

# Quantum<sup>®</sup>

Total Ankle System  
with Reusable Instruments



SURGICAL TECHNIQUE

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# Quantum® Total Ankle System

## System Introduction

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



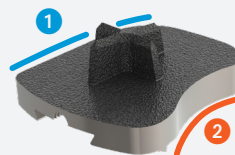
### Intuitive Instrumentation:

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

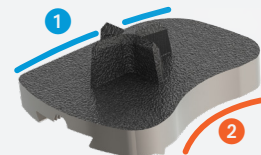
### Tibial Components:

- » 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

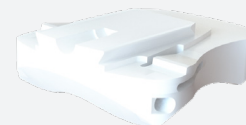


Long Tibial Implant

### 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

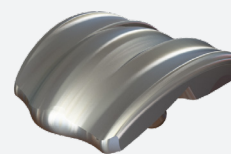


Tibial Insert

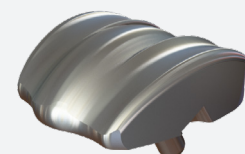
### Talar Components:

- » 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

# Advanced Cutting Guide

## Reusable Advanced Cutting Guide Introduction

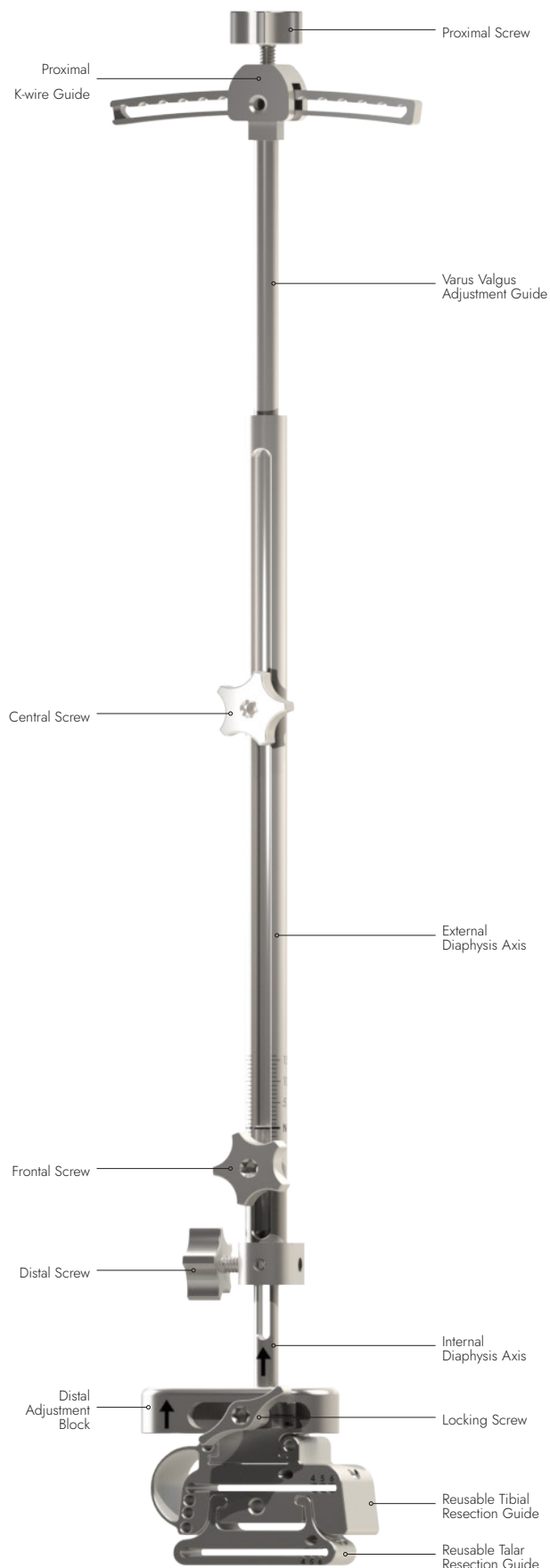
The Quantum® Reusable Advanced Cutting Guide is used to align and perform the horizontal tibial and talar resections and the vertical stamping for the medial malleolus.

Multiple adjustment tools are incorporated to control the resection height, AP slope, Varus/Valgus alignment, rotation, and ML position before performing the cuts.

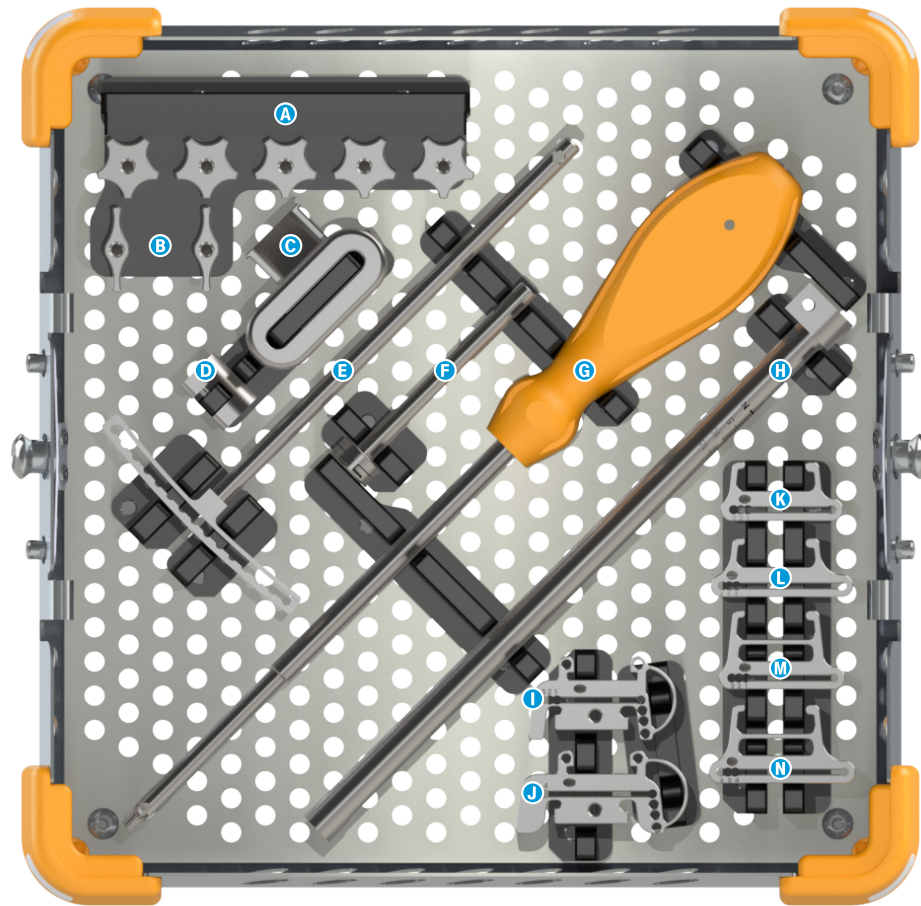
**Note:** *The resections are coupled when using the Advanced Cutting Guide, allowing for the minimal resection level necessary for implantation of the Quantum® implant construct.*

Two sets of Tibial and Talar Resection Guides are provided with the system: Sizes 2-3, and Sizes 4-6.

Each Tibial and Talar Resection Guide features lateral holes corresponding to each size within their respective size ranges. Manually place a 2.5mm K-wire into the proximal medial hole and appropriate lateral hole, and confirm sizing under fluoroscopy, prior to full insertion of the K-wires with power.



# Advanced Cutting Guide Instrument Tray



## Reusable Advanced Cutting Guide . . . . . M05 10015

DESCRIPTION	CATALOG NO.	QTY.
<b>A</b> Tibial Axis Locking Screw	M05 01351	5
<b>B</b> Distal Locking Screw	M05 01381	2
<b>C</b> Distal Adjustment Block	M05 01371	1
<b>D</b> Proximal K-wire Guide	M05 01321	1
<b>E</b> Varus Valgus Adjustment T	M05 01331	1
<b>F</b> Internal Diaphysis Axis	M05 01361	1
<b>G</b> Non-Cannulated T25 Screwdriver	G01 01641	1
<b>H</b> External Diaphysis Axis	M05 01341	1
<b>I</b> Reusable Tibial Resection Guide (Size 2-3)	M05 01421	1
<b>J</b> Reusable Tibial Resection Guide (Size 4-6)	M05 01431	1
<b>K</b> Reusable STD Talar Resection Guide (Size 2-3)	M05 01441	1
<b>L</b> Reusable STD Talar Resection Guide (Size 4-6)	M05 01451	1
<b>M</b> Reusable FC Talar Resection Guide (Size 2-3)	M05 01461	1
<b>N</b> Reusable FC Talar Resection Guide (Size 4-6)	M05 01471	1

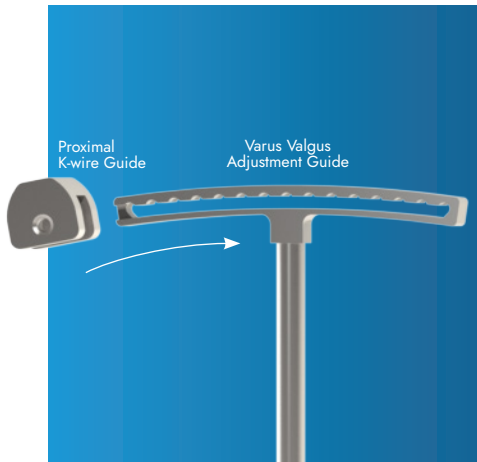


Figure 1

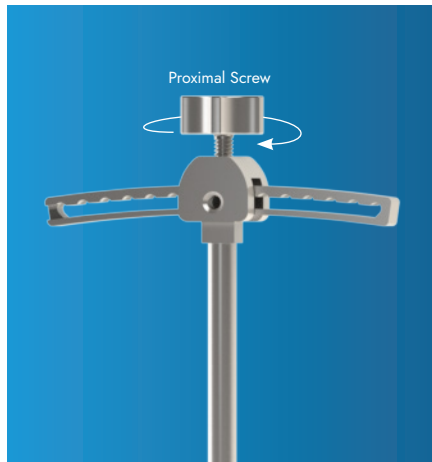


Figure 2

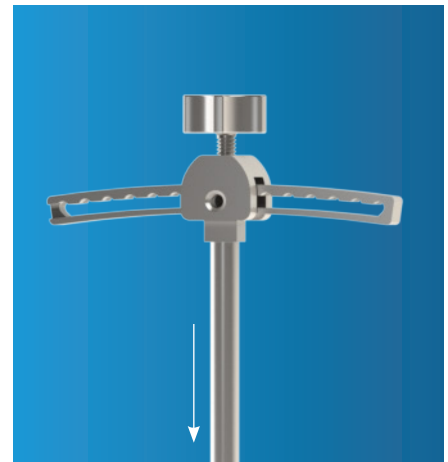


Figure 3

### Guide Assembly

Assemble the Proximal K-wire Guide onto the proximal aspect of the Varus Valgus Adjustment Guide (**Figure 1**) and secure in place with one of the provided Tibial Axis Locking Screws (Proximal Screw) (**Figure 2**). Then insert the Varus Valgus Adjustment Guide into the proximal aspect of the External Diaphysis Axis. Secure the Varus Valgus Adjustment Guide to the External Diaphysis Axis with one of the provided Tibial Axis Locking Screws (Central Screw) (**Figure 3**).



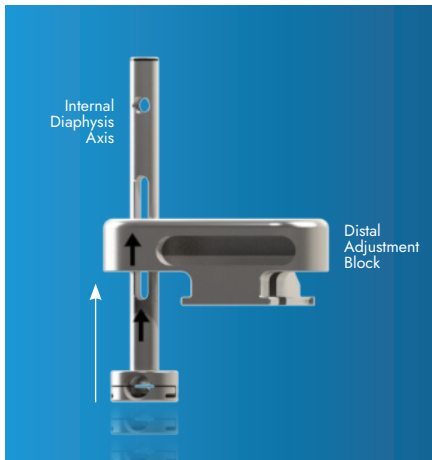


Figure 4

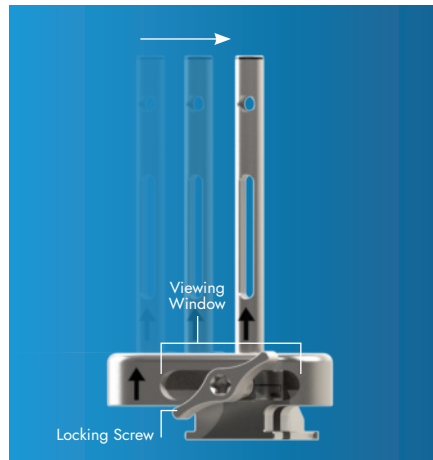


Figure 5

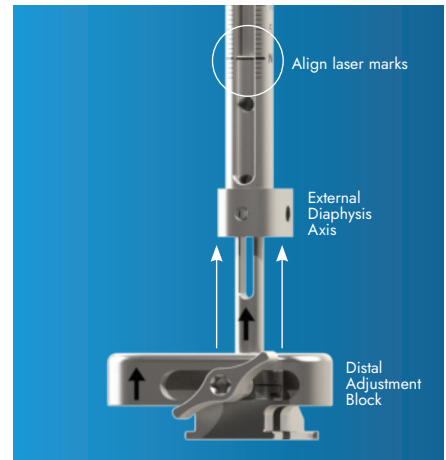


Figure 6

Insert the Internal Diaphysis Axis through the hole on the distal aspect of the Distal Adjustment Block, using the laser-marked arrows as guidance (Figure 4). Once fully inserted, slide the Internal Diaphysis Axis to the center of the viewing window and secure in place with one of the provided Distal Locking Screws (Locking Screw) (Figure 5).

Insert the protruding cylindrical portion of the Internal Diaphysis Axis into the distal aspect of the External Diaphysis Axis until the laser mark located at the proximal aspect of the Internal Diaphysis Axis is flush with the “N” laser mark on the External Diaphysis Axis (Figure 6). Secure in place with one of the provided Tibial Axis Locking Screws (Frontal Screw) to set the Guide at the nominal resection level (Figure 7A).

Assemble one of the two remaining Tibial Axis Locking Screws (Distal Screw) into the distal-lateral threaded hole on the External Diaphysis Axis to complete the Guide Assembly (Figure 7B).

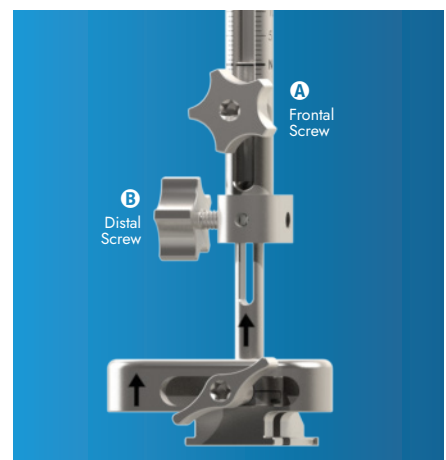


Figure 7

**Note:** To ensure stability of the Guide Assembly, all screws must be slightly tightened. At each subsequent step, specific Screws will be loosened to allow for the adjustment of alignment parameters and re-tightened to secure the new position.



Figure 8

### Surgical Approach

Perform a longitudinal anterior incision, lateral to the anterior tibialis. Identify and remove all osteophytes.

Remove the anterior margin of the distal tibia to expose the tibial plafond and provide a clear view of the talar dome.

Insert a 1.27mm saw blade into the tibio-talar joint line resting at the intersection of the apex of the talar dome and the tibial plafond (Figure 8).

**Important:** The location of this blade will serve as the reference point for the Reusable Advanced Cutting Guide. Proper placement is necessary.

**Note:** Saw blades are not provided with the system. A narrow graduated saw blade that is 1.27mm thick, approximately 13mm wide, and at least 80mm long is recommended for use.

### Positioning of the Guide

Slightly loosen the Proximal, Central, Distal and Frontal Screws, taking care to ensure that threads are still engaged to maintain the structural stability of the Guide.

Align the Guide's proximal hole with the anterior tibial tuberosity and place a 2.5mm K-wire through the Guide (Figure 9A).

Slide the Tibial Resection Guide corresponding with the desired implant size range onto the distal aspect of the jig. While taking care to orient the Resection Guide with the arch located medially extend the Alignment Guide until in contact with the saw blade at the ankle joint line (Figure 9B). Lock the Central Screw using the provided Screwdriver to maintain the course length of the jig assembly (Figure 9C).

**Note:** A residual malleolar distance of 10mm is represented by the outer edge of the medial arch. The final medial-lateral placement will be adjusted at a later step.

**Tip:** The Tibial Resection Guide is not locked to the jig until secured in place with K-wires. Take care to maintain control of the Guide and prevent an instrument drop.

Align the Guide parallel with the tibial mechanical axis. Confirm alignment under fluoroscopy and insert a 2.5mm K-wire through the most distal hole of the Guide's axis (located next to the Distal Screw) (Figure 9D). Remove the saw blade from the joint line.

**Note:** The Guide's Axis should be positioned at the center of the distal metaphysis.



Figure 9





Figure 10



Figure 11

The tibial resection plane should be horizontal to the anatomic axis to compensate for possible varus or valgus deformity. If adjustment of Varus/Valgus alignment is required, loosen the Proximal Screw and slide the Guide relative the pin placed in the tibial tuberosity (**Figure 10**). Lock the Proximal Screw once in the desired alignment.

If AP slope adjustment is necessary, loosen the Proximal and Distal Screws and translate the guide along the K-wires to achieve a neutral slope perpendicular to the tibial mechanical axis (**Figure 11**). Secure the adjustment by locking the Proximal and Distal Screws.

### Adjustment of Resection Height

If needed, the resection height can be adjusted to compensate for patient anatomy.

To make this adjustment, loosen the Frontal Screw and slide the distal portion of the Guide to the necessary level:

- » Increase tibial resection: Slide the distal portion of the Guide proximally from "N"
- » Reduce tibial resection: Slide the distal portion of the Guide distally from "N"

Once the desired resection level is achieved, tighten the Frontal Screw.

**Note:** The recommended nominal tibial resection of 9mm is indicated by the "N" on the Guide. This resection level corresponds to the height of the Tibial Implant with the thinnest (5mm) Tibial Insert.

### Adjustment of Mediolateral Position and Rotation

Correct medio-lateral positioning is achieved when K-wires placed in the medial and lateral holes in the Tibial Resection Guide's cutting slot are aligned axially with the angles formed by the medial and lateral malleoli and the tibial plafond.

**Note:** The medial arch on the Tibial Resection Guide represents a 10mm residual medial malleolar distance when aligned with the medial cortex (**Figure 12A**).

Rotation may be checked and adjusted by placing the Tibial Axis in the distal hole of the Tibial Resection Guide and aligning the axis with the bisecting axis of the two malleolar grooves (**Figure 12B**).

**Note:** Rotational adjustment of the Guide will impact the medio-lateral position. Both parameters should be evaluated together.

Upon confirmation of position and rotation of the guide, tighten the Locking Screw (**Figure 12C**).

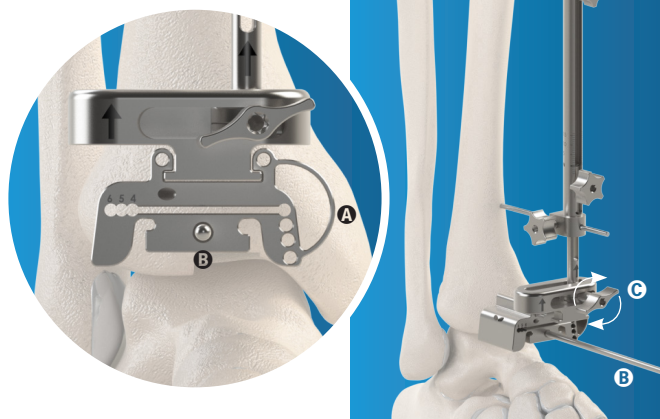


Figure 12

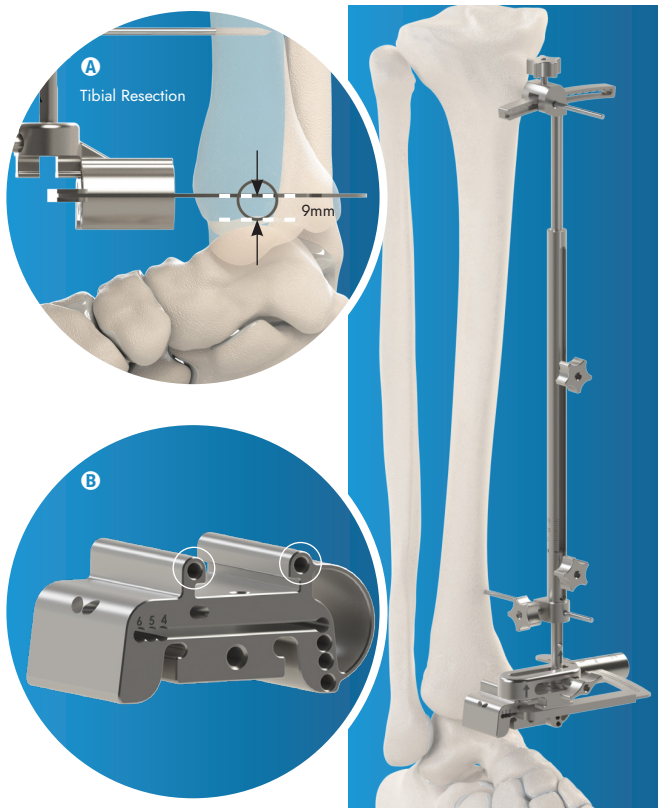


Figure 13

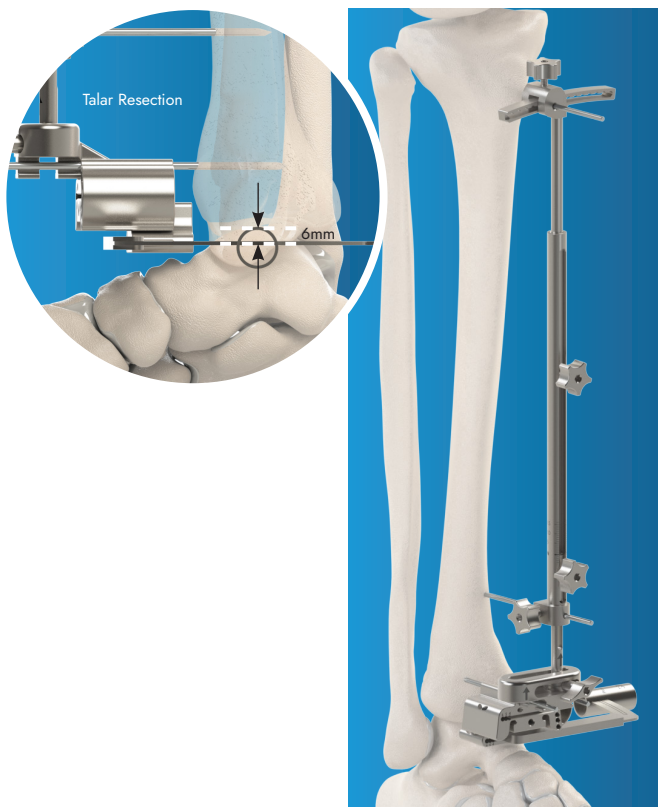


Figure 14

### Fluoroscopic Verification (Standard Talar Component Configuration Shown)

Insert the Visualization Bow into the cutting slot of the Tibial Resection Guide.

Depending on the desired talar component, slide the corresponding Control Cylinder onto the Visualization Bow with the “Up” inscription oriented proximally.

**Note:** The Visualization Bow may be inserted medially or laterally based on surgeon preference. Take care to ensure proper orientation of the Control Cylinder before proceeding to the next step.

The Visualization Bow corresponds with the cut trajectory while the distal portion of the Control Cylinder corresponds to the 9mm nominal tibial resection (Figure 13A).

**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 a lateral view.

Adjust the position of the Tibial Resection Guide as needed based on the anterior and lateral fluoroscopic views, by loosening and retightening the associated screws on the jig.

Once proper alignment has been obtained, secure the Tibial Resection Guide with two parallel 2.5mm K-wires located proximally in the Tibial Resection Guide (Figure 13B).

### Positioning of the Talar Resection Guide

Slide the corresponding Talar Resection Guide (based on sizing and desired component style) into the Tibial Resection Guide until in contact with the talar neck with the ankle in a neutral position.

Insert the Visualization Bow, with the appropriate Control Cylinder assembled from the previous step, into the cutting slot of the Talar Resection Guide.

**Note:** The Visualization Bow may be inserted medially or laterally based on surgeon preference. Take care to ensure proper orientation of the Control Cylinder before proceeding to the next step.

With the ankle in a neutral position, the Visualization Bow corresponds with the cut trajectory while the proximal portion of the Control Cylinder corresponds to the nominal talar resection (6mm for Standard and 11mm for Flat Cut) (Figure 14).

Confirm placement with fluoroscopic verification.

**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 a lateral view.

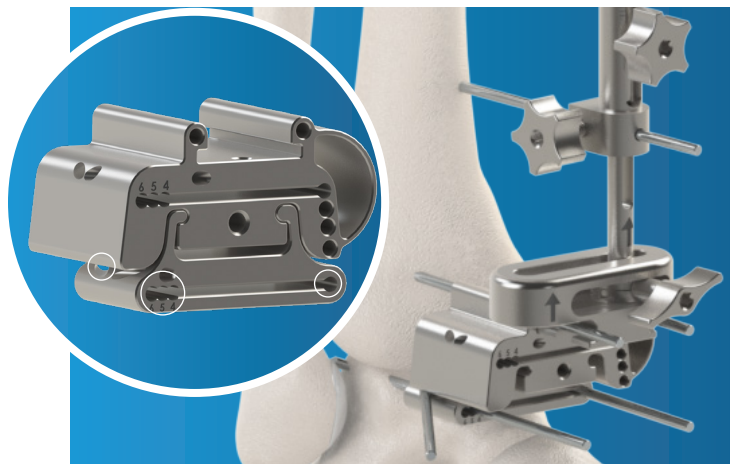


Figure 15

**Note:** If necessary, the talar resection height can be modified by loosening the Frontal Screw and adjusting the resection depth relative to the laser markings on the jig as detailed in the next section.

Once the cut trajectory and resection level are confirmed, secure the Talar Resection Guide in place with two parallel 2.5mm K-wires and a third oblique K-wire to lock the Guide in place (**Figure 15**).

**Note:** Three lateral K-wire holes are present that correspond to the three implant sizes compatible with the chosen Tibial and Talar Resection Guide grouping. Take care to place the lateral parallel K-wire in the most lateral hole that allows for secure fixation to the bone.

### Optional: Adjustment of Talar Resection Height

If needed, the talar resection height may be adjusted to compensate for patient anatomy.

**Important:** If the talar resection height requires adjustment, the talar cut will be performed before the tibial resection. Remove all K-wires from the Tibial Resection Guide, noting the indicated resection level on the anterior aspect of the jig.

To make this adjustment, loosen the Frontal Screw and slide the distal portion of the Guide to the necessary level:

- » Increase talar resection: Slide the distal portion of the Guide distally from "N"
- » Reduce talar resection: Slide the distal portion of the Guide proximally from "N"

Once the desired resection level is achieved, tighten the Frontal Screw.

Insert the Visualization Bow, with the appropriate Control Cylinder assembled from the previous step, into the cutting slot of the Talar Resection Guide.

**Note:** The Visualization Bow may be inserted medially or laterally based on surgeon preference. Take care to ensure proper orientation of the Control Cylinder before proceeding to the next step.

With the ankle in a neutral position, the Visualization Bow corresponds with the cut trajectory while the proximal portion of the Control Cylinder corresponds to the nominal talar resection (6mm for Standard and 11mm for Flat Cut).

Confirm placement with fluoroscopic verification.

**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 a lateral view.

Once the cut trajectory and resection level are confirmed, secure the Talar Resection Guide in place with two parallel 2.5mm K-wires and a third oblique K-wire to lock the Guide in place.

Complete the talar resection through the cutting slot in the Talar Resection Guide. A narrow graduated 1.27mm thick by 80mm long saw blade is used.

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

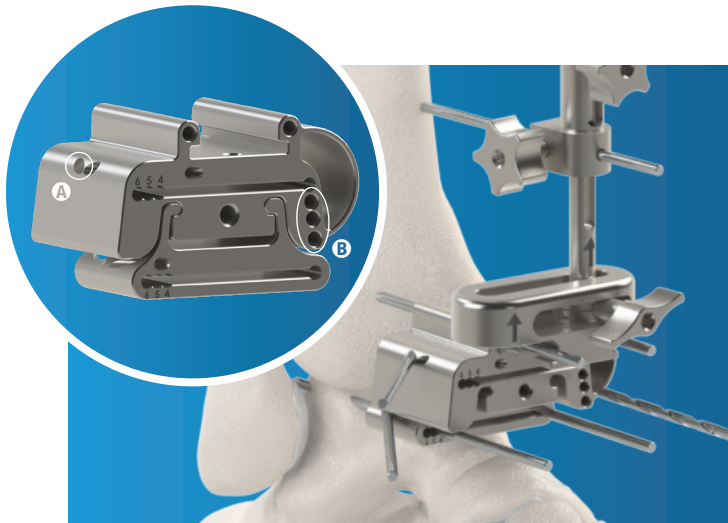


Figure 16

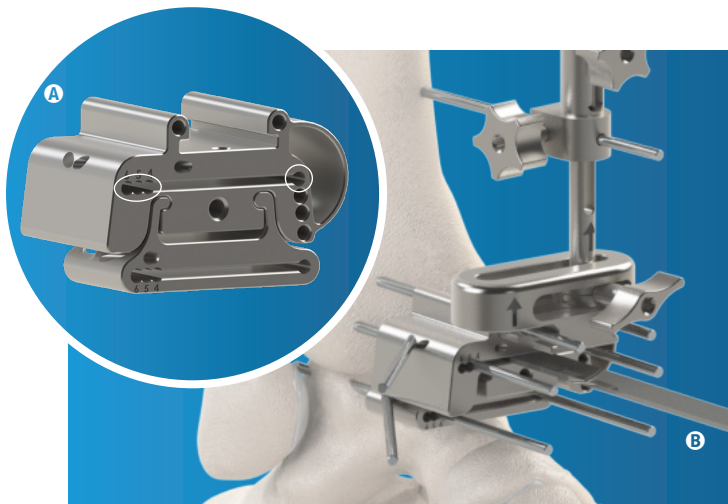


Figure 17

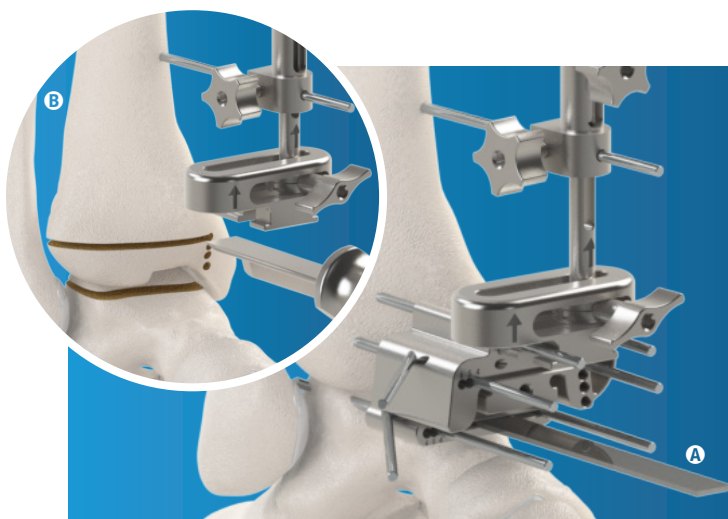


Figure 18

### Tibial Vertical Cut

**⚠ Important:** If the talar resection level was adjusted as detailed in the previous section, the tibial resection level needs to be reset to the original planned level. Loosen the Frontal Screw and set the resection level at the original location relative to the anterior aspect of the jig. Once the original position is achieved, replace the two parallel 2.5mm K-wires through the Tibial Resection Guide taking care to locate them in the previously created holes.

Insert a third 2.5mm K-wire into the oblique hole of the Tibial Resection Guide to lock the Guide in place (**Figure 16A**).

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, proceeding proximally in sequence, and stopping before preparing the most proximal hole (**Figure 16B**).

Insert two 2.5mm K-wires into the medial and lateral holes of the cutting slot once stamping is complete (**Figure 17A**).

### Tibial Horizontal Cut

Complete the horizontal tibial cut through the cutting slot in the Tibial Resection Guide (**Figure 17B**). A narrow graduated 1.27mm thick by 80mm long saw blade is used.

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

### Talar Resection

Complete the talar resection through the cutting slot in the Talar Resection Guide (**Figure 18A**). A narrow graduated 1.27mm thick by 80mm long saw blade is used.

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

Remove all K-wires from both Resection Guides.

Refine the prepared cuts as needed taking care to avoid any modification to the alignment planes. Then clear the joint space of the resection bones. 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 (**Figure 18B**). Upon reaching the posterior cortex, the estimated tibial implant size is indicated by the laser markings on the Corner Chisel.

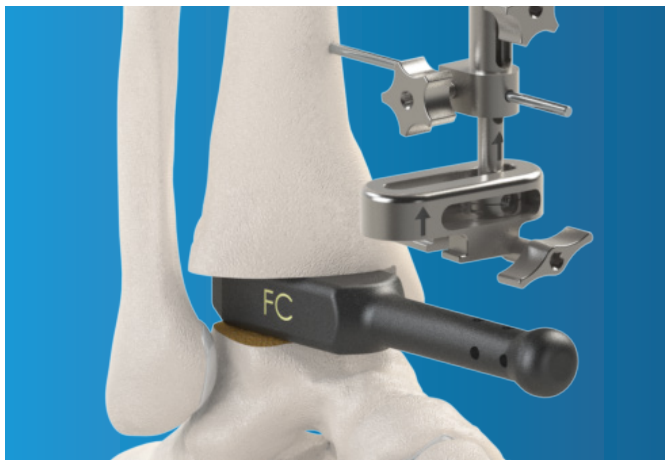


Figure 19

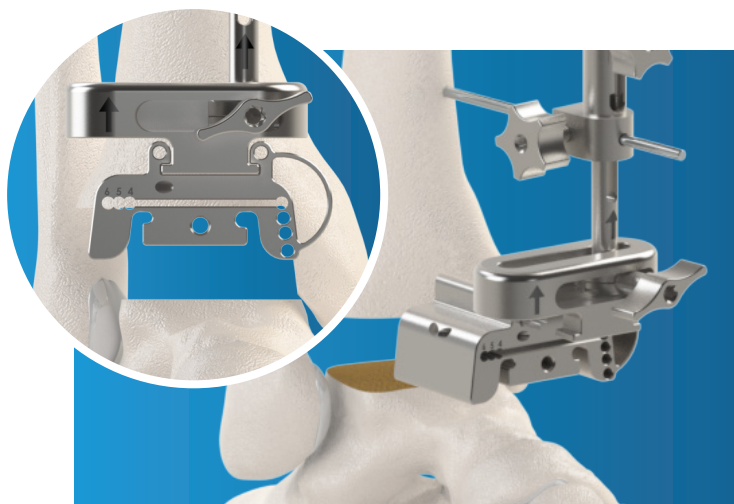


Figure 20

### Resection Verification and Optional Recut

Insert the Gap Sizer into the prepared joint line with the laser marking associated with the chosen Talar Implant style facing the resected bone surface (**Figure 19**).

- » For Chamfer: "STD" will be in contact with the bone
- » For Flat Cut: "FC" will be in contact with the bone

The Tibial Axis 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, a recut is necessary.

To perform a recut, place the Tibial Resection Guide onto the distal end of the jig and loosen the Frontal Screw. Slide the distal portion of the jig proximally until the desired resection level is achieved (**Figure 20**).

Tighten the Frontal Screw and secure the Tibial Resection Guide in place with K-wires. Perform the medial stamping and horizontal tibial cut as previously described.

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

Reinsert the Gap Stick into the prepared joint line to confirm adequate space has been achieved.

Upon confirmation, remove all K-wires from the Tibial Resection Guide and the Reusable Advanced Cutting Guide, and remove all components from the surgical field.

### Remaining Surgical Steps

Refer to the following pages for the remaining surgical steps, beginning with the Final Talar Preparation section for the appropriate style talar component.

## Standard Talar Technique

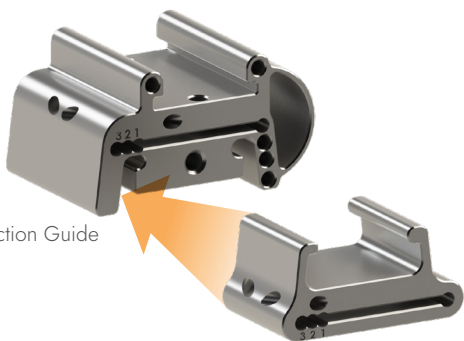


Figure 21.  
Tibial Resection Guide

Figure 22.  
Standard Talar Resection Guide



Figure 23. Assembled Resection Guides for Standard Talus

**Note:** The Advanced Cutting Guide may be utilized as detailed earlier in this document as an alternative to Steps 1 - 4 in this section. If the Advanced Cutting Guide is utilized for the case, please proceed to Step 5 on Page 18.

### 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 21 & 22).

Both parts are assembled over the patient's anatomy by sliding the talar cutting block into the tibial cutting block (Figure 23).

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 24).

**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 graduated saw blade into the joint space, then rest the base of the Tibial Resection Guide onto the blade to approximate the initial location of the tibial resection level through the cut slot. (Figure 25).

**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 24. Initial Placement of Tibial Guide



Figure 25. Insertion of Reference Saw Blade

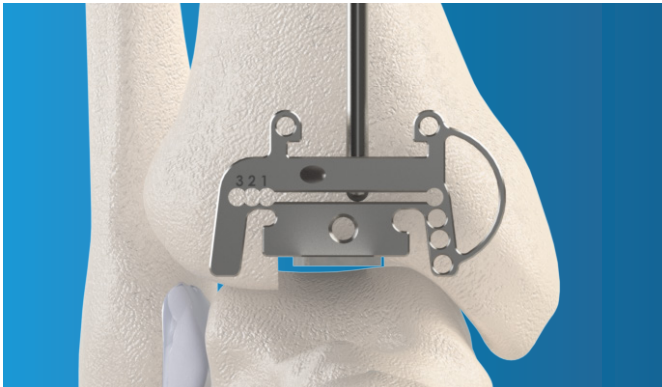


Figure 26. Tibial Axis Visualization and Alignment

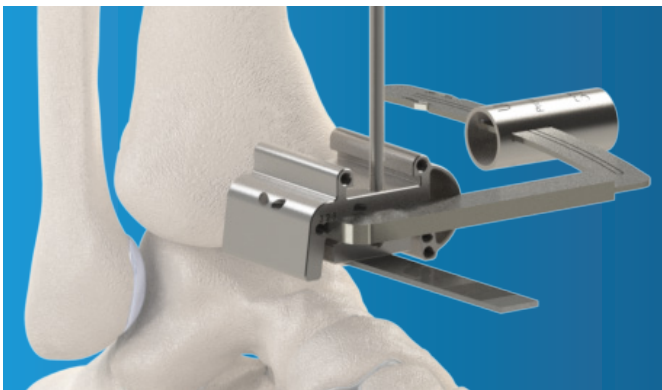


Figure 27. Assembly of Visualization Bow

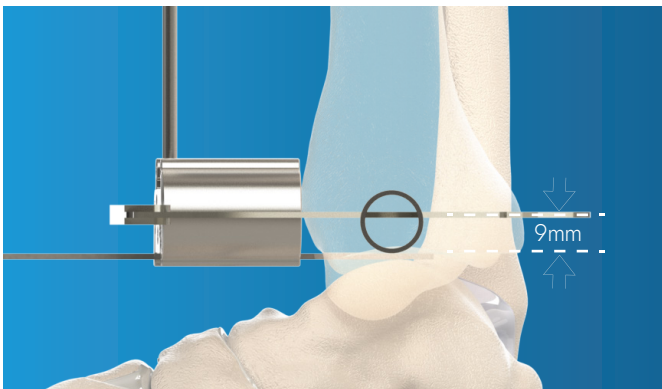


Figure 28. Tibial Cut Trajectory and Nominal Resection

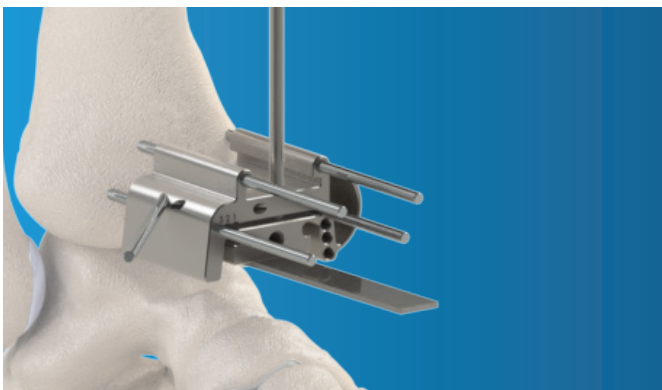


Figure 29. Tibial Resection Guide Fixation

Insert the Tibial Axis into the hole located on the Tibial section 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 26).

Insert the Visualization Bow into the cutting slot of the Resection Guide (Figure 27).

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 28).

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 in the Tibial Resection Guide. Insert a third 2.5mm K-wire into the oblique hole of the Tibial Resection Guide to lock the Guide in place. Remove the Visualization Bow. (Figure 29A)

Two additional 2.5mm K-wires are inserted into the cut slot's medial and lateral boundaries as malleolar protection (Figure 29B).

**Note:** Three lateral K-wire holes are present within the cut slot that correspond to the three implant sizes compatible with the chosen Tibial and Talar Resection Guide grouping. Take care to place the lateral parallel K-wire in the most lateral hole that allows for secure fixation to the bone.

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

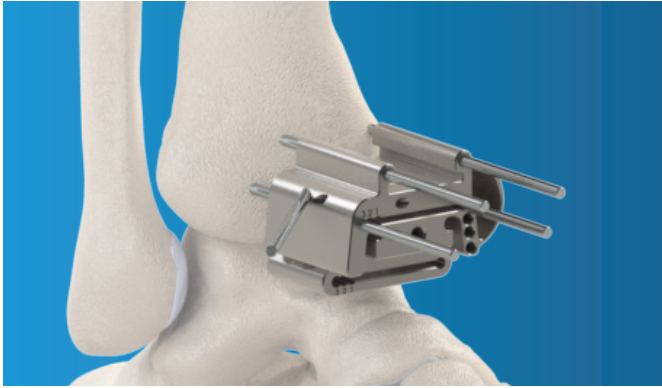


Figure 30. Assembly of Standard Talar Resection Guide

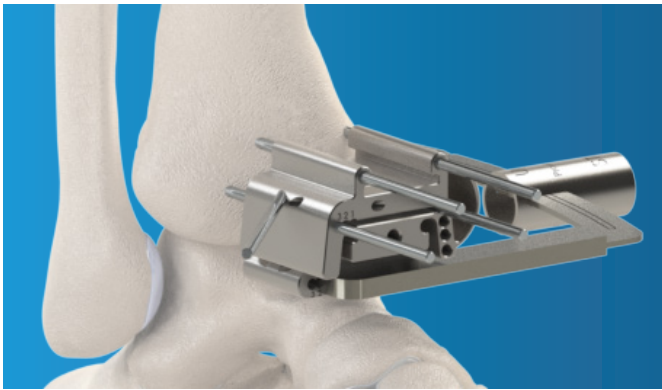


Figure 31. Assembly of Visualization Bow

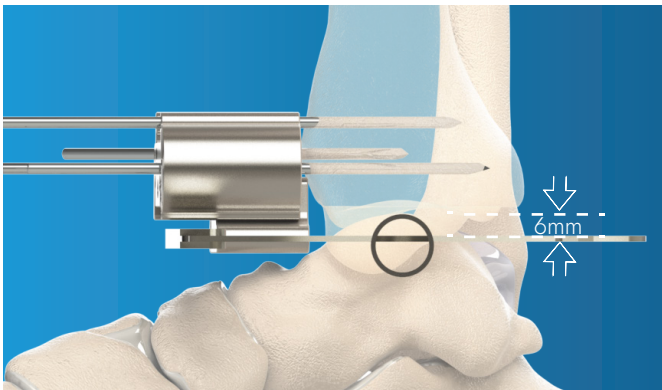


Figure 32. Talar Cut Trajectory and Nominal Resection

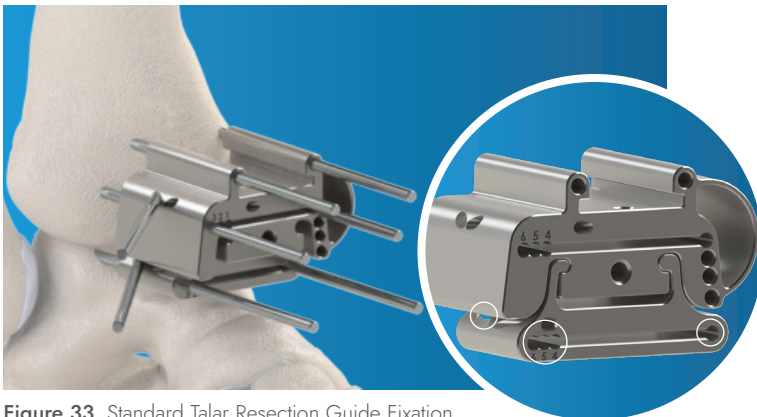


Figure 33. Standard Talar Resection Guide Fixation

### 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 30**).

Insert the Visualization Bow into the cutting slot of the Talar Resection Guide (**Figure 31**).

**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 32**).

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 33**).

**Note:** Three lateral K-wire holes are present that correspond to the three implant sizes compatible with the chosen Tibial and Talar Resection Guide grouping. Take care to place the lateral parallel K-wire in the most lateral hole that allows for secure fixation to the bone.



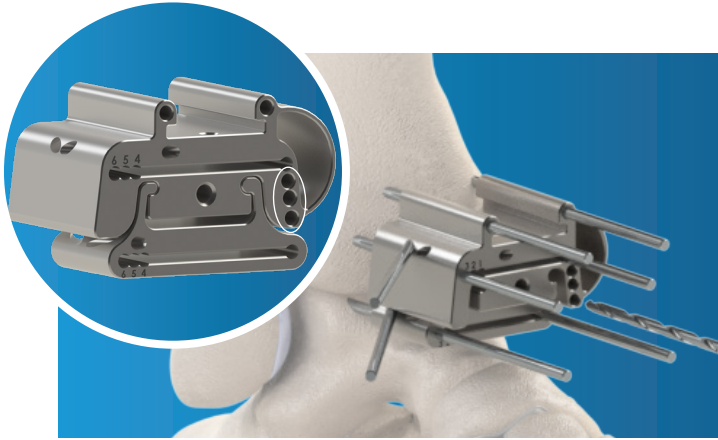


Figure 34. Tibial Stamping

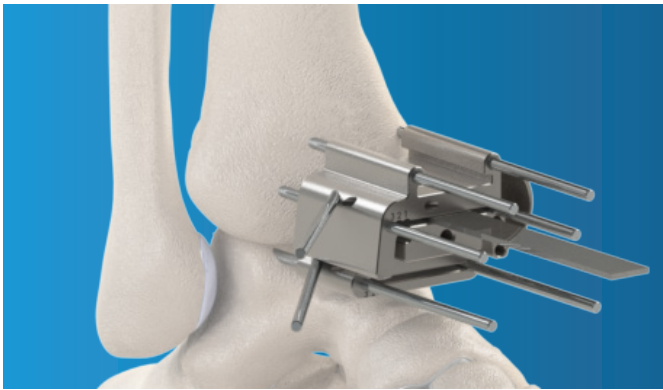


Figure 35. Tibial Resection



Figure 36. Standard Talar Resection

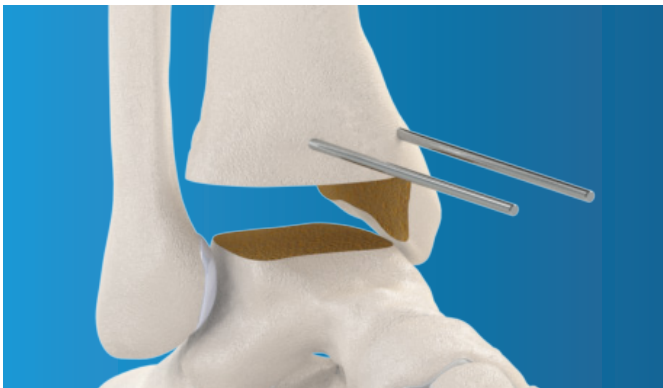


Figure 37. Resection Guide Removal

### 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 34**).

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 35**).

**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 36**).

**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 37**).

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.

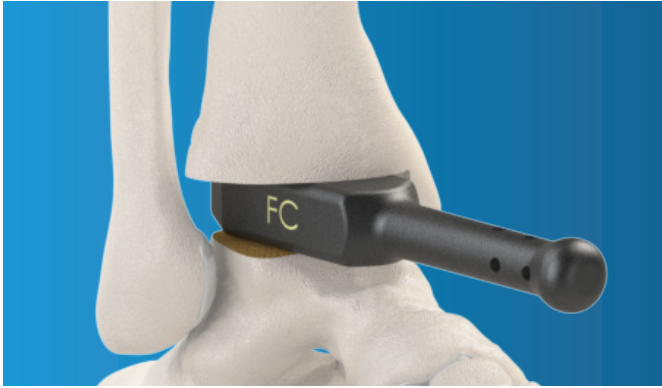


Figure 38. Gap Check for Standard Talus

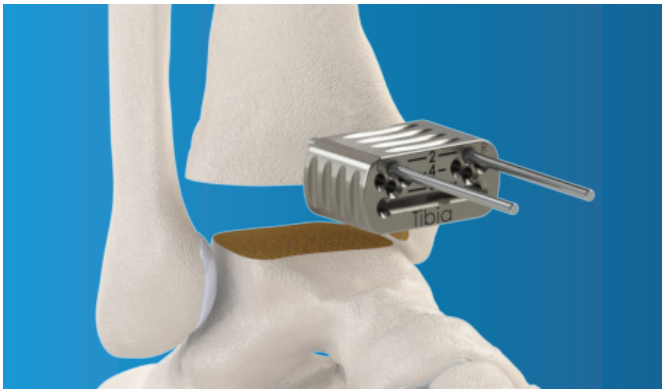


Figure 39. Tibial Recut Block



Figure 40. Alignment of Standard Talar Template

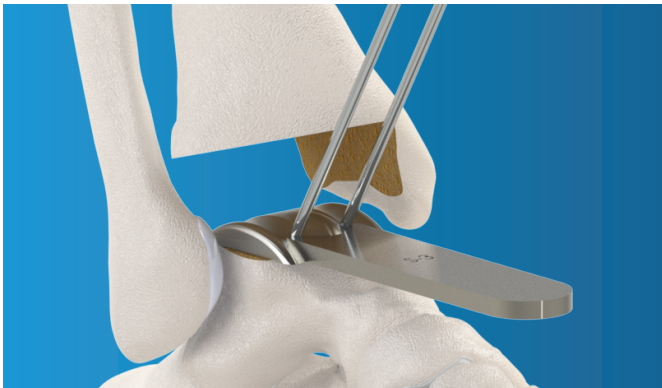


Figure 41. K-wire Fixation of Standard Talar Template

#### 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 38).

**⚠ 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 Tibial Axis 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 39).

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. 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 40).

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.

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 41).

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

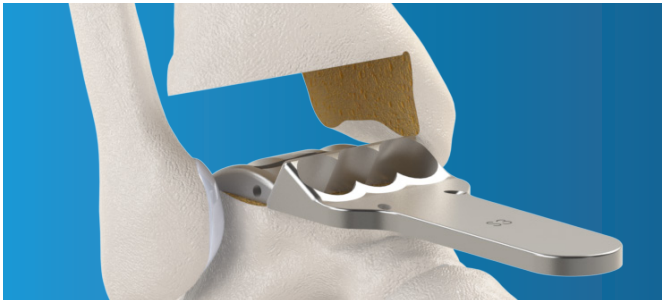


Figure 42. Alignment of Talar Chamfer Resection Guide

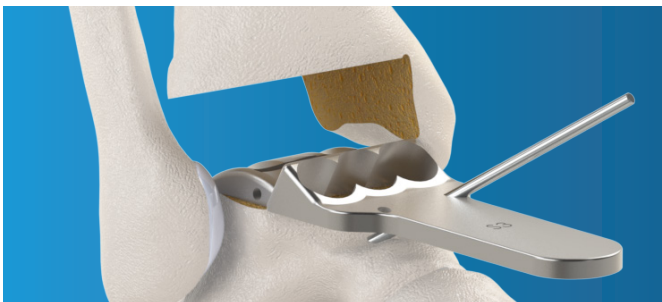


Figure 43. K-wire Fixation of Talar Chamfer Resection Guide

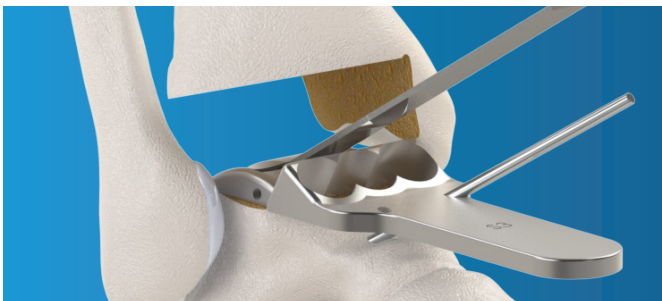


Figure 44. Posterior Chamfer Resection

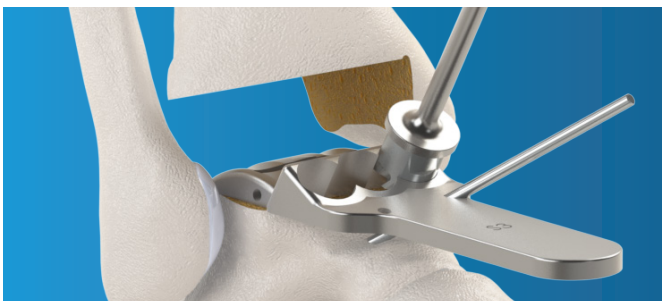


Figure 45. Anterior Chamfer Reaming



Figure 46. Placement of K-wires and Peg Preparation

### 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 42) and secure it in place with one K-wire through the anterior hole on the guide (Figure 43).

**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 44).

**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 45).

**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 46).

Remove both K-wires.



Figure 47. Impaction of Standard Talar Trial

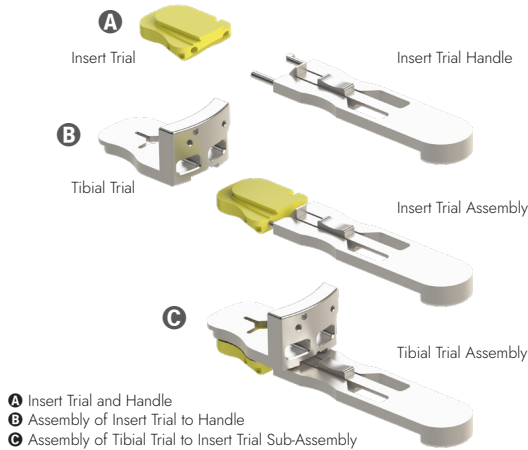


Figure 48. Tibial Trial Assembly



Figure 49. Alignment of Tibial Trial Assembly

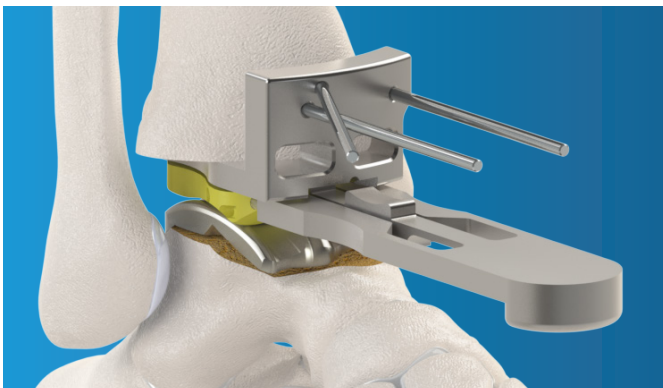


Figure 50. K-wire Fixation of Tibial Trial Assembly

## 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 47).

Confirm placement with fluoroscopic verification.

### Tibial Trial Assembly

Retrieve the Insert Trial Handle and appropriate Insert Trial from the instrument tray. Take care to ensure size and side are correct (Figure 48A).

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

Squeeze the sides of the Insert Trial Handle and insert the posts into the anterior aspect of the Insert Trial until securely engaged (Figure 48B).

Select the appropriate Tibial Trial from the instrument set, taking care to ensure 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 48C).

### Positioning of the Tibial Trial Assembly

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 Standard Talar Trial (Figure 49).

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 50).

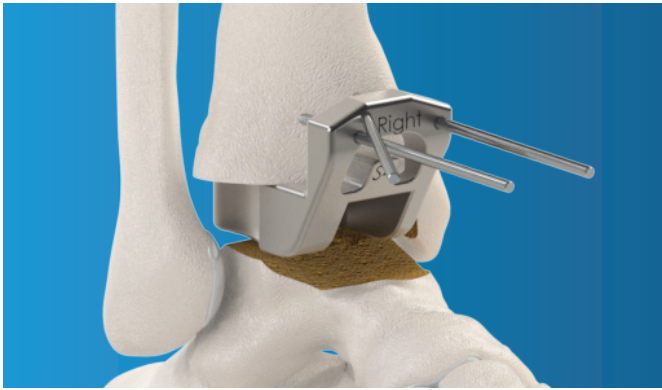


Figure 51. Alignment of Tibial Broach Guide

## 7. Tibial Stem Preparation

### Placement of Tibial Broach Guide

Remove the oblique 2.5mm K-wire from the Tibial Trial. Slide the Tibial Trial Assembly out of the joint space, over the remaining parallel K-wires, then remove the Talar Trial from the surgical site.

Select the corresponding Tibial Broach Guide from the set and assemble it over the previously placed parallel K-wires. Confirm flush seating of the Tibial Broach Guide with the anterior tibial cortex, then secure the Broach Guide in place using the oblique 2.5mm K-wire (**Figure 51**).

### Tibial Broaching

Place the Impactor Screw into the notch at the base of the Impaction Frame, and thread the Handle onto the Screw until full contact with the Frame is achieved with the Handle and Screw (**Figure 52A**).

Assemble the AP Tibial Broach to the Quick Connect feature on the Impaction Frame, confirming a secure connection is obtained (**Figure 52B**).

Slide the assembly into the prepared joint space while aligning the AP Broach with the Tibial Broach Guide's mating feature (**Figure 52C**).

Prepare the AP plane of the Tibial Stem by striking the Impaction Frame Hitting Plate with an axial force to drive the AP Broach into the tibia. Continue impacting until complete contact between the Broach and the Broach Guide is obtained (**Figure 53**).

Carefully remove the AP Broach and Impaction Frame from the Broach Guide.

Using the Quick Connect feature, disengage the AP Broach from the Impaction Frame and replace it with the ML Broach.

Repeat the alignment and preparation steps detailed above.

A final broaching step is then performed by disengaging the ML Broach and using the Final Broach for another pass.

Remove the oblique K-wire from the Broach Guide to allow removal, while leaving the two parallel K-wires in place.

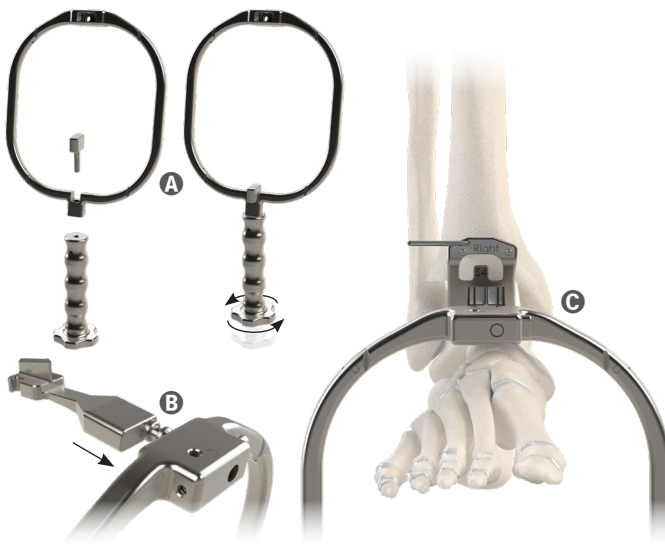


Figure 52. Alignment of AP Tibial Broach

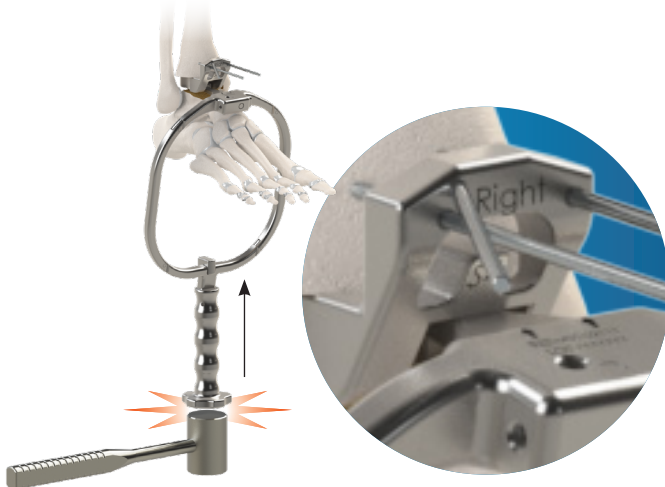


Figure 53. AP Tibial Broaching

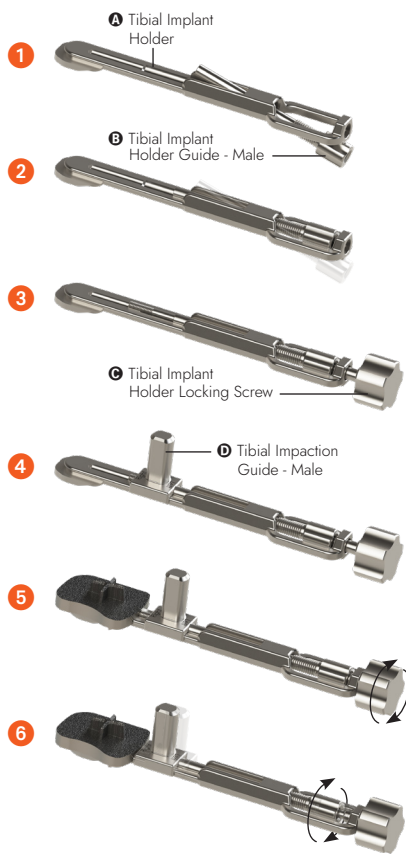


Figure 54. Assembly of Tibial Implant Holder



Figure 55. Addition of Female Impaction Guide



Figure 56. Alignment of Tibial Implant Holder

## 8. Implantation

### Assembly of the Tibial Implant Holder (Figure 54)

- 1 Insert the Tibial Implant Holder Guide - Male **B** at an incline through the Tibial Implant Holder **A**.
  - 2 Pivot the Male Guide distally to align the thru-holes.
- Note:** Do not tighten the Guide into the Holder at this point.
- 3 Insert the Tibial Implant Holder Locking Screw **C** to the round opening on the Tibial Implant Holder **A**, passing through the Tibial Implant Holder Guide - Male **B**.
  - 4 Slide the Tibial Impaction Guide - Male **D** onto the mating end of the Tibial Implant Holder **A** until in contact with the Tibial Implant Holder Guide - Male **B**.

**Important:** Refer to the laser markings on the Tibial Impaction Guide - Male **D** when assembling to confirm proper orientation for the operative side. (i.e. For a Right side operation, the "Right" marking will be located on the end closest to the implant when assembled correctly.)

- 5 Obtain the appropriate Final Tibial Implant and assemble it to the Tibial Implant Holder until the posterior aspect of the dovetail mating feature is in contact with the Holder. Then, turn the Tibial Implant Holder Locking Screw clockwise to engage the anterior threads on the Implant and secure it to the Holder.
- 6 With the Tibial Implant fixed to the Tibial Implant Holder, turn the Tibial Implant Holder Guide - Male **B** clockwise to advance it toward the Tibial Implant until seated flush to the Implant.

### Final Tibial Implant Placement

Assemble the Impactor Plate to the Impaction Frame using the Quick Connect Feature.

Slide the Female Impaction Guide over the parallel K-wires, confirming flush seating of the Female Impaction Guide with the anterior tibial cortex. Then, place a single oblique K-wire through the Female Impaction Guide to secure it in place (Figure 55).

Carefully maneuver the Tibial Implant Holder and Tibial Implant into position, referencing the Male Impaction Guide relative to the Female Impaction Guide, aligning the boss and thru-hole features. (Figure 56).

**Note:** Axially oriented manual pressure may be applied to start implant seating at this point.

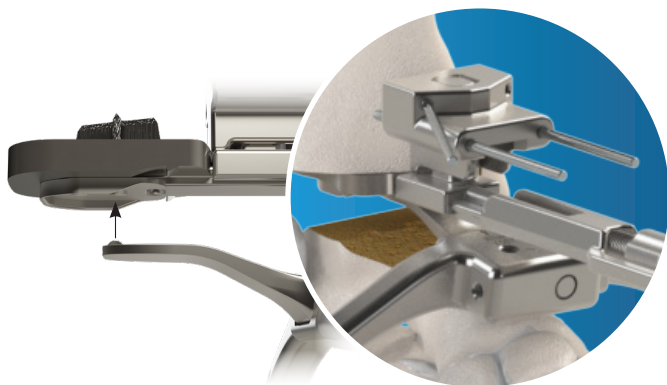


Figure 57. Seat Tibial Implant

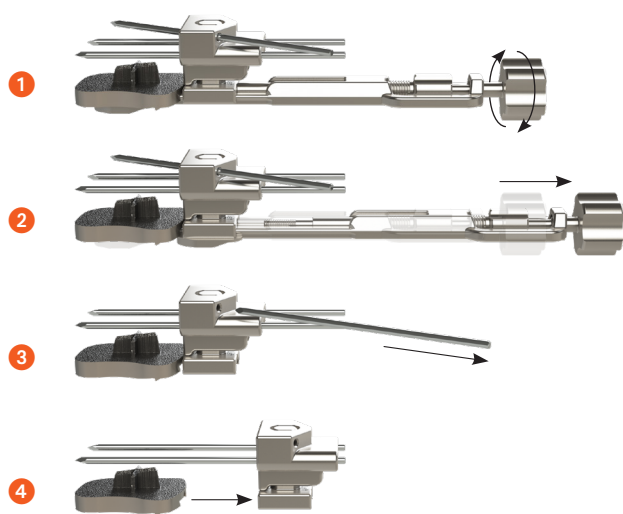


Figure 58. Removal of Tibial Implant Holder



Figure 59. Inserted Articular Surface Protector



Figure 60. Standard Talar Implant Insertion

Align the Impactor Tip with one of the grooves on the plantar aspect of the Implant Holder and strike the Impaction Frame Hitting Plate with an axial force to advance the Tibial Implant until full seating is observed (Figure 57).

**! Important:** Take care to verify complete insertion and seating of the Tibial Implant before moving to the next step.

### Removal of Tibial Implant Holder (Figure 58)

- 1 Upon confirmation of full seating of the Tibial Implant, rotate the Locking Screw counterclockwise until the Tibial Implant is disengaged from the Tibial Implant Holder Assembly.
- 2 Slide the subassembly consisting of the Tibial Implant Holder, Tibial Implant Holder Guide - Male, and Locking Screw, out of the joint space, leaving the Male and Female Impaction Guides in place.
- 3 Remove the oblique K-wire from the Female Impaction Guide.
- 4 Slide the Male and Female Impaction Guides along the parallel K-wires to remove them from the surgical site.

The parallel K-wires may be removed at this point.

### 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 59).

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 60).

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.

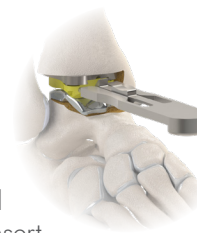
### Final Trialing

Utilizing the Insert Trial identified earlier in the case, a final trialing step may be performed here.

Assemble the Insert Trial to the Insert Trial Handle, and slide the lock detail of the Insert Trial into the dovetail of the final Tibial Implant.

Mobilize the ankle to confirm the appropriate final Insert thickness, and remove the Insert Trial upon confirmation.

**! Note:** Take care to prevent movement of the Tibial Implant during range of motion testing and removal of the Insert Trial to avoid impacting the primary fixation of the Implant.



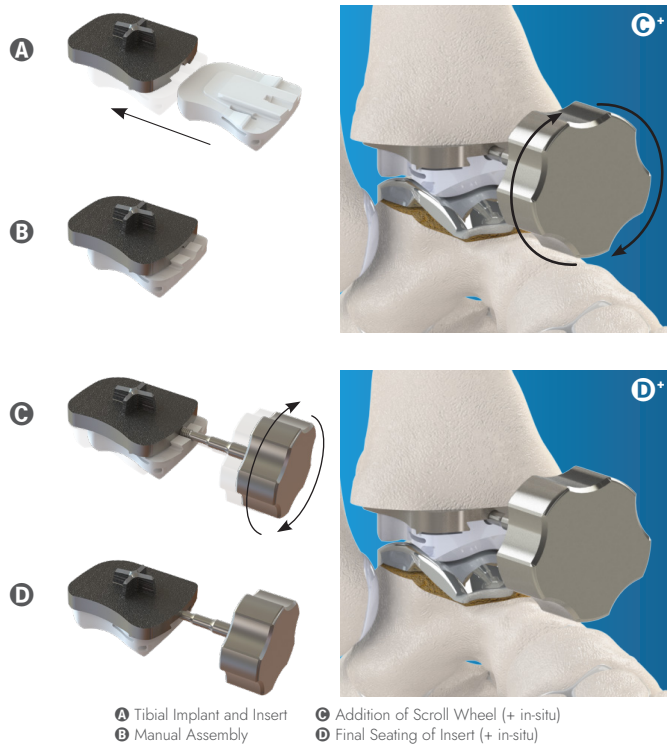


Figure 61. Tibial Insert Placement



Figure 62. Final Standard Talus Construct

### Final Insert Assembly

Align the final Tibial Insert with the anterior portion of the implanted Tibial Implant (**Figure 61A**). Initiate insert placement by manually sliding it into the Tibial Implant's grooves until contacting the dovetail locking feature (**Figure 61B**).

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 61C & 61C+**).

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 61D & 61D+**).

**⚠ 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 Talus 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 62**).

Close the surgical site per surgeon preference.



# Flat-Cut Talar Technique

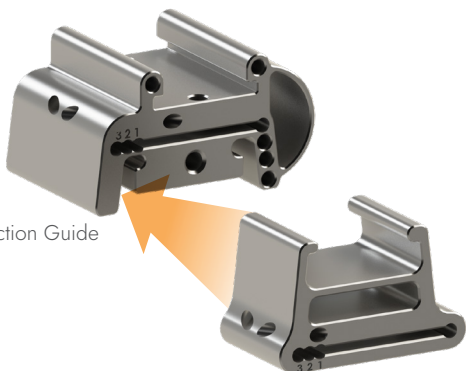


Figure 63. Tibial Resection Guide

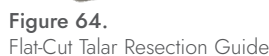


Figure 64. Flat-Cut Talar Resection Guide

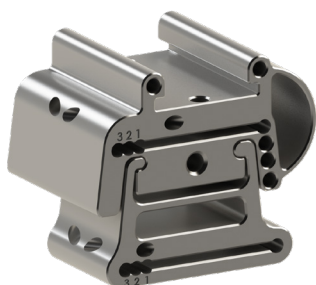


Figure 65. Assembled Resection Guides for Flat-Cut Talus



Figure 66. Initial Placement of Tibial Guide



Figure 67. Insertion of Reference Saw Blade

**Note:** The Advanced Cutting Guide may be utilized as detailed earlier in this document as an alternative to Steps 1 - 4 in this section. If the Advanced Cutting Guide is utilized for the case, please proceed to Step 5 on Page 29.

## 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 63 & 64).

Both parts are assembled over the patient's anatomy by sliding the talar cutting block into the tibial cutting block (Figure 65).

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 66).

**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 graduated saw blade into the joint space, then rest the base of the Tibial Resection Guide onto the blade to approximate the initial location of the tibial resection level through the cut slot (Figure 67).

**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.

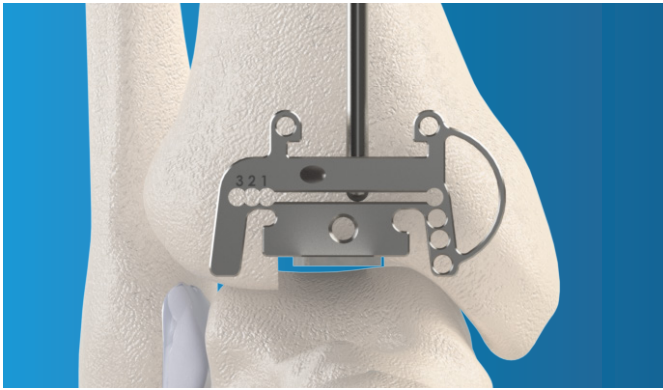


Figure 68. Tibial Axis Visualization and Alignment

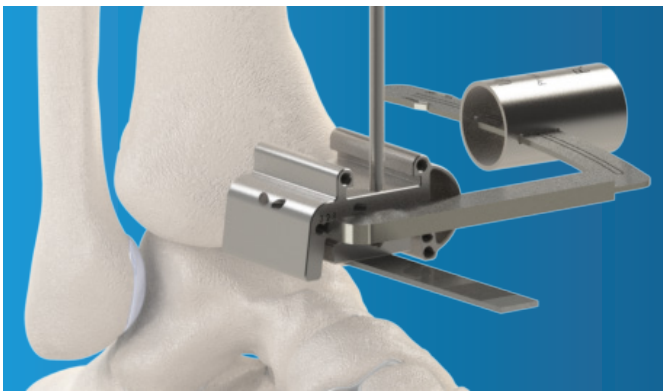


Figure 69. Assembly of Visualization Bow

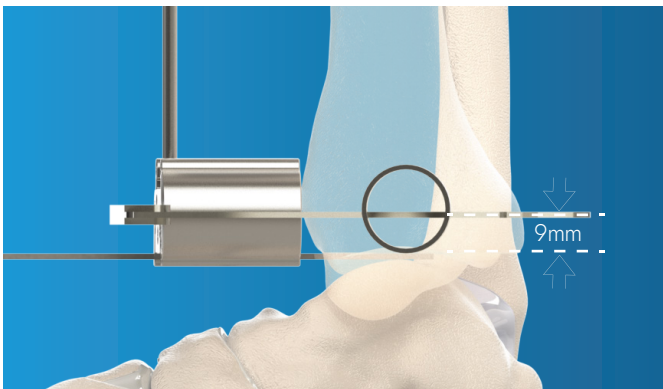


Figure 70. Tibial Cut Trajectory and Nominal Resection

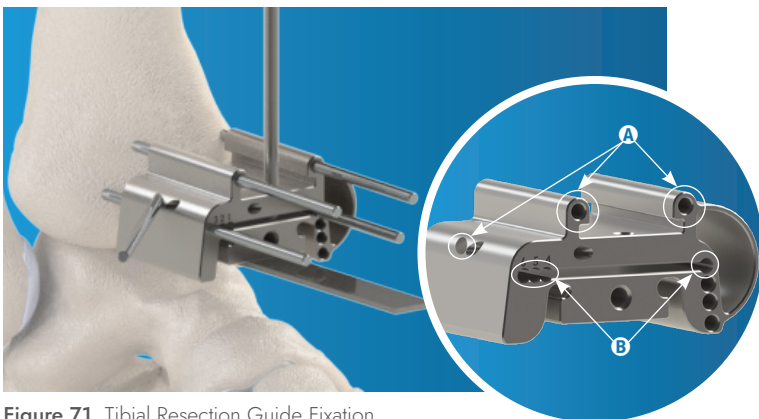


Figure 71. Tibial Resection Guide Fixation

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 68).

Insert the Visualization Bow into the cutting slot of the Resection Guide (Figure 69).

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 70).

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 in the Tibial Resection Guide. Insert a third 2.5mm K-wire into the oblique hole of the Tibial Resection Guide to lock the Guide in place. Remove the Visualization Bow. (Figure 71A)

Two additional 2.5mm K-wires are inserted into the cut slot's medial and lateral boundaries as malleolar protection (Figure 71B).

**Note:** Three lateral K-wire holes are present within the cut slot that correspond to the three implant sizes compatible with the chosen Tibial and Talar Resection Guide grouping. Take care to place the lateral parallel K-wire in the most lateral hole that allows for secure fixation to the bone.

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

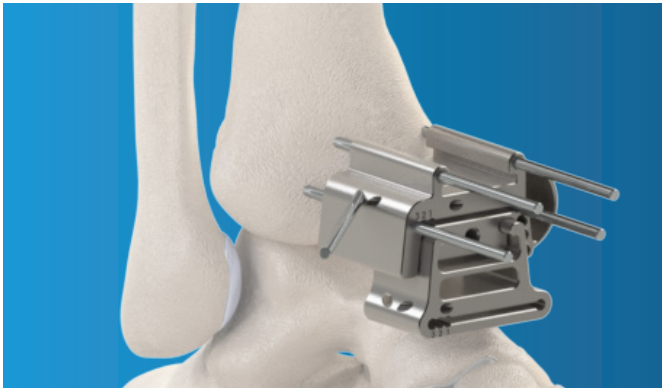


Figure 72. Assembly of Flat-Cut Talar Resection Guide

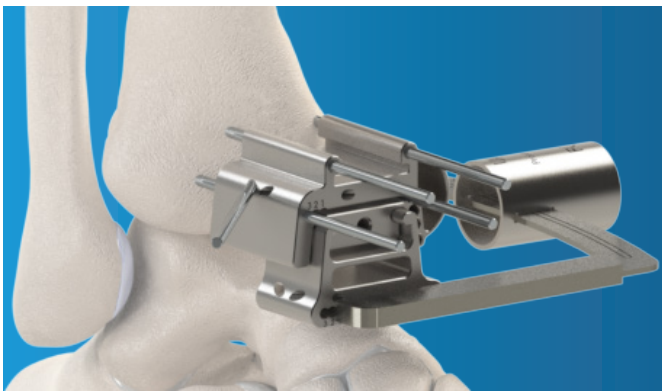


Figure 73. Assembly of Visualization Bow

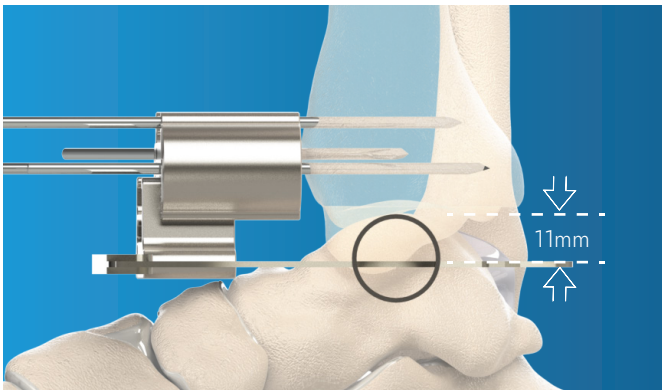


Figure 74. Talar Cut Trajectory and Nominal Resection

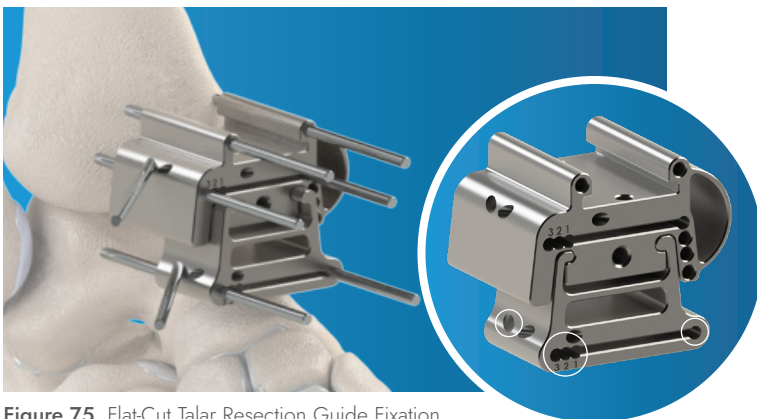


Figure 75. Flat-Cut Talar Resection Guide Fixation

### 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 72).

Insert the Visualization Bow into the cutting slot of the Talar Resection Guide (Figure 73).

**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 74).

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 75).

**Note:** Three lateral K-wire holes are present that correspond to the three implant sizes compatible with the chosen Tibial and Talar Resection Guide grouping. Take care to place the lateral parallel K-wire in the most lateral hole that allows for secure fixation to the bone.

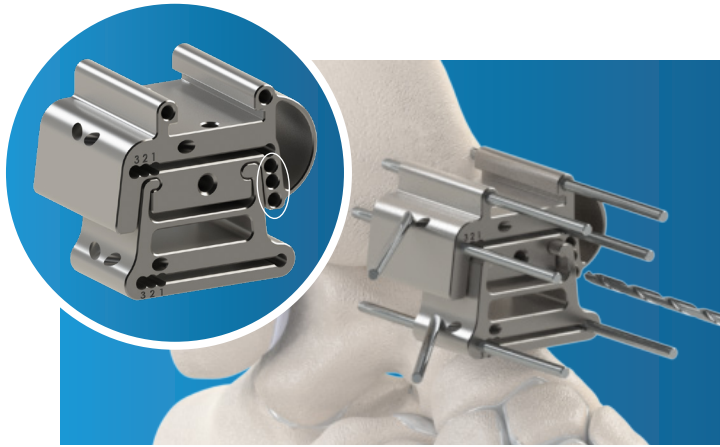


Figure 76. Tibial Stamping

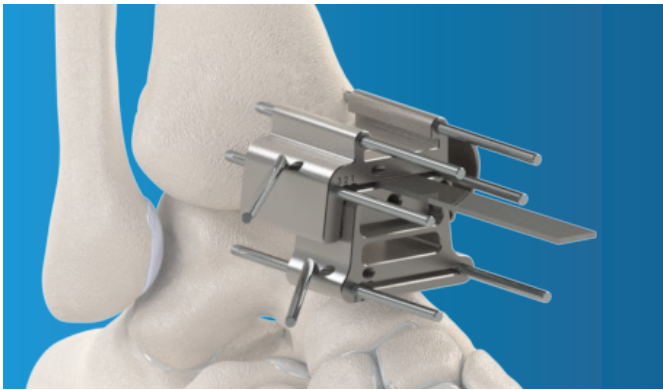


Figure 77. Tibial Resection



Figure 78. Flat-Cut Talar Resection



Figure 79. 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 76).

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 77).

**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 78).

**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 79).

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 80. Gap Check for Flat-Cut Talus

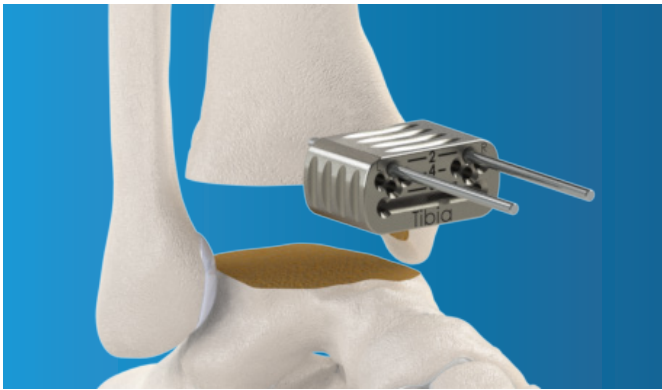


Figure 81. Tibial Recut Block



Figure 82. Alignment of Flat-Cut Talar Template



Figure 83. 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 80).

**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 Tibial Axis 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 81).

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 82).

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.

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 83).

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

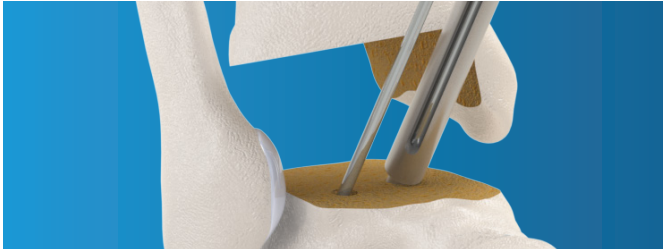


Figure 84. Placement of K-wires and Lug Preparation



Figure 85. Impaction of Flat-Cut Talar Trial

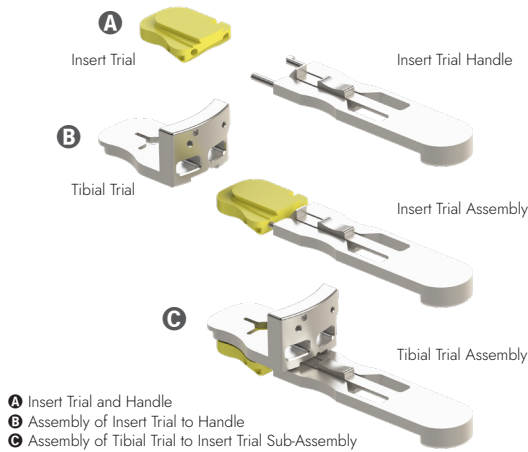


Figure 86. Tibial Trial Assembly



Figure 87. Alignment of Tibial Trial Assembly



Figure 88. K-wire Fixation of Tibial Trial Assembly

## 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 84).

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 85).

Confirm placement with fluoroscopic verification.

### Tibial Trial Assembly

Retrieve the Insert Trial Handle and appropriate Insert Trial from the instrument tray. Take care to ensure size and side are correct. (Figure 86A).

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

Squeeze the sides of the Insert Trial Handle and insert the posts into the anterior aspect of the Insert Trial until securely engaged (Figure 86B).

Select the appropriate Tibial Trial from the instrument set, taking care to ensure 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 86C).

### Positioning of the Tibial Trial Assembly

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 Flat Cut Talar Trial (Figure 87).

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 88).

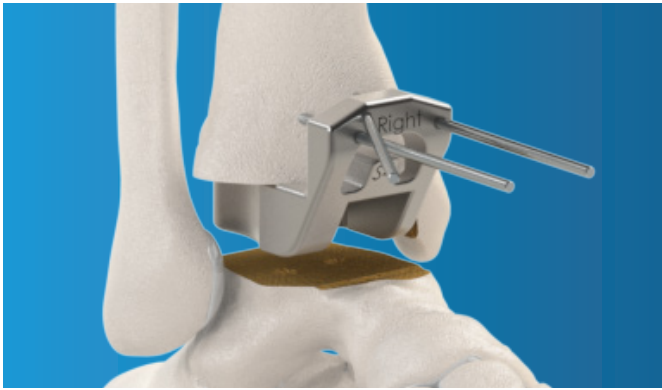


Figure 89. Alignment of Tibial Broach Guide

## 7. Tibial Stem Preparation

### Placement of Tibial Broach Guide

Remove the oblique 2.5mm K-wire from the Tibial Trial. Slide the Tibial Trial Assembly out of the joint space, over the remaining parallel K-wires, then remove the Talar Trial from the surgical site.

Select the corresponding Tibial Broach Guide from the set and assemble it over the previously placed parallel K-wires. Confirm flush seating of the Tibial Broach Guide with the anterior tibial cortex, then secure the Broach Guide in place using the oblique 2.5mm K-wire (**Figure 89**).

### Tibial Broaching

Place the Impactor Screw into the notch at the base of the Impaction Frame, and thread the Handle onto the Screw until full contact with the Frame is achieved with the Handle and Screw (**Figure 90A**).

Assemble the AP Tibial Broach to the Quick Connect feature on the Impaction Frame, confirming a secure connection is obtained (**Figure 90B**).

Slide the assembly into the prepared joint space while aligning the AP Broach with the Tibial Broach Guide's mating feature (**Figure 90C**).

Prepare the AP plane of the Tibial Stem by striking the Impaction Frame Hitting Plate with an axial force to drive the AP Broach into the tibia. Continue impacting until complete contact between the Broach and the Broach Guide is obtained (**Figure 91**).

Carefully remove the AP Broach and Impaction Frame from the Broach Guide.

Using the Quick Connect feature, disengage the AP Broach from the Impaction Frame and replace it with the ML Broach.

Repeat the alignment and preparation steps detailed above.

A final broaching step is then performed by disengaging the ML Broach and using the Final Broach for another pass.

Remove the oblique K-wire from the Broach Guide to allow removal, while leaving the two parallel K-wires in place.

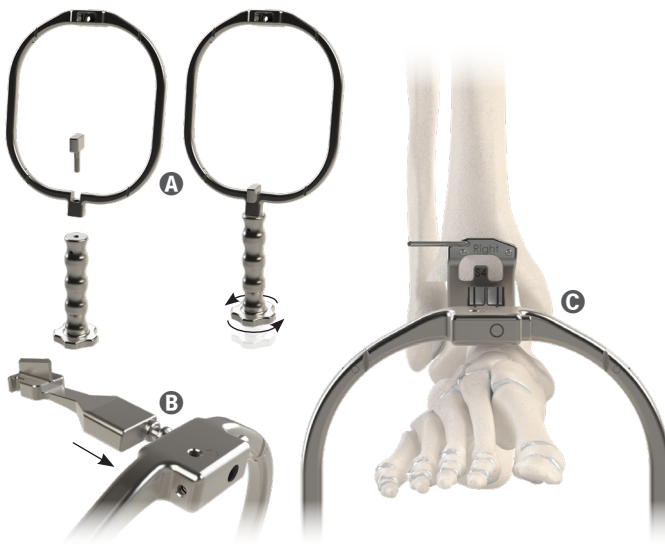


Figure 90. Alignment of AP Tibial Broach

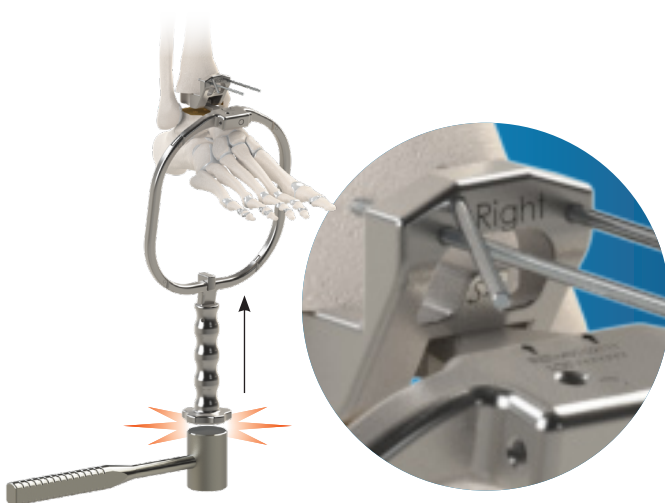


Figure 91. AP Tibial Broaching

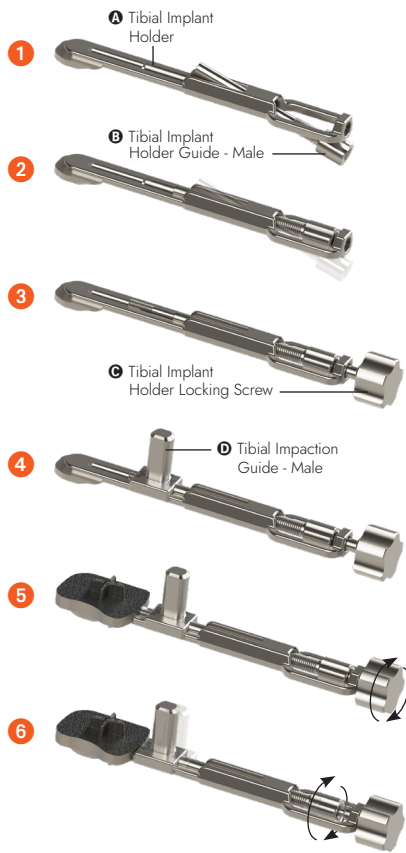


Figure 92. Assembly of Tibial Implant Holder



Figure 93. Addition of Female Impaction Guide

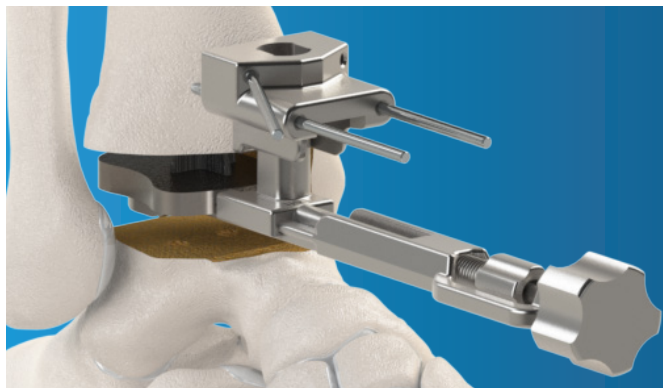


Figure 94. Alignment of Tibial Implant Holder

## 8. Implantation

### Assembly of the Tibial Implant Holder (Figure 92)

- 1 Insert the Tibial Implant Holder Guide - Male **B** at an incline through the Tibial Implant Holder **A**.
- 2 Pivot the Male Guide distally to align the thru-holes.
  - Note:** Do not tighten the Guide into the Holder at this point.
- 3 Insert the Tibial Implant Holder Locking Screw **C** to the round opening on the Tibial Implant Holder **A**, passing through the Tibial Implant Holder Guide - Male **B**.
- 4 Slide the Tibial Impaction Guide - Male **D** onto the mating end of the Tibial Implant Holder **A** until in contact with the Tibial Implant Holder Guide - Male **B**.

**Important:** Refer to the laser markings on the Tibial Impaction Guide - Male **D** when assembling to confirm proper orientation for the operative side. (i.e. For a Right side operation, the "Right" marking will be located on the end closest to the implant when assembled correctly.)

- 5 Obtain the appropriate Final Tibial Implant and assemble it to the Tibial Implant Holder until the posterior aspect of the dovetail mating feature is in contact with the Holder. Then, turn the Tibial Implant Holder Locking Screw clockwise to engage the anterior threads on the Implant and secure it to the Holder.
- 6 With the Tibial Implant fixed to the Tibial Implant Holder, turn the Tibial Implant Holder Guide - Male **B** clockwise to advance it toward the Tibial Implant until seated flush to the Implant.

### Final Tibial Implant Placement

Assemble the Impactor Plate to the Impaction Frame using the Quick Connect Feature.

Slide the Female Impaction Guide over the parallel K-wires, confirming flush seating of the Female Impaction Guide with the anterior tibial cortex. Then, place a single oblique K-wire through the Female Impaction Guide to secure it in place (Figure 93).

Carefully maneuver the Tibial Implant Holder and Tibial Implant into position, referencing the Male Impaction Guide relative to the Female Impaction Guide, aligning the boss and thru-hole features. (Figure 94).

**Note:** Axially oriented manual pressure may be applied to start implant seating at this point.



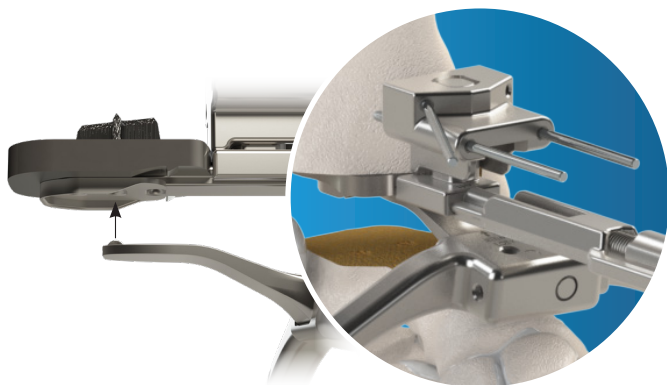


Figure 95. Seat Tibial Implant

Align the Impactor Tip with one of the grooves on the plantar aspect of the Implant Holder and strike the Impaction Frame Hitting Plate with an axial force to advance the Tibial Implant until full seating is observed (Figure 95).

**Important:** Take care to verify complete insertion and seating of the Tibial Implant before moving to the next step.

### Removal of Tibial Implant Holder (Figure 96)

- 1 Upon confirmation of full seating of the Tibial Implant, rotate the Locking Screw counterclockwise until the Tibial Implant is disengaged from the Tibial Implant Holder Assembly.
- 2 Slide the subassembly consisting of the Tibial Implant Holder, Tibial Implant Holder Guide - Male, and Locking Screw, out of the joint space, leaving the Male and Female Impaction Guides in place.
- 3 Remove the oblique K-wire from the Female Impaction Guide.
- 4 Slide the Male and Female Impaction Guides along the parallel K-wires to remove them from the surgical site.

The parallel K-wires may be removed at this point.

### 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 97).

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 98).

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.

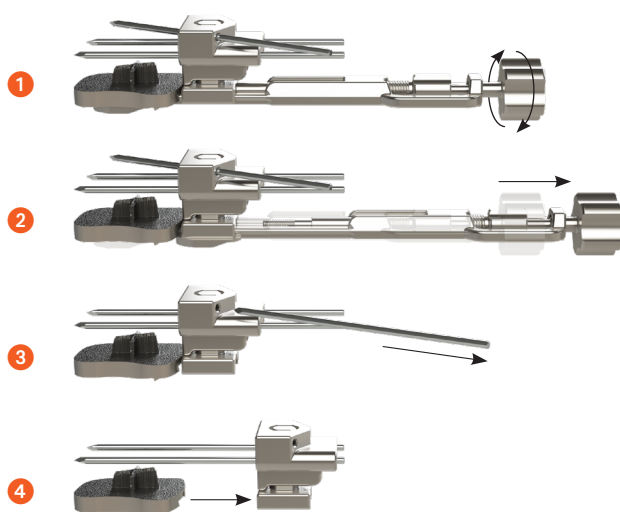


Figure 96. Removal of Tibial Implant Holder



Figure 97. Inserted Articular Surface Protector



Figure 98. Flat-Cut Talar Implant Insertion

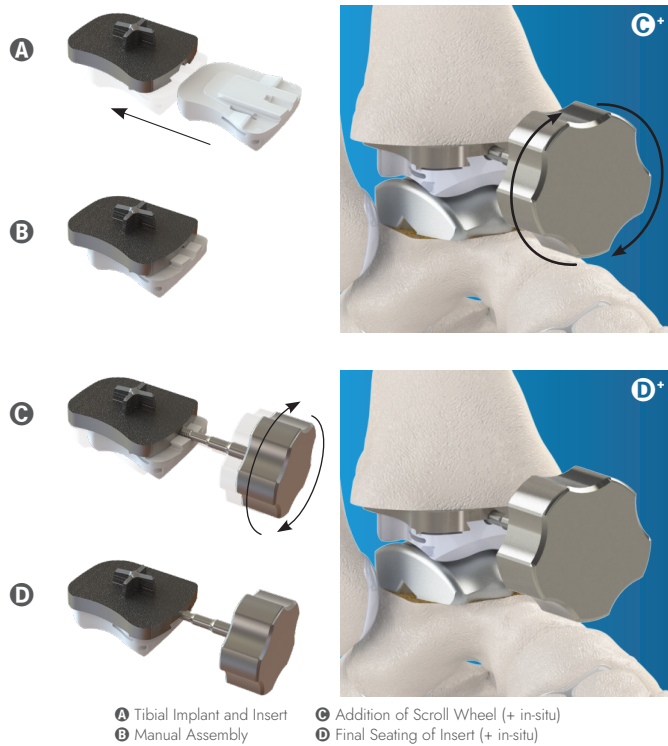


Figure 99. Tibial Insert Placement



Figure 100. Final Flat-Cut Talus Construct

### Final Trialing

Utilizing the Insert Trial identified earlier in the case, a final trialing step may be performed here.

Assemble the Insert Trial to the Insert Trial Handle, and slide the lock detail of the Insert Trial into the dovetail of the final Tibial Implant.

Mobilize the ankle to confirm the appropriate final Insert thickness, and remove the Insert Trial upon confirmation.

**! Note:** Take care to prevent movement of the Tibial Implant during range of motion testing and removal of the Insert Trial to avoid impacting the primary fixation of the Implant.



### Final Insert Assembly

Align the final Tibial Insert with the anterior portion of the implanted Tibial Implant (Figure 99A). Initiate insert placement by manually sliding it into the Tibial Implant's grooves until contacting the dovetail locking feature (Figure 99B).

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 99C & 99C+).

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 99D & 99D+).

**! 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.

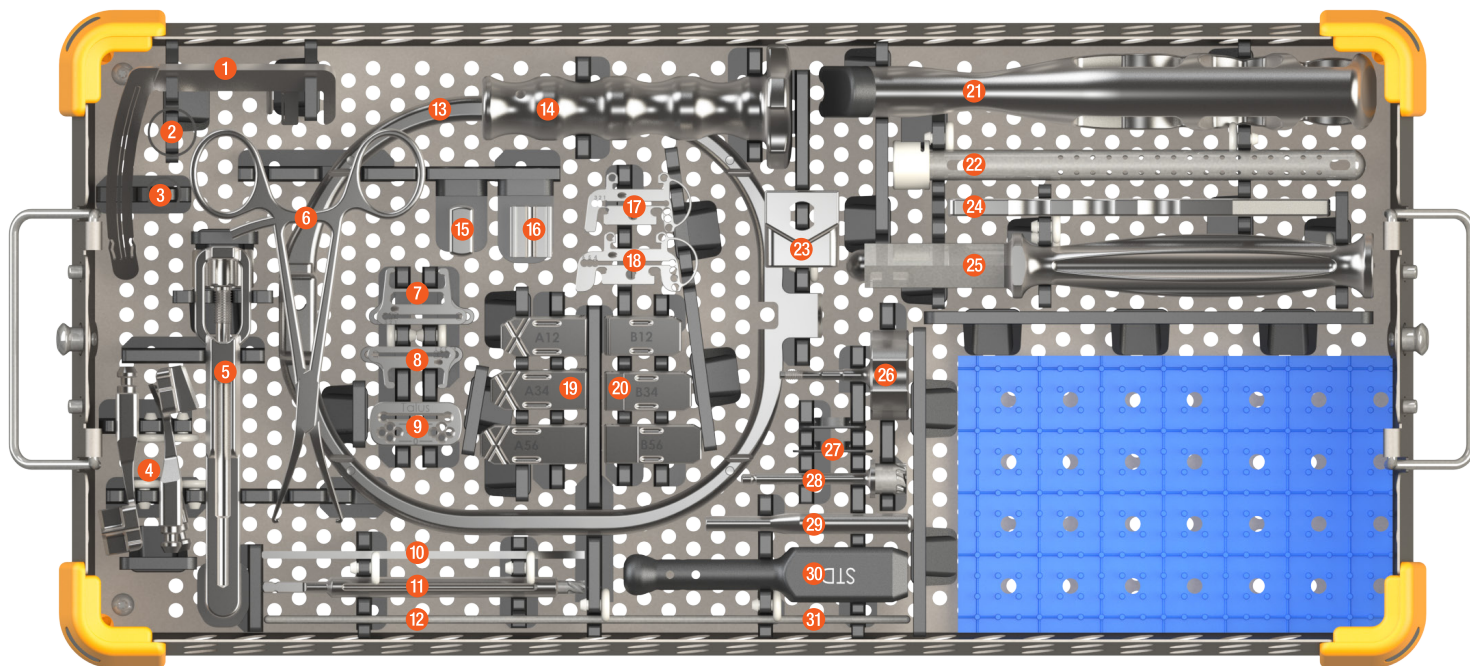
### Final Verification and Closure

Mobilize the ankle and confirm complete implant seating with fluoroscopic verification (Figure 100).

Close the surgical site per surgeon preference.

# Instrumentation

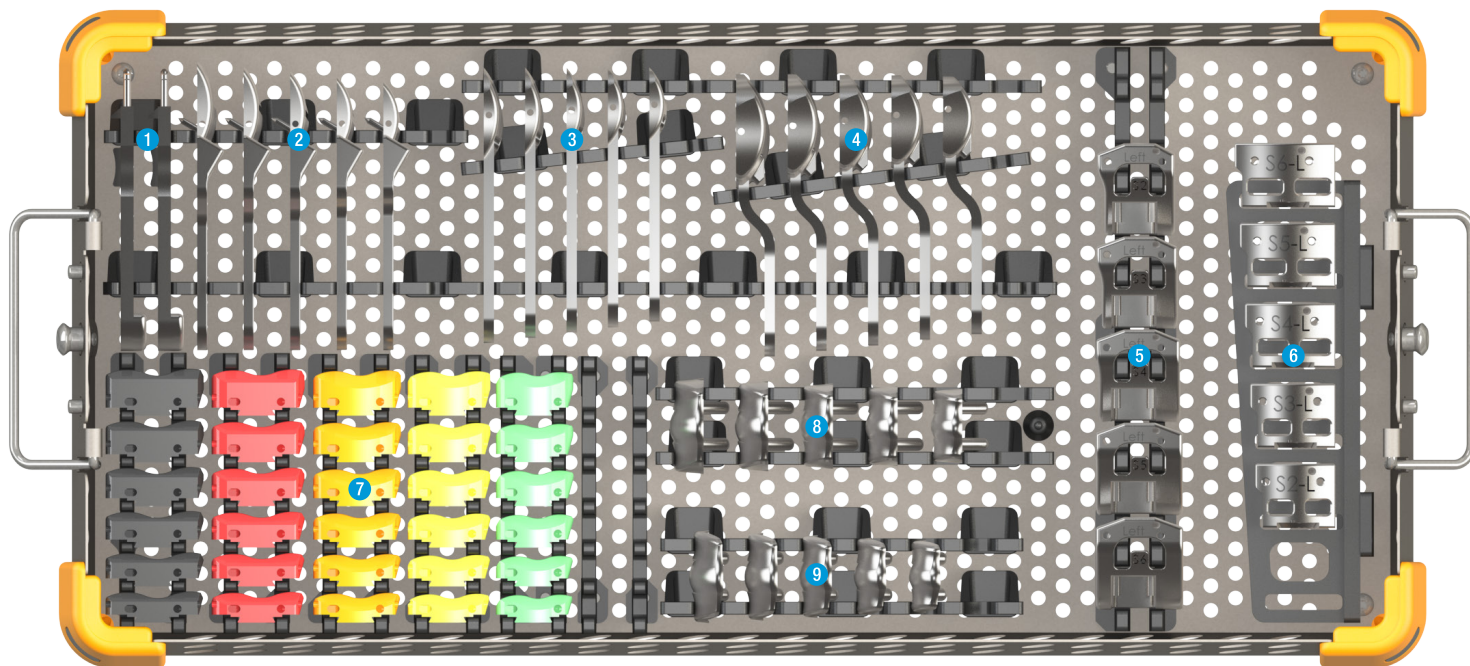
## General Tray Contents



<b>1</b> Visualization Bow . . . . .	M05 00891	<b>18</b> Reusable Tibial Resection Guide (Sizes 4-6) . . . . .	M05 01431
<b>2</b> Control Cylinder for Flat-Cut Talus . . . . .	M05 01171	<b>19</b> Resection Guides for Tibial PSI	
<b>3</b> Control Cylinder for Standard Talus . . . . .	M05 00901	A12 . . . . .	M05 00821
<b>4</b> Tibial Broaches and Impactor		A34 . . . . .	M05 00831
AP Tibial Broach . . . . .	M05 02071	A56 . . . . .	M05 00841
ML Tibial Broach . . . . .	M05 02081	<b>20</b> Resection Guides for Talar PSI	
Final Tibial Broach . . . . .	M05 02061	B12 . . . . .	M05 00851
Impaction Plate . . . . .	M05 01901	B34 . . . . .	M05 00861
<b>5</b> Tibial Implant Holder Components		B56 . . . . .	M05 00871
Tibial Implant Holder . . . . .	M05 01911	<b>21</b> Talar Implant Impactor . . . . .	M05 00751
Tibial Implant Holder Guide (Male) . . . . .	M05 02091	<b>22</b> K-wire Storage Tube (x2) . . . . .	G01 40021
Tibial Implant Holder Locking Screw . . . . .	M05 02101	<b>23</b> Tibial Impaction Guide (Female) . . . . .	M05 01921
<b>6</b> Implant and Trial Holder . . . . .	M05 00741	<b>24</b> Pin Puller* . . . . .	D11288M
<b>7</b> Reusable FC Talar Resection Guides		<b>25</b> Corner Chisel . . . . .	M05 01241
Sizes 2-3 . . . . .	M05 01461	Hockey Stick (Beneath Corner Chisel) . . . . .	M05 01251
Sizes 4-6 . . . . .	M05 01471	<b>26</b> Scroll Wheel . . . . .	M05 00811
<b>8</b> Reusable STD Talar Resection Guides		<b>27</b> Articular Surface Protectors	
Sizes 2-3 . . . . .	M05 01441	Sizes 2-3 . . . . .	M05 01301
Sizes 4-6 . . . . .	M05 01451	Sizes 4-6 . . . . .	M05 01311
<b>9</b> Recut Block . . . . .	M05 00881	<b>28</b> Anterior Chamfer Reamer . . . . .	M05 00701
<b>10</b> Insert Extractor (x2) . . . . .	M05 01161	<b>29</b> Pin Pusher . . . . .	M05 00971
<b>11</b> Talar Peg Drills		<b>30</b> Gap Sizer . . . . .	M05 00961
Cannulated Peg Drill (for Standard Talus) . . . . .	M05 00661	<b>31</b> 2.5mm Tibial Drill (Beneath Tibial Axis) . . . . .	M05 00711
Cannulated Peg Drill (for Flat-Cut Talus) . . . . .	M05 00671	<b>Drills and K-wires</b>	
<b>12</b> Tibial Axis . . . . .	M05 00911	2.5 x 70mm K-wire . . . . .	K10 NS257
<b>13</b> Impaction Frame Quick Coupling . . . . .	M05 02111	2.5 x 100mm K-wire . . . . .	K10 NS251
<b>14</b> Impaction Frame Handle . . . . .	M05 01491	2.5mm Tibial Drill . . . . .	M05 00711
<b>15</b> Impactor Screw . . . . .	M05 01501	2.5 x 76mm Olive Wire (US Only) . . . . .	M05 01232
<b>16</b> Tibial Impaction Guide (Male) . . . . .	M05 01931	2.5 x 100mm Olive Wire . . . . .	M05 01231
<b>17</b> Reusable Tibial Resection Guide (Sizes 2-3) . . . . .	M05 01421		

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

# Side Specific Tray Contents



**1** Insert Trial Handle (x2) . . . . . M05 00253

**2** Talar Chamfer Resection Guides

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

**3** Standard Talar Templates

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

**4** Flat-Cut Talar Templates

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

**5** Tibial Broach Guides

<b>Left:</b>		<b>Right:</b>	
Size 2 . . . . . M05 01951		Size 2 . . . . . M05 02011	
Size 3 . . . . . M05 01961		Size 3 . . . . . M05 02021	
Size 4 . . . . . M05 01971		Size 4 . . . . . M05 02031	
Size 5 . . . . . M05 01981		Size 5 . . . . . M05 02041	
Size 6 . . . . . M05 01991		Size 6 . . . . . M05 02051	

**6** Tibial Trials

<b>Left:</b>		<b>Right:</b>	
Size 2 . . . . . M05 00083		Size 2 . . . . . M05 00023	
Size 3 . . . . . M05 00093		Size 3 . . . . . M05 00033	
Size 4 . . . . . M05 00103		Size 4 . . . . . M05 00043	
Size 5 . . . . . M05 00113		Size 5 . . . . . M05 00053	
Size 6 . . . . . M05 00123		Size 6 . . . . . M05 00063	

**7** Insert Trials

<b>Left:</b>		<b>Right:</b>	
Size 2	5mm . . . . . M05 00203	Size 2	5mm . . . . . M05 00143
	6mm . . . . . M05 00204		6mm . . . . . M05 00144
	7mm . . . . . M05 00205		7mm . . . . . M05 00145
	8mm . . . . . M05 00206		8mm . . . . . M05 00146
	9mm . . . . . M05 00207		9mm . . . . . M05 00147
	11mm . . . . . M05 00208		11mm . . . . . M05 00148
Size 3	5mm . . . . . M05 00213	Size 3	5mm . . . . . M05 00153
	6mm . . . . . M05 00214		6mm . . . . . M05 00154
	7mm . . . . . M05 00215		7mm . . . . . M05 00155
	8mm . . . . . M05 00216		8mm . . . . . M05 00156
	9mm . . . . . M05 00217		9mm . . . . . M05 00157
	11mm . . . . . M05 00218		11mm . . . . . M05 00158
Size 4	5mm . . . . . M05 00223	Size 4	5mm . . . . . M05 00163
	6mm . . . . . M05 00224		6mm . . . . . M05 00164
	7mm . . . . . M05 00225		7mm . . . . . M05 00165
	8mm . . . . . M05 00226		8mm . . . . . M05 00166
	9mm . . . . . M05 00227		9mm . . . . . M05 00167
	11mm . . . . . M05 00228		11mm . . . . . M05 00168
Size 5	5mm . . . . . M05 00233	Size 5	5mm . . . . . M05 00173
	6mm . . . . . M05 00234		6mm . . . . . M05 00174
	7mm . . . . . M05 00235		7mm . . . . . M05 00175
	8mm . . . . . M05 00236		8mm . . . . . M05 00176
	9mm . . . . . M05 00237		9mm . . . . . M05 00177
	11mm . . . . . M05 00238		11mm . . . . . M05 00178
Size 6	5mm . . . . . M05 00243	Size 6	5mm . . . . . M05 00183
	6mm . . . . . M05 00244		6mm . . . . . M05 00184
	7mm . . . . . M05 00245		7mm . . . . . M05 00185
	8mm . . . . . M05 00246		8mm . . . . . M05 00186
	9mm . . . . . M05 00247		9mm . . . . . M05 00187
	11mm . . . . . M05 00248		11mm . . . . . M05 00188

**8** Flat-Cut Talar Trials

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

**9** Standard Talar Trials

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

## General Information

### System Introduction

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, malleolar gutter clearance, and joint laxity. The tibial resection level is governed by these determinations.*

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
- » Evaluation of the tibial implant sagittal slope considering the patient's anatomy

**Note:** *The tibial component 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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# Quantum<sup>®</sup> Total Ankle System

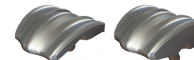
## Ordering Information

### QUANTUM<sup>®</sup> Tibial Implants



STANDARD		LONG	
PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
M50 ST120	Tibial Implant, Standard, 2R	M50 ST121	Tibial Implant, Long, 2R
M50 ST130	Tibial Implant, Standard, 3R	M50 ST131	Tibial Implant, Long, 3R
M50 ST140	Tibial Implant, Standard, 4R	M50 ST141	Tibial Implant, Long, 4R
M50 ST150	Tibial Implant, Standard, 5R	M50 ST151	Tibial Implant, Long, 5R
M50 ST160	Tibial Implant, Standard, 6R	M50 ST161	Tibial Implant, Long, 6R
M50 ST220	Tibial Implant, Standard, 2L	M50 ST221	Tibial Implant, Long, 2L
M50 ST230	Tibial Implant, Standard, 3L	M50 ST231	Tibial Implant, Long, 3L
M50 ST240	Tibial Implant, Standard, 4L	M50 ST241	Tibial Implant, Long, 4L
M50 ST250	Tibial Implant, Standard, 5L	M50 ST251	Tibial Implant, Long, 5L
M50 ST260	Tibial Implant, Standard, 6L	M50 ST261	Tibial Implant, Long, 6L

### QUANTUM<sup>®</sup> Talar Implants



STANDARD		FLAT-CUT	
PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
M50 SC132	Talar Implant, Standard, 2R	M50 SC142	Talar Implant, Flat-Cut, 2R
M50 SC133	Talar Implant, Standard, 3R	M50 SC143	Talar Implant, Flat-Cut, 3R
M50 SC134	Talar Implant, Standard, 4R	M50 SC144	Talar Implant, Flat-Cut, 4R
M50 SC135	Talar Implant, Standard, 5R	M50 SC145	Talar Implant, Flat-Cut, 5R
M50 SC136	Talar Implant, Standard, 6R	M50 SC146	Talar Implant, Flat-Cut, 6R
M50 SC232	Talar Implant, Standard, 2L	M50 SC242	Talar Implant, Flat-Cut, 2L
M50 SC233	Talar Implant, Standard, 3L	M50 SC243	Talar Implant, Flat-Cut, 3L
M50 SC234	Talar Implant, Standard, 4L	M50 SC244	Talar Implant, Flat-Cut, 4L
M50 SC235	Talar Implant, Standard, 5L	M50 SC245	Talar Implant, Flat-Cut, 5L
M50 SC236	Talar Implant, Standard, 6L	M50 SC246	Talar Implant, Flat-Cut, 6L

### QUANTUM<sup>®</sup> Tibial Fixed Inserts



SIZE 2		SIZE 3 Continued		SIZE 4 Continued		SIZE 5 Continued	
PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
M50 SU125	Fixed Insert, 2R, 5mm	M50 SU139	Fixed Insert, 3R, 9mm	M50 SU245	Fixed Insert, 4L, 5mm	M50 SU259	Fixed Insert, 5L, 9mm
M50 SU126	Fixed Insert, 2R, 6mm	M50 SU131	Fixed Insert, 3R, 11mm	M50 SU246	Fixed Insert, 4L, 6mm	M50 SU251	Fixed Insert, 5L, 11mm
M50 SU127	Fixed Insert, 2R, 7mm	M50 SU132	Fixed Insert, 3R, 13mm	M50 SU247	Fixed Insert, 4L, 7mm	M50 SU252	Fixed Insert, 5L, 13mm
M50 SU128	Fixed Insert, 2R, 8mm	M50 SU133	Fixed Insert, 3R, 15mm	M50 SU248	Fixed Insert, 4L, 8mm	M50 SU253	Fixed Insert, 5L, 15mm
M50 SU129	Fixed Insert, 2R, 9mm	M50 SU235	Fixed Insert, 3L, 5mm	M50 SU249	Fixed Insert, 4L, 9mm		
M50 SU121	Fixed Insert, 2R, 11mm	M50 SU236	Fixed Insert, 3L, 6mm	M50 SU241	Fixed Insert, 4L, 11mm		
M50 SU122	Fixed Insert, 2R, 13mm	M50 SU237	Fixed Insert, 3L, 7mm	M50 SU242	Fixed Insert, 4L, 13mm		
M50 SU123	Fixed Insert, 2R, 15mm	M50 SU238	Fixed Insert, 3L, 8mm	M50 SU243	Fixed Insert, 4L, 15mm		
M50 SU225	Fixed Insert, 2L, 5mm	M50 SU239	Fixed Insert, 3L, 9mm				
M50 SU226	Fixed Insert, 2L, 6mm	M50 SU231	Fixed Insert, 3L, 11mm				
M50 SU227	Fixed Insert, 2L, 7mm	M50 SU232	Fixed Insert, 3L, 13mm				
M50 SU228	Fixed Insert, 2L, 8mm	M50 SU233	Fixed Insert, 3L, 15mm				
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		SIZE 4		SIZE 5		SIZE 6	
PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION	PART NUMBER	DESCRIPTION
M50 SU135	Fixed Insert, 3R, 5mm	M50 SU145	Fixed Insert, 4R, 5mm	M50 SU155	Fixed Insert, 5R, 5mm	M50 SU165	Fixed Insert, 6R, 5mm
M50 SU136	Fixed Insert, 3R, 6mm	M50 SU146	Fixed Insert, 4R, 6mm	M50 SU156	Fixed Insert, 5R, 6mm	M50 SU166	Fixed Insert, 6R, 6mm
M50 SU137	Fixed Insert, 3R, 7mm	M50 SU147	Fixed Insert, 4R, 7mm	M50 SU157	Fixed Insert, 5R, 7mm	M50 SU167	Fixed Insert, 6R, 7mm
M50 SU138	Fixed Insert, 3R, 8mm	M50 SU148	Fixed Insert, 4R, 8mm	M50 SU158	Fixed Insert, 5R, 8mm	M50 SU168	Fixed Insert, 6R, 8mm
		M50 SU149	Fixed Insert, 4R, 9mm	M50 SU159	Fixed Insert, 5R, 9mm	M50 SU169	Fixed Insert, 6R, 9mm
		M50 SU141	Fixed Insert, 4R, 11mm	M50 SU151	Fixed Insert, 5R, 11mm	M50 SU161	Fixed Insert, 6R, 11mm
		M50 SU142	Fixed Insert, 4R, 13mm	M50 SU152	Fixed Insert, 5R, 13mm	M50 SU162	Fixed Insert, 6R, 13mm
		M50 SU143	Fixed Insert, 4R, 15mm	M50 SU153	Fixed Insert, 5R, 15mm	M50 SU163	Fixed Insert, 6R, 15mm
				M50 SU255	Fixed Insert, 5L, 5mm	M50 SU265	Fixed Insert, 6L, 5mm
				M50 SU256	Fixed Insert, 5L, 6mm	M50 SU266	Fixed Insert, 6L, 6mm
				M50 SU257	Fixed Insert, 5L, 7mm	M50 SU267	Fixed Insert, 6L, 7mm
				M50 SU258	Fixed Insert, 5L, 8mm	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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#### 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

#### RECOMMENDATION

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

#### REIMBURSEMENT

Reimbursement may vary from country to country. Check with local authorities.

#### MANUFACTURER

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