SURGICAL TECHNIQUE SUPPLEMENT

Reusable Advanced Cutting Guide

QUANTUM®
Total Ankle System

In2Bones
a CONMED company

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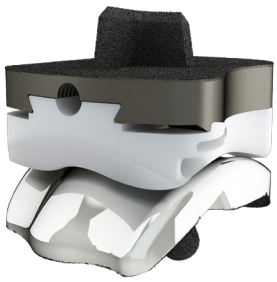
QUANTUM® Total Ankle System



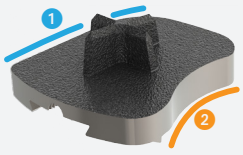
The QUANTUM® Total Ankle System is designed to address the complexity of TAR and allow reproducible outcomes for every surgeon.

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

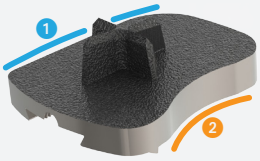
Intuitive Instrumentation:
- Two single-level trays for case execution
  - Additional half tray for the Reusable Advanced Cutting Guide
- Streamlined procedure and tray design intended to reduce the dependency on specialists

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

SIZE X or X+1



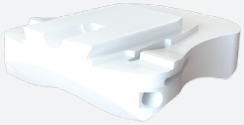
Standard Tibial Implant



Long Tibial Implant

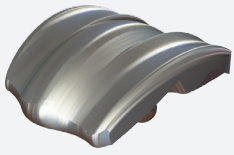
Tibial Inserts:
- Side-specific implants for sizes 2 through 6, in 8 thicknesses (5-15mm)
- Dovetail locking feature
- Vacuum sealed and gamma sterilized
- Ultra-high molecular weight polyethylene

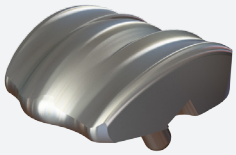
SIZE X


Tibial Insert

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

SIZE X


Standard Talar Implant


Flat-Cut Talar Implant

*Data on file

Reusable Advanced Cutting Guide Introduction

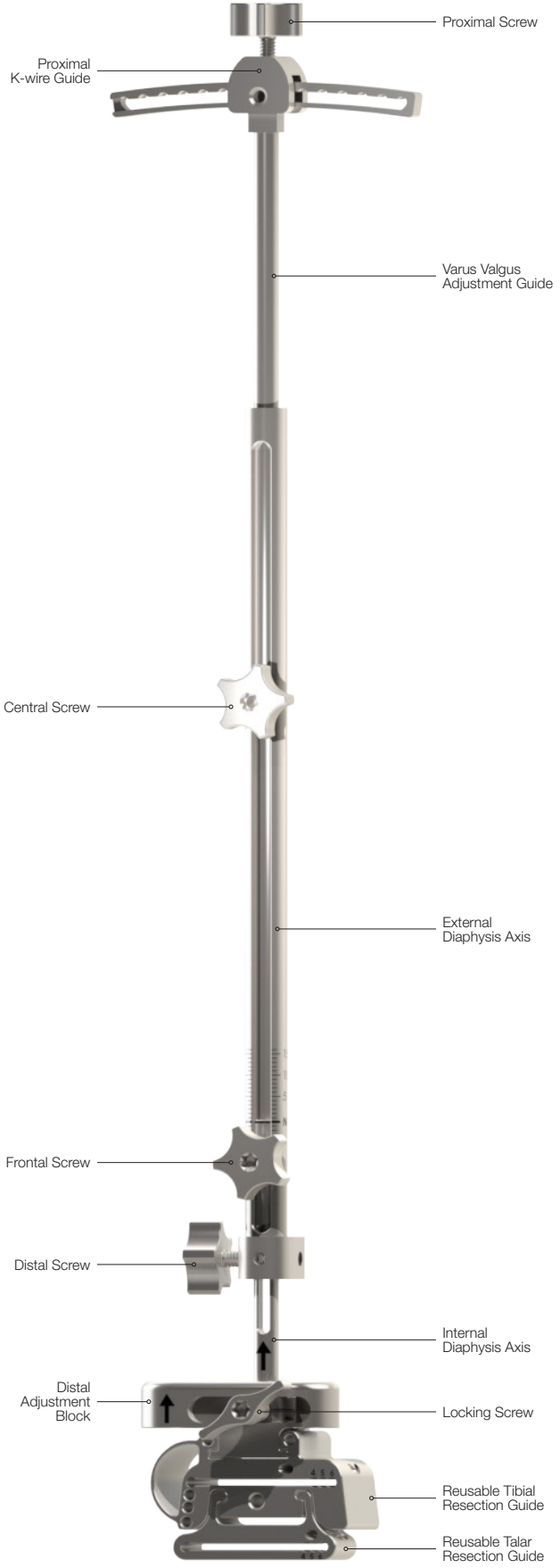
The QUANTUM® Reusable Advanced Cutting Guide is used to align and perform the horizontal tibial and talar resections.

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

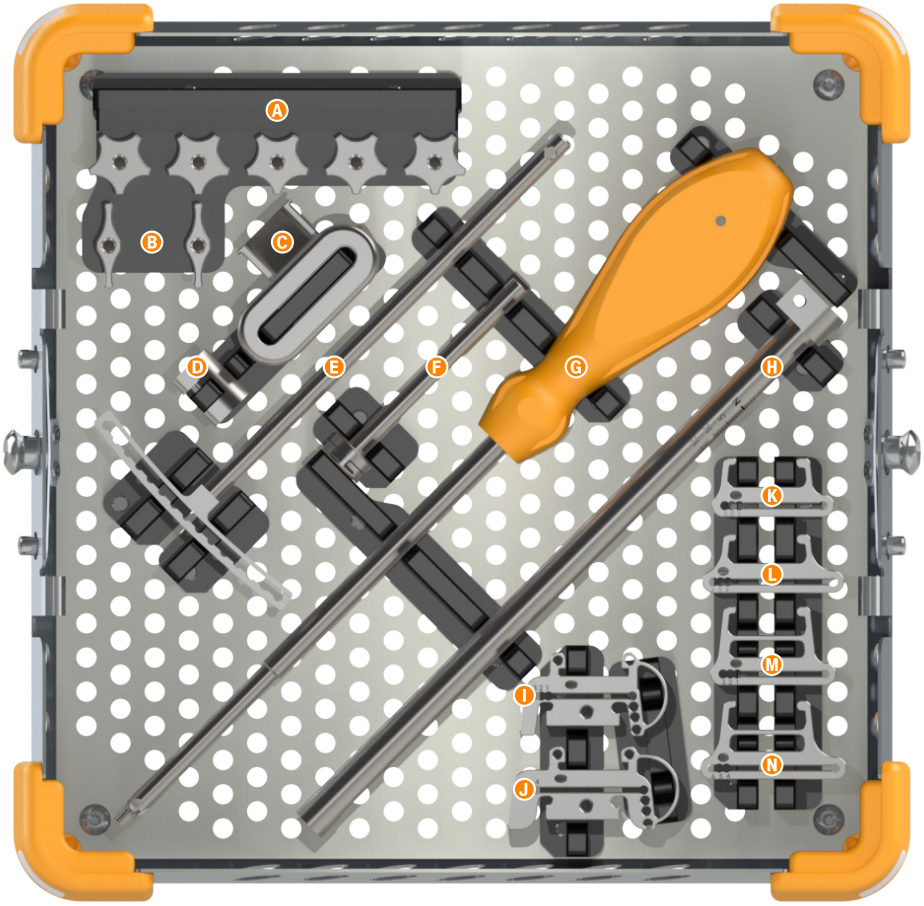
Note: *The resections are coupled when using the Advanced Cutting Guide, allowing for the minimal resection level necessary for implantation of the QUANTUM implant construct.*

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.



Reusable Advanced Cutting Guide – M05 10015



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

Note: *When using the Reusable Advanced Cutting Guide, it is necessary to utilize the Reusable Tibial and Talar Resection Guides from this tray. The Tibial and Talar Resection Guides located in the General Instrument Tray will not assemble to the jig due to the lack of the channel feature that mates with the distal portion of the Distal Adjustment Block.*

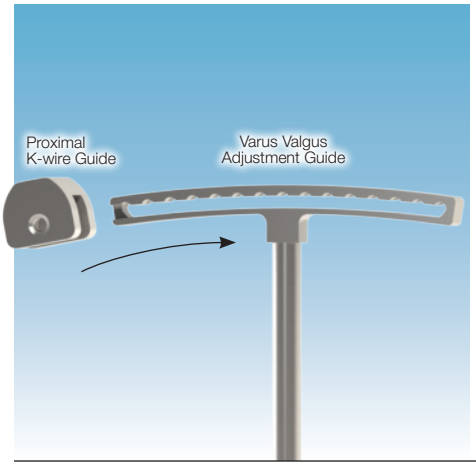


Figure 1

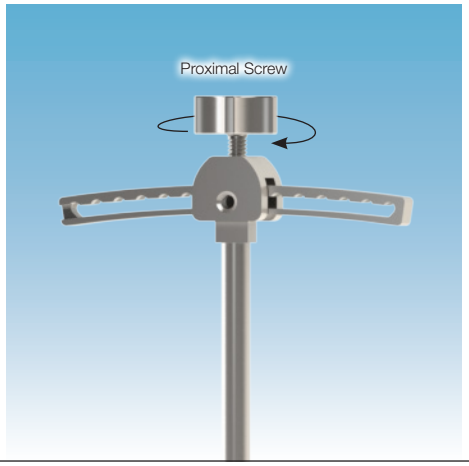


Figure 2

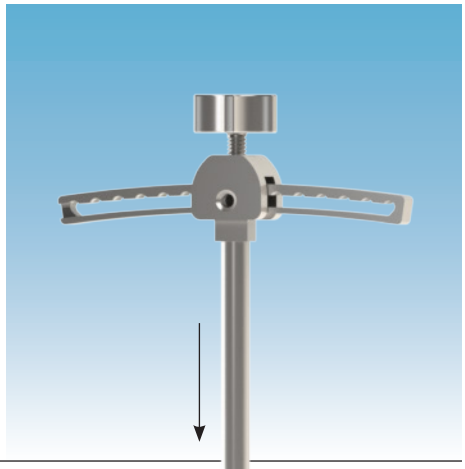


Figure 3

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**

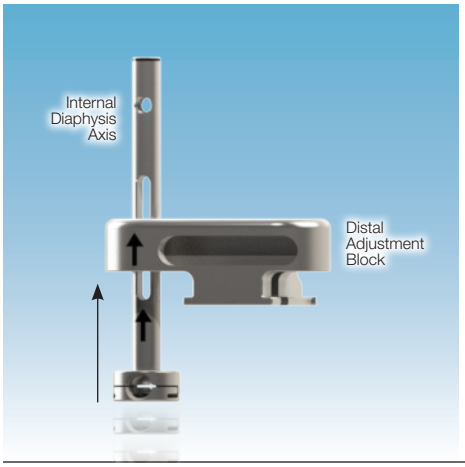
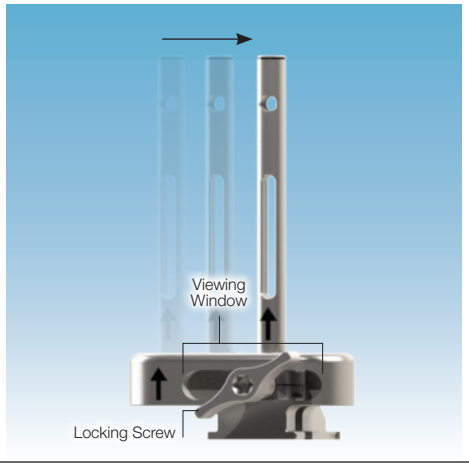


Figure 4



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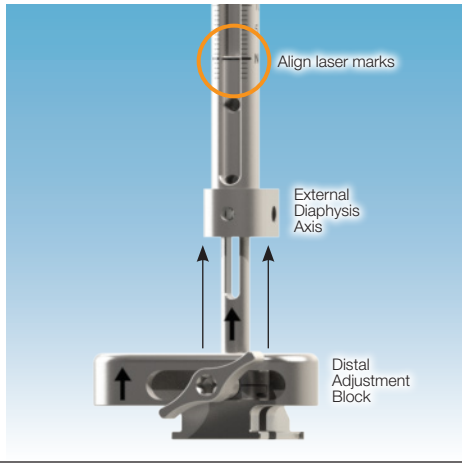


Figure 6

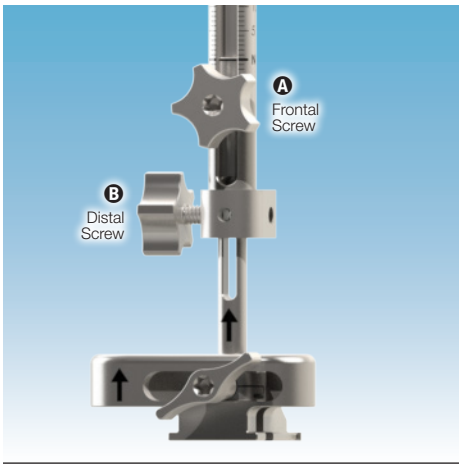


Figure 7

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**

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.*

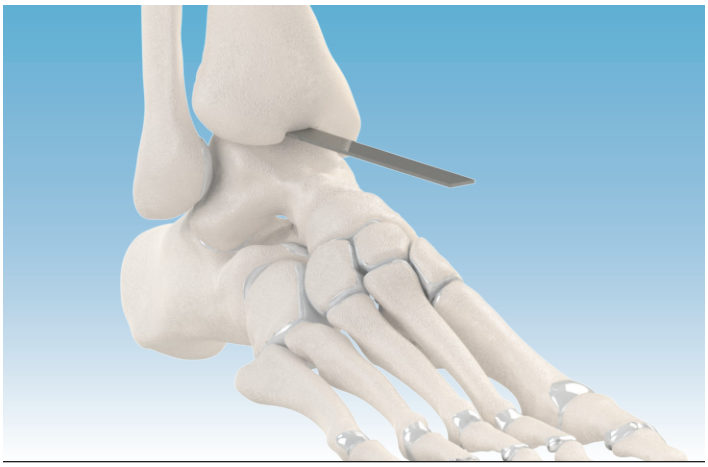


Figure 8

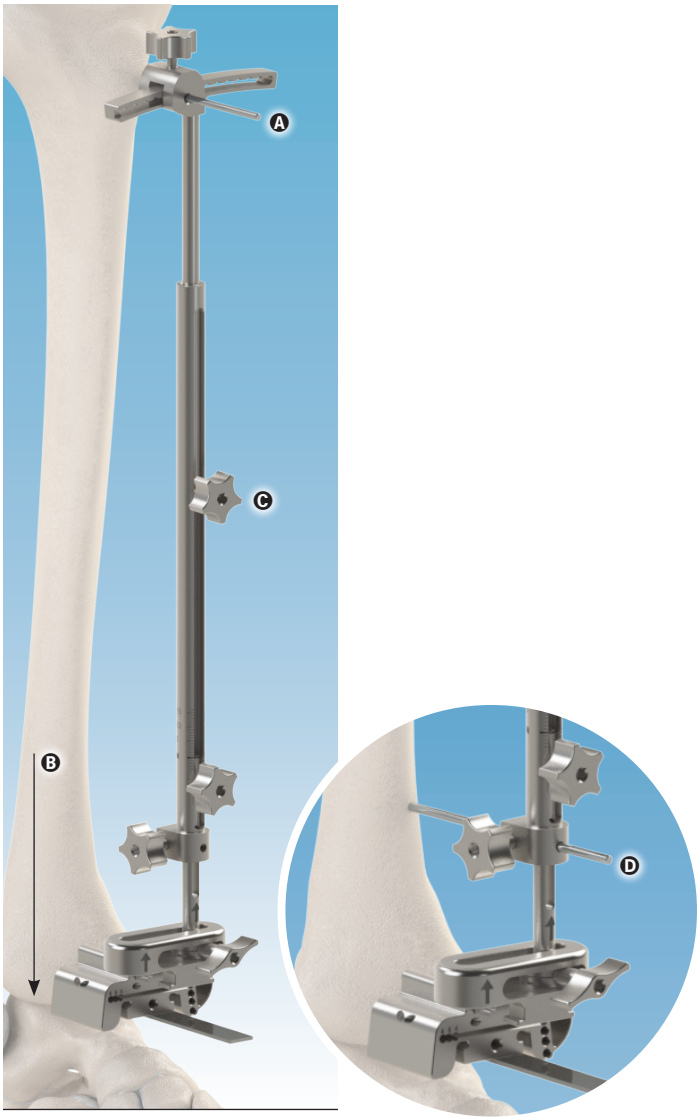


Figure 9

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 10

Figure 11

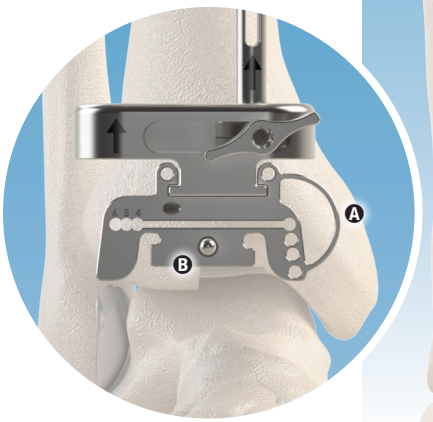


Figure 12

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**

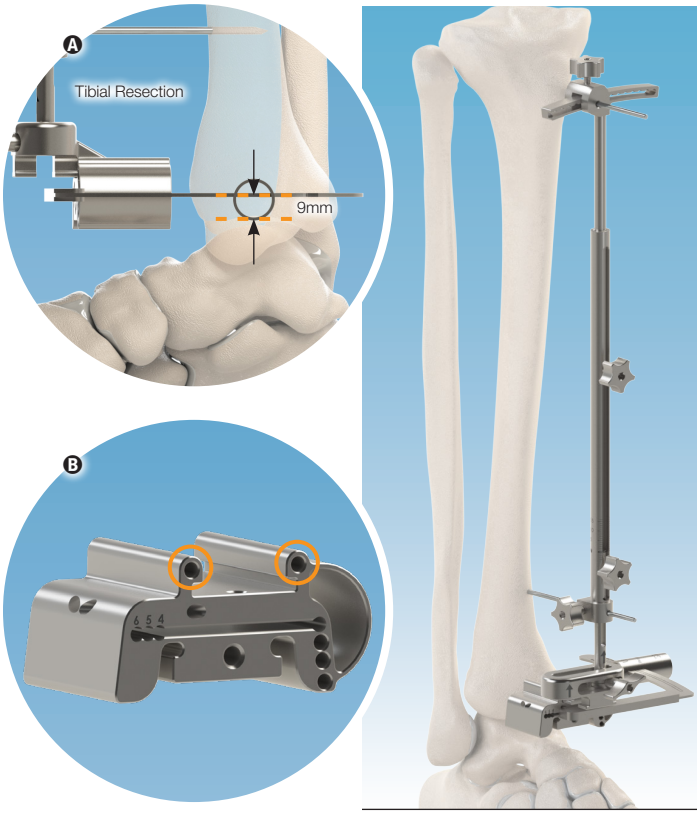


Figure 13

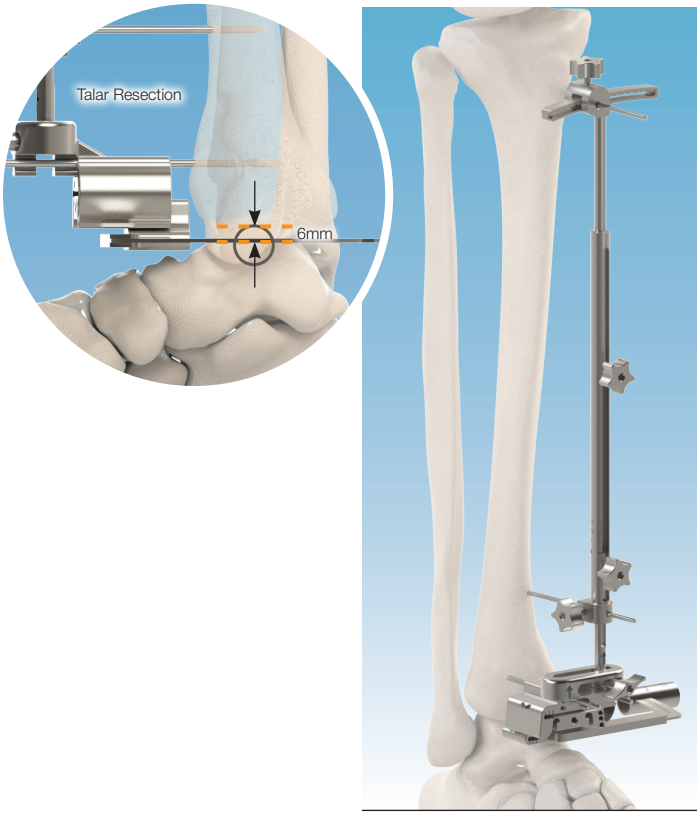


Figure 14

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.*

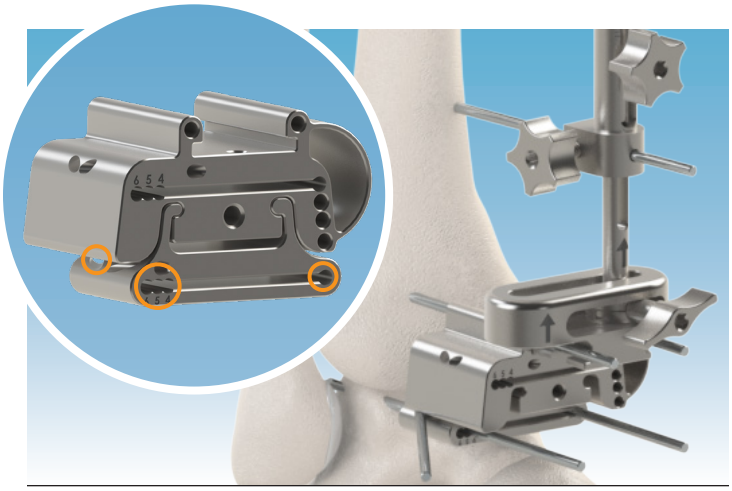


Figure 15

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.*

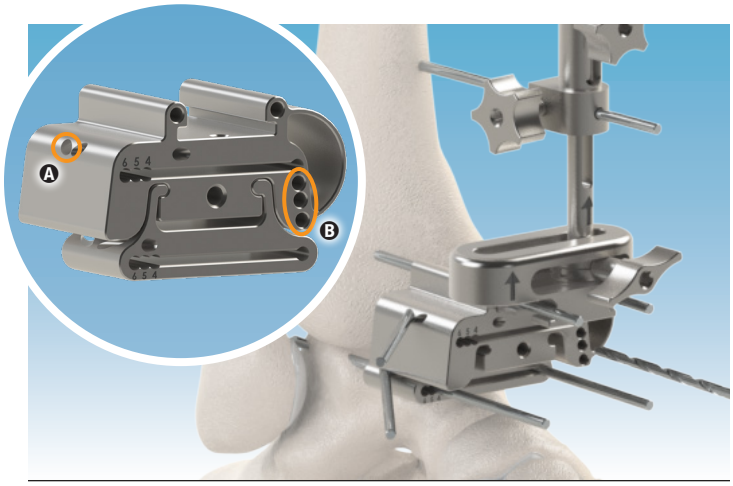


Figure 16

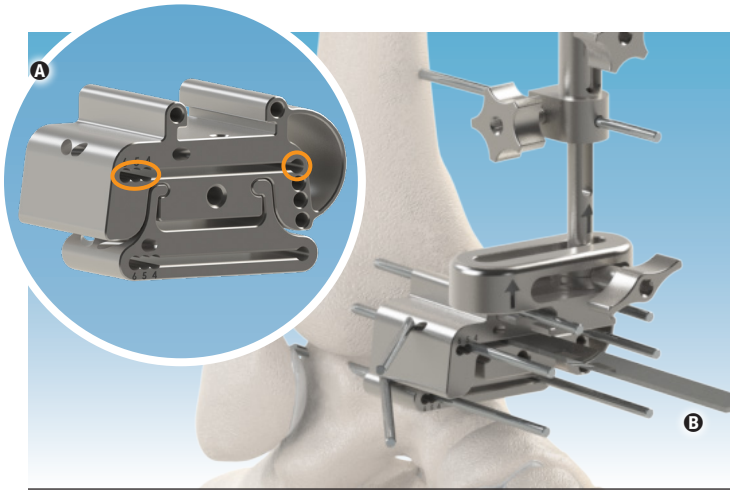


Figure 17

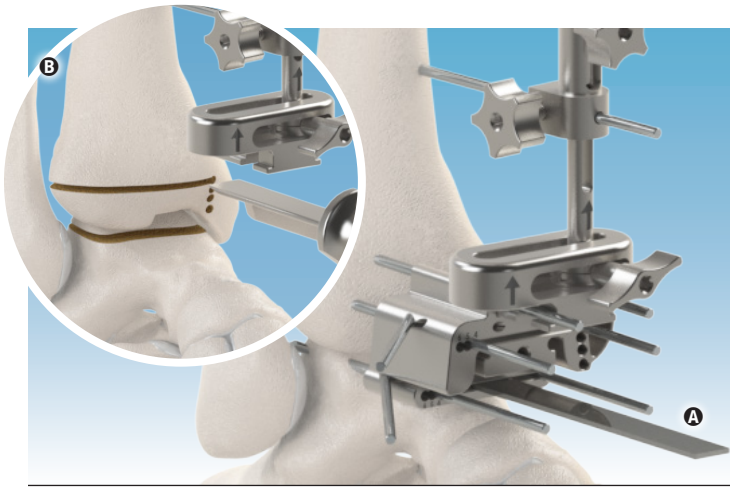


Figure 18

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.*

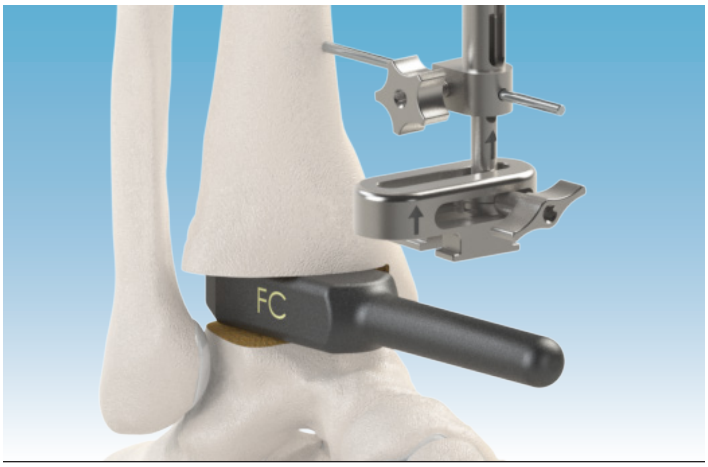


Figure 19

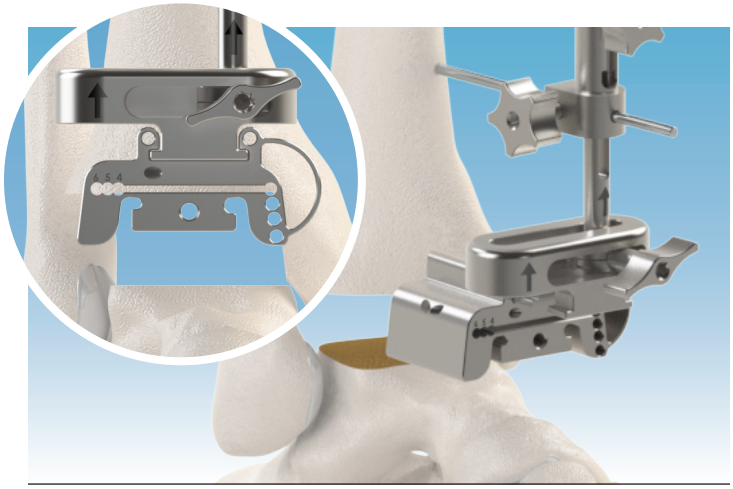


Figure 20

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

If the Gap Sizer indicates that the existing resections will not accommodate the minimum construct thickness, 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.

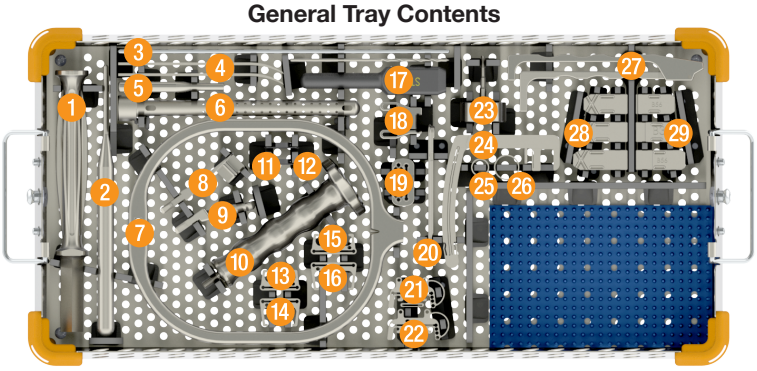
Upon confirmation, remove all K-wires from the Tibial Resection Guide and the Reusable Advanced Cutting Guide, and remove all components from the surgical field.

Remaining Surgical Steps

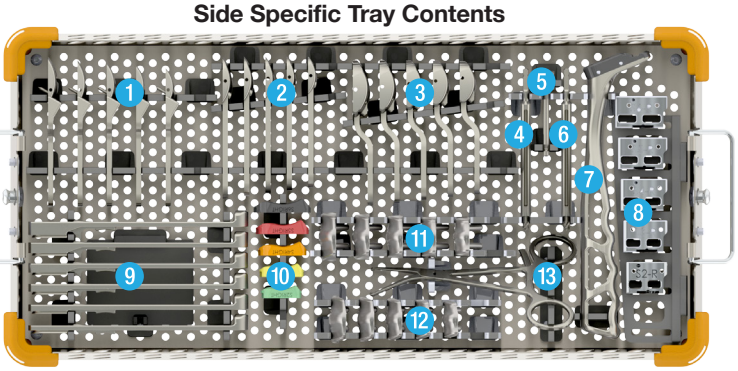
Refer to the Reusable Instruments Surgical Technique for the remaining surgical steps, beginning with the Final Talar Preparation section for the appropriate style talar component.

Instrumentation

General Tray Contents



Side Specific Tray Contents



General Tray Contents

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

Side Specific Tray Contents

1. Talar Chamfer Resection Guides

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

2. Standard Talar Templates

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

3. Flat-Cut Talar Templates

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

Side Specific Tray Contents Continued...

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

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

9. Insert Trial Plates

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

10. Insert Trials

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

11. Flat-Cut Talar Trials

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

12. Standard Talar Trials

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

13. Implant and Trial Holder M05 00741

Drills and K-Wires

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

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

General Information

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

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

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

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

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

Examination of the healthy side should be used for comparison.

Key planning elements defined from the anterior view:

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

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

Key planning elements defined from the lateral view:

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

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

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

Indications / Contraindications

INDICATIONS:

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

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

CONTRAINDICATIONS:

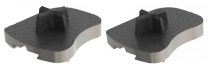
The QUANTUM Total Ankle Prosthesis is contraindicated for the following conditions:

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

In2Bones®, as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. This Surgical Technique Manual is furnished for information purposes as an aid to properly use the device and its dedicated instruments.

Ordering Information

QUANTUM® Tibial Implants



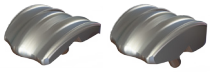
STANDARD

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

LONG

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

QUANTUM® Talar Implants



STANDARD

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

FLAT-CUT

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

QUANTUM® Tibial Fixed Inserts

SIZE 2

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

SIZE 3

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

SIZE 3 Continued

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

SIZE 4

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

SIZE 4 Continued

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

SIZE 5

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

SIZE 5 Continued

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

SIZE 6

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

REGULATORY INFORMATION
In2Bones, as the manufacturer of this device, does not practice medicine. The surgeon who performs any implant procedure is responsible for determining and using the appropriate surgical techniques for implanting the device in each patient. The Surgical Technique is furnished for information purposes, as an aid to properly use the device and its dedicated instruments.

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

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

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

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