Smith+Nephew

CADENCE◊

Total Ankle Replacement System

Flat Cut Revision Surgical Technique

Table of Contents

Note Bena

The following technique is for informational and educational purposes only. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques according to their own clinical judgment for each of their patients. For more information on the product, including its indications for use, contraindications, and product safety information, please refer to the product's label and the Instructions for Use packaged with the product.

Prior to performing this technique, please consult the Instructions for Use documentation provided with each device for additional health and safety information, including indications, contraindications, warnings and precautions.

Introduction

The CADENCE◊ Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.

The CADENCE Total Ankle System is indicated for use to treat:

- Systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g. degenerative disease)
- Secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved)

CADENCE Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis, provided sufficient bone stock is present.

Note: In the United States, this device is intended for cemented use only.

Note: Outside the United States, this device is intended for cemented or cementless use.

The following conditions present an increased risk of failure:

- Severe osteoporosis; marked bone loss or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Osteomalacia
- Metabolic disorders
- Demonstrates physiological or anatomical anomalies
- Undergoing immunosuppressive therapy
- Malignancy/local bone tumors
- Compromised wound healing
- History of mental illness/instability and non-compliance
- History of drug abuse and/or addiction

Warning: This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.

System Features and Benefits

CADENCE Total Ankle System provides the following features and benefits:

Designed for anatomic fit through[1-3]

Multiple interchangeable implant combinations to treat different patient anatomies[2,5]

Anatomic tibial tray with fibular sulcus[1,3]

Anatomic talar implant with conical axis of rotation[1-4]

Advanced anatomic design through biased poly inserts[5]

Designed for efficiency in the operating room through

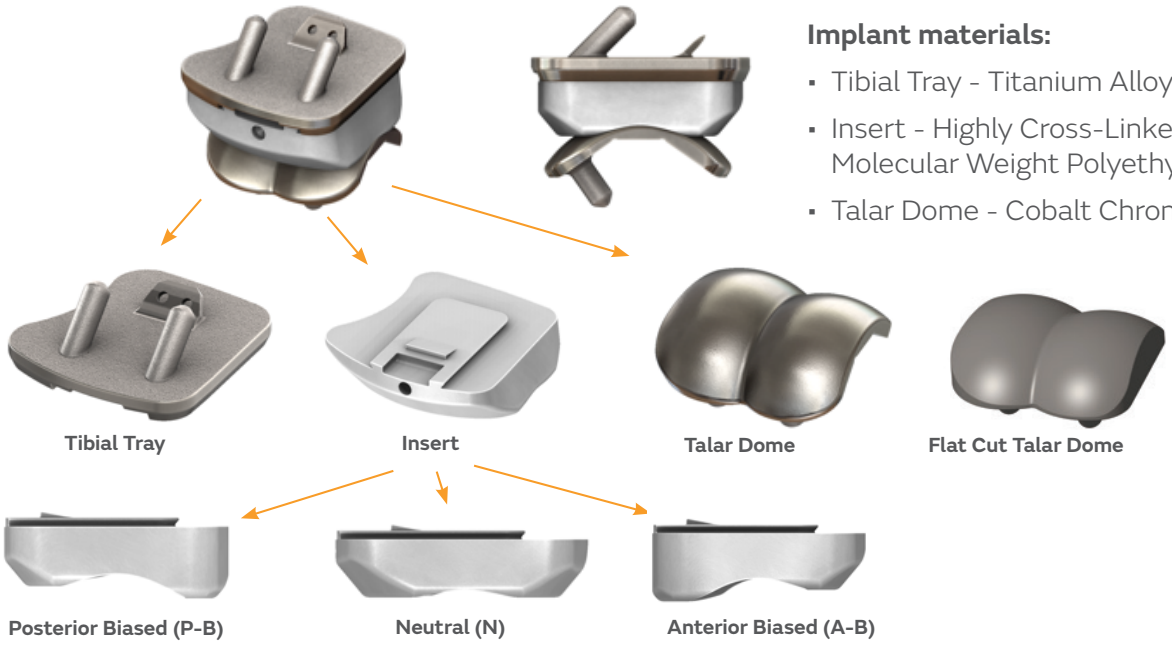
Reproducible implant alignment due to instruments with fluoroscopic cues[5,6,7]

Pins that set the location of multiple guides for talar preparation

Instrument tray layout designed to facilitate procedural flow

The CADENCE◊ Total Ankle System had a faster mean OR time compared to reported OR times of Wright Medical (Stryker) Infinity™ and InBoneTM with Prophecy™ PSI*

*Indirect comparison from published articles[8-10]



Implant materials:

- Tibial Tray - Titanium Alloy (Ti-6Al-4V ELI)
- Insert - Highly Cross-Linked Ultra High Molecular Weight Polyethylene
- Talar Dome - Cobalt Chromium Alloy (CoCrMo)

CADENCE◊ Total Ankle System

Positioning of the Patient

The patient is placed in the supine position with the foot near the end of the table. A bump is placed under the ipsilateral hip to achieve neutral rotation of the operative extremity.

The affected ankle is positioned with a bump under the tibia so that the heel is off of the table.

Surgical Approach

An anterior longitudinal incision is made extending across the midline of the ankle joint to the dorsal medial border of the midfoot.

The retinaculum is identified and incised.

As this dissection is taken inferiorly the ankle joint capsule is exposed, then perform a midline arthrotomy. Medial dissection is taken to the medial gutter so that the medial malleolus and the deltoid ligament can be visualized. Laterally, the dissection is taken so that the anterior inferior tibiofibular syndesmotic ligament and the tubercle of Chaput are visible. The lateral talofibular articulation and the medial aspect of the fibula should be visible by the end of this lateral exposure.

Osteophytes on the tibia are removed, particularly on the antero-lateral aspect. Osteophytes on the talar neck and anterior aspect of the medial malleolus are also removed.

Pin Placement

Tip: For all steps where a bone pin is placed through a guide, check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

This is applicable to the following steps: Step 1-Figure 11, Step 1-Figure 17, Step 3-Figure 28 and 29, Step 3-Figure 30, Step 3-Figure 31, Step 5-Figure 44, Step 5-Figure 45, Step 6-Figure 49, Step 6-Figure 50, Step 9-Figure 59, Step 12-Figure 65 and Step 16-Figure 75.

Make sure to avoid soft tissue structures when pinning the Talar Cut Guide, the Talar Flat Cut Guide, and the 2mm Talar Cut Guide through the most medial and lateral pin holes.

The CADENCE Total Ankle System was developed in conjunction with:

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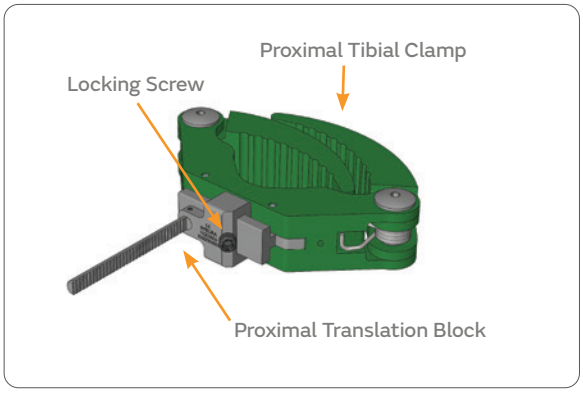


Figure 1

Surgical Technique

Step 1: Tibial Alignment Guide Initial Positioning

Assembly

The Distal Tibial Alignment Block, the Tibial Rod, the Proximal Tibial Clamp, the Rod Connector, and the Proximal Translation Block are assembled on the table before positioning on the patient.

Slide the Proximal Translation Block to the center location of the Proximal Tibial Clamp. **(Figure 1)**

Assemble a hex screwdriver by attaching a Screwdriver Handle to an AO Hex Driver.

Tighten locking screw with the assembled hex screwdriver.

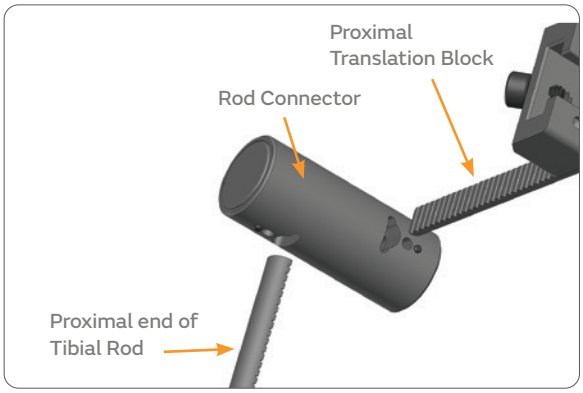


Figure 2

Slide the anterior end of the Proximal Translation Block through mating hole in the Rod Connector. Slide the proximal end of the Tibial Rod through mating hole in the Rod Connector. **(Figure 2)**

Press buttons on both ends of the Rod Connector one at a time to allow the Tibial Rod and Proximal Translation Block to slide freely into position.

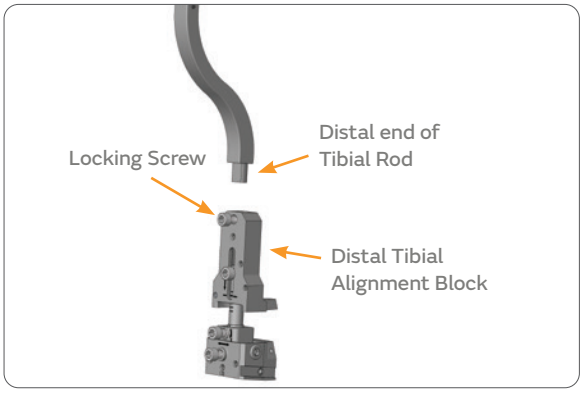


Figure 3

Place distal end of the Tibial Rod into mating hole of the Distal Tibial Alignment Block. Tighten Locking Screw with hex screwdriver. **(Figure 3)**

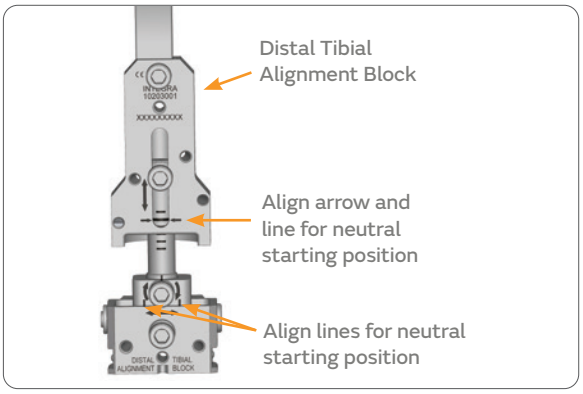


Figure 4

Ensure that the Distal Tibial Alignment Block is placed in its neutral starting positions. **(Figure 4)**

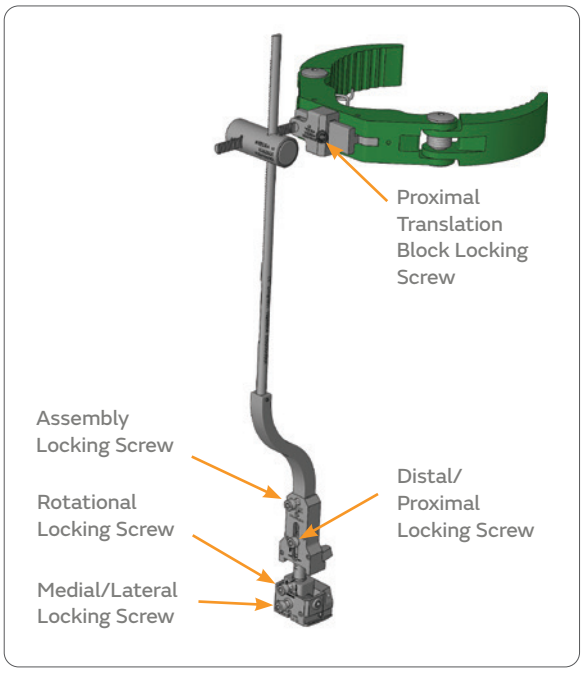


Figure 5

Ensure that the 5 tibial alignment guide Locking Screws are in position and initially locked. **(Figure 5)**

Note: Spare Locking Screws can be found in the Pins and Accessories Module

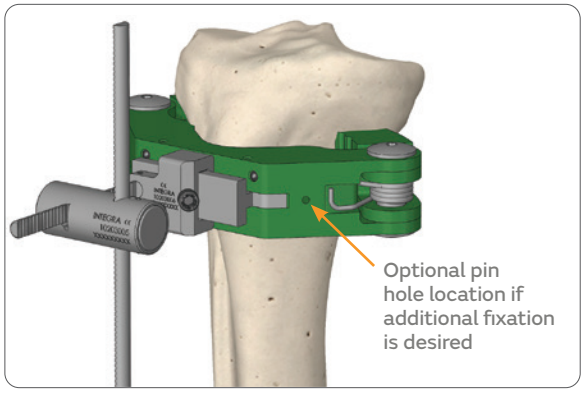


Figure 6

Initial Patient Positioning

The Proximal Tibial Clamp is adjusted to the tibial tuberosity while its arms are held open and then closed around the proximal calf. **(Figure 6)**

Tip: If additional fixation is desired at the Proximal Tibial Clamp, a Long Shouldered Bone Pin may be placed through the medial hole on the clamp.

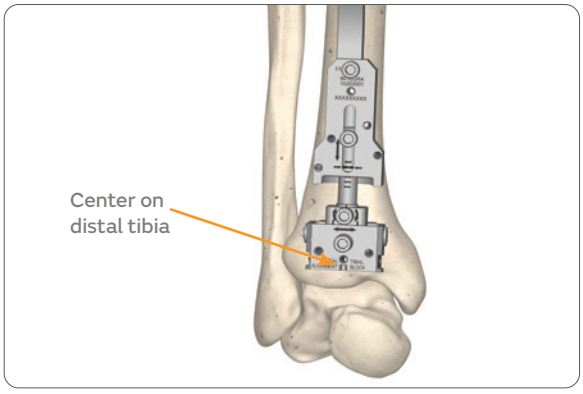


Figure 7

The Distal Tibial Alignment Block is positioned on the center of the distal tibia. The Distal Tibial Alignment Block should sit flush with the distal tibia. **(Figure 7)**

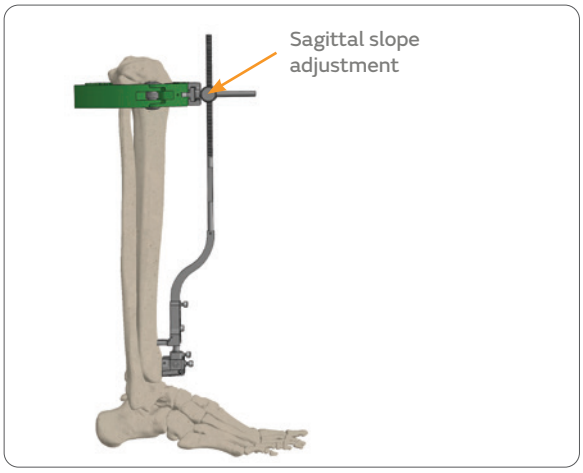


Figure 8

Adjust the Tibial Rod by depressing the Rod Connector button closest to the Proximal Translation Block. Position the rod until it is parallel to the tibia in the sagittal plane. **(Figure 8)**

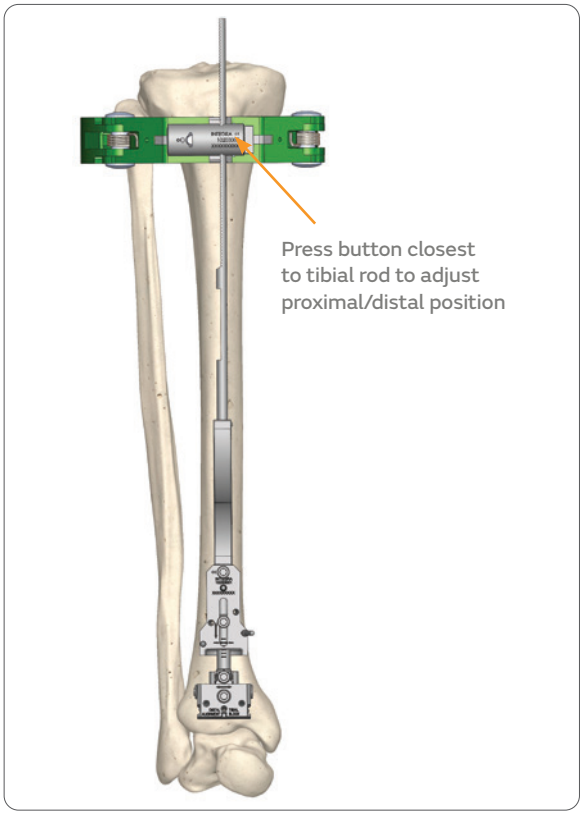


Figure 9

Set Initial Distal/Proximal Resection Height

Align the Gap Sizer with the anterior lip of the distal tibia with "Tibial Side" oriented superiorly. **(Figure 9)**

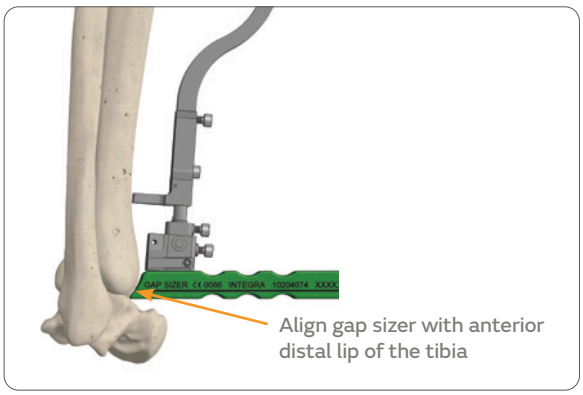


Figure 10

Adjust the initial distal/proximal location of the Distal Tibial Alignment Block by depressing the button on the Rod Connector closest to the Tibial Rod. Bring the Distal Tibial Alignment Block into contact with the proximal surface of the Gap Sizer. **(Figure 10)**

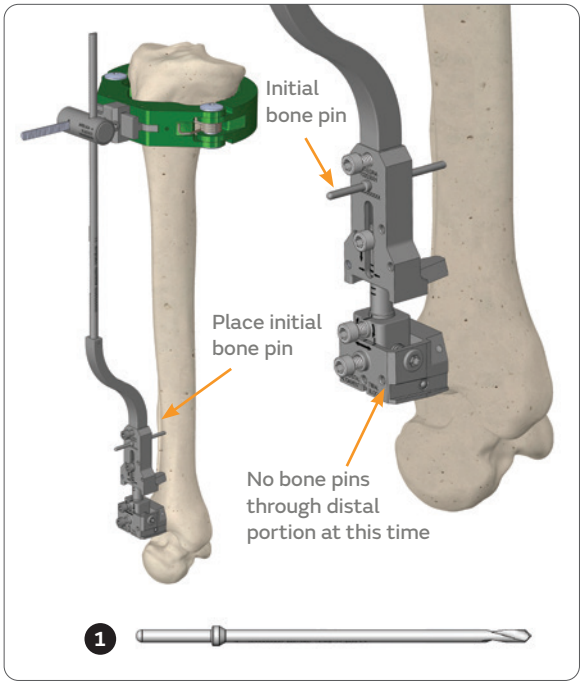


Figure 11

Secure with Bone Pin

Place a Long Shouldered Bone Pin through the proximal portion of the Distal Tibial Alignment Block to hold the position. Do not place a bone pin through the distal portion of the Distal Tibial Alignment Block at this time to allow for fine position adjustments in subsequent steps. **(Figure 11)**

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

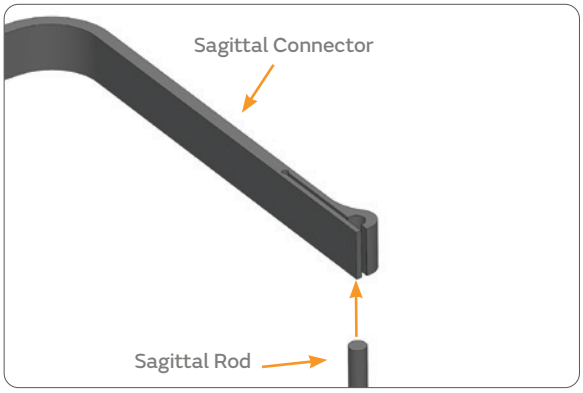


Figure 12

Attach the Sagittal Rod to the Sagittal Connector. **(Figure 12)**

Snap the Sagittal Connector to the Tibial Rod.**(Figure 13)**

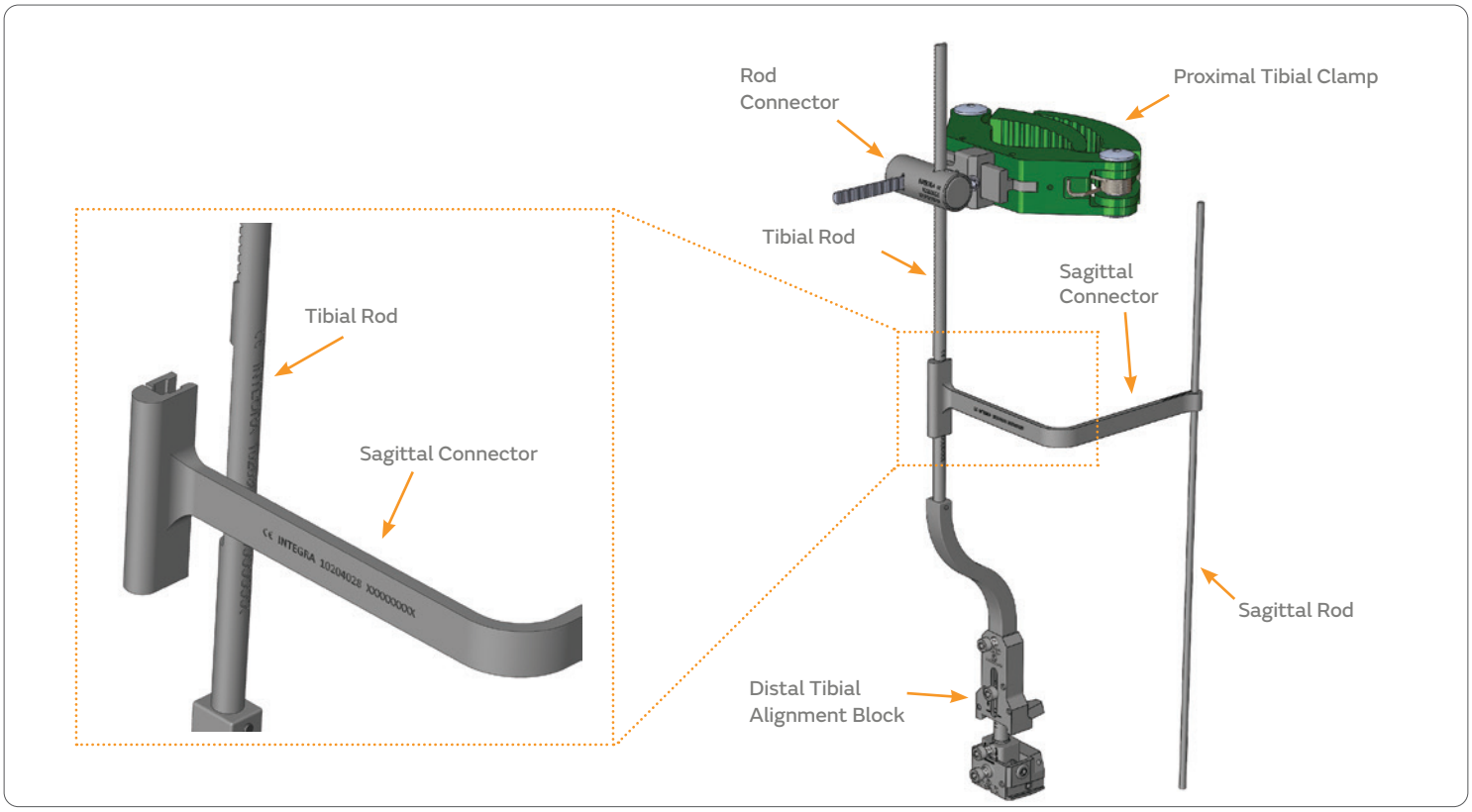


Figure 13

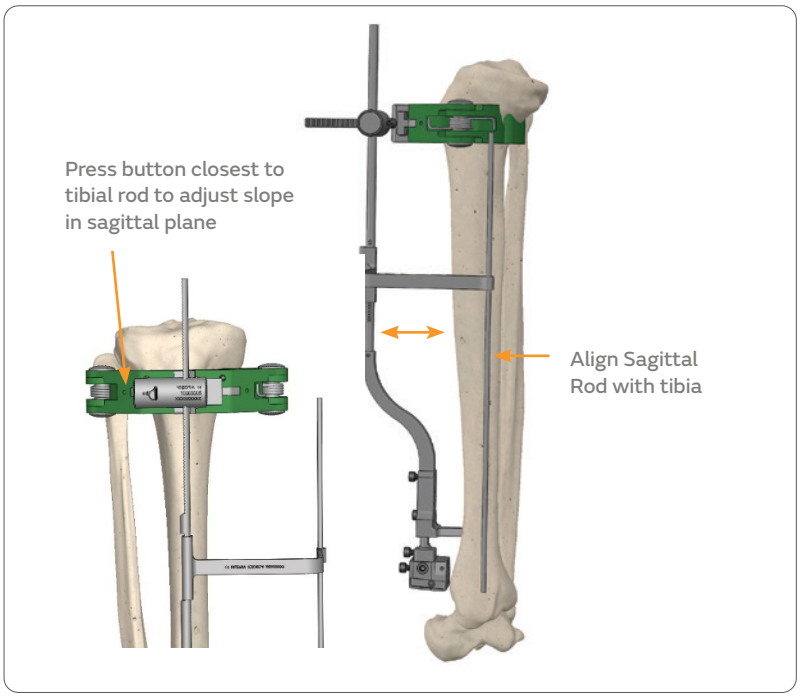


Figure 14

Establish sagittal plane orientation

If needed, adjust the anterior/posterior position of the Rod Connector, to bring the Sagittal Rod in alignment (or parallel) with the axis of the tibia in the sagittal plane. Adjustments can be made by depressing Rod Connector button closest to the Proximal Translation Block. **(Figure 14)**

Confirm using fluoroscopy.

Remove Sagittal Rod and Sagittal Connector.

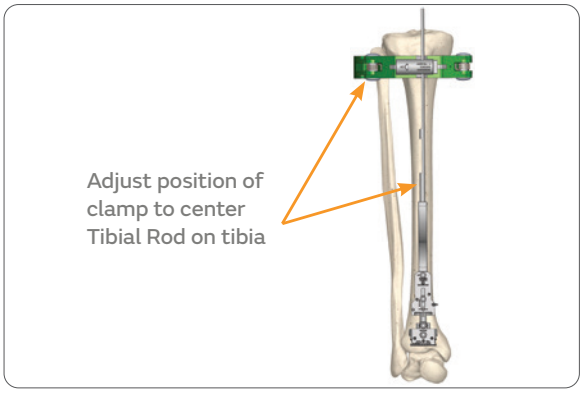


Figure 15

Varus / Valgus Adjustment

Make adjustments, if needed, to the position of the Proximal Tibial Clamp by translating the Proximal Translation Block, pivoting the alignment guide on the distal pin and changing the angle in the coronal plane. Goal is neutral coronal plane alignment for the overall Tibial Alignment Guide. **(Figure 15)**

Confirm using fluoroscopy.

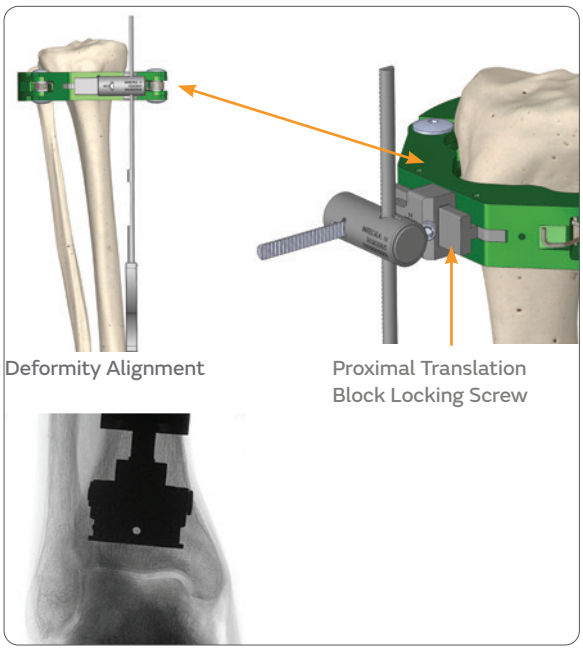


Figure 16

Adjustments can be made after loosening the locking screw on the Proximal Translation Block. Re-tighten the Locking Screw after adjustment. **(Figure 16)**

Note: Medial translation moves the tibial alignment guide into valgus, lateral translation moves the tibial alignment guide into varus.

Tip: To tighten the Proximal Translation Block Locking Screw, it may be necessary to raise the Rod Connector to access the Locking Screw. Return Rod Connector to desired position after securing the Locking Screw.

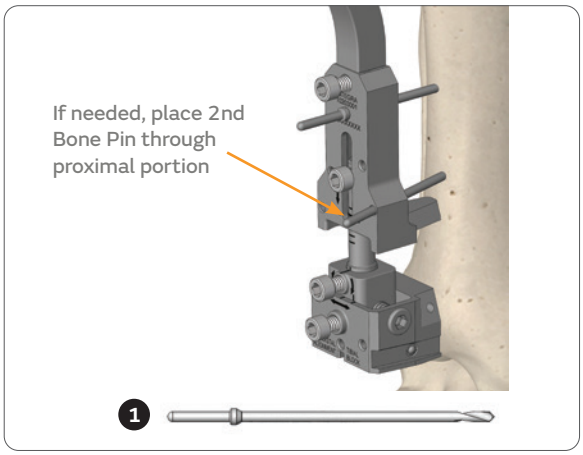


Figure 17

If needed, use a second long shoulder pin through the proximal portion of the Distal Tibial Alignment Block to hold the position. **(Figure 17)**

Tip: If a second pin is placed through the Distal Tibial Alignment Block, no more adjustments can be made in the coronal or sagittal plane for the tibial cut.

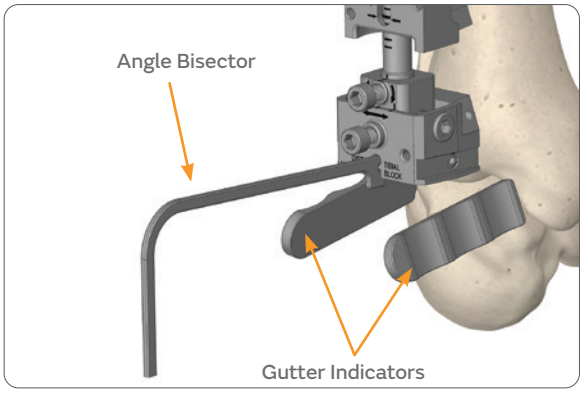


Figure 18

Step 2: Adjust Tibial Alignment Guide

Establish Rotational Alignment

Place the thin end of the Gutter Indicators into both the medial gutter and the lateral gutter. **(Figure 18)**

Place the Angle Bisector into the central hole of the distal portion of the Distal Tibial Alignment Block.

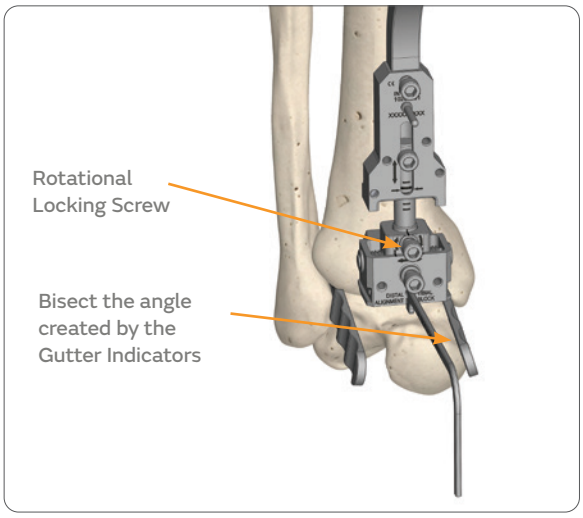


Figure 19

Loosen the Locking Screw that controls rotation and adjust the rotational position of the Distal Tibial Alignment Block to the desired angle and/or until the Angle Bisector bisects the angle created by the two Gutter Indicators. **(Figure 19)**

Lock the rotational Locking Screw after establishing the proper rotational alignment.

Tip: The proper rotational alignment can be double checked by assessing the alignment of the Angle Bisector with the second metatarsal.

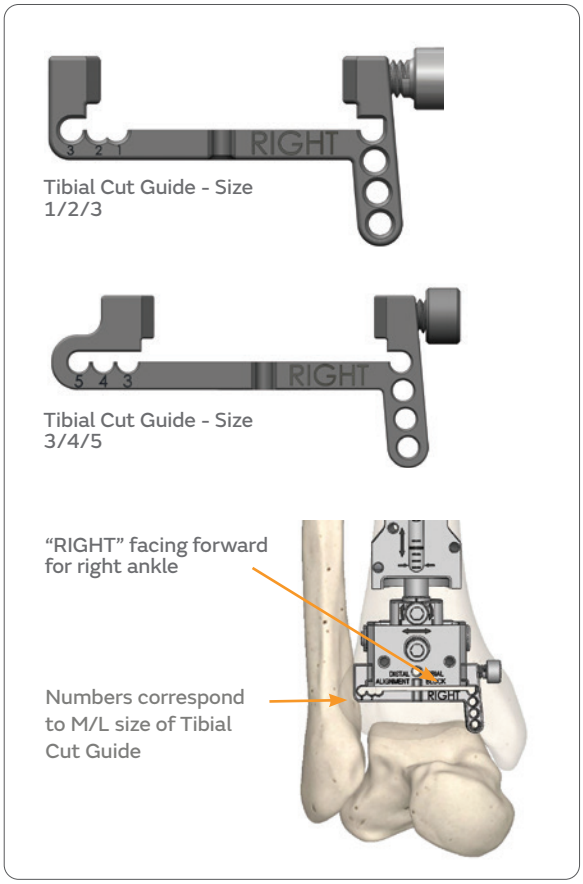


Figure 20

Establish Tibial Resection Level

Depending on the size of the tibia, select either the Size 1/2/3 Tibial Cut Guide or the Size 3/4/5 Tibial Cut Guide. **(Figure 20)**

The most lateral hole on the selected Tibial Cut Guide should be able to extend to at least the medial border of the fibula while the medial holes are aligned with the proximal medial border of the talus. This serves as a gross positional check. Finer Medial/Lateral position adjustments will be made after setting desired resection height. If this position cannot be achieved, select the larger Tibial Cut Guide.

A fluoroscopy check may be necessary to accurately assess the lateral extent of the Tibial Cut Guide in relation to the fibula. Perfect circles should be seen through the lateral holes on the Tibial Cut Guide under fluoro.

Slide selected Tibial Cut Guide onto the Distal Tibial Alignment Block until the anterior face of the cut guide is flush with the anterior face of the Distal Tibial Alignment Block. Tighten the Locking Screw on the Tibial Cut Guide

(Figure 20)

Tip: The marking signifying the correct side ("LEFT" or "RIGHT") should be facing forward when in position (i.e. If a right ankle, the word "RIGHT" should be on the anterior side of the Tibial Cut Guide when placed in position).

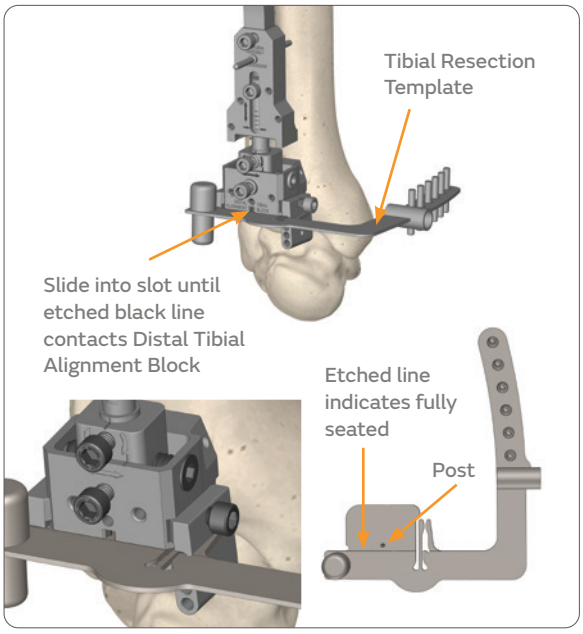


Figure 21

Place the Tibial Resection Template into the slot of the selected Tibial Cut Guide. Advance Tibial Resection Template until the etched black line contacts the Distal Tibial Alignment Block. **(Figure 21)**

Tip: The post on the Tibial Resection Template should slide into either the slot in the Distal Tibial Alignment Block or the slot in the Tibial Cut Guide to ensure that the Tibial Resection Template is securely seated.

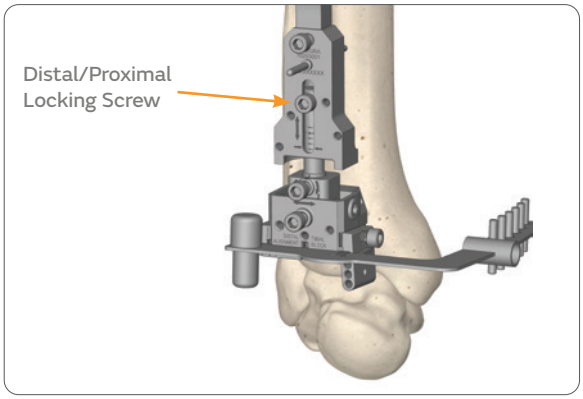


Figure 22

Loosen the distal/proximal Locking Screw on the Distal Tibial Alignment Block. **(Figure 22)**

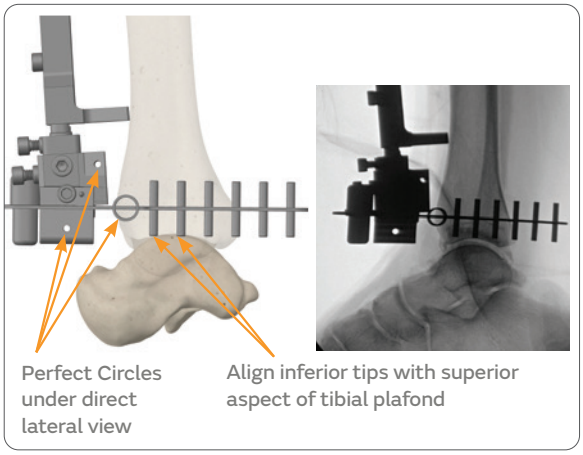


Figure 23

Using fluoroscopy, adjust the distal/proximal location of the Tibial Cut Guide until the inferior tips of the posts on the Tibial Resection Template are aligned with the most superior aspect of the distal tibial plafond. **(Figure 23)**

Tip: A direct lateral view during this step is critical to ensure the proper amount of tibial resection. The fluoroscopy targets on both the Tibial Cut Guide and the Tibial Resection Template will be perfect circles under a direct lateral view.

Tip: The posts on the Tibial Resection Template may be used to assess sagittal plane alignment relative to the long axis of the tibia. If needed, adjust the slope on the tibial alignment guide.

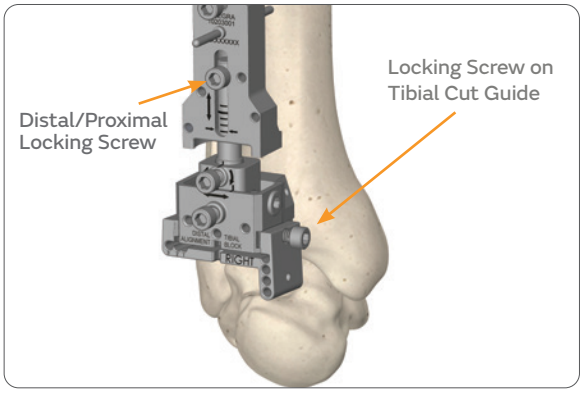


Figure 24

Once the proper distal/proximal location is achieved, lock the distal/proximal Locking Screw on the Distal Tibial Alignment Block and remove the Tibial Resection Template. **(Figure 24)**

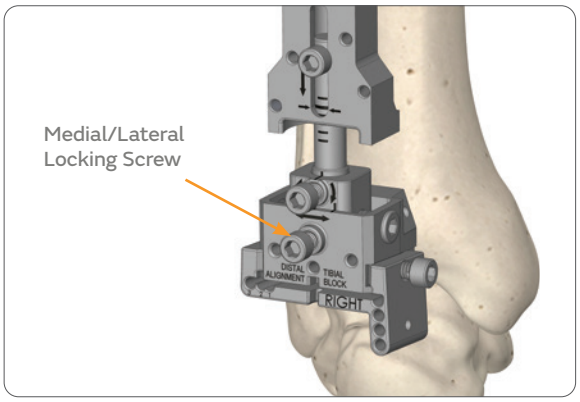


Figure 25

Loosen the medial/lateral Locking Screw on the Distal Tibial Alignment Block. **(Figure 25)**

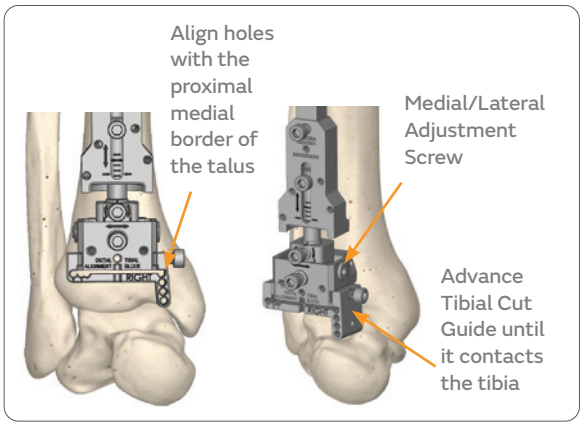


Figure 26 Figure 27

Using the medial/lateral adjustment screw on the Distal Tibial Alignment Block, align centers of the medial holes of the Tibial Cut Guide with the proximal medial border of the talus. Once proper medial/lateral location is achieved, tighten the Medial/Lateral Locking Screw on the Distal Tibial Alignment Block. Loosen the Locking Screw on the Tibial Cut Guide, then advance the cut guide until it contacts the tibia. Tighten the Locking Screw to re-secure the cut guide. **(Figure 26 and 27)**

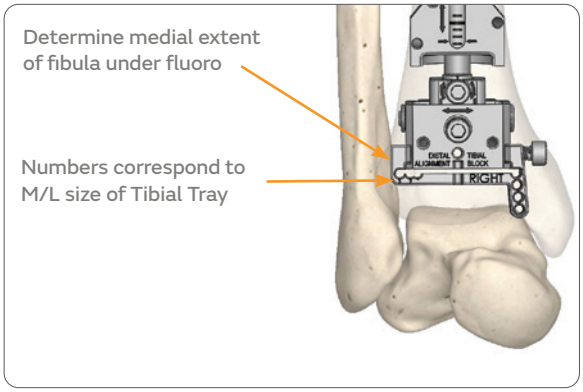


Figure 28

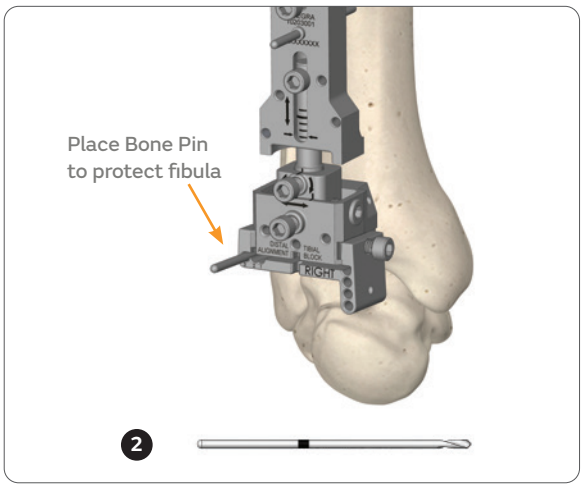
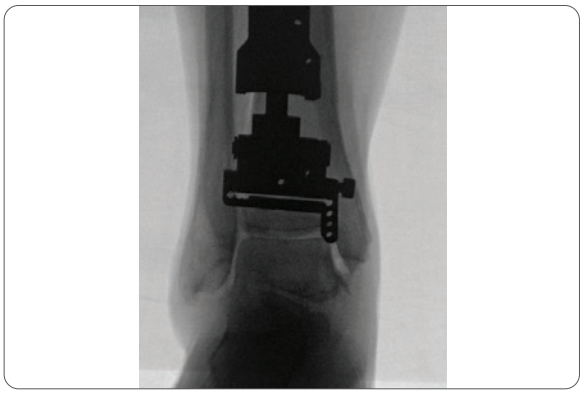


Figure 29



Step 3: Tibial Bone Resection

Using fluoroscopy, confirm the medial holes of the Tibial Cut Guide are aligned with proximal medial border of the talus. Ensure that perfect circles through the medial pin holes of the Tibial Cut Guide are seen under fluoroscopy.

Determine the medial extent of the fibula and place a Short Straight Bone Pin into the most lateral bone pin position possible in the Tibial Cut Guide without hitting or damaging the fibula. Ensure that perfect circles through the lateral pin holes of the Tibial Cut Guide are seen under fluoroscopy. **(Figure 28 and Figure 29)**

Tip: The fibula is posterior and medial to the tubercle of Chaput. Cutting straight posterior from this point would transect the fibula.

Tip: The numbers marking the lateral bone pin positions on the Tibial Cut Guide correspond to the medial/lateral widths of the tibial implants. The bone pin position selected during this step can be used to provide an initial assessment of the correct tibial implant size to be used.

Warning: Do not use the Straight Bone Pin - Drill Tip on any holes in line with the saw slot of the Tibial Cut Guide; use of this pin may result in damage to pin and instrumentation.

Tip: A Long Shouldered Bone Pin may be inserted through the distal portion of the Distal Tibial Alignment Block for added stability during the tibial cut.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

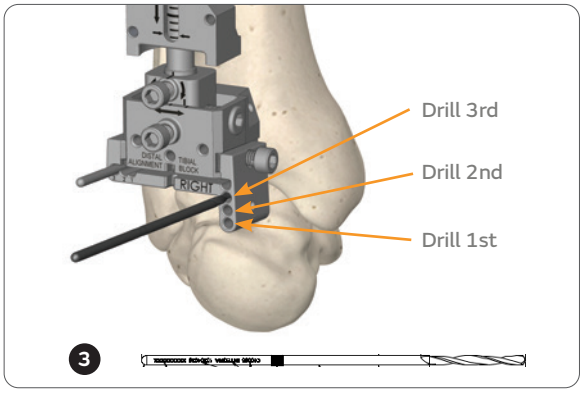


Figure 30

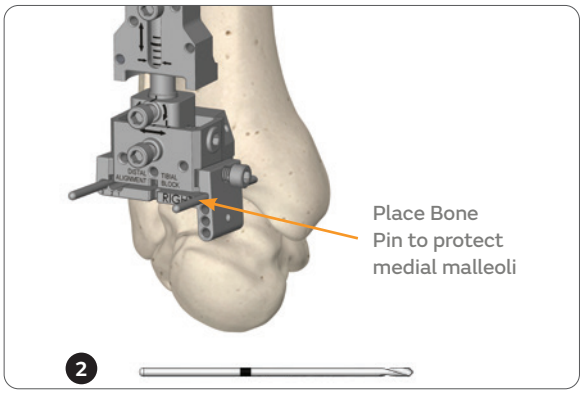


Figure 31

Marking the Resection and Protecting the Malleoli

Using a Straight Bone Pin – Drill Tip, mark the medial resection line of the distal tibia by drilling bicortically through each of the three medial distal holes on the Tibial Cut Guide. **(Figure 30)**

Tip: Drill distal holes first, proximal hole last.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

Place a Short Straight Bone Pin in the hole adjacent to the saw slot to protect the medial malleoli during resection **(Figure 31)**

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

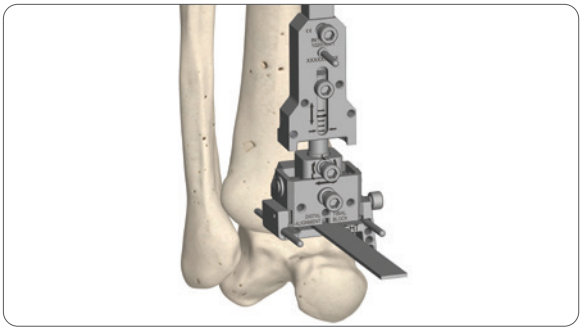


Figure 32

Cutting Bone

A 1.27mm thick oscillating saw blade is recommended to carefully cut through the posterior cortex of the tibia. **(Figure 32)**

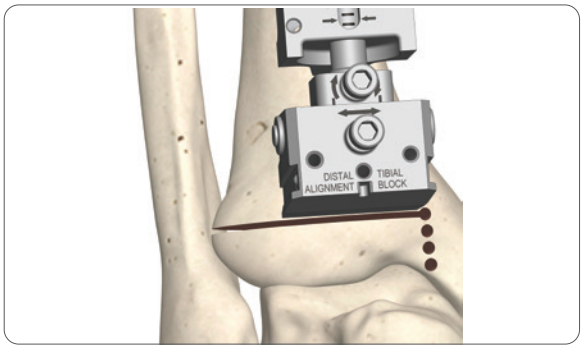


Figure 33

After completing the saw cut, remove the Tibial Cut Guide and the Short Straight Bone Pins to gain access to the resected tibial bone. Using general instruments, ensure that the saw cut is extended laterally through the Tubercle of Chaput. Ensure that the depth of resection reaches but does not violate the fibula. **(Figure 33)**

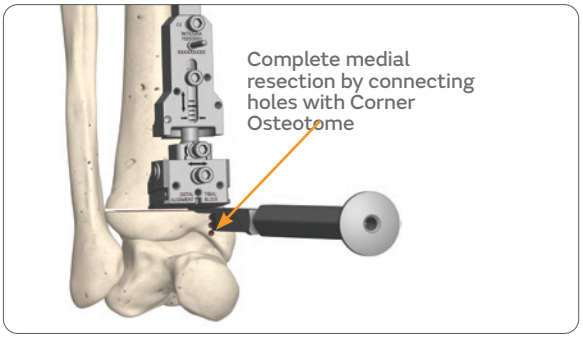


Figure 34

Complete the medial resection of the tibia by cutting the bone remaining between the previously drilled holes with the Corner Osteotome. **(Figure 34)**

Tip: A reciprocating saw may also be used to complete the medial resection of the tibia.

Warning: Do not lever medial-lateral with the corner osteotome; levering medial-lateral increases risk of fracturing medial malleolus.

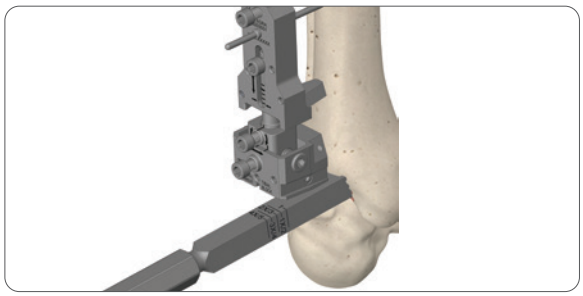


Figure 35

Tip: Check etchings on the Corner Osteotome, which correspond to AP depth of implants, to ensure sufficient bone is resected and avoid over-insertion.

The Slap Hammer may be used to assist in extracting the Corner Osteotome from bone. **(Figure 35)**

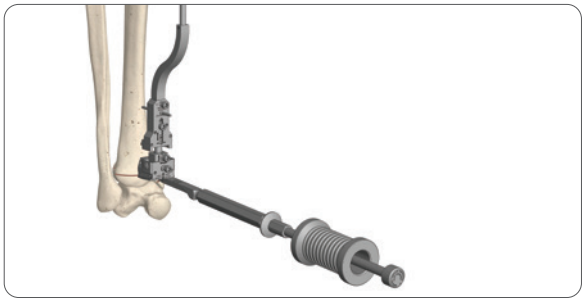


Figure 36

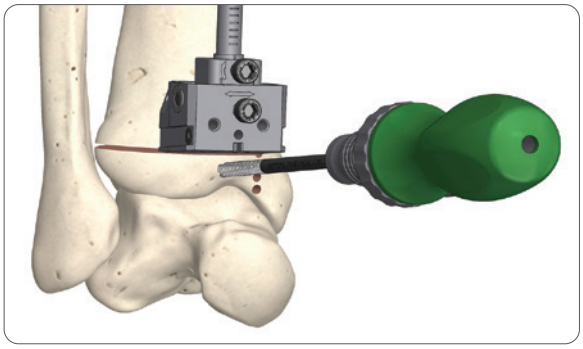


Figure 37

Remove Resected Bone

Using osteotomes, rongeurs, or other surgical instruments remove the resected tibial bone. **(Figure 36)**

Alternatively, the 5.0mm Diameter Bone Pin can be used in conjunction with the Screwdriver Handle to obtain leverage on the resected tibial bone and aid in removal. The 5.0mm Diameter Bone Pin should be driven bicortically. **(Figure 37)**

Warning: The 5.0mm Diameter Bone Pin should be inserted parallel to the tibial resection to avoid gouging the distal tibia by protruding through the proximal surface of the tibial resection during placement.

Warning: Be careful not to apply medially or laterally directed force to remove the resected bone. Internal and external rotation levering can put the malleoli at risk for fracture.

Tip: It is often easier to remove the posterior aspect of the tibial resection after the flat cut has been made on the talus. (See step 5) Removal of enough of the anterior aspect of the tibial resection to allow full placement of the Talar Flat Cut Guide is required at this time. As a check, the flat section of the selected Talar Flat Cut Guide should sit on top of the talus.

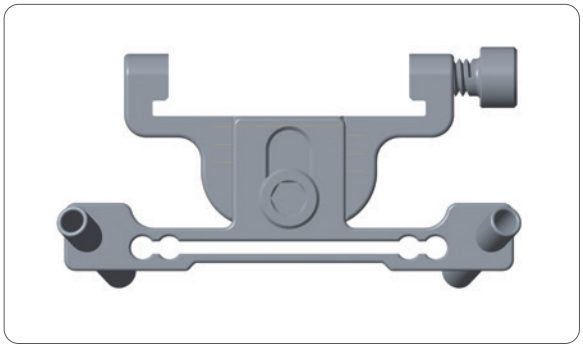


Figure 38

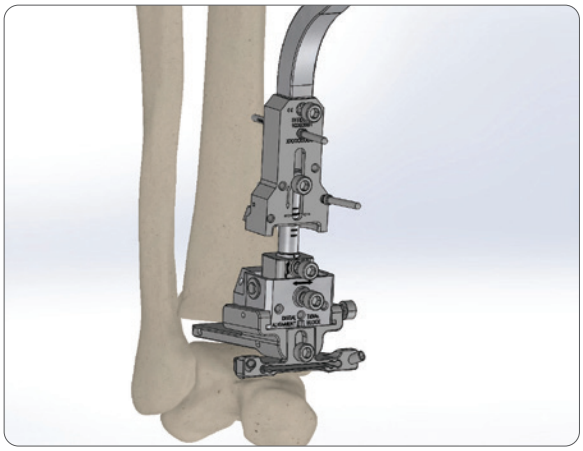


Figure 39

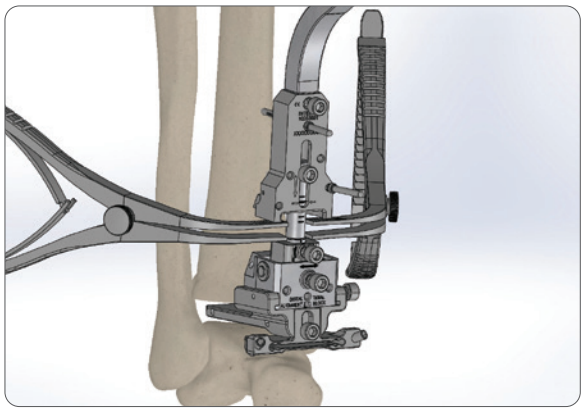


Figure 40

Step 4: Preparing for Flat Cut Talar Resection

Note: If any bone pins were placed through the distal-most portion of the Distal Tibial Alignment Block, they must be removed at this time.

Loosen the Distal/Proximal Locking Screw on the Distal Tibial Alignment Block. Place talar flat cut guide into position on the Distal Tibial Alignment Block. Advance the cut guide on the Distal Tibial Alignment Block until it contacts bone. **(Figure 38)**

Note: If there is uneven wear on the talar dome, remove the cartilage from the unworn condyle of the talus prior to placing the talar flat cut guide.

Secure the Locking Screw on the Talar Flat Cut Guide. **(Figure 39)**

Using the two Lamina Spreaders, extend the Talar Flat Cut Guide as far distally as possible until the collateral ligaments are tensioned and the Talar Flat Cut Guide is compressed against the underlying talus. **(Figure 40)**

Note: It may be necessary to remove any osteophytes from the talar neck at this time to ensure that the flat cut guide can travel as far distally as needed.

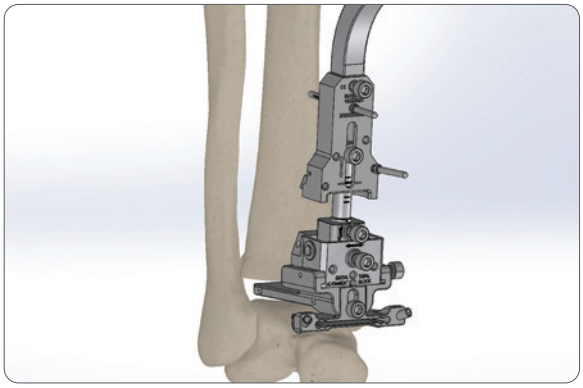


Figure 41

Lock the distal/proximal Locking Screw on the Distal Tibial Alignment Block. Remove Lamina Spreaders. **(Figure 41)**

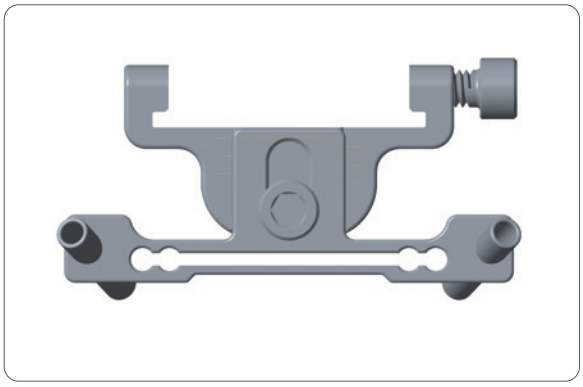


Figure 42

The level of talar resection may be evaluated under lateral fluoroscopy by either placing a free saw blade through the Talar Flat Cut Guide saw slot or a bone pin through a hole in line with the saw slot. Resection level may be adjusted by loosening the Locking Screw on the front of the Talar Flat Cut Guide until desired resection height is achieved. **(Figure 42)**

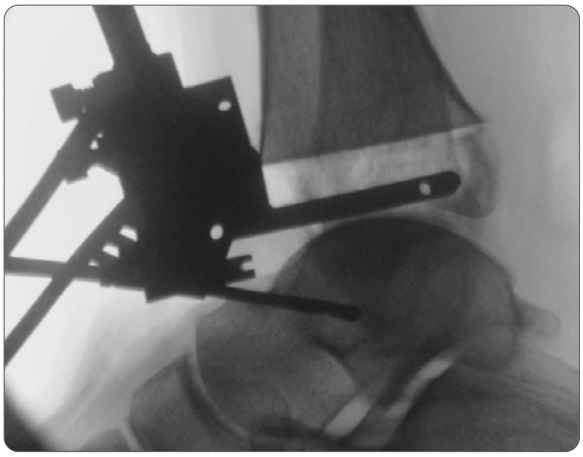


Figure 43

Alignment of the hindfoot in the sagittal plane is checked visually. Neutral dorsiflexion of the hindfoot is the desired position. A lateral fluoroscopy view should be obtained to confirm talar position in the sagittal plane. A perfect circle should be seen through both the paddle of the cut guide and the Distal Tibial Alignment Block to ensure true lateral view. The slope of the paddle represents slope of talar cut, which should be parallel to prior tibial resection. **(Figure 43)**

Note: The markings on the front of the guide are offset from each other and represent 1mm increments of talar resection.

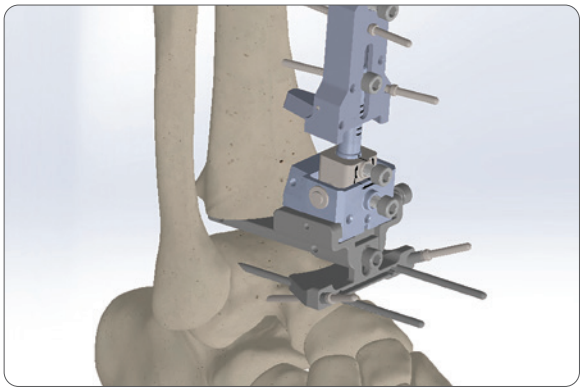


Figure 44

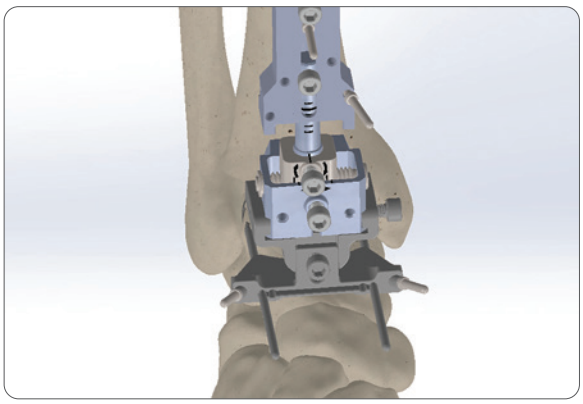


Figure 45

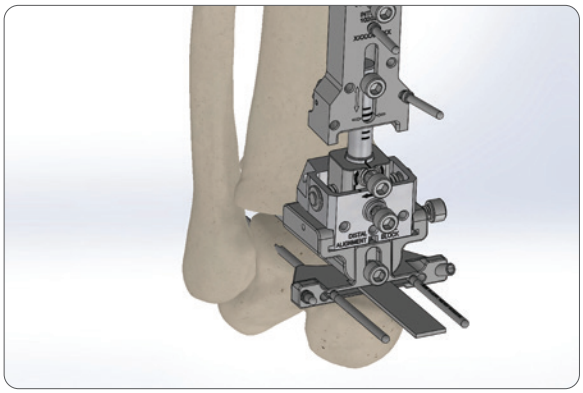


Figure 46

Figure 47

Step 5: Talar Bone Resection

Marking the Resection and Protecting the Malleoli

While the foot is held in neutral plantigrade position, insert two Medium or Long Shouldered Bone Pins through the Talar Flat Cut Guide and into the talus using the outermost holes. **(Figure 44)**

Tip: If Long Shouldered Bone Pins are used it may be necessary to advance the pins under fluoroscopic view to ensure they do not breach the subtalar joint.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

Insert a Short Straight Bone Pin on both the medial side and the lateral side of the saw slot of the Talar Flat Cut Guide. This is to protect the malleoli while performing the talar resection; Bone Pins should be placed in positions that allow the entire proximal surface of the talus to be resected while still preventing damage to the malleoli. **(Figure 45)**

Warning: Do not use the Straight Bone Pin - Drill Tip on any holes in line with the saw slot of the Tibial Cut Guide; use of this pin may result in damage to pins and instrumentation.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

Cutting Bone

A narrow width 1.27mm thick oscillating saw blade is recommended to carefully cut through the posterior cortex. **(Figure 46)**

Remove all bone pins, Talar Flat Cut Guide, and the entire Tibial Alignment Guide.

Remove Resected Bone

Using osteotomes, rongeurs, or other surgical instruments, remove all resected talar bone and any remaining resected tibial bone. Take care to protect both the medial and lateral malleoli from inadvertent fracture during this process. **(Figure 47)**

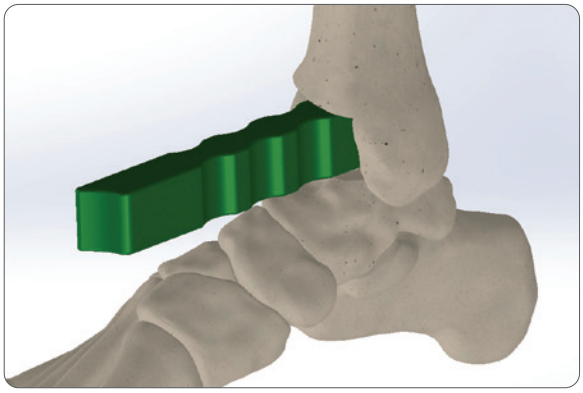


Figure 48

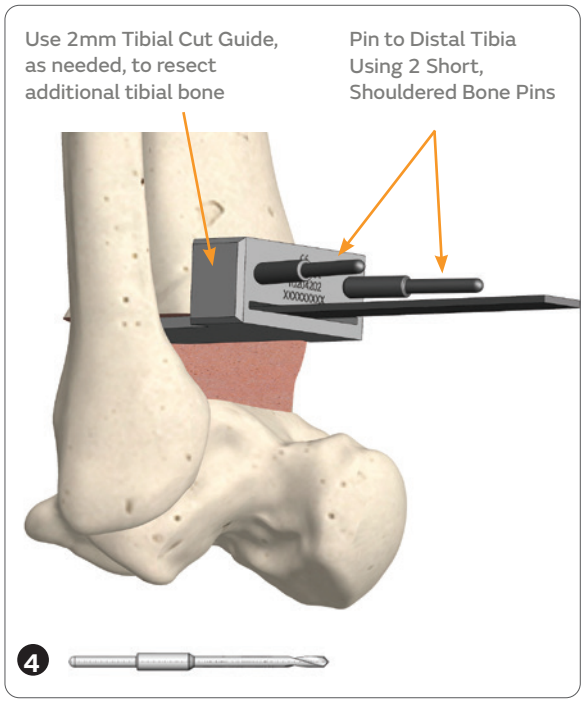


Figure 49

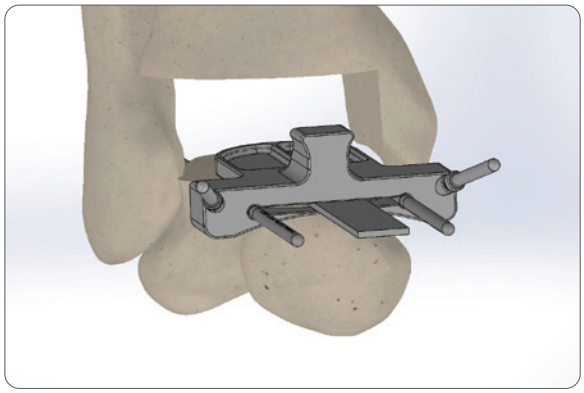


Figure 50

Step 6: Verify Required Implant Gap

Use the Gap Sizer to ensure that sufficient tibial and talar bone has been resected. Position the Gap Sizer so that the finger grooves are oriented vertically and are facing in the medial and lateral directions. Reference **Figure 48** for correct orientation.

Note: The height of the Gap Sizer represents minimum resection for a Size 2 Flat Cut Talar Dome with 6mm Poly. The Flat Cut Talar Domes increase by 0.5mm in height with each size increase.

If additional bone resection is needed, attach either the 2mm Tibial or 2mm Talar Cut Guide.

2mm Tibial Cut Guide:

Using a Lamina Spreader in the posterior aspect of the ankle joint, ensure that the 2mm Tibial Cut Guide is opposed to the overlying tibia throughout the length of the cut tibial surface. **(Figure 49)**

Pin the 2mm Tibial Cut Guide to the distal tibia using two Short Shouldered Bone Pins. Perform the additional tibial resection, extending carefully to the back, through the posterior cortex. A 1.27mm thick saw blade is recommended for this step. Repeat this process as needed until the minimum amount of bone has been resected.

Remove 2mm Tibial Cut Guide and Bone Pins after desired bone is resected. Recheck resulting gap with Gap Sizer.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

2mm Talar Cut Guide:

Place the 2mm Talar Cut Guide in the joint space. Ensure the guide is flat on the talus. This may be checked visually using a lateral fluoroscopic view. Laminar spreaders may be used for this purpose. Pin the guide to the talus using the outermost pin holes with Medium Shouldered Bone Pins. If desired, Short Straight Bone Pins may be placed in the saw slot to protect medial and lateral malleoli from the oscillating sweep of the saw blade. Perform the resection through the saw slot. A 1.27mm thick saw blade is recommended for this step. Remove the pins from the guide and remove guide from the joint space. **(Figure50)**

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

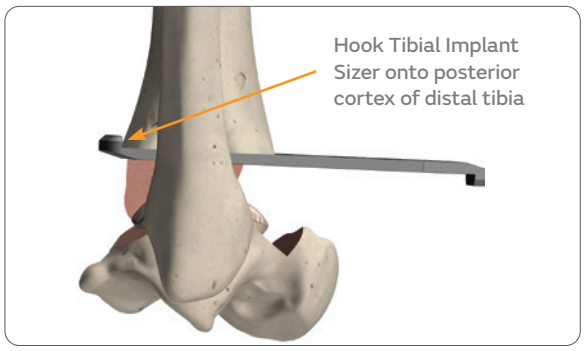


Figure 51

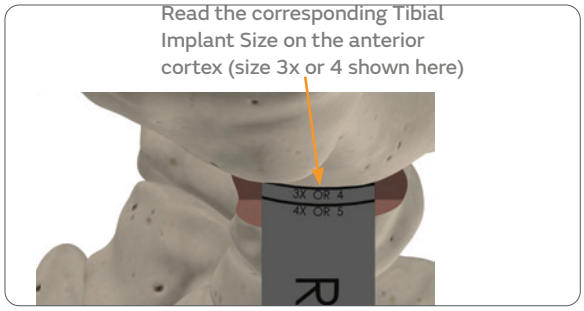


Figure 52

Step 7: Tibial Component Sizing

Use the Tibial Implant Sizer to measure the anterior/posterior length of the distal tibia. Ensure that the correct side, "RIGHT" or "LEFT" is facing up on the Tibial Implant Sizer. **(Figure 51)**

With the Tibial Implant Sizer hooked onto the posterior cortex of the distal tibia, determine the line on the Tibial Implant Sizer that most closely approximates the anterior cortex of the distal tibia and read the corresponding tibial implant size. **(Figure 52)**

Tip: Confirm sizing at multiple sections along the resected tibia. The smallest size of the readings should be chosen to avoid extending the baseplate into the soft tissue.

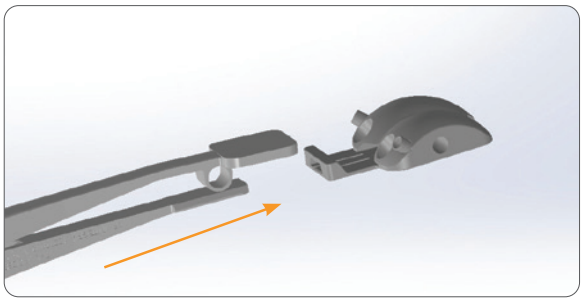


Figure 53

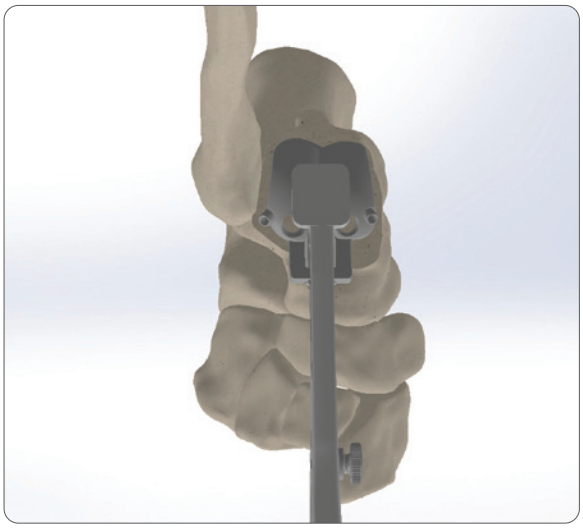


Figure 54

Step 8: Select Talar Dome Size

Select a Flat Cut Talar Trial and insert into the Talar Sizer Holder. Slide tip of Talar Sizer Holder into the selected Talar Trial until it "clicks." **(Figure 53)**

Place the selected Flat Cut Talar Trial onto the cut surface of the talus. The size and shape of the Talar Trial corresponds to the size and shape of the talar implant component. **(Figure 54)**

Tip: For optimal sizing, the outer surfaces of the Talar Trial should match the outer edge of the talar bone in both the medial/lateral and anterior/posterior directions.

Note: If patient anatomy is in between two sizes, select the smaller size.

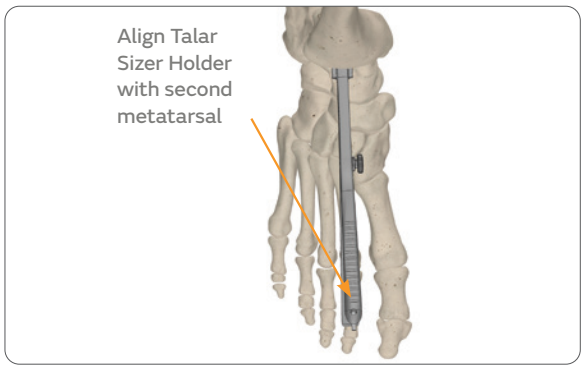


Figure 55

Step 9 ▪ Flat Cut Talar Trial Placement

Align Sizers

After choosing the proper size, establish the proper rotational alignment of the selected Talar Trial by aligning the handle of the Talar Sizer Holder with the desired rotational position set in Step 2-Figure 19. **(Figure 55)**

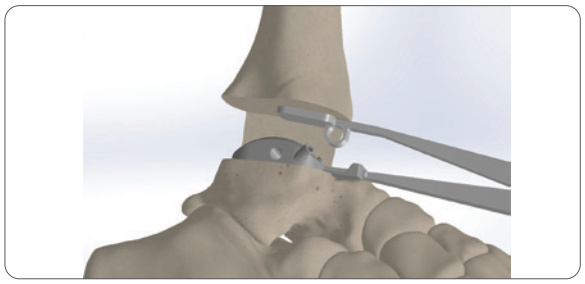


Figure 56

With the foot in neutral, expand the Talar Sizer Holder against the distal tibia to maintain the proper medial/lateral, anterior/posterior, and rotational alignment of the Talar Trial. **(Figure 56)**

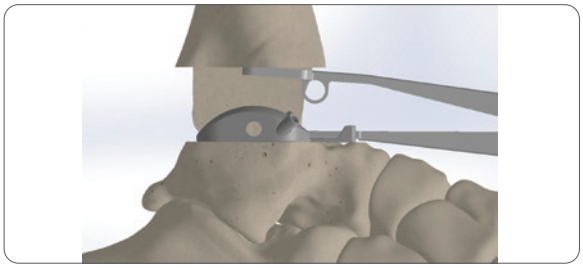


Figure 57

Using fluoroscopy, check both the anterior/posterior and medial/lateral alignment of the Talar Trial. Ideally, the radius of curvature of the simulated articular surface of the Talar Trial should blend smoothly with the posterior radius of curvature of the natural talus. The medial and lateral borders of the talar trial should align with the medial and lateral cortical borders of the talus.**(Figure 57 and 58)**

Note: The perfect circle in the Talar Trial represents the AP center point of the trial.

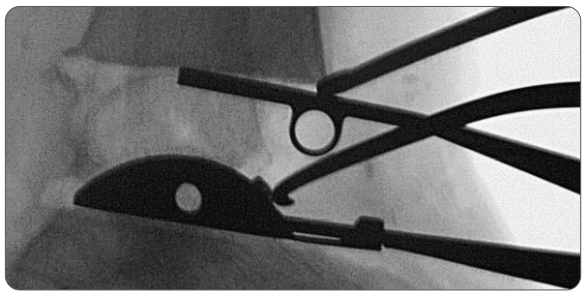


Figure 58

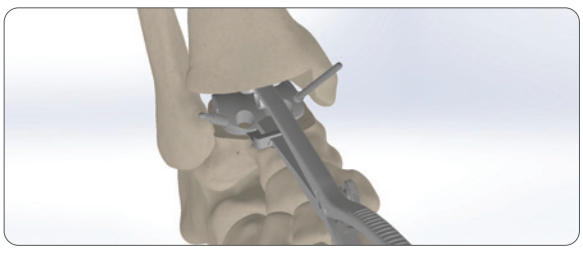


Figure 59

Pin the trial to the talus using Short Shouldered Bone Pins. Disengage and remove the Talar Sizer Holder. **(Figure 59)**

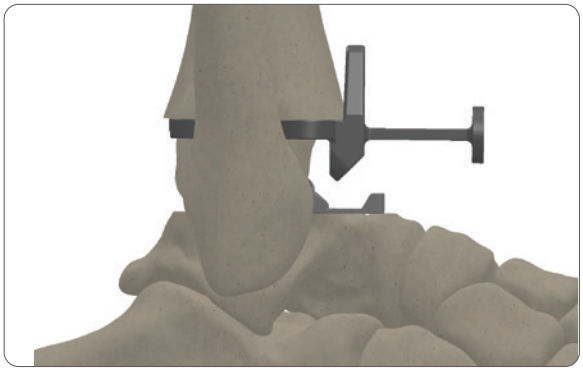


Figure 60

Step 10: Select Tibial Tray Size

Select the Tibial Trial corresponding to the lateral pin placed through the Tibial Cut Guide during the tibial resection (Step 3-Figure 28 and 29) and the A/P length determined from the Tibial Implant Sizer (Step 7).

Place the selected Tibial Trial into the joint space and confirm appropriate coverage. Use the chart below to aid in choosing the proper tibial implant size. **(Figure 60)**

Warning: Avoid oversizing; if the Tibial Trial fits snug into the joint space with little to no space to move, consider downsizing one size.

Selected Talar implant size					M/L Width Determined by Tibial Tray Trial	A/P Length Determined from Tibial Implant Sizer	Recommended Tibial Tray Implant size
1					1	1	1
					1	1x or 2	1x
	2				2	1x or 2	2
					2	2x or 3	2x
		3			3	2x or 3	3
					3	3x or 4	3x
			4		4	3x or 4	4
					4	4x or 5	4x
				5	5	4x or 5	5*

Note: "X" sizes have the same ML width as the corresponding standard size but have the same AP length as the next standard size up. Example, Size 1X has the same ML width as Size 1 but the AP length of Size 2.

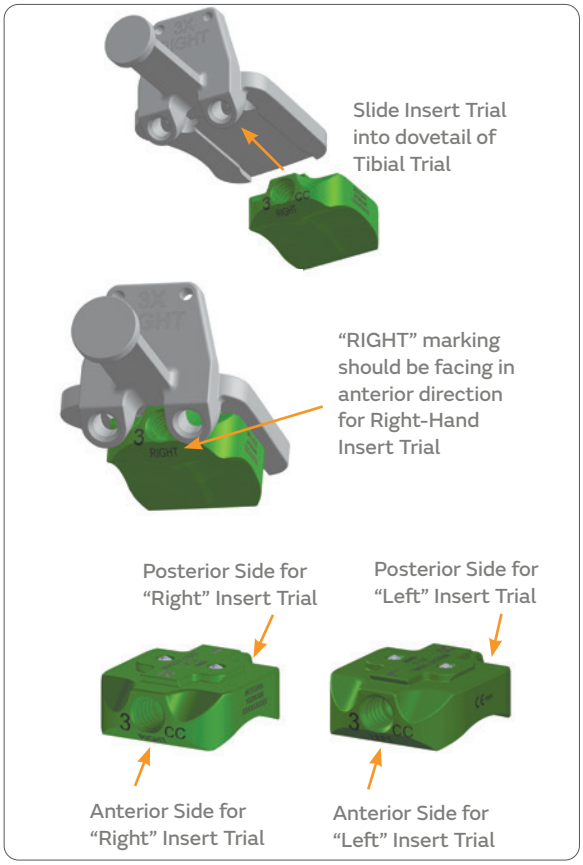


Figure 61

Step 11: Place Tibial Tray Trial with Insert Trials

Select the Tibial Trial corresponding to chosen tibial implant size (Step 10).

Select the Insert Trial corresponding in size to the Talar Trial placed on the talus (Step 9). For example, if a Size 4 Talar Trial was placed on the talus, choose a Size 4 Insert Trial. Initially, choose the 6mm thickness of the Insert Trial for evaluation of joint spacing and kinematics.

Slide the Insert Trial into the dovetail of the Tibial Trial. **(Figure 61)**

Tip: The Insert Trials are reversible and can be used as either a right-hand or left-hand Insert Trial. When selecting a right-hand Insert Trial, the "RIGHT" and "R" markings should be facing in the anterior direction. When selecting a left-hand Insert Trial, the "LEFT" and "L" markings should be facing in the anterior direction.

Tip: Use of the Joint Distractor may be necessary to place Insert Trials. Place one tip of the Joint Distractor on the tibia and one on the talus. Place one Long, Shouldered Bone Pin through each of the tips and into the bone. Then, expand the Joint Distractor to open the joint space.

Biased Inserts

Tip: CADENCE Total Ankle System also features Anterior Biased Insert and Posterior Biased Insert implants to provide additional joint constraint/support on patients with either an anterior or posterior subluxed talus.

If it is determined through a lateral, fluoroscopic evaluation of the implant trials that the patient may benefit from the use of an Anterior or Posterior Biased Insert implant, the Biased Insert Trial Extensions can be used to evaluate their benefit and make a final determination if biased insert implants should be used.

Choose the Biased Insert Trial Extension corresponding in size to the chosen Insert Trial.

Tip: The Biased Insert Trial Extension will be the same color as the insert trial.

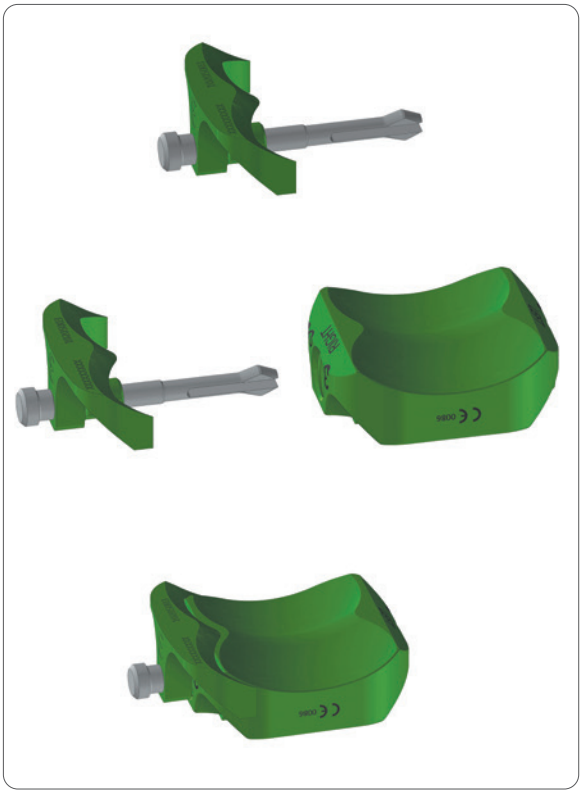


Figure 62

Push the post of the Biased Insert Trial Extension into the threaded hole in the center of the Insert Trial until the mating surfaces of the two components are flush. **(Figure 62)**

The Biased Insert Trial Extension should be placed on

the anterior surface of the Insert Trial for simulation of an Anterior Biased Insert implant. Conversely, the Biased Insert Trial Extension should be placed on the posterior surface of the Insert Trial for simulation of a Posterior Biased Insert implant.

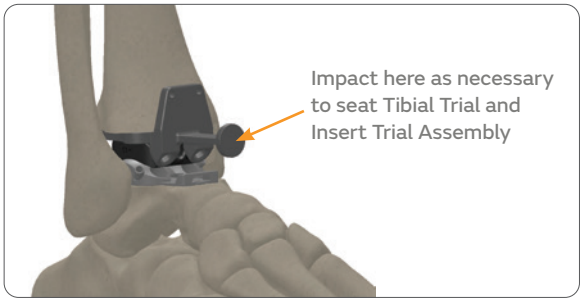


Figure 63

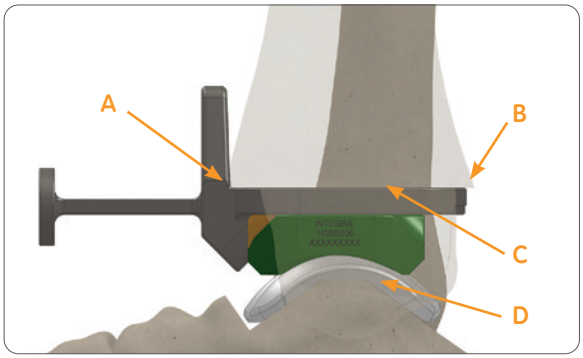
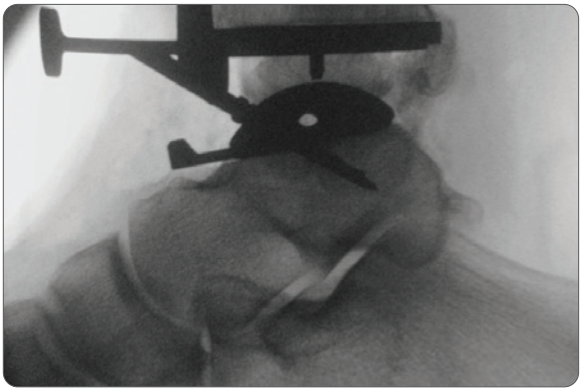


Figure 64



Place the Tibial Trial and Insert Trial assembly into position on the distal tibia. Mate the articular surface of the Insert Trial with the articular surface of the Talar Trial. Plantar flexion of the foot may be necessary to increase access to the joint space when placing trials. **(Figure 63)**

A mallet may be necessary to seat the Tibial Trial and Insert Trial assembly.

The Tibial Trial will find its optimal position in the frontal, sagittal, and rotational planes. If the joint is found to be too loose, the poly insert trial size may be increased.

Verify that the Tibial Trial is placed properly on the resected tibia and that the Talar Trial is placed properly on the resected talus. **(Figure 64)**

Verify the following visually or under fluoroscopy:

A. The anterior aspect of the Tibial Trial is flush against the anterior cortex of the distal tibial.

B. Posterior aspect of the Tibial Trial extends to but not past the posterior cortex of the distal tibia.

C. Proximal surface of the Tibial Trial is sitting flush across the entire distal surface of the tibia.

D. Flat surface of the Talar Trial is sitting flush with the flat resected surface of the proximal talus.

Figure 65

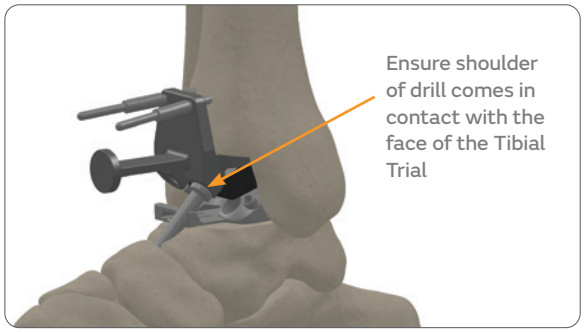


Figure 66

Figure 67

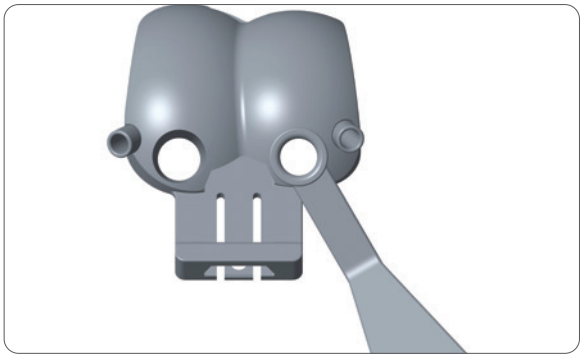


Figure 68

Step 12: Final Tibial Bone Preparation

After confirming proper placement of the Tibial Trial, place two Short Shouldered Bone Pins through the two bone pin holes in the anterior face of the Tibial Trial to maintain its position. **(Figure 65)**

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

Place either the Post Drill or the Flex Shaft Drill up through one of the holes in the tibial trial. Drill a tibial implant post hole into the tibia. Ensure that the shoulder of the implant Post Drill or Flex Shaft Drill comes into contact with the face of the Tibial Trial to ensure that the post hole is drilled to the correct depth. **(Figure 66)**

Repeat for the second hole in the Tibial Trial.

Remove the two Short Shouldered Bone Pins from the Tibial Trial and the Insert Trial. **(Figure 67)**

Step 13: Preparation for Talar Implant

Fully seat the Drill Guide in to the Talar Trial until a firm end feel is achieved. Drill the peg holes using the Post Drill to its hard stop. Remove the Drill Guide from the Talar Trial. Remove pins from Talar Trial and remove the trial from the joint space. **(Figure 68)**

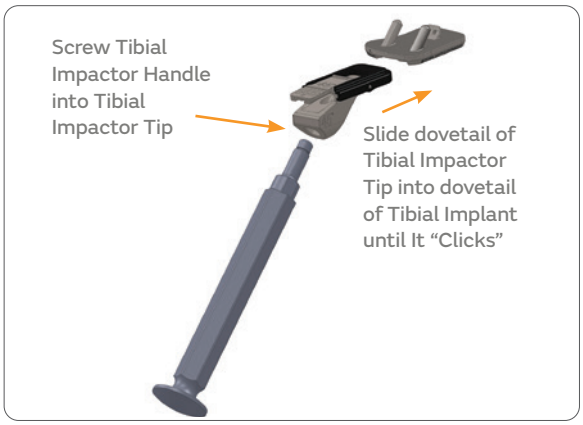


Figure 69

Recommended Method for Tibial Implant Impaction

Figure 70

Figure 71

Figure 72

Step 14: Secure Tibial Tray

Select and open the Tibial Tray implant corresponding in size to the Tibial Trial (Step 11).

Apply bone cement to the flat, titanium plasma sprayed surface of the Tibial Tray. Do not apply bone cement to the posts or the posterior wedge.

Thread the Tibial Impactor Handle into the black-tipped 45° Tibial Impactor Tip. Slide the dovetail feature of the black-tipped 45° Tibial Impactor Tip into the dovetail of the Tibial Tray until it "clicks" to fully engage the Tibial Tray. **(Figure 69)**

1. Gently engage the anterior peg tips of the Tibial Tray into the prepared peg holes. **(Figure 70)**
2. Ensure implant is parallel to the tibial cut, confirm with fluoroscopy. Gently tap the Tibial Impactor Handle, while keeping the Tibial Tray parallel to tibial cut, until the posterior wedge of the Tibial Tray engages into the bone. **(Figure 71)**
3. Continue impacting, under observation of fluoroscopy, until the implant is fully seated. **(Figure 72)**

Figure 73

If needed, the Gap Sizer may be used to complete insertion. Insert the Gap Sizer at an angle and press or gently impact on the posterior end of the Tibial Tray until fully seated. Confirm with fluoroscopy.

Warning: Do not impact the Tibial Impactor Handle unless the Tibial Tray is parallel to the resected tibia. (Figure 73)

Impaction of Tibial Tray while in angular alignment relative to the resected tibia may result in posterior tibial fractures and/or reduced fixation.

Warning: Avoid excessive impaction of the Tibial Tray to minimize risk of over insertion.

Impact only until the anterior portion of the tibial tray is aligned with the anterior tibia.

Tip: Plantar flex the foot as necessary to achieve proper positioning of the Tibial Tray, prior to impaction. If proper positioning cannot be achieved with the black-tipped 45° Tibial Impactor Tip, the green-tipped Tibial Impactor Tip can also be used; perform step 14 using the green-tipped Tibial Impactor Tip in place of the black-tipped 45° Tibial Impactor Tip.

After fully seating the Tibial Tray, depress the thumb lever on the Tibial Impactor Tip, then slide anteriorly to disengage the Tibial Tray.

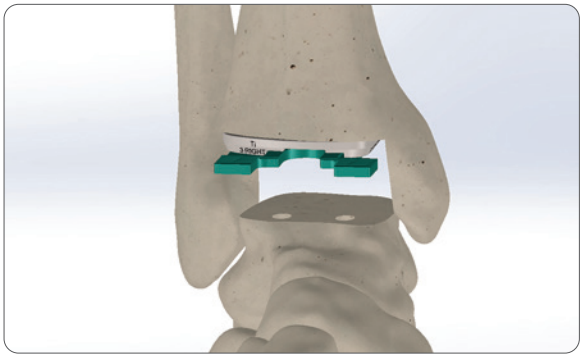


Figure 74

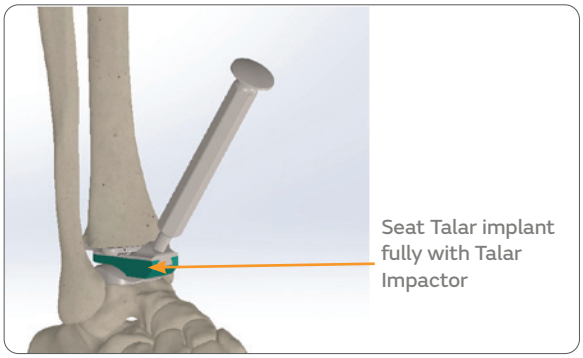


Figure 75

Step 15: Secure Talar Dome

Insert the dovetail feature of the Implant Protector fully into the dovetail of the Tibial Tray such that the Implant Protector covers the entire distal face of the Tibial Tray implant. This will serve to protect both the Tibial Tray and Talar Dome implants from damage while placing the Talar Dome. **(Figure 74)**

Select and open the Talar Dome implant corresponding in size to the Talar Trial from step 9.

Apply bone cement to the flat, titanium plasma sprayed surfaces of the Talar Dome. Do not apply bone cement to the posts.

Place the posts of the Talar Dome implant into the post holes prepared in the talus.

Use the Talar Impactor to fully seat the Talar Dome implant. **(Figure 75)**

Tip: Rotate the Talar Impactor to selectively apply posterior impaction and anterior impaction to ensure full seating of the Talar Dome implant.

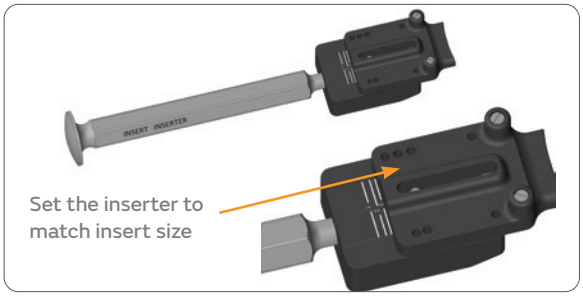


Figure 76

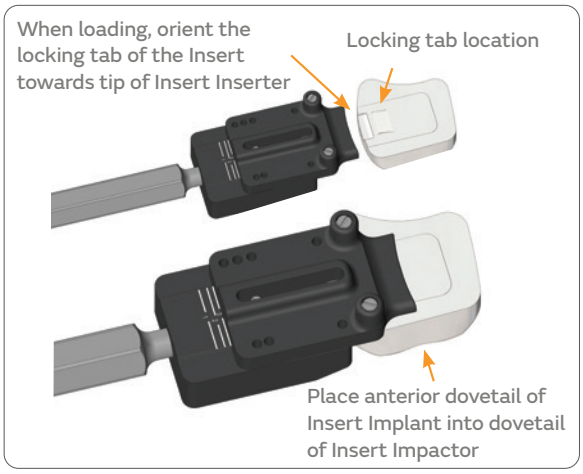


Figure 77

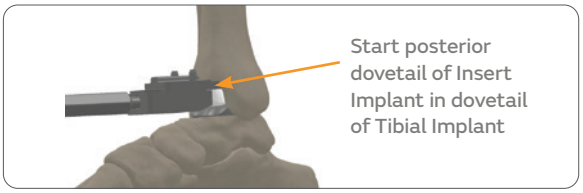


Figure 78

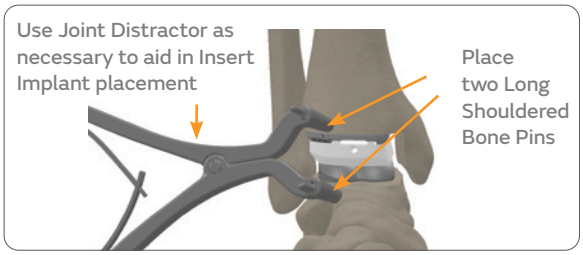


Figure 79

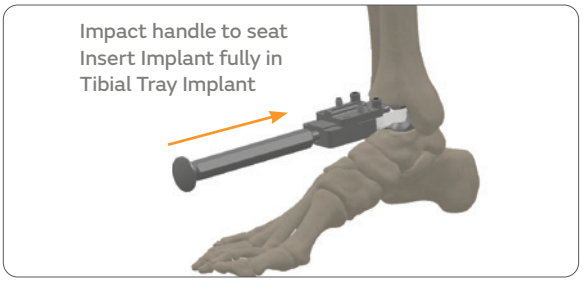


Figure 80

Step 16: Secure Insert

Remove the Implant Protector from the Tibial Tray implant.

Prepare the Insert Inserter by sliding the top portion of the instrument forward until it is flush with the etched line corresponding to the selected Insert Trial size. **(Figure 76)**

Select and open the Insert implant corresponding in size and thickness to the Insert Trial chosen in previous steps. **(Figure 77)**

Slide the anterior portion of the dovetail feature of the Insert implant into the dovetail of the Insert Inserter.

Tip: The locking tab feature of the Insert implant faces anterior; the locking tab feature of the Insert implant is loaded into the Insert Inserter

After the Insert implant is placed on the Insert Inserter, recheck etching corresponds to selected size.

Place the exposed posterior portion of the dovetail feature of the Insert implant into the dovetail of the Tibial Tray implant. The tip of the Insert Inserter should contact the anterior face of the Tibial Tray implant **(Figure 78)**

Push the Insert implant into the Tibial Tray implant as far as possible manually.

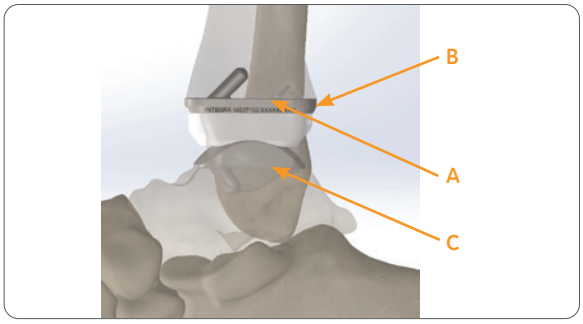
Tip: Use of the Joint Distractor may be necessary to place a posterior biased insert implant. **(Figure 79)**

Place one tip of the Joint Distractor on the tibia and one on the talus. Place one Long, Shouldered Bone Pin through each of the tips and into the bone. Then, expand the Joint Distractor to open the joint spacing.

Tip: Check the guide hole trajectory by setting the pin in the guide hole prior to drilling.

Using a mallet, gently impact the handle of the Insert Inserter until the Insert implant is seated fully in the Tibial Tray implant. An audible click can be heard when the Insert implant is fully seated **(Figure 80)**

Warning: Prior to impaction, ensure that the exposed posterior portion of the dovetail feature of the Insert implant is engaged into the Tibial Tray implant. If the posterior portion of the dovetail feature is not engaged, impaction may prevent proper securing of the insert.



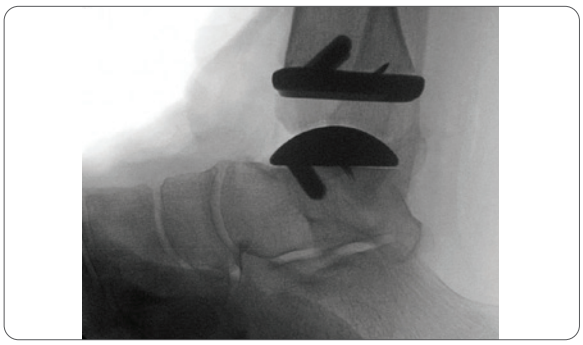
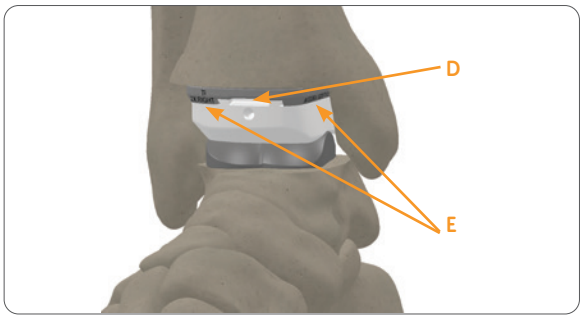


Figure 81



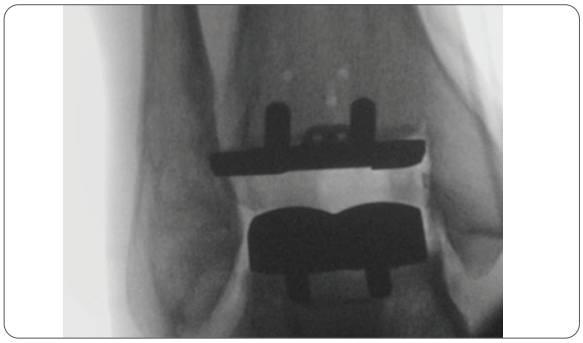


Figure 82

Step 17: Verify Final Implant

Under a lateral fluoroscopic view, verify the following: **(Figure 81)**

A. Proximal surface of the tibial implant is sitting flush across the entire distal surface of the tibia.

B. Posterior aspect of the tibial implant extends to but not past the posterior cortex of the tibia.

C. Flat surface of the talar implant is sitting flush with the resected flat surface of the talus.

Visually verify the tibial, talar, and insert implants are seated properly.

D. Anterior aspect of the tibial implant is flush against the anterior cortex of the tibial.

E. Insert implant is seated fully in the tibial implant and there is no gap between the anterior surfaces of the two implants.

Perform a dynamic flexion/extension test on the foot to check the joint's kinematics and to evaluate joint tension. **(Figure 82)**

Implant Removal

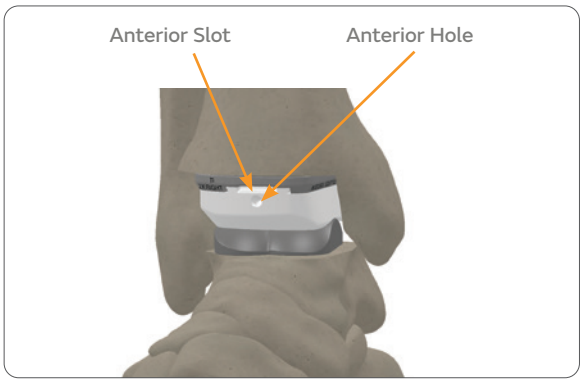


Figure 83

Figure 84

The following techniques may be used to remove specific implant components (Insert, Talar Dome, or Tibial Tray) of the Integra CADENCE◊ Total Ankle System.

Use any power (i.e. sagittal saw, reciprocating saw) and general instruments (i.e. osteotomes, rongeurs) necessary around implanted components to loosen bone-cement interface and/or facilitate removal.

Insert Removal

The insert may be removed through one of two ways:

1. Place an osteotome into the anterior slot on the Insert and twist to separate the insert from the tray. **(Figure 83)**
2. Thread the 5.0mm DIA Bone Pin into the anterior hole of the Insert. Attach the Screwdriver Handle to the 5.0mm DIA Bone Pin, then pull straight back to remove the Insert. **(Figure 84)**

Warning: When the 5.0mm DIA Bone Pin is threaded into the Insert, do not lever the Bone Pin in a cranial-caudal direction during Insert removal. Levering the Bone Pin during this step may cause damage or breakage to the instrument.

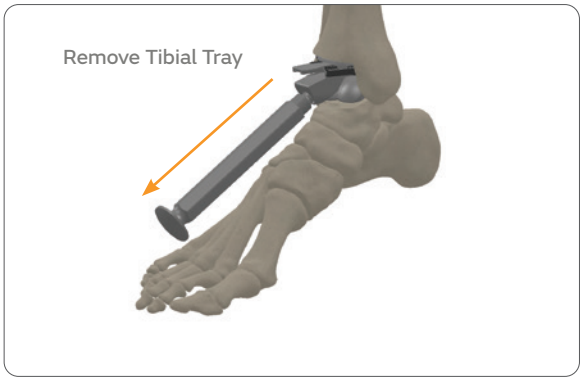


Figure 85

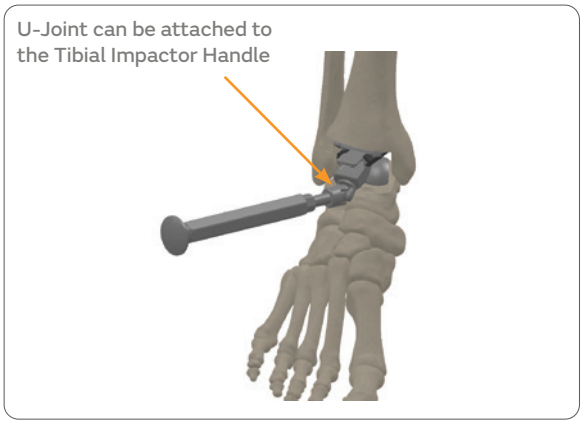


Figure 86

Tibial Tray Removal

Thread the Tibial Impactor Handle into the green-tipped Tibial Impactor Tip. Slide the dovetail feature of the green-tipped Tibial Impactor Tip into the dovetail of the Tibial Tray implant until it "clicks" and engages the Tibial Tray. **(Figure 85)**

Pull the Tibial Impactor Handle to remove the implant. **(Figure 86)**

Tip: A U-joint may be attached to the Tibial Impactor Handle for improved access during extraction.

Warning: Do not use the Slap Hammer for extraction of the tibial tray; using the Slap Hammer may result in damaged instrumentation and delayed removal of components.

Talar Dome Removal - Flat Cut Talus

The Talar Dome may be separated from the talus using an osteotome or other general surgical instruments.

Implants

Tibial Tray and Talar Dome Implants

Reference	Description
Tibial Trays	
10207101	Tibial Tray, Size 1, Right
10207111	Tibial Tray, Size 1X, Right
10207102	Tibial Tray, Size 2, Right
10207112	Tibial Tray, Size 2X, Right
10207103	Tibial Tray, Size 3, Right
10207113	Tibial Tray, Size 3X, Right
10207104	Tibial Tray, Size 4, Right
10207114	Tibial Tray, Size 4X, Right
10207105*	Tibial Tray, Size 5, Right
Talar Domes	
10208101	Talar Dome, Size 1, Right
10208102	Talar Dome, Size 2, Right
10208103	Talar Dome, Size 3, Right
10208104	Talar Dome, Size 4, Right
10208105*	Talar Dome, Size 5, Right
10208111	Flat Cut Talar Dome, Size 1, Right
10208112	Flat Cut Talar Dome, Size 2, Right
10208113	Flat Cut Talar Dome, Size 3, Right
10208114	Flat Cut Talar Dome, Size 4, Right

Tibial Tray and Talar Dome Implants

Reference	Description
Tibial Trays	
10207201	Tibial Tray, Size 1, Left
10207211	Tibial Tray, Size 1X, Left
10207202	Tibial Tray, Size 2, Left
10207212	Tibial Tray, Size 2X, Left
10207203	Tibial Tray, Size 3, Left
10207213	Tibial Tray, Size 3X, Left
10207204	Tibial Tray, Size 4, Left
10207214	Tibial Tray, Size 4X, Left
10207205*	Tibial Tray, Size 5, Left
Talar Domes	
10208201	Talar Dome, Size 1, Left
10208202	Talar Dome, Size 2, Left
10208203	Talar Dome, Size 3, Left
10208204	Talar Dome, Size 4, Left
10208205*	Talar Dome, Size 5, Left
10208211	Flat Cut Talar Dome, Size 1, Left
10208212	Flat Cut Talar Dome, Size 2, Left
10208213	Flat Cut Talar Dome, Size 3, Left
10208214	Flat Cut Talar Dome, Size 4, Left

*Available by special order only

Neutral (N) Insert Implants

Reference	Description
Neutral Inserts	
10209106	Insert, Size 1, Right, 6mm, Neutral
10209107	Insert, Size 1, Right, 7mm, Neutral
10209108	Insert, Size 1, Right, 8mm, Neutral
10209109	Insert, Size 1, Right, 9mm, Neutral
10209110	Insert, Size 1, Right, 10mm, Neutral
10209111	Insert, Size 1, Right, 11mm, Neutral
10209112	Insert, Size 1, Right, 12mm, Neutral
10209206	Insert, Size 2, Right, 6mm, Neutral
10209207	Insert, Size 2, Right, 7mm, Neutral
10209208	Insert, Size 2, Right, 8mm, Neutral
10209209	Insert, Size 2, Right, 9mm, Neutral
10209210	Insert, Size 2, Right, 10mm, Neutral
10209211	Insert, Size 2, Right, 11mm, Neutral
10209212	Insert, Size 2, Right, 12mm, Neutral
10209306	Insert, Size 3, Right, 6mm, Neutral
10209307	Insert, Size 3, Right, 7mm, Neutral
10209308	Insert, Size 3, Right, 8mm, Neutral
10209309	Insert, Size 3, Right, 9mm, Neutral
10209310	Insert, Size 3, Right, 10mm, Neutral
10209311	Insert, Size 3, Right, 11mm, Neutral
10209312	Insert, Size 3, Right, 12mm, Neutral
10209406	Insert, Size 4, Right, 6mm, Neutral
10209407	Insert, Size 4, Right, 7mm, Neutral
10209408	Insert, Size 4, Right, 8mm, Neutral
10209409	Insert, Size 4, Right, 9mm, Neutral
10209410	Insert, Size 4, Right, 10mm, Neutral
10209411	Insert, Size 4, Right, 11mm, Neutral
10209412	Insert, Size 4, Right, 12mm, Neutral
10209506*	Insert, Size 5, Right, 6mm, Neutral
10209507*	Insert, Size 5, Right, 7mm, Neutral
10209508*	Insert, Size 5, Right, 8mm, Neutral
10209509*	Insert, Size 5, Right, 9mm, Neutral
10209510*	Insert, Size 5, Right, 10mm, Neutral
10209511*	Insert, Size 5, Right, 11mm, Neutral
10209512*	Insert, Size 5, Right, 12mm, Neutral

Neutral (N) Insert Implants

Reference	Description
Neutral Inserts	
10209116	Insert, Size 1, Left, 6mm, Neutral
10209117	Insert, Size 1, Left, 7mm, Neutral
10209118	Insert, Size 1, Left, 8mm, Neutral
10209119	Insert, Size 1, Left, 9mm, Neutral
10209120	Insert, Size 1, Left, 10mm, Neutral
10209121	Insert, Size 1, Left, 11mm, Neutral
10209122	Insert, Size 1, Left, 12mm, Neutral
10209216	Insert, Size 2, Left, 6mm, Neutral
10209217	Insert, Size 2, Left, 7mm, Neutral
10209218	Insert, Size 2, Left, 8mm, Neutral
10209219	Insert, Size 2, Left, 9mm, Neutral
10209220	Insert, Size 2, Left, 10mm, Neutral
10209221	Insert, Size 2, Left, 11mm, Neutral
10209222	Insert, Size 2, Left, 12mm, Neutral
10209316	Insert, Size 3, Left, 6mm, Neutral
10209317	Insert, Size 3, Left, 7mm, Neutral
10209318	Insert, Size 3, Left, 8mm, Neutral
10209319	Insert, Size 3, Left, 9mm, Neutral
10209320	Insert, Size 3, Left, 10mm, Neutral
10209321	Insert, Size 3, Left, 11mm, Neutral
10209322	Insert, Size 3, Left, 12mm, Neutral
10209416	Insert, Size 4, Left, 6mm, Neutral
10209417	Insert, Size 4, Left, 7mm, Neutral
10209418	Insert, Size 4, Left, 8mm, Neutral
10209419	Insert, Size 4, Left, 9mm, Neutral
10209420	Insert, Size 4, Left, 10mm, Neutral
10209421	Insert, Size 4, Left, 11mm, Neutral
10209422	Insert, Size 4, Left, 12mm, Neutral
10209516*	Insert, Size 5, Left, 6mm, Neutral
10209517*	Insert, Size 5, Left, 7mm, Neutral
10209518*	Insert, Size 5, Left, 8mm, Neutral
10209519*	Insert, Size 5, Left, 9mm, Neutral
10209520*	Insert, Size 5, Left, 10mm, Neutral
10209521*	Insert, Size 5, Left, 11mm, Neutral
10209522*	Insert, Size 5, Left, 12mm, Neutral

*Available by special order only

Anterior-Biased (A-B) Insert Implants

Reference	Description
Anterior Biased Inserts	
10209126	Insert, Size 1, Right, 6mm, Anterior Biased
10209127	Insert, Size 1, Right, 7mm, Anterior Biased
10209128	Insert, Size 1, Right, 8mm, Anterior Biased
10209129	Insert, Size 1, Right, 9mm, Anterior Biased
10209130	Insert, Size 1, Right, 10mm, Anterior Biased
10209131	Insert, Size 1, Right, 11mm, Anterior Biased
10209132	Insert, Size 1, Right, 12mm, Anterior Biased
10209226	Insert, Size 2, Right, 6mm, Anterior Biased
10209227	Insert, Size 2, Right, 7mm, Anterior Biased
10209228	Insert, Size 2, Right, 8mm, Anterior Biased
10209229	Insert, Size 2, Right, 9mm, Anterior Biased
10209230	Insert, Size 2, Right, 10mm, Anterior Biased
10209231	Insert, Size 2, Right, 11mm, Anterior Biased
10209232	Insert, Size 2, Right, 12mm, Anterior Biased
10209326	Insert, Size 3, Right, 6mm, Anterior Biased
10209327	Insert, Size 3, Right, 7mm, Anterior Biased
10209328	Insert, Size 3, Right, 8mm, Anterior Biased
10209329	Insert, Size 3, Right, 9mm, Anterior Biased
10209330	Insert, Size 3, Right, 10mm, Anterior Biased
10209331	Insert, Size 3, Right, 11mm, Anterior Biased
10209332	Insert, Size 3, Right, 12mm, Anterior Biased
10209426	Insert, Size 4, Right, 6mm, Anterior Biased
10209427	Insert, Size 4, Right, 7mm, Anterior Biased
10209428	Insert, Size 4, Right, 8mm, Anterior Biased
10209429	Insert, Size 4, Right, 9mm, Anterior Biased
10209430	Insert, Size 4, Right, 10mm, Anterior Biased
10209431	Insert, Size 4, Right, 11mm, Anterior Biased
10209432	Insert, Size 4, Right, 12mm, Anterior Biased
10209526*	Insert, Size 5, Right, 6mm, Anterior Biased
10209527*	Insert, Size 5, Right, 7mm, Anterior Biased
10209528*	Insert, Size 5, Right, 8mm, Anterior Biased
10209529*	Insert, Size 5, Right, 9mm, Anterior Biased
10209530*	Insert, Size 5 Right, 10mm, Anterior Biased
10209531*	Insert, Size 5, Right, 11mm, Anterior Biased
10209532*	Insert, Size 5, Right, 12mm, Anterior Biased

Reference	Description
Anterior Biased Inserts	
10209136	Insert, Size 1, Left, 6mm, Anterior Biased
10209137	Insert, Size 1, Left, 7mm, Anterior Biased
10209138	Insert, Size 1, Left, 8mm, Anterior Biased
10209139	Insert, Size 1, Left, 9mm, Anterior Biased
10209140	Insert, Size 1, Left, 10mm, Anterior Biased
10209141	Insert, Size 1, Left, 11mm, Anterior Biased
10209142	Insert, Size 1, Left, 12mm, Anterior Biased
10209236	Insert, Size 2, Left, 6mm, Anterior Biased
10209237	Insert, Size 2, Left, 7mm, Anterior Biased
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10209338	Insert, Size 3, Left, 8mm, Anterior Biased
10209339	Insert, Size 3, Left, 9mm, Anterior Biased
10209340	Insert, Size 3, Left, 10mm, Anterior Biased
10209341	Insert, Size 3, Left, 11mm, Anterior Biased
10209342	Insert, Size 3, Left, 12mm, Anterior Biased
10209436	Insert, Size 4, Left, 6mm, Anterior Biased
10209437	Insert, Size 4, Left, 7mm, Anterior Biased
10209438	Insert, Size 4, Left, 8mm, Anterior Biased
10209439	Insert, Size 4, Left, 9mm, Anterior Biased
10209440	Insert, Size 4, Left, 10mm, Anterior Biased
10209441	Insert, Size 4, Left, 11mm, Anterior Biased
10209442	Insert, Size 4, Left, 12mm, Anterior Biased
10209536*	Insert, Size 5, Left, 6mm, Anterior Biased
10209537*	Insert, Size 5, Left, 7mm, Anterior Biased
10209538*	Insert, Size 5, Left, 8mm, Anterior Biased
10209539*	Insert, Size 5, Left, 9mm, Anterior Biased
10209540*	Insert, Size 5, Left, 10mm, Anterior Biased
10209541*	Insert, Size 5, Left, 11mm, Anterior Biased
10209542*	Insert, Size 5, Left, 12mm, Anterior Biased

*Available by special order only

Posterior Biased (P-B) Insert Implants

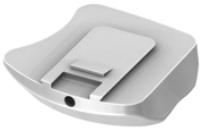
Reference	Description
Posterior Biased Inserts	
10209146	Insert, Size 1, Right, 6mm, Posterior Biased
10209147	Insert, Size 1, Right, 7mm, Posterior Biased
10209148	Insert, Size 1, Right, 8mm, Posterior Biased
10209149	Insert, Size 1, Right, 9mm, Posterior Biased
10209150	Insert, Size 1, Right, 10mm, Posterior Biased
10209151	Insert, Size 1, Right, 11mm, Posterior Biased
10209152	Insert, Size 1, Right, 12mm, Posterior Biased
10209246	Insert, Size 2, Right, 6mm, Posterior Biased
10209247	Insert, Size 2, Right, 7mm, Posterior Biased
10209248	Insert, Size 2, Right, 8mm, Posterior Biased
10209249	Insert, Size 2, Right, 9mm, Posterior Biased
10209250	Insert, Size 2, Right, 10mm, Posterior Biased
10209251	Insert, Size 2, Right, 11mm, Posterior Biased
10209252	Insert, Size 2, Right, 12mm, Posterior Biased
10209346	Insert, Size 3, Right, 6mm, Posterior Biased
10209347	Insert, Size 3, Right, 7mm, Posterior Biased
10209348	Insert, Size 3, Right, 8mm, Posterior Biased
10209349	Insert, Size 3, Right, 9mm, Posterior Biased
10209350	Insert, Size 3, Right, 10mm, Posterior Biased
10209351	Insert, Size 3, Right, 11mm, Posterior Biased
10209352	Insert, Size 3, Right, 12mm, Posterior Biased
10209446	Insert, Size 4, Right, 6mm, Posterior Biased
10209447	Insert, Size 4, Right, 7mm, Posterior Biased
10209448	Insert, Size 4, Right, 8mm, Posterior Biased
10209449	Insert, Size 4, Right, 9mm, Posterior Biased
10209450	Insert, Size 4, Right, 10mm, Posterior Biased
10209451	Insert, Size 4, Right, 11mm, Posterior Biased
10209452	Insert, Size 4, Right, 12mm, Posterior Biased
10209546*	Insert, Size 5, Right, 6mm, Posterior Biased
10209547*	Insert, Size 5, Right, 7mm, Posterior Biased
10209548*	Insert, Size 5, Right, 8mm, Posterior Biased
10209549*	Insert, Size 5, Right, 9mm, Posterior Biased
10209550*	Insert, Size 5, Right, 10mm, Posterior Biased
10209551*	Insert, Size 5, Right, 11mm, Posterior Biased
10209552*	Insert, Size 5, Right, 12mm, Posterior Biased

Reference	Description
Posterior Biased Inserts	
10209156	Insert, Size 1, Left, 6mm, Posterior Biased
10209157	Insert, Size 1, Left, 7mm, Posterior Biased
10209158	Insert, Size 1, Left, 8mm, Posterior Biased
10209159	Insert, Size 1, Left, 9mm, Posterior Biased
10209160	Insert, Size 1, Left, 10mm, Posterior Biased
10209161	Insert, Size 1, Left, 11mm, Posterior Biased
10209162	Insert, Size 1, Left, 12mm, Posterior Biased
10209256	Insert, Size 2, Left, 6mm, Posterior Biased
10209257	Insert, Size 2, Left, 7mm, Posterior Biased
10209258	Insert, Size 2, Left, 8mm, Posterior Biased
10209259	Insert, Size 2, Left, 9mm, Posterior Biased
10209260	Insert, Size 2, Left, 10mm, Posterior Biased
10209261	Insert, Size 2, Left, 11mm, Posterior Biased
10209262	Insert, Size 2, Left, 12mm, Posterior Biased
10209356	Insert, Size 3, Left, 6mm, Posterior Biased
10209357	Insert, Size 3, Left, 7mm, Posterior Biased
10209358	Insert, Size 3, Left, 8mm, Posterior Biased
10209359	Insert, Size 3, Left, 9mm, Posterior Biased
10209360	Insert, Size 3, Left, 10mm, Posterior Biased
10209361	Insert, Size 3, Left, 11mm, Posterior Biased
10209362	Insert, Size 3, Left, 12mm, Posterior Biased
10209456	Insert, Size 4, Left, 6mm, Posterior Biased
10209457	Insert, Size 4, Left, 7mm, Posterior Biased
10209458	Insert, Size 4, Left, 8mm, Posterior Biased
10209459	Insert, Size 4, Left, 9mm, Posterior Biased
10209460	Insert, Size 4, Left, 10mm, Posterior Biased
10209461	Insert, Size 4, Left, 11mm, Posterior Biased
10209462	Insert, Size 4, Left, 12mm, Posterior Biased
10209556*	Insert, Size 5, Left, 6mm, Posterior Biased
10209557*	Insert, Size 5, Left, 7mm, Posterior Biased
10209558*	Insert, Size 5, Left, 8mm, Posterior Biased
10209559*	Insert, Size 5, Left, 9mm, Posterior Biased
10209560*	Insert, Size 5, Left, 10mm, Posterior Biased
10209561*	Insert, Size 5, Left, 11mm, Posterior Biased
10209562*	Insert, Size 5, Left, 12mm, Posterior Biased

*Available by special order only

CADENCE◊ Total Ankle System – Implant Compatibility Chart

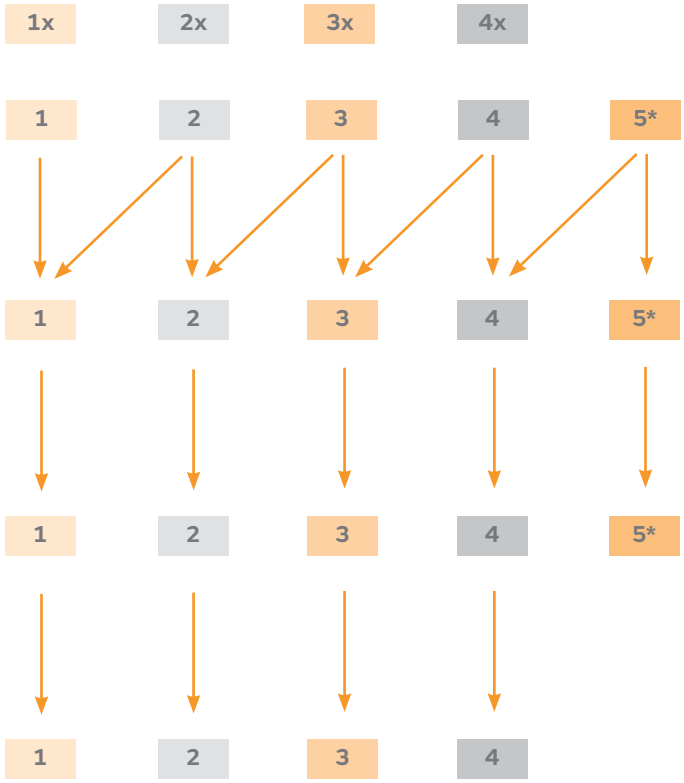
Tibial Tray



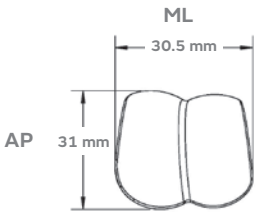
Insert

Chamfer Cut Talar Dome

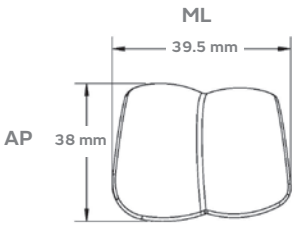
Flat Cut Talar Dome



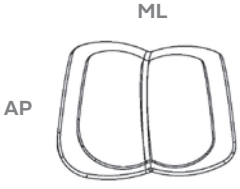
Chamfer Cut Talar Dome Dimensions



Size 1



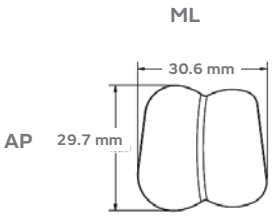
Size 5*



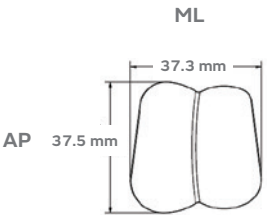
Size 1 and 5*

	AP (mm)	ML (mm)
Size 1	31.0	30.5
Size 2	32.5	31.0
Size 3	34.0	34.0
Size 4	36.0	37.0
Size 5*	38.0	39.5

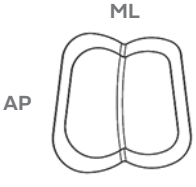
Flat Cut Talar Dome Dimensions



Size 1



Size 4



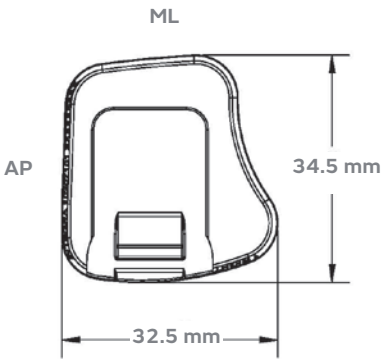
Size 1 and 4

	AP (mm)	ML (mm)
Size 1	29.7	30.6
Size 2	31.4	31.0
Size 3	33.6	34.2
Size 4	37.5	37.3

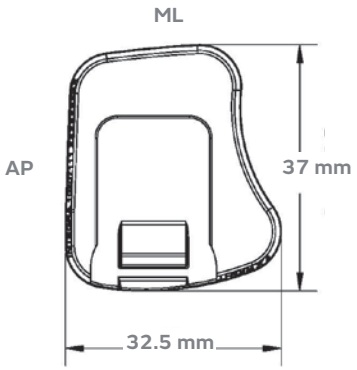
*Available by special order only

Tibial Tray Dimensions

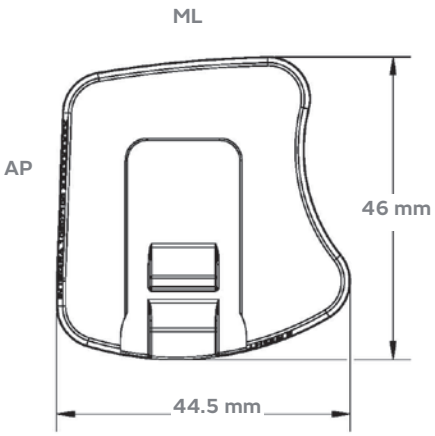
Size 1



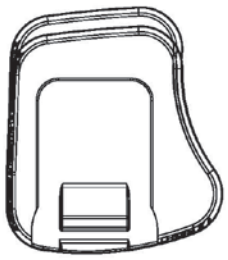
Size 1X



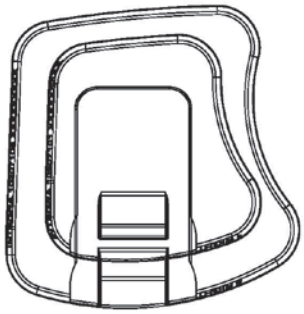
Size 5*



Size 1 and 1X



Size 1 and 5*

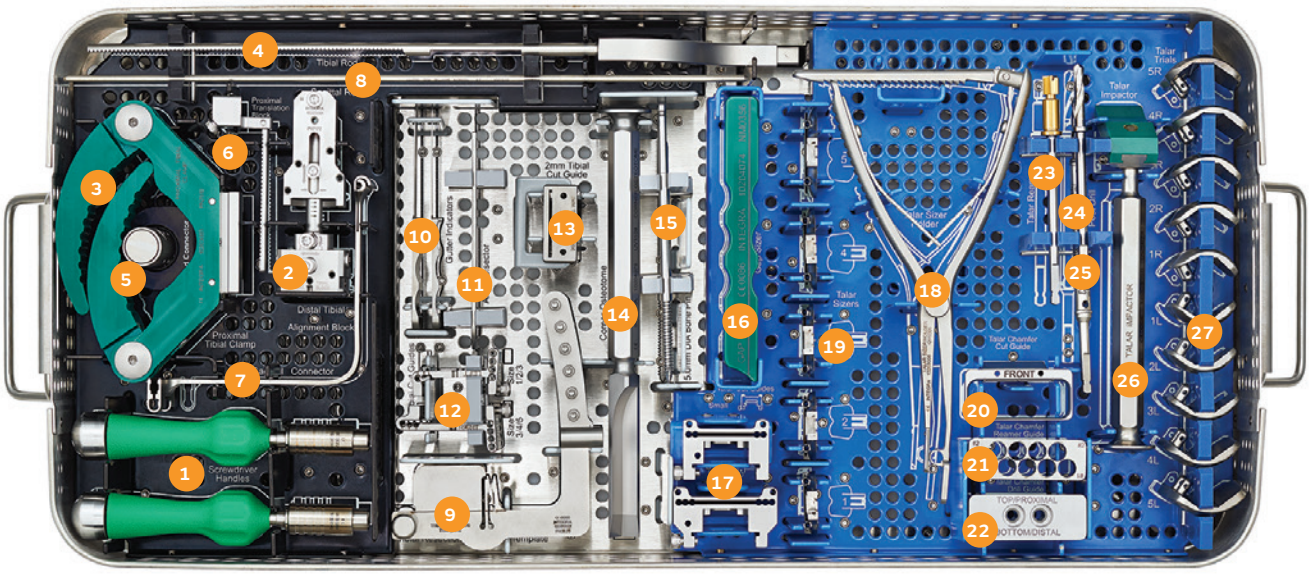


	AP (mm)	ML (mm)
Size 1	34.5	32.5
Size 1x	37.0	32.5
Size 2	37.0	34.0
Size 2x	40.0	34.0
Size 3	40.0	37.0
Size 3x	43.0	37.0
Size 4	43.0	40.0
Size 4x	46.0	40.0
Size 5*	46.0	44.5

*Available by special order only

Instruments Cases and Instruments

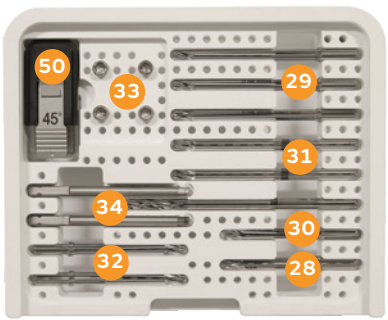
Instrument Case, Bone Resection Instruments



Item.	Instrument	Reference	Qty
1	Screwdriver Handle	10204145	2
2	Distal Tibial Alignment Block	10203001	1
3	Proximal Tibial Clamp	10203003	1
4	Tibial Rod	10203004	1
5	Rod Connector	10203005	1
6	Proximal Translation Block	10203006	1
7	Sagittal Connector	10204028	1
8	Sagittal Rod	10204029	1
9	Tibial Resection Template	10203012	1
10	Gutter Indicator	10204150	2
11	Bisector	10204148	1
12	Tibial Cut Guide - Size 1/2/3	10203023	1
	Tibial Cut Guide - Size 3/4/5	10203024	1
13	2mm Tibial Cut Guide	10204202	1
14	Corner Osteotome	10204079	1

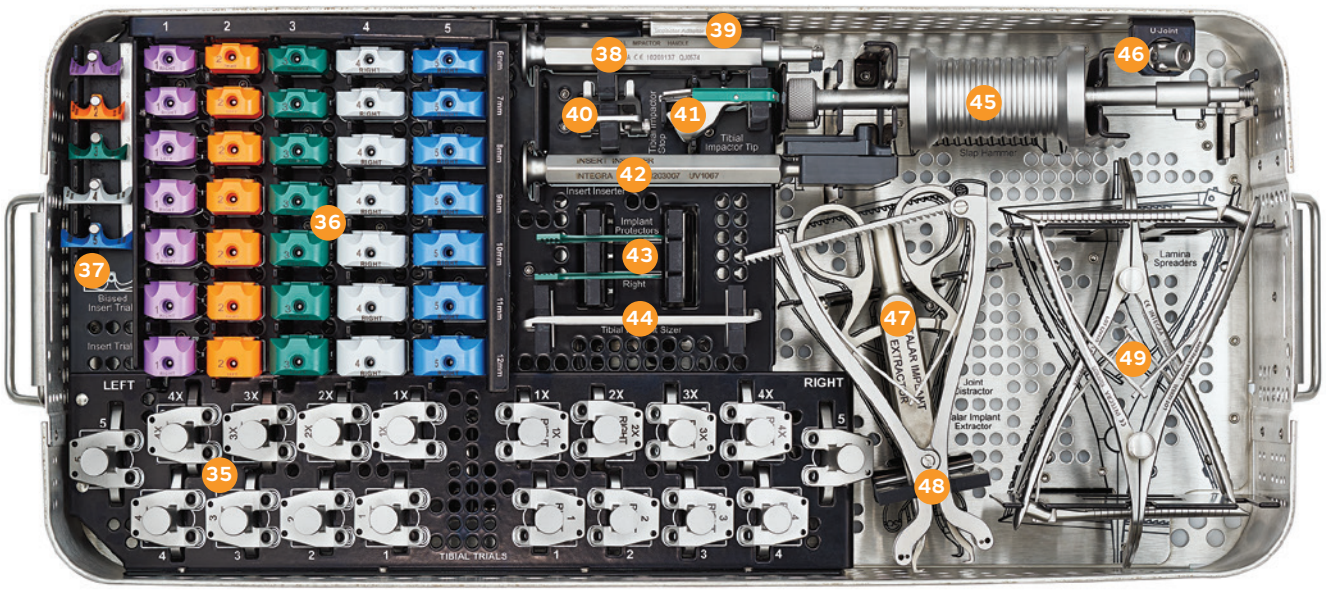
Item.	Instrument	Reference	Qty
15	5.0mm DIA Bone Pin	10204191	1
16	Gap Sizer	10204074	1
17	Talar Cut Guide - Small	10203031	1
	Talar Cut Guide - Large	10203032	1
18	Talar Sizer Holder	10203008	1
19	Talar Sizers	10204085-10204089	1 each
20	Talar Chamfer Cut Guide	10203030	1
21	Talar Chamfer Reamer Guide	10204031	1
22	Talar Chamfer Drill Guide	10204033	1
23	Talar Reamer	10204057	1
24	Post Drill	10204058	1
25	Flex Shaft Drill	10203020	1
26	Talar Impactor	10203098	1
27	Talar Trials	10205101-10205105 10205201-10205205	1 each

Pins and Accessories Module



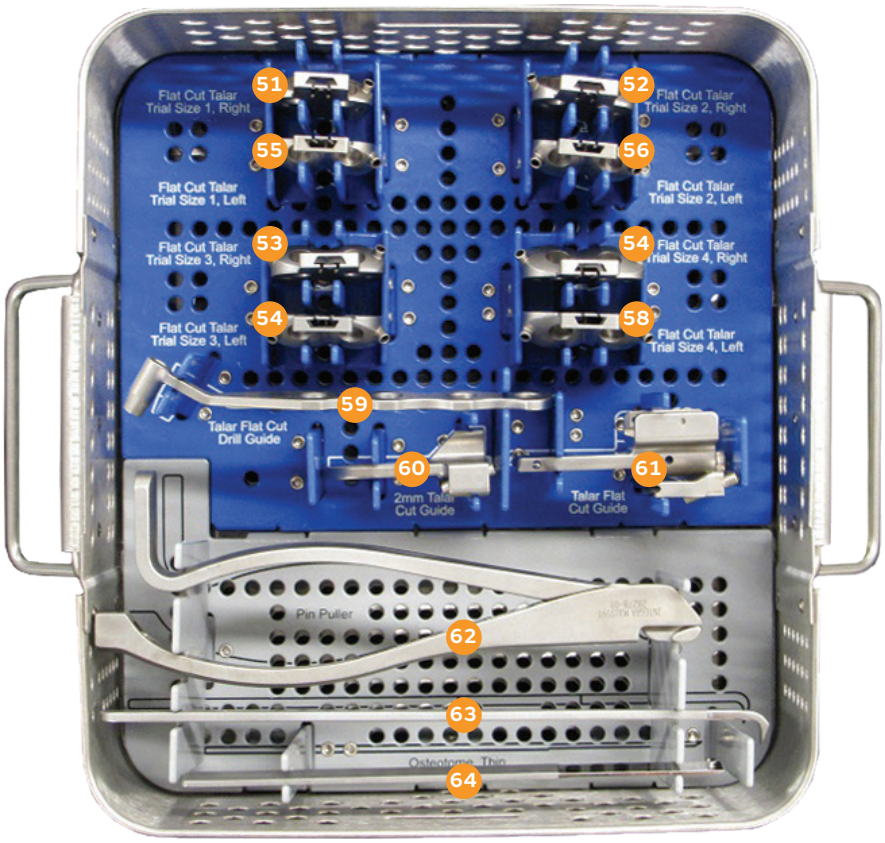
Item.		Instrument	Reference	Qty
29 =	1	Shouldered Bone Pin - Long	10204023	6
31 =	2	Short Straight Bone Pin	10204026	4
30 =	3	Straight Bone Pin - Drill Tip	10204025	2
28 =	4	Shouldered Bone Pin - Short	10204022	4
32 =	5	Shouldered Bone Pin - Medium	10204027	4
33		Locking Screw	10204217	4
34		AO Hex Driver	10204146	2
50		45° Tibial Impactor Tip	10203102	1

Instrument Case – Trials, Insertion, and Removal Instruments



Item.	Instrument	Reference	Qty
35	Tibial Trials	10204270-10204288	1 each
36	Insert Trials	10206106-10206512	1 each
37	Biased Insert Trial Extensions	10205001-10205005	1 each
38	Tibial Impactor Handle	10203137	1
39	Tibial Impactor Adaptor	10204106	1
40	Tibial Impactor Stop	10203108	1
41	Tibial Impactor Tip	10203101	1
42	Insert Inserter	10203007	1
43	Implant Protectors	10204305-10204306	1 each
44	Tibial implant sizer	10204076	1
45	Slap Hammer	10203194	1
46	U-Joint	10203196	1
47	Talar Implant Extractor	10203028	1
48	Joint Distractor	119.653ND	1
49	Lamina Spreader	10203035	2

Instrument Case, CADENCE° Flat Cut Instruments



Item.	Instrument	Reference	Qty
51	Flat Cut Talar Trial, Size 1, Right	10200111	1
52	Flat Cut Talar Trial, Size 2, Right	10200112	1
53	Flat Cut Talar Trial, Size 3, Right	10200113	1
54	Flat Cut Talar Trial, Size 4, Right	10200114	1
55	Flat Cut Talar Trial, Size 1, Left	10200211	1
56	Flat Cut Talar Trial, Size 2, Left	10200212	1
57	Flat Cut Talar Trial, Size 3, Left	10200213	1
58	Flat Cut Talar Trial, Size 4, Left	10200214	1
59	Talar Flat Cut Drill Guide	10200101	1
60	2mm Talar Cut Guide	10200102	1
61	Talar Flat Cut Guide	10200104	1
62	Pin Puller	MJU359T	1
63	Curette	MJU085T	1
64	Thin Osteotome	MJU357T	1

Saw Blades

Item Number	SAW6944T	SAW6945T	SAW6946T	SAW6947T	SAW6948T	SAW6949T	SAW6950T
Depth	70.0 mm	85.0 mm	80.0 mm	90.0 mm	75.0 mm	90.0 mm	70.0 mm
Width	13.0 mm	21.0 mm	13.0 mm	21.0 mm	13.0 mm	21.0 mm	12.5 mm
Cut Thk	1.27 mm	1.27 mm	1.27 mm	1.27 mm	1.27 mm	1.27 mm	0.94 mm
Hub	Stryker System 7	Stryker System 7	Hall Versipower	Hall Versipower	Hall Power Pro	Hall Power Pro	Brasseler
							

Notes

Notes

Notes

Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Smith+Nephew representative or distributor if you have questions about the availability of Smith+Nephew products in your area.

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References

1. Materialise 2013. Anatomical Data Mining Report Internal Report. **2.** Integra 2021. Analysis of Cadence Talar Dome Articulating Surfaces, Size to Size Internal Report ER-04-1020-0012. **3.** Innovative Medical Device Solutions 2014. Anatomic Fit Analysis for Tibial Tray and Talar Dome. Internal Report. 1229-9012. **4.** Gross CE, Palanca AA, DeOrio JK. Design Rationale for Total Ankle Arthroplasty Systems: An Update. J Am Acad Orthop Surg. 2018;26(10):353-359. **5.** Hyer CF, Parekh SG, Pedowitz DI, Hester WA, Lowe J, Daniels TR. Cadence Total Ankle Arthroplasty. In: Roukis TS, Hyer CF, Berlet GC, Bibbo C, Penner MJ, eds. Primary and Revision Total Ankle Replacement: Evidence-Based Surgical Management Cham: Springer International Publishing; 2021. **6.** Kooner S, Kayum S, Pinsker EB, et al. Two-Year Outcomes After Total Ankle Replacement With a Novel Fixed-Bearing Implant. Foot and Ankle International. 2021;42(8):1002-1010. **7.** Rushing CJ, Law R, Hyer CF. Early Experience With the CADENCE Total Ankle Prosthesis. J Foot Ankle Surg. 2021;60(1):67-73. **8.** Integra 2020. Annual Progress Report Study ID Number: T-CTAS-001 A POST-MARKET, PROSPECTIVE, NON-RANDOMIZED, MULTI-CENTER, OPENLABEL CLINICAL EVALUATION OF INTEGRA® CADENCE™ TOTAL ANKLE SYSTEM IN PRIMARY ANKLE JOINT REPLACEMENT. Internal Report. T-CTAS-001. **9.** Hamid KS, Matson AP, Nwachukwu BU, Scott DJ, Mather RC, 3rd, DeOrio JK. Determining the Cost-Savings Threshold and Alignment Accuracy of Patient-Specific Instrumentation in Total Ankle Replacements. Foot Ankle Int. 2017;38(1):49-57. **10.** Savage-Elliott I, Wu VJ, Wu I, Heffernan JT, Rodriguez R. Comparison of Time and Cost Savings Using Different Cost Methodologies for Patient-Specific Instrumentation vs Standard Referencing in Total Ankle Arthroplasty. Foot Ankle Orthop. 2019;4(4):2473011419884278.