

# ANTHEM<sup>®</sup>

## Distal Tibia Fracture System



*Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.*

*Life moves us* 

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

# SURGICAL TECHNIQUE GUIDE

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# ANTHEM<sup>®</sup>

## Distal Tibia Fracture System

The ANTHEM<sup>®</sup> Distal Tibia Fracture System provides low-profile, anatomically contoured plates in a comprehensive set to treat a variety of distal tibia fractures.

This system offers a variety of polyaxial locking plates, including Medial Locking, Anterolateral Locking (standard and wide), T-Plates, and L-Plates. A Metaphyseal Plate set is also available for fragment-specific plating.

Unique instruments such as the tactile Polyaxial Drill Guides are included in the set to simplify the plating technique.



## Polyaxial Locking Options

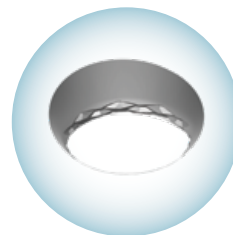
All plates feature robust polyaxial locking options, allowing for  $\pm 20^\circ$  (a  $40^\circ$  cone) of angulation



**Optimized screw trajectories**



**Market-leading angulation  
designed for stability**



**Polyaxial design  
 $\pm 20^\circ$  (a  $40^\circ$  cone) of angulation**

# Comprehensive System

One set provides polyaxial plating options for all distal tibia plating approaches



**Medial**  
2.5/3.5mm and  
3.5mm Options

**Anterolateral**  
2.5/3.5mm and  
3.5mm Options

**T-Plates and  
L-Plates**



**Straight Metaphyseal Plate**

**Long - Y Metaphyseal Plate**

**Long - T Metaphyseal Plate**

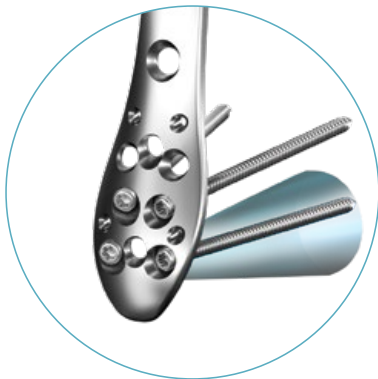
# MEDIAL LOCKING PLATE

## Anatomic Contour

- Distal end of the plate is designed to optimize medial malleolus stability while also providing a low profile distally (1.8-2.2mm thick)
- Designed for optimal fit to minimize intraoperative contouring and hardware prominence

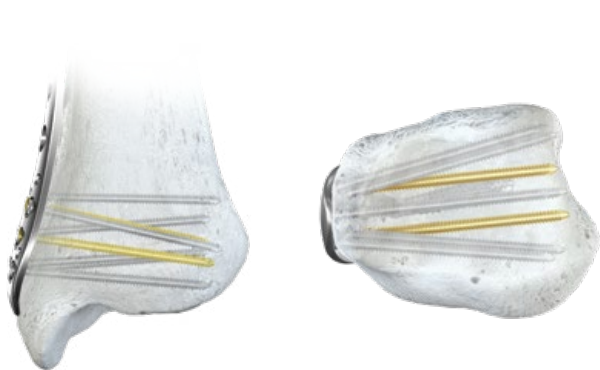
## Distal Locking Options

- Polyaxial locking rafting screws are designed for maximum screw density to capture multiple fracture fragments while allowing for rafting of the articular surface
- 2.5mm and 3.5mm options available



## Kickstand Screws

- Designed to provide additional stability to the construct and angled inferiorly to cross the most common extra-articular fractures



# ANTEROLATERAL LOCKING PLATE

## Anatomic Contour

- Distal anterior contour is designed to sit more medial to avoid impeding the incisura and to allow visualization of the Chaput fragment area
- Two distal widths offered to accommodate varying patient anatomy



Standard



Wide

## Suture/K-Wire Holes

- Facilitate reattachment of soft tissues distally after plate insertion

## Rafting Screws

- Six 2.5mm polyaxial locking rafting screw options are designed to support simple and very comminuted fractures of the articular surface



# IMPLANT OVERVIEW

## Medial Plates

### 2.5/3.5mm Locking Plate

- 2.5mm polyaxial distal locking provides for maximum fixation options
- 3.5mm polyaxial locking options in the shaft of the plate
- 1.8mm thickness distally
- Left/right specific

### 3.5mm Locking Plate

- 3.5mm polyaxial distal locking provides for maximum fixation options
- 3.5mm polyaxial locking options in the shaft of the plate
- 2.2mm thickness distally
- Left/right specific



2.5/3.5mm  
Medial Locking Plate



3.5mm  
Medial Locking Plate

## Anterolateral Plates

### 2.5/3.5mm Locking Plate

- 2.5mm polyaxial locking holes distally and 3.5mm polyaxial locking holes proximally

### Wide 2.5/3.5mm Locking Plate

- 2.5mm polyaxial locking holes distally and 3.5mm polyaxial locking holes proximally
- Extended anterior coverage to accommodate various patient anatomies

### 3.5mm Locking Plate

- 3.5mm polyaxial locking holes distally and proximally



2.5/3.5mm  
Anterolateral Plate



Wide 2.5/3.5mm  
Anterolateral Plate



3.5mm  
Anterolateral Plate

## Auxiliary Plates

### T-Plate

- 3.5mm kickstand screws provide additional stability
- Distal screws are angled 5° superiorly
- Designed for an anterior or posterior approach
- 2.6mm plate thickness



T-Plate



L-Plate

### L-Plate

- Removable tab that can be used to buttress fragments or provide additional fixation
- Designed for an anterior or posterior approach
- 1.9mm plate thickness
- Left/right specific

### Metaphyseal Plates

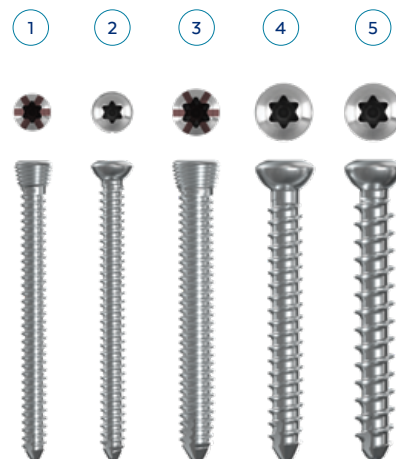
- Comprehensive plate selection that includes 2.5mm polyaxial locking distally and 3.5mm polyaxial locking proximally
- 1.4mm thick distally and 2.0mm thick proximally to minimize plate prominence



Metaphyseal Plates

## Screws

- ① 2.5mm Locking
- ② 2.5mm Non-Locking
- ③ 3.5mm Locking
- ④ 3.5mm Non-Locking
- ⑤ 4.0 Cancellous\*



\*Screws available in ANTHEM® Ankle Fracture Screw Module

## SURGICAL TECHNIQUE

# ANTHEM<sup>®</sup>

## Medial Locking Distal Tibia Plate

Refer to the package insert (also printed at the back of this manual) for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

### STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate length and location of screws to ensure the proper plate type, plate position, and screw placement.



Posteromedial incision

### STEP 2 PATIENT POSITIONING

Position the patient supine. Using fluoroscopy, examine the fracture with AP, mortise, and lateral views.

### STEP 3 APPROACH

Create a medial/posteromedial incision to the distal tibia that allows for fracture reduction. Carefully avoid surrounding tissue.



Medial incision

## STEP

## 4

## FRACTURE REDUCTION

Perform appropriate reduction of the fracture. Ensure that bone length, alignment, and rotation are properly restored. Proper reduction should be confirmed using fluoroscopy. Compression may be achieved by driving lag screws through the fragments. Ensure that lag screw placement does not interfere with the plate.



Fracture reduction

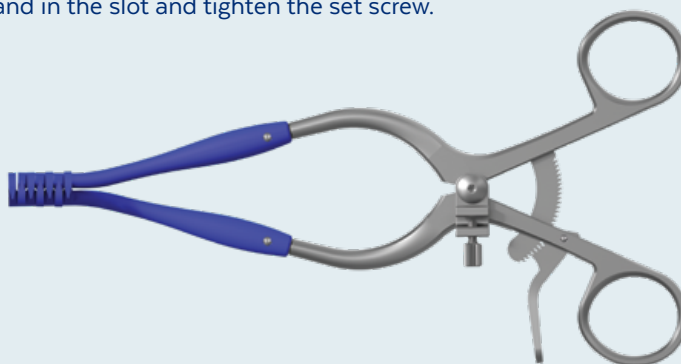


### RADIOLUCENT RETRACTION

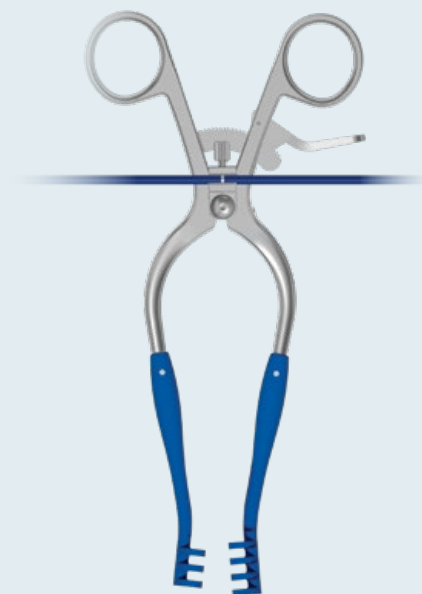
The **Stabilizing Radiolucent Weitlaners** are designed for fracture site visibility. The **Malleable Band** secures the Stabilizing Radiolucent Weitlaners to the patient.

To assemble the Malleable Band, use a **T8 Driver** to loosen the set screw.

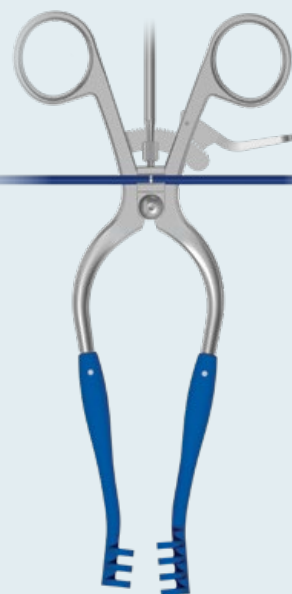
Place the Malleable Band in the slot and tighten the set screw.



Loosening set screw



Placing Malleable Band



Tightening set screw

## STEP 5 PLATE SELECTION

Select the Medial Locking Plate type that best accommodates the patient's anatomy and fracture pattern.



2.5/3.5mm Medial Locking Plate



3.5mm Medial Locking Plate

### Medial Plate Insertion

Insert the plate through the incision, taking care to avoid damaging soft tissue. Position the plate on the medial distal tibia. Confirm plate position using fluoroscopy. K-wires or reduction clamps may be used to provisionally fix the plate to the bone. The Curved Cobb may be used to create a submuscular path for the plate prior to percutaneous insertion. Additionally, suture may be used with the Curved Cobb to guide the plate during insertion.

#### USING THE CURVED COBB - PROXIMAL ENTRY

##### Subcutaneous Insertion

The Curved Cobb may be used to position long plates. Select the desired length plate. Position the plate on top of the skin and use a marking pen to mark the skin at the proximal end of the plate. Make a small incision at this proximal mark. **(A)** Pass the Curved Cobb through this incision to the level of the distal incision.

**(B)** Suture the proximal portion of the plate to the Curved Cobb and retract the Curved Cobb from the proximal incision. This helps guide the plate to remain on the tibial shaft. **(C)** Cut the suture and remove it from the plate. Provisionally secure the plate to the bone using clamps or wires.



# PLATE PLACEMENT (CONT'D)

## Medial Plate Insertion (Cont'd)

### USING THE CURVED COBB - DISTAL ENTRY

#### Subcutaneous Insertion

The Curved Cobb may be used to position long plates. Select the desired length plate. Position the plate on top of the skin and use a marking pen to mark the skin at the proximal end of the plate. Make a small incision at this proximal mark. **(A)** Pass the Curved Cobb through the distal incision to the level of the proximal incision.

Attach suture to the suture hole in the head of the Curved Cobb. **(B)** Retract the Curved Cobb from the distal incision while holding onto the free end of the suture. **(C)** Cut suture attached to the Curved Cobb and attach this end of the suture to the proximal portion of the plate. **(D)** Guide the plate through the distal incision and submuscularly up the tibial shaft by pulling the free end of the suture.







Cut the suture and remove it from the plate. Provisionally secure the plate to the bone using clamps or wires.











### Screw Compatibility

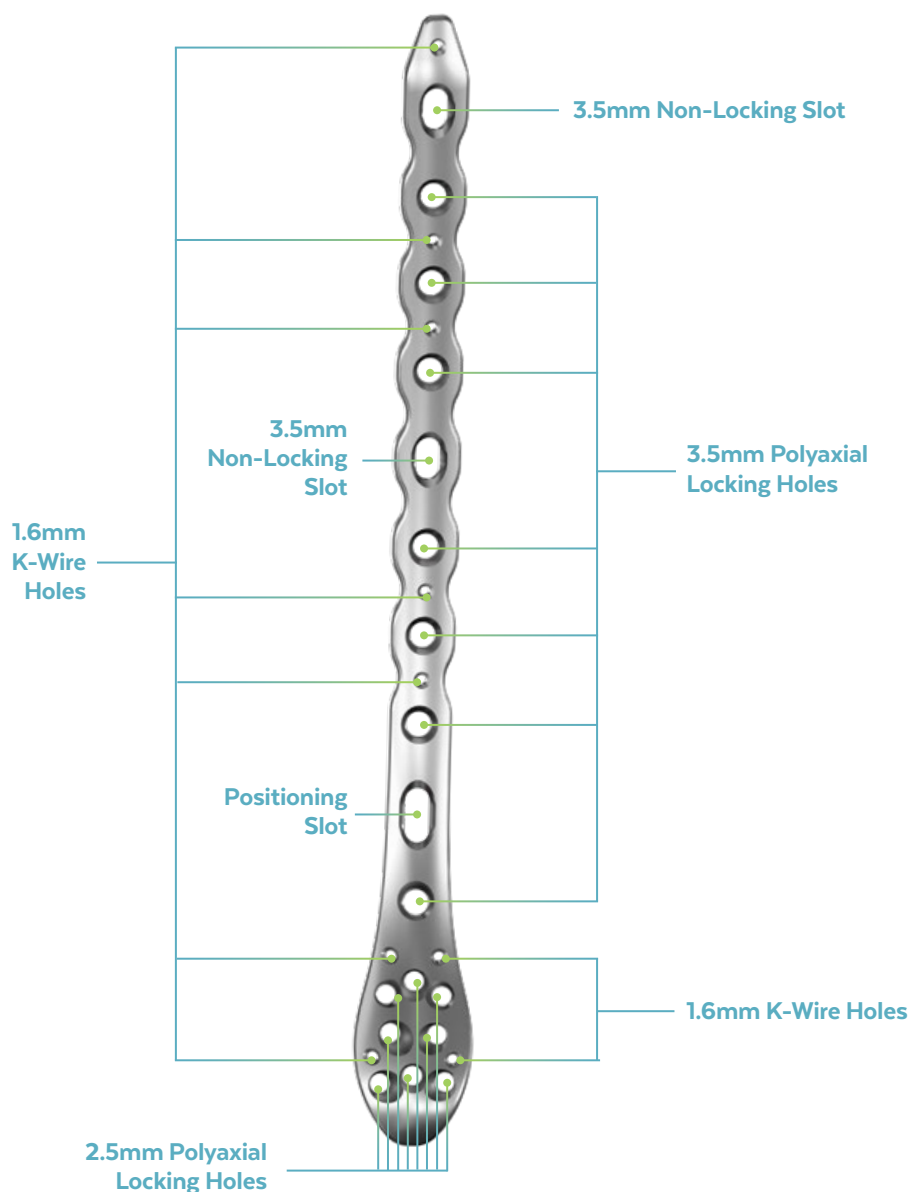
Screw compatibility is shown below for the Medial Locking Plate. If screw-plate locking is desired in a polyaxial hole, only use locking screws. MonoAx® Locking Screws may not be used in polyaxial holes. The 3.5mm Non-Locking Slots may be used for dynamic compression. Screw insertion order depends on fracture type, preliminary reduction, and surgeon preference. All non-locking screws should be placed prior to any locking screws. The positioning slot may be used to adjust plate position (see page 16 for details).

## 2.5/3.5mm Medial Locking Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	







2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	





Positioning Slot/ 3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

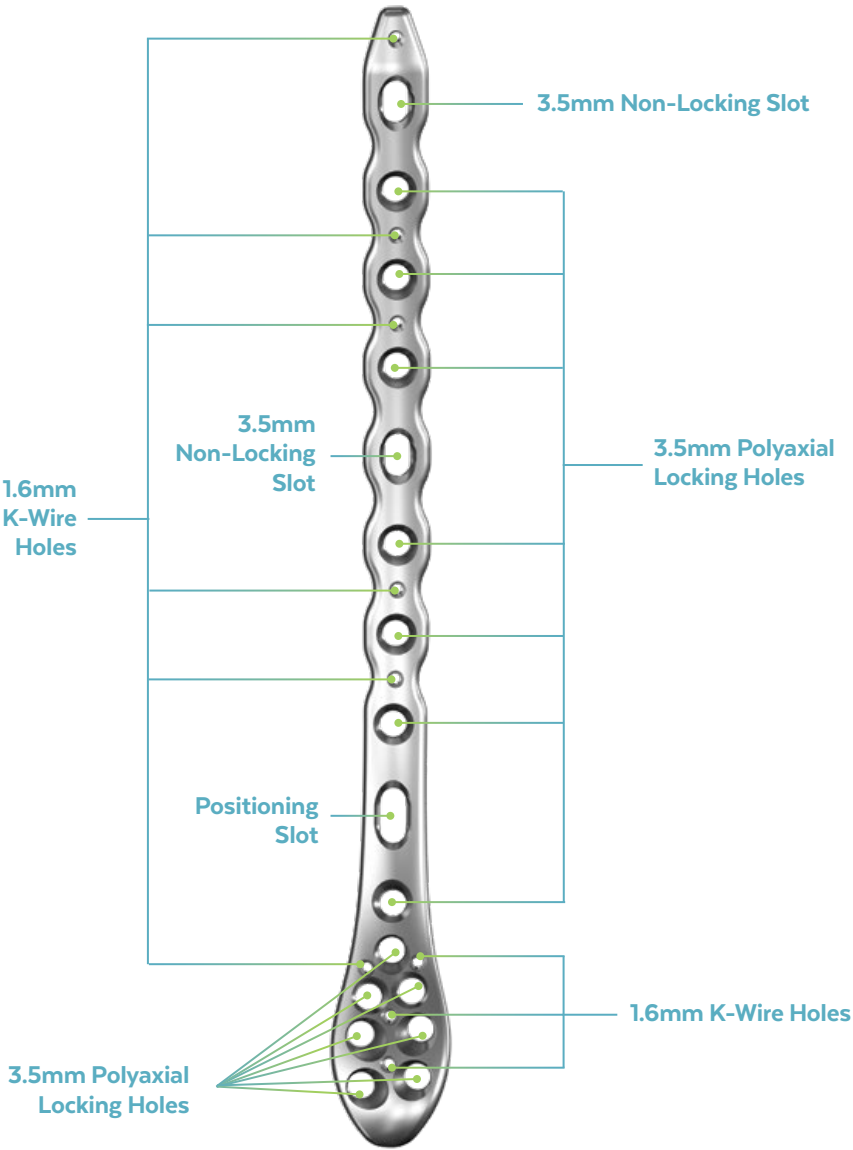


# SCREW INSERTION (CONT'D)

## 3.5mm Medial Locking Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	


Positioning Slot/ 3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	



Positioning Slot Screw

3.5mm Non-Locking Screws

The positioning slot is used to adjust plate position.

3.5mm Non-Locking Slots		
	 3.5mm Non-Locking	
	 4.0mm Cancellous*	



2.5/3.5mm  
Medial Locking Plate

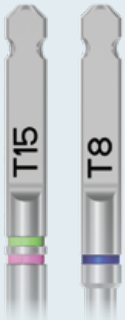


3.5mm  
Medial Locking Plate

 **COLOR-CODED INSTRUMENTS**

Drills and drill guides are color-coded by screw size.

Color	Screw Diameter	Drill Diameter
Blue	2.5mm	1.8mm
Fuschia	3.5mm	2.7mm
Light Green	4.0mm	2.7mm



# SCREW INSERTION (CONT'D)

## Positioning Slot Screw

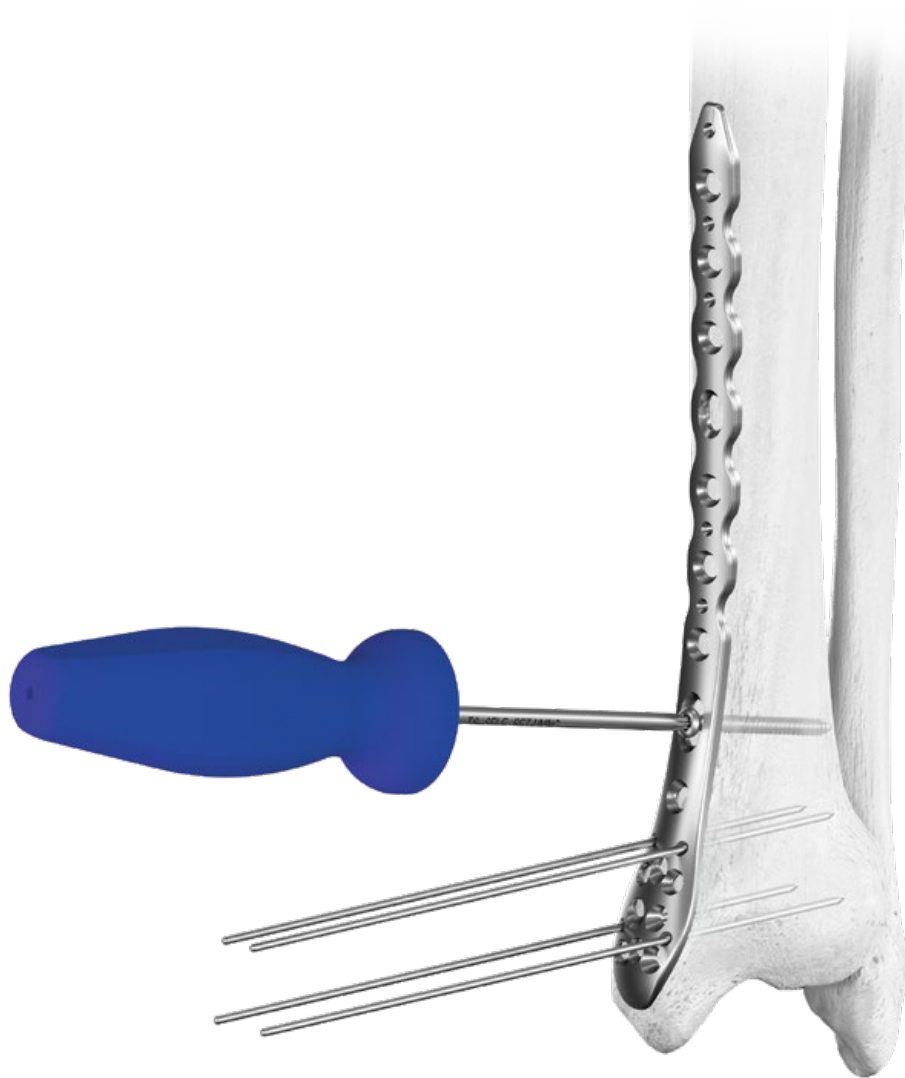
### 3.5mm Non-Locking and 4.0mm Cancellous Screws

Placing the positioning slot non-locking screw prior to other screws allows for minor plate position adjustments.

Use the 2.7mm Drill to drill to the desired depth. Measure screw length using the **Depth Gauge**. Use the **Self-Retaining T15 Driver** or **Screw Holding Forceps** to select the desired screw. Verify length and diameter using the gauges within the screw modules.

Insert a 3.5mm Non-Locking Screw into the elongated slot using the T15 Driver and the **Quick-Connect Handle** manually or under power. Confirm plate position using fluoroscopy.

Adjust plate position as necessary before final tightening manually. Confirm screw position using fluoroscopy.


















Positioning slot screw

# Polyaxial Distal Screws

## 2.5/3.5mm Locking, 2.5/3.5mm Non-Locking, and 4.0mm Cancellous Screws

Determine the appropriate combination of locking and non-locking screws for the desired fixation. If screw-plate locking is desired in a polyaxial hole, only use locking screws.

3.5mm Polyaxial Locking Holes		
		
		
		

2.5mm Polyaxial Locking Holes		
		
		



2.5/3.5mm  
Medial Locking Plate



3.5mm  
Medial Locking Plate

\*Screws available in ANTHEM® Ankle Fracture Screw Module

# SCREW INSERTION (CONT'D)

## Polyaxial Distal Screws

### 2.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the **1.8mm Drill Bit** and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the **Self-Retaining T8 Driver** or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 2.5mm Locking or Non-Locking Screws into the screw holes using the T8 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 2.5mm Locking Screws using the 1.2Nm Torque-Limiting Attachment.

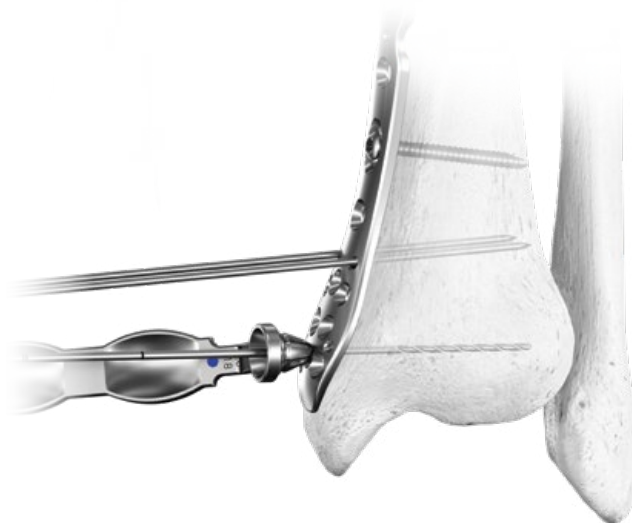
### 3.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

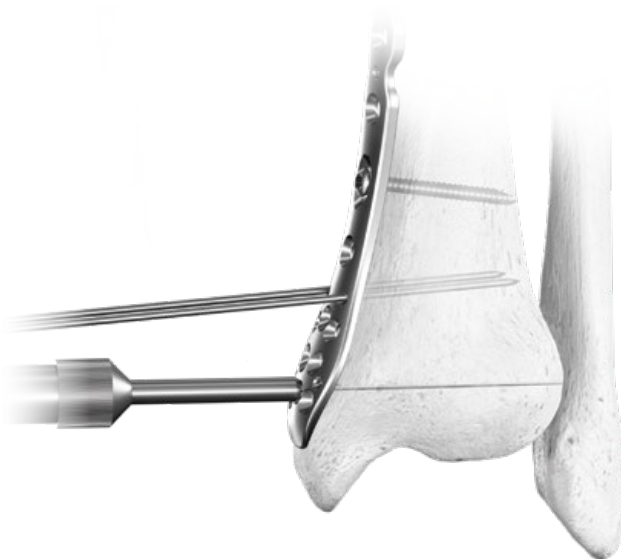
Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 3.5mm Locking or Non-Locking Screws into the screw holes using the T15 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



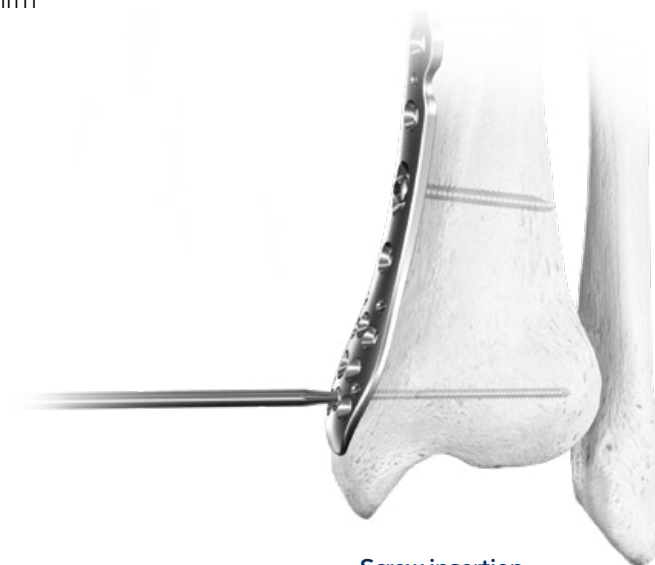
Insert 3.5mm Locking Screws using the 2.5Nm Torque-Limiting Attachment.



Pre-drilling



Measuring with Depth Gauge



Screw insertion

## NOMINAL DRILL GUIDE OPTIONS

**1.8mm Speed Lock Drill Guide (2.5mm Screws)** ●

**2.7mm Speed Lock Drill Guide (3.5mm Screws)** ● ●

The Speed Lock Drill Guide may be used to drill nominal trajectories. The thumb lock locks the drill guide to the plate at the nominal screw trajectory.



Speed Lock Drill Guides

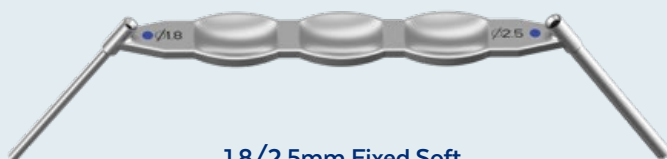


Speed Lock Drill Guide  
locked in place

**1.8/2.5mm Fixed Soft Tissue Protector** ●

**2.7/3.5mm Fixed Soft Tissue Protector** ● ●

Fixed angle soft tissue protectors may be used to drill nominal trajectories.



1.8/2.5mm Fixed Soft  
Tissue Protector



2.7/3.5mm Fixed Soft  
Tissue Protector

# SCREW INSERTION (CONT'D)

## POLYAXIAL DRILL GUIDE OPTIONS

**1.8mm Soft Tissue Protector (2.5mm screws)** ●

**2.7mm Soft Tissue Protector (3.5mm screws)** ●●

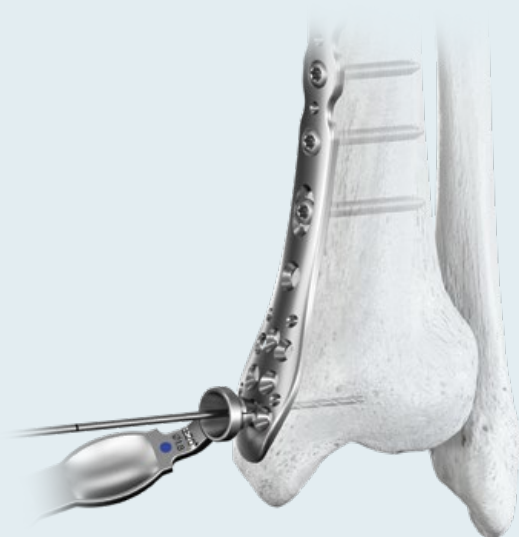
The Soft Tissue Protector allows for  $\pm 20^\circ$  (a  $40^\circ$  cone) of angulation on the polyaxial end and the nominal trajectory on the nominal end.



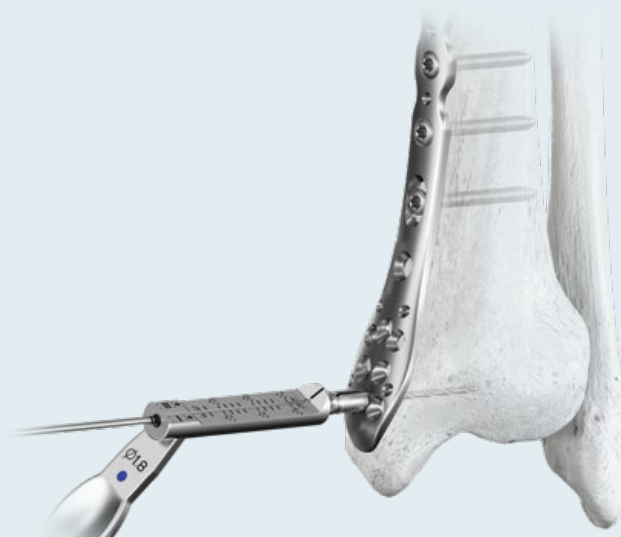
1.8mm Soft Tissue Protector



2.7mm Soft Tissue Protector



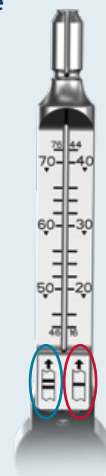
1.8mm Polyaxial Drill Guide



1.8mm Nominal Drill Guide



The 1.8mm Calibrated Drill Guide is used with the 1.8mm Drill. The single line on the drill corresponds to 16-44mm screws. The double line on the drill corresponds to 46-76mm screws.














1.8mm Calibrated Nominal Drill Guide

# Shaft Holes

## 3.5mm Locking, 3.5mm Non-Locking, and 4.0mm Cancellous Screws

Determine the appropriate combination of locking and non-locking screws for proper fixation. If screw-plate locking is desired in a polyaxial hole, only use locking screws.

3.5mm Polyaxial Locking Holes		
	 3.5mm Locking	
	 3.5mm Non-Locking	
	 4.0mm Cancellous*	

3.5mm Non-Locking Slots		
	 3.5mm Non-Locking	
	 4.0mm Cancellous*	



2.5/3.5mm  
Medial Locking Plate



3.5mm  
Medial Locking Plate

Confirm proximal plate positioning using fluoroscopy. Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm Locking or Non-Locking Screws with the T15 Driver with the Quick-Connect Handle manually or under power. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.

For hard cortical bone, it is recommended to use the cortical tap before screw insertion.

\*Screws available in ANTHEM® Ankle Fracture Screw Module

## SCREW INSERTION (CONT'D)

### 3.5mm Non-Locking Slot and 4.0mm Cancellous Screw

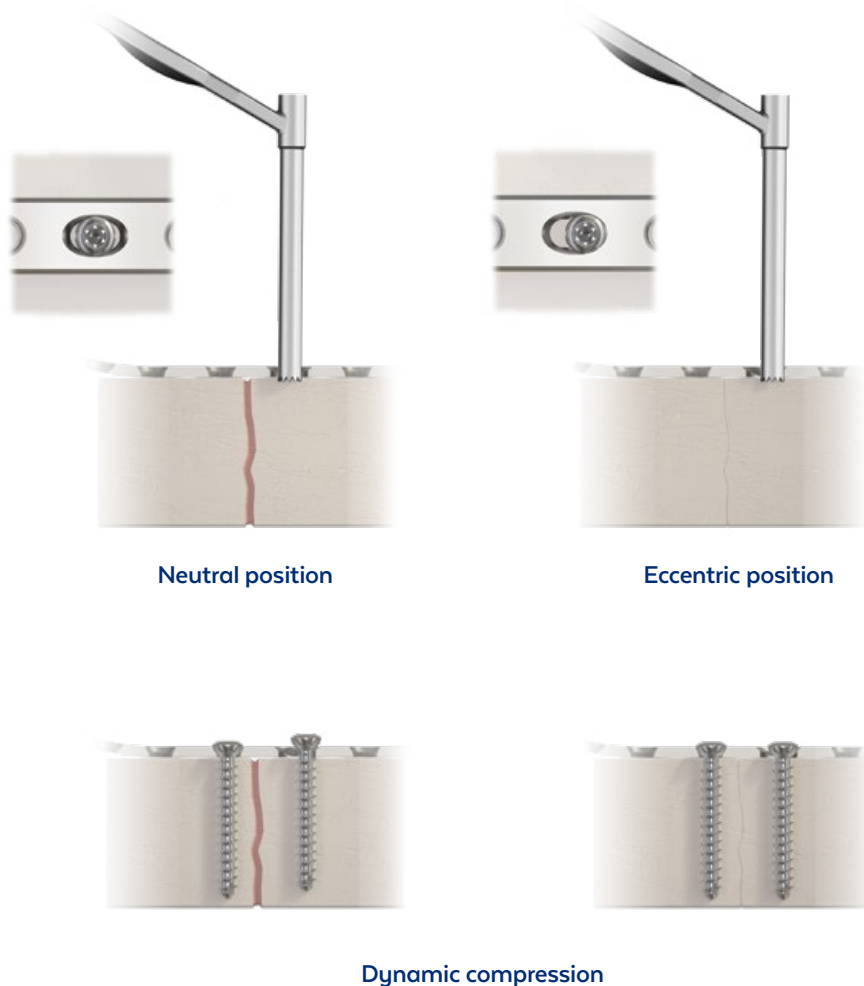
Dynamic compression of the fracture may be achieved by eccentrically placing a Non-Locking Screw through the 3.5mm Non-Locking Slot. If compression is not desired, place the screw in a neutral position.

Place a 3.5mm Non-Locking Screw distal to the fracture. Insert the 2.7/3.5mm Fixed Soft Tissue Protector eccentrically in the slotted hole.

Use the 2.7mm Drill to drill to the desired depth. Measure screw length using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw. Verify length and diameter using the gauges within the screw module.

Insert a 3.5mm Non-Locking Screw into the elongated slot using the T15 Driver and the Quick-Connect Handle manually or under power. Confirm plate position using fluoroscopy. Adjust plate position as necessary before final tightening manually. Confirm screw position using fluoroscopy.

For hard cortical bone, it is recommended to use the cortical tap before screw insertion.



## STEP

## 8

## VERIFY PLACEMENT

Confirm reduction and fixation using fluoroscopy. Ensure that screw tips are not intra-articular. Check screw placement in all planes, as angulation and direction may be difficult to visualize.



AP view



Lateral view

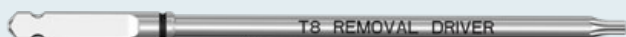
## OPTIONAL: REMOVAL

If removal is required, unlock and remove all locking screws from the plate with the appropriate screwdriver first. Then remove non-locking screws using the corresponding screwdrivers. This prevents simultaneous rotation of the plate. Once all screws are removed from the bone, the plate may be removed. For 2.5mm screws, use the **Non-Self-Retaining T8 Driver**. For 3.5mm screws, use the **Non-Self-Retaining T15 Driver**.



### NON-SELF-RETAINING DRIVERS

Non-Self-Retaining Drivers help to maximize torque applied to the screw head during screw insertion and/or removal.



T8 Non-Self-Retaining Drivers



T15 Non-Self-Retaining Drivers

## SURGICAL TECHNIQUE

# ANTHEM<sup>®</sup>

## Anterolateral Locking Distal Tibia Plate

Refer to the package insert (also printed at the back of this manual) for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

### STEP

### 1

## PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan.  
Estimate the appropriate length and location of screws to ensure the proper plate type, plate position, and screw placement.

### STEP

### 2

## PATIENT POSITIONING

Position the patient supine. Using fluoroscopy, examine the fracture with AP and lateral views.

### STEP

### 3

## APPROACH

Create an anterolateral incision to the distal tibia that allows for fracture reduction. Carefully avoid surrounding tissue.

### STEP

### 4

## FRACTURE REDUCTION

Perform appropriate reduction of the fracture. Ensure that bone length, alignment, and rotation are properly restored. Proper reduction should be confirmed using fluoroscopy. Compression may be achieved by driving lag screws through the fragments. Ensure that lag screw placement does not interfere with the plate.



**Anterolateral  
incision**

## STEP

## 5

## PLATE SELECTION

Select the Anterolateral Locking Plate type that best accommodates the patient's anatomy and fracture pattern.



2.5/3.5mm  
Standard  
Anterolateral



2.5/3.5mm  
Wide Anterolateral



3.5mm  
Standard  
Anterolateral

### Anterolateral Plate Insertion

Position the plate on the anterolateral distal tibia. Confirm plate position using fluoroscopy. K-wires or reduction clamps may be used to provisionally fix the plate to the bone. The Curved Cobb may be used to create a submuscular path for the plate prior to percutaneous insertion. Additionally, suture may be used with the Curved Cobb to guide the plate during insertion.

#### USING THE CURVED COBB - PROXIMAL ENTRY

##### Subcutaneous Insertion

The Curved Cobb may be used to position long plates. Select the desired length plate. Position the plate on top of the skin and use a marking pen to mark the skin at the proximal end of the plate. Make a small incision at this proximal mark. **(A)** Pass the Curved Cobb through this incision to the level of the distal incision (A).

**(B)** Suture the proximal portion of the plate to the Curved Cobb and retract the Curved Cobb from the proximal incision. This helps guide the plate to remain on the tibial shaft. **(C)** Cut the suture and remove it from the plate. Provisionally secure the plate to the bone using clamps or wires.



# PLATE PLACEMENT (CONT'D)

## Anterolateral Plate Insertion (Cont'd)

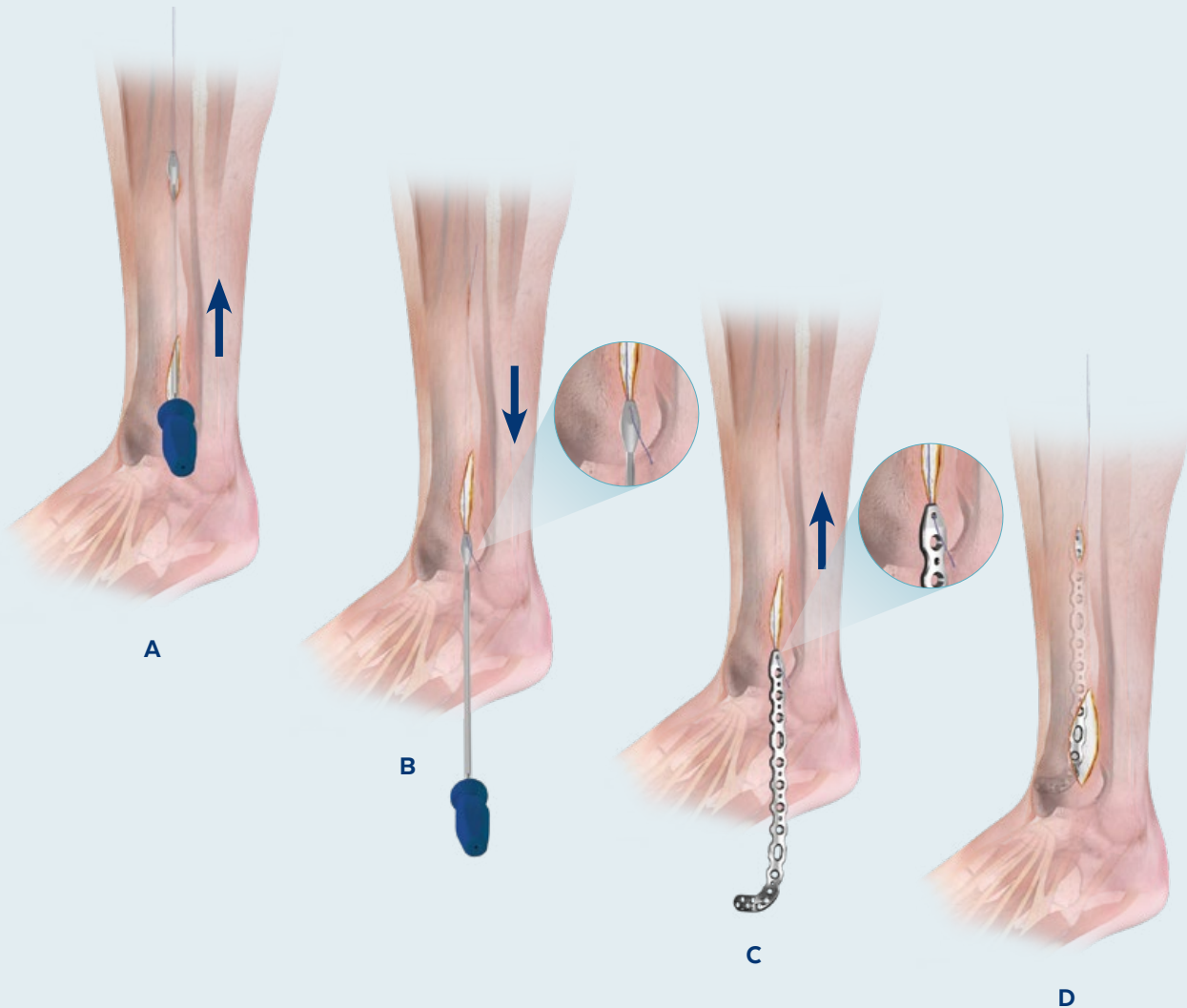
### USING THE CURVED COBB - DISTAL ENTRY

#### Subcutaneous Insertion

The Curved Cobb may be used to position long plates. Select the desired length plate. Position the plate on top of the skin and use a marking pen to mark the skin at the proximal end of the plate. Make a small incision at this proximal mark. **(A)** Pass the Curved Cobb through the distal incision to the level of the proximal incision.

Attach suture to the suture hole in the head of the Curved Cobb. **(B)** Retract the Curved Cobb from the distal incision while holding onto the free end of the suture. **(C)** Cut suture attached to the Curved Cobb and attach this end of the suture to the proximal portion of the plate. **(D)** Guide the plate through the distal incision and submuscularly up the tibial shaft by pulling the free end of the suture.







Cut the suture and remove it from the plate. Provisionally secure the plate to the bone using clamps or wires.











### Screw Compatibility

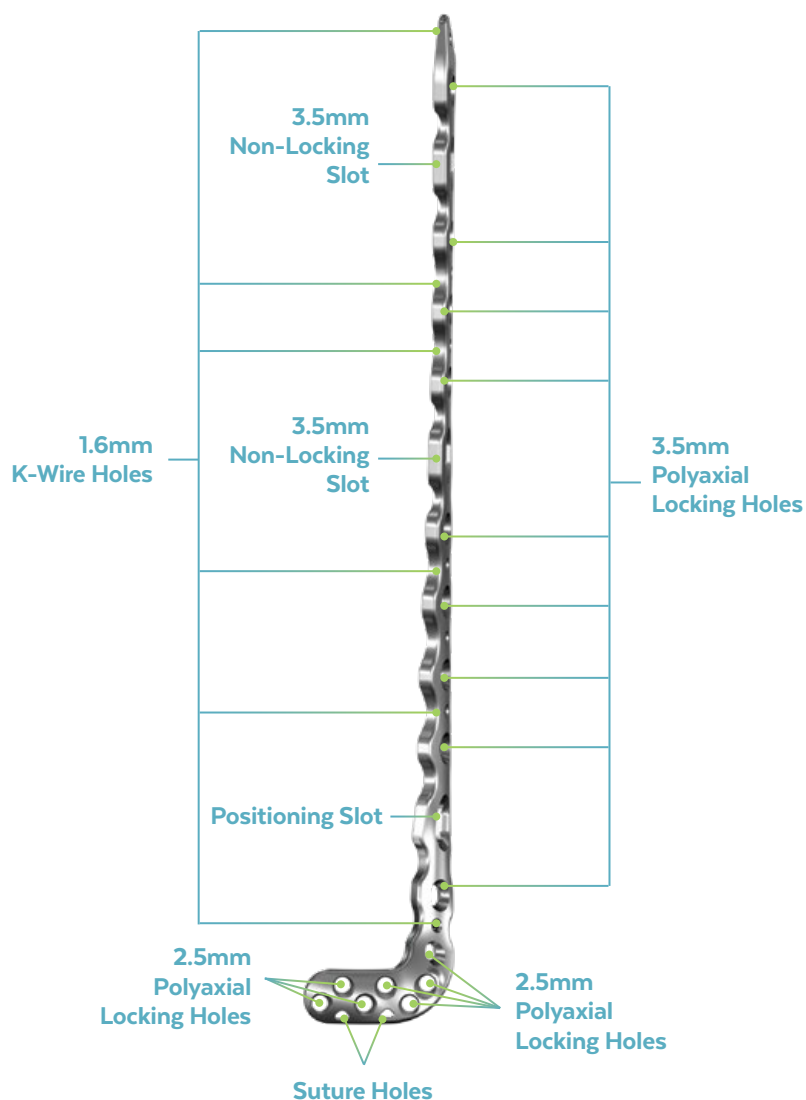
Screw compatibility is shown below for the Anterolateral Locking Plate. If screw-plate locking is desired in a polyaxial hole, only use locking screws. The 3.5mm Non-Locking Slots may be used for dynamic compression. Screw insertion order depends on fracture type, preliminary reduction, and surgeon preference. All non-locking screws should be placed prior to any locking screws. The positioning slot may be used to adjust plate position (see page 34 for details).

## 2.5/3.5mm Anterolateral Locking Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	







Positioning Slot/ 3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	











# SCREW INSERTION (CONT'D)

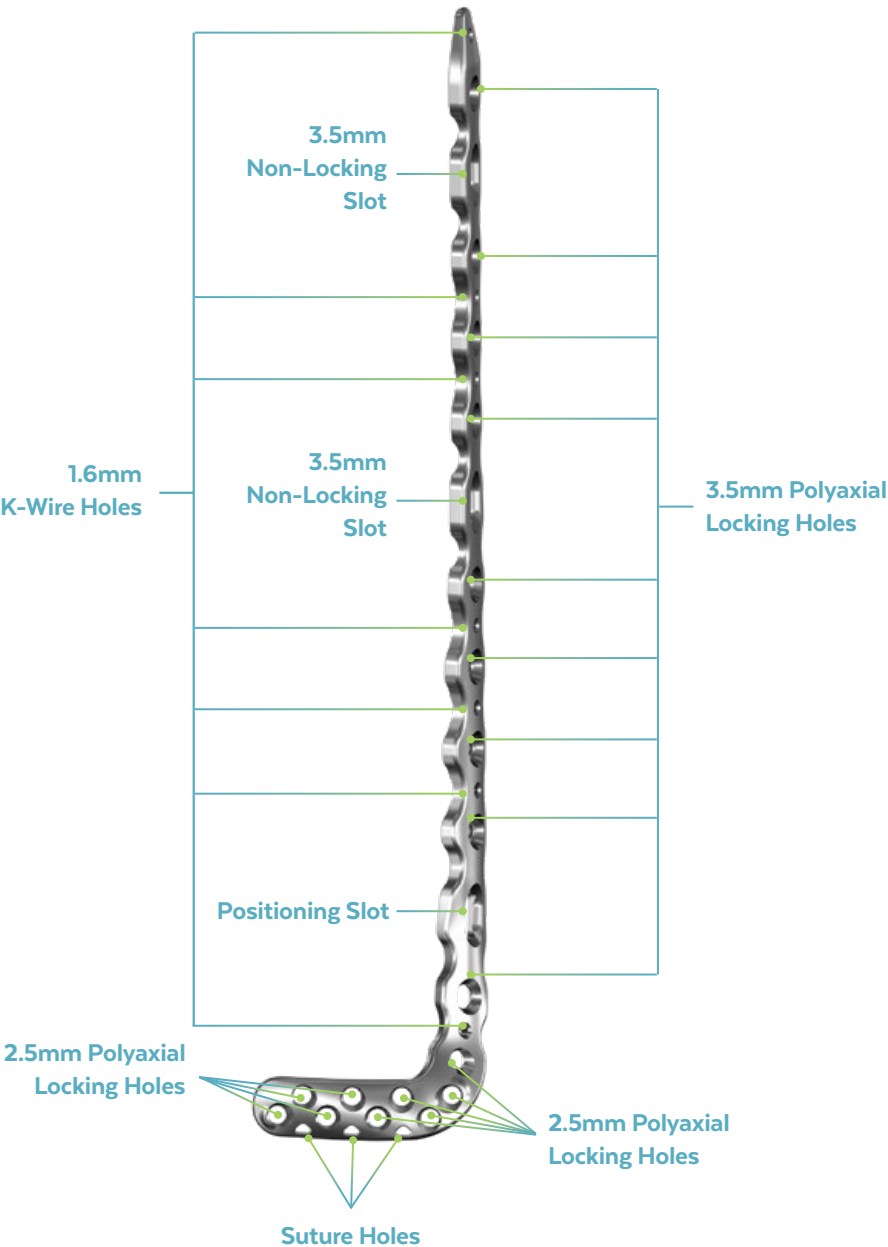
## Screw Compatibility

### Wide 2.5/3.5mm Anterolateral Locking Plate







3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	





2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	





Positioning Slot/ 3.5mm Non-locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

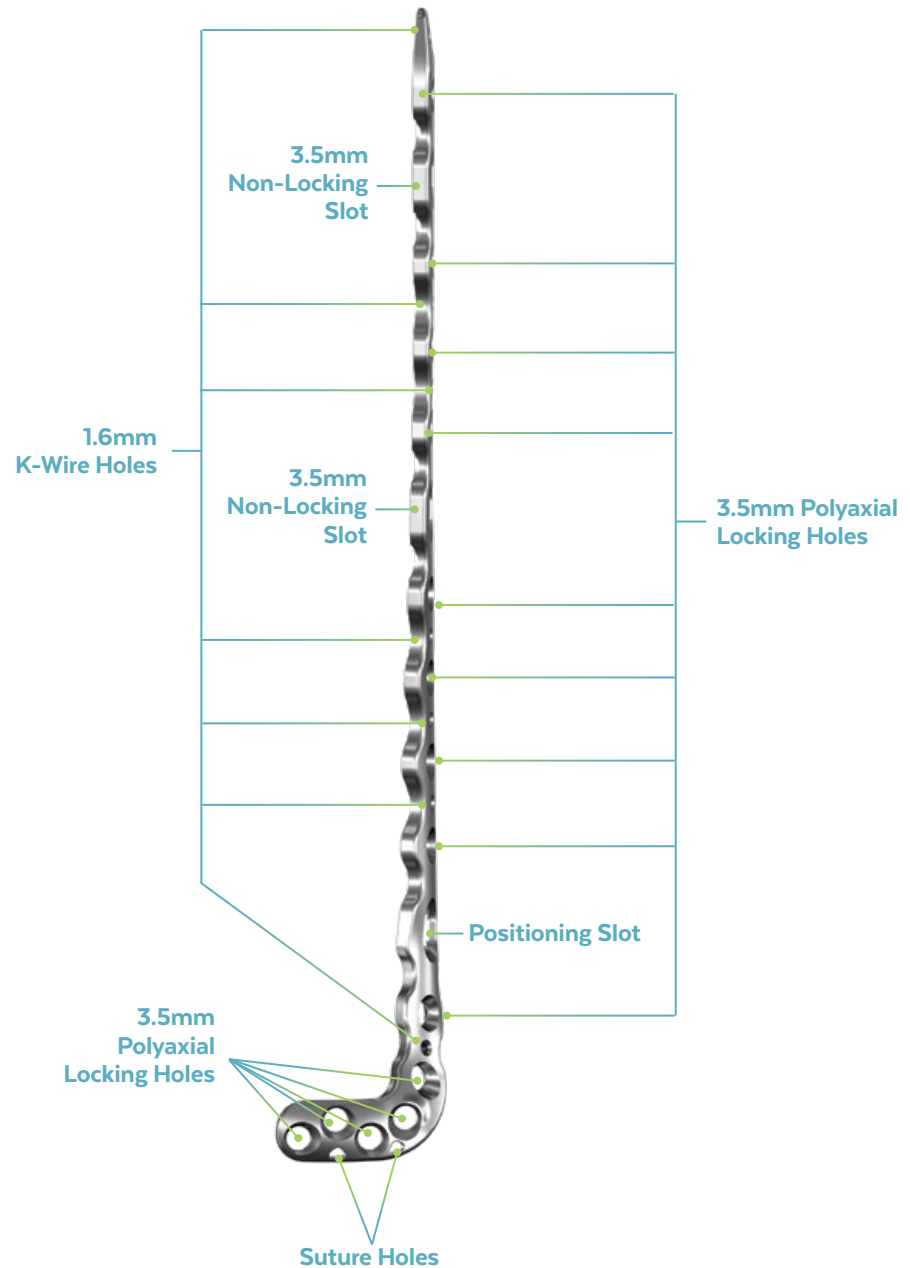


## 3.5mm Anterolateral Locking Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	

Positioning Slot/ 3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	



# SCREW INSERTION (CONT'D)

## Positioning Slot Screw

### 3.5mm Non-Locking and 4.0mm Cancellous Screws

The positioning slot is used to adjust plate position.

3.5mm Non-Locking Slots		
	 3.5mm Non-Locking	
	 4.0mm Cancellous*	



2.5/3.5mm  
Anterolateral  
Locking Plate



Wide 2.5/3.5mm  
Anterolateral  
Locking Plate

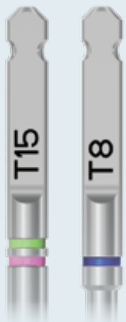


3.5mm  
Anterolateral  
Locking Plate

## COLOR-CODED INSTRUMENTS

Drills and drill guides are color-coded by screw size.

Color	Screw Diameter	Drill Diameter
Blue	2.5mm	1.8mm
Fuschia	3.5mm	2.7mm
Light Green	4.0mm	2.7mm



## Positioning Slot Screw

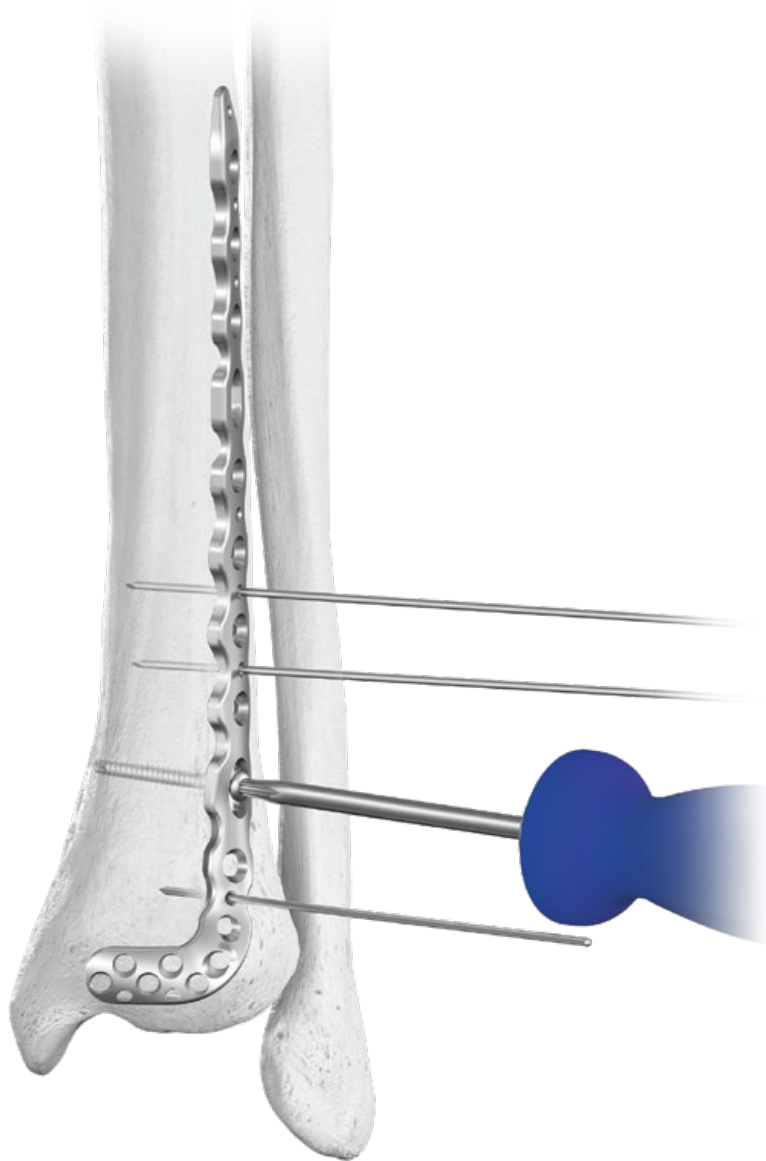
### *3.5mm Locking, 3.5mm Non-Locking, and 4.0mm Cancellous Screws*

Placing the positioning slot non-locking screw prior to other screws allows for minor plate position adjustments.

Use the 2.7mm Drill to drill to the desired depth. Measure screw length using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw. Verify length and diameter using the gauges within the screw module.

Insert a 3.5mm Non-Locking Screw into the elongated slot using the T15 Driver and the Quick-Connect Handle manually or under power. Confirm plate position using fluoroscopy.

Adjust plate position as necessary before final tightening manually. Confirm screw position using fluoroscopy.


















Positioning Slot Screw

# SCREW INSERTION (CONT'D)

## 2.5/3.5mm Locking, 2.5/3.5mm Non-Locking, and 4.0mm Cancellous Screws

Determine the appropriate combination of locking and non-locking screws for the desired fixation. If screw-plate locking is desired in a polyaxial hole, only use locking screws.

3.5mm Polyaxial Locking Holes		
		
		
		

2.5mm Polyaxial Locking Holes		
		
		



2.5/3.5mm Anterolateral Locking Plate



Wide 2.5/3.5mm Anterolateral Locking Plate



3.5mm Anterolateral Locking Plate

## Polyaxial Distal Screws

### 2.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the 1.8mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T8 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 2.5mm Locking or Non-Locking Screws into the screw holes using the T8 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 2.5mm Locking Screws using the 1.2Nm Torque-Limiting Attachment.

### 3.5mm Locking, 3.5mm Non-Locking, and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

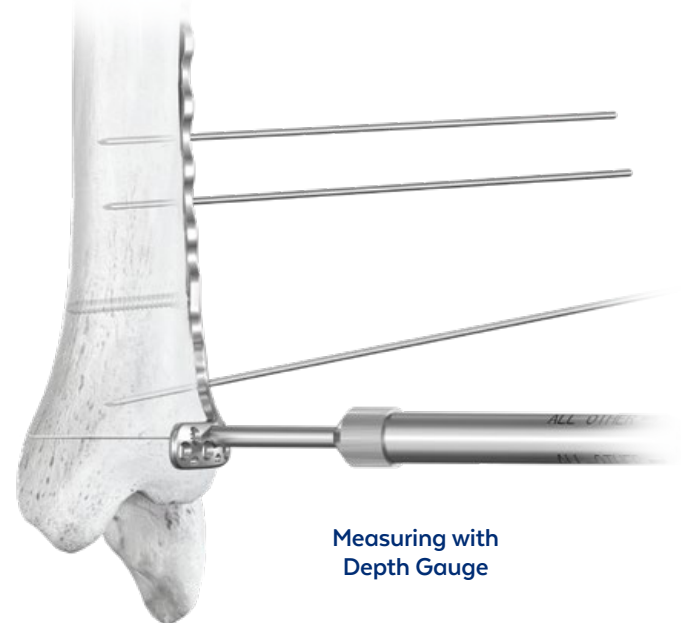
Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 3.5mm Locking or Non-Locking Screws into the screw holes using the T15 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 3.5mm Locking Screws using the 2.5Nm Torque-Limiting Attachment.



Pre-drilling



Measuring with Depth Gauge













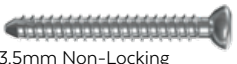




Screw insertion

# SCREW INSERTION (CONT'D)

## Shaft Holes

3.5mm Locking, 3.5mm Non-Locking, and 4.0mm Cancellous Screws

3.5mm Polyaxial Locking Holes		
		
		
		

3.5mm Non-Locking Slots		
		
		



2.5/3.5mm  
Anterolateral  
Locking Plate



Wide 2.5/3.5mm  
Anterolateral  
Locking Plate



3.5mm  
Anterolateral  
Locking Plate

Confirm proximal plate positioning using fluoroscopy. Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with the bone. Insert 3.5mm Locking or Non-Locking Screws into the screw holes using the T15 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.

For hard cortical bone, it is recommended to use the cortical tap before screw insertion.

## STEP

## 8

## VERIFY PLACEMENT

Confirm reduction and fixation using fluoroscopy. Ensure that screw tips are not intra-articular. Check screw placement in all planes, as angulation and direction may be difficult to visualize.



AP view



Lateral view

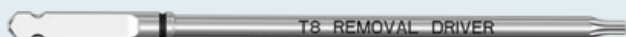
## OPTIONAL: REMOVAL

If removal is required, unlock and remove all locking screws from the plate with the appropriate screwdriver first. Then remove non-locking screws using the corresponding screwdrivers. This prevents simultaneous rotation of the plate. Once all screws are removed from the bone, the plate may be removed. For 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm screws, use the Non-Self-Retaining T15 Driver.



### NON-SELF-RETAINING DRIVERS

Non-Self-Retaining Drivers help to maximize torque applied to the screw head during screw insertion and/or removal.



T8 Non-Self-Retaining Drivers



T15 Non-Self-Retaining Drivers

## SURGICAL TECHNIQUE

# ANTHEM<sup>®</sup>

## Auxiliary T- and L-Plates

Refer to the package insert (also printed at the back of this manual) for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

### STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate length and location of screws to ensure the proper plate type, plate position, and screw placement.

### STEP 2 PATIENT POSITIONING

Position the patient in the desired operative position. Using fluoroscopy, examine the fracture with AP and lateral views.

### STEP 3 APPROACH

Create an anterior or posterior incision to the distal tibia that allows for fracture reduction. Carefully avoid surrounding tissue.



Anterior incision



Posterior incision

**STEP****4****FRACTURE REDUCTION**

Perform appropriate reduction of the fracture. Ensure that bone length, alignment, and rotation are properly restored. Proper reduction should be confirmed using fluoroscopy. Compression may be achieved by driving lag screws through the fragments. Ensure that lag screw placement does not interfere with the plate.

**STEP****5****PLATE SELECTION**

Select the auxiliary plate type that best accommodates the patient's anatomy and fracture pattern.



T-Plate

L-Plate

**STEP****6****PLATE PLACEMENT**







Insert the plate through the incision, taking care to avoid damaging soft tissue. Position the plate. Confirm plate position using fluoroscopy. K-wires or reduction clamps may be used to provisionally fix the plate to the bone.





### Screw Compatibility



Screw compatibility is shown below for the T-Plate and L-Plate. If screw-plate locking is desired in a polyaxial hole, only use locking screws. The 3.5mm Non-Locking Slots may be used for dynamic compression. Screw insertion order depends on fracture type, preliminary reduction, and surgeon preference.

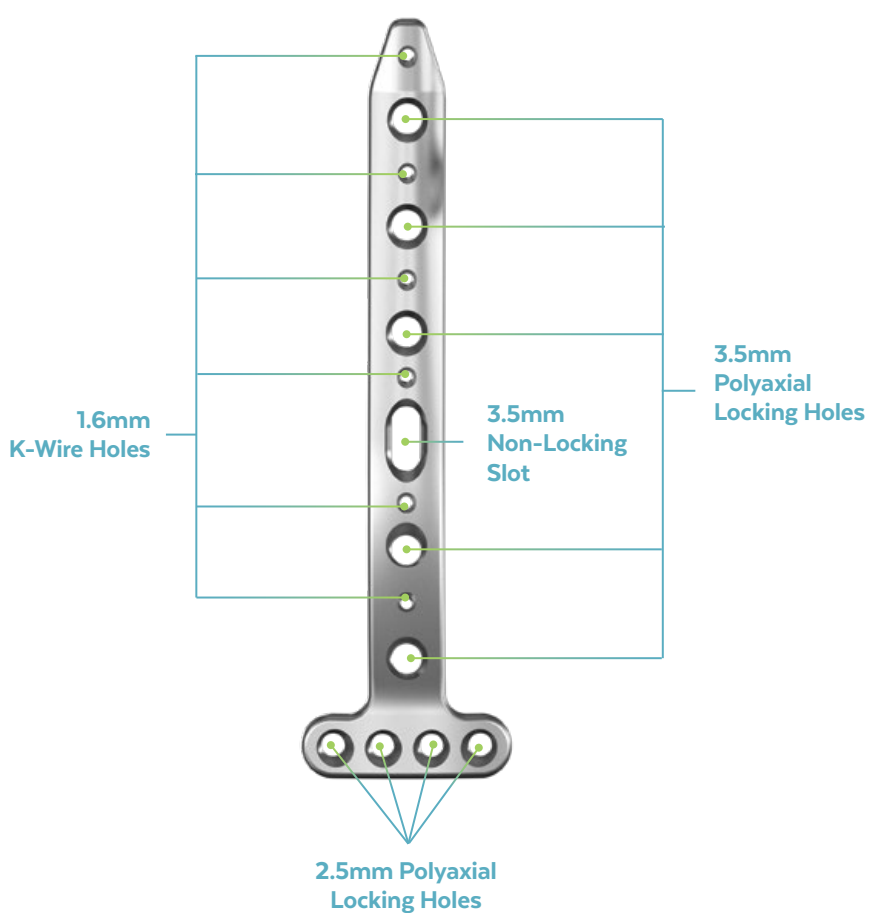
All non-locking screws should be placed prior to any locking screws.

### T-Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	







3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	











# SCREW INSERTION (CONT'D)

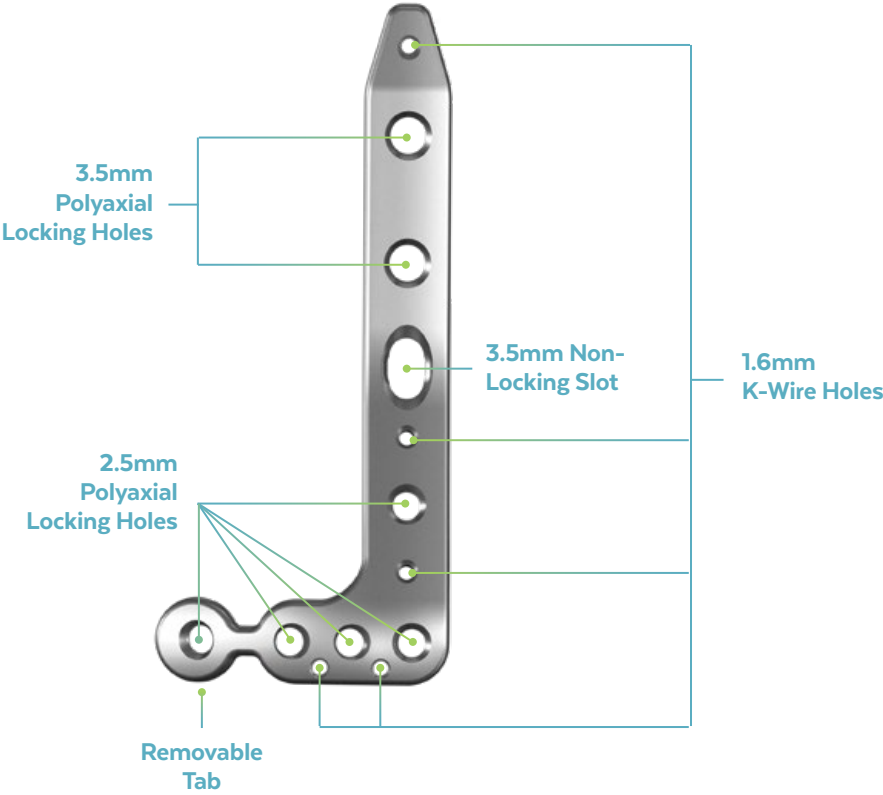
## Screw Compatibility

### L-Plate

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	

3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	



## 3.5mm Non-Locking Slot Screws and 4.0mm Cancellous Screws

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking screw through the 3.5mm Non-Locking Slot. If compression is not desired, place the screw in a neutral position (page 24).

Place a 3.5mm Non-Locking Screw distal to the fracture. Insert the 2.7/3.5mm Fixed Soft Tissue Protector eccentrically in the slotted hole.

Use the 2.7mm Drill to drill to the desired depth. Measure screw length using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw. Verify length and diameter using the gauges within the screw module.

Insert a 3.5mm Non-Locking Screw into the elongated slot using the T15 Driver and the Quick-Connect Handle manually or under power. Confirm plate position using fluoroscopy. Adjust plate position as necessary before final tightening manually. Confirm screw position using fluoroscopy.

For hard cortical bone, it is recommended to use the cortical tap before screw insertion.

## Polyaxial Distal Screws

### 2.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the 1.8mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T8 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 2.5mm Locking or Non-Locking Screws into the screw holes using the T8 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 2.5mm Locking Screws using the 1.2Nm Torque-Limiting Attachment.

### 3.5mm Locking, Non-Locking, and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 3.5mm Locking or Non-Locking Screws into the screw holes using the T15 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 3.5mm Locking Screws using the 2.5Nm Torque-Limiting Attachment.

## OPTIONAL: L-PLATE TAB REMOVAL

Clamp onto the tab with large forceps or surgical pliers. Bend the tab downward then upward. Repeat until the tabs break off.



Clamping tab with large forceps



Bending tab downward



Bending tab upward

**STEP****8****VERIFY PLACEMENT**

Confirm reduction and fixation using fluoroscopy. Ensure that screw tips are not intra-articular. Check screw placement in all planes, as angulation and direction may be difficult to visualize.



L-Plate AP view



L-Plate lateral view

## VERIFY PLACEMENT (CONT'D)



T-Plate AP view



T-Plate lateral view

## OPTIONAL: REMOVAL

If removal is required, unlock and remove all locking screws from the plate with the appropriate screwdriver first. Then remove non-locking screws using the corresponding screwdrivers. This prevents simultaneous rotation of the plate. Once all screws are removed from the bone, the plate may be removed. For 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm screws, use the Non-Self-Retaining T15 Driver.



### NON-SELF-RETAINING DRIVERS

Non-Self-Retaining Drivers help to maximize torque applied to the screw head during screw insertion and/or removal.



T8 Non-Self-Retaining Drivers



T15 Non-Self-Retaining Drivers

## SURGICAL TECHNIQUE

# ANTHEM<sup>®</sup>

## Metaphyseal Locking Distal Tibia Plate

Refer to the package insert (also printed at the back of this manual) for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

### STEP

### 1

## PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate length and location of screws to ensure the proper plate type, plate position, and screw placement.

### STEP

### 2

## APPROACH AND FRACTURE REDUCTION

Place the patient in the desired operative position. Create an incision to access the fracture site. Reduce the fracture using the appropriate reduction method for the fracture type. Carefully avoid surrounding tissue.

Ensure that bone length, alignment, and rotation are properly restored. Joint fractures often require anatomic reduction while functional reduction is usually sufficient for diaphyseal and meta-diaphyseal fractures.

Once reduction is achieved, Point-to-Point Reduction Forceps or K-wires may be used to provisionally hold the bone fragments in place. Confirm reduction under fluoroscopy. Compression may be achieved by driving lag screws through the fragments. Ensure that lag screw placement does not interfere with the plate.

Fracture reduction  
with forceps



## STEP

## 3

## PLATE SELECTION

Select the Metaphyseal Locking Plate type that best accommodates the patient anatomy and fracture pattern. Plates can be cut and contoured to fit patient anatomy.



Metaphyseal plates should be used in conjunction with additional plate fixation when used for non-load-bearing stabilization and reduction of long bone fragments.



Straight Metaphyseal



Long - Y Metaphyseal



Long - T Metaphyseal

## STEP

## 4

## PLATE PLACEMENT







Insert the plate through the incision, taking care to avoid damaging soft tissue. Position the plate. Confirm plate position using fluoroscopy. K-wires or reduction clamps may be used to provisionally fix the plate to the bone. Compression may be achieved by driving lag screws through the fragments.





### Screw Compatibility





Screw compatibility is shown below for the Metaphyseal Locking Plates. If screw-plate locking is desired in a polyaxial hole, only use locking screws. The 3.5mm Non-Locking Slots may be used for dynamic compression. Screw insertion order depends on fracture type, preliminary reduction, and surgeon preference.

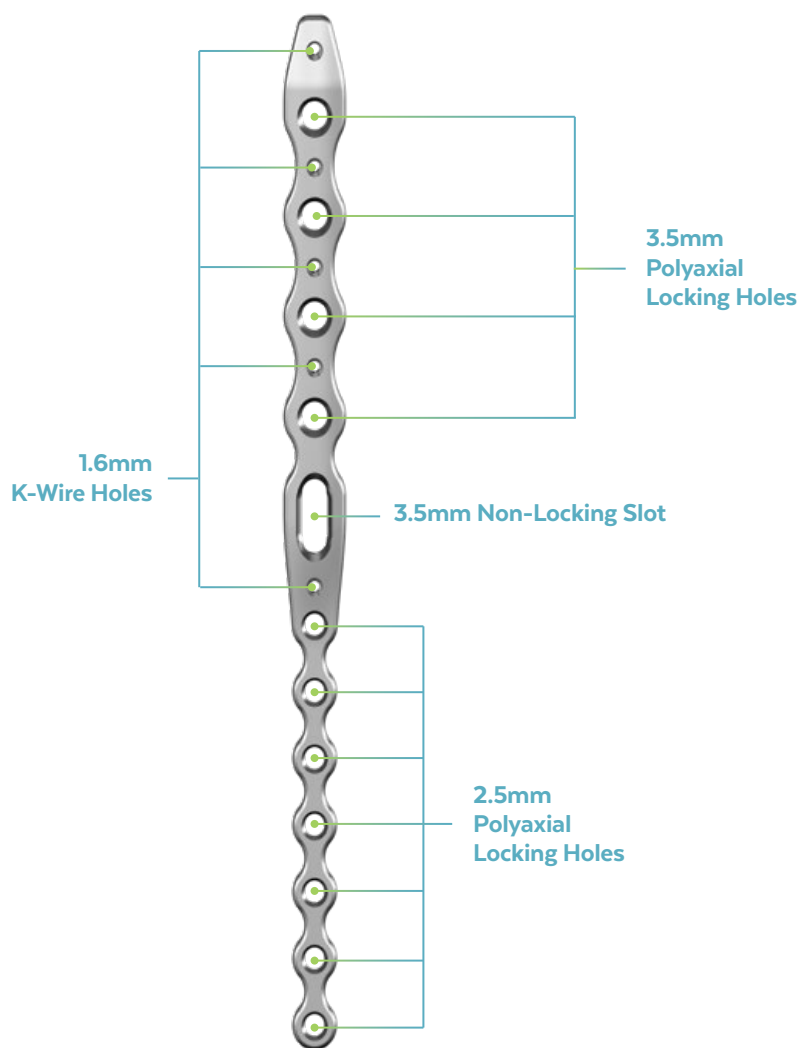
All Non-locking Screws should be placed prior to any locking screws.

### Straight Metaphyseal







3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	





2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	





3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

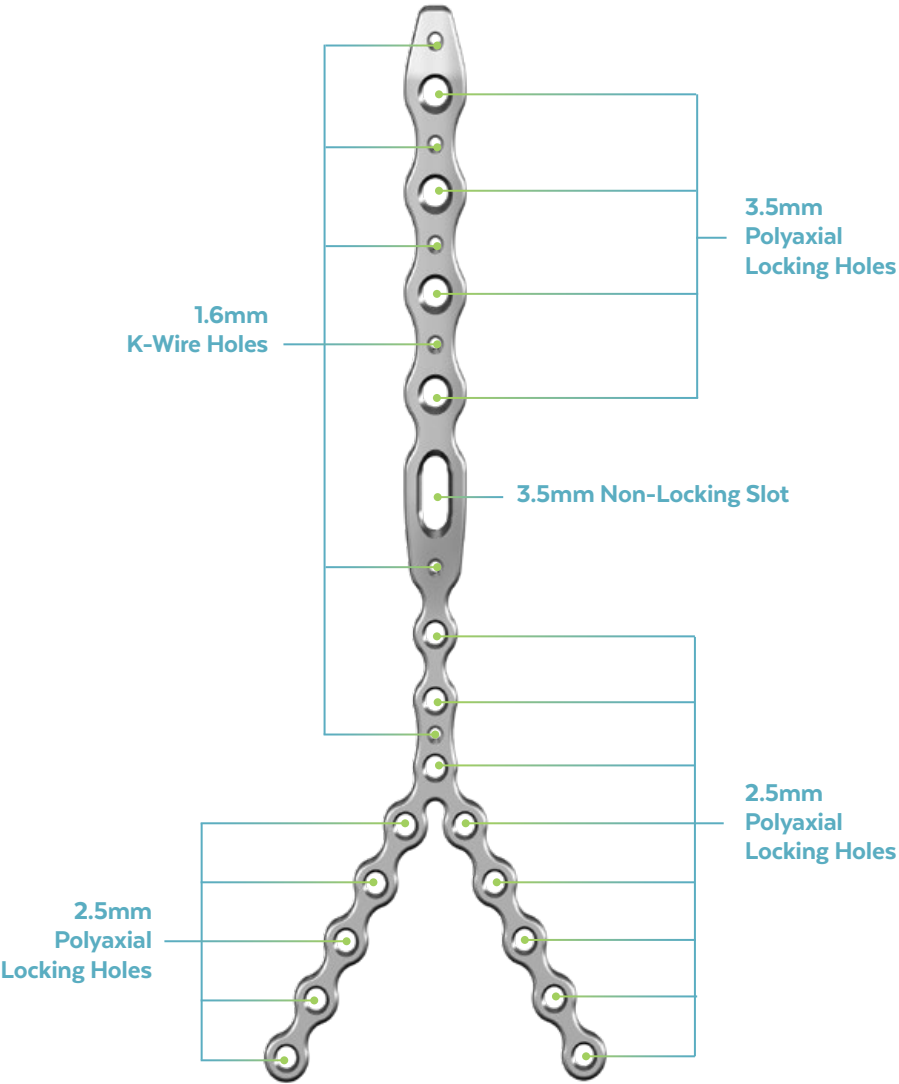


# Long - Y Metaphyseal

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	

3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	













\*Screws available in ANTHEM® Ankle Fracture Screw Module





# SCREW INSERTION (CONT'D)

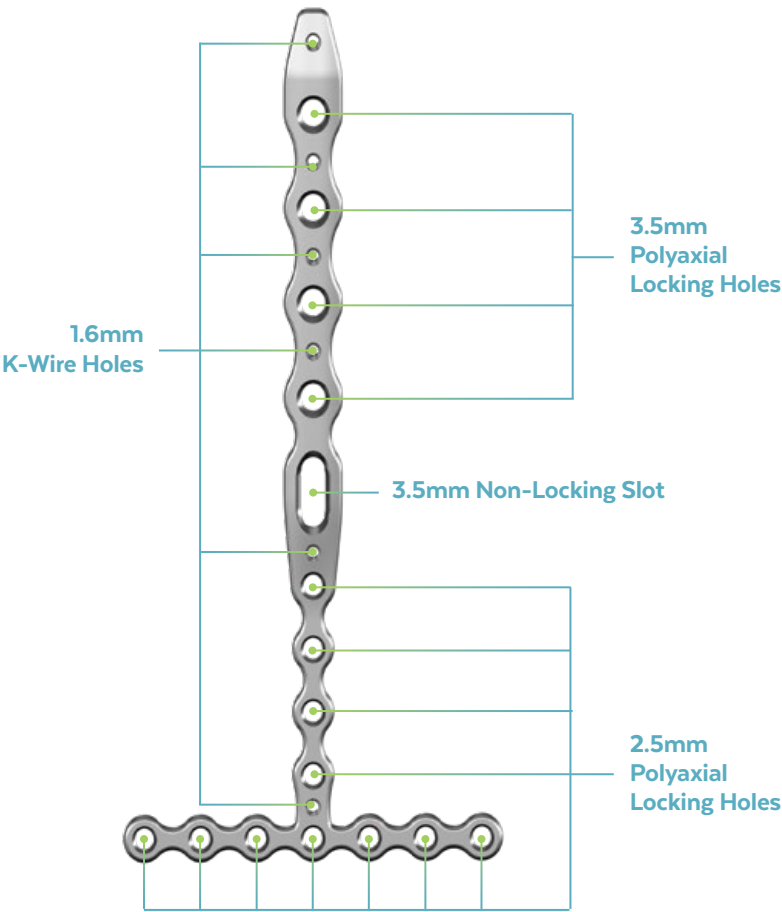
## Screw Compatibility

### Long - T Metaphyseal

3.5mm Polyaxial Locking Holes	
	
3.5mm Locking	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	

2.5mm Polyaxial Locking Holes	
	
2.5mm Locking	
	
2.5mm Non-Locking	

3.5mm Non-Locking Slots	
	
3.5mm Non-Locking	
	
4.0mm Cancellous*	



### 3.5mm Non-Locking Slot Screws and 4.0mm Cancellous Screws

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking screw through the 3.5mm Non-Locking Slot. If compression is not desired, place the screw in a neutral position (page 24).

Place a 3.5mm Non-Locking Screw distal to the fracture. Insert the 2.7/3.5mm Fixed Soft Tissue Protector into the oblong hole with no downward pressure. Place the selected Soft Tissue Protector eccentrically in the slotted hole.

Use the 2.7mm Drill to drill to the desired depth. Measure screw length using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw. Verify length and diameter using the gauges within the screw module.

Insert a 3.5mm Non-Locking Screw into the elongated slot using the T15 Driver and the Quick-Connect Handle manually or under power. Confirm plate position using fluoroscopy.

Adjust plate position as necessary before final tightening manually. Confirm screw position using fluoroscopy.

### Polyaxial Distal Screws

#### 2.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the 1.8mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T8 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 2.5mm Locking or Non-Locking Screws into the screw holes using the T8 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 2.5mm Locking Screws using the 1.2Nm Torque-Limiting Attachment.

#### 3.5mm Locking, Non-Locking, and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (pages 21-22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Ensure the plate is in secure contact with bone before placing locking screws. Insert 3.5mm Locking or Non-Locking Screws into the screw holes using the T15 Driver. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Insert 3.5mm Locking Screws using the 2.5Nm Torque-Limiting Attachment.

**STEP****6****VERIFY PLACEMENT**

Insert the plate through the incision, taking care to avoid damaging soft tissue. Confirm reduction and fixation using fluoroscopy. Ensure that screw tips are not intra-articular. Check screw placement in all planes, as angulation and direction may be difficult to visualize.



**AP view**



**Lateral view**

## OPTIONAL: REMOVAL

If removal is required, unlock and remove all locking screws from the plate with the appropriate screwdriver first. Then remove non-locking screws using the corresponding screwdrivers. This prevents simultaneous rotation of the plate. Once all screws are removed from the bone, the plate may be removed. For 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm screws, use the Non-Self-Retaining T15 Driver.



### NON-SELF-RETAINING DRIVERS

Non-Self-Retaining Drivers help to maximize torque applied to the screw head during screw insertion and/or removal.



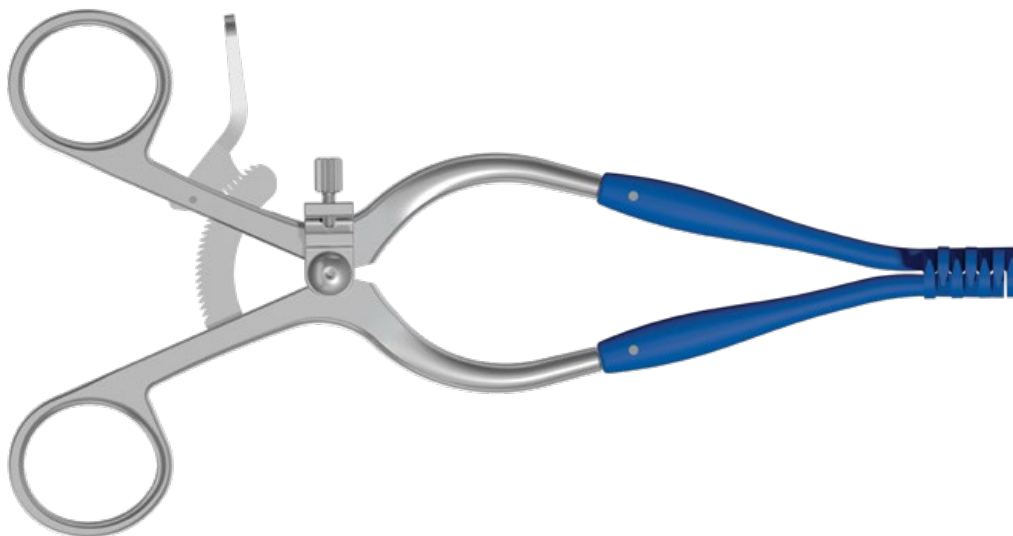
T8 Non-Self-Retaining Drivers



T15 Non-Self-Retaining Drivers

# INSTRUMENT OVERVIEW

## RETRACTION INSTRUMENTS



Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip 6171.0002



Malleable Wire Replacement 6171.7008



Curved Cobb 6170.7001

## REDUCTION INSTRUMENTS



1.6mm K-Wire, Drill Tip, 150mm 6170.1016



1.6mm K-Wire, Trocar Tip, 150mm 6179.1116



2.0mm K-Wire, Trocar Tip, 150mm 6179.1120



1.8mm Plate Holding K-Wire, 20mm 6170.1218



1.8mm Plate Holding K-Wire, 25mm 6170.1219



1.8mm Plate Holding K-Wire, 30mm 6170.1220



Ball Spike Pusher 6170.7003



Dental Pick, Curved Tip, Large Handle 6170.7005

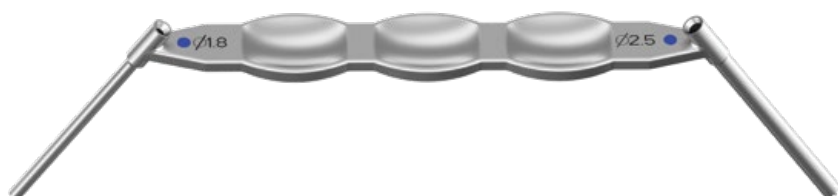
## DRILL GUIDES



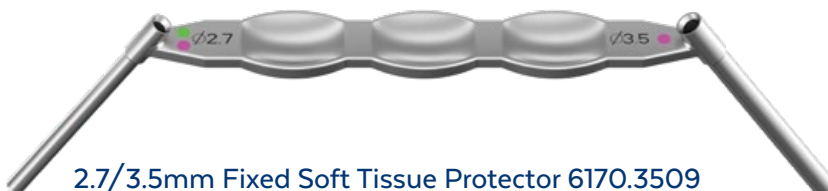
1.8mm Polyaxial Soft Tissue Protector 6170.3506



2.7mm Polyaxial Soft Tissue Protector 6170.3507



1.8/2.5mm Fixed Soft Tissue Protector 6170.3508



2.7/3.5mm Fixed Soft Tissue Protector 6170.3509



1.8mm Speed Lock Drill Guide, Long  
6171.4218



2.7mm Speed Lock Drill Guide, Long  
6171.4227

## DRILLS



1.8mm Drill Bit, AO QC, 170mm 6170.5018



2.7mm Drill Bit, AO QC, 180mm 6170.5027



2.5mm Drill Bit, 110mm, AO Quick-Connect 6179.5025



3.5mm Drill Bit, 110mm, AO Quick-Connect 6179.5035

## DEPTH GAUGE



Depth Gauge, 70mm 6170.7004

## COUNTERSINK



Countersink, AO Quick-Connect 6179.7000

## HANDLES



Medium Handle, AO Quick-Connect 6188.7001

## DRIVERS



T8 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect 6179.6108



T15 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect 6179.6115



Driver, T8 SR, 100mm, AO Quick-Connect 6187.5708



Driver, T15 SR, 100mm, AO Quick-Connect 6187.5715



Driver, T15 NSR, 200mm, AO Quick-Connect 6187.3815



Screw Retention Sleeve 6187.3350

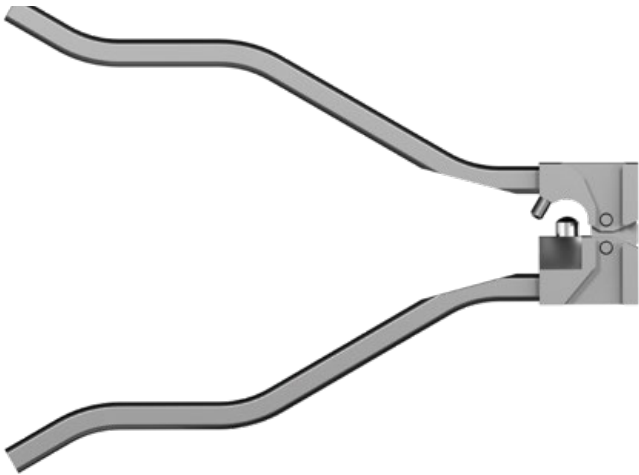


Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect 6187.3801

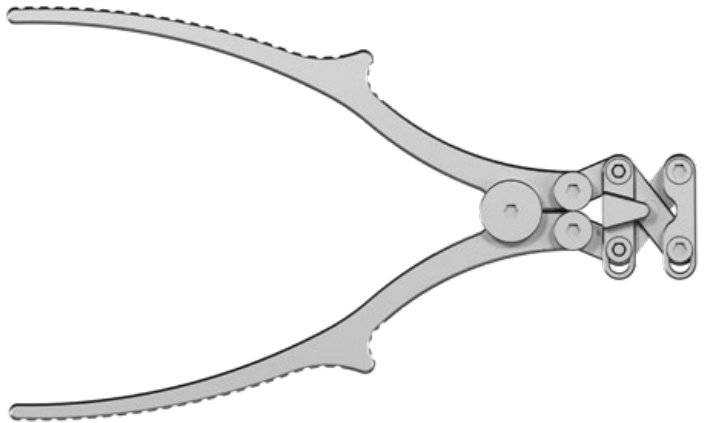


Torque-Limiting Attachment, 1.2Nm, AO Quick-Connect 6171.5012

## PLATE BENDERS



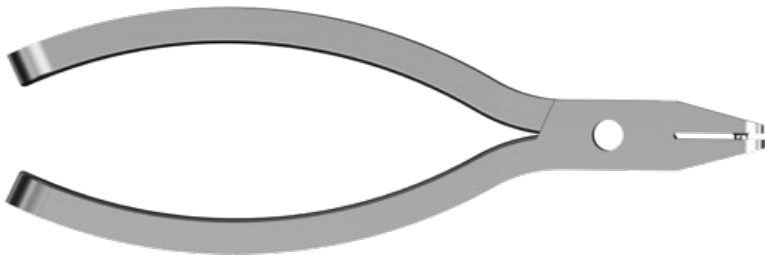
French Bender 6170.7010



Metaphyseal Plate Bender 6170.7110



*In Situ* Bender 6170.7000



Metaphyseal Plate Bending Pliers 6170.2000

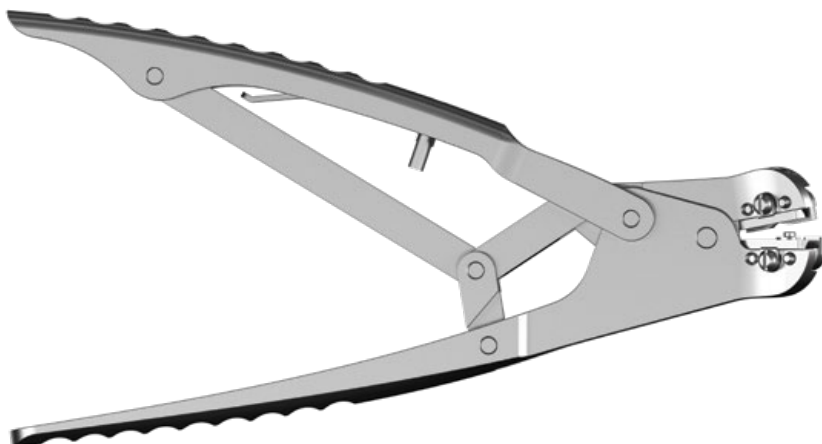


Plate Cutting Pliers 6170.2001

# ANTHEM<sup>®</sup> SS Distal Tibia IMPLANT AND INSTRUMENT SET 9170.9001

Part No.	Description	Qty	Part No.	Description	Qty
2170.0204	T-Plate, 2.5/3.5mm Polyaxial, 4 hole, 76mm, SS	1	6179.5035	3.5mm Drill Bit, 110mm, AO Quick-Connect	1
2170.0206	T-Plate, 2.5/3.5mm Polyaxial, 6 hole, 106mm, SS	1	6179.6108	T8 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	1
2170.0208	T-Plate, 2.5/3.5mm Polyaxial, 8 hole, 136mm, SS	1	6179.6115	T15 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	1
2170.1203	L-Plate, 2.5/3.5mm Polyaxial, Left, 3 hole, 80mm, SS	1	6179.7000	Countersink, AO Quick-Connect	1
2170.1204	L-Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 95mm, SS	1	6187.3350	Screw Retention Sleeve	1
2170.2203	L-Plate, 2.5/3.5mm Polyaxial, Right, 3 hole, 80mm, SS	1	6187.3801	Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect	1
2170.2204	L-Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 95mm, SS	1	6187.3815	Driver, T15 NSR, 200mm, AO Quick-Connect	1
6170.1016	1.6mm K-Wire, Drill Tip, 150mm	15	6187.5708	Driver, T8 SR, 100mm, AO Quick-Connect	2
6170.1218	1.8mm Plate Holding K-Wire	3	6187.5715	Driver, T15 SR, 100mm, AO Quick-Connect	2
6170.3506	1.8mm Polyaxial Soft Tissue Protector	1	6188.7001	Medium Handle, AO Quick-Connect	2
6170.3507	2.7mm Polyaxial Soft Tissue Protector	1	9170.0001	SS Implant and Instrument Graphic Case	
6170.3508	1.8/2.5mm Fixed Soft Tissue Protector	1			
6170.3509	2.7/3.5mm Fixed Soft Tissue Protector	1			
6170.5018	1.8mm Drill Bit, AO QC, 170mm	2			
6170.5027	2.7mm Drill Bit, AO QC, 180mm	2			
6170.7001	Curved Cobb	1			
6170.7003	Ball Spike Pusher	1			
6170.7004	Depth Gauge, 70mm	1			
6170.7005	Dental Pick, Curved Tip, Large Handle	1			
6170.7010	French Bender	1			
6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip	1			
6171.4218	1.8mm Speed Lock Drill Guide, Long	1			
6171.4227	2.7mm Speed Lock Drill Guide, Long	1			
6171.5012	Torque-Limiting Attachment, 1.2Nm, AO Quick-Connect	1			
6171.7008	Malleable Wire Replacement	4			
6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	15			
6179.1120	2.0mm K-Wire, Trocar Tip, 150mm	15			
6179.5025	2.5mm Drill Bit, 110mm, AO Quick-Connect	1			

# ANTHEM® Ti Distal Tibia

## IMPLANT AND INSTRUMENT SET 9170.9002

Part No.	Description	Qty	Part No.	Description	Qty
1170.0204	T-Plate, 2.5/3.5mm Polyaxial, 4 hole, 76mm, Ti	1	6179.5025	2.5mm Drill Bit, 110mm, AO Quick-Connect	1
1170.0206	T-Plate, 2.5/3.5mm Polyaxial, 6 hole, 106mm, Ti	1	6179.5035	3.5mm Drill Bit, 110mm, AO Quick-Connect	1
1170.0208	T-Plate, 2.5/3.5mm Polyaxial, 8 hole, 136mm, Ti	1	6179.6108	T8 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	1
1170.1203	L-Plate, 2.5/3.5mm Polyaxial, Left, 3 hole, 80mm, Ti	1	6179.6115	T15 Driver, Non-Self-Retaining, 100mm, AO Quick-Connect	1
1170.1204	L-Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 95mm, Ti2	1	6179.7000	Countersink, AO Quick-Connect	1
1170.2203	L-Plate, 2.5/3.5mm Polyaxial, Right, 3 hole, 80mm, Ti	1	6187.3350	Screw Retention Sleeve	1
1170.2204	L-Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 95mm, Ti	1	6187.3801	Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect	1
6170.1016	1.6mm K-Wire, Drill Tip, 150mm	15	6187.3815	Driver, T15 NSR, 200mm, AO Quick-Connect	1
6170.1218	1.8mm Trocar Tip Plate Holding K-Wire, 20mm	3	6187.5708	Driver, T8 SR, 100mm, AO Quick-Connect	2
6170.3506	1.8mm Polyaxial Soft Tissue Protector	1	6187.5715	Driver, T15 SR, 100mm, AO Quick-Connect	2
6170.3507	2.7mm Polyaxial Soft Tissue Protector	1	6188.7001	Medium Handle, AO Quick-Connect	2
6170.3508	1.8/2.5mm Fixed Soft Tissue Protector	1	9170.0002	Ti Implant and Instrument Graphic Case	
6170.3509	2.7/3.5mm Fixed Soft Tissue Protector	1			
6170.5018	1.8mm Drill Bit, AO QC, 170mm	2			
6170.5027	2.7mm Drill Bit, AO QC, 180mm	2			
6170.7001	Curved Cobb	1			
6170.7003	Ball Spike Pusher	1			
6170.7004	Depth Gauge, 70mm	1			
6170.7005	Dental Pick, Curved Tip, Large Handle	1			
6170.7010	French Bender	1			
6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8", Sharp Tip	1			
6171.4218	1.8mm Speed Lock Drill Guide, Long	1			
6171.4227	2.7mm Speed Lock Drill Guide, Long	1			
6171.5012	Torque-Limiting Attachment, 1.2Nm, AO Quick-Connect	1			
6171.7008	Malleable Wire Replacement	4			
6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	15			
6179.1120	2.0mm K-Wire, Trocar Tip, 150mm	15			

# ANTHEM® SS Distal Tibia Screw Module

## IMPLANT SET 9170.9003

### Non-Locking Screws

Part No.	Description	Qty	Part No.	Description	Qty
2171.6508	Non-Locking Screw, 2.5x8mm, SS	2	2179.3020	Non-Locking Screw, 3.5x20mm, SS	4
2171.6510	Non-Locking Screw, 2.5x10mm, SS	2	2179.3022	Non-Locking Screw, 3.5x22mm, SS	4
2171.6512	Non-Locking Screw, 2.5x12mm, SS	2	2179.3024	Non-Locking Screw, 3.5x24mm, SS	6
2171.6514	Non-Locking Screw, 2.5x14mm, SS	2	2179.3026	Non-Locking Screw, 3.5x26mm, SS	6
2171.6516	Non-Locking Screw, 2.5x16mm, SS	2	2179.3028	Non-Locking Screw, 3.5x28mm, SS	6
2171.6518	Non-Locking Screw, 2.5x18mm, SS	2	2179.3030	Non-Locking Screw, 3.5x30mm, SS	6
2171.6520	Non-Locking Screw, 2.5x20mm, SS	2	2179.3032	Non-Locking Screw, 3.5x32mm, SS	6
2171.6522	Non-Locking Screw, 2.5x22mm, SS	2	2179.3034	Non-Locking Screw, 3.5x34mm, SS	6
2171.6524	Non-Locking Screw, 2.5x24mm, SS	2	2179.3036	Non-Locking Screw, 3.5x36mm, SS	6
2171.6526	Non-Locking Screw, 2.5x26mm, SS	2	2179.3038	Non-Locking Screw, 3.5x38mm, SS	6
2171.6528	Non-Locking Screw, 2.5x28mm, SS	2	2179.3040	Non-Locking Screw, 3.5x40mm, SS	6
2171.6530	Non-Locking Screw, 2.5x30mm, SS	4	2179.3042	Non-Locking Screw, 3.5x42mm, SS	6
2171.6532	Non-Locking Screw, 2.5x32mm, SS	4	2179.3044	Non-Locking Screw, 3.5x44mm, SS	6
2171.6534	Non-Locking Screw, 2.5x34mm, SS	4	2179.3046	Non-Locking Screw, 3.5x46mm, SS	4
2171.6536	Non-Locking Screw, 2.5x36mm, SS	4	2179.3048	Non-Locking Screw, 3.5x48mm, SS	4
2171.6538	Non-Locking Screw, 2.5x38mm, SS	4	2179.3050	Non-Locking Screw, 3.5x50mm, SS	4
2171.6540	Non-Locking Screw, 2.5x40mm, SS	6	2179.3052	Non-Locking Screw, 3.5x52mm, SS	3
2171.6542	Non-Locking Screw, 2.5x42mm, SS	6	2179.3054	Non-Locking Screw, 3.5x54mm, SS	3
2171.6544	Non-Locking Screw, 2.5x44mm, SS	6	2179.3056	Non-Locking Screw, 3.5x56mm, SS	3
2171.6546	Non-Locking Screw, 2.5x46mm, SS	6	2179.3058	Non-Locking Screw, 3.5x58mm, SS	3
2171.6548	Non-Locking Screw, 2.5x48mm, SS	6	2179.3060	Non-Locking Screw, 3.5x60mm, SS	3
2171.6550	Non-Locking Screw, 2.5x50mm, SS	6	2179.3065	Non-Locking Screw, 3.5x65mm, SS	3
2171.6552	Non-Locking Screw, 2.5x52mm, SS	6	6179.2000	Screw Holding Forceps	1
2171.6554	Non-Locking Screw, 2.5x54mm, SS	6			
2171.6556	Non-Locking Screw, 2.5x56mm, SS	6			
2171.6558	Non-Locking Screw, 2.5x58mm, SS	6			
2171.6560	Non-Locking Screw, 2.5x60mm, SS	6			
2171.6565	Non-Locking Screw, 2.5x65mm, SS	6			
2179.3008	Non-Locking Screw, 3.5x8mm, SS	2			
2179.3010	Non-Locking Screw, 3.5x10mm, SS	2			
2179.3012	Non-Locking Screw, 3.5x12mm, SS	2			
2179.3014	Non-Locking Screw, 3.5x14mm, SS	2			
2179.3016	Non-Locking Screw, 3.5x16mm, SS	2			
2179.3018	Non-Locking Screw, 3.5x18mm, SS	2			

# ANTHEM® SS Distal Tibia Screw Module

## IMPLANT SET 9170.9003

### Locking Screws

Part No.	Description	Qty	Part No.	Description	Qty
7171.5508	Locking Screw, 2.5x8mm CoCr	2	7179.5020	Locking Screw, 3.5x20mm, CoCr	6
7171.5510	Locking Screw, 2.5x10mm, CoCr	2	7179.5022	Locking Screw, 3.5x22mm, CoCr	6
7171.5512	Locking Screw, 2.5x12mm, CoCr	2	7179.5024	Locking Screw, 3.5x24mm, CoCr	6
7171.5514	Locking Screw, 2.5x14mm, CoCr	2	7179.5026	Locking Screw, 3.5x26mm, CoCr	6
7171.5516	Locking Screw, 2.5x16mm, CoCr	2	7179.5028	Locking Screw, 3.5x28mm, CoCr	6
7171.5518	Locking Screw, 2.5x18mm, CoCr	2	7179.5030	Locking Screw, 3.5x30mm, CoCr	6
7171.5520	Locking Screw, 2.5x20mm, CoCr	6	7179.5032	Locking Screw, 3.5x32mm, CoCr	6
7171.5522	Locking Screw, 2.5x22mm, CoCr	6	7179.5034	Locking Screw, 3.5x34mm, CoCr	6
7171.5524	Locking Screw, 2.5x24mm, CoCr	6	7179.5036	Locking Screw, 3.5x36mm, CoCr	6
7171.5526	Locking Screw, 2.5x26mm, CoCr	6	7179.5038	Locking Screw, 3.5x38mm, CoCr	6
7171.5528	Locking Screw, 2.5x28mm, CoCr	6	7179.5040	Locking Screw, 3.5x40mm, CoCr	6
7171.5530	Locking Screw, 2.5x30mm, CoCr	6	7179.5042	Locking Screw, 3.5x42mm, CoCr	6
7171.5532	Locking Screw, 2.5x32mm CoCr	6	7179.5044	Locking Screw, 3.5x44mm, CoCr	6
7171.5534	Locking Screw, 2.5x34mm CoCr	6	7179.5046	Locking Screw, 3.5x46mm, CoCr	6
7171.5536	Locking Screw, 2.5x36mm CoCr	6	7179.5048	Locking Screw, 3.5x48mm, CoCr	6
7171.5538	Locking Screw, 2.5x38mm CoCr	6	7179.5050	Locking Screw, 3.5x50mm, CoCr	6
7171.5540	Locking Screw, 2.5x40mm CoCr	6	7179.5052	Locking Screw, 3.5x52mm, CoCr	6
7171.5542	Locking Screw, 2.5x42mm CoCr	6	7179.5054	Locking Screw, 3.5x54mm, CoCr	6
7171.5544	Locking Screw, 2.5x44mm CoCr	6	7179.5056	Locking Screw, 3.5x56mm, CoCr	6
7171.5546	Locking Screw, 2.5x46mm CoCr	6	7179.5058	Locking Screw, 3.5x58mm, CoCr	6
7171.5548	Locking Screw, 2.5x48mm CoCr	6	7179.5060	Locking Screw, 3.5x60mm, CoCr	6
7171.5550	Locking Screw, 2.5x50mm CoCr	6	7179.5065	Locking Screw, 3.5x65mm, CoCr	6
7171.5552	Locking Screw, 2.5x52mm CoCr	6			
7171.5554	Locking Screw, 2.5x54mm CoCr	6	9170.0003	ANTHEM® Distal Tibia SS Screw Module	
7171.5556	Locking Screw, 2.5x56mm CoCr	6			
7171.5558	Locking Screw, 2.5x58mm CoCr	6			
7171.5560	Locking Screw, 2.5x60mm CoCr	6			
7171.5565	Locking Screw, 2.5x65mm CoCr	6			
7179.5008	Locking Screw, 3.5x8mm, CoCr	2			
7179.5010	Locking Screw, 3.5x10mm, CoCr	2			
7179.5012	Locking Screw, 3.5x12mm, CoCr	2			
7179.5014	Locking Screw, 3.5x14mm, CoCr	2			
7179.5016	Locking Screw, 3.5x16mm, CoCr	2			
7179.5018	Locking Screw, 3.5x18mm, CoCr	2			

# ANTHEM<sup>®</sup> Ti Distal Tibia Screw Module

## IMPLANT SET 9170.9004

### Non-Locking Screws

Part No.	Description	Qty	Part No.	Description	Qty
1171.6508	Non-Locking Screw, 2.5x8mm, Ti	2	1179.3020	Non-Locking Screw, 3.5x20mm, Ti	4
1171.6510	Non-Locking Screw, 2.5x10mm, Ti	2	1179.3022	Non-Locking Screw, 3.5x22mm, Ti	4
1171.6512	Non-Locking Screw, 2.5x12mm, Ti	2	1179.3024	Non-Locking Screw, 3.5x24mm, Ti	6
1171.6514	Non-Locking Screw, 2.5x14mm, Ti	2	1179.3026	Non-Locking Screw, 3.5x26mm, Ti	6
1171.6516	Non-Locking Screw, 2.5x16mm, Ti	2	1179.3028	Non-Locking Screw, 3.5x28mm, Ti	6
1171.6518	Non-Locking Screw, 2.5x18mm, Ti	2	1179.3030	Non-Locking Screw, 3.5x30mm, Ti	6
1171.6520	Non-Locking Screw, 2.5x20mm, Ti	2	1179.3032	Non-Locking Screw, 3.5x32mm, Ti	6
1171.6522	Non-Locking Screw, 2.5x22mm, Ti	2	1179.3034	Non-Locking Screw, 3.5x34mm, Ti	6
1171.6524	Non-Locking Screw, 2.5x24mm, Ti	2	1179.3036	Non-Locking Screw, 3.5x36mm, Ti	6
1171.6526	Non-Locking Screw, 2.5x26mm, Ti	2	1179.3038	Non-Locking Screw, 3.5x38mm, Ti	6
1171.6528	Non-Locking Screw, 2.5x28mm, Ti	2	1179.3040	Non-Locking Screw, 3.5x40mm, Ti	6
1171.6530	Non-Locking Screw, 2.5x30mm, Ti	4	1179.3042	Non-Locking Screw, 3.5x42mm, Ti	6
1171.6532	Non-Locking Screw, 2.5x32mm, Ti	4	1179.3044	Non-Locking Screw, 3.5x44mm, Ti	6
1171.6534	Non-Locking Screw, 2.5x34mm, Ti	4	1179.3046	Non-Locking Screw, 3.5x46mm, Ti	4
1171.6536	Non-Locking Screw, 2.5x36mm, Ti	4	1179.3048	Non-Locking Screw, 3.5x48mm, Ti	4
1171.6538	Non-Locking Screw, 2.5x38mm, Ti	4	1179.3050	Non-Locking Screw, 3.5x50mm, Ti	4
1171.6540	Non-Locking Screw, 2.5x40mm, Ti	6	1179.3052	Non-Locking Screw, 3.5x52mm, Ti	3
1171.6542	Non-Locking Screw, 2.5x42mm, Ti	6	1179.3054	Non-Locking Screw, 3.5x54mm, Ti	3
1171.6544	Non-Locking Screw, 2.5x44mm, Ti	6	1179.3056	Non-Locking Screw, 3.5x56mm, Ti	3
1171.6546	Non-Locking Screw, 2.5x46mm, Ti	6	1179.3058	Non-Locking Screw, 3.5x58mm, Ti	3
1171.6548	Non-Locking Screw, 2.5x48mm, Ti	6	1179.3060	Non-Locking Screw, 3.5x60mm, Ti	3
1171.6550	Non-Locking Screw, 2.5x50mm, Ti	6	1179.3065	Non-Locking Screw, 3.5x65mm, Ti	3
1171.6552	Non-Locking Screw, 2.5x52mm, Ti	6	6179.2000	Screw Holding Forceps	1
1171.6554	Non-Locking Screw, 2.5x54mm, Ti	6			
1171.6556	Non-Locking Screw, 2.5x56mm, Ti	6			
1171.6558	Non-Locking Screw, 2.5x58mm, Ti	6			
1171.6560	Non-Locking Screw, 2.5x60mm, Ti	6			
1171.6565	Non-Locking Screw, 2.5x65mm, Ti	6			
1179.3008	Non-Locking Screw, 3.5x8mm, Ti	2			
1179.3010	Non-Locking Screw, 3.5x10mm, Ti	2			
1179.3012	Non-Locking Screw, 3.5x12mm, Ti	2			
1179.3014	Non-Locking Screw, 3.5x14mm, Ti	2			
1179.3016	Non-Locking Screw, 3.5x16mm, Ti	2			
1179.3018	Non-Locking Screw, 3.5x18mm, Ti	2			

# ANTHEM® Ti Distal Tibia Screw Module

## IMPLANT SET 9170.9004

### Locking Screws

Part No.	Description	Qty	Part No.	Description	Qty
7171.5508	Locking Screw, 2.5x8mm CoCr	2	7179.5020	Locking Screw, 3.5x20mm, CoCr	6
7171.5510	Locking Screw, 2.5x10mm, CoCr	2	7179.5022	Locking Screw, 3.5x22mm, CoCr	6
7171.5512	Locking Screw, 2.5x12mm, CoCr	2	7179.5024	Locking Screw, 3.5x24mm, CoCr	6
7171.5514	Locking Screw, 2.5x14mm, CoCr	2	7179.5026	Locking Screw, 3.5x26mm, CoCr	6
7171.5516	Locking Screw, 2.5x16mm, CoCr	2	7179.5028	Locking Screw, 3.5x28mm, CoCr	6
7171.5518	Locking Screw, 2.5x18mm, CoCr	2	7179.5030	Locking Screw, 3.5x30mm, CoCr	6
7171.5520	Locking Screw, 2.5x20mm, CoCr	6	7179.5032	Locking Screw, 3.5x32mm, CoCr	6
7171.5522	Locking Screw, 2.5x22mm, CoCr	6	7179.5034	Locking Screw, 3.5x34mm, CoCr	6
7171.5524	Locking Screw, 2.5x24mm, CoCr	6	7179.5036	Locking Screw, 3.5x36mm, CoCr	6
7171.5526	Locking Screw, 2.5x26mm, CoCr	6	7179.5038	Locking Screw, 3.5x38mm, CoCr	6
7171.5528	Locking Screw, 2.5x28mm, CoCr	6	7179.5040	Locking Screw, 3.5x40mm, CoCr	6
7171.5530	Locking Screw, 2.5x30mm, CoCr	6	7179.5042	Locking Screw, 3.5x42mm, CoCr	6
7171.5532	Locking Screw, 2.5x32mm CoCr	6	7179.5044	Locking Screw, 3.5x44mm, CoCr	6
7171.5534	Locking Screw, 2.5x34mm CoCr	6	7179.5046	Locking Screw, 3.5x46mm, CoCr	6
7171.5536	Locking Screw, 2.5x36mm CoCr	6	7179.5048	Locking Screw, 3.5x48mm, CoCr	6
7171.5538	Locking Screw, 2.5x38mm CoCr	6	7179.5050	Locking Screw, 3.5x50mm, CoCr	6
7171.5540	Locking Screw, 2.5x40mm CoCr	6	7179.5052	Locking Screw, 3.5x52mm, CoCr	6
7171.5542	Locking Screw, 2.5x42mm CoCr	6	7179.5054	Locking Screw, 3.5x54mm, CoCr	6
7171.5544	Locking Screw, 2.5x44mm CoCr	6	7179.5056	Locking Screw, 3.5x56mm, CoCr	6
7171.5546	Locking Screw, 2.5x46mm CoCr	6	7179.5058	Locking Screw, 3.5x58mm, CoCr	6
7171.5548	Locking Screw, 2.5x48mm CoCr	6	7179.5060	Locking Screw, 3.5x60mm, CoCr	6
7171.5550	Locking Screw, 2.5x50mm CoCr	6	7179.5065	Locking Screw, 3.5x65mm, CoCr	6
7171.5552	Locking Screw, 2.5x52mm CoCr	6			
7171.5554	Locking Screw, 2.5x54mm CoCr	6	9170.0004	ANTHEM® Distal Tibia Ti Screw Module	
7171.5556	Locking Screw, 2.5x56mm CoCr	6			
7171.5558	Locking Screw, 2.5x58mm CoCr	6			
7171.5560	Locking Screw, 2.5x60mm CoCr	6			
7171.5565	Locking Screw, 2.5x65mm CoCr	6			
7179.5008	Locking Screw, 3.5x8mm, CoCr	2			
7179.5010	Locking Screw, 3.5x10mm, CoCr	2			
7179.5012	Locking Screw, 3.5x12mm, CoCr	2			
7179.5014	Locking Screw, 3.5x14mm, CoCr	2			
7179.5016	Locking Screw, 3.5x16mm, CoCr	2			
7179.5018	Locking Screw, 3.5x18mm, CoCr	2			

# ANTHEM® SS Distal Tibia 2.5/3.5mm Plate IMPLANT SET 9170.9005

Part No.	Description	Qty
2170.1004	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 100mm, SS	1
2170.1006	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 6 hole, 130mm, SS	1
2170.1008	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 160mm, SS	1
2170.1010	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 190mm, SS	1
2170.1012	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 12 hole, 220mm, SS	1
2170.1014	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 14 hole, 250mm, SS	1
2170.1104	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 85mm, SS	1
2170.1106	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 6 hole, 115mm, SS	1
2170.1108	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 145mm, SS	1
2170.1110	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 175mm, SS	1
2170.1112	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 12 hole, 205mm, SS	1
2170.1114	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 14 hole, 235mm, SS	1
2170.1704	ANTHEM® SS Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 85mm	1
2170.1706	ANTHEM® SS Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 6 hole, 115mm	1
2170.1708	ANTHEM® SS Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 145mm	1
2170.1710	ANTHEM® SS Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 175mm	1
2170.2004	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 100mm, SS	1
2170.2006	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 130mm, SS	1
2170.2008	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 160mm, SS	1
2170.2010	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 190mm, SS	1
2170.2012	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 12 hole, 220mm, SS	1
2170.2014	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 14 hole, 250mm, SS	1
2170.2104	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 85mm, SS	1
2170.2106	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 115mm, SS	1
2170.2108	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 145mm, SS	1
2170.2110	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 175mm, SS	1
2170.2112	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 12 hole, 205mm, SS	1
2170.2114	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 14 hole, 235mm, SS	1
2170.2704	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 85mm, SS	1
2170.2706	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 115mm, SS	1
2170.2708	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 145mm, SS	1
2170.2710	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 175mm, SS	1
9170.0005	ANTHEM® Distal Tibia SS 2.5/3.5mm Plate Module	

# ANTHEM® Ti Distal Tibia 2.5/3.5mm Plate IMPLANT SET 9170.9006

Part No.	Description	Qty
1170.1004	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 100mm, Ti	1
1170.1006	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 6 hole, 130mm, Ti	1
1170.1008	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 160mm, Ti	1
1170.1010	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 190mm, Ti	1
1170.1012	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 12 hole, 220mm, Ti	1
1170.1014	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 14 hole, 250mm, Ti	1
1170.1104	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 85mm, Ti	1
1170.1106	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 6 hole, 115mm, Ti	1
1170.1108	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 145mm, Ti	1
1170.1110	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 175mm, Ti	1
1170.1112	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 12 hole, 205mm, Ti	1
1170.1114	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 14 hole, 235mm, Ti	1
1170.1704	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 4 hole, 85mm, Ti	1
1170.1706	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/ 3.5mm Polyaxial, Left, 6 hole, 115mm, Ti	1
1170.1708	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 8 hole, 145mm, Ti	1
1170.1710	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Left, 10 hole, 175mm, Ti	1
1170.2004	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 100mm, Ti	1
1170.2006	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 130mm, Ti	1
1170.2008	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 160mm, Ti	1
1170.2010	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 190mm, Ti	1
1170.2012	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 12 hole, 220mm, Ti	1
1170.2014	ANTHEM® Medial Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 14 hole, 250mm, Ti	1
1170.2104	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 85mm, Ti	1
1170.2106	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 115mm, Ti	1
1170.2108	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 145mm, Ti	1
1170.2110	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 175mm, Ti	1
1170.2112	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 12 hole, 205mm, Ti	1
1170.2114	ANTHEM® Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 14 hole, 235mm, Ti	1
1170.2704	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 4 hole, 85mm, Ti	1
1170.2706	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 6 hole, 115mm, Ti	1
1170.2708	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 8 hole, 145mm, Ti	1
1170.2710	ANTHEM® Wide Anterolateral Distal Tibia Plate, 2.5/3.5mm Polyaxial, Right, 10 hole, 175mm, Ti	1
9170.0006	ANTHEM® Distal Tibia Ti 2.5/3.5mm Plate Module	

# ANTHEM<sup>®</sup> SS Distal Tibia 3.5mm Plate IMPLANT SET 9170.9007

Part No.	Description	Qty
2170.1024	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 4 hole, 100mm, SS	1
2170.1026	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 6 hole, 130mm, SS	1
2170.1028	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 8 hole, 160mm, SS	1
2170.1030	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 10 hole, 190mm, SS	1
2170.1032	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 12 hole, 220mm, SS	1
2170.1034	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 14 hole, 250mm, SS	1
2170.1124	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 4 hole, 85mm, SS	1
2170.1126	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 6 hole, 115mm, SS	1
2170.1128	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 8 hole, 145mm, SS	1
2170.1130	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 10 hole, 175mm, SS	1
2170.1132	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 12 hole, 205mm, SS	1
2170.1134	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 14 hole, 235mm, SS	1
2170.2024	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 4 hole, 100mm, SS	1
2170.2026	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 6 hole, 130mm, SS	1
2170.2028	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 8 hole, 160mm, SS	1
2170.2030	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 10 hole, 190mm, SS	1
2170.2032	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 12 hole, 220mm, SS	1
2170.2034	ANTHEM <sup>®</sup> Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 14 hole, 250mm, SS	1
2170.2124	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 4 hole, 85mm, SS	1
2170.2126	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 6 hole, 115mm, SS	1
2170.2128	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 8 hole, 145mm, SS	1
2170.2130	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 10 hole, 175mm, SS	1
2170.2132	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 12 hole, 205mm, SS	1
2170.2134	ANTHEM <sup>®</sup> Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 14 hole, 235mm, SS	1
9170.0007	ANTHEM <sup>®</sup> Distal Tibia SS 3.5mm Plate Module	

# ANTHEM® Ti Distal Tibia 3.5mm Plate IMPLANT SET 9170.9008

Part No.	Description	Qty
1170.1024	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 4 hole, 100mm, Ti	1
1170.1026	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 6 hole, 130mm, Ti	1
1170.1028	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 8 hole, 160mm, Ti	1
1170.1030	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 10 hole, 190mm, Ti	1
1170.1032	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 12 hole, 220mm, Ti	1
1170.1034	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Left, 14 hole, 250mm, Ti	1
1170.1124	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 4 hole, 85mm, Ti	1
1170.1126	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 6 hole, 115mm, Ti	1
1170.1128	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 8 hole, 145mm, Ti	1
1170.1130	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 10 hole, 175mm, Ti	1
1170.1132	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 12 hole, 205mm, Ti	1
1170.1134	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Left, 14 hole, 235mm, Ti	1
1170.2024	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 4 hole, 100mm, Ti	1
1170.2026	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 6 hole, 130mm, Ti	1
1170.2028	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 8 hole, 160mm, Ti	1
1170.2030	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 10 hole, 190mm, Ti	1
1170.2032	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 12 hole, 220mm, Ti	1
1170.2034	ANTHEM® Medial Distal Tibia Plate, 3.5mm Polyaxial, Right, 14 hole, 250mm, Ti	1
1170.2124	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 4 hole, 85mm, Ti	1
1170.2126	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 6 hole, 115mm, Ti	1
1170.2128	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 8 hole, 145mm, Ti	1
1170.2130	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 10 hole, 175mm, Ti	1
1170.2132	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 12 hole, 205mm, Ti	1
1170.2134	ANTHEM® Anterolateral Distal Tibia Plate, 3.5mm Polyaxial, Right, 14 hole, 235mm, Ti	1
9170.0008	ANTHEM® Distal Tibia Ti 3.5mm Plate Module	

# ANTHEM® SS Metaphyseal Plate IMPLANT SET 9170.9009

Part No.	Description	Qty
2170.9003	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 3 hole 125mm SS	2
2170.9005	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 5 hole 155mm SS	2
2170.9007	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 7 hole 185mm SS	2
2170.9363	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 3 hole 131mm SS	2
2170.9365	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 5 hole 161mm SS	2
2170.9367	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 7 hole 191mm SS	2
2170.9723	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 3 hole 105mm SS	2
2170.9725	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 5 hole 135mm SS	2
2170.9727	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 7 hole 165mm SS	2
6170.2000	Metaphyseal Plate Bending Pliers	2
6170.2001	Plate Cutting Pliers	1
6170.7000	<i>In Situ</i> Bender	2
6170.7110	Metaphyseal Plate Bender	1
9170.0009	ANTHEM® Distal Tibia SS Metaphyseal Plate and Instrument Set	

# ANTHEM® Ti Metaphyseal Plate IMPLANT SET 9170.9010

Part No.	Description	Qty
1170.9003	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 3 hole 125mm Ti	2
1170.9005	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 5 hole 155mm Ti	2
1170.9007	ANTHEM® Metaphyseal Straight Plate 2.5/3.5mm Polyaxial 7 hole 185mm Ti	2
1170.9363	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 3 hole 131mm Ti	2
1170.9365	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 5 hole 161mm Ti	2
1170.9367	ANTHEM® Metaphyseal Y Long Plate 2.5/3.5mm Polyaxial 7 hole 191mm Ti	2
1170.9723	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 3 hole 105mm Ti	2
1170.9725	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 5 hole 135mm Ti	2
1170.9727	ANTHEM® Metaphyseal T Long Plate 2.5/3.5mm Polyaxial 7 hole 165mm Ti	2
6170.2000	Metaphyseal Plate Bending Pliers	2
6170.2001	Plate Cutting Pliers	1
6170.7000	<i>In Situ</i> Bender	2
6170.7110	Metaphyseal Plate Bender	1
9170.0010	ANTHEM® Distal Tibia Ti Metaphyseal Plate and Instrument Set	

# IMPORTANT INFORMATION ON THE ANTHEM® DISTAL TIBIA FRACTURE SYSTEM

## DESCRIPTION

The ANTHEM® Fracture System is a family of plates and screws designed to be used for internal bone fixation. The implants are available in various sizes and shapes to accommodate patient anatomy, and may be contoured or straight, with locking and non-locking screws. ANTHEM® implants are manufactured from titanium, titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F67, F136, F1295, F1472, F1537, F2229, F138 and F139. All implants are for single use only.

## INDICATIONS

The ANTHEM® Fracture System is indicated for fixation of fractures, osteotomies, arthrodesis and reconstruction of bones for the appropriate size of the device to be used in adult patients, including the clavicle, scapula, humerus, radius, ulna, small bones (metacarpals, metatarsals, phalanges), wrist, pelvis, femur, tibia, fibula, ankle, and foot. The clavicle hook plate may be used for dislocations of the acromioclavicular joint. Mini fragment plates are also indicated for fixation of fractures of the acetabulum, patella, and bone fragments, replantation, malunions and nonunion, and for non-load bearing stabilization and reduction of long bone fragments. Metaphyseal plates are indicated for non-load bearing stabilization and reduction of long bone fragments, and for fixation of bones including the radius and ulna.

Small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius, distal tibia, metaphyseal, and mini fragment plates may be used in adolescents (12-21 years of age). Plating may be used in patients with osteopenic bone.

## CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- Any active or suspended latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, infection or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Use of plating on or around growth plates in pediatric patients.
- Material sensitivity, documented or suspected.
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the device itself.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

## WARNINGS

The correct implant selection is extremely important. Failure to use the appropriate implant for the fracture condition may accelerate clinical failure. Failure to use the proper component to maintain adequate blood supply and provide rigid fixation may result in loosening, bending, cracking or fracture of the implant and/or bone. The correct implant size for a given patient can be determined by evaluating the patient's height, weight, functional demands and anatomy. Every implant must be used in the correct anatomic location, consistent with accepted standards of internal fixation.

## PRECAUTIONS

The implantation of fixation devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implant size.

Surgical implants must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

## MR SAFETY INFORMATION

These devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

## CAUTIONS

### *Pre-operative*

- These implants are for single use only.

- Implants that came in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

### *Intra-operative*

- Avoid surface damage of implants.
- Discard all damaged or mishandled implants.
- Contouring or bending of an implant should be avoided where possible, because it may reduce its fatigue strength and can cause failure under load.
- Implants are available in different versions, varying for example in length, diameter, material and number of drilled holes. Select the required version carefully.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- Implants which consist of several components must only be used in the prescribed combination (refer to the ANTHEM® Surgical Technique Guide).
- After the procedure check the proper positioning of all implants using the image intensifier.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified (refer to the ANTHEM® Surgical Technique Guide).

### *Post-operative*

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

### *Informing the Patient*

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn each patient that the device cannot and does not replicate a normally healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

## ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. The following are the most frequent adverse effects involving the use of internal fracture fixation devices:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Internal fixation devices are load sharing devices which are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue. Loads on the device produced by load bearing and the patient's activity level will dictate the longevity of the device.
- Conditions attributable to non-union, osteoporosis, osteomalacia, diabetes, inhibited revascularization and poor bone formation can cause loosening, bending, cracking, fracture of the device or premature loss of rigid fixation with the bone.

# IMPORTANT INFORMATION ON THE ANTHEM® DISTAL TIBIA FRACTURE SYSTEM

- Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the effected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

## PACKAGING

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

The instruments are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, as described in the CLEANING section below.

## HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidentally contaminated.

## CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.

10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

## CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

## STERILIZATION

These implants may be available sterile or nonsterile. Instruments are available nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of  $10^{-6}$ . Sterile products are packaged in a heat sealed, Tyvek pouch or in a container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of  $10^{-6}$ . The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:











- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in<sup>2</sup> total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

*These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.*

**CAUTION:** Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		PRESCRIPTION USE ONLY

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## NOTES

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Globus Medical  
Valley Forge Business Center  
2560 General Armistead Avenue  
Audubon, PA 19403  
[www.globusmedical.com](http://www.globusmedical.com)

Customer Service:

Phone 1-866-GLOBUS1 (or 1-866-456-2871)

Fax 1-866-GLOBUS3 (or 1-866-456-2873)

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description, indications, contraindications, warnings, precautions and other important information.

GMTGD256  
08.22 Rev B