed Insert, 6R, 8mm
M50 SU169	Fixed Insert, 6R, 9mm
M50 SU161	Fixed Insert, 6R, 11mm
M50 SU162	Fixed Insert, 6R, 13mm
M50 SU163	Fixed Insert, 6R, 15mm
M50 SU265	Fixed Insert, 6L, 5mm
M50 SU266	Fixed Insert, 6L, 6mm
M50 SU267	Fixed Insert, 6L, 7mm
M50 SU268	Fixed Insert, 6L, 8mm
M50 SU269	Fixed Insert, 6L, 9mm
M50 SU261	Fixed Insert, 6L, 11mm
M50 SU262	Fixed Insert, 6L, 13mm
M50 SU263	Fixed Insert, 6L, 15mm

REGULATORY INFORMATION
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RECOMMENDATION
It is recommended to carefully read the instructions for use available in the package insert.

DEVICES
- EC Classification (EC Directive MDD 93/42/EC):
- Implant: CE Class IIb – CE2797
- Instruments connected to a power driver: Class IIa – CE2797
- Trial implants: Class IIa – CE2797
- EC Regulation 2017/745/EC:
- Invasive reusable surgical instruments: Class Ir - CE2797
- Other instruments: Class I - CE

REIMBURSEMENT
Reimbursement may vary from countries to countries. Check with local authorities.

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