



GLOBUS
MEDICAL



ANTHEM[®]

Proximal 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

ANTHEM[®]

Proximal Tibia Fracture System

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ANTHEM®

Proximal Tibia Fracture System

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.

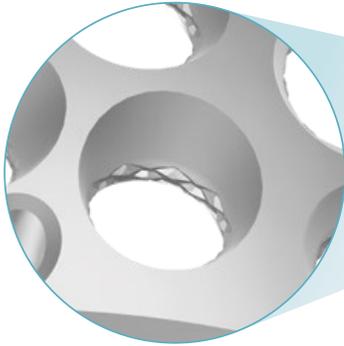
The system features three styles of Lateral Proximal Tibia Plates, a Medial Locking Plate, and a Posteromedial Buttress Plate to address intra-articular and extra-articular fractures of the proximal tibia.

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



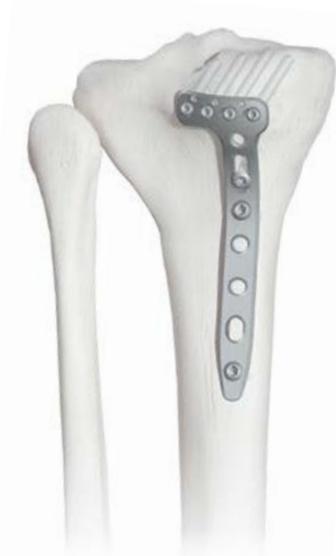
XR Lateral Locking Plate

Comprehensive System

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

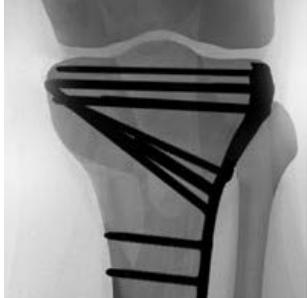
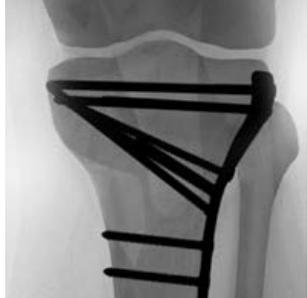


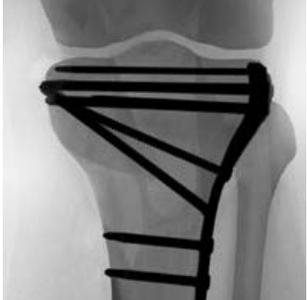
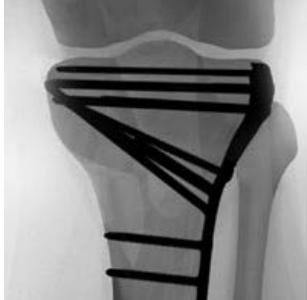
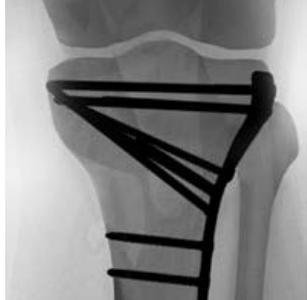
Medial Locking Plate

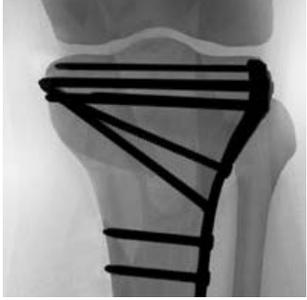
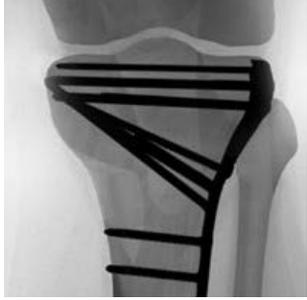
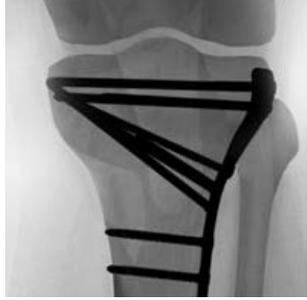


Posteromedial Buttress Plate

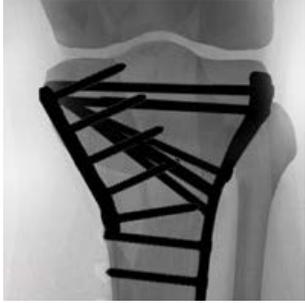
SCHATZKER CLASSIFICATION AND SAMPLE CONSTRUCTS

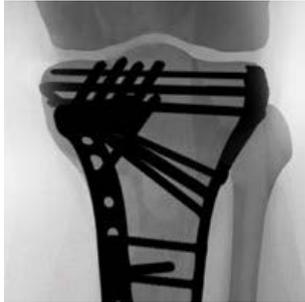
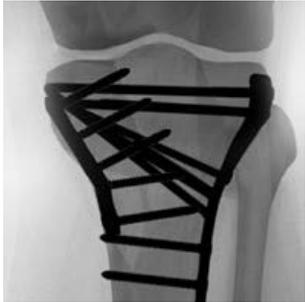
TYPE I	LATERAL NON-LOCKING	XR LATERAL LOCKING	LATERAL LOCKING
			

TYPE II	LATERAL NON-LOCKING	XR LATERAL LOCKING	LATERAL LOCKING
			

TYPE III	LATERAL NON-LOCKING	XR LATERAL LOCKING	LATERAL LOCKING
			

TYPE IV	MEDIAL	POSTEROMEDIAL
		

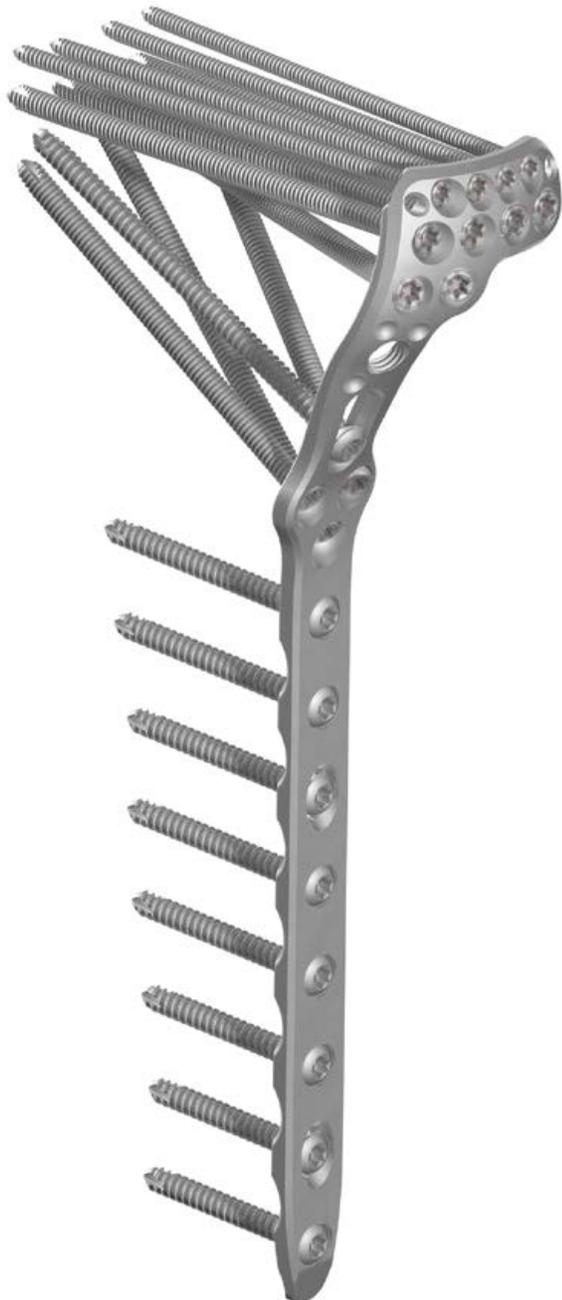
TYPE V	XR LATERAL LOCKING +MEDIAL	XR LATERAL LOCKING +POSTEROMEDIAL	XR LATERAL LOCKING + SMALL FRAGMENT
			

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 ($\pm 20^\circ$ 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



Medial Locking Plate

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



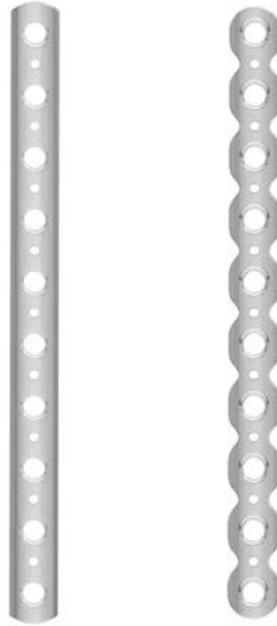
Posteromedial Buttress Plate

- 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

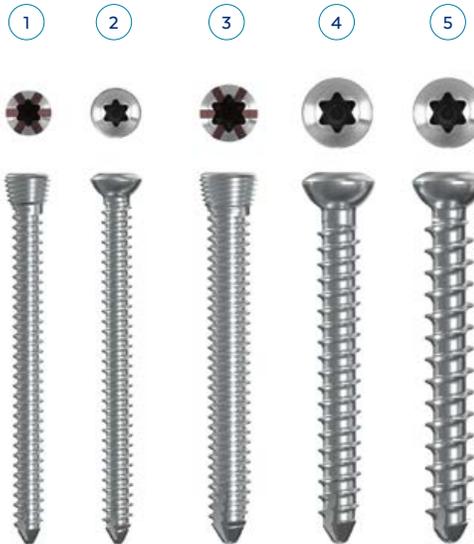


One Third
Tubular Plates

Reconstruction
Plates

Screws

- ① 2.5mm Locking
- ② 2.5mm Non-Locking
- ③ 3.5mm Locking
- ④ 3.5mm Non-Locking
- ⑤ 4.0 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 iliotibial 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.

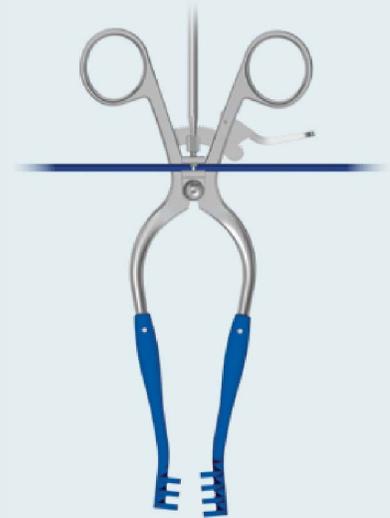
To assemble the Malleable Band, use a **T8 Driver** to loosen the set screw. Place the Malleable Band in the slot and tighten the screw.



Loosening the set screw



Placing the Malleable Band



Tightening the 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

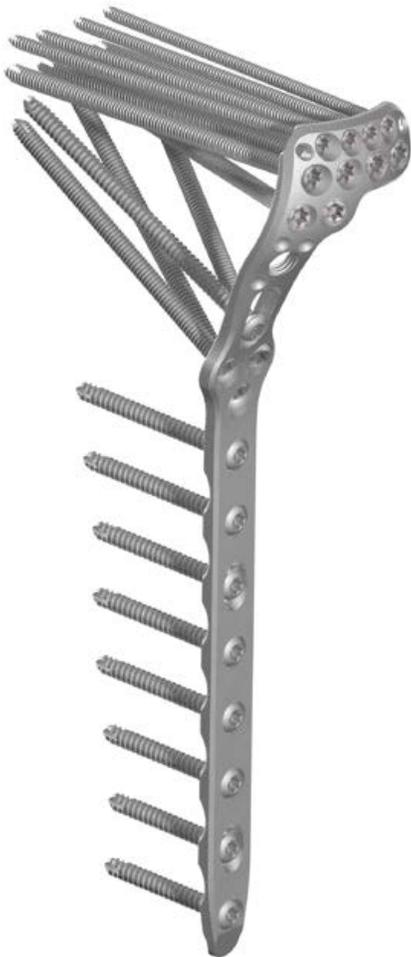
Reduce the fracture and verify that the articular surface is anatomically reduced using fluoroscopy. Provisional fixation may be performed using K-wires.

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

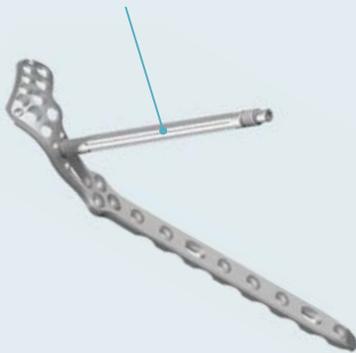
Position the plate the lateral proximal tibia. Confirm placement using fluoroscopy. Alternatively, the plate may be attached to the Aiming Arm for placement.



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.

Plate Attachment Bolt



Attachment Post

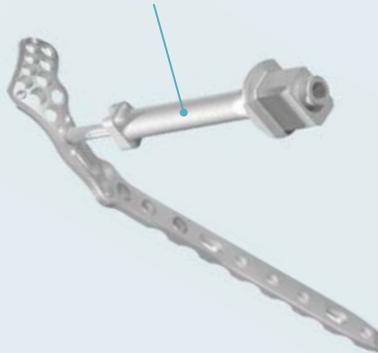


Plate placement



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.

Arm Attachment Nut



Aiming Arm

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

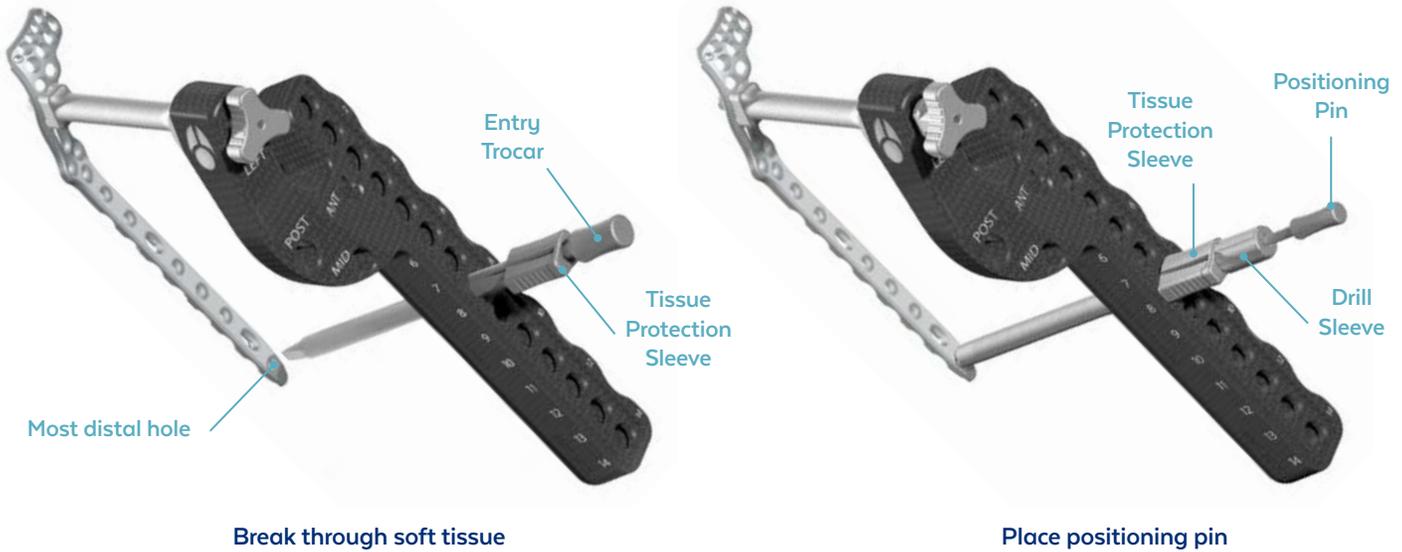
7

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.

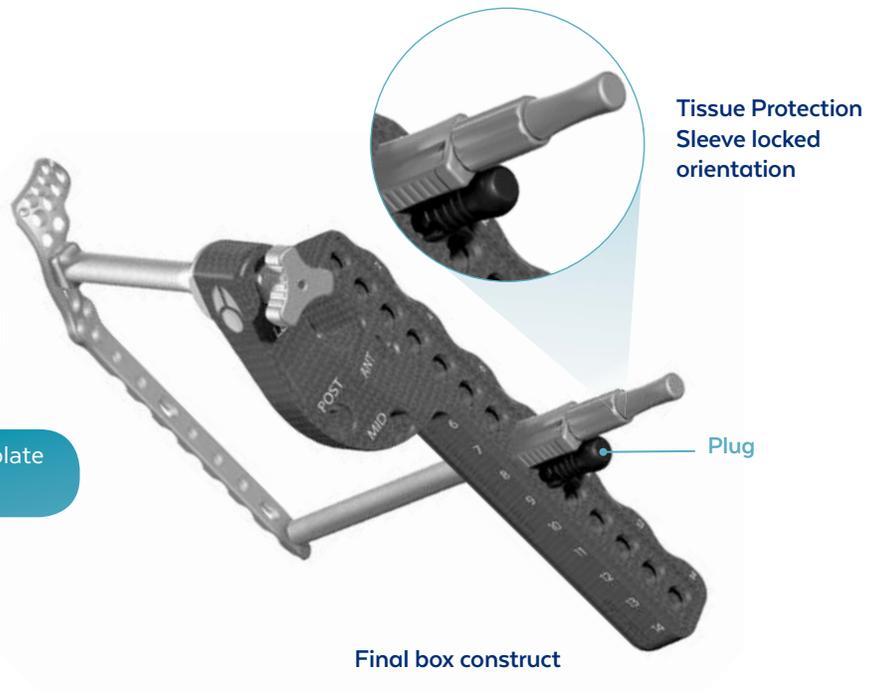
Confirm plate position using lateral fluoroscopy. Place a K-wire through the Drill Sleeve to ensure the plate position is maintained in the sagittal plane. Complete the box construct for diaphyseal targeting.



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.

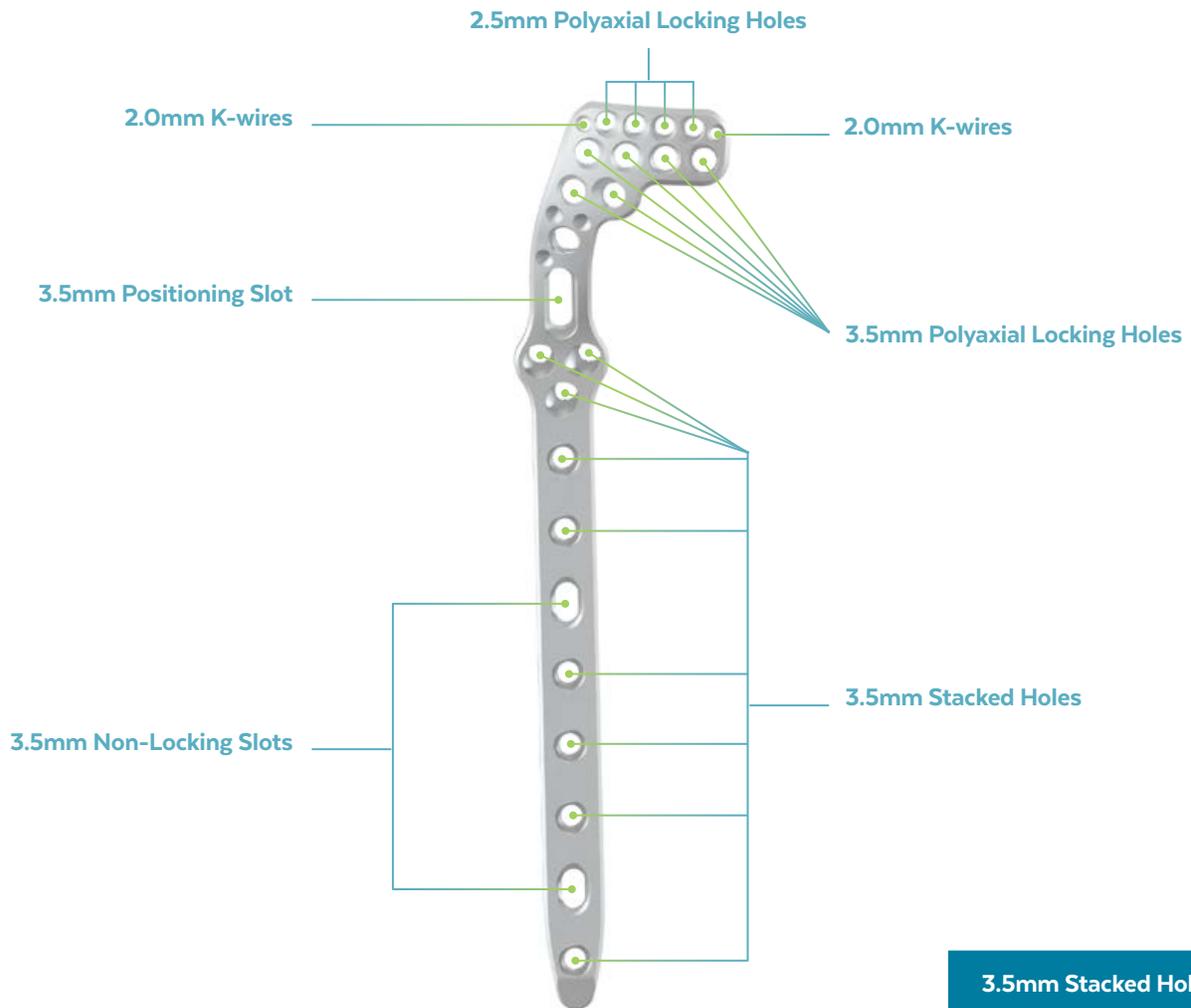


Screw Compatibility

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	

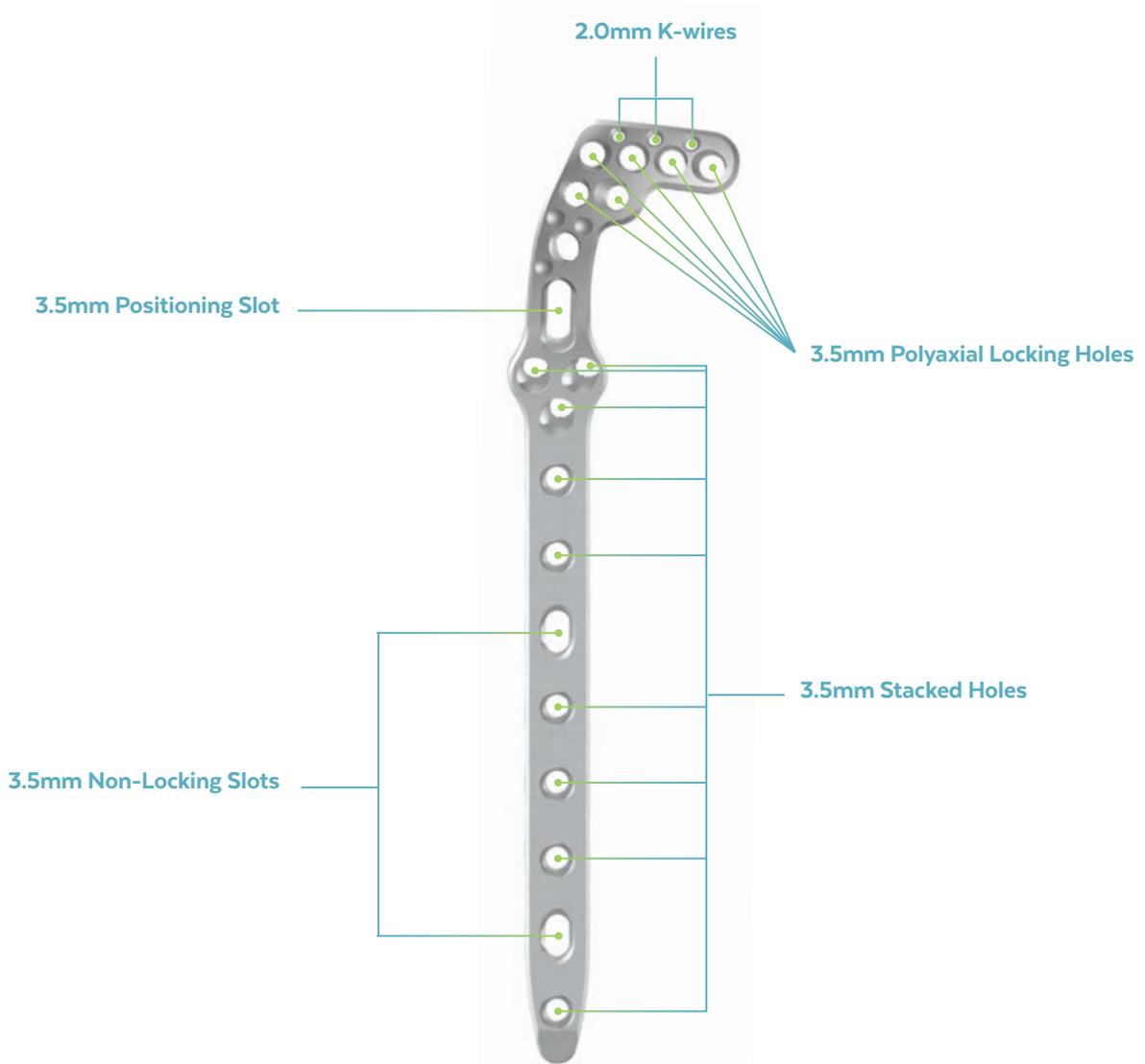
2.5mm Polyaxial Locking Holes	
2.5mm Locking	
2.5mm Non-Locking	

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	

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	

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 performed 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

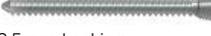


Screw insertion

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		
		
		

3.5mm Polyaxial Locking Holes		
		
		
		



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.



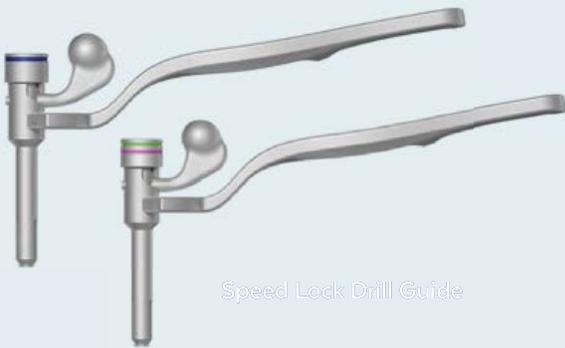
Insert 3.5mm Locking Screws using the **2.5Nm Torque Limiting Attachment**.

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) ●●

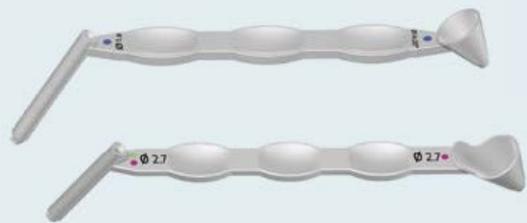
The Speed Lock Drill Guide may be used to drill nominal trajectories. The thumb lock locks the drill guide to the plate at the nominal screw trajectory.



Speed Lock Drill Guide 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 $\pm 20^\circ$ cone of angulation on the polyaxial end and the nominal trajectory on the nominal end.



Soft Tissue Protector

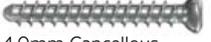


Polyaxial Guide



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.

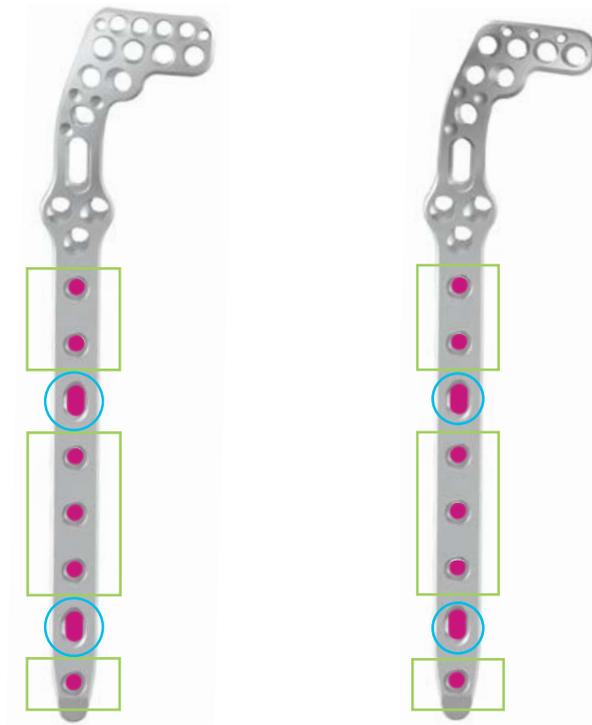


SCREW INSERTION (CONT'D)

Distal Screws in XR Lateral Locking and Lateral Locking Plates

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

3.5mm Non-Locking Slot		
	 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

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.

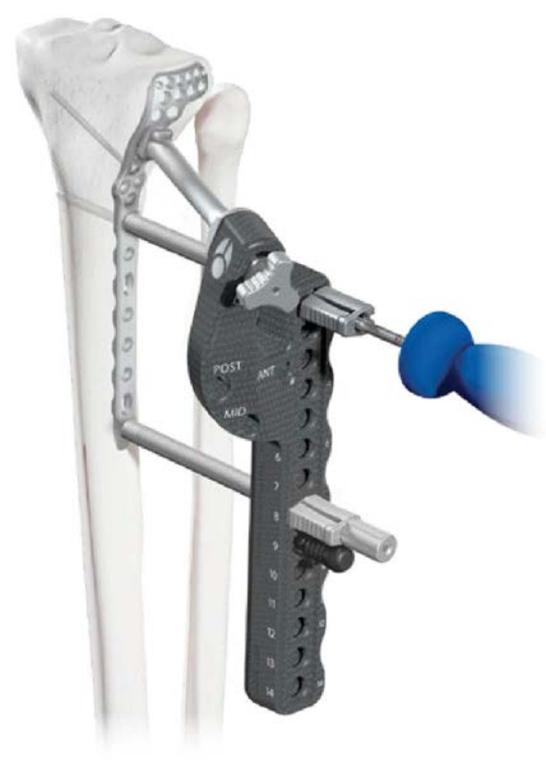
Distal Screw Insertion



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

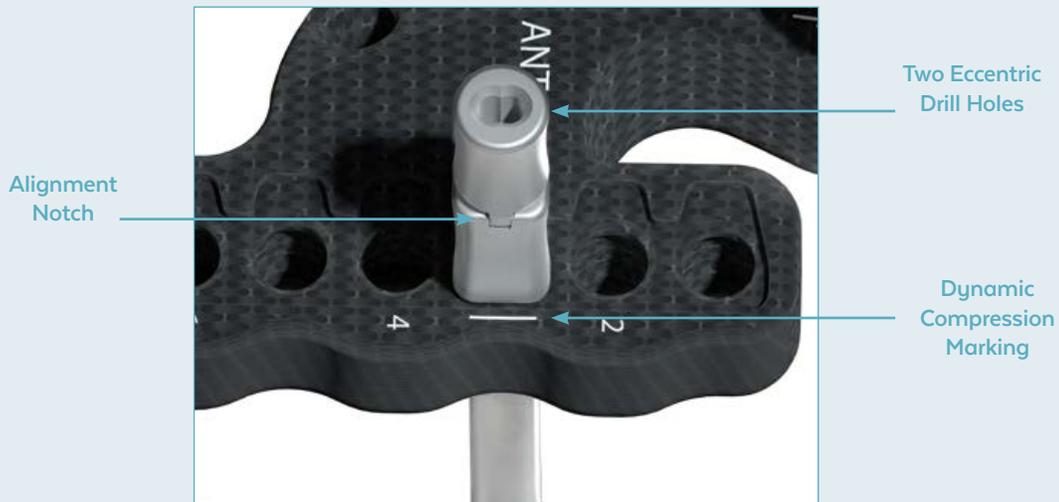
Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a slotted hole. All 3.5mm Non-Locking and 4.0mm Cancellous Screws may be used for dynamic compression. If compression is not desired, place the screw in a neutral position by using the 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 to the proximal tibia that allows for fracture reduction. Dissect through the fascia and split the iliotibial 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.

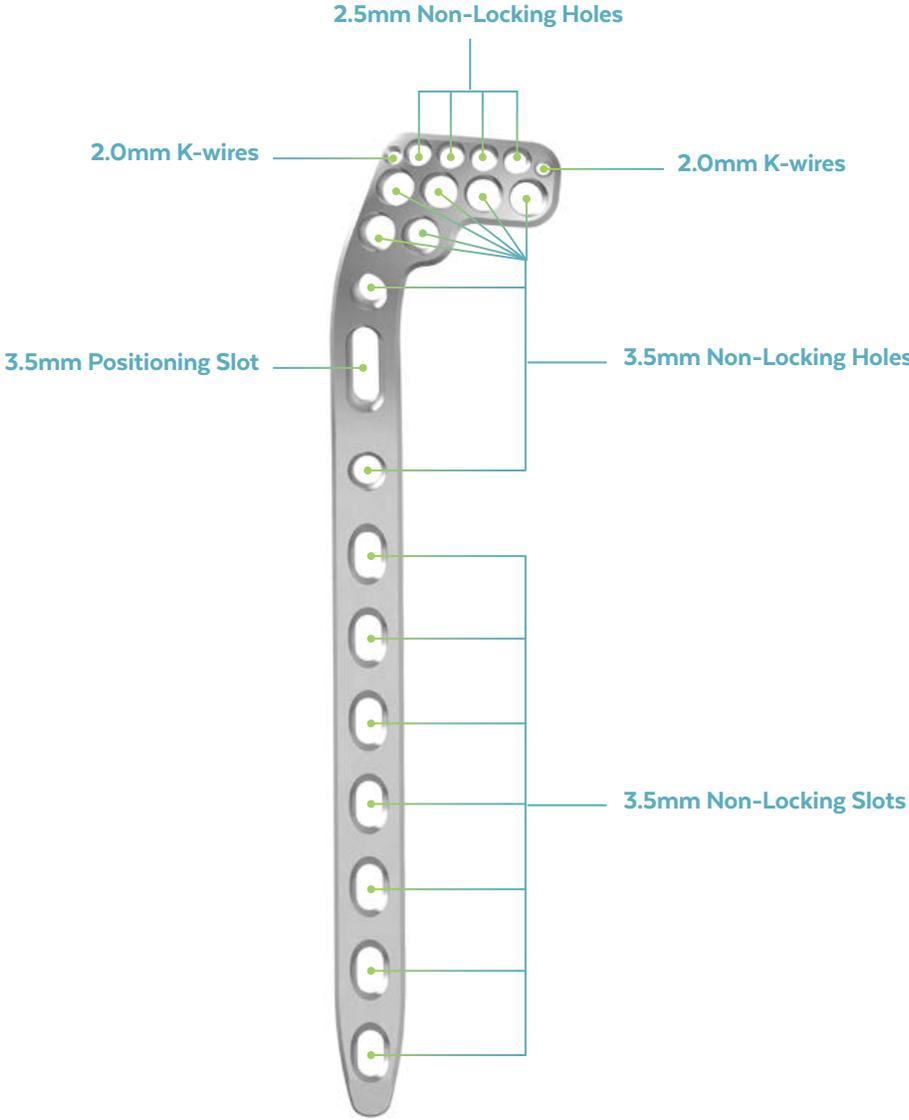
K-wires or reduction clamps may be used to provisionally fix the plate to the bone.

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



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

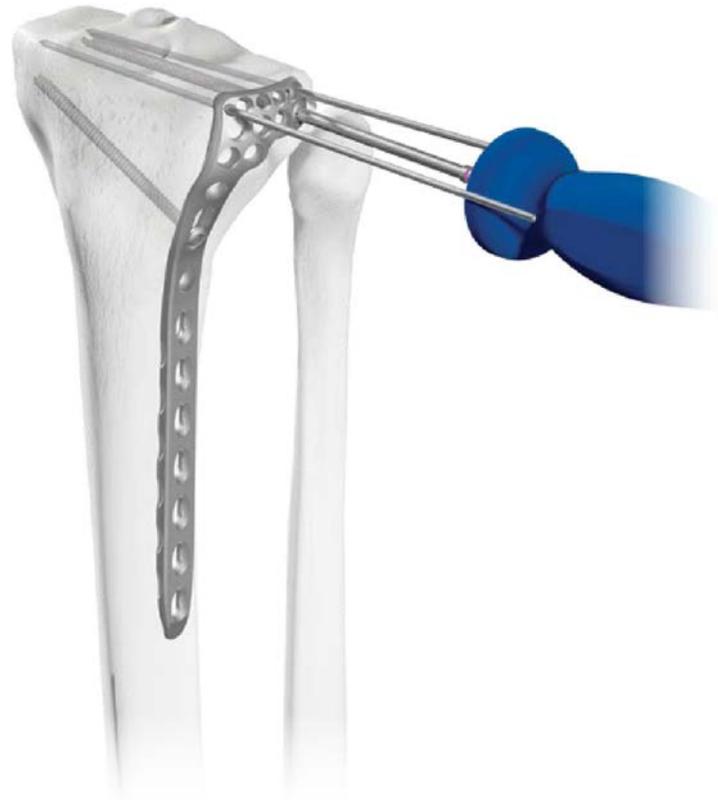
Pre-drill to the desired depth using the 2.7x190mm mm Drill Bit and the **3.5mm Soft Tissue Protector**. Measure hole depth using the Depth Gauge. Use the Self-Retaining T15 Driver or Screw Holding Forceps to select the desired screw.

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 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.

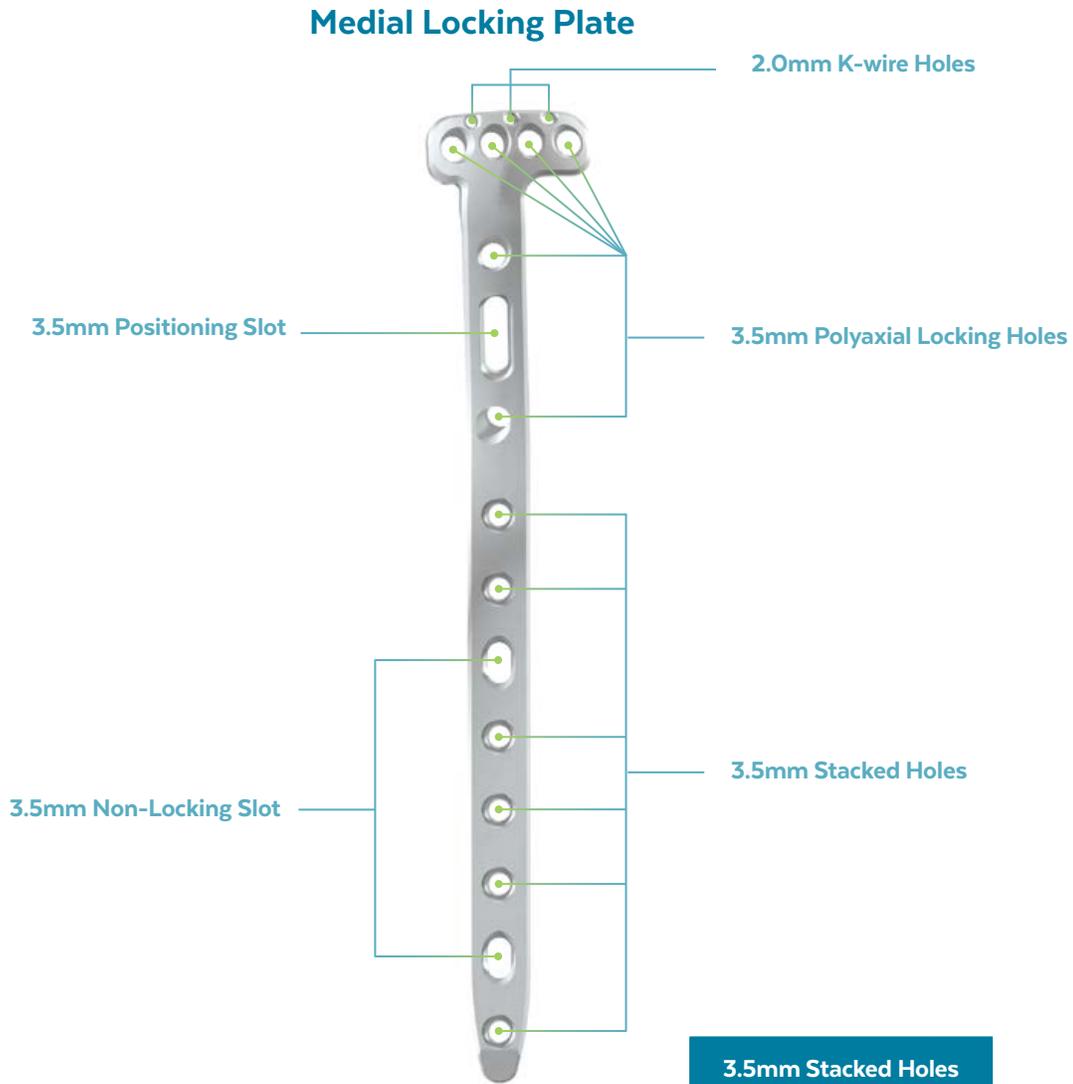
K-wires or reduction clamps may be used to provisionally fix the plate to the bone.

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.



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

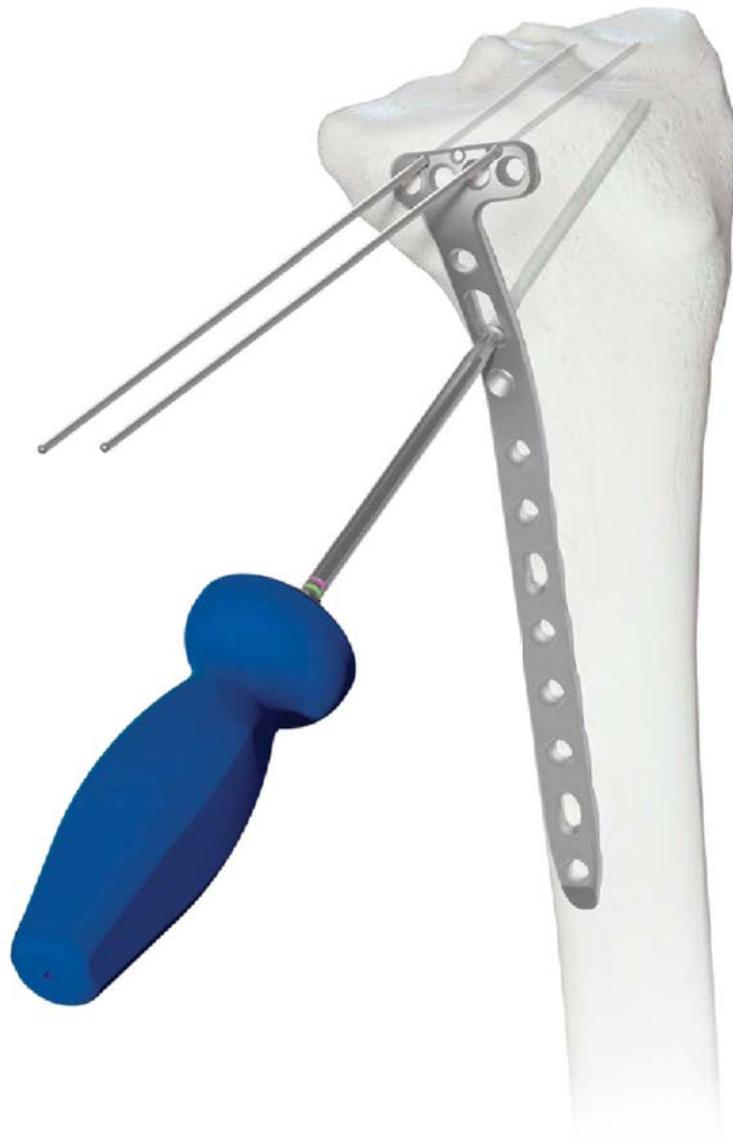
3.5mm Non-Locking Screws and 4.0mm Cancellous Screws

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

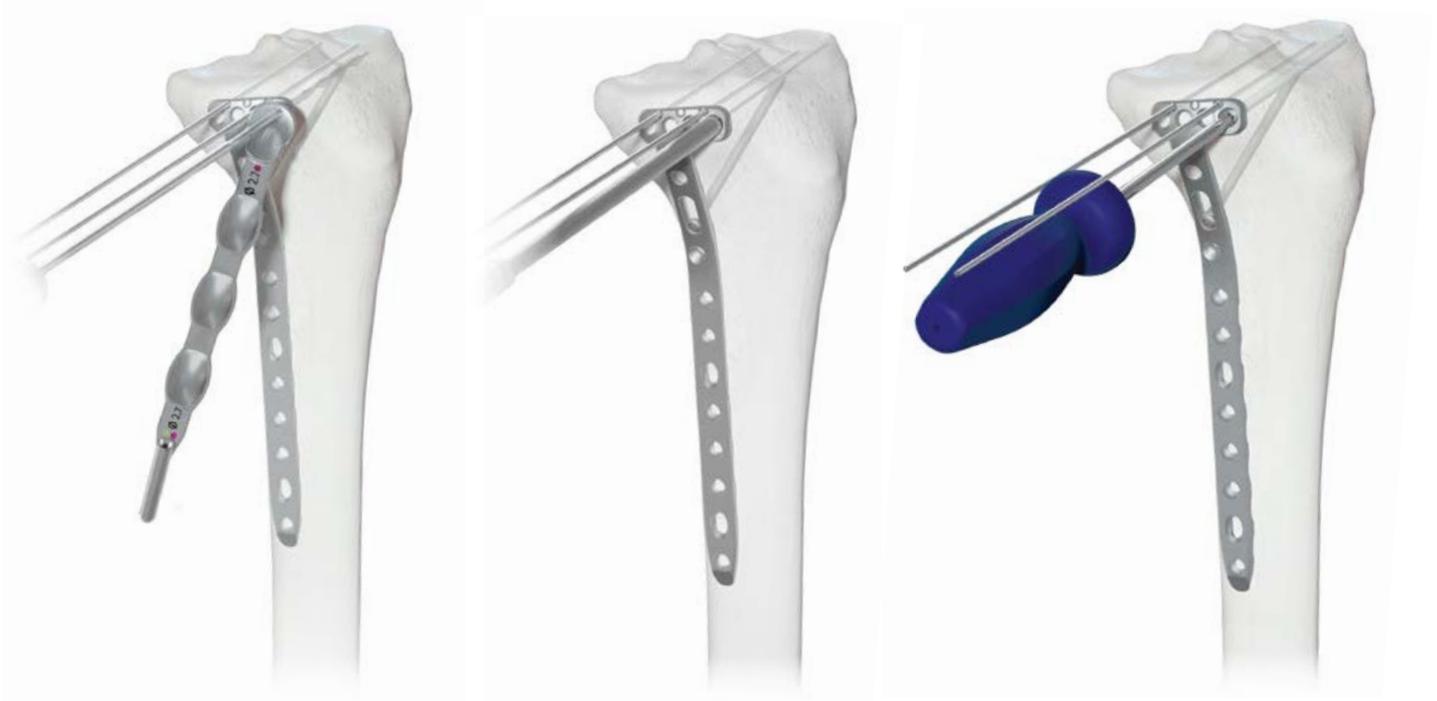
3.5mm Locking and Non-Locking Screws and 4.0mm Cancellous Screws

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.

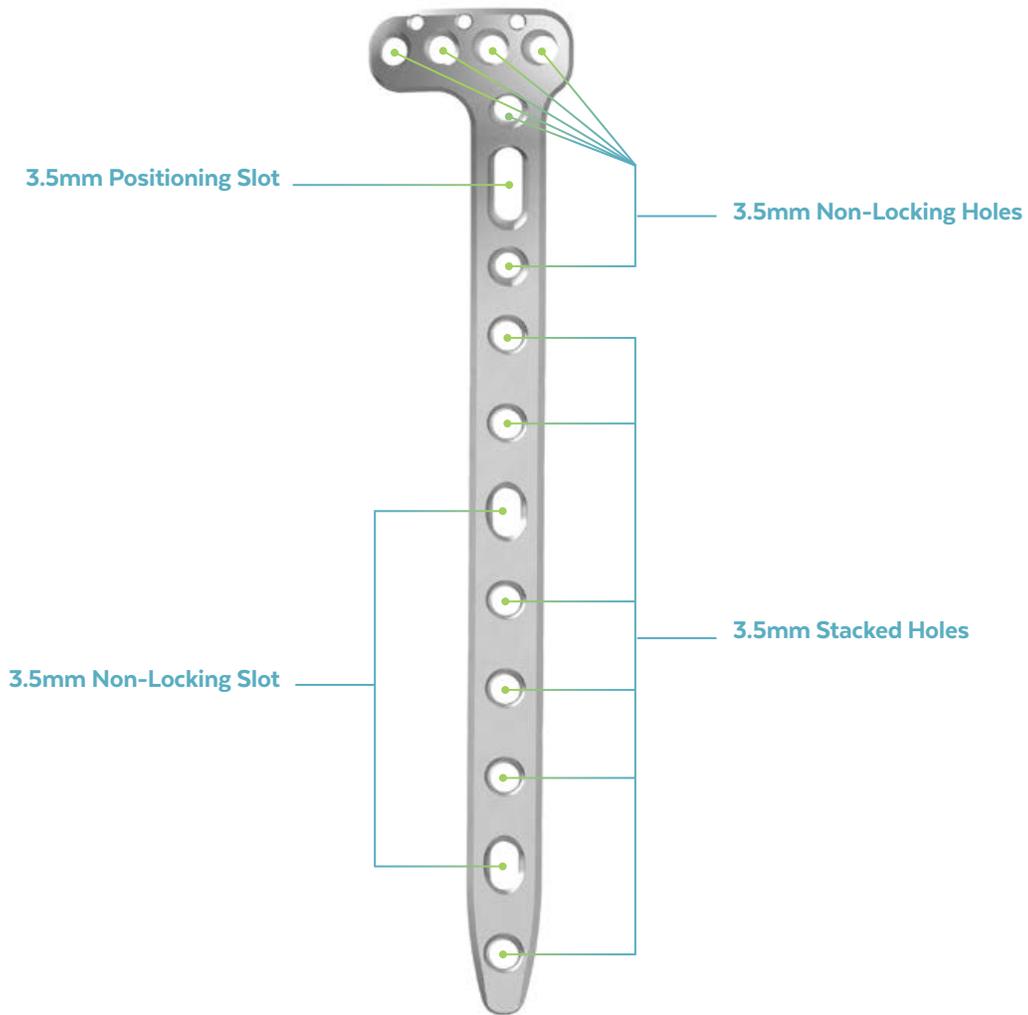
STEP 6

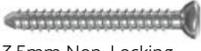
SCREW INSERTION

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 Stacked Holes	
	
	
	
	

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



6187.1000 Plate Attachment Bolt



6187.1100 Attachment Post, Left



6187.2100 Attachment Post, Right



6187.1300 Arm Attachment Nut



6187.3000 Aiming Arm, Left



6187.4000 Aiming Arm, Right



6187.3100 Tissue Protection Sleeve

AIMING ARM INSTRUMENTS (CONT'D)



6187.3110 Entry Trocar



6187.3150 Plug



6187.3200 Drill Sleeve



6187.3201 Dynamic Compression Sleeve



6187.3202 Drill Sleeve, Long



6187.3500 K-wire Sleeve



6187.3227 Drill, 2.7x280mm, Calibrated



6187.3235 Drill, 3.5x280mm, Calibrated



6187.3300 Positioning Pin



6187.3400 Plate Reduction Device, 230mm, AO Quick Connect



6187.3600 Depth Gauge

AIMING ARM INSTRUMENTS (CONT'D)



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



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



6187.3350 Sleeve, Screw Retention



6187.3935 Tap, 3.5x280mm, AO Quick Connect



6187.3940 Tap, 4.0x280mm, AO Quick Connect



6187.3105 Sleeve, Kickstand

K-WIRES



6179.1113 K-wire, 1.25x150mm, Trocar Tip



6187.0180 K-wire, 1.8x150mm, Trocar Tip

K-WIRES (CONT'D)



6179.1116 K-wire, 1.6x150mm, Trocar Tip



6187.0200 K-wire, 2.0x250mm, Trocar Tip



6187.0201 K-wire, 2.0x250mm, Drill Tip



6179.1216 1.6mm Plate Holding K-Wire

FORCEPS

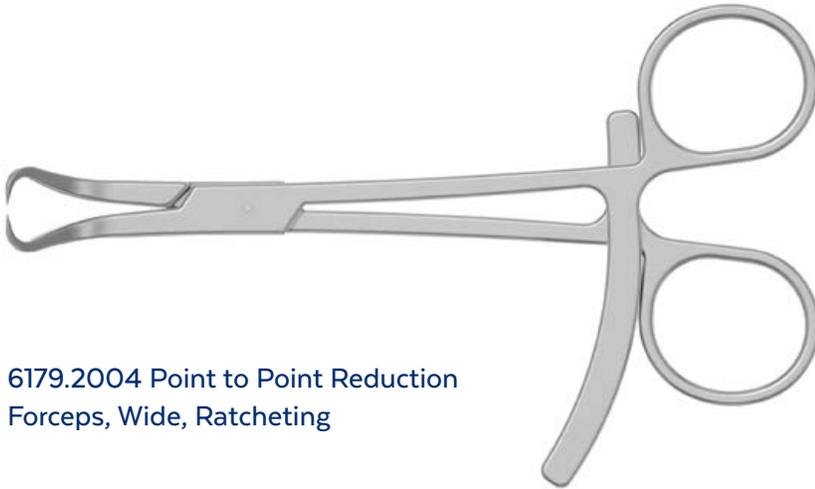


6179.2001 Lobster Claw Reduction
Forceps, Ratcheting



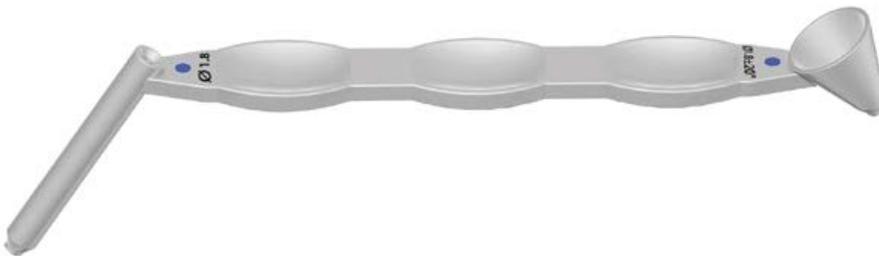
6179.2003 Point to Point Reduction
Forceps, Narrow, Ratcheting

FORCEPS (CONT'D)



6179.2004 Point to Point Reduction Forceps, Wide, Ratcheting

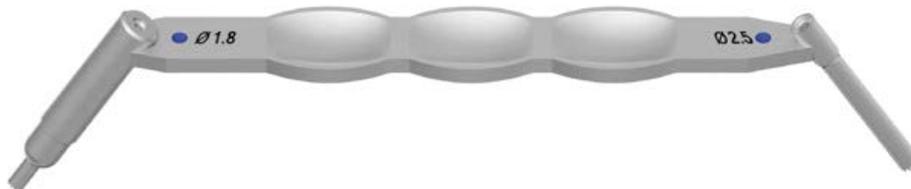
DRILL GUIDES



6171.3118 1.8mm Polyaxial Soft Tissue Protector



6186.3127 2.7mm Polyaxial Soft Tissue Protector



6179.3125 2.5mm Soft Tissue Protector



6179.3135 3.5mm Soft Tissue Protector

DRILL GUIDES (CONT'D)



6179.3227 2.7mm Locking Drill Guide



6179.3316 1.6mm K-Wire Sleeve Insert



6171.4218 1.8mm Speed Lock Drill Guide



6171.4227 2.7mm Speed Lock Drill Guide

DRILLS



6187.5018 Drill, 1.8x190mm, AO Quick Connect



6187.5025 Drill, 2.5x140mm, AO Quick Connect



6187.5027 Drill, 2.7x190mm, AO Quick Connect



6187.5035 Drill, 3.5x140mm, AO Quick Connect

TAPS AND COUNTERSINKS



6179.5125 2.5mm Non-Locking Tap, AO Quick Connect



6179.5135 3.5mm Non-Locking Tap, AO Quick Connect



6179.5140 4.0mm Cancellous Tap, AO Quick Connect



6179.7000 Countersink, AO Quick Connect

HANDLES



6188.7001 Handle, AO Quick Connect

PLATE BENDING INSTRUMENTS

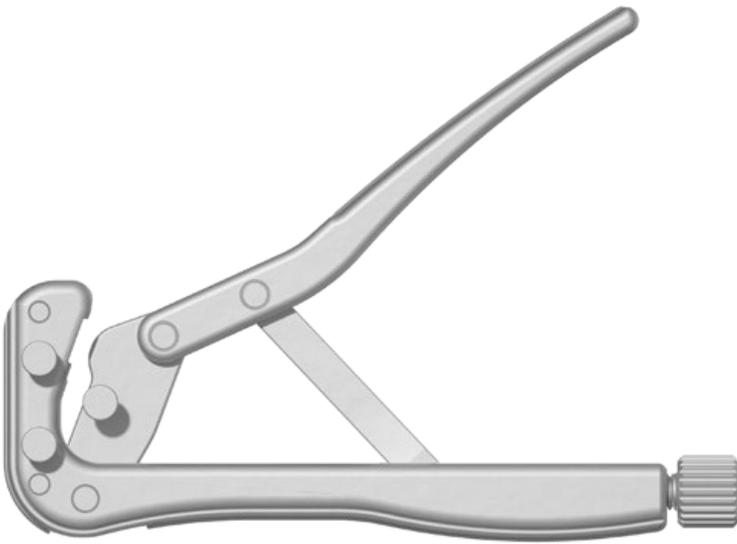


6179.7002 Plate Bending Iron



6179.7003 Plate Bending Iron Inverted

PLATE BENDING INSTRUMENTS (CONT'D)



6179.7005 Universal Bending Clamp

RETRACTORS



6179.7014 Radiolucent Hohmann Retractor, 8mm



6179.7015 Radiolucent Hohmann Retractor, 15mm



6171.7008 Malleable Wire Replacement

RETRACTORS (CONT'D)



6171.0002 Radiolucent Weitlaners 3x4, 8"

TORQUE LIMITERS



6171.5012 Torque Limiting Attachment, 1.2Nm, AO Quick Connect



6187.3801 Torque Limiting Attachment, 2.5Nm, AO Quick Connect

ELEVATOR/DENTAL PICK



6179.7019 Periosteal Elevator, 6mm Width, Curved



6179.7025 Dental Pick, Large Handle

DRIVERS



6187.5708 Driver, T8 SR, 100mm



6187.5715 Driver, T15 SR, 100mm



6187.5808 Driver, T8 NSR, 100mm



6187.5815 Driver, T15 NSR, 100mm

ADDITIONAL INSTRUMENTS



6179.7023 Plate Reduction Device, AO Quick Connect



6179.2000 Screw Holding Forceps



6179.2007 Wire Bending Pliers

ANTHEM[®] SS PROXIMAL TIBIA FRACTURE SYSTEM IMPLANT SET 9187.9001

PART NO.	DESCRIPTION	QTY
2187.1102	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 2 Hole, 76mm, SS	1
2187.1104	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 4 Hole, 102mm, SS	1
2187.1106	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 6 Hole, 128mm, SS	1
2187.1108	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 8 Hole, 154mm, SS	1
2187.2102	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 2 Hole, 76mm, SS	1
2187.2104	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 4 Hole, 102mm, SS	1
2187.2106	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 6 Hole, 128mm, SS	1
2187.2108	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 8 Hole, 154mm, SS	1
2187.3102	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 2 Hole, 88mm, SS	1
2187.3104	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 4 Hole, 114mm, SS	1
2187.3106	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 6 Hole, 140mm, SS	1
2187.3108	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 8 Hole, 166mm, SS	1
2187.3110	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 10 Hole, 192mm, SS	1
2187.3112	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 12 Hole, 218mm, SS	1
2187.3302	ANTHEM [®] Medial Proximal Tibia Plate, Left, 2 Hole, 91mm, SS	1
2187.3304	ANTHEM [®] Medial Proximal Tibia Plate, Left, 4 Hole, 117mm, SS	1
2187.3306	ANTHEM [®] Medial Proximal Tibia Plate, Left, 6 Hole, 143mm, SS	1
2187.3308	ANTHEM [®] Medial Proximal Tibia Plate, Left, 8 Hole, 169mm, SS	1
2187.3310	ANTHEM [®] Medial Proximal Tibia Plate, Left, 10 Hole, 195mm, SS	1
2187.3312	ANTHEM [®] Medial Proximal Tibia Plate, Left, 12 Hole, 221mm, SS	1
2187.3502	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 2 Hole, 69mm, SS	1
2187.3504	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 4 Hole, 95mm, SS	1
2187.3506	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 6 Hole, 121mm, SS	1
2187.3702	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 2 Hole, 86mm, SS	1
2187.3704	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 4 Hole, 112mm, SS	1
2187.3706	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 6 Hole, 138mm, SS	1
2187.3708	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 8 Hole, 164mm, SS	1
2187.3710	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 10 Hole, 190mm, SS	1
2187.3712	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 12 Hole, 216mm, SS	1
2187.4102	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 2 Hole, 88mm, SS	1
2187.4104	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 4 Hole, 114mm, SS	1
2187.4106	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 6 Hole, 140mm, SS	1
2187.4108	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 8 Hole, 166mm, SS	1
2187.4110	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 10 Hole, 192mm, SS	1
2187.4112	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 12 Hole, 218mm, SS	1

PART NO.	DESCRIPTION	QTY
2187.4302	ANTHEM® Medial Proximal Tibia Plate, Right, 2 Hole, 91mm, SS	1
2187.4304	ANTHEM® Medial Proximal Tibia Plate, Right, 4 Hole, 117mm, SS	1
2187.4306	ANTHEM® Medial Proximal Tibia Plate, Right, 6 Hole, 143mm, SS	1
2187.4308	ANTHEM® Medial Proximal Tibia Plate, Right, 8 Hole, 169mm, SS	1
2187.4310	ANTHEM® Medial Proximal Tibia Plate, Right, 10 Hole, 195mm, SS	1
2187.4312	ANTHEM® Medial Proximal Tibia Plate, Right, 12 Hole, 221mm, SS	1
2187.4502	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 2 Hole, 69mm, SS	1
2187.4504	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 4 Hole, 95mm, SS	1
2187.4506	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 6 Hole, 121mm, SS	1
2187.4702	ANTHEM® Lateral Proximal Tibia Plate, Right, 2 Hole, 86mm, SS	1
2187.4704	ANTHEM® Lateral Proximal Tibia Plate, Right, 4 Hole, 112mm, SS	1
2187.4706	ANTHEM® Lateral Proximal Tibia Plate, Right, 6 Hole, 138mm, SS	1
2187.4708	ANTHEM® Lateral Proximal Tibia Plate, Right, 8 Hole, 164mm, SS	1
2187.4710	ANTHEM® Lateral Proximal Tibia Plate, Right, 10 Hole, 190mm, SS	1
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
1187.1102	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 2 Hole, 76mm, Ti	1
1187.1104	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 4 Hole, 102mm, Ti	1
1187.1106	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Left, 6 Hole, 128mm, Ti	1
1187.2102	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 2 Hole, 76mm, Ti	1
1187.2104	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 4 Hole, 102mm, Ti	1
1187.2106	ANTHEM [®] Lateral Non-Locking Proximal Tibia Plate, Right, 6 Hole, 128mm, Ti	1
1187.3102	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 2 Hole, 88mm, Ti	1
1187.3104	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 4 Hole, 114mm, Ti	1
1187.3106	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 6 Hole, 140mm, Ti	1
1187.3108	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 8 Hole, 166mm, Ti	1
1187.3110	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 10 Hole, 192mm, Ti	1
1187.3112	ANTHEM [®] Lateral Proximal Tibia Plate XR, Left, 12 Hole, 218mm, Ti	1
1187.3302	ANTHEM [®] Medial Proximal Tibia Plate, Left, 2 Hole, 91mm, Ti	1
1187.3304	ANTHEM [®] Medial Proximal Tibia Plate, Left, 4 Hole, 117mm, Ti	1
1187.3306	ANTHEM [®] Medial Proximal Tibia Plate, Left, 6 Hole, 143mm, Ti	1
1187.3308	ANTHEM [®] Medial Proximal Tibia Plate, Left, 8 Hole, 169mm, Ti	1
1187.3310	ANTHEM [®] Medial Proximal Tibia Plate, Left, 10 Hole, 195mm, Ti	1
1187.3312	ANTHEM [®] Medial Proximal Tibia Plate, Left, 12 Hole, 221mm, Ti	1
1187.3502	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 2 Hole, 69mm, Ti	1
1187.3504	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 4 Hole, 95mm, Ti	1
1187.3506	ANTHEM [®] Posteromedial Proximal Tibia Plate, Left, 6 Hole, 121mm, Ti	1
1187.3702	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 2 Hole, 86mm, Ti	1
1187.3704	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 4 Hole, 112mm, Ti	1
1187.3706	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 6 Hole, 138mm, Ti	1
1187.3708	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 8 Hole, 164mm, Ti	1
1187.3710	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 10 Hole, 190mm, Ti	1
1187.3712	ANTHEM [®] Lateral Proximal Tibia Plate, Left, 12 Hole, 216mm, Ti	1
1187.4102	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 2 Hole, 88mm, Ti	1
1187.4104	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 4 Hole, 114mm, Ti	1
1187.4106	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 6 Hole, 140mm, Ti	1
1187.4108	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 8 Hole, 166mm, Ti	1
1187.4110	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 10 Hole, 192mm, Ti	1
1187.4112	ANTHEM [®] Lateral Proximal Tibia Plate XR, Right, 12 Hole, 218mm, Ti	1
1187.4302	ANTHEM [®] Medial Proximal Tibia Plate, Right, 2 Hole, 91mm, Ti	1
1187.4304	ANTHEM [®] Medial Proximal Tibia Plate, Right, 4 Hole, 117mm, Ti	1

PART NO.	DESCRIPTION	QTY
1187.4306	ANTHEM® Medial Proximal Tibia Plate, Right, 6 Hole, 143mm, Ti	1
1187.4308	ANTHEM® Medial Proximal Tibia Plate, Right, 8 Hole, 169mm, Ti	1
1187.4310	ANTHEM® Medial Proximal Tibia Plate, Right, 10 Hole, 195mm, Ti	1
1187.4312	ANTHEM® Medial Proximal Tibia Plate, Right, 12 Hole, 221mm, Ti	1
1187.4502	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 2 Hole, 69mm, Ti	1
1187.4504	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 4 Hole, 95mm, Ti	1
1187.4506	ANTHEM® Posteromedial Proximal Tibia Plate, Right, 6 Hole, 121mm, Ti	1
1187.4702	ANTHEM® Lateral Proximal Tibia Plate, Right, 2 Hole, 86mm, Ti	1
1187.4704	ANTHEM® Lateral Proximal Tibia Plate, Right, 4 Hole, 112mm, Ti	1
1187.4706	ANTHEM® Lateral Proximal Tibia Plate, Right, 6 Hole, 138mm, Ti	1
1187.4708	ANTHEM® Lateral Proximal Tibia Plate, Right, 8 Hole, 164mm, Ti	1
1187.4710	ANTHEM® Lateral Proximal Tibia Plate, Right, 10 Hole, 190mm, Ti	1
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

PART NO.	DESCRIPTION	QTY	PART NO.	DESCRIPTION	QTY
6179.2000	Screw Holding Forceps	1	7179.3040	Non-Locking Screw, 3.5x40mm, CoCr	5
7171.5530	Locking Screw, 2.5x30mm, CoCr	4	7179.3042	Non-Locking Screw, 3.5x42mm, CoCr	5
7171.5535	Locking Screw, 2.5x35mm CoCr	4	7179.3044	Non-Locking Screw, 3.5x44mm, CoCr	5
7171.5540	Locking Screw, 2.5x40mm CoCr	4	7179.3046	Non-Locking Screw, 3.5x46mm, CoCr	5
7171.5545	Locking Screw, 2.5x45mm CoCr	4	7179.3048	Non-Locking Screw, 3.5x48mm, CoCr	5
7171.5550	Locking Screw, 2.5x50mm CoCr	4	7179.3050	Non-Locking Screw, 3.5x50mm, CoCr	5
7171.5555	Locking Screw, 2.5x55mm CoCr	4	7179.3052	Non-Locking Screw, 3.5x52mm, CoCr	5
7171.5560	Locking Screw, 2.5x60mm CoCr	4	7179.3054	Non-Locking Screw, 3.5x54mm, CoCr	5
7171.5565	Locking Screw, 2.5x65mm CoCr	4	7179.3056	Non-Locking Screw, 3.5x56mm, CoCr	5
7171.5570	Locking Screw, 2.5x70mm CoCr	4	7179.3058	Non-Locking Screw, 3.5x58mm, CoCr	5
7171.5575	Locking Screw, 2.5x75mm CoCr	4	7179.3060	Non-Locking Screw, 3.5x60mm, CoCr	5
7171.5580	Locking Screw, 2.5x80mm CoCr	4	7179.3065	Non-Locking Screw, 3.5x65mm, CoCr	5
7171.5585	Locking Screw, 2.5x85mm, CoCr	4	7179.3070	Non-Locking Screw, 3.5x70mm, CoCr	5
7171.5590	Locking Screw, 2.5x90mm, CoCr	4	7179.3075	Non-Locking Screw, 3.5x75mm, CoCr	5
7171.5595	Locking Screw, 2.5x95mm, CoCr	4	7179.3080	Non-Locking Screw, 3.5x80mm, CoCr	5
7171.6530	Non-Locking Screw, 2.5x30mm, CoCr	4	7179.3085	Non-Locking Screw, 3.5x85mm, CoCr	5
7171.6535	Non-Locking Screw, 2.5x35mm, CoCr	4	7179.3090	Non-Locking Screw, 3.5x90mm, CoCr	5
7171.6540	Non-Locking Screw, 2.5x40mm, CoCr	4	7179.3095	Non-Locking Screw, 3.5x95mm, CoCr	5
7171.6545	Non-Locking Screw, 2.5x45mm, CoCr	4	7179.4040	Cancellous Screw, 4.0x40mm, Fully Threaded, CoCr	2
7171.6550	Non-Locking Screw, 2.5x50mm, CoCr	4	7179.4045	Cancellous Screw, 4.0x45mm, Fully Threaded, CoCr	2
7171.6555	Non-Locking Screw, 2.5x55mm, CoCr	4	7179.4050	Cancellous Screw, 4.0x50mm, Fully Threaded, CoCr	2
7171.6560	Non-Locking Screw, 2.5x60mm, CoCr	4	7179.4055	Cancellous Screw, 4.0x55mm, Fully Threaded, CoCr	2
7171.6565	Non-Locking Screw, 2.5x65mm, CoCr	4	7179.4060	Cancellous Screw, 4.0x60mm, Fully Threaded, CoCr	2
7171.6570	Non-Locking Screw, 2.5x70mm, CoCr	4	7179.4065	Cancellous Screw, 4.0x65mm, Fully Threaded, CoCr	2
7171.6575	Non-Locking Screw, 2.5x75mm, CoCr	4	7179.4070	Cancellous Screw, 4.0x70mm, Fully Threaded, CoCr	2
7171.6580	Non-Locking Screw, 2.5x80mm, CoCr	4	7179.4075	Cancellous Screw, 4.0x75mm, Fully Threaded, CoCr	2
7171.6585	Non-Locking Screw, 2.5x85mm, CoCr	4	7179.4080	Cancellous Screw, 4.0x80mm, Fully Threaded, CoCr	2
7171.6590	Non-Locking Screw, 2.5x90mm, CoCr	4	7179.4085	Cancellous Screw, 4.0x85mm, Fully Threaded, CoCr	2
7171.6595	Non-Locking Screw, 2.5x95mm, CoCr	4	7179.4090	Cancellous Screw, 4.0x90mm, Fully Threaded, CoCr	2
7179.3020	Non-Locking Screw, 3.5x20mm, CoCr	5	7179.4095	Cancellous Screw, 4.0x95mm, Fully Threaded, CoCr	2
7179.3022	Non-Locking Screw, 3.5x22mm, CoCr	5			
7179.3024	Non-Locking Screw, 3.5x24mm, CoCr	5			
7179.3026	Non-Locking Screw, 3.5x26mm, CoCr	5			
7179.3028	Non-Locking Screw, 3.5x28mm, CoCr	5			
7179.3030	Non-Locking Screw, 3.5x30mm, CoCr	5			
7179.3032	Non-Locking Screw, 3.5x32mm, CoCr	5			
7179.3034	Non-Locking Screw, 3.5x34mm, CoCr	5			
7179.3036	Non-Locking Screw, 3.5x36mm, CoCr	5			
7179.3038	Non-Locking Screw, 3.5x38mm, CoCr	5			

PART NO.	DESCRIPTION	QTY	PART NO.	DESCRIPTION	QTY
7179.5020	Locking Screw, 3.5x20mm, CoCr	5	7179.5090	Locking Screw, 3.5x90mm, CoCr	5
7179.5022	Locking Screw, 3.5x22mm, CoCr	5	7179.5095	Locking Screw, 3.5x95mm, CoCr	5
7179.5024	Locking Screw, 3.5x24mm, CoCr	5	7179.8040	Cancellous Screw, 4.0x40mm, Partially Threaded, CoCr	2
7179.5026	Locking Screw, 3.5x26mm, CoCr	5	7179.8045	Cancellous Screw, 4.0x45mm, Partially Threaded, CoCr	2
7179.5028	Locking Screw, 3.5x28mm, CoCr	5	7179.8050	Cancellous Screw, 4.0x50mm, Partially Threaded, CoCr	2
7179.5030	Locking Screw, 3.5x30mm, CoCr	5	7179.8055	Cancellous Screw, 4.0x55mm, Partially Threaded, CoCr	2
7179.5032	Locking Screw, 3.5x32mm, CoCr	5	7179.8060	Cancellous Screw, 4.0x60mm, Partially Threaded, CoCr	2
7179.5034	Locking Screw, 3.5x34mm, CoCr	5	7179.8065	Cancellous Screw, 4.0x65mm, Partially Threaded, CoCr	2
7179.5036	Locking Screw, 3.5x36mm, CoCr	5	7179.8070	Cancellous Screw, 4.0x70mm, Partially Threaded, CoCr	2
7179.5038	Locking Screw, 3.5x38mm, CoCr	5	7179.8075	Cancellous Screw, 4.0x75mm, Partially Threaded, CoCr	2
7179.5040	Locking Screw, 3.5x40mm, CoCr	5	7179.8080	Cancellous Screw, 4.0x80mm, Partially Threaded, CoCr	2
7179.5042	Locking Screw, 3.5x42mm, CoCr	5	7179.8085	Cancellous Screw, 4.0x85mm, Partially Threaded, CoCr	2
7179.5044	Locking Screw, 3.5x44mm, CoCr	5	7179.8090	Cancellous Screw, 4.0x90mm, Partially Threaded, CoCr	2
7179.5046	Locking Screw, 3.5x46mm, CoCr	5	7179.8095	Cancellous Screw, 4.0x95mm, Partially Threaded, CoCr	2
7179.5048	Locking Screw, 3.5x48mm, CoCr	5	9187.0003	ANTHEM® CoCr Proximal Tibia Fracture System Graphic Case	
7179.5050	Locking Screw, 3.5x50mm, CoCr	5			
7179.5052	Locking Screw, 3.5x52mm, CoCr	5			
7179.5054	Locking Screw, 3.5x54mm, CoCr	5			
7179.5056	Locking Screw, 3.5x56mm, CoCr	5			
7179.5058	Locking Screw, 3.5x58mm, CoCr	5			
7179.5060	Locking Screw, 3.5x60mm, CoCr	5			
7179.5065	Locking Screw, 3.5x65mm, CoCr	5			
7179.5070	Locking Screw, 3.5x70mm, CoCr	5			
7179.5075	Locking Screw, 3.5x75mm, CoCr	5			
7179.5080	Locking Screw, 3.5x80mm, CoCr	5			
7179.5085	Locking Screw, 3.5x85mm, CoCr	5			

ANTHEM[®] PROXIMAL TIBIA FRACTURE SYSTEM

SS SMALL FRAGMENT MODULE 9187.9004

PART NO.	DESCRIPTION	QTY
2179.0004	ANTHEM [®] Reconstruction Plate, 4 Hole, 46mm, SS	2
2179.0006	ANTHEM [®] Reconstruction Plate, 6 Hole, 70mm, SS	2
2179.0008	ANTHEM [®] Reconstruction Plate, 8 Hole, 94mm, SS	2
2179.0010	ANTHEM [®] Reconstruction Plate, 10 Hole, 118mm, SS	2
2179.1304	ANTHEM [®] One Third Tubular Plate, 4 Hole, 48mm, SS	2
2179.1306	ANTHEM [®] One Third Tubular Plate, 6 Hole, 72mm, SS	2
2179.1308	ANTHEM [®] One Third Tubular Plate, 8 Hole, 96mm, SS	2
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	
1179.0004	ANTHEM® Reconstruction Plate, 4 Hole, 46mm, Ti	2
1179.0006	ANTHEM® Reconstruction Plate, 6 Hole, 70mm, Ti	2
1179.0008	ANTHEM® Reconstruction Plate, 8 Hole, 94mm, Ti	2
1179.0010	ANTHEM® Reconstruction Plate, 10 Hole, 118mm, Ti	2
1179.1304	ANTHEM® One Third Tubular Plate, 4 Hole, 48mm, Ti	2
1179.1306	ANTHEM® One Third Tubular Plate, 6 Hole, 72mm, Ti	2
1179.1308	ANTHEM® One Third Tubular Plate, 8 Hole, 96mm, Ti	2
1179.1310	ANTHEM® One Third Tubular Plate, 10 Hole, 120mm, Ti	2
9187.0005	ANTHEM® Ti Proximal Tibia Small Fragment Module	1

ANTHEM[®] PROXIMAL TIBIA FRACTURE SYSTEM

INSTRUMENT SET 9187.9006

PART NO.	DESCRIPTION	QTY
6187.0180	K-wire, 1.8x150mm, Trocar	10
6187.0200	K-wire, 2.0x250mm, Trocar	10
6187.0201	K-wire, 2.0x250mm, Drill	5
6187.1000	Plate Attachment Bolt	2
6187.1100	Attachment Post, Left	1
6187.2100	Attachment Post, Right	1
6187.1300	Arm Attachment Nut	3
6187.3000	Aiming Arm, Left	1
6187.4000	Aiming Arm, Right	1
6187.3100	Tissue Protection Sleeve	4
6187.3105	Kickstand Sleeve	2
6187.3110	Entry Trocar	2
6187.3150	Plug	4
6187.3200	Drill Sleeve	4
6187.3201	Dynamic Compression Sleeve	2
6187.3202	Drill Sleeve, Long	2
6187.3227	Drill, 2.7x280mm, Calibrated, AO Quick Connect	2
6187.3235	Drill, 3.5x280mm, Calibrated, AO Quick Connect	2
6187.3300	Positioning Pin	2
6187.3350	Screw Retention Sleeve	1
6187.3400	Plate Reduction Device, 230mm, AO Quick Connect	1
6187.3500	K-wire Sleeve	2
6187.3600	Depth Gauge	1
6187.3715	Driver, T15 SR, 170mm, AO Quick Connect	1
6187.3801	Torque Limiting Attachment, 2.5Nm, AO Quick Connect	1
6187.3815	Driver, T15 NSR, 200mm, AO Quick Connect	1
6187.3935	Tap, 3.5x280mm, AO Quick Connect	1
6187.3940	Tap, 4.0x280mm, AO Quick Connect	1
6187.5018	Drill, 1.8x190mm, AO Quick Connect	2
6187.5025	Drill, 2.5x140mm, AO Quick Connect	2
6187.5027	Drill, 2.7x190mm, AO Quick Connect	2
6187.5035	Drill, 3.5x140mm, AO Quick Connect	2
6187.5708	Driver, T8 SR, 100mm, AO Quick Connect	1
6187.5715	Driver, T15 SR, 100mm, AO Quick Connect	1
6187.5808	Driver, T8 NSR, 100mm, AO Quick Connect	1
6187.5815	Driver, T15 NSR, 100mm, AO Quick Connect	1

PART NO.	DESCRIPTION	QTY
6179.1113	K-wire, 1.25x150mm, Trocar Tip	10
6179.1116	K-wire, 1.6x150mm, Trocar Tip	10
6179.1216	1.6mm Plate Holding K-Wire	2
6179.2001	Lobster Claw Reduction Forceps, ratcheting	2
6179.2003	Point to Point Reduction Forceps, narrow, ratcheting	1
6179.2004	Point to Point Reduction Forceps, wide, ratcheting	1
6179.2007	Wire Bending Pliers	1
6179.3125	2.5mm Soft Tissue Protector	1
6179.3135	3.5mm Soft Tissue Protector	1
6179.3227	2.7mm Locking Drill Guide	2
6179.3316	1.6mm K-Wire Sleeve Insert	1
6179.5125	2.5mm Non-Locking Tap	1
6179.5135	3.5mm Non-Locking Tap	1
6179.5140	4.0mm Cancellous Tap	1
6179.7000	Countersink, AO Quick Connect	1
6179.7002	Plate Bending Iron	1
6179.7003	Plate Bending Iron Inverted	1
6179.7005	Universal Bending Clamp	1
6179.7014	Radiolucent Hohmann Retractor, 8mm	2
6179.7015	Radiolucent Hohmann Retractor, 15mm	2
6179.7019	Periosteal Elevator, 6mm Width, Curved	2
6179.7023	Plate Reduction Device	1
6179.7025	Dental Pick, Large Handle	2
6179.7031	Depth Gauge, 110mm	1
6171.0002	Radiolucent Weitlaners 3x4, 8"	1
6171.3118	1.8mm Polyaxial Soft Tissue Protector	1
6171.4218	1.8mm Speedlock Drill Guide	1
6171.4227	2.7mm Speedlock Drill Guide	1
6171.5012	Torque Limiting Attachment, 1.2Nm, AO Quick Connect	1
6171.7008	Malleable Wire Replacement	5
6186.3127	2.7mm Polyaxial Soft Tissue Protector	1
6188.7001	Handle, AO Quick Connect	1

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 nonunions, and for non-load bearing stabilization and reduction of long bone fragments.

Small fragment, mini fragment, proximal tibia, clavicle and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius 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® 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. 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 in² 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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