ANTHEM®

Proximal Tibia Fracture System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

ANTHEM®

Proximal Tibia Fracture System

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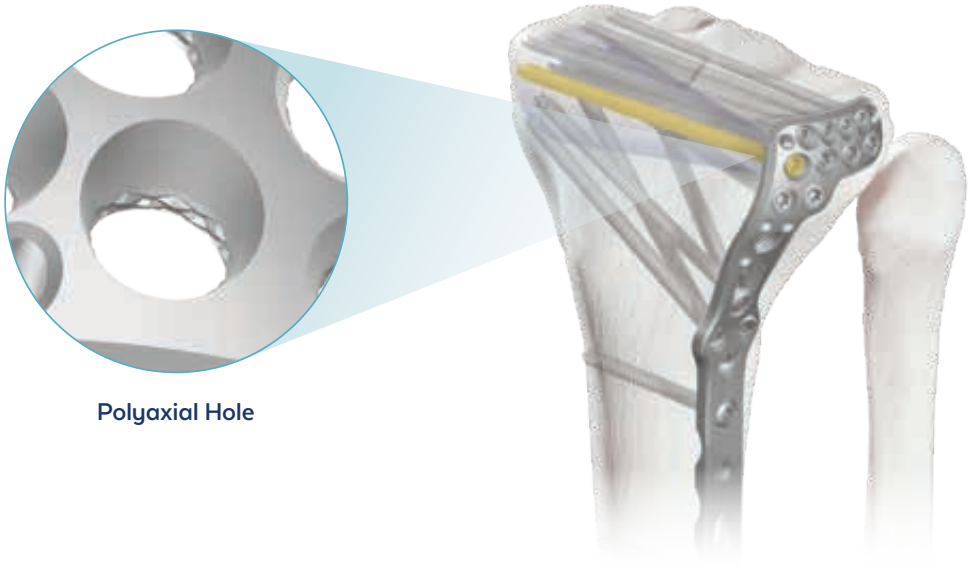
The ANTHEM® Proximal Tibia Fracture System provides low profile, anatomically contoured plates in a comprehensive set to treat a variety of tibial plateau and proximal tibia metaphyseal fractures.

The system features three styles of Lateral Proximal Tibia Plates, a Medial Locking Plate, and a Posteromedial Buttress Plate to address intra-articular and extra-articular fractures of the proximal tibia.

Streamlined and radiolucent instruments are designed to simplify the minimally invasive plating technique.

Lateral Plating Options

- **ANTHEM® XR Lateral Locking Plate** features an additional row of 2.5mm polyaxial locking screw options and a triple kickstand designed to provide additional medial column support
- **ANTHEM® Lateral Plate** features a triple kickstand to provide additional medial column support
- **Non-Locking Lateral Plate** features a low profile design for simple lateral fracture patterns



Polyaxial Hole

XR Lateral Locking Plate

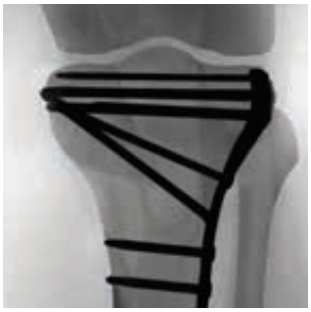
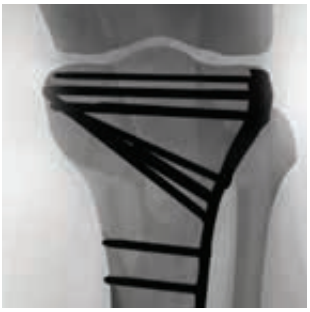
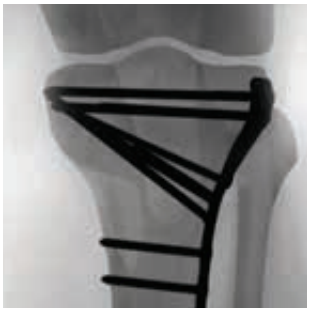
Comprehensive System

- Includes a Medial Locking and Posteromedial Buttress Plate
- Innovative radiolucent instruments for minimally invasive lateral procedures and retraction
- Select Small Fragment Plates included

Medial Locking Plate

Posteromedial Buttress Plate

SCHATZKER CLASSIFICATION AND SAMPLE CONSTRUCTS

TYPE I	LATERAL NON-LOCKING	XR LATERAL LOCKING	LATERAL LOCKING
			

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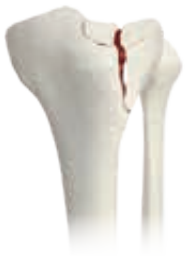	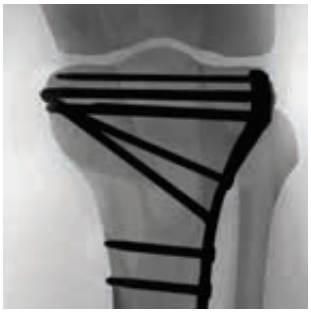	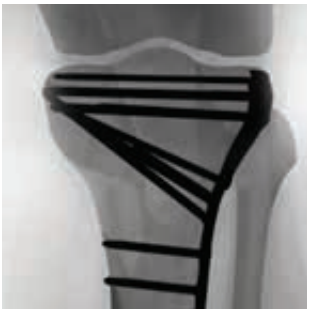	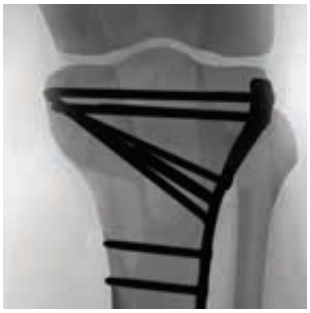

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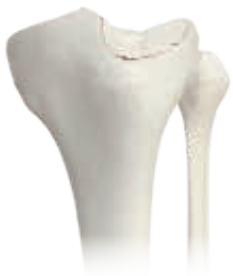
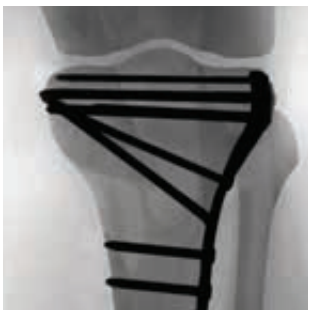
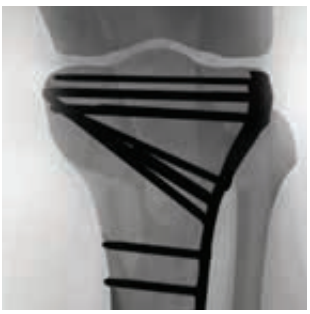
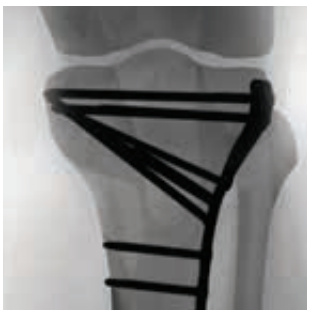
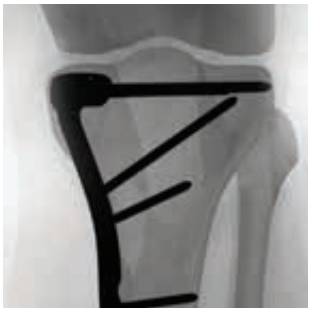
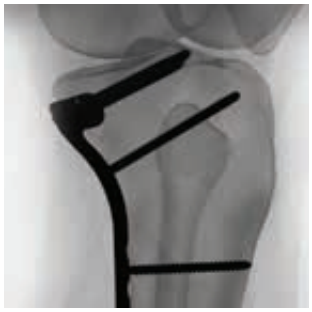
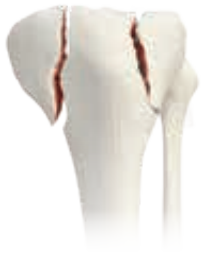
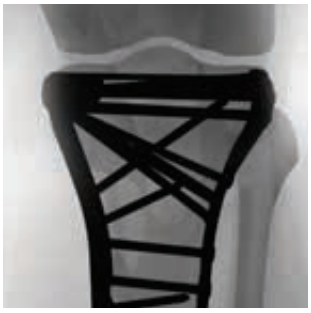
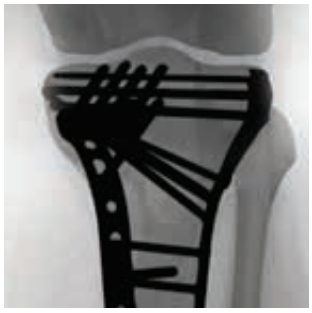
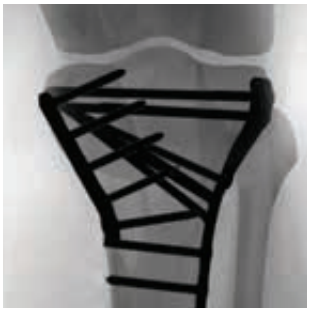
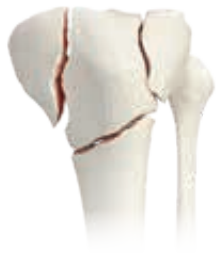
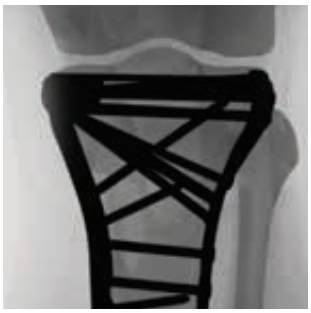
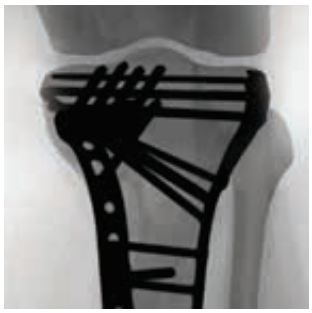
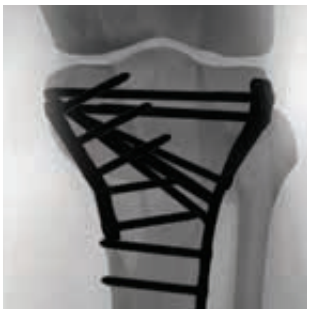
			

TYPE IV	MEDIAL	POSTEROMEDIAL
		

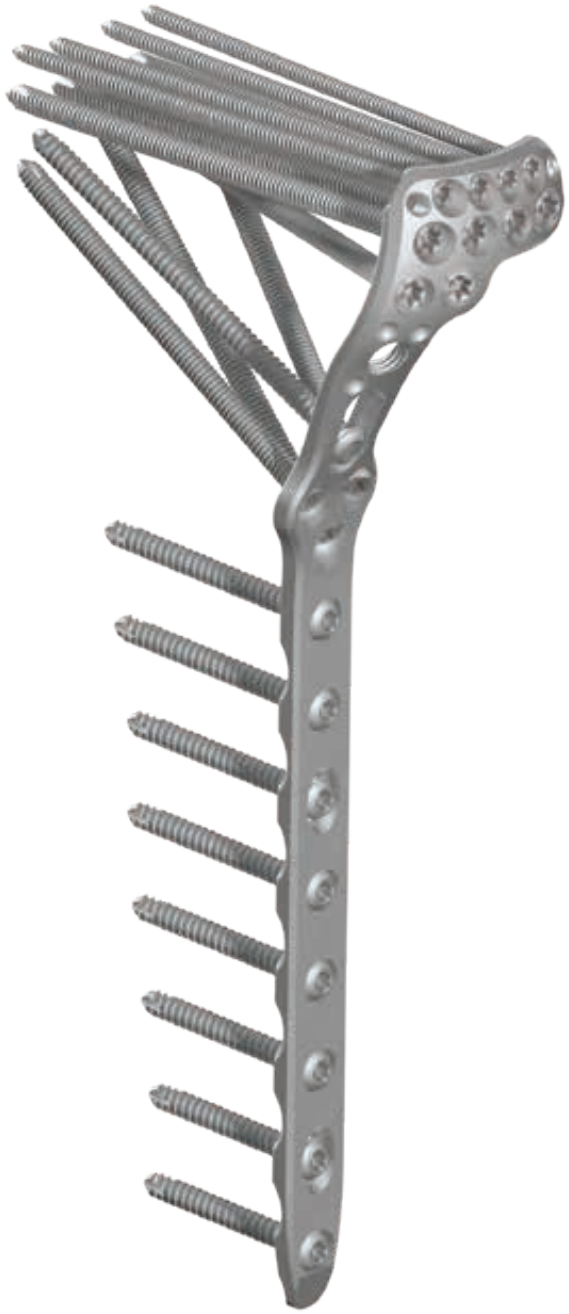
TYPE V	XR LATERAL LOCKING +MEDIAL	XR LATERAL LOCKING +POSTEROMEDIAL	XR LATERAL LOCKING + SMALL FRAGMENT
			

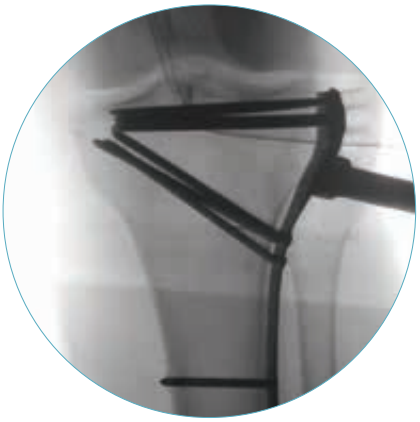
TYPE VI	XR LATERAL LOCKING +MEDIAL	XR LATERAL LOCKING +POSTEROMEDIAL	XR LATERAL LOCKING + SMALL FRAGMENT
			

XR LATERAL LOCKING PLATE

Anatomic Plate

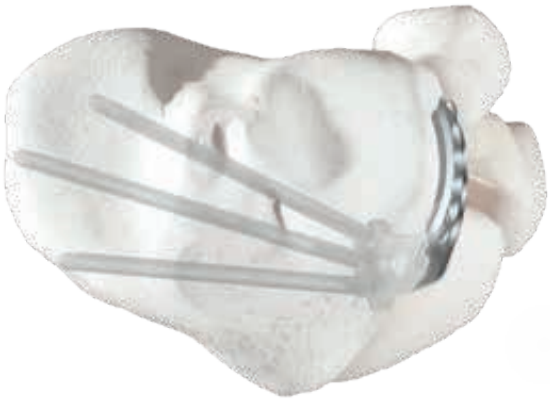
- Designed for an optimal fit to minimize intraoperative contouring and hardware prominence
- Proximal anterior contour designed to reduce tissue irritation





Rafting Screw Support

- Two rows of polyaxial rafting screws to support the articular surface
- Polyaxial locking holes (±20° cone of angulation) allow angled screw trajectories around prosthetics and accommodate varying patient anatomies

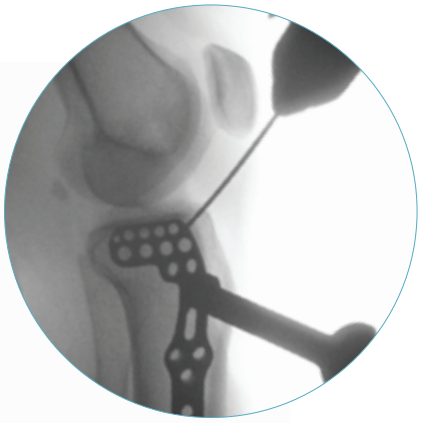


Triple Kickstand

- Multiple points of fixed angle support of medial column from laterally based plate
- Additional options for unstable bicondylar and proximal tibia metaphyseal fractures

Radiolucent Aiming Arm

- Optimized for lateral imaging using fluoroscopy and minimally invasive screw insertion
- Can be used with lateral locking plates
- Simplified assembly
- Self-retained tissue protection sleeves



Lateral view

IMPLANT OVERVIEW

Lateral Plates

Locking Plates

- XR Lateral Locking Plate
  - Additional row of 2.5mm polyaxial holes supports articular surface for complex articular injuries
- Lateral Locking Plate
  - Triple kickstand provides additional support of the medial column

Non-Locking Plate

- Lateral Non-Locking Plate
  - Low profile plate designed for buttressing of simple lateral tibial plateau fractures

XR Lateral Locking Plates

Lateral Locking Plates

Lateral Non-Locking Plates

Medial Locking Plate

- Designed to sit more posteriorly than competitive plates to reduce soft tissue irritation

Posteromedial Buttress Plate

- Versatile low profile plate designed to buttress posteromedial articular fragments

Small Fragment Locking Plates

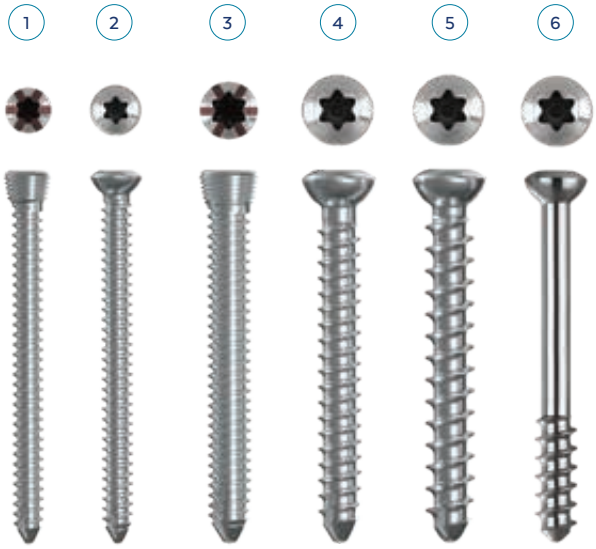
- One-Third Tubular and Reconstruction Plates are provided for additional fragment-specific fixation options

One-Third Tubular Plates

Reconstruction Plates

Screws

1. 2.5mm Locking
2. 2.5mm Non-Locking
3. 3.5mm Locking
4. 3.5mm Non-Locking
5. 4.0mm Cancellous
6. 4.0mm Partially Threaded Cancellous



SURGICAL TECHNIQUE

ANTHEM®

Lateral Locking Proximal 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 for the desired plate position.

STEP 2 PATIENT POSITIONING

Position the patient supine. Examine the fracture using fluoroscopy.

STEP 3 APPROACH

Create an anterolateral, lateral curved, or straight incision that allows access to the fracture. Carefully avoid surrounding soft tissue. Dissect through the fascia and split the illiotibial band.

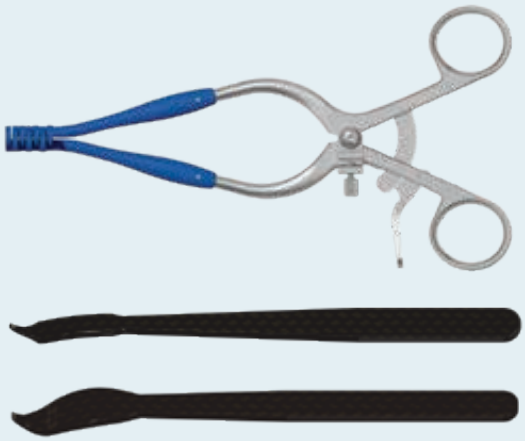
Lateral curved incision

RADIOLUCENT RETRACTION

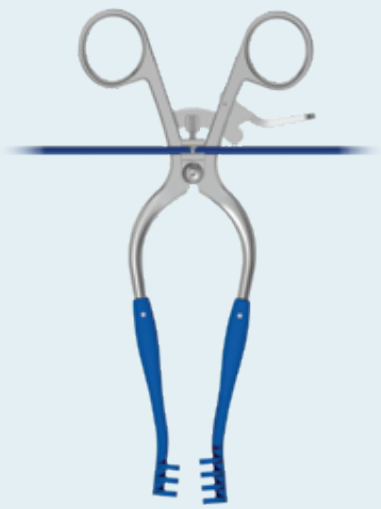
The **Stabilizing Radiolucent Weitlaners** and **Radiolucent Hohmann Retractors** are designed for fracture site visibility.

The **Malleable Band** secures the Stabilizing Radiolucent Weitlaners to the patient.

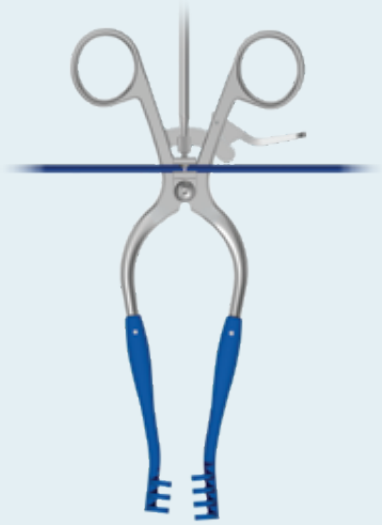
To assemble the Malleable Band, use a **T8 Driver** to loosen the set screw. Place the Malleable Band in the slot and tighten the screw.



Loosening set screw



Placing Malleable Band



Tightening set screw

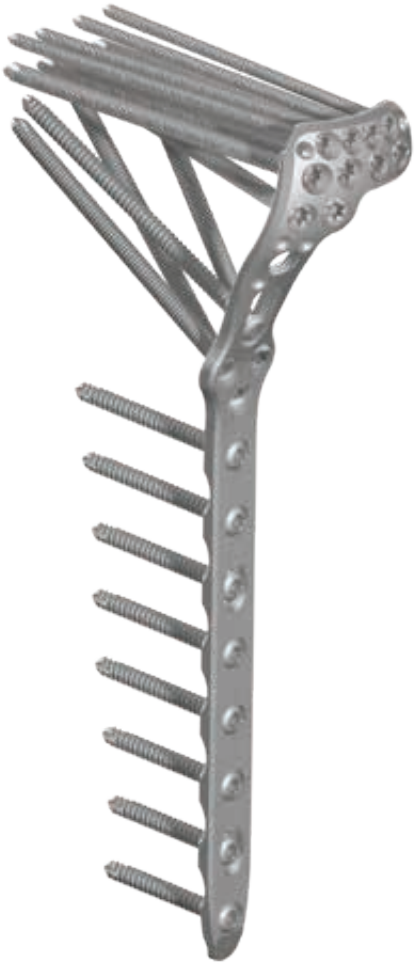
Once assembled, position the Stabilizing Radiolucent Weitlaner and retract the incision with the radiolucent arms. Wrap the band around the patient's leg to secure the retractor.

STEP 4 FRACTURE REDUCTION

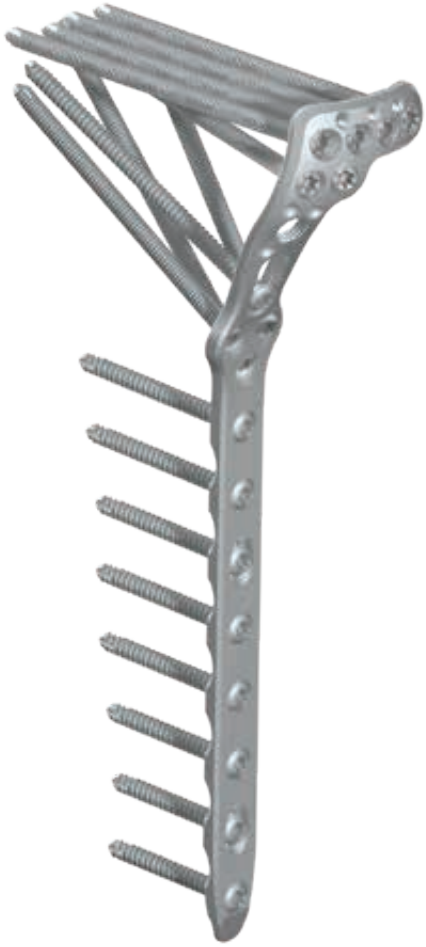
Reduce the fracture and verify that the articular surface is anatomically reduced using fluoroscopy. Provisional fixation may be performed using K-wires.

STEP 5 PLATE SELECTION

Select the lateral locking plate type and length that best accommodates the patient anatomy and fracture pattern.



XR Lateral Locking Plate
Left or right orientation



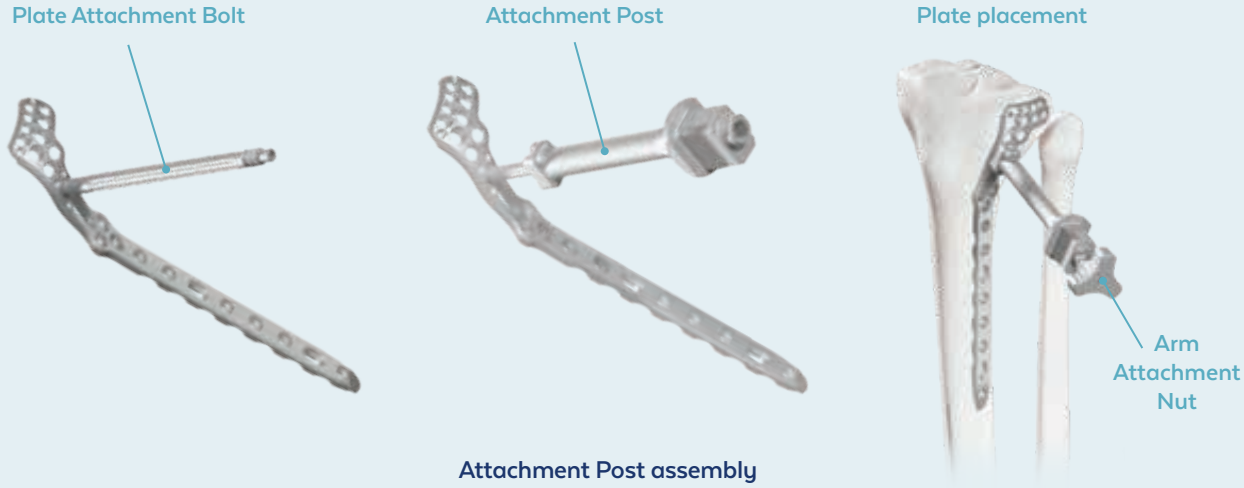
Lateral Locking Plate
Left or right orientation

STEP 6 PLATE PLACEMENT

Position the plate on the lateral proximal tibia. Confirm placement using fluoroscopy. Alternatively, the plate may be attached to the Aiming Arm for placement.

AIMING ARM ASSEMBLY

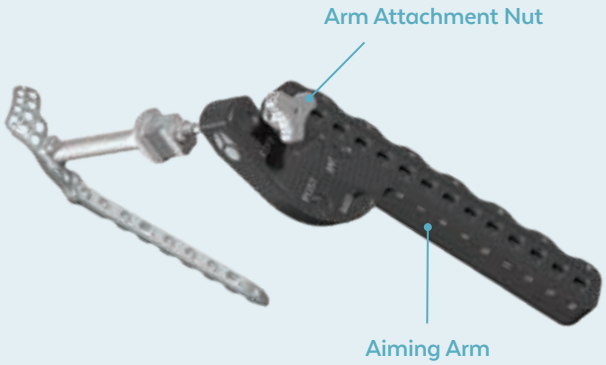
Thread the **Plate Attachment Bolt** into the hole above the positioning slot in the neck of the plate. Slide the **Attachment Post** (left/right-specific) over the bolt and down to the plate. Align the spherical locators to the indentations on the plate. Use the **Arm Attachment Nut** to secure the post to the plate. The Attachment Post may be used for plate positioning.



Attachment Post assembly

The **Aiming Arm** is left/right-specific and allows visualization of plate position.

Attach the Aiming Arm to the Attachment Post assembly by placing it over the post. Secure the Aiming Arm to the post with the Arm Attachment Nut.



Aiming Arm assembly

Position the plate on the proximal tibia. Confirm placement using lateral fluoroscopy or CT. Verify that the holes of the Aiming Arm align with the plate holes.

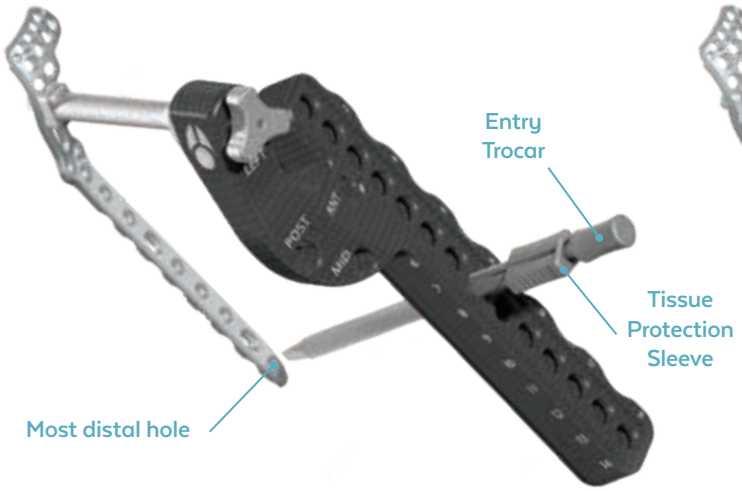
Lateral view

STEP 7 CREATING A BOX CONSTRUCT

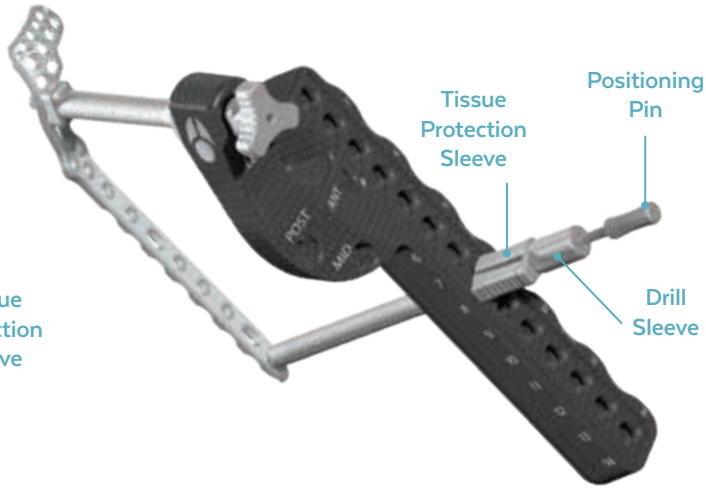
With the Aiming Arm attached to the plate, use the **Tissue Protection Sleeve** and **Entry Trocar** to determine incision location, and make a small incision. Advance the Entry Trocar to break through to soft tissue until the Tissue Protection Sleeve snaps into place.

Remove the Entry Trocar and replace it with the **Drill Sleeve** and **Positioning Pin**. Thread the Drill Sleeve into the most distal plate hole and remove the Positioning Pin.

Confirm plate position using lateral fluoroscopy. Place a K-wire through the Drill Sleeve to ensure the plate position is maintained in the sagittal plane. Complete the box construct for diaphyseal targeting.



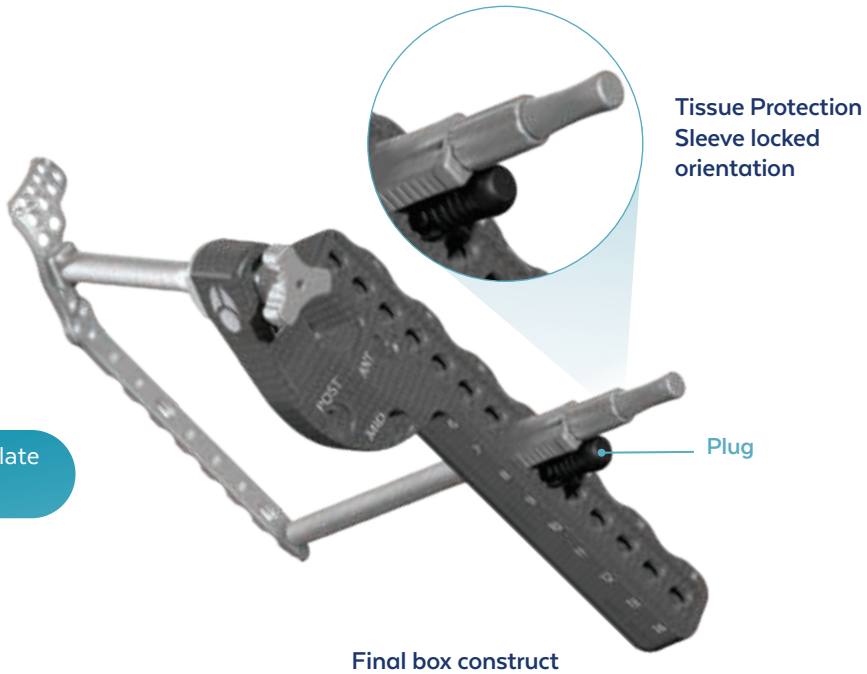
Break through soft tissue



Place positioning pin

Plugs may be used with the Aiming Guide to indicate the last hole or holes that have been filled with screws.

K-wires may also be placed through the plate attachment post for preliminary fixation.



Final box construct

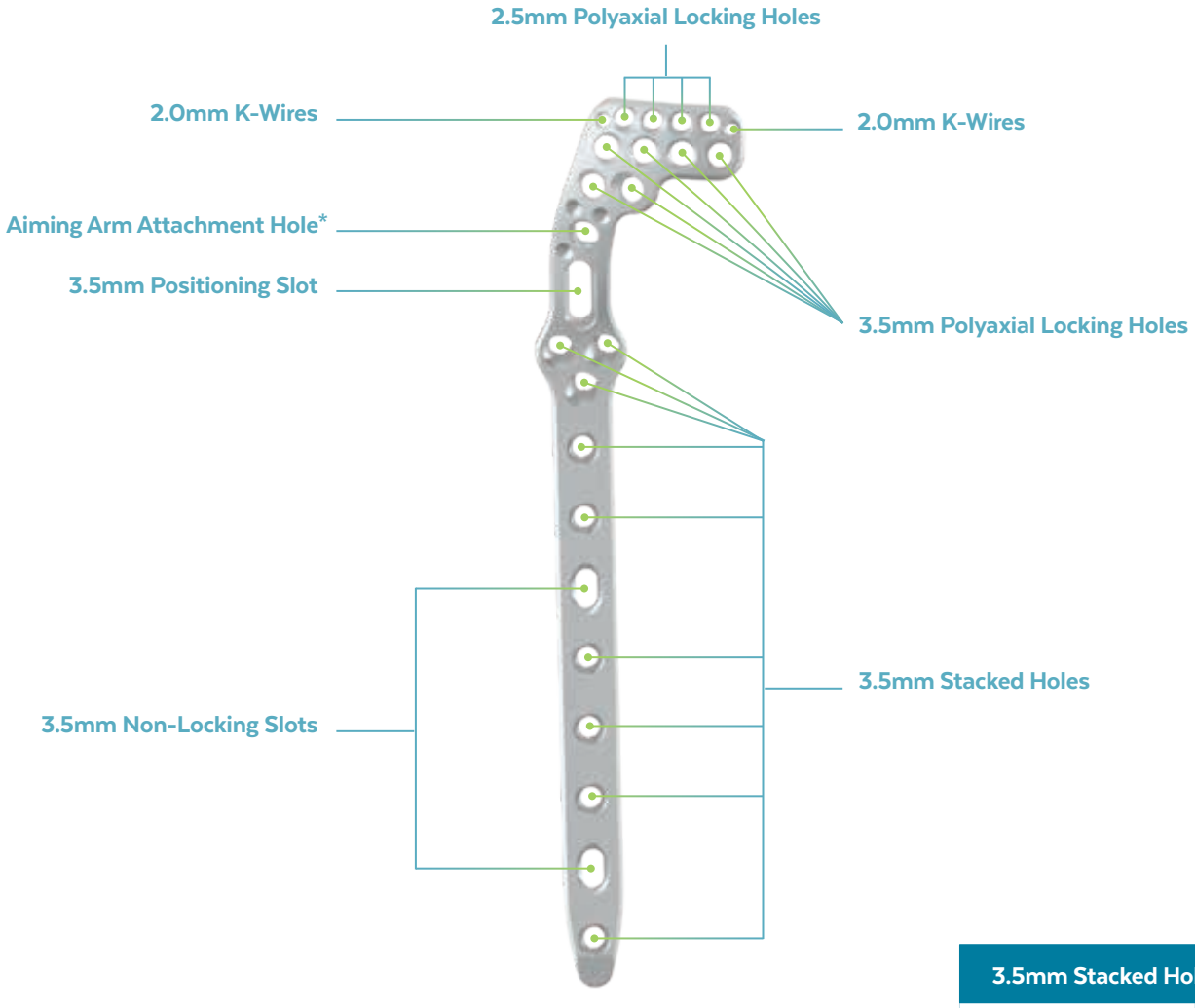
STEP 8 SCREW INSERTION

Screw Compatibility

Screw compatibility is shown below for the XR Lateral Locking Plate and the Lateral Locking Plate. If screw-plate locking is desired in a polyaxial hole, use locking screws only. MonoAx® Locking Screws may not be used in polyaxial holes.

All non-locking screws should be placed prior to any locking screws. Screw insertion order depends upon fracture type, preliminary reduction, and surgeon preference. Screws may be inserted through the proximal periarticular end of the plate or through the distal diaphyseal section.

XR Lateral Locking Plate



3.5mm Positioning Slot or Non-Locking Slot	
3.5mm Non-Locking	
4.0mm Cancellous	

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

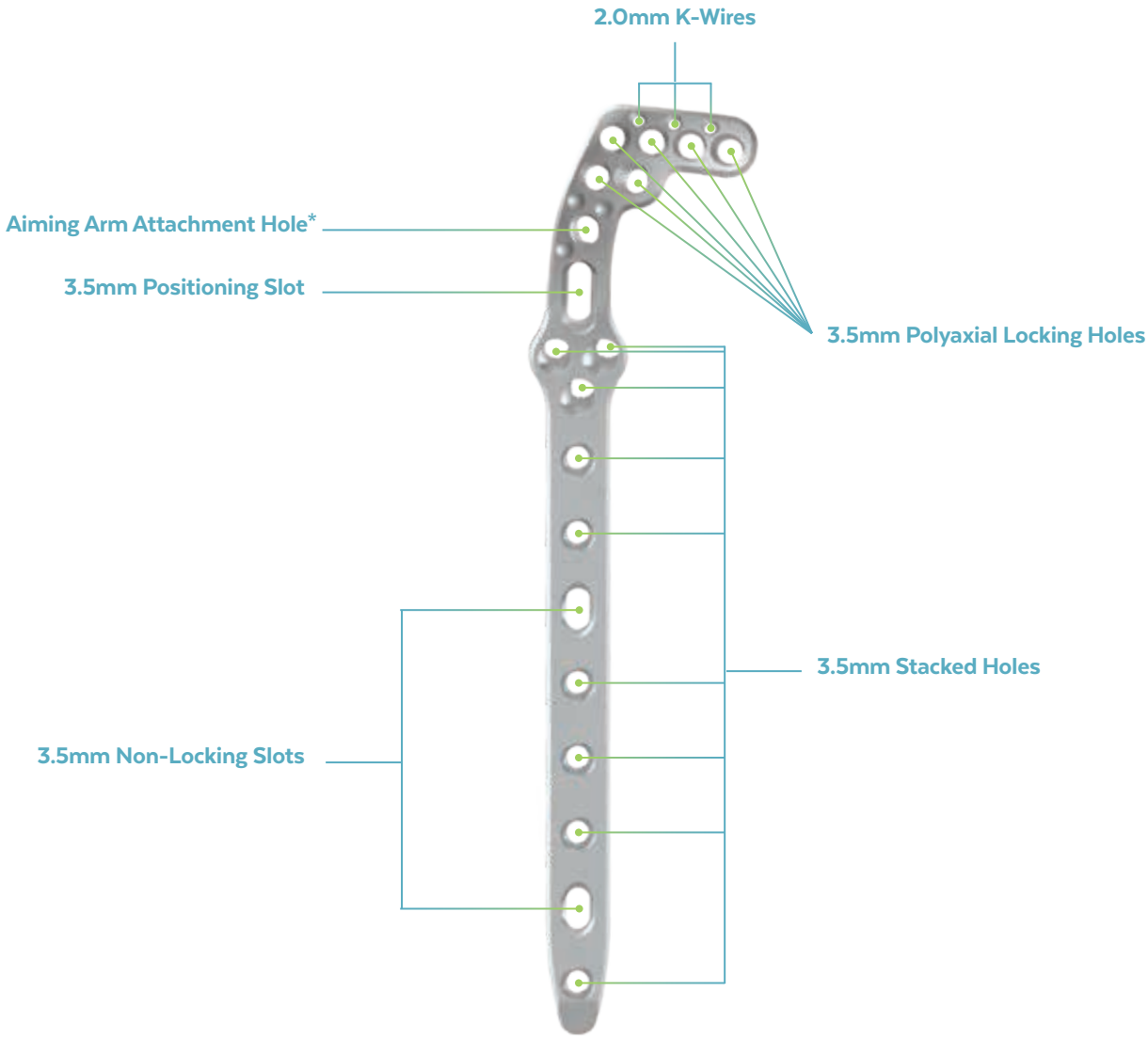
3.5mm Polyaxial Locking Holes	
3.5mm Locking	
3.5mm Non-Locking	
4.0mm Cancellous	

3.5mm Stacked Holes	
3.5mm Locking	
3.5mm MonoAx® Locking	
3.5mm Non-Locking	
4.0mm Cancellous	

*Not compatible with screws

SCREW INSERTION (CONT'D)

Lateral Locking Plate



3.5mm Positioning Slot or Non-Locking Slot	
3.5mm Non-Locking	
4.0mm Cancellous	

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

3.5mm Stacked Holes	
3.5mm Locking	
3.5mm MonoAx® Locking	
3.5mm Non-Locking	
4.0mm Cancellous	

**Not compatible with screws*

Positioning Slot Screw

3.5mm Non-Locking Screws and 4.0mm Cancellous Screws

The positioning slot is used to adjust plate position.

3.5mm Positioning Slot		
●	 3.5mm Non-Locking	
●	 4.0mm Cancellous	

XR Lateral Locking Plate

Lateral 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)

Placing the positioning slot non-locking screw first allows for minor plate position adjustments. Insertion of the positioning slot screw cannot be peformed through the Aiming Arm.

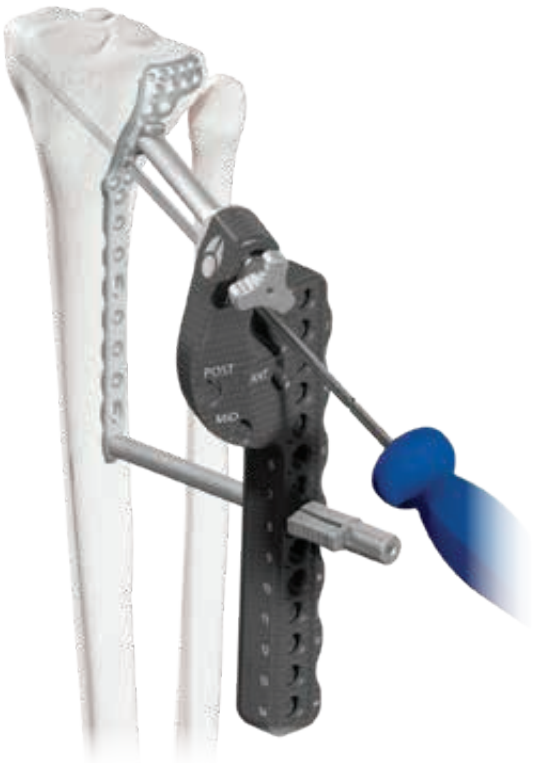
Use the **2.7x190mm Drill** or the **2.7x280mm Calibrated Drill** to drill to the desired depth. Measure screw length using the **Depth Gauge**. Use the **Self-Retaining T15 Driver** or **Screw Holding Forceps** to select the desired screw. Verify length and diameter using the gauges within the screw module.

Insert a 3.5mm Non-Locking or 4.0mm Cancellous Screw into the elongated slot using the **T15 Driver** manually or under power. Confirm plate position using fluoroscopy.

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

Drilling positioning slot

Measuring with Depth Gauge



Screw insertion

Proximal Screws in XR Lateral Locking and Lateral Locking Plates

Determine the appropriate combination of locking, non-locking, and cancellous screws for proper fixation.

If screw-plate locking is desired in a polyaxial hole, only use locking screws.

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

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

XR Lateral Locking Plate

Lateral Locking Plate

Polyaxial Proximal Rafting

2.5mm Locking and Non-Locking Screws

Pre-drill to the desired depth using the **1.8x190mm Drill Bit** and the selected drill guide (see page 22). If desired, insert **1.8mm K-Wires** in the 2.5mm polyaxial holes of the XR Lateral Locking Plate to pre-drill.

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. Insert 2.5mm screws using the T8 Driver with the Quick-Connect Handle manually or under power. 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 and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (see page 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 and Non-Locking Screws and 4.0mm Cancellous Screws using 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.

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

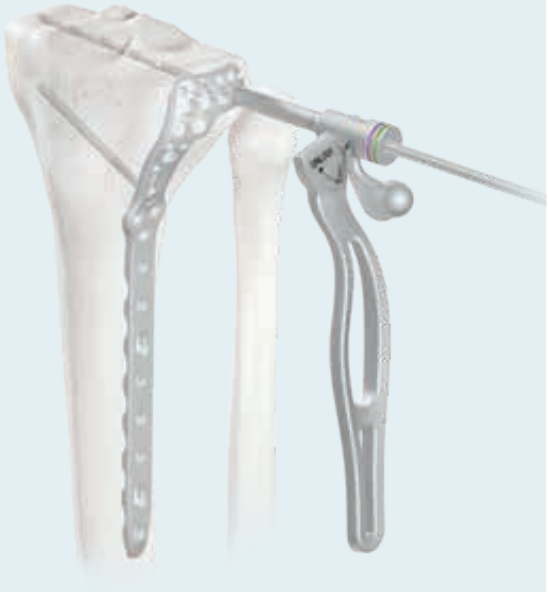
SCREW INSERTION (CONT'D)

POLYAXIAL 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.

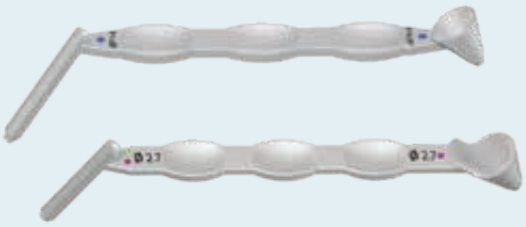
Speed Lock Drill Guide



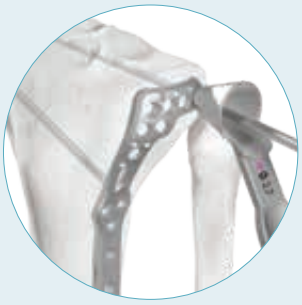
Speed Lock Drill Guide locked in place

1.8mm Soft Tissue Protector (2.5mm Screws) ●
2.7mm Soft Tissue Protector (3.5mm Screws) ● ●

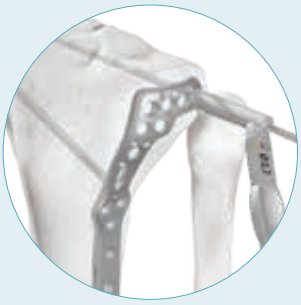
The Soft Tissue Protector allows for a ±20° cone of angulation on the polyaxial end and the nominal trajectory on the nominal end.



Soft Tissue Protector



Polyaxial Guide



Nominal Guide

Kickstand Screws in XR Lateral Locking and Lateral Locking Plates

3.5mm Stacked Holes		
●	 3.5mm Locking	
●	 3.5mm MonoAx® Locking	
●	 3.5mm Non-Locking	
●	 4.0mm Cancellous	

XR Lateral Locking Plate

Lateral Locking Plate

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

Insert the **Kickstand Screw Protection Sleeve** and the **Drill Sleeve** into the kickstand holes on the Aiming Arm, targeting the anterior (ANT), medial (MED), or posterior (POST) aspects of the medial condyle. Rotate the drill sleeve clockwise to engage the plate.

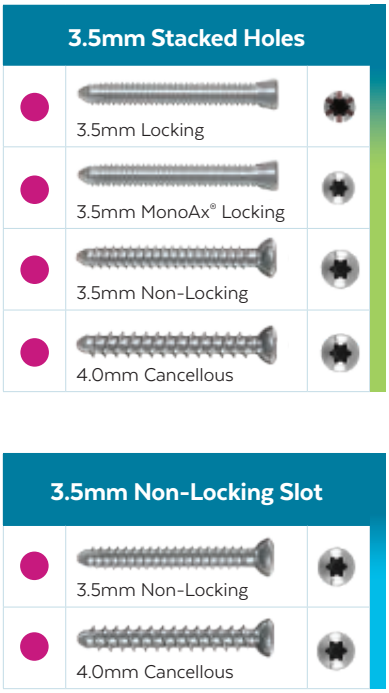
Pre-drill to the desired depth using the Calibrated 2.7mm Drill Bit. Measure hole depth using the Depth Gauge and remove the Drill Sleeve.

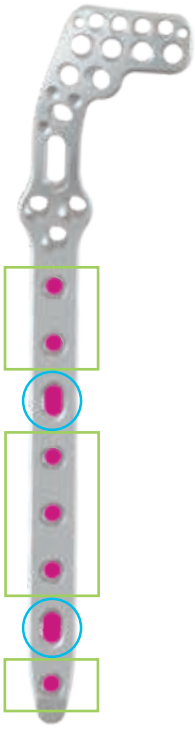
Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw. Verify the length and diameter using the gauges within the screw module. Insert 3.5mm Locking or Non-Locking Screws or 4.0mm Cancellous Screws using the T15 Driver with the Quick-Connect Handle manually or under power.

If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.

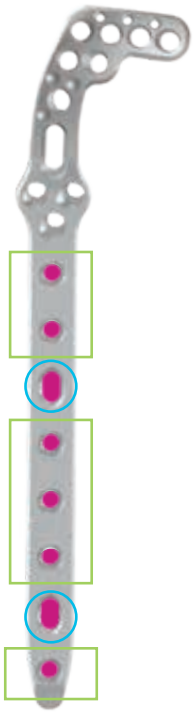
SCREW INSERTION (CONT'D)

Distal Screws in XR Lateral Locking and Lateral Locking Plates





XR Lateral Locking Plate



Lateral Locking Plate

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

Confirm distal plate position using fluoroscopy. Insert the assembled Tissue Sleeve and Trocar in the desired hole and create a skin incision. Remove the Trocar and insert the Drill Sleeve and Positioning Pin. Thread the Drill Sleeve into the hole for stability and remove the Positioning Pin.

Pre-drill to the desired depth using the Calibrated 2.7mm Drill Bit. Measure hole depth using the Calibrated Drill Bit or remove the drill and determine screw length with the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

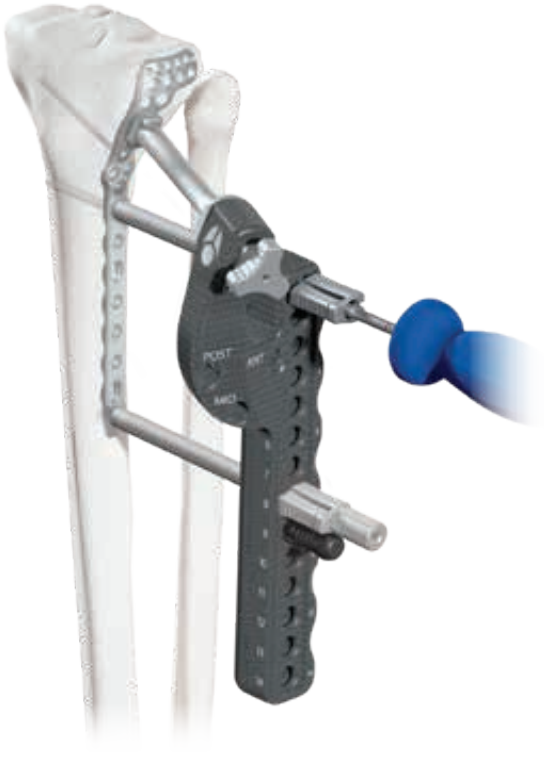
Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm or 4.0mm Cancellous Screws using the T15 Driver with the Quick-Connect Handle manually or under power.

If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.

Distal Screw Insertion

Tissue Sleeve and Trocar inserting into Aiming Arm

Drill insertion



Screw insertion

Suture Attachment

Sutures may be used to augment fracture fixation or repair soft tissue. The meniscus or other localized injured soft tissue may be optionally repaired with sutures following plate application.

SCREW INSERTION (CONT'D)

DYNAMIC COMPRESSION THROUGH AIMING ARM

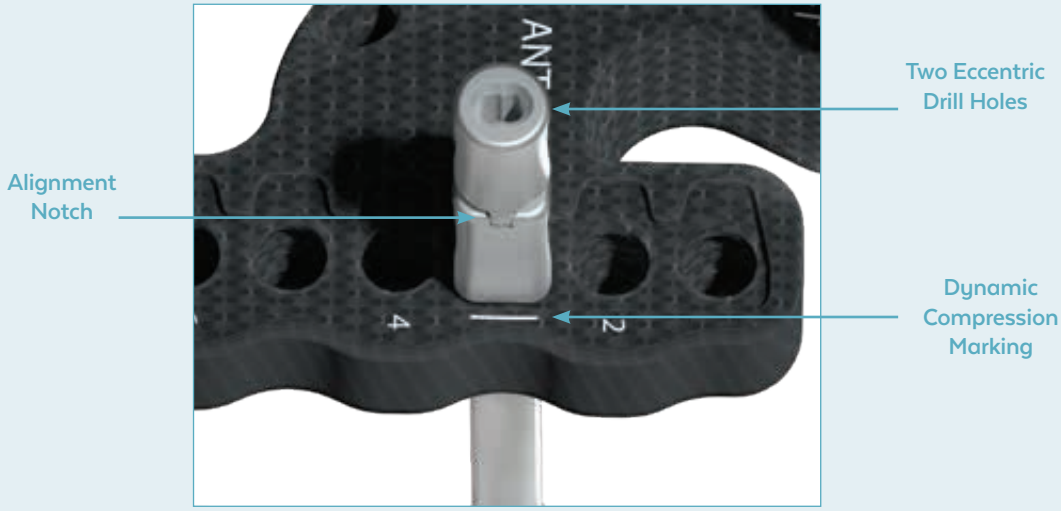
Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a slotted hole. All 3.5mm Non-Locking and 4.0mm Cancellous Screws may be used for dynamic compression. If compression is not desired, place the screw in a neutral position by using the Drill Sleeve.

Dynamic compression can be facilitated through the Aiming Arm. Only holes indicated by a white line on the Aiming Arm support dynamic compression.

After inserting the Tissue Protection Sleeve, insert the Dynamic Compression Sleeve until the alignment tab fits inside the notch of the Tissue Sleeve. Holes in the Dynamic Compression Sleeve align the drill to the eccentric position in either direction.

Determine the desired direction of compression and drill to the desired depth in the appropriate hole. Remove the Dynamic Compression Sleeve and measure hole depth using the Depth Gauge.

Use the T15 Driver or Screw Holding Forceps to select the desired screw. Using the T15 Driver with the Quick-Connect Handle, insert the screw into the desired hole.



Dynamic Compression Sleeve Assembly

Dynamic compression

STEP 9 VERIFY PLACEMENT

Confirm screw placement, screw trajectories, and joint reconstruction in all planes using fluoroscopy, radiographs, and/or CT. Ensure that screw tips are not intra-articular.

FINAL CONSTRUCT

XR Lateral Locking Plate

Lateral view

AP view

Lateral Locking Plate

Lateral view

AP view

OPTIONAL: REMOVAL

Detach sutures from the construct. Unlock all screws from the plate with a non-self-retaining driver, but do not remove the locking screws. This prevents simultaneous rotation of the plate and screws during removal. For 2.5mm screws, use the **Non-Self-Retaining T8 Driver**. For 3.5mm and 4.0mm screws, use the **Non-Self-Retaining T15 Driver**. Remove all locking, non-locking, and cancellous screws using the T8 or T15 Non-Self-Retaining Driver. Once all screws are removed, the plate may be removed.

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 Driver

T15 Non-Self-Retaining Driver

SURGICAL TECHNIQUE

ANTHEM®

Lateral Non-Locking Proximal 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 for the desired plate position.

STEP 2 PATIENT POSITIONING

Position the patient supine. Examine the fracture using fluoroscopy.

STEP 3 APPROACH

Create an anterolateral, lateral curved, or straight incision in the proximal tibia that allows for fracture reduction. Dissect through the fascia and split the illiotibial band. Carefully avoid surrounding soft tissue.

Lateral curved incision

STEP 4 FRACTURE REDUCTION

Reduce the fracture and verify that the articular surface is anatomically reduced using fluoroscopy. Provisional fixation may be performed using K-wires and/or independent lag screws.

Confirm reduction using fluoroscopy.

STEP 5 PLATE PLACEMENT

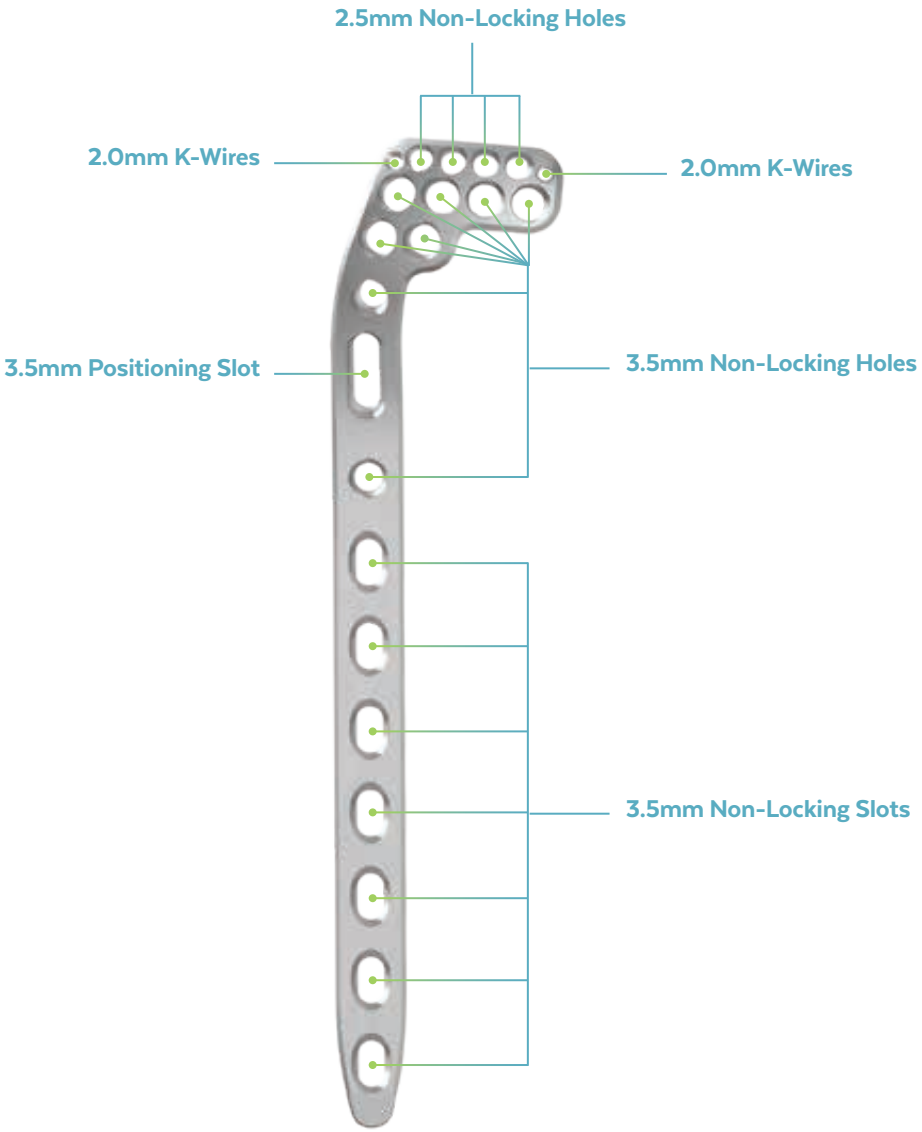
Position the plate on the lateral proximal tibia. Confirm plate position using fluoroscopy.

K-wires or reduction clamps may be used to provisionally fix the plate to the bone.

STEP 6 SCREW INSERTION

The Lateral Non-Locking Plate accepts 2.5mm and 3.5mm Non-Locking and 4.0mm Cancellous Screws. The 3.5mm Non-Locking slots may be used for dynamic compression (see page 33).

Lateral Non-Locking Plate



2.5mm Non-Locking Holes	
2.5mm Non-Locking	

3.5 Non-Locking Holes or Slots	
3.5mm Non-Locking	
4.0mm Cancellous	

Positioning Slot Screw

3.5mm Non-Locking or 4.0mm Cancellous Screws

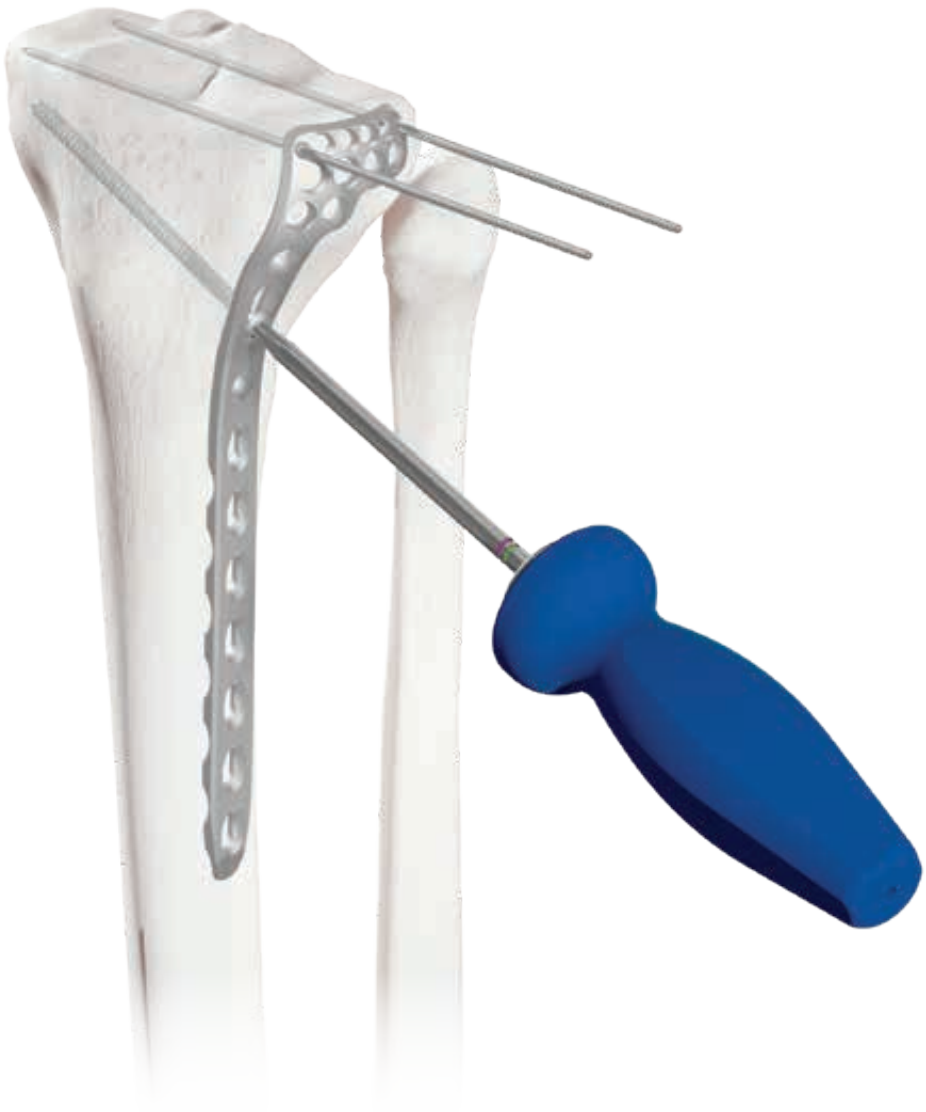
Placing the positioning slot non-locking screw first allows for minor plate position adjustments.

Use the 2.7x190mm 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 or 4.0mm Cancellous 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.



Screw insertion - Positioning Slot Screw

SCREW INSERTION (CONT'D)

Proximal Screws

2.5mm Non-Locking Screws

Pre-drill to the desired depth using the 1.8x190mm Drill Bit and the **2.5mm Soft Tissue Protector**. 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. Insert 2.5mm Non-Locking Screws using the T8 Driver with the Quick-Connect Handle manually or under power.

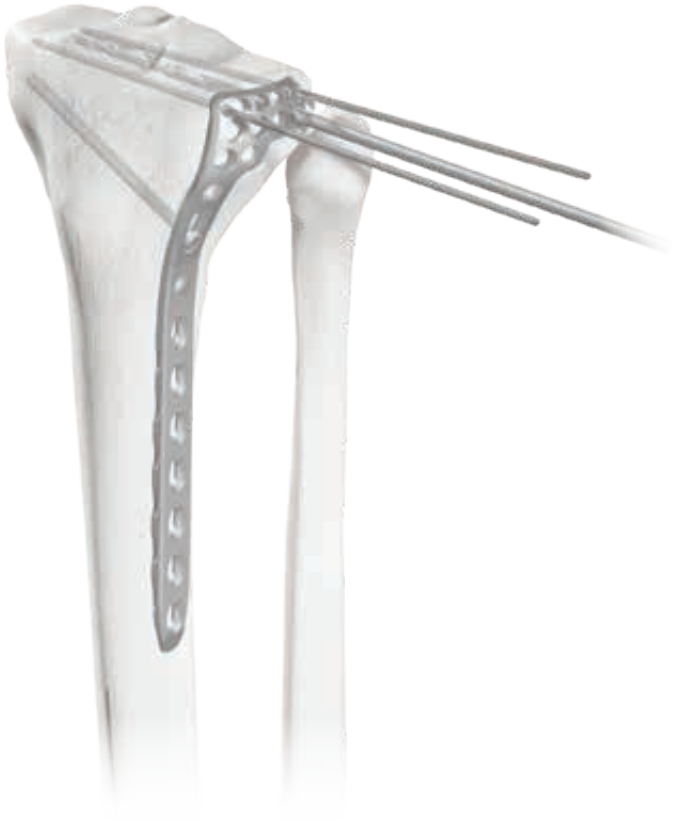
If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.

3.5mm Non-Locking and 4.0mm Cancellous Screws

Pre-drill to the desired depth using the 2.7x190mm Drill Bit and the **3.5mm Soft Tissue Protector**. 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 Non-Locking Screws or 4.0mm Cancellous Screws using 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.



Drilling

Screw insertion

Distal Screws

3.5mm Non-Locking or 4.0mm Cancellous Screws

Screws may be placed eccentrically in the slotted holes to provide fracture compression.

Pre-drill to the desired depth using the 2.7mm Drill Bit and the **3.5mm Soft Tissue Protector**. Measure hole depth using the Depth Gauge. Use the 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 Non-Locking Screws or 4.0mm Cancellous Screws using 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.

DYNAMIC COMPRESSION

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a 3.5mm Non-Locking Slot. All 3.5mm Non-Locking and 4.0mm Cancellous Screws may be used for dynamic compression. If compression is not desired, place the screw in a neutral position.

Place a non-locking or cancellous screw distal to the fracture. Select a slotted hole on the proximal side of the fracture line. Insert the **3.5mm Soft Tissue Protector, Spring Loaded** into the oblong hole with no downward pressure. Place the selected Soft Tissue Protector eccentrically in the slotted hole.

Drill to the desired depth with the selected drill. Measure hole depth using the Depth Gauge. Use the T15 Driver or Screw Holding Forceps to select the desired screw. Using the T15 Driver with the Quick-Connect Handle, insert the screw into the desired hole. A power drill with a torque-limiting adapter may be used to insert the screw under power if desired.

Neutral position

Eccentric position

Dynamic compression

STEP 7 VERIFY PLACEMENT

Confirm screw placement, screw trajectories, and joint reconstruction in all planes using fluoroscopy, radiographs, and/or CT. Ensure the screw tips are not intra-articular.

FINAL CONSTRUCT

Lateral view

AP view

OPTIONAL: REMOVAL

To remove 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm and 4.0mm screws, use the Non-Self-Retaining T15 Driver. Remove all non-locking and cancellous screws using the T8 or T15 Non-Self-Retaining Driver.

NON-SELF-RETAINING DRIVERS

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

T8 Non-Self-Retaining Driver

T15 Non-Self-Retaining Driver

SURGICAL TECHNIQUE

ANTHEM®

Medial Locking Proximal 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. Estimate the appropriate length and location of screws for the desired plate position.

STEP 2 PATIENT POSITIONING

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

STEP 3 APPROACH

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

Medial incision

STEP 4 FRACTURE REDUCTION

Reduce the fracture and verify that the articular surface is anatomically restored using fluoroscopy. Provisional fixation may be performed using K-wires.

STEP 5 PLATE PLACEMENT

Position the plate on the medial proximal tibia. Confirm plate position using fluoroscopy.

K-wires or reduction clamps may be used to provisionally fix the plate to the bone.

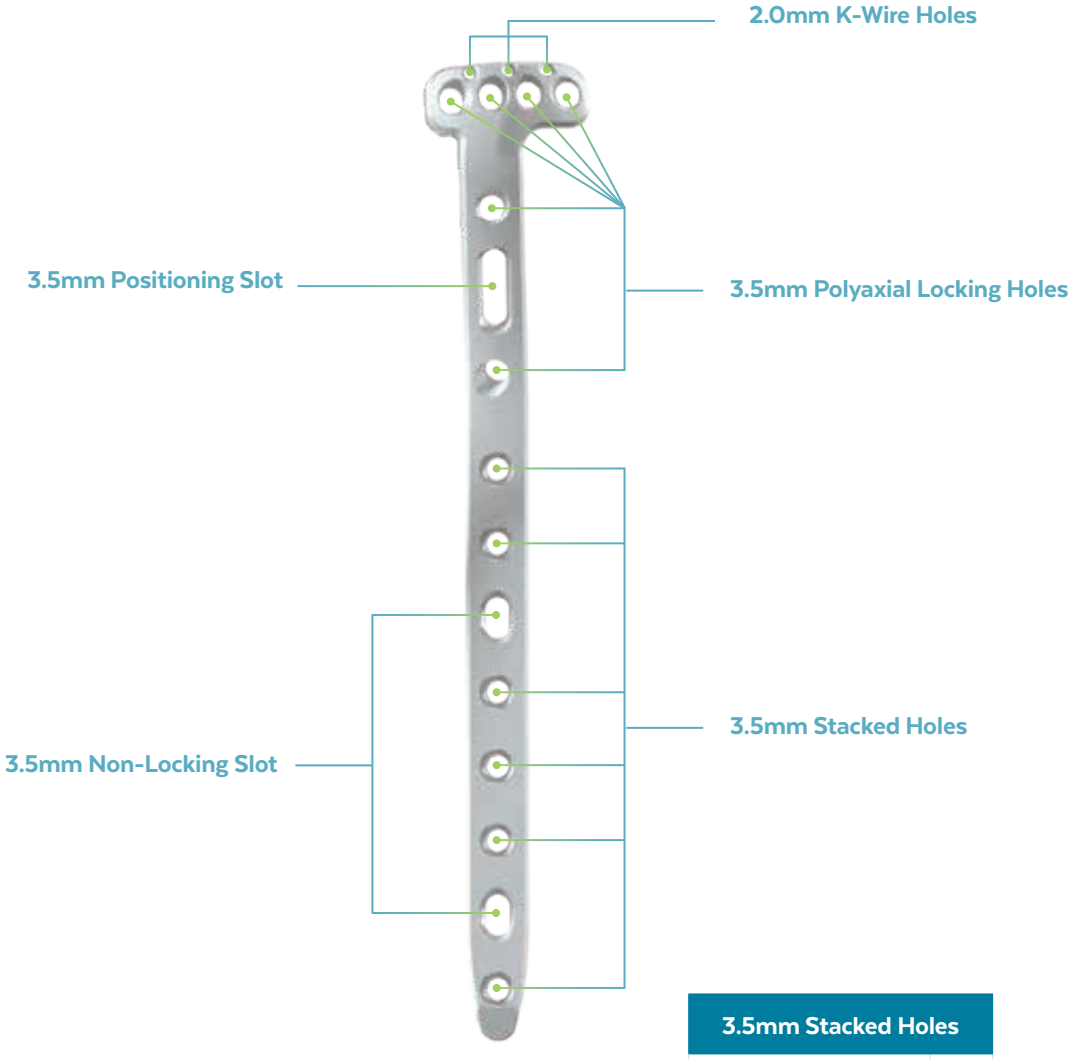
STEP 6 SCREW INSERTION

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® screws may not be used in polyaxial holes. The 3.5mm Non-Locking slots may be used for dynamic compression (see page 33). Screw insertion order depends upon fracture type, preliminary reduction, and surgeon preference. Screws may be inserted through the proximal periarticular end of the plate or through the distal diaphyseal section.

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

Medial Locking Plate



3.5mm Positioning Slot or Non-Locking Slot	
3.5mm Non-Locking	
4.0mm Cancellous	

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

3.5mm Stacked Holes	
3.5mm Locking	
3.5mm MonoAx® Locking	
3.5mm Non-Locking	
4.0mm Cancellous	

Positioning Slot Screw

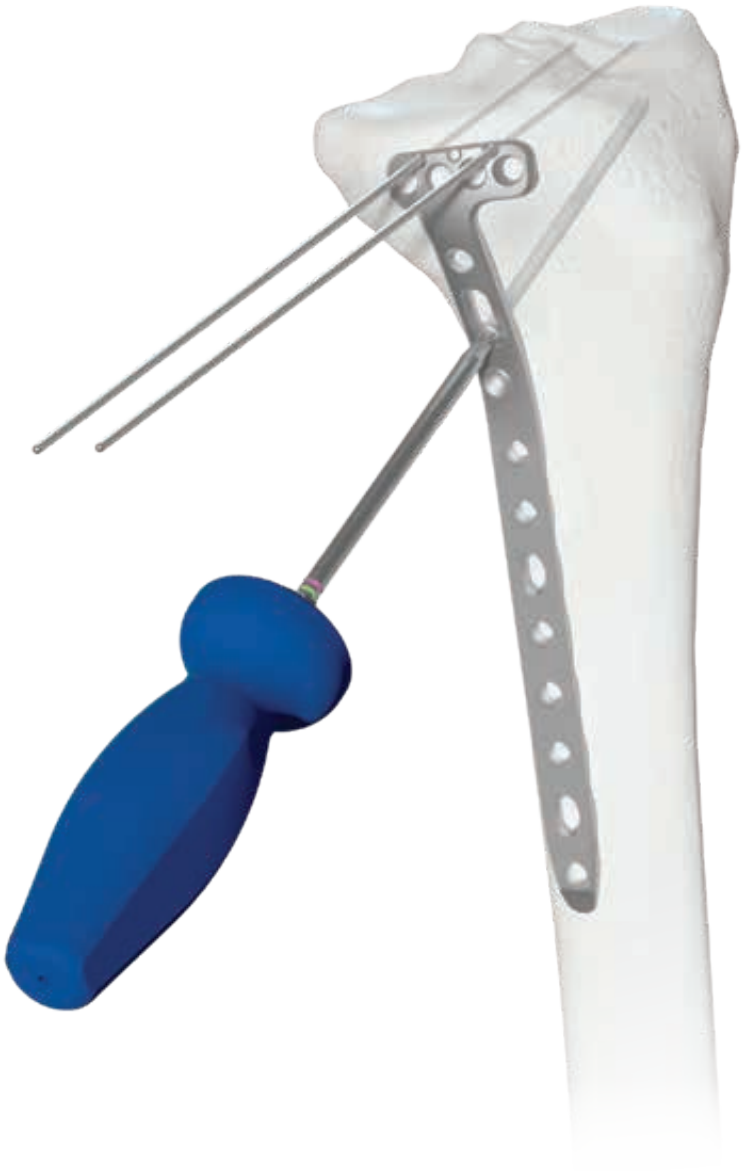
3.5mm Non-Locking Screws and 4.0mm Cancellous Screws

Placing the positioning slot non-locking screw first 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 or 4.0mm Cancellous 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.



Screw insertion - Positioning Slot Screw

Polyaxial Proximal Screws

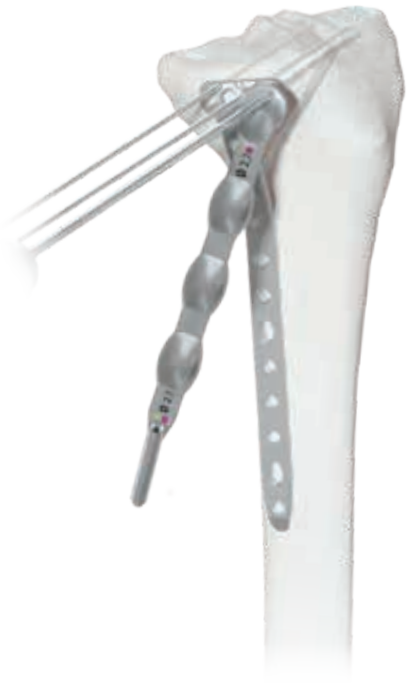
Polyaxial Rafting Screws

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

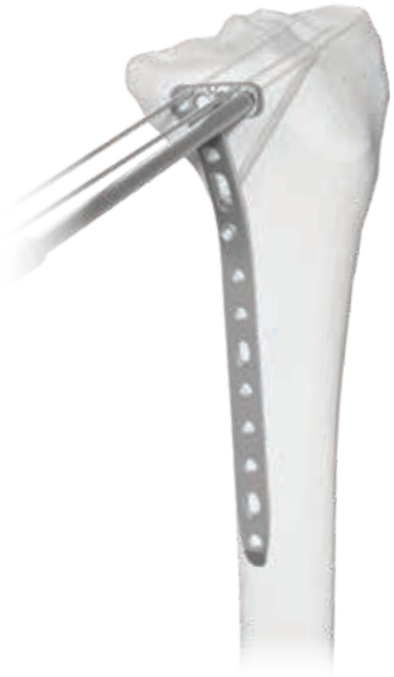
Pre-drill to the desired depth using the 2.7mm Drill Bit and the selected drill guide (see page 22). Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

Verify screw length and diameter using the gauges within the screw module. Insert 3.5mm Locking or Non-Locking Screws or 4.0mm Cancellous Screws using 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.

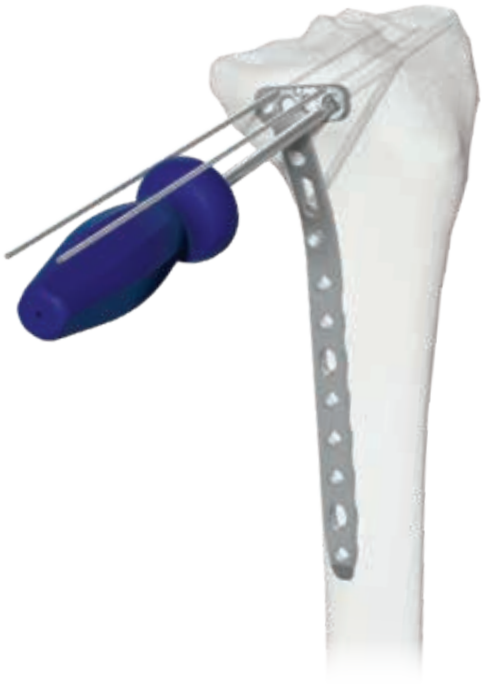
Insert 3.5mm Locking Screws using the **2.5Nm Torque-Limiting Attachment**.



Drilling with Polyaxial Guide



Measuring with Depth Gauge



Screw insertion - Polyaxial Proximal Screws

Distal Screws

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

Screws may be placed eccentrically in the 3.5mm Non-Locking Slots to provide fracture compression (see page 33).

Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector. Measure hole depth using the Depth Gauge. Use the 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 or 4.0mm Cancellous Screws using 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.

STEP 7 VERIFY PLACEMENT

Confirm screw placement, screw trajectories, and joint reconstruction in all planes using fluoroscopy. Ensure that screw tips are not intra-articular.

FINAL CONSTRUCT

Lateral view

AP view

OPTIONAL: REMOVAL

Unlock all screws from the plate with a non-self-retaining driver, but do not remove the locking screws. This prevents simultaneous rotation of the plate and screws during removal. For 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm and 4.0mm screws, use the Non-Self-Retaining T15 Driver. Remove all locking, non-locking, and cancellous screws using the T8 or T15 Non-Self-Retaining Driver. Once all screws are removed, the plate may be removed.

NON-SELF-RETAINING DRIVERS

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

T15 Non-Self-Retaining Driver

SURGICAL TECHNIQUE

ANTHEM®

Posteromedial Buttress Proximal 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

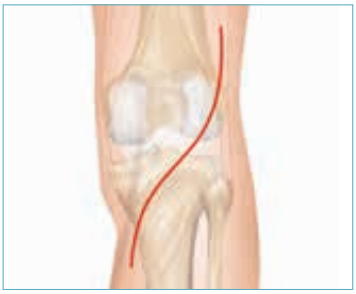
Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate length and location of screws for the desired plate position.

STEP 2 PATIENT POSITIONING

Position the patient supine or prone. Examine the fracture using fluoroscopy.

STEP 3 APPROACH

Create a posteromedial or posterior incision to the proximal tibia that allows for fracture reduction. Carefully avoid surrounding soft tissue.



Posterior incision

STEP 4 FRACTURE REDUCTION

Reduce the fracture and verify that the articular surface is anatomically reduced using fluoroscopy. Provisional fixation may be performed using K-wires and/or independent lag screws.

Confirm reduction using fluoroscopy.

STEP 5 PLATE PLACEMENT

Position the plate on the proximal tibia. Confirm plate position using fluoroscopy.

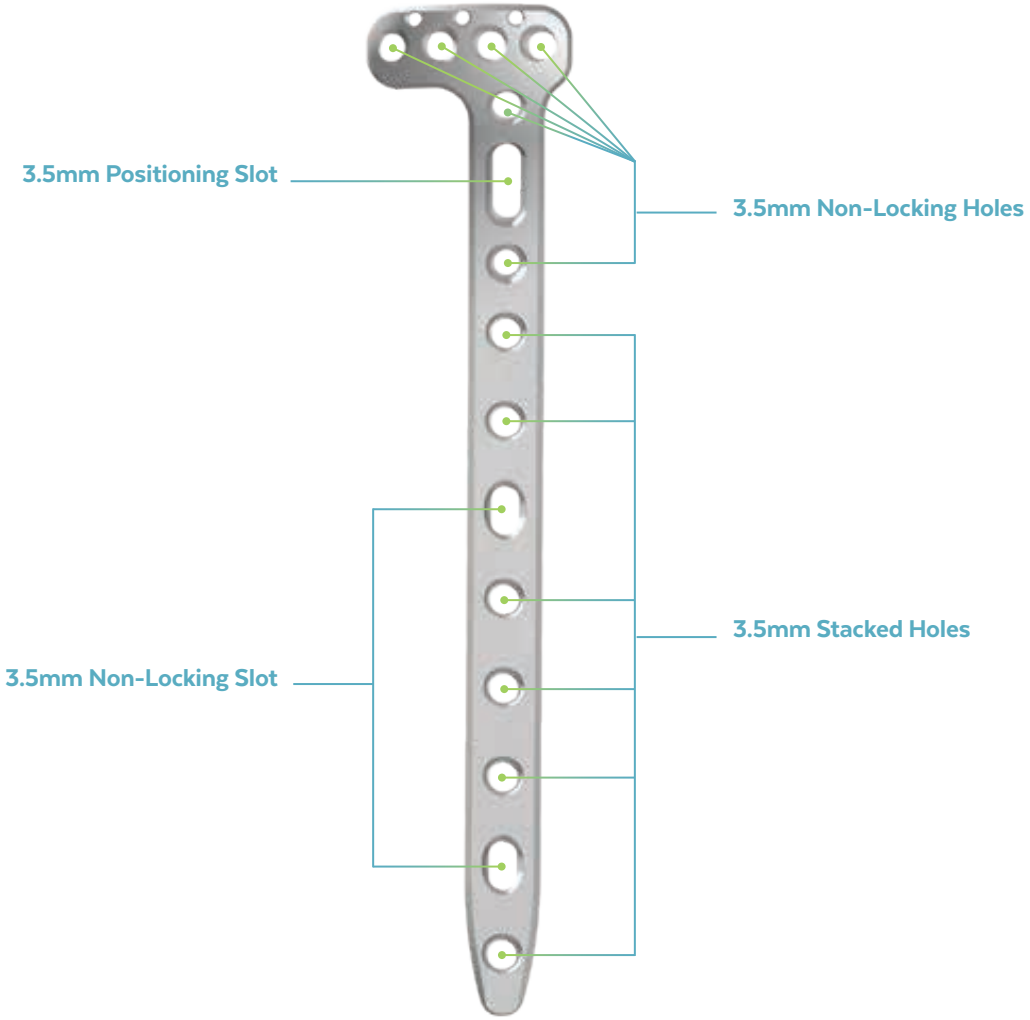
K-wires or reduction clamps may be used to provisionally fix the plate to the bone.

STEP 6 SCREW INSERTION

Screw Compatibility

Screw compatibility is shown below for the Posteromedial Buttress Plate. If screw-plate locking is desired in a polyaxial hole, only use locking screws. MonoAx® screws may not be used in polyaxial holes. The 3.5mm Non-Locking Slots may be used for dynamic compression (see page 33).

Posteromedial Buttress Plate



3.5mm Non-Locking Holes or Slots	
3.5mm Non-Locking	
4.0mm Cancellous	

3.5mm Stacked Holes	
3.5mm Locking	
3.5mm MonoAx® Locking	
3.5mm Non-Locking	
4.0mm Cancellous	

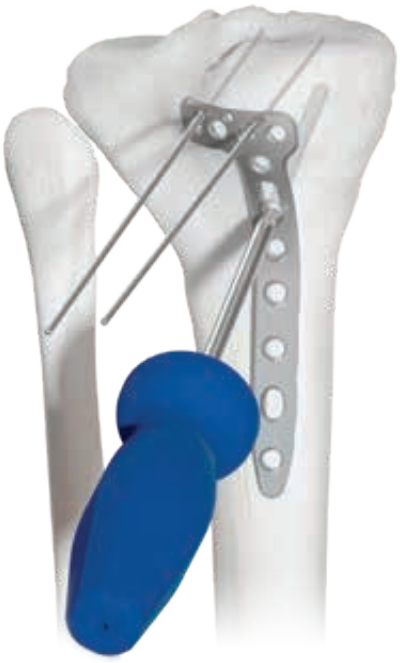
Positioning Slot Screw

Placing the positioning slot non-locking screw first 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 screw length and diameter using the gauges within the screw module.

Using the T15 Driver and the Quick-Connect Handle, insert a 3.5mm Non-Locking or 4.0mm Cancellous Screw into the elongated slot. Confirm plate position using fluoroscopy.

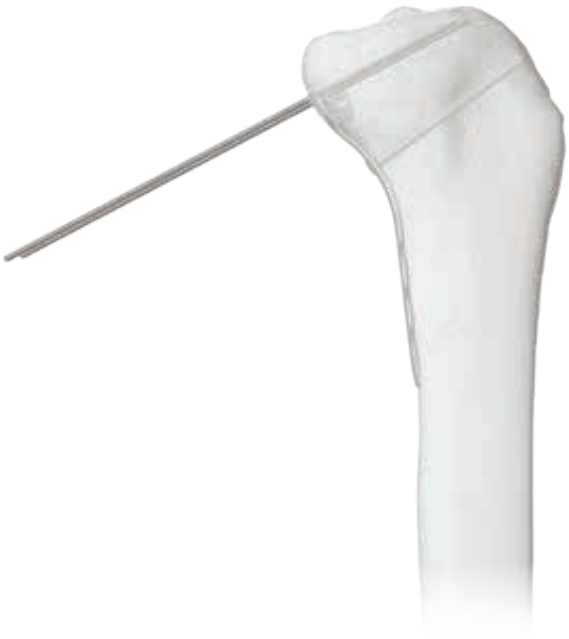
Adjust plate position as necessary before final tightening. Confirm screw position using fluoroscopy.



Positioning Slot Screw

The Posteromedial Buttress Plate is designed to be undercontoured. The thin profile flexes to the bone when lagged down.

Positioning Slot Screw insertion



Buttressing

SCREW INSERTION (CONT'D)

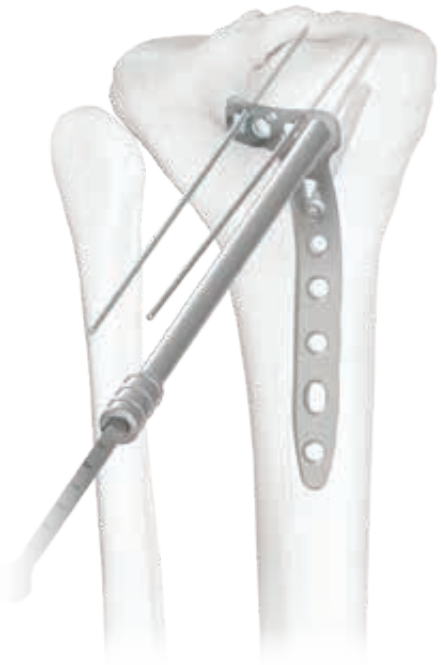
Proximal Screws

3.5mm Non-Locking Screws and 4.0mm Cancellous Screws

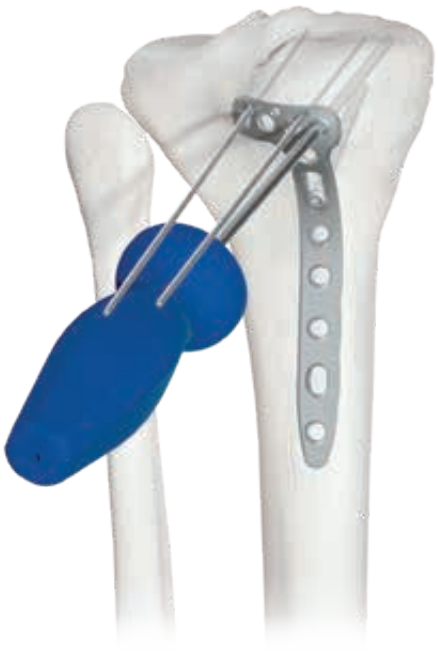
Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector. Measure hole depth using the Depth Gauge. Use the T15 Driver or Screw Holding Forceps to select the desired non-locking screw.

Verify the screw length and diameter using the gauges within the screw module. Insert 3.5mm Non-Locking or 4.0mm Cancellous Screws using 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.

Drilling



Measuring with Depth Gauge



Screw insertion

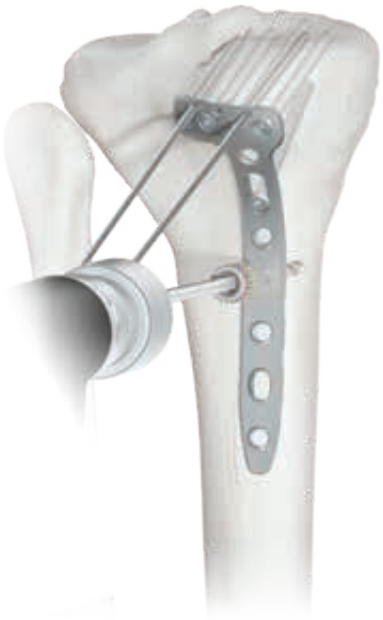
Distal Screws

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

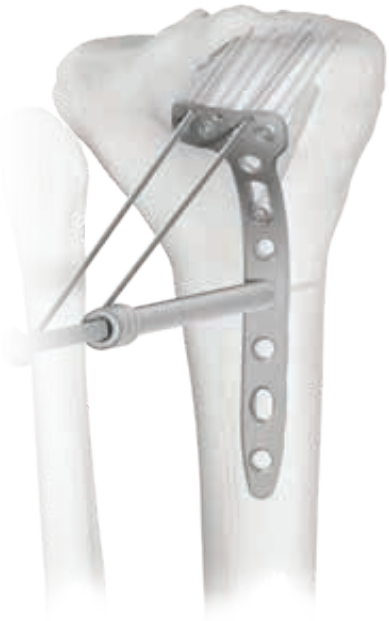
Screws may be placed eccentrically in the 3.5mm Non-Locking Slots to provide fracture compression. (Refer to page 33 for instructions on achieving dynamic compression.)

Pre-drill to the desired depth using the 2.7mm Drill Bit and the 3.5mm Soft Tissue Protector. Measure hole depth using the Depth Gauge. Use the T15 Driver or Screw Holding Forceps to select the desired screw.

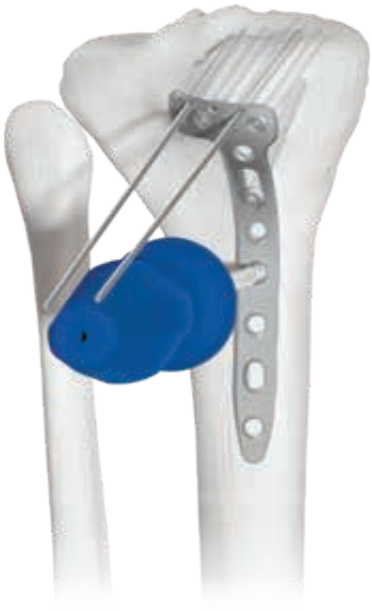
Verify the screw length and diameter using the gauges within the screw module. Insert 3.5mm or 4.0mm Cancellous screws using the T15 Driver with the Quick-Connect Handle manually or under power. If under power, final tightening should be performed manually. Confirm screw position using fluoroscopy.



Drilling



Measuring with Depth Gauge



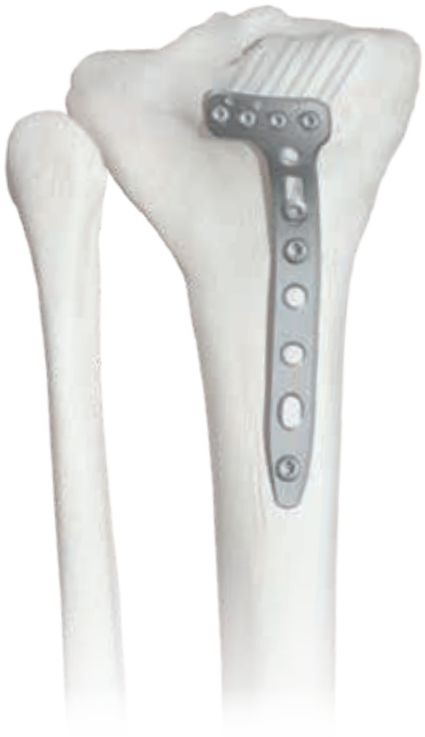
Screw insertion

STEP 7 VERIFY PLACEMENT

Confirm screw placement, screw trajectories, and joint reconstruction in all planes using fluoroscopy. Ensure that screw tips are not intra-articular.

FINAL CONSTRUCT

Lateral view



AP view

OPTIONAL: REMOVAL

Unlock all screws from the plate with a non-self-retaining driver, but do not remove the locking screws. This prevents simultaneous rotation of the plate and screws during removal. For 2.5mm screws, use the Non-Self-Retaining T8 Driver. For 3.5mm and 4.0mm screws, use the Non-Self-Retaining T15 Driver. Remove all locking, non-locking, and cancellous screws using the T8 or T15 Non-Self-Retaining Driver. Once all screws are removed, the plate may be removed.

NON-SELF-RETAINING DRIVERS

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

T15 Non-Self-Retaining Driver

INSTRUMENT OVERVIEW

AIMING ARM INSTRUMENTS

Plate Attachment Bolt 6187.1000

Attachment Post, Left 6187.1100

Attachment Post, Right 6187.2100

Arm Attachment Nut 6187.1300

Aiming Arm, Left 6187.3000

Aiming Arm, Right 6187.4000

Tissue Protection Sleeve 6187.3100

AIMING ARM INSTRUMENTS (CONT'D)

Entry Trocar 6187.3110

Plug 6187.3150

Drill Sleeve 6187.3200

Dynamic Compression Sleeve 6187.3201

Drill Sleeve, Long 6187.3202

K-Wire Sleeve 6187.3500

Drill, 2.7x280mm, Calibrated 6187.3227

Drill, 3.5x280mm, Calibrated 6187.3235

Positioning Pin 6187.3300

Plate Reduction Device, 230mm, AO Quick-Connect 6187.3400

Depth Gauge 6187.3600

AIMING ARM INSTRUMENTS (CONT'D)

Driver, T15 SR, 170mm, AO Quick-Connect 6187.3715

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

Sleeve, Screw Retention 6187.3350

Tap, 3.5x280mm, AO Quick-Connect 6187.3935

Tap, 4.0x280mm, AO Quick-Connect 6187.3940

Sleeve, Kickstand 6187.3105

K-WIRES

K-Wire, 1.25x150mm, Trocar Tip 6179.1113

K-Wire, 1.8x150mm, Trocar Tip 6187.0180

K-WIRES (CONT'D)

K-Wire, 1.6x150mm, Trocar Tip 6179.1116

K-Wire, 2.0x250mm, Trocar Tip 6187.0200

K-Wire, 2.0x250mm, Drill Tip 6187.0201

1.6mm Plate Holding K-Wire 6179.1216

FORCEPS

Lobster Claw Reduction Forceps, Ratcheting 6179.2001

Point-to-Point Reduction Forceps, Narrow, Ratcheting 6179.2003

FORCEPS (CONT'D)

Point-to-Point Reduction Forceps, Wide, Ratcheting 6179.2004

DRILL GUIDES

1.8mm Polyaxial Soft Tissue Protector 6171.3118

2.7mm Polyaxial Soft Tissue Protector 6186.3127

2.5mm Soft Tissue Protector 6179.3125

3.5mm Soft Tissue Protector 6179.3135

DRILL GUIDES (CONT'D)

2.7mm Locking Drill Guide 6179.3227

1.6mm K-Wire Sleeve Insert 6179.3316

1.8mm Speed Lock Drill Guide 6171.4218

2.7mm Speed Lock Drill Guide 6171.4227

DRILLS

Drill, 1.8x190mm, AO Quick-Connect 6187.5018

Drill, 2.5x140mm, AO Quick-Connect 6187.5025

Drill, 2.7x190mm, AO Quick-Connect 6187.5027

Drill, 3.5x140mm, AO Quick-Connect 6187.5035

TAPS AND COUNTERSINKS

2.5mm Non-Locking Tap, AO Quick-Connect 6179.5125

3.5mm Non-Locking Tap, AO Quick-Connect 6179.5135

4.0mm Cancellous Tap, AO Quick-Connect 6179.5140

Countersink, AO Quick-Connect 6179.7000

HANDLES

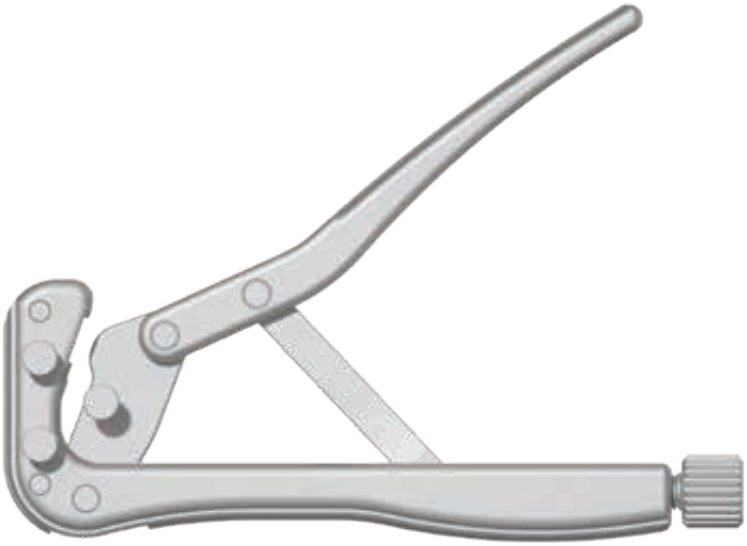
Handle, AO Quick-Connect 6188.7001

PLATE BENDING INSTRUMENTS

Plate Bending Iron 6179.7002

Plate Bending Iron Inverted 6179.7003

PLATE BENDING INSTRUMENTS (CONT'D)



Universal Bending Clamp 6179.7005

RETRACTORS

Radiolucent Hohmann Retractor, 8mm 6179.7014

Radiolucent Hohmann Retractor, 15mm 6179.7015

Malleable Wire Replacement 6171.7008

RETRACTORS (CONT'D)

Radiolucent Weitlaners 3x4, 8" 6171.0002

TORQUE LIMITERS

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

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

ELEVATOR/DENTAL PICK

Periosteal Elevator, 6mm Width, Curved 6179.7019

Dental Pick, Large Handle 6179.7025

DRIVERS

Driver, T8 SR, 100mm 6187.5708

Driver, T15 SR, 100mm 6187.5715

Driver, T8 NSR, 100mm 6187.5808

Driver, T15 NSR, 100mm 6187.5815

ADDITIONAL INSTRUMENTS

Plate Reduction Device, AO Quick-Connect 6179.7023

Screw Holding Forceps 6179.2000

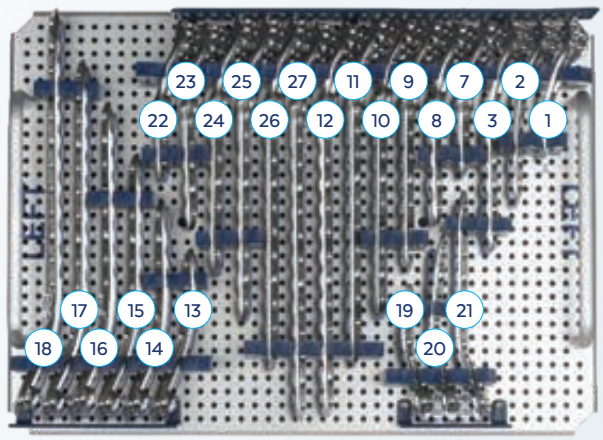
Wire Bending Pliers 6179.2007

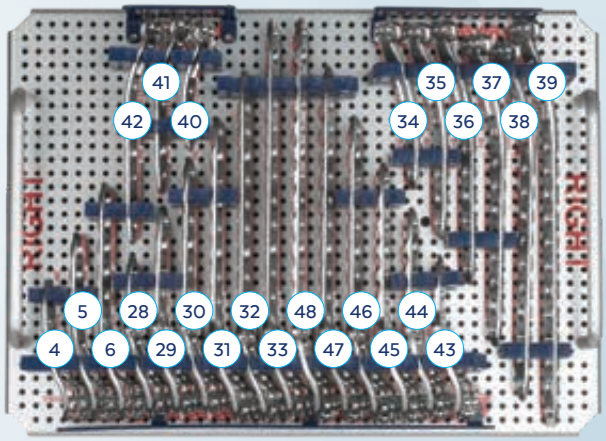
ANTHEM® SS PROXIMAL TIBIA FRACTURE SYSTEM
IMPLANT SET 9187.9001

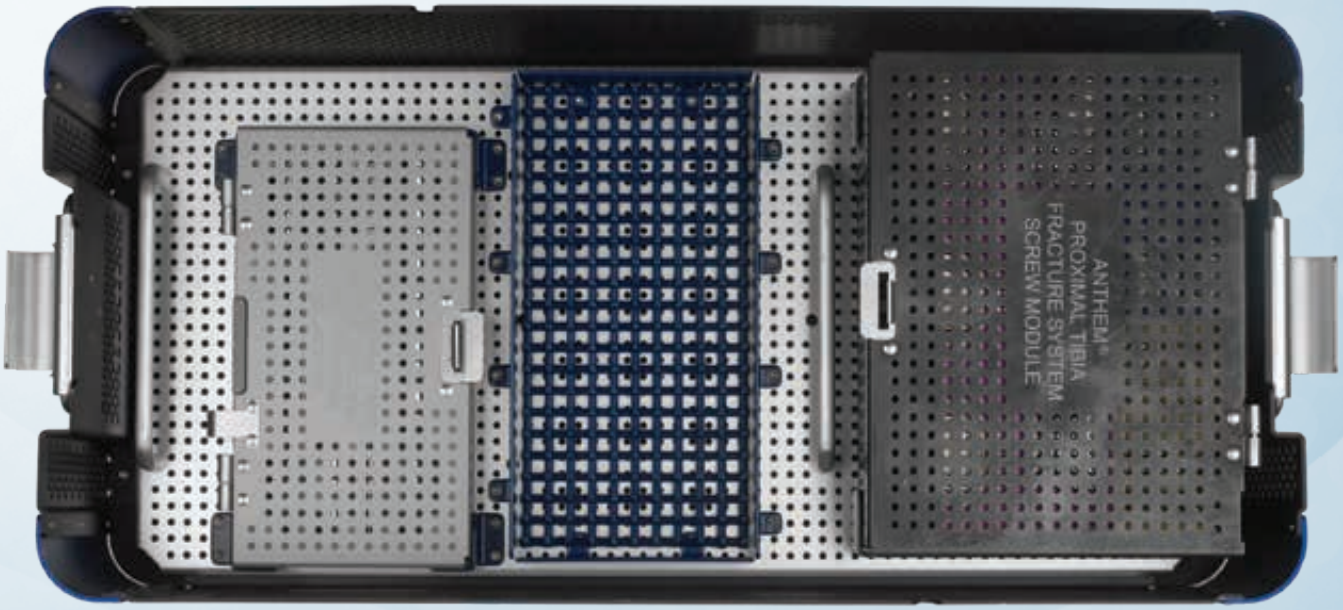
	Part No.	Description	Qty
1	2187.1102	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 2 Hole, 76mm, SS	1
2	2187.1104	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 4 Hole, 102mm, SS	1
3	2187.1106	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 6 Hole, 128mm, SS	1
4	2187.2102	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 2 Hole, 76mm, SS	1
5	2187.2104	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 4 Hole, 102mm, SS	1
6	2187.2106	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 6 Hole, 128mm, SS	1
7	2187.3102	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 2 Hole, 88mm, SS	1
8	2187.3104	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 4 Hole, 114mm, SS	1
9	2187.3106	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 6 Hole, 140mm, SS	1
10	2187.3108	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 8 Hole, 166mm, SS	1
11	2187.3110	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 10 Hole, 192mm, SS	1
12	2187.3112	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 12 Hole, 218mm, SS	1
13	2187.3302	ANTHEM® Medial Proximal Tibia Plate, Left, 2 Hole, 91mm, SS	1
14	2187.3304	ANTHEM® Medial Proximal Tibia Plate, Left, 4 Hole, 117mm, SS	1
15	2187.3306	ANTHEM® Medial Proximal Tibia Plate, Left, 6 Hole, 143mm, SS	1
16	2187.3308	ANTHEM® Medial Proximal Tibia Plate, Left, 8 Hole, 169mm, SS	1
17	2187.3310	ANTHEM® Medial Proximal Tibia Plate, Left, 10 Hole, 195mm, SS	1
18	2187.3312	ANTHEM® Medial Proximal Tibia Plate, Left, 12 Hole, 221mm, SS	1
19	2187.3502	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 2 Hole, 69mm, SS	1
20	2187.3504	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 4 Hole, 95mm, SS	1
21	2187.3506	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 6 Hole, 121mm, SS	1
22	2187.3702	ANTHEM® Lateral Proximal Tibia Plate, Left, 2 Hole, 86mm, SS	1
23	2187.3704	ANTHEM® Lateral Proximal Tibia Plate, Left, 4 Hole, 112mm, SS	1
24	2187.3706	ANTHEM® Lateral Proximal Tibia Plate, Left, 6 Hole, 138mm, SS	1
25	2187.3708	ANTHEM® Lateral Proximal Tibia Plate, Left, 8 Hole, 164mm, SS	1
26	2187.3710	ANTHEM® Lateral Proximal Tibia Plate, Left, 10 Hole, 190mm, SS	1
27	2187.3712	ANTHEM® Lateral Proximal Tibia Plate, Left, 12 Hole, 216mm, SS	1
28	2187.4102	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 2 Hole, 88mm, SS	1
29	2187.4104	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 4 Hole, 114mm, SS	1
30	2187.4106	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 6 Hole, 140mm, SS	1
31	2187.4108	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 8 Hole, 166mm, SS	1
32	2187.4110	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 10 Hole, 192mm, SS	1
33	2187.4112	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 12 Hole, 218mm, SS	1
34	2187.4302	ANTHEM® Medial Proximal Tibia Plate, Right, 2 Hole, 91mm, SS	1
35	2187.4304	ANTHEM® Medial Proximal Tibia Plate, Right, 4 Hole, 117mm, SS	1
36	2187.4306	ANTHEM® Medial Proximal Tibia Plate, Right, 6 Hole, 143mm, SS	1
37	2187.4308	ANTHEM® Medial Proximal Tibia Plate, Right, 8 Hole, 169mm, SS	1
38	2187.4310	ANTHEM® Medial Proximal Tibia Plate, Right, 10 Hole, 195mm, SS	1
39	2187.4312	ANTHEM® Medial Proximal Tibia Plate, Right, 12 Hole, 221mm, SS	1

ANTHEM® SS PROXIMAL TIBIA FRACTURE SYSTEM
IMPLANT SET 9187.9001

	Part No.	Description	Qty
40	2187.4502	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 2 Hole, 69mm, SS	1
41	2187.4504	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 4 Hole, 95mm, SS	1
42	2187.4506	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 6 Hole, 121mm, SS	1
43	2187.4702	ANTHEM® Lateral Proximal Tibia Plate, Right, 2 Hole, 86mm, SS	1
44	2187.4704	ANTHEM® Lateral Proximal Tibia Plate, Right, 4 Hole, 112mm, SS	1
45	2187.4706	ANTHEM® Lateral Proximal Tibia Plate, Right, 6 Hole, 138mm, SS	1
46	2187.4708	ANTHEM® Lateral Proximal Tibia Plate, Right, 8 Hole, 164mm, SS	1
47	2187.4710	ANTHEM® Lateral Proximal Tibia Plate, Right, 10 Hole, 190mm, SS	1
48	2187.4712	ANTHEM® Lateral Proximal Tibia Plate, Right, 12 Hole, 216mm, SS	1
	9187.0001	ANTHEM® SS Proximal Tibia Fracture System Graphic Case	





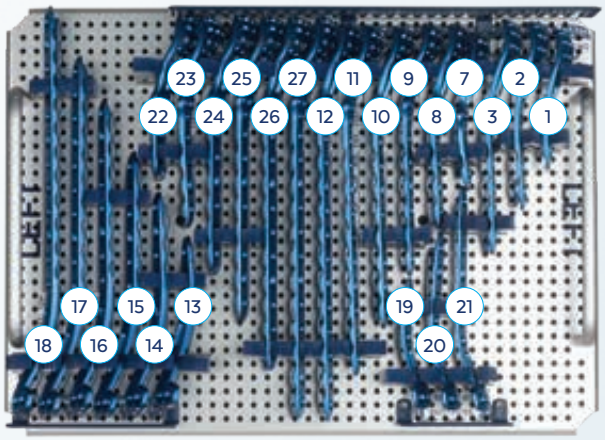


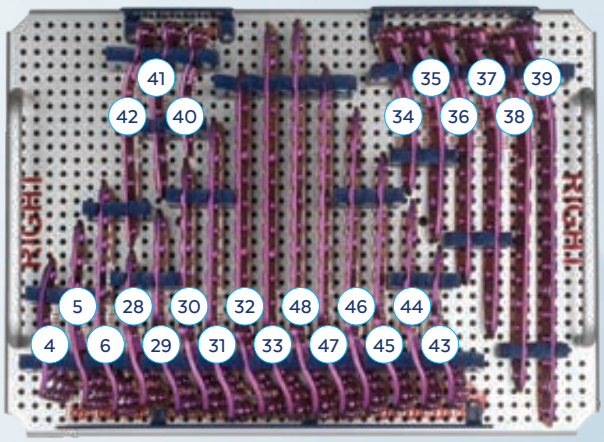
ANTHEM® Ti PROXIMAL TIBIA FRACTURE SYSTEM
IMPLANT SET 9187.9002

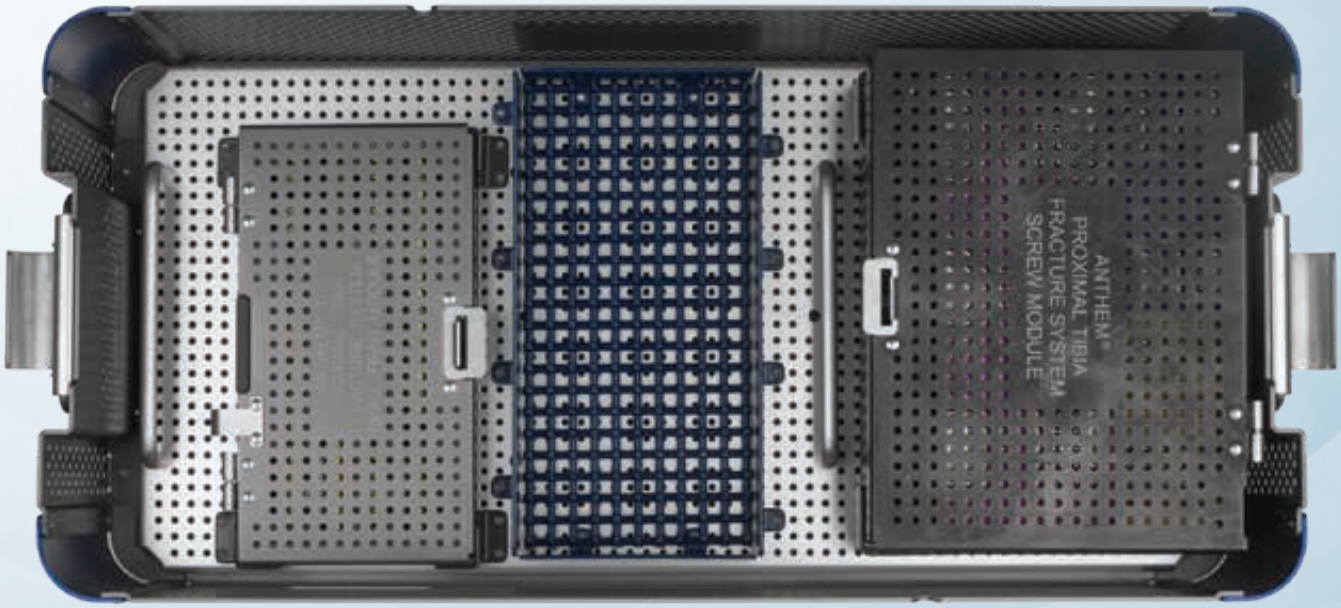
	Part No.	Description	Qty
1	1187.1102	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 2 Hole, 76mm, Ti	1
2	1187.1104	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 4 Hole, 102mm, Ti	1
3	1187.1106	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Left, 6 Hole, 128mm, Ti	1
4	1187.2102	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 2 Hole, 76mm, Ti	1
5	1187.2104	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 4 Hole, 102mm, Ti	1
6	1187.2106	ANTHEM® Lateral Non-Locking Proximal Tibia Plate, Right, 6 Hole, 128mm, Ti	1
7	1187.3102	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 2 Hole, 88mm, Ti	1
8	1187.3104	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 4 Hole, 114mm, Ti	1
9	1187.3106	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 6 Hole, 140mm, Ti	1
10	1187.3108	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 8 Hole, 166mm, Ti	1
11	1187.3110	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 10 Hole, 192mm, Ti	1
12	1187.3112	ANTHEM® Lateral Proximal Tibia Plate XR, Left, 12 Hole, 218mm, Ti	1
13	1187.3302	ANTHEM® Medial Proximal Tibia Plate, Left, 2 Hole, 91mm, Ti	1
14	1187.3304	ANTHEM® Medial Proximal Tibia Plate, Left, 4 Hole, 117mm, Ti	1
15	1187.3306	ANTHEM® Medial Proximal Tibia Plate, Left, 6 Hole, 143mm, Ti	1
16	1187.3308	ANTHEM® Medial Proximal Tibia Plate, Left, 8 Hole, 169mm, Ti	1
17	1187.3310	ANTHEM® Medial Proximal Tibia Plate, Left, 10 Hole, 195mm, Ti	1
18	1187.3312	ANTHEM® Medial Proximal Tibia Plate, Left, 12 Hole, 221mm, Ti	1
19	1187.3502	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 2 Hole, 69mm, Ti	1
20	1187.3504	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 4 Hole, 95mm, Ti	1
21	1187.3506	ANTHEM® Posteromedial Proximal Tibia Plate, Left, 6 Hole, 121mm, Ti	1
22	1187.3702	ANTHEM® Lateral Proximal Tibia Plate, Left, 2 Hole, 86mm, Ti	1
23	1187.3704	ANTHEM® Lateral Proximal Tibia Plate, Left, 4 Hole, 112mm, Ti	1
24	1187.3706	ANTHEM® Lateral Proximal Tibia Plate, Left, 6 Hole, 138mm, Ti	1
25	1187.3708	ANTHEM® Lateral Proximal Tibia Plate, Left, 8 Hole, 164mm, Ti	1
26	1187.3710	ANTHEM® Lateral Proximal Tibia Plate, Left, 10 Hole, 190mm, Ti	1
27	1187.3712	ANTHEM® Lateral Proximal Tibia Plate, Left, 12 Hole, 216mm, Ti	1
28	1187.4102	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 2 Hole, 88mm, Ti	1
29	1187.4104	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 4 Hole, 114mm, Ti	1
30	1187.4106	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 6 Hole, 140mm, Ti	1
31	1187.4108	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 8 Hole, 166mm, Ti	1
32	1187.4110	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 10 Hole, 192mm, Ti	1
33	1187.4112	ANTHEM® Lateral Proximal Tibia Plate XR, Right, 12 Hole, 218mm, Ti	1
34	1187.4302	ANTHEM® Medial Proximal Tibia Plate, Right, 2 Hole, 91mm, Ti	1
35	1187.4304	ANTHEM® Medial Proximal Tibia Plate, Right, 4 Hole, 117mm, Ti	1
36	1187.4306	ANTHEM® Medial Proximal Tibia Plate, Right, 6 Hole, 143mm, Ti	1
37	1187.4308	ANTHEM® Medial Proximal Tibia Plate, Right, 8 Hole, 169mm, Ti	1
38	1187.4310	ANTHEM® Medial Proximal Tibia Plate, Right, 10 Hole, 195mm, Ti	1
39	1187.4312	ANTHEM® Medial Proximal Tibia Plate, Right, 12 Hole, 221mm, Ti	1

ANTHEM® Ti PROXIMAL TIBIA FRACTURE SYSTEM
IMPLANT SET 9187.9002

	Part No.	Description	Qty
40	1187.4502	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 2 Hole, 69mm, Ti	1
41	1187.4504	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 4 Hole, 95mm, Ti	1
42	1187.4506	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 6 Hole, 121mm, Ti	1
43	1187.4702	ANTHEM® Lateral Proximal Tibia Plate, Right, 2 Hole, 86mm, Ti	1
44	1187.4704	ANTHEM® Lateral Proximal Tibia Plate, Right, 4 Hole, 112mm, Ti	1
45	1187.4706	ANTHEM® Lateral Proximal Tibia Plate, Right, 6 Hole, 138mm, Ti	1
46	1187.4708	ANTHEM® Lateral Proximal Tibia Plate, Right, 8 Hole, 164mm, Ti	1
47	1187.4710	ANTHEM® Lateral Proximal Tibia Plate, Right, 10 Hole, 190mm, Ti	1
48	1187.4712	ANTHEM® Lateral Proximal Tibia Plate, Right, 12 Hole, 216mm, Ti	1
	9187.0002	ANTHEM® Ti Proximal Tibia Fracture System Graphic Case	







ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
SCREW MODULE 9187.9003

1 2.5 Non-Locking, CoCr

Part No.	Length	Qty
7171.6530	30mm	4
7171.6535	35mm	4
7171.6540	40mm	4
7171.6545	45mm	4
7171.6550	50mm	4
7171.6555	55mm	4
7171.6560	60mm	4
7171.6565	65mm	4
7171.6570	70mm	4
7171.6575	75mm	4
7171.6580	80mm	4
7171.6585	85mm	4
7171.6590	90mm	4
7171.6595	95mm	4

2 2.5 Locking, CoCr

Part No.	Length	Qty
7171.5530	30mm	4
7171.5535	35mm	4
7171.5540	40mm	4
7171.5545	45mm	4
7171.5550	50mm	4
7171.5555	55mm	4
7171.5560	60mm	4
7171.5565	65mm	4
7171.5570	70mm	4
7171.5575	75mm	4
7171.5580	80mm	4
7171.5585	85mm	4
7171.5590	90mm	4
7171.5595	95mm	4

3 3.5 Non-Locking, CoCr

Part No.	Length	Qty
7179.3020	20mm	5
7179.3022	22mm	5
7179.3024	24mm	5
7179.3026	26mm	5
7179.3028	28mm	5
7179.3030	30mm	5
7179.3032	32mm	5
7179.3034	34mm	5
7179.3036	36mm	5
7179.3038	38mm	5
7179.3040	40mm	5
7179.3042	42mm	5
7179.3044	44mm	5
7179.3046	46mm	5
7179.3048	48mm	5
7179.3050	50mm	5
7179.3052	52mm	5
7179.3054	54mm	5
7179.3056	56mm	5
7179.3058	58mm	5
7179.3060	60mm	5
7179.3065	65mm	5
7179.3070	70mm	5
7179.3075	75mm	5
7179.3080	80mm	5
7179.3085	85mm	5
7179.3090	90mm	5
7179.3095	95mm	5

4 3.5 Locking, CoCr

Part No.	Length	Qty
7179.5020	20mm	5
7179.5022	22mm	5
7179.5024	24mm	5
7179.5026	26mm	5
7179.5028	28mm	5
7179.5030	30mm	5
7179.5032	32mm	5
7179.5034	34mm	5
7179.5036	36mm	5
7179.5038	38mm	5
7179.5040	40mm	5
7179.5042	42mm	5
7179.5044	44mm	5
7179.5046	46mm	5
7179.5048	48mm	5
7179.5050	50mm	5
7179.5052	52mm	5
7179.5054	54mm	5
7179.5058	58mm	5
7179.5056	56mm	5
7179.5060	60mm	5
7179.5065	65mm	5
7179.5070	70mm	5
7179.5075	75mm	5
7179.5080	80mm	5
7179.5085	85mm	5
7179.5090	90mm	5
7179.5095	95mm	5

ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
SCREW MODULE 9187.9003

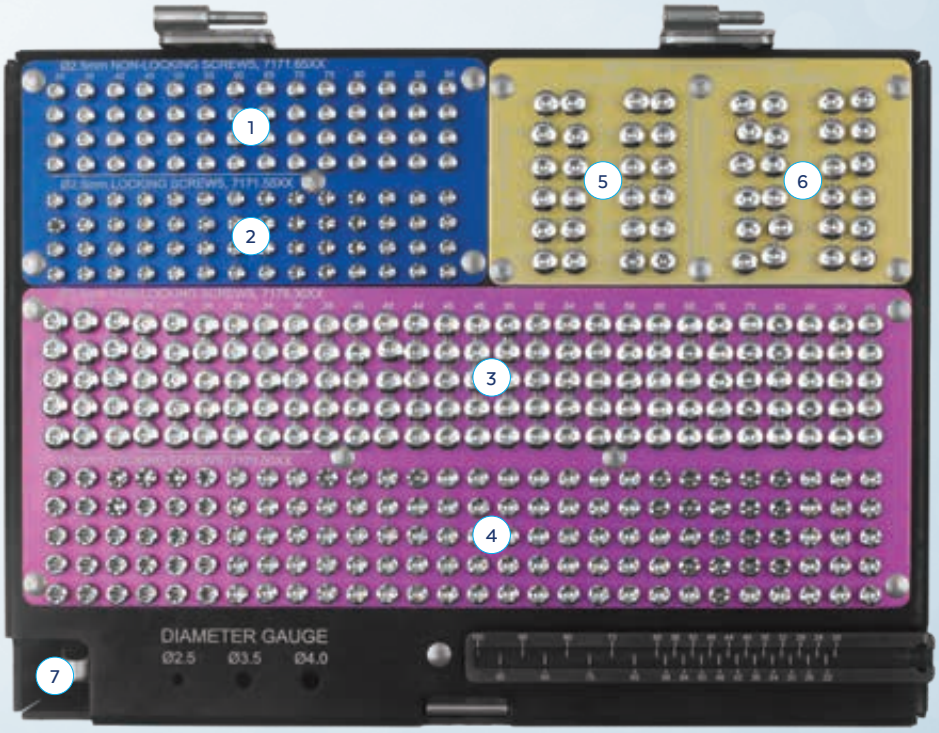
5 4.0 Cancellous, Fully Threaded, CoCr

Part No.	Length	Qty
7179.4040	40mm	2
7179.4045	45mm	2
7179.4050	50mm	2
7179.4055	55mm	2
7179.4060	60mm	2
7179.4065	65mm	2
7179.4070	70mm	2
7179.4075	75mm	2
7179.4080	80mm	2
7179.4085	85mm	2
7179.4090	90mm	2
7179.4095	95mm	2

6 4.0 Cancellous, Partially Threaded, CoCr

Part No.	Length	Qty
7179.8040	40mm	2
7179.8045	45mm	2
7179.8050	50mm	2
7179.8055	55mm	2
7179.8060	60mm	2
7179.8065	65mm	2
7179.8070	70mm	2
7179.8075	75mm	2
7179.8080	80mm	2
7179.8085	85mm	2
7179.8090	90mm	2
7179.8095	95mm	2

Part No.	Description	Qty
7 6179.2000	Screw Holding Forceps	1
9187.0003	ANTHEM® CoCr Proximal Tibia Fracture System Graphic Case	

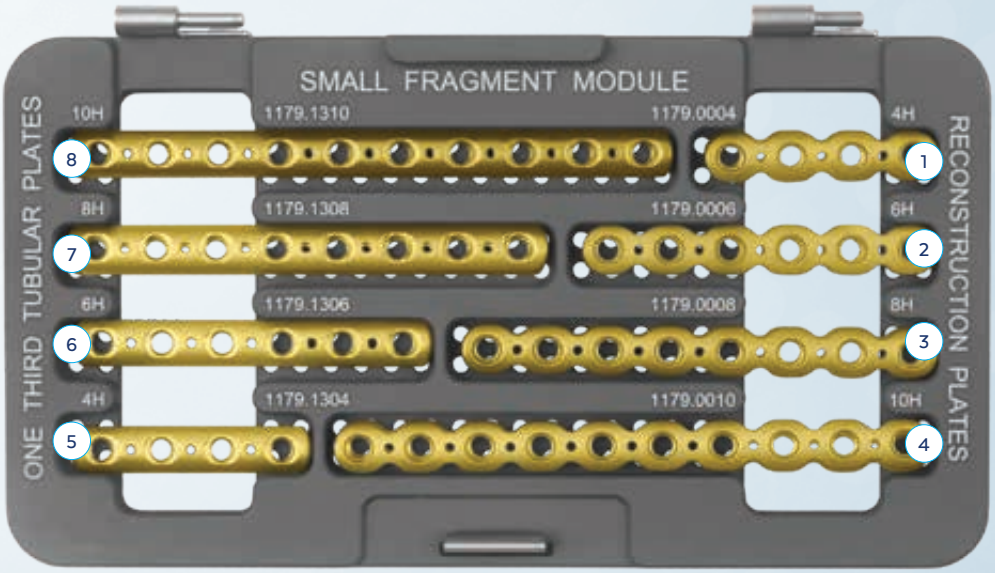


ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
SS SMALL FRAGMENT MODULE 9187.9004

	Part No.	Description	Qty
1	2179.0004	ANTHEM® Reconstruction Plate, 4 Hole, 46mm, SS	2
2	2179.0006	ANTHEM® Reconstruction Plate, 6 Hole, 70mm, SS	2
3	2179.0008	ANTHEM® Reconstruction Plate, 8 Hole, 94mm, SS	2
4	2179.0010	ANTHEM® Reconstruction Plate, 10 Hole, 118mm, SS	2
5	2179.1304	ANTHEM® One-Third Tubular Plate, 4 Hole, 48mm, SS	2
6	2179.1306	ANTHEM® One-Third Tubular Plate, 6 Hole, 72mm, SS	2
7	2179.1308	ANTHEM® One-Third Tubular Plate, 8 Hole, 96mm, SS	2
8	2179.1310	ANTHEM® One-Third Tubular Plate, 10 Hole, 120mm, SS	2
	9187.0004	ANTHEM® SS Proximal Tibia Small Fragment Module	

ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
Ti SMALL FRAGMENT MODULE 9187.9005

	Part No.	Description	Qty
1	1179.0004	ANTHEM® Reconstruction Plate, 4 Hole, 46mm, Ti	2
2	1179.0006	ANTHEM® Reconstruction Plate, 6 Hole, 70mm, Ti	2
3	1179.0008	ANTHEM® Reconstruction Plate, 8 Hole, 94mm, Ti	2
4	1179.0010	ANTHEM® Reconstruction Plate, 10 Hole, 118mm, Ti	2
5	1179.1304	ANTHEM® One-Third Tubular Plate, 4 Hole, 48mm, Ti	2
6	1179.1306	ANTHEM® One-Third Tubular Plate, 6 Hole, 72mm, Ti	2
7	1179.1308	ANTHEM® One-Third Tubular Plate, 8 Hole, 96mm, Ti	2
8	1179.1310	ANTHEM® One-Third Tubular Plate, 10 Hole, 120mm, Ti	2
	9187.0005	ANTHEM® Ti Proximal Tibia Small Fragment Module	

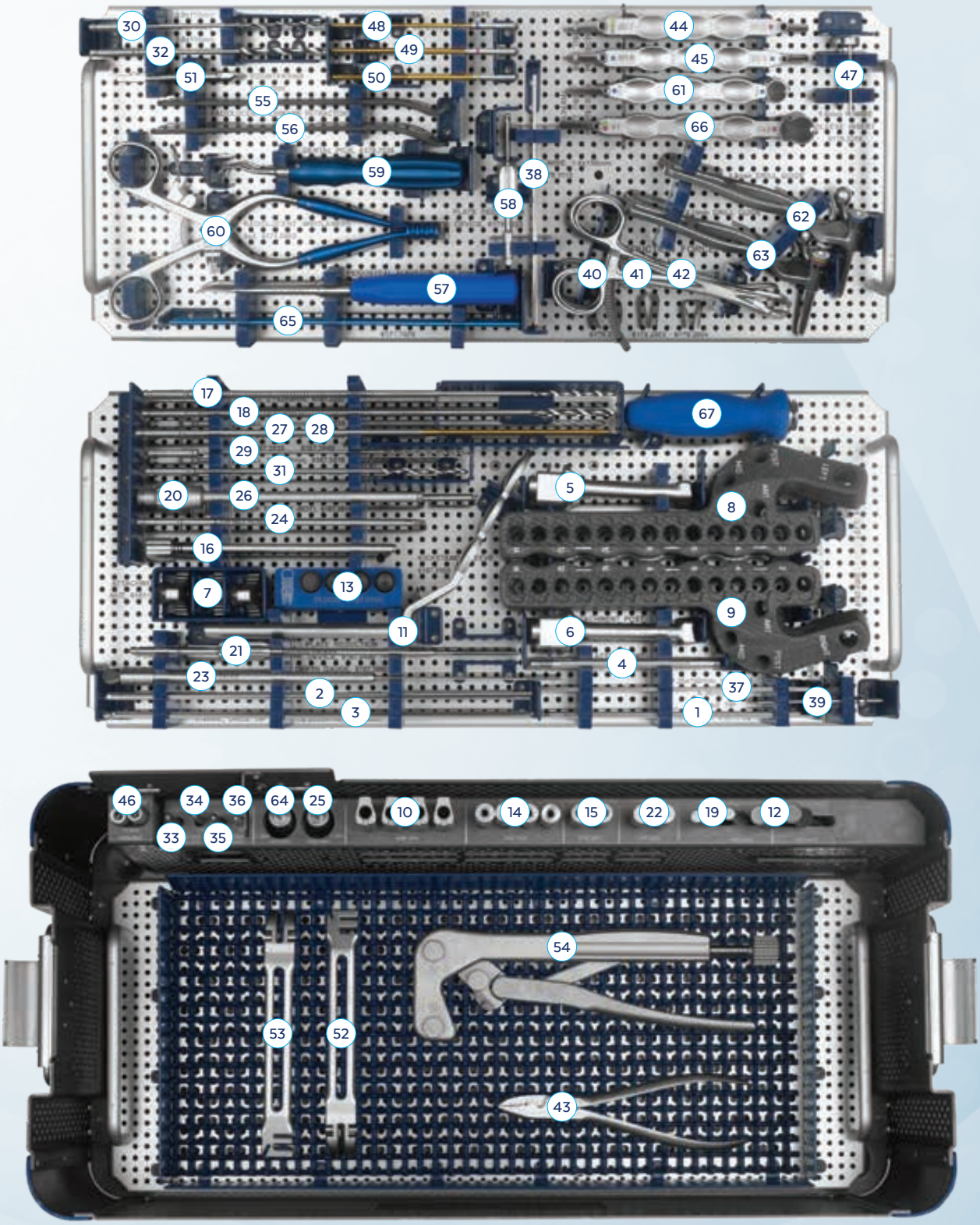


ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
INSTRUMENT SET 9187.9006

	Part No.	Description	Qty
1	6187.0180	K-Wire, 1.8x150mm, Trocar	10
2	6187.0200	K-Wire, 2.0x250mm, Trocar	10
3	6187.0201	K-Wire, 2.0x250mm, Drill	5
4	6187.1000	Plate Attachment Bolt	2
5	6187.1100	Attachment Post, Left	1
6	6187.2100	Attachment Post, Right	1
7	6187.1300	Arm Attachment Nut	3
8	6187.3000	Aiming Arm, Left	1
9	6187.4000	Aiming Arm, Right	1
10	6187.3100	Tissue Protection Sleeve	4
11	6187.3105	Kickstand Sleeve	2
12	6187.3110	Entry Trocar	2
13	6187.3150	Plug	4
14	6187.3200	Drill Sleeve	4
15	6187.3201	Dynamic Compression Sleeve	2
16	6187.3202	Drill Sleeve, Long	2
17	6187.3227	Drill, 2.7x280mm, Calibrated, AO Quick-Connect	2
18	6187.3235	Drill, 3.5x280mm, Calibrated, AO Quick-Connect	2
19	6187.3300	Positioning Pin	2
20	6187.3350	Screw Retention Sleeve	1
21	6187.3400	Plate Reduction Device, 230mm, AO Quick-Connect	1
22	6187.3500	K-Wire Sleeve	2
23	6187.3600	Depth Gauge	1
24	6187.3715	Driver, T15 SR, 170mm, AO Quick-Connect	1
25	6187.3801	Torque-Limiting Attachment, 2.5Nm, AO Quick-Connect	1
26	6187.3815	Driver, T15 NSR, 200mm, AO Quick-Connect	1
27	6187.3935	Tap, 3.5x280mm, AO Quick-Connect	1
28	6187.3940	Tap, 4.0x280mm, AO Quick-Connect	1
29	6187.5018	Drill, 1.8x190mm, AO Quick-Connect	2
30	6187.5025	Drill, 2.5x140mm, AO Quick-Connect	2
31	6187.5027	Drill, 2.7x190mm, AO Quick-Connect	2
32	6187.5035	Drill, 3.5x140mm, AO Quick-Connect	2
33	6187.5708	Driver, T8 SR, 100mm, AO Quick-Connect	1
34	6187.5715	Driver, T15 SR, 100mm, AO Quick-Connect	1
35	6187.5808	Driver, T8 NSR, 100mm, AO Quick-Connect	1
36	6187.5815	Driver, T15 NSR, 100mm, AO Quick-Connect	1

	Part No.	Description	Qty
37	6179.1113	K-Wire, 1.25x150mm, Trocar Tip	10
38	6179.1116	K-Wire, 1.6x150mm, Trocar Tip	10
39	6179.1216	1.6mm Plate Holding K-Wire	2
40	6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
41	6179.2003	Point-to-Point Reduction Forceps, Narrow, Ratcheting	1
42	6179.2004	Point-to-Point Reduction Forceps, Wide, Ratcheting	1
43	6179.2007	Wire Bending Pliers	1
44	6179.3125	2.5mm Soft Tissue Protector	1
45	6179.3135	3.5mm Soft Tissue Protector	1
46	6179.3227	2.7mm Locking Drill Guide	2
47	6179.3316	1.6mm K-Wire Sleeve Insert	1
48	6179.5125	2.5mm Non-Locking Tap	1
49	6179.5135	3.5mm Non-Locking Tap	1
50	6179.5140	4.0mm Cancellous Tap	1
51	6179.7000	Countersink, AO Quick-Connect	1
52	6179.7002	Plate Bending Iron	1
53	6179.7003	Plate Bending Iron Inverted	1
54	6179.7005	Universal Bending Clamp	1
55	6179.7014	Radiolucent Hohmann Retractor, 8mm	2
56	6179.7015	Radiolucent Hohmann Retractor, 15mm	2
57	6179.7019	Periosteal Elevator, 6mm Width, Curved	2
58	6179.7023	Plate Reduction Device	1
59	6179.7025	Dental Pick, Large Handle	2
60	6171.0002	Radiolucent Weitlaners 3x4, 8”	1
61	6171.3118	1.8mm Polyaxial Soft Tissue Protector	1
62	6171.4218	1.8mm Speedlock Drill Guide	1
63	6171.4227	2.7mm Speedlock Drill Guide	1
64	6171.5012	Torque-Limiting Attachment, 1.2Nm, AO Quick-Connect	1
65	6171.7008	Malleable Wire Replacement	5
66	6186.3127	2.7mm Polyaxial Soft Tissue Protector	1
67	6188.7001	Handle, AO Quick-Connect	1

ANTHEM® PROXIMAL TIBIA FRACTURE SYSTEM
INSTRUMENT SET 9187.9006



IMPORTANT INFORMATION ON THE ANTHEM® 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.

In addition, small fragment, mini fragment, proximal tibia, clavicle, metaphyseal, and distal fibula plates are indicated for use in infant, child, and adolescent pediatric subgroups and small stature adults. Distal radius, distal tibia, metaphyseal, and mini fragment plates are indicated for use in adolescents (12-21 years of age). Plating can 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.

MRI 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 results 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, osteomalicia, 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.
- Improper alignment can cause a mal-union of the bone and/or bending, cracking or even breakage of the device.

IMPORTANT INFORMATION ON THE ANTHEM® FRACTURE SYSTEM

- 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 accidently 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 Enzol® (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 Enzol® (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^2 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			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

DI201A REV F

NOTES

NOTES

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Audubon, PA 19403
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