GLOBUS MEDICAL

ANTHEM®

Distal Femur Fracture System

SURGICAL TECHNIQUE GUIDE

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

ANTHEM® Distal Femur Fracture System

ANTHEM®

Distal Femur Fracture System

The ANTHEM® Distal Femur Fracture System offers anatomically contoured plates in a comprehensive set to treat a variety of distal femur fractures.

The system features Broad and Narrow Lateral Locking Plates and a Medial Locking Plate with abundant fixation options. The lateral plates have dual kickstand screws to offer additional support to the medial condyle. Robust polyaxial locking screws allow for ±15° (30° cone) of angulation.

Streamlined and radiolucent instruments simplify the minimally invasive lateral locked plating technique.

IMPLANT OVERVIEW

Lateral Locking Plates

Narrow Lateral Locking Plate

- 2-hole shaft pattern minimizing the plate profile
- 1 or 2 4.5mm non-locking slot options
- 4.5mm polyaxial locking options
- 7 condylar holes for distal fixation
- 2 oblique kickstand holes provide additional fixation options targeting the medial condyle

Narrow Lateral Locking Plate

Broad Lateral Locking Plate

- 3-hole shaft pattern provides maximum options for fixation around an existing implant
- 4.5mm polyaxial locking options in every screw hole
- 8 condylar holes for distal fixation
- 2 oblique kickstand holes provide additional fixation options targeting the medial condyle

Broad Lateral Locking Plate

Medial Locking Plate

- 4.5mm polyaxial locking options in every screw hole
- 6 condylar holes for distal fixation
- 1 oblique kickstand hole provides an additional fixation option targeting the lateral condyle

Medial Locking Plate

Screw Offerings

1. 4.5mm Locking Solid (20-110mm)
2. 4.5mm Blunt Tip Locking (8-20mm)
3. 4.5mm Non-Locking Solid (20-95mm)
4. 5.5mm Cancellous (50-95mm)
5. 5.5mm Partially Threaded Cancellous (50-95mm; thread length is 16mm for screws ≤ 75mm, and 32mm for screws ≥ 80mm)*
6. 4.5mm Locking Cannulated (35-110mm)
7. 5.5mm Cannulated Cancellous (40-95mm)
8. 5.5mm Partially Threaded Cannulated Cancellous (40-95mm; thread length is 16mm for screws ≤ 75mm, and 32mm for screws ≥ 80mm)*

*Additionally available

SURGICAL TECHNIQUE

ANTHEM®
Distal Femur Fracture System

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

A lateral or medial approach may be used. Determine the desired approach and refer to the corresponding section in this technique guide.

ANTHEM® Lateral Distal Femoral Plate

(See page 7.)

Narrow Lateral Locking Plate

Broad Lateral Locking Plate

ANTHEM® Medial Distal Femoral Plate

(See page 27.)

Medial Locking Plate

ANTHEM® Lateral Distal Femoral Plate

STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate plate length and type based on the fracture type and patient anatomy. Plan the plate position and screw placement.

STEP 2 PATIENT POSITIONING

Position the patient lateral or supine with the option to flex the knee up to 60° using a leg support.

Allow for X-ray access in both anterior-posterior (AP) and lateral views. Ensure that a true lateral view of the femur is obtainable in this position.

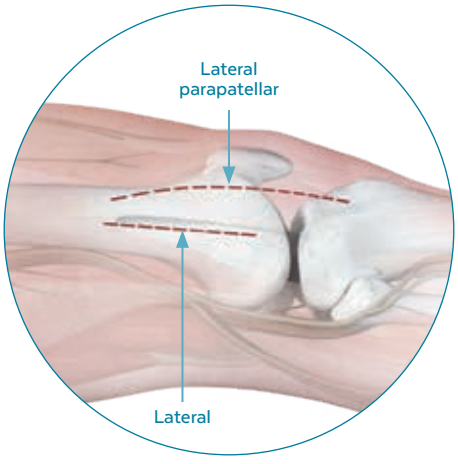
STEP 3 SURGICAL APPROACH

Use a lateral or lateral parapatellar approach based on fracture type, location, and presence of a prosthesis. Different fracture types may require other lateral approaches.

The lateral approach is recommended for simple articular or extra-articular fractures.

The lateral parapatellar approach is recommended for complex intra-articular fractures.

Radiolucent Weitlaners and **Radiolucent Hohmann Retractors** may be used to aid in fracture site visibility.



Lateral approach options

STEP 4 FRACTURE REDUCTION

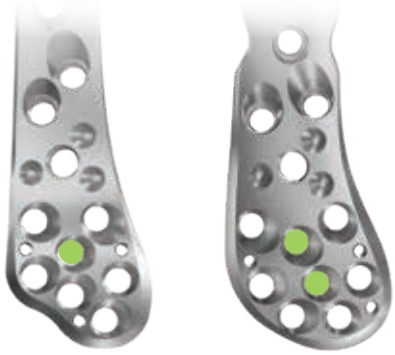
Reduce the fracture using the appropriate method for the fracture type. Confirm reduction using fluoroscopy. Compression may be achieved using lag screws. Ensure that lag screw placement does not interfere with the plate.

STEP 5 PLATE PLACEMENT

Insert the plate between the vastus lateralis muscle and the periosteum. This may be performed by manually holding the plate or using the **Aiming Arm Assembly** (see page 9).

2.5mm K-Wires or reduction clamps may be used to provisionally fix the plate to the bone.

Both lateral plates have reference holes with nominal screw trajectories designed to be parallel to the joint surface.



Narrow Plate Broad Plate

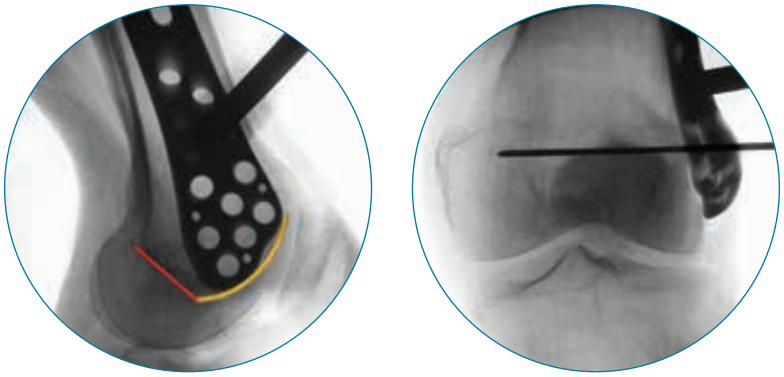
Reference hole, nominal trajectory

KEY

— Blumensaat line

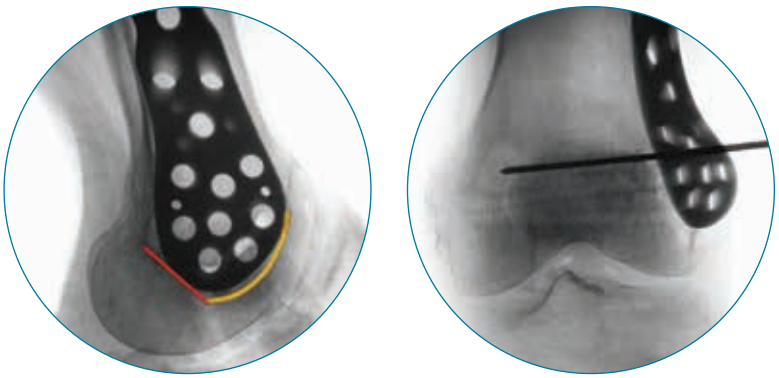
— Trochlea line

Narrow Plate Placement



Lateral AP

Broad Plate Placement



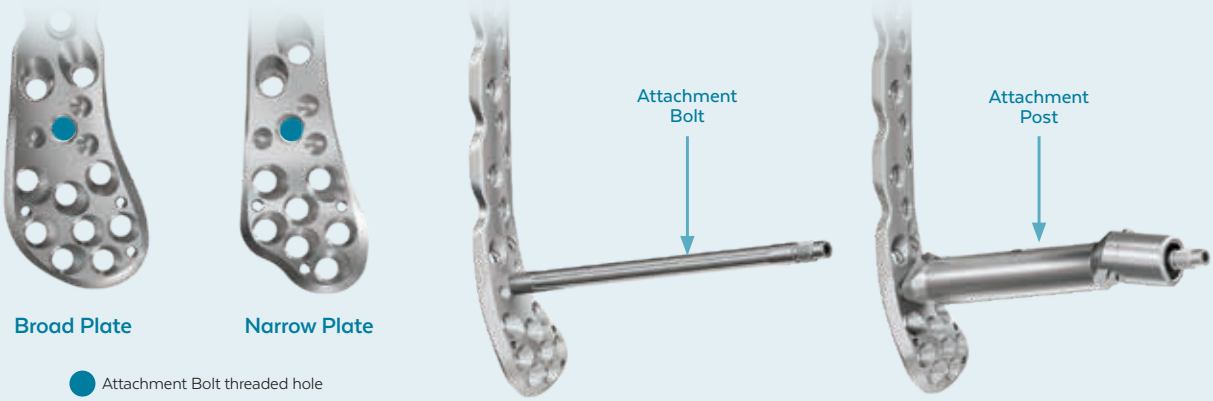
Lateral AP

AIMING ARM ASSEMBLY

The Aiming Arm may be assembled before or after positioning the plate on the bone. For patients with a high body mass index (BMI), assemble the arm after positioning to avoid interference with soft tissue.

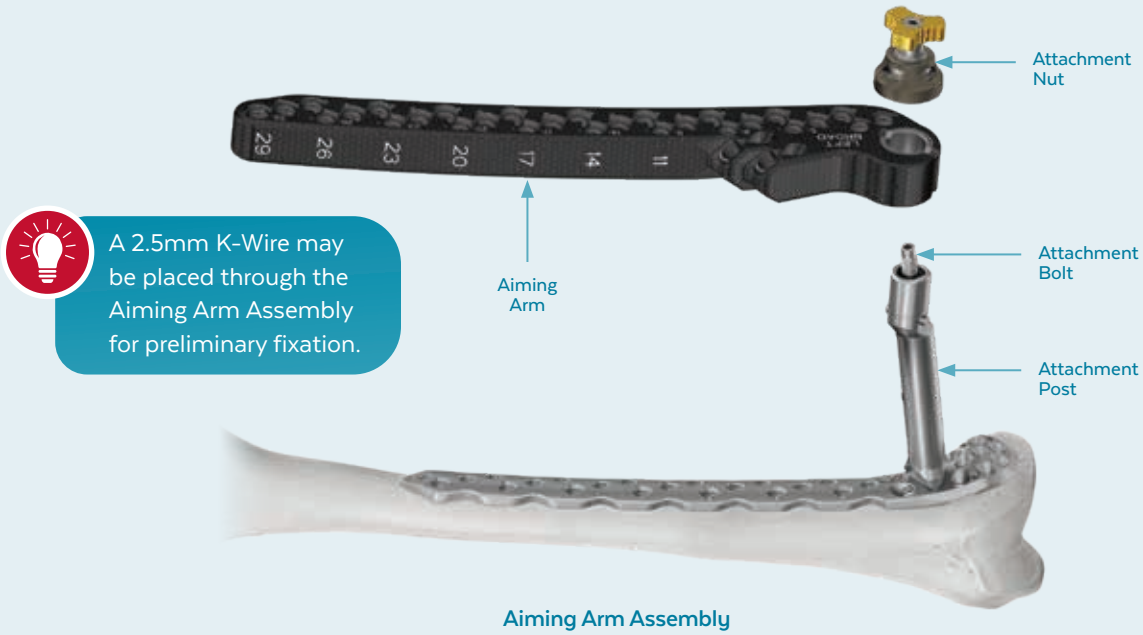
Thread the **Attachment Bolt** into the threaded hole in the neck of the plate until tight.

Slide the **Attachment Post** (left/right-specific) over the bolt and down to the plate. Align the spherical locators on the Attachment Post with the indentations on the plate.



Place the Aiming Arm over the Attachment Post. Hand tighten the **Attachment Nut** on the Attachment Bolt. Final tighten using the **Combination Wrench** on the neck of the Attachment Nut.

Create a box construct for targeting screws through the Aiming Arm Assembly (see page 10). Position the plate on the distal femur and confirm plate placement using fluoroscopy.



Aiming Arm Assembly

PLATE PLACEMENT (CONT'D)

AIMING ARM

The **Aiming Arm, Narrow** is used with the Narrow Lateral Plate. The **Aiming Arm, Broad** is used with the Broad Lateral Plate. Both aiming arms are reversible for use with left or right plates and are radiolucent to allow visualization of plate position.

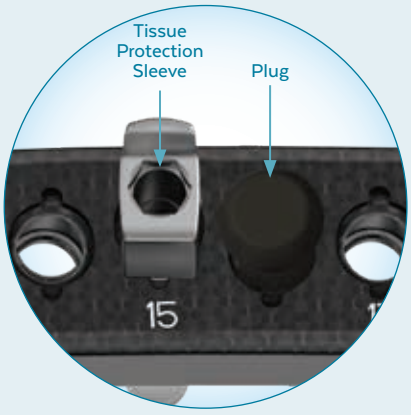
Tissue protection sleeves snap into the Aiming Arm holes and self-retain. The Aiming Arm, Narrow has two possible orientations for the tissue sleeve to snap in. The Aiming Arm, Broad has four possible orientations.

Holes 1 and 6 on the Aiming Arm, Narrow, are 4.5mm Non-Locking Slots, as shown below.

Aiming Arm, Broad

Aiming Arm, Narrow

Radiolucent Aiming Arm



Tissue Protection Sleeve orientation

Plugs may be used with the Aiming Arm to identify the most proximal hole on the plate or holes that have been filled with screws.

Creating a Box Construct

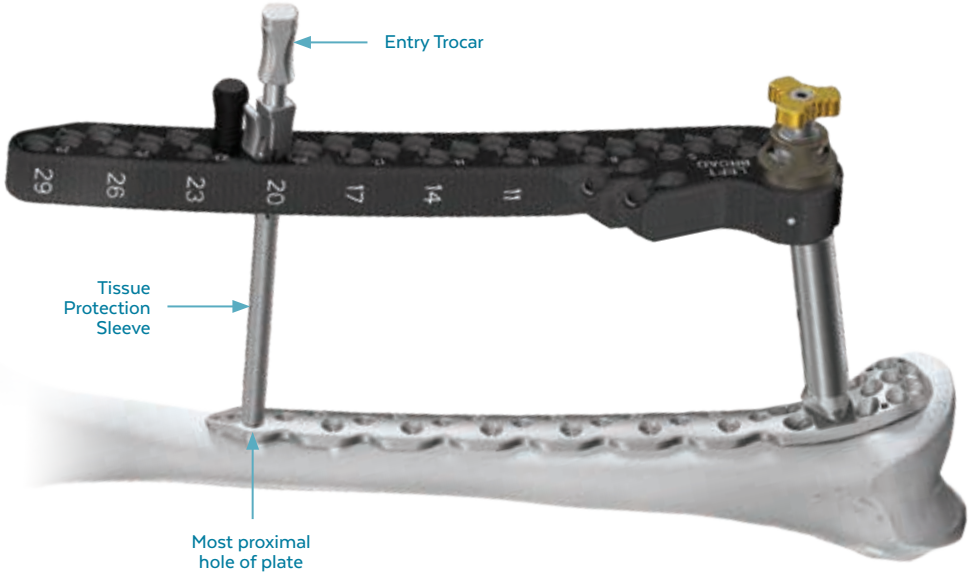
Insert the the **Entry Trocar** into the **Tissue Protection Sleeve**. With the Aiming Arm Assembly attached to the plate, use the Tissue Protection Sleeve and Entry Trocar to determine the incision location corresponding to the most proximal hole in the plate. Make a small incision with a scalpel.

Alternatively, create the initial incision using the **Scalpel Blade Handle**, as described below.

Advance the tissue sleeve and trocar to penetrate the soft tissue. Snap the tissue sleeve into the Aiming Arm by lining the tab on the tissue sleeve with one of the tabs in the Aiming Arm and remove the trocar.

Alternatively, the **Snap Fit Handle** may be used with the Entry Trocar or **Drill Sleeve**.

Snap Fit Handle



Box construct

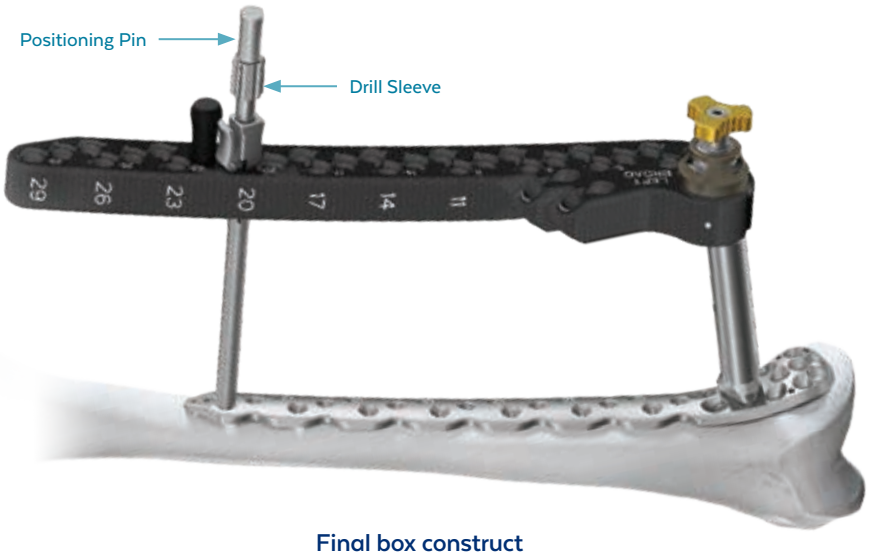
SCALPEL BLADE HANDLE

The Scalpel Blade Handle may be used to create the initial incision through the Aiming Arm. Attach a #10 scalpel blade and fully insert the scalpel blade handle through the desired hole in the Aiming Arm. Remove the scalpel blade from soft tissue, rotate 180˚, and re-insert. This creates an incision large enough for the Tissue Protection Sleeve and Entry Trocar assembly.

Scalpel Blade Handle

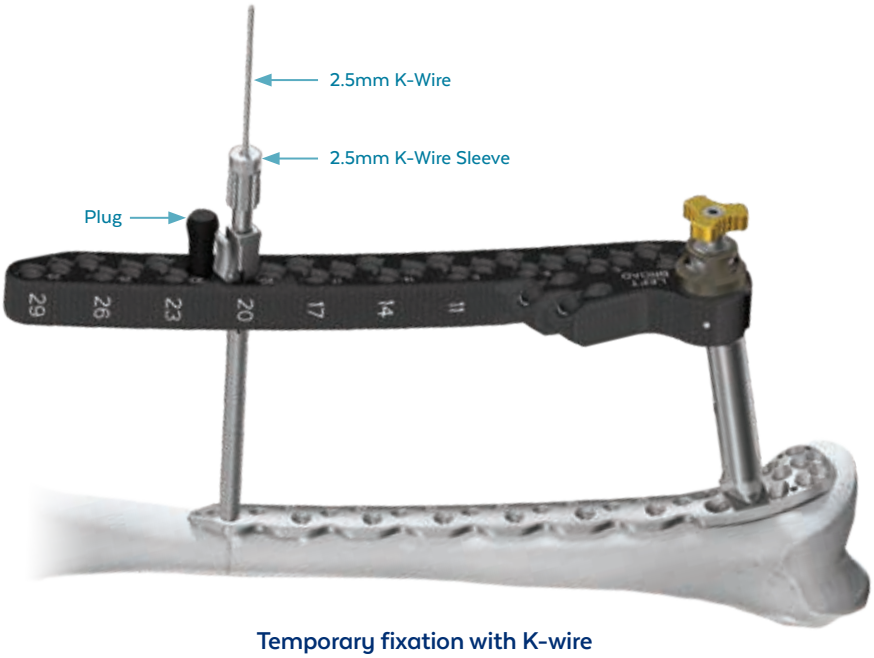
PLATE PLACEMENT (CONT'D)

Insert the Drill Sleeve and **Positioning Pin** through the tissue sleeve. Thread the Drill Sleeve into the plate and remove the positioning pin.



Final box construct

Confirm plate position using fluoroscopy. To ensure that plate position is maintained in the sagittal plane, insert the **3.4x350mm Drill** through the Drill Sleeve. Alternatively, insert the **2.5mm K-Wire Sleeve** into the Drill Sleeve and a **2.5x320mm K-Wire** through the K-wire sleeve.



Temporary fixation with K-wire

Creating a box construct aids in screw targeting through the Aiming Arm Assembly.

USING THE PLATE REDUCTION DEVICE

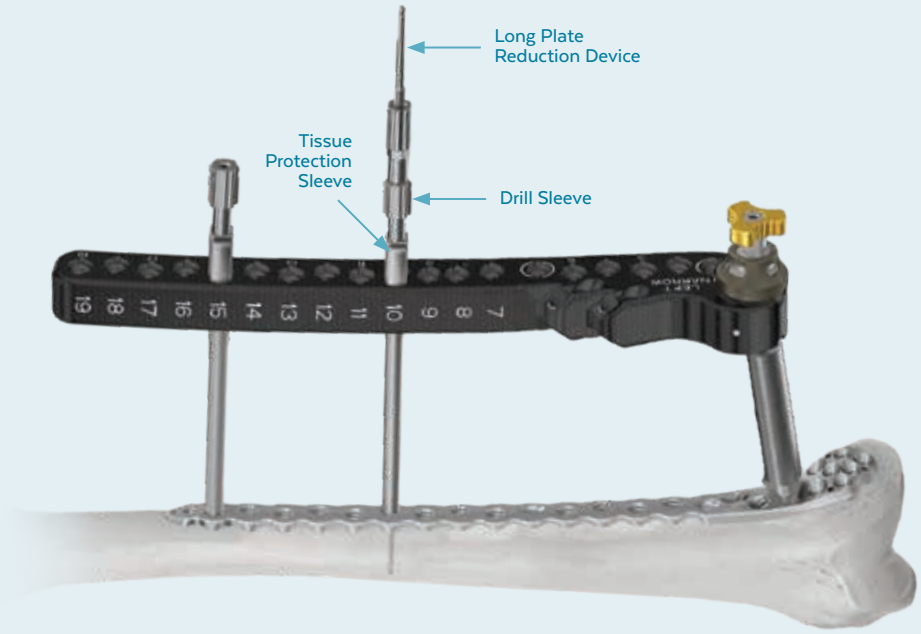
Use the Short or **Long Plate Reduction Device** to to help reduce bone fragments to the plate.

A screw may be inserted into the plate after the plate reduction device is removed using the screw insertion method described in Step 6.

The Long Plate Reduction Device may be used in any hole through the Aiming Arm corresponding to a plate hole. Insert a Tissue Protection Sleeve and securely fasten a Drill Sleeve through the Aiming Arm into the plate. Attach the reduction device to power, and insert it through the Drill Sleeve. Drill into the bone and stop before the tip of the instrument reaches the far cortex.

To aid in reduction, the Snap Fit Handle or a Combination Wrench may be used to tighten or loosen the nut on the Long Plate Reduction Device. The nuts are also interchangeable between the short and long plate reduction devices.

Tighten the nut by hand against the top surface of the Drill Sleeve until the desired reduction is achieved. Monitor reduction using radiographic imaging.



Long Plate Reduction Device

The **Short Plate Reduction Device** may be used in any plate hole. Attach the Short Plate Reduction Device to power. Drill into the bone and stop before the tip reaches the far cortex.

Tighten the nut by hand against the top surface of the Drill Sleeve until the desired reduction is achieved. Monitor reduction using radiographic imaging.

Short Plate
Reduction Device

STEP 6 SCREW INSERTION

Screw Compatibility

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

All non-locking screws should be placed prior to any locking screws. Screw insertion order depends upon fracture type, preliminary reduction, and surgeon preference.

COLOR-CODED INSTRUMENTS

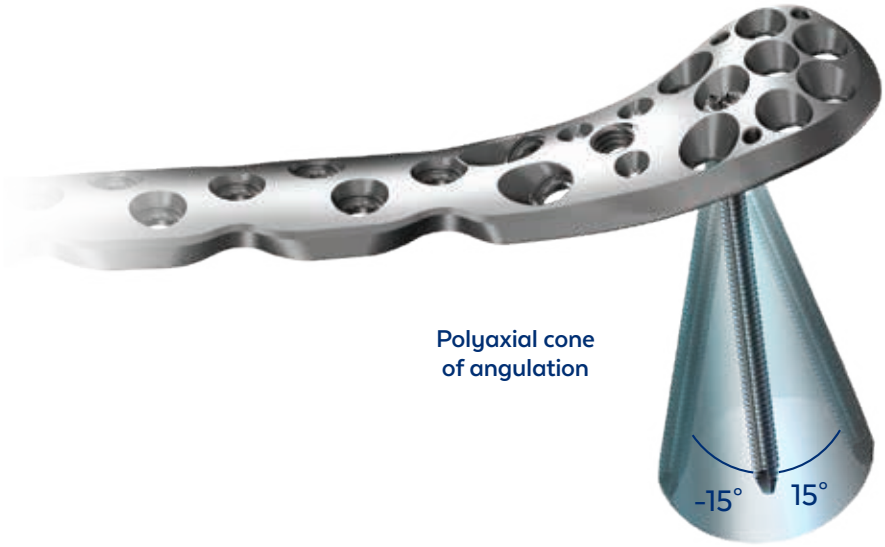
Instruments are color-coded by screw size.

Color	Screw Diameter	Drill Diameter Solid Screw	Drill Diameter Cannulated Screw
Light Blue	4.5mm	3.4mm	3.6mm
Green	5.5mm	3.4mm	3.6mm

Polyaxial Locking Options

All plates feature robust polyaxial locking options, allowing for ±15° (30° cone) of angulation in every locking hole.

Final tightening for locking screws should be performed manually using the **7Nm Torque-Limiting T-Handle**.



All polyaxial locking holes accept both locking and non-locking screws.

DRILL GUIDE OPTIONS

3.4mm Polyaxial Drill Guide

The **3.4mm Polyaxial Drill Guide** has a dedicated side to drill nominally or with ±15° (30° cone) of angulation and is used with the **3.4mm Drill, 90mm Calibration** or **3.4mm Drill, 150mm Calibration**.

3.4mm Polyaxial Drill Guide, Long

The 3.4mm Polyaxial Drill Guide, Long allows for ±15° (30° cone) of angulation and is used with the **3.4mm Drill, 120mm Calibration**.

4.5/3.4mm Drill Guide

The 4.5/3.4mm Drill Guide is used for nominal trajectories through the plate.

This guide is used with the 4.5mm Drill and 3.4mm Drill for the lag-by technique with 4.5mm non-locking screws.

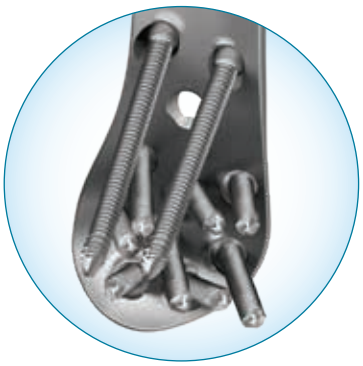
5.5/3.4mm Drill Guide

The 5.5/3.4mm Drill Guide can only be used directly on bone.

This guide is used with the 5.5mm Drill and 3.4mm Drill for the lag-by technique with 5.5mm cancellous screws.

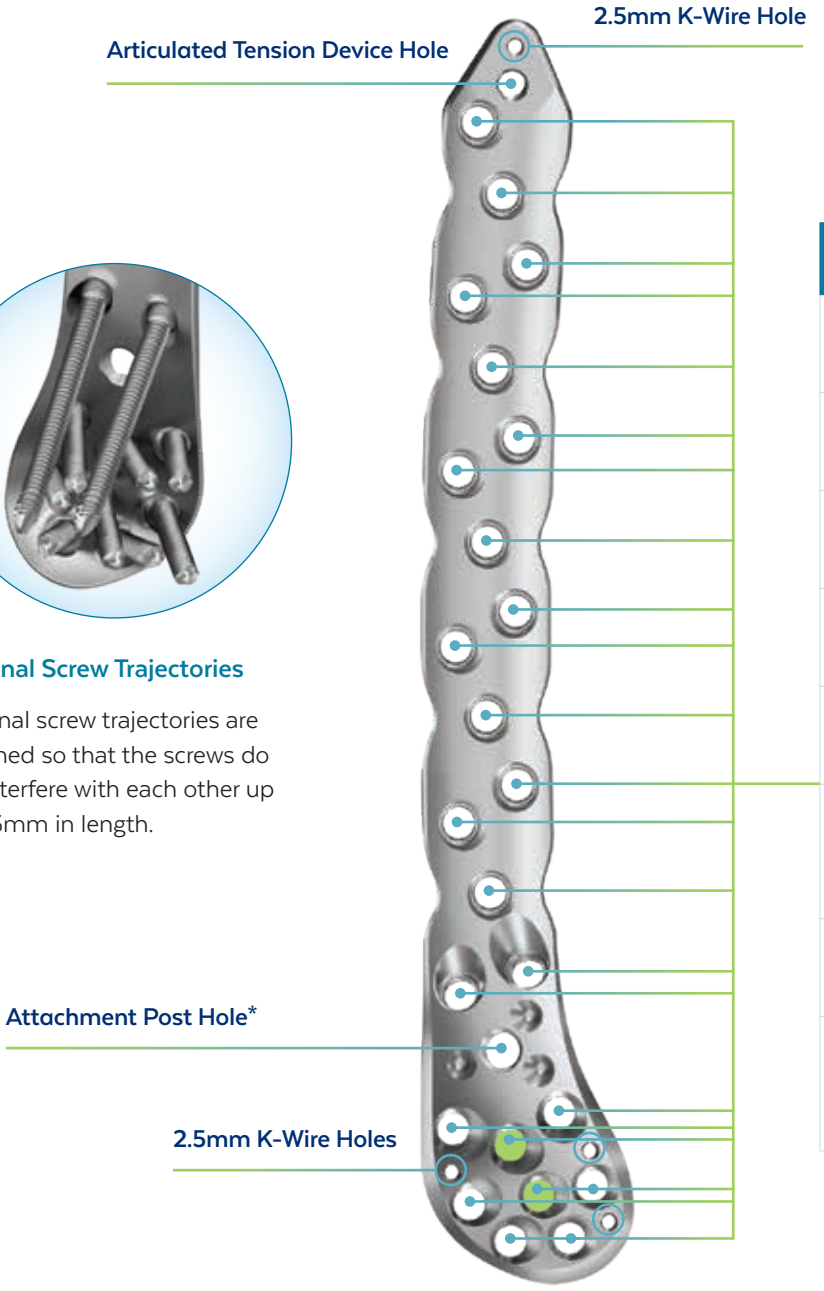
SCREW INSERTION (CONT'D)

Broad Lateral Locking Plate



Nominal Screw Trajectories

Nominal screw trajectories are designed so that the screws do not interfere with each other up to 105mm in length.

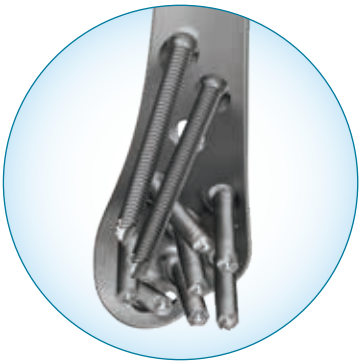


4.5mm Polyaxial Locking Holes	
4.5mm Locking	
4.5mm Blunt Tip Locking	
4.5mm Non-Locking	
4.5mm Locking Cannulated	
5.5mm Cancellous	
5.5mm Partially Threaded Cancellous	
5.5mm Cannulated Cancellous	
5.5mm Partially Threaded Cannulated Cancellous	

● Nominally 95° holes to place screws parallel to the joint

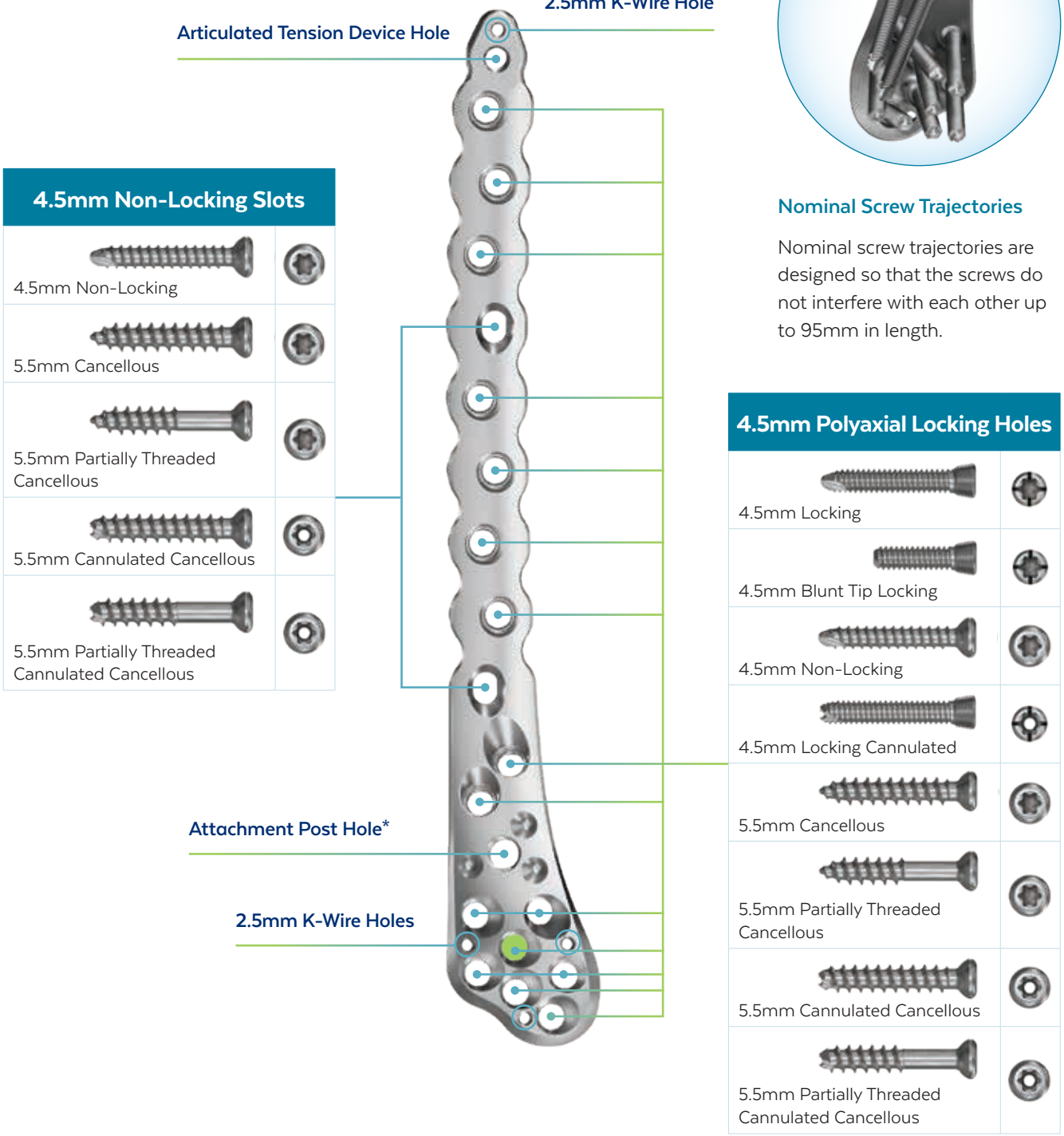
*The Attachment Bolt Hole is not designed to interface with screws.

Narrow Lateral Locking Plate



Nominal Screw Trajectories

Nominal screw trajectories are designed so that the screws do not interfere with each other up to 95mm in length.



4.5mm Non-Locking Slots

- 4.5mm Non-Locking
- 5.5mm Cancellous
- 5.5mm Partially Threaded Cancellous
- 5.5mm Cannulated Cancellous
- 5.5mm Partially Threaded Cannulated Cancellous

4.5mm Polyaxial Locking Holes

- 4.5mm Locking
- 4.5mm Blunt Tip Locking
- 4.5mm Non-Locking
- 4.5mm Locking Cannulated
- 5.5mm Cancellous
- 5.5mm Partially Threaded Cancellous
- 5.5mm Cannulated Cancellous
- 5.5mm Partially Threaded Cannulated Cancellous

● Nominally 95° holes to place screws parallel to the joint

*The Attachment Bolt Hole is not designed to interface with screws.

SCREW INSERTION (CONT'D)

Distal Screws

Confirm plate position using fluoroscopy. Select a 3.4mm drill based on the desired depth. Pre-drill to the desired depth using the 3.4mm Polyaxial Drill Guide.

Measure hole depth using the **Depth Gauge** or by reading the depth from the calibrated drill.

Use the **Self-Retaining T25 Driver** or **Screw Holding Forceps** to select the desired screw. Verify screw length and diameter using the gauges within the screw module.

Insert 4.5mm Locking or Non-Locking Screws or 5.5mm Cancellous Screws using the T25 Driver with the **Quick-Connect Handle** manually or under power.

Final tightening should be performed manually using the 7Nm Torque-Limiting T-Handle. Confirm screw position using fluoroscopy.

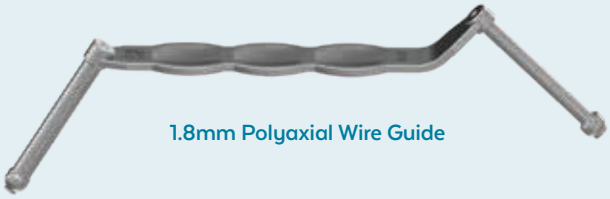
Distal screw insertion

Screws may be inserted under power using the **3.5Nm Torque-Limiting Attachment**.

CANNULATED SCREWS

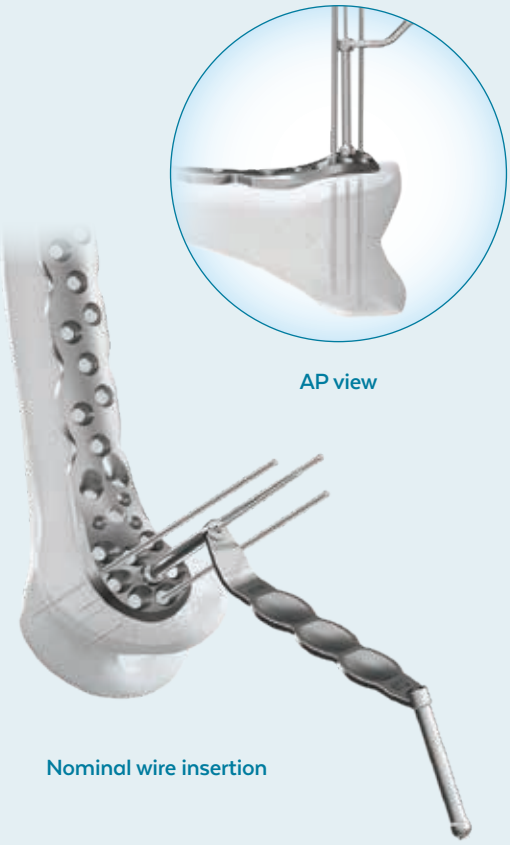
Cannulated screws are available for use with the plate.

The **1.8mm Polyaxial Wire Guide** has a dedicated side to insert a guide wire nominally or with ±15° (30° cone) of angulation. Insert the **1.8mm Guide Wire** through the desired side of the guide into the bone. Confirm guide wire position and depth using fluoroscopy.



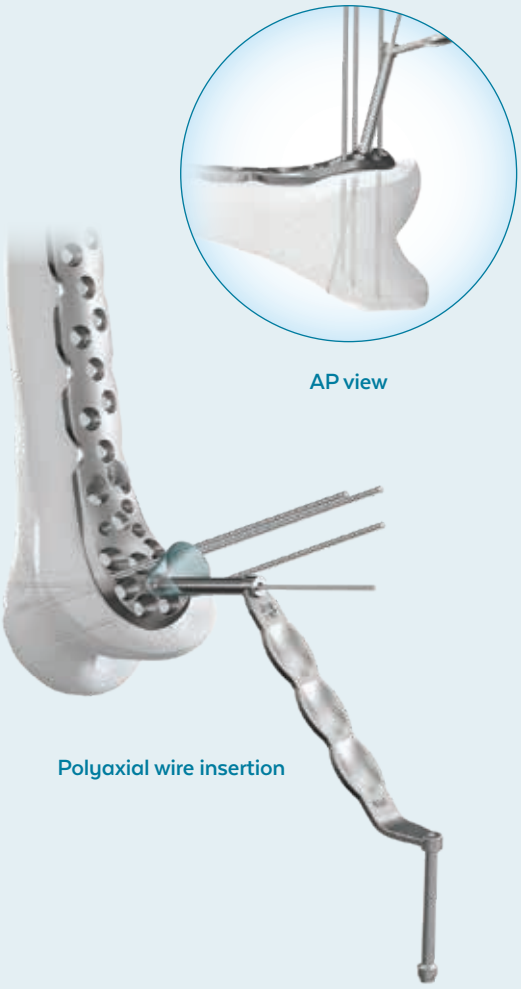
1.8mm Polyaxial Wire Guide

AVAILABLE CANNULATED SCREWS	
 4.5mm Locking Cannulated	
 5.5mm Cannulated Cancellous	
 5.5mm Partially Threaded Cannulated Cancellous	



AP view

Nominal wire insertion



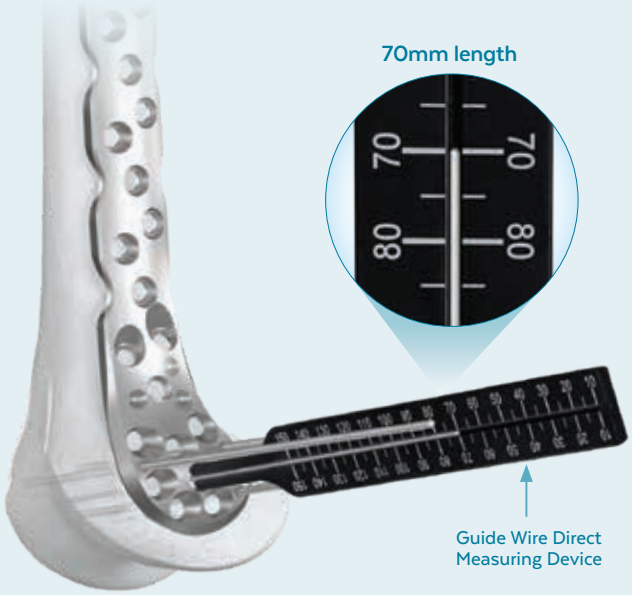
AP view

Polyaxial wire insertion

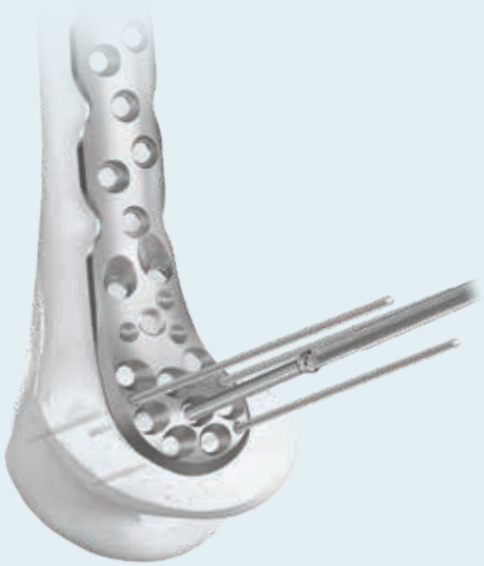
SCREW INSERTION (CONT'D)

CANNULATED SCREWS CONT'D

Measure hole depth by inserting the **Guide Wire Direct Measuring Device** over the guide wire and seating it flush against the plate.



Guide wire measurement



Cannulated screw insertion

Use the **3.6mm Cannulated Drill** to drill over the guide wire to the desired depth. Confirm drill position and depth using fluoroscopy.

Use the Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauge within the screw module.

Using the **T25 Cannulated Driver**, insert the screw over the guide wire. Screws may be inserted using the **3.5Nm Torque-Limiting Attachment, Hall Quick-Connect** manually or under power. Remove the guide wire once the screw is inserted.

Perform final tightening manually with the T25 Solid Driver and 7Nm Torque-Limiting T-Handle.

The **5.5mm Cannulated Drill** is available for the lag-by technique with a 5.5mm Cannulated Cancellous Screw.

Kickstand Screws

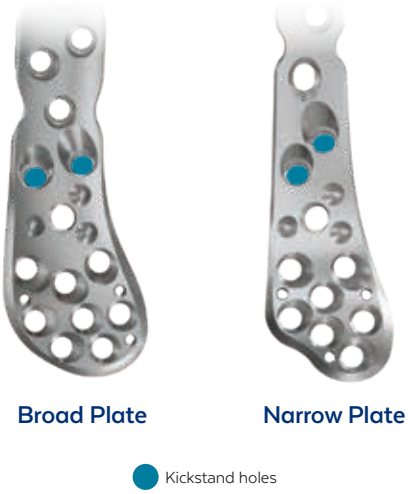
Both lateral plates feature dual kickstand holes designed for posteromedial fixation of the distal femur. Screws may be inserted through the kickstand holes using a Drill Guide or the Aiming Arm.

If using a Drill Guide, refer to Distal Screw Insertion, page 18.

If using the Aiming Arm, follow the steps below.

Insert the **Kickstand Sleeve** and Entry Trocar into the kickstand hole to determine the location of the incision. See image at right. Make a small incision with a scalpel at this location.

Advance the Kickstand Sleeve and Entry Trocar to break through the soft tissue. Remove the trocar.



Broad Plate Narrow Plate

Kickstand holes

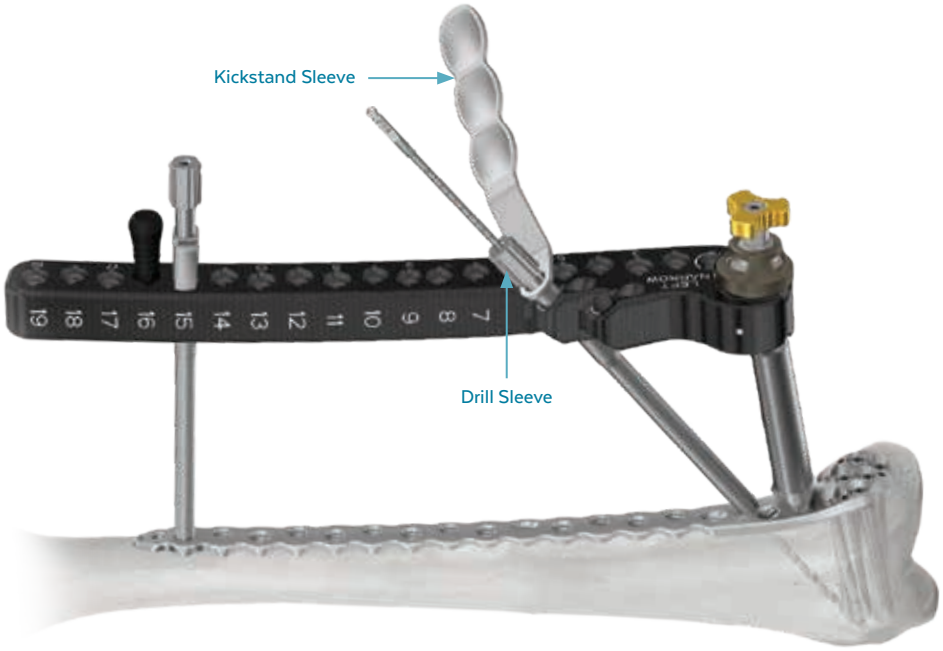
Insert the Drill Sleeve and Positioning Pin through the Kickstand Sleeve. Thread the Drill Sleeve into the plate and remove the positioning pin.

Pre-drill to the desired depth using the 3.4x350mm Drill. Measure hole depth by reading the calibrated drill. Alternatively, remove the Drill Sleeve and insert the Depth Gauge through the Kickstand Sleeve. Confirm that the outer sleeve of the Depth Gauge is contacting the plate before reading the depth.

Use the Self-Retaining T25 Driver or Screw Holding Forceps to select the desired screw.

Verify the screw length and diameter using the gauges within the screw module. Insert 4.5mm Locking or Non-Locking Screws or 5.5mm Cancellous Screws using the T25 Driver with the Quick-Connect Handle, manually or under power.

Final tightening should be performed manually using the 7Nm Torque-Limiting T-Handle. Confirm screw position using fluoroscopy.



Kickstand screw insertion

SCREW INSERTION (CONT'D)

Proximal Screws

Confirm plate position using fluoroscopy. Proximal screws may be inserted using a Drill Guide or the Aiming Arm.

If using a Drill Guide, refer to Distal Screw Insertion, page 18.

If using the Aiming Arm, follow steps below.

Insert the Tissue Protection Sleeve and Entry Trocar into the desired hole to determine the location of the incision. Make a small incision with a scalpel. Alternatively, use the Scalpel Blade Handle, page 11.

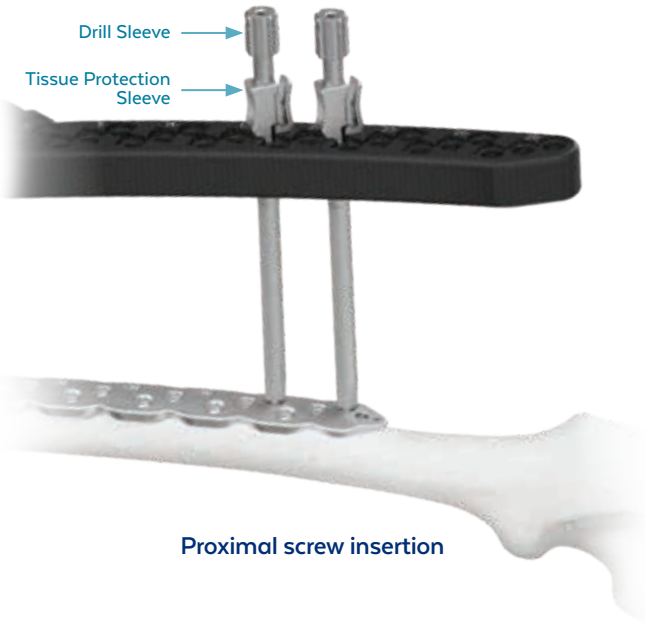
Advance the tissue sleeve and trocar to penetrate the soft tissue. Snap the tissue sleeve into the Aiming Arm and remove the trocar. If the tissue sleeve is not fully seated in the Aiming Arm, the trocar and Drill Sleeve will not pass through.

Proximal screw preparation

The **Snap Fit Handle** can be used for insertion of the Entry Trocar or Drill Sleeve.

Insert the Drill Sleeve and Positioning Pin through the tissue sleeve. Thread the Drill Sleeve into the plate and remove the positioning pin.

Pre-drill to the desired depth using the 3.4x350mm Drill. Measure hole depth by reading the calibrated drill. Optionally, remove the Drill Guide and use the Depth Gauge through the tissue sleeve. Confirm that the outer sleeve of the Depth Gauge is contacting the plate before reading the depth.



Proximal screw insertion

If the Drill Sleeve cannot engage the plate, the **Drill Sleeve, Long**, may be used instead.

Use the Self-Retaining T25 Driver or Screw Holding Forceps to select the desired screw.

Verify the screw length and diameter using the gauges within the screw module. Insert 4.5mm Locking or Non-Locking Screws or 5.5mm Cancellous Screws using the T25 Driver with the Quick-Connect Handle, manually or under power.

Final tightening should be performed manually using the 7Nm Torque-Limiting T-Handle. Confirm screw position using fluoroscopy.

In hard cortical bone, it is recommended to use the **Cortical Tap** before screw insertion. The tap may be used directly through the Tissue Protection Sleeve.

LAG-BY TECHNIQUE

Drills are available for over-drilling using the lag-by technique with 4.5mm non-locking and 5.5mm cancellous screws.

To perform the lag-by technique with the Aiming Arm, refer to Proximal Screw Insertion (page 22) until the pre-drilling step through the Drill Sleeve. Remove the Drill Sleeve, and use the **4.5x276mm Piloted Drill** or **5.5x276mm Piloted Drill** through the Tissue Protection Sleeve to over-drill to the desired depth.

Measure hole depth using the Depth Gauge. Follow the remaining instructions for proximal screw insertion.

Drill, 4.5x276mm, Piloted, Calibrated, AO Quick-Connect

SCREW INSERTION (CONT'D)

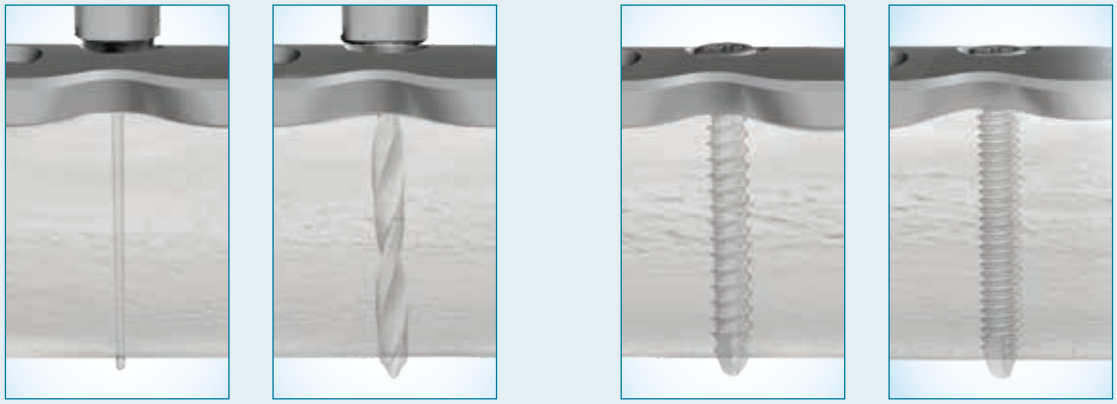
CALIBRATED MEASUREMENTS

The calibrated drill and Depth Gauge are used to measure hole depth for full thread engagement in the far cortex.

Depth Gauge

Calibrated drill

The screw tip extends past the end of the depth gauge when inserted into the plate.



Depth Gauge Probe

3.4mm Drill

Non-Locking Screw

Locking Screw

STEP 7 OPTIONAL: DYNAMIC COMPRESSION

Dynamic compression of the fracture may be achieved by eccentrically placing a non-locking or cancellous screw through a 4.5mm non-locking slot in the Narrow Lateral Plate.

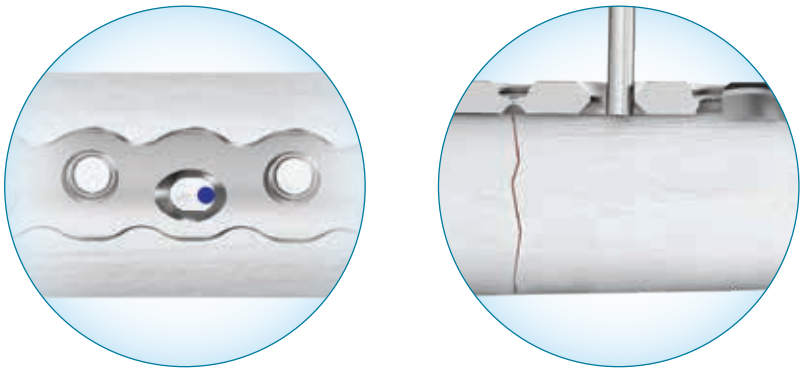
Place a non-locking or cancellous screw proximal to the fracture. Select a non-locking slot on the distal side of the fracture line. Insert the 3.4mm side of the 5.5/3.4mm Drill Guide eccentrically into the dynamic compression slot.

Drill to the desired depth with the 3.4mm drill. Measure the hole depth using the Depth Gauge.

Use the Self-Retaining T25 Driver or Screw Holding Forceps to select the desired screw. Verify screw length and diameter using the gauges within the screw module.

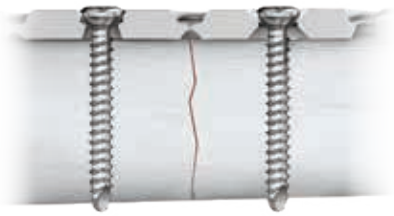
Using the T25 Driver with the Quick-Connect Handle, insert the screw into the desired hole.

If compression is not desired, place the screw in a neutral position.

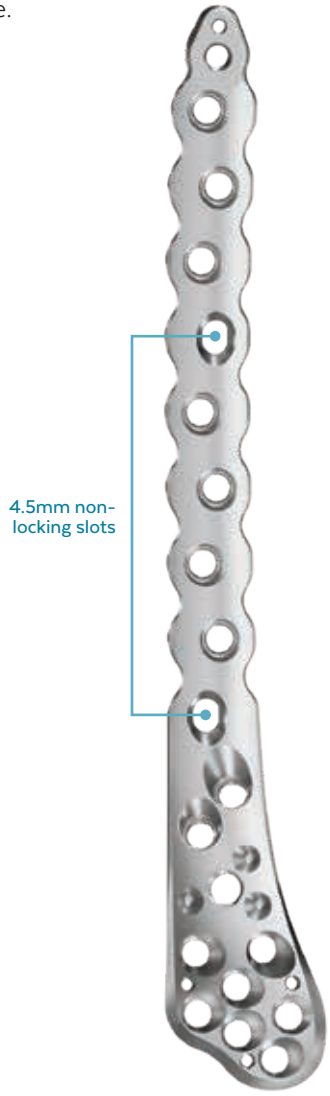


Drill sleeve positioned eccentrically in non-locking slot

Screw partially inserted eccentrically



Screw fully inserted and fracture compressed



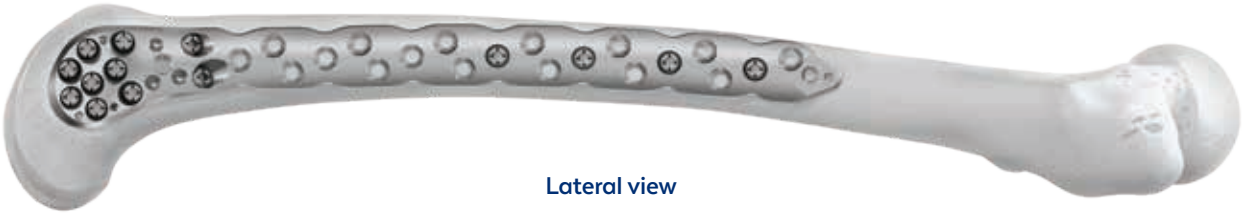
4.5mm non-locking can be targeted neutrally through the holes outlined in white on the Aiming Arm, Narrow using the Drill Sleeve, Long.

STEP 8 VERIFY PLACEMENT

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

FINAL CONSTRUCT

AP view



Lateral view

OPTIONAL: REMOVAL

Unlock all screws from the plate with a **Non-Self-Retaining T25 Driver**, but do not remove the locking screws. This prevents simultaneous rotation of the plate and screws during removal. Once all locking screws are unlocked from the plate, completely remove all locking, non-locking, and cancellous screws from the bone. After all screws are removed from the bone, the plate may be removed.

NON-SELF-RETAINING DRIVERS

Non-self-retaining drivers help to maximize torque applied to the screw head during insertion or removal. These drivers are designed to prevent screw head stripping in challenging clinical scenarios, and are color-coded with a black band.

T25 Driver, Non-Self-Retaining,
Small AO Quick-Connect

T25 Driver, Non-Self-Retaining, Cannulated,
Hall Quick-Connect

ANTHEM® Medial Distal Femoral Plate

STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Estimate the appropriate plate length and type based on the fracture type and patient anatomy. Plan the plate position and screw placement.

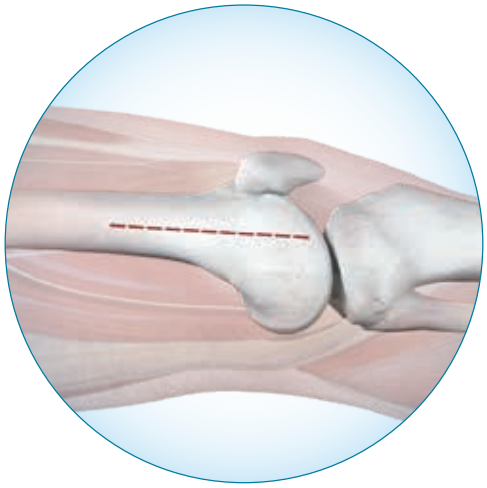
STEP 2 PATIENT POSITIONING

Position the patient supine with the option to flex the knee. Ensure visualization with fluoroscopy is possible.

STEP 3 SURGICAL APPROACH

Use a medial subvastus approach after determining the fracture type and fracture location.

Radiolucent Weitlaners and **Radiolucent Hohmann Retractors** may be used to aid in fracture site visibility.



Medial subvastus approach

STEP 4 FRACTURE REDUCTION

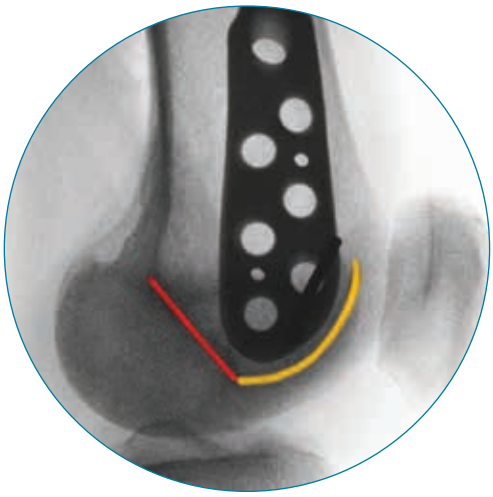
Reduce the fracture using the appropriate method for the fracture type. Confirm reduction using fluoroscopy. Compression may be achieved using lag screws. Ensure that lag screw placement does not interfere with the plate.

STEP 5 PLATE PLACEMENT

Position the Medial Plate anteromedially on the distal femur. It is designed to be placed as shown below.

The plate may be temporarily held in place by inserting 2.5mm K-Wires through the proximal and distal K-wire holes in the plate.

MEDIAL PLATE PLACEMENT



Lateral

AP

KEY

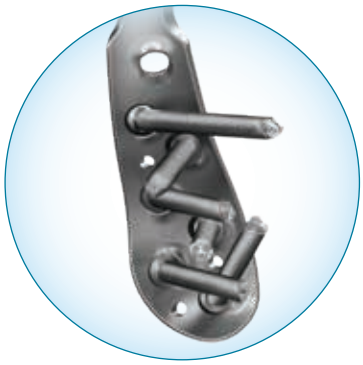
— Blumensaat line
— Trochlea line

Screw Compatibility

Screw compatibility is shown below for the Medial Locking Plates. If screw-plate locking is desired in a polyaxial hole, use locking screws only.

All non-locking screws should be placed prior to any locking screws. Screw insertion order depends upon fracture type, preliminary reduction, and surgeon preference.

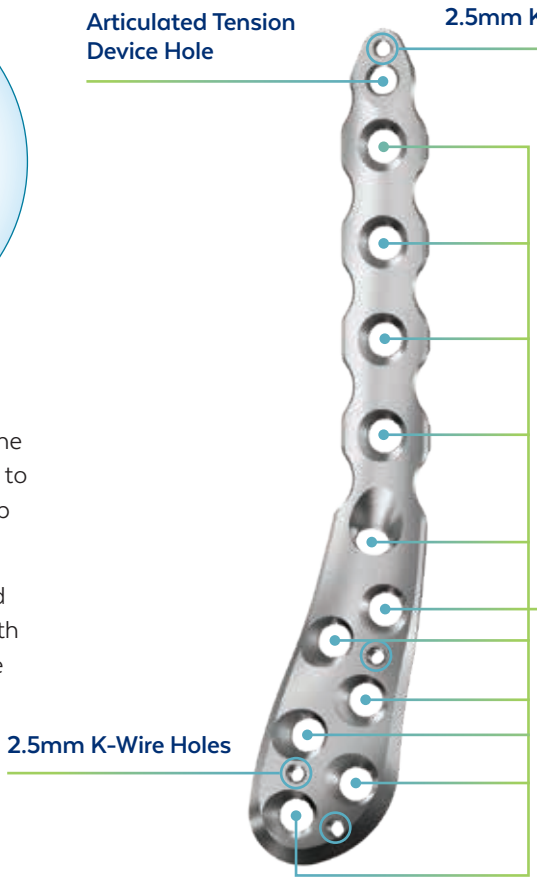
Medial Locking Plate



Nominal Screw Trajectories

Nominal screw trajectories in the head of the plate are designed to not interfere with each other up to 105mm.

The kickstand screw hole could interfere at a nominal angle with the most proximal screw in the head of the plate.



4.5mm Polyaxial Locking Holes	
4.5mm Locking	
4.5mm Blunt Tip Locking	
4.5mm Non-Locking	
4.5mm Locking Cannulated	
5.5mm Cancellous	
5.5mm Partially Threaded Cancellous	
5.5mm Cannulated Cancellous	
5.5mm Partially Threaded Cannulated Cancellous	

STEP 6 SCREW INSERTION

Confirm plate position using fluoroscopy. All distal and proximal screws are inserted using the same instructions.

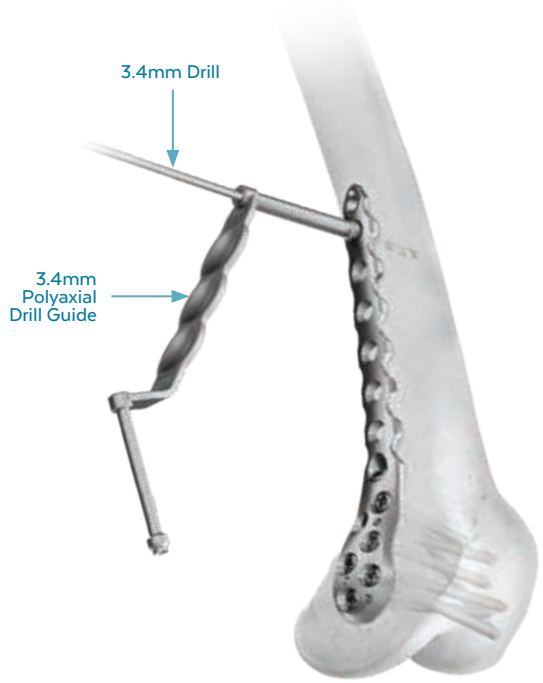
Pre-drill to the desired depth using the **3.4mm Drill Bit** and **3.4mm Polyaxial Drill Guide**.

Measure hole depth using the **Depth Gauge** or by reading the depth from a calibrated drill.

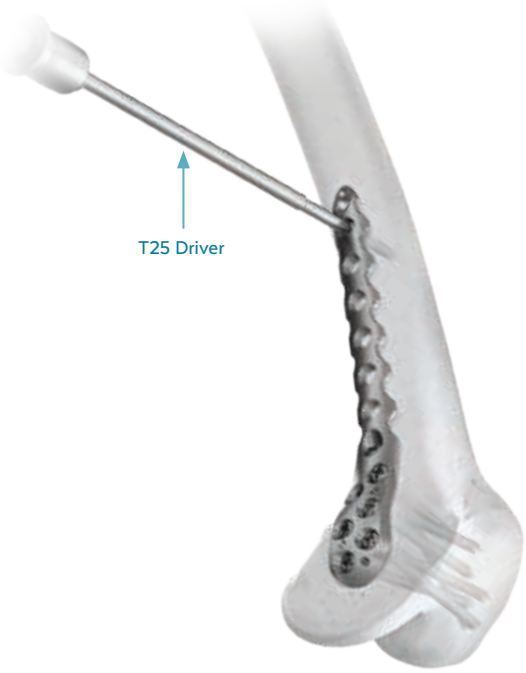
Use the **Self-Retaining T25 Drive**r or **Screw Holding Forceps** to select the desired screw. Verify screw length and diameter using the gauges within the screw module.

Insert 4.5mm Locking or Non-Locking Screws or 5.5mm Cancellous Screws using the T25 Driver with the **Quick-Connect Handle** manually or under power.

Final tightening should be performed manually using the **7Nm Torque-Limiting T-Handle**. Confirm screw position using fluoroscopy.



Pre-drilling for screw insertion



Screw insertion by hand

Screws may be inserted under power using the **3.5Nm Torque-Limiting Attachment**.

STEP 7 VERIFY PLACEMENT

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

FINAL CONSTRUCT

Medial Plate final construct

OPTIONAL: REMOVAL

Unlock all screws from the plate with a Non-Self-Retaining T25 Driver, but do not remove the locking screws. This prevents simultaneous rotation of the plate and screws during removal. Once all locking screws are unlocked from the plate, completely remove all locking, non-locking, and cancellous screws from the bone. After all screws are removed from the bone, the plate can be removed.

NON-SELF-RETAINING DRIVERS

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

T25 Driver, Non-Self-Retaining, AO Quick-Connect

T25 Driver, Non-Self-Retaining, Cannulated, Hall Quick-Connect

INSTRUMENT OVERVIEW

AIMING ARM INSTRUMENTS

Plate Attachment Bolt 6195.1000

Attachment Post, Left 6195.1110

Attachment Post, Right 6195.1210

Aiming Arm Attachment Nut 6195.1350

Aiming Arm, Narrow 6195.2010

Aiming Arm, Broad 6195.3010

Tissue Protection Sleeve 6195.4015

Entry Trocar 6195.4030

Snap Fit Handle 6195.4060

Drill Sleeve 6195.4160

Drill Sleeve, Long 6195.4165

Positioning Pin 6195.4130

AIMING ARM INSTRUMENTS (CONT'D)

2.5mm K-Wire Sleeve 6195.4110

Kickstand Sleeve 6195.4020

Combination Wrench 6173.0110

Aiming Arm Plug 6195.4210

Scalpel Blade Handle 6195.4050

DEPTH GAUGE

Depth Gauge 6206.0030

CANNULATED INSTRUMENTS

Guide Wire, 1.8x200mm, CoCr Trocar Tip 6206.1118

Guide Wire, 1.8x200mm, CoCr, Drill Tip 6206.1618

Guide Wire Direct Measuring Device 6206.0035

1.8mm Polyaxial Wire Guide 6206.3008

DRILL GUIDES

4.5/3.4mm Drill Guide 6206.3001

5.5/3.4mm Drill Guide 6206.3002

3.4mm Polyaxial Drill Guide 6206.3005

Polyaxial Drill Guide, Long 6195.4170

DRILLS

Drill, 3.4x350mm, Calibrated, AO Quick-Connect 6195.5034

Drill, 4.5x276mm, Piloted, Calibrated, AO Quick-Connect 6195.5045

Drill, 5.5x276mm, Piloted, Calibrated, AO Quick-Connect 6195.5055

Drill, 3.4x245mm, 150mm Calibration, AO Quick-Connect 6206.5034

Drill, 3.4x185mm, 90mm Calibration, AO Quick-Connect 6206.5234

Drill, 4.5x195mm, AO Quick-Connect 6206.5445

Drill, 5.5x195mm, AO Quick-Connect 6206.5455

Drill, 3.6x245mm, Cannulated, AO Quick-Connect 6206.5536

Drill, 5.5x195mm, Cannulated, AO Quick-Connect 6206.5555

DRIVERS

T25 Driver, Self-Retaining, 225mm, AO Quick-Connect 6195.6125

T25 Driver, Self-Retaining, 150mm, AO Quick-Connect 6206.6125

T25 Driver, Non-Self-Retaining, 150mm, AO Quick-Connect 6206.6225

T25 Driver, Non-Self-Retaining, 150mm, Cannulated, Hall Quick-Connect 6206.6425

TAPS

Tap, 4.5x320mmm, AO Quick-Connect 6195.7045

Tap, 5.5x320mm, AO Quick-Connect 6195.7055

Tap, 4.5x195mm, AO Quick-Connect 6206.7045

Tap, 5.5x195mm, AO Quick-Connect 6206.7055

TORQUE LIMITERS

Torque-Limiting Attachment, 3.5Nm, AO Quick-Connect 6206.0025

Torque-Limiting Attachment, 3.5Nm, Hall Quick-Connect 6206.0020

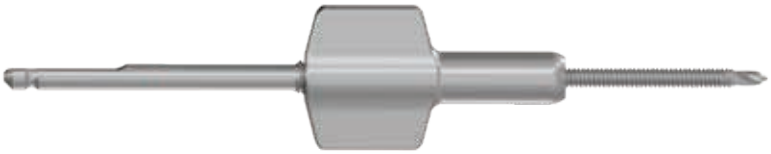
RETRACTION

Large Hohmann Retractor, Standard 6206.4001

Large Hohmann Retractor, Narrow 6206.4003

Stabilizing Radiolucent Weitlaner, 3x4mm, 8in, Sharp Tip 6171.0002

REDUCTION



Short Plate Reduction Device 6206.0045

Long Plate Reduction Device 6195.0045

1.25mm K-Wire, Trocar Tip, 150mm 6179.1113

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

K-Wire, 2.5x200mm, SS, Trocar Tip 6206.1025

K-Wire, 2.5x200mm, SS, Drill Tip 6206.1525

K-Wire, 2.5x320mm, SS, Drill Tip 6195.1525

ADDITIONAL SCREW INSTRUMENTS

Screw Forceps 6206.0060

Countersink, 4.5mm and 5.5mm Screws 6206.0040

HANDLES

Inline Handle, AO Quick-Connect, Fixed 6179.7001

T-Handle, AO Quick-Connect, Limiting 7Nm 6206.2707

Inline Handle, Hall Quick-Connect, Fixed 6206.2300

RECOMMENDED SETS

ANTHEM® LATERAL DISTAL FEMORAL PLATE

Required Sets
9195.9001/9195.9002 ANTHEM® Distal Femur Titanium Plate Set (Left/Right) *OR* 9195.9003/9195.9004 ANTHEM® Distal Femur Stainless Steel Plate Set (Left/Right)
9195.9005 ANTHEM® Distal Femur Instrument Set*
9206.9003 ANTHEM® Large Fragment Titanium Screw Set *OR* 9206.9004 ANTHEM® Large Fragment Stainless Steel Screw Set
9206.9005 ANTHEM® Large Fragment Instrument Set

Optional Sets
9206.9006 ANTHEM® Large Fragment Titanium Cannulated Cancellous Screw Module *OR* 9206.9007 ANTHEM® Large Fragment Stainless Steel Cannulated Cancellous Screw Module
9206.9008 ANTHEM® Large Fragment Cannulated Locking Screw Module
9206.9009 ANTHEM® Large Fragment Cannulated Instrument Set

*Required to target lateral plates

ANTHEM® MEDIAL DISTAL FEMORAL PLATE

Required Sets
9195.9001/9195.9002 ANTHEM® Distal Femur Titanium Plate Set (Left/Right) *OR* 9195.9003/9195.9004 ANTHEM® Distal Femur Stainless Steel Plate Set (Left/Right)
9206.9003 ANTHEM® Large Fragment Titanium Screw Set *OR* 9206.9004 ANTHEM® Large Fragment Stainless Steel Screw Set
9206.9005 ANTHEM® Large Fragment Instrument Set

Optional Sets
9195.9005 ANTHEM® Distal Femur Instrument Set
9206.9006 ANTHEM® Large Fragment Titanium Cannulated Cancellous Screw Module *OR* 9206.9007 ANTHEM® Large Fragment Stainless Steel Cannulated Cancellous Screw Module
9206.9008 ANTHEM® Large Fragment Cannulated CoCr Screw Module
9206.9009 ANTHEM® Large Fragment Cannulated Instrument Set

ANTHEM® Distal Femur
Titanium Left Plate Set 9195.9001

Part No.	Description	Qty
1195.1203	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 3 Hole, 137mm	1
1195.1205	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 5 Hole, 169mm	1
1195.1207	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 7 Hole, 202mm	1
1195.1209	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 9 Hole, 234mm	1
1195.1211	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 11 Hole, 267mm	1
1195.1213	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 13 Hole, 299mm	1
1195.1215	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 15 Hole, 331mm	1
1195.1217	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 17 Hole, 363mm	1
1195.1219	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 19 Hole, 395mm	1
1195.1221	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 21 Hole, 427mm	1
1195.1223	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Left, 23 Hole, 458mm	1
1195.3205	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 5 Hole, 137mm	1
1195.3208	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 8 Hole, 169mm	1
1195.3211	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 11 Hole, 202mm	1
1195.3214	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 14 Hole, 234mm	1
1195.3217	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 17 Hole, 267mm	1
1195.3220	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 20 Hole, 299mm	1
1195.3223	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 23 Hole, 331mm	1
1195.3226	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 26 Hole, 363mm	1
1195.3229	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 29 Hole, 395mm	1
1195.3232	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 32 Hole, 427mm	1
1195.3235	ANTHEM® Ti Lateral Broad Distal Femur Plate, Left, 35 Hole, 458mm	1
1195.5202	ANTHEM® Ti Medial Distal Femur Plate, Left, 2 Hole, 112mm	1
1195.5204	ANTHEM® Ti Medial Distal Femur Plate, Left, 4 Hole, 146mm	1
1195.5206	ANTHEM® Ti Medial Distal Femur Plate, Left, 6 Hole, 180mm	1
9195.0001	ANTHEM® Distal Femur Left Plate Graphic Case - Ti	

ANTHEM® Distal Femur
Titanium Right Plate Set 9195.9002

Part No.	Description	Qty
1195.2203	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 3 Hole, 137mm	1
1195.2205	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 5 Hole, 169mm	1
1195.2207	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 7 Hole, 202mm	1
1195.2209	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 9 Hole, 234mm	1
1195.2211	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 11 Hole, 267mm	1
1195.2213	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 13 Hole, 299mm	1
1195.2215	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 15 Hole, 331mm	1
1195.2217	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 17 Hole, 363mm	1
1195.2219	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 19 Hole, 395mm	1
1195.2221	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 21 Hole, 427mm	1
1195.2223	ANTHEM® Ti Lateral Narrow Distal Femur Plate, Right, 23 Hole, 458mm	1
1195.4205	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 5 Hole, 137mm	1
1195.4208	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 8 Hole, 169mm	1
1195.4211	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 11 Hole, 202mm	1
1195.4214	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 14 Hole, 234mm	1
1195.4217	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 17 Hole, 267mm	1
1195.4220	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 20 Hole, 299mm	1
1195.4223	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 23 Hole, 331mm	1
1195.4226	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 26 Hole, 363mm	1
1195.4229	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 29 Hole, 395mm	1
1195.4232	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 32 Hole, 427mm	1
1195.4235	ANTHEM® Ti Lateral Broad Distal Femur Plate, Right, 35 Hole, 458mm	1
1195.6202	ANTHEM® Ti Medial Distal Femur Plate, Right, 2 Hole, 112mm	1
1195.6204	ANTHEM® Ti Medial Distal Femur Plate, Right, 4 Hole, 146mm	1
1195.6206	ANTHEM® Ti Medial Distal Femur Plate, Right, 6 Hole, 180mm	1
9195.0002	ANTHEM® Distal Femur Right Plate Graphic Case - Ti	

ANTHEM® Distal Femur
Stainless Steel Left Plate Set 9195.9003

Part No.	Description	Qty
2195.1003	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 3 Hole, 137mm	1
2195.1005	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 5 Hole, 169mm	1
2195.1007	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 7 Hole, 202mm	1
2195.1009	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 9 Hole, 234mm	1
2195.1011	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 11 Hole, 267mm	1
2195.1013	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 13 Hole, 299mm	1
2195.1015	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 15 Hole, 331mm	1
2195.1017	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 17 Hole, 363mm	1
2195.1019	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 19 Hole, 395mm	1
2195.1021	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 21 Hole, 427mm	1
2195.1023	ANTHEM® SS Lateral Narrow Distal Femur Plate, Left, 23 Hole, 458mm	1
2195.3005	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 5 Hole, 137mm	1
2195.3008	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 8 Hole, 169mm	1
2195.3011	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 11 Hole, 202mm	1
2195.3014	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 14 Hole, 234mm	1
2195.3017	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 17 Hole, 267mm	1
2195.3020	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 20 Hole, 299mm	1
2195.3023	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 23 Hole, 331mm	1
2195.3026	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 26 Hole, 363mm	1
2195.3029	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 29 Hole, 395mm	1
2195.3032	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 32 Hole, 427mm	1
2195.3035	ANTHEM® SS Lateral Broad Distal Femur Plate, Left, 35 Hole, 458mm	1
2195.5002	ANTHEM® SS Medial Distal Femur Plate, Left, 2 Hole, 112mm	1
2195.5004	ANTHEM® SS Medial Distal Femur Plate, Left, 4 Hole, 146mm	1
2195.5006	ANTHEM® SS Medial Distal Femur Plate, Left, 6 Hole, 180mm	1
9195.0003	ANTHEM® Distal Femur Left Plate Graphic Case - SS	

ANTHEM® Distal Femur
Stainless Steel Right Plate Set 9195.9004

Part No.	Description	Qty
2195.2003	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 3 Hole, 137mm	1
2195.2005	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 5 Hole, 169mm	1
2195.2007	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 7 Hole, 202mm	1
2195.2009	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 9 Hole, 234mm	1
2195.2011	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 11 Hole, 267mm	1
2195.2013	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 13 Hole, 299mm	1
2195.2015	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 15 Hole, 331mm	1
2195.2017	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 17 Hole, 363mm	1
2195.2019	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 19 Hole, 395mm	1
2195.2021	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 21 Hole, 427mm	1
2195.2023	ANTHEM® SS Lateral Narrow Distal Femur Plate, Right, 23 Hole, 458mm	1
2195.4005	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 5 Hole, 137mm	1
2195.4008	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 8 Hole, 169mm	1
2195.4011	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 11 Hole, 202mm	1
2195.4014	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 14 Hole, 234mm	1
2195.4017	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 17 Hole, 267mm	1
2195.4020	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 20 Hole, 299mm	1
2195.4023	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 23 Hole, 331mm	1
2195.4026	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 26 Hole, 363mm	1
2195.4029	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 29 Hole, 395mm	1
2195.4032	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 32 Hole, 427mm	1
2195.4035	ANTHEM® SS Lateral Broad Distal Femur Plate, Right, 35 Hole, 458mm	1
2195.6002	ANTHEM® SS Medial Distal Femur Plate, Right, 2 Hole, 112mm	1
2195.6004	ANTHEM® SS Medial Distal Femur Plate, Right, 4 Hole, 146mm	1
2195.6006	ANTHEM® SS Medial Distal Femur Plate, Right, 6 Hole, 180mm	1
9195.0004	ANTHEM® Distal Femur Right Plate Graphic Case - SS	

ANTHEM® Distal Femur
Instrument Set 9195.9005

Part No.	Description	Qty
6195.0045	Plate Reduction Device	2
6195.1000	Plate Attachment Bolt	2
6195.1110	Attachment Post, Left	1
6195.1210	Attachment Post, Right	1
6195.1350	Aiming Arm Attachment Nut	2
6195.1525	K-Wire, 2.5x320mm, Drill Tip	10
6195.2010	Aiming Arm, Narrow	1
6195.3010	Aiming Arm, Broad	1
6195.4015	Tissue Protection Sleeve	4
6195.4020	Kickstand Sleeve	2
6195.4030	Entry Trocar	2
6195.4050	Scalpel Blade Handle	1
6195.4060	Snap Fit Handle	1
6195.4110	2.5mm K-Wire Sleeve	2
6195.4130	Positioning Pin	1
6195.4160	Drill Sleeve	4
6195.4165	Drill Sleeve, Long	2
6195.4170	3.4mm Polyaxial Drill Guide, Long	1
6195.4210	Plug	4
6195.5034	Drill, 3.4x350mm, Calibrated, AO Quick-Connect	2
6195.5045	Drill, 4.5x276mm, Piloted, Cal, AO Quick-Connect	2
6195.5055	Drill, 5.5x276mm, Piloted, Cal, AO Quick-Connect	2
6195.6125	T25 Driver, SR, 225mm, AO Quick-Connect	2
6195.7045	Tap, 4.5x320mm, AO Quick-Connect	1
6195.7055	Tap, 5.5x320mm, AO Quick-Connect	1
9195.0005	ANTHEM® Distal Femur Instrument Graphic Case	

ANTHEM® Large Fragment
Titanium Screw Set 9206.9003

4.5mm Non-Locking

Part No.	Description	Qty
1206.2020	Non-Locking Screw, 4.5x20mm, Ti	4
1206.2022	Non-Locking Screw, 4.5x22mm, Ti	4
1206.2024	Non-Locking Screw, 4.5x24mm, Ti	4
1206.2026	Non-Locking Screw, 4.5x26mm, Ti	4
1206.2028	Non-Locking Screw, 4.5x28mm, Ti	4
1206.2030	Non-Locking Screw, 4.5x30mm, Ti	4
1206.2032	Non-Locking Screw, 4.5x32mm, Ti	4
1206.2034	Non-Locking Screw, 4.5x34mm, Ti	4
1206.2036	Non-Locking Screw, 4.5x36mm, Ti	4
1206.2038	Non-Locking Screw, 4.5x38mm, Ti	4
1206.2040	Non-Locking Screw, 4.5x40mm, Ti	4
1206.2042	Non-Locking Screw, 4.5x42mm, Ti	4
1206.2044	Non-Locking Screw, 4.5x44mm, Ti	4
1206.2046	Non-Locking Screw, 4.5x46mm, Ti	4
1206.2048	Non-Locking Screw, 4.5x48mm, Ti	4
1206.2050	Non-Locking Screw, 4.5x50mm, Ti	2
1206.2052	Non-Locking Screw, 4.5x52mm, Ti	2
1206.2054	Non-Locking Screw, 4.5x54mm, Ti	2
1206.2056	Non-Locking Screw, 4.5x56mm, Ti	2
1206.2058	Non-Locking Screw, 4.5x58mm, Ti	2
1206.2060	Non-Locking Screw, 4.5x60mm, Ti	2
1206.2062	Non-Locking Screw, 4.5x62mm, Ti	2
1206.2064	Non-Locking Screw, 4.5x64mm, Ti	2
1206.2066	Non-Locking Screw, 4.5x66mm, Ti	2
1206.2068	Non-Locking Screw, 4.5x68mm, Ti	2
1206.2070	Non-Locking Screw, 4.5x70mm, Ti	2
1206.2075	Non-Locking Screw, 4.5x75mm, Ti	2
1206.2080	Non-Locking Screw, 4.5x80mm, Ti	2
1206.2085	Non-Locking Screw, 4.5x85mm, Ti	2
1206.2090	Non-Locking Screw, 4.5x90mm, Ti	2
1206.2095	Non-Locking Screw, 4.5x95mm, Ti	2

4.5mm Locking

Part No.	Description	Qty
7206.1020	Locking Screw, 4.5x20mm, CoCr	4
7206.1022	Locking Screw, 4.5x22mm, CoCr	4
7206.1024	Locking Screw, 4.5x24mm, CoCr	4
7206.1026	Locking Screw, 4.5x26mm, CoCr	4
7206.1028	Locking Screw, 4.5x28mm, CoCr	4
7206.1030	Locking Screw, 4.5x30mm, CoCr	4
7206.1032	Locking Screw, 4.5x32mm, CoCr	4
7206.1034	Locking Screw, 4.5x34mm, CoCr	4
7206.1036	Locking Screw, 4.5x36mm, CoCr	4
7206.1038	Locking Screw, 4.5x38mm, CoCr	4
7206.1040	Locking Screw, 4.5x40mm, CoCr	4
7206.1042	Locking Screw, 4.5x42mm, CoCr	4
7206.1044	Locking Screw, 4.5x44mm, CoCr	4
7206.1046	Locking Screw, 4.5x46mm, CoCr	4
7206.1048	Locking Screw, 4.5x48mm, CoCr	4
7206.1050	Locking Screw, 4.5x50mm, CoCr	4
7206.1052	Locking Screw, 4.5x52mm, CoCr	4
7206.1054	Locking Screw, 4.5x54mm, CoCr	4
7206.1056	Locking Screw, 4.5x56mm, CoCr	4
7206.1058	Locking Screw, 4.5x58mm, CoCr	4
7206.1060	Locking Screw, 4.5x60mm, CoCr	4
7206.1062	Locking Screw, 4.5x62mm, CoCr	4
7206.1064	Locking Screw, 4.5x64mm, CoCr	4
7206.1066	Locking Screw, 4.5x66mm, CoCr	4
7206.1068	Locking Screw, 4.5x68mm, CoCr	4
7206.1070	Locking Screw, 4.5x70mm, CoCr	4
7206.1075	Locking Screw, 4.5x75mm, CoCr	6
7206.1080	Locking Screw, 4.5x80mm, CoCr	6
7206.1085	Locking Screw, 4.5x85mm, CoCr	6
7206.1090	Locking Screw, 4.5x90mm, CoCr	6
7206.1095	Locking Screw, 4.5x95mm, CoCr	6
7206.1100	Locking Screw, 4.5x100mm, CoCr	2
7206.1105	Locking Screw, 4.5x105mm, CoCr	2
7206.1110	Locking Screw, 4.5x110mm, CoCr	2

ANTHEM® Large Fragment
Titanium Screw Set 9206.9003

5.5mm Cancellous

Part No.	Description	Qty
1206.3050	Cancellous Screw, 5.5x50mm, Fully Threaded, Ti	2
1206.3055	Cancellous Screw, 5.5x55mm, Fully Threaded, Ti	2
1206.3060	Cancellous Screw, 5.5x60mm, Fully Threaded, Ti	2
1206.3065	Cancellous Screw, 5.5x65mm, Fully Threaded, Ti	2
1206.3070	Cancellous Screw, 5.5x70mm, Fully Threaded, Ti	2
1206.3075	Cancellous Screw, 5.5x75mm, Fully Threaded, Ti	2
1206.3080	Cancellous Screw, 5.5x80mm, Fully Threaded, Ti	2
1206.3085	Cancellous Screw, 5.5x85mm, Fully Threaded, Ti	2
1206.3090	Cancellous Screw, 5.5x90mm, Fully Threaded, Ti	2
1206.3095	Cancellous Screw, 5.5x95mm, Fully Threaded, Ti	2

Implants and Instruments

Part No.	Description	Qty
1206.0010	Washer, 12x5.5mm, Ti	6
6206.0060	Screw Forceps	1

4.5mm Blunt Tip Locking

Part No.	Description	Qty
7206.7008	Locking Screw, 4.5x8mm, Blunt Tip, CoCr	2
7206.7010	Locking Screw, 4.5x10mm, Blunt Tip, CoCr	2
7206.7012	Locking Screw, 4.5x12mm, Blunt Tip, CoCr	2
7206.7014	Locking Screw, 4.5x14mm, Blunt Tip, CoCr	2
7206.7016	Locking Screw, 4.5x16mm, Blunt Tip, CoCr	2
7206.7018	Locking Screw, 4.5x18mm, Blunt Tip, CoCr	2
7206.7020	Locking Screw, 4.5x20mm, Blunt Tip, CoCr	2

9206.0003	Large Fragment Ti Screw Graphic Case	

ANTHEM® Large Fragment
Stainless Steel Screw Set 9206.9004

4.5mm Non-Locking

Part No.	Description	Qty
2206.2020	Non-Locking Screw, 4.5x20mm, SS	4
2206.2022	Non-Locking Screw, 4.5x22mm, SS	4
2206.2024	Non-Locking Screw, 4.5x24mm, SS	4
2206.2026	Non-Locking Screw, 4.5x26mm, SS	4
2206.2028	Non-Locking Screw, 4.5x28mm, SS	4
2206.2030	Non-Locking Screw, 4.5x30mm, SS	4
2206.2032	Non-Locking Screw, 4.5x32mm, SS	4
2206.2034	Non-Locking Screw, 4.5x34mm, SS	4
2206.2036	Non-Locking Screw, 4.5x36mm, SS	4
2206.2038	Non-Locking Screw, 4.5x38mm, SS	4
2206.2040	Non-Locking Screw, 4.5x40mm, SS	4
2206.2042	Non-Locking Screw, 4.5x42mm, SS	4
2206.2044	Non-Locking Screw, 4.5x44mm, SS	4
2206.2046	Non-Locking Screw, 4.5x46mm, SS	4
2206.2048	Non-Locking Screw, 4.5x48mm, SS	4
2206.2050	Non-Locking Screw, 4.5x50mm, SS	2
2206.2052	Non-Locking Screw, 4.5x52mm, SS	2
2206.2054	Non-Locking Screw, 4.5x54mm, SS	2
2206.2056	Non-Locking Screw, 4.5x56mm, SS	2
2206.2058	Non-Locking Screw, 4.5x58mm, SS	2
2206.2060	Non-Locking Screw, 4.5x60mm, SS	2
2206.2062	Non-Locking Screw, 4.5x62mm, SS	2
2206.2064	Non-Locking Screw, 4.5x64mm, SS	2
2206.2066	Non-Locking Screw, 4.5x66mm, SS	2
2206.2068	Non-Locking Screw, 4.5x68mm, SS	2
2206.2070	Non-Locking Screw, 4.5x70mm, SS	2
2206.2075	Non-Locking Screw, 4.5x75mm, SS	2
2206.2080	Non-Locking Screw, 4.5x80mm, SS	2
2206.2085	Non-Locking Screw, 4.5x85mm, SS	2
2206.2090	Non-Locking Screw, 4.5x90mm, SS	2
2206.2095	Non-Locking Screw, 4.5x95mm, SS	2

4.5mm Locking

Part No.	Description	Qty
7206.1020	Locking Screw, 4.5x20mm, CoCr	4
7206.1022	Locking Screw, 4.5x22mm, CoCr	4
7206.1024	Locking Screw, 4.5x24mm, CoCr	4
7206.1026	Locking Screw, 4.5x26mm, CoCr	4
7206.1028	Locking Screw, 4.5x28mm, CoCr	4
7206.1030	Locking Screw, 4.5x30mm, CoCr	4
7206.1032	Locking Screw, 4.5x32mm, CoCr	4
7206.1034	Locking Screw, 4.5x34mm, CoCr	4
7206.1036	Locking Screw, 4.5x36mm, CoCr	4
7206.1038	Locking Screw, 4.5x38mm, CoCr	4
7206.1040	Locking Screw, 4.5x40mm, CoCr	4
7206.1042	Locking Screw, 4.5x42mm, CoCr	4
7206.1044	Locking Screw, 4.5x44mm, CoCr	4
7206.1046	Locking Screw, 4.5x46mm, CoCr	4
7206.1048	Locking Screw, 4.5x48mm, CoCr	4
7206.1050	Locking Screw, 4.5x50mm, CoCr	4
7206.1052	Locking Screw, 4.5x52mm, CoCr	4
7206.1054	Locking Screw, 4.5x54mm, CoCr	4
7206.1056	Locking Screw, 4.5x56mm, CoCr	4
7206.1058	Locking Screw, 4.5x58mm, CoCr	4
7206.1060	Locking Screw, 4.5x60mm, CoCr	4
7206.1062	Locking Screw, 4.5x62mm, CoCr	4
7206.1064	Locking Screw, 4.5x64mm, CoCr	4
7206.1066	Locking Screw, 4.5x66mm, CoCr	4
7206.1068	Locking Screw, 4.5x68mm, CoCr	4
7206.1070	Locking Screw, 4.5x70mm, CoCr	4
7206.1075	Locking Screw, 4.5x75mm, CoCr	6
7206.1080	Locking Screw, 4.5x80mm, CoCr	6
7206.1085	Locking Screw, 4.5x85mm, CoCr	6
7206.1090	Locking Screw, 4.5x90mm, CoCr	6
7206.1095	Locking Screw, 4.5x95mm, CoCr	6
7206.1100	Locking Screw, 4.5x100mm, CoCr	2
7206.1105	Locking Screw, 4.5x105mm, CoCr	2
7206.1110	Locking Screw, 4.5x110mm, CoCr	2

ANTHEM® Large Fragment
Stainless Steel Screw Set 9206.9004

5.5mm Cancellous

Part No.	Description	Qty
2206.3050	Cancellous Screw, 5.5x50mm, Fully Threaded, SS	2
2206.3055	Cancellous Screw, 5.5x55mm, Fully Threaded, SS	2
2206.3060	Cancellous Screw, 5.5x60mm, Fully Threaded, SS	2
2206.3065	Cancellous Screw, 5.5x65mm, Fully Threaded, SS	2
2206.3070	Cancellous Screw, 5.5x70mm, Fully Threaded, SS	2
2206.3075	Cancellous Screw, 5.5x75mm, Fully Threaded, SS	2
2206.3080	Cancellous Screw, 5.5x80mm, Fully Threaded, SS	2
2206.3085	Cancellous Screw, 5.5x85mm, Fully Threaded, SS	2
2206.3090	Cancellous Screw, 5.5x90mm, Fully Threaded, SS	2
2206.3095	Cancellous Screw, 5.5x95mm, Fully Threaded, SS	2

4.5mm Blunt Tip Locking

Part No.	Description	Qty
7206.7008	Locking Screw, 4.5x8mm, Blunt Tip, CoCr	2
7206.7010	Locking Screw, 4.5x10mm, Blunt Tip, CoCr	2
7206.7012	Locking Screw, 4.5x12mm, Blunt Tip, CoCr	2
7206.7014	Locking Screw, 4.5x14mm, Blunt Tip, CoCr	2
7206.7016	Locking Screw, 4.5x16mm, Blunt Tip, CoCr	2
7206.7018	Locking Screw, 4.5x18mm, Blunt Tip, CoCr	2
7206.7020	Locking Screw, 4.5x20mm, Blunt Tip, CoCr	2

Implants and Instruments

Part No.	Description	Qty
2206.0010	Washer, 12x5.5mm, SS	6
6206.0060	Screw Forceps	1
9206.0004	Large Fragment SS Screw Graphic Case	

ANTHEM® Large Fragment
Instrument Set 9206.9005

Part No.	Description	Qty
6171.0002	Stabilizing Radiolucent Weitlaner 3x4, 8”, Sharp Tip	1
6173.0110	Combination Wrench	1
6179.1113	1.25mm K-Wire, Trocar Tip, 150mm	10
6179.1116	1.6mm K-Wire, Trocar Tip, 150mm	10
6179.7001	Inline Handle, AO Quick-Connect, Fixed	1
6206.0025	Torque-Limiting Attachment, 3.5Nm, AO Quick-Connect	1
6206.0030	Depth Gauge	1
6206.0040	Countersink, 4.5 and 5.5mm Screws	1
6206.0045	Plate Reduction Device	2
6206.1025	K-Wire, 2.5x200mm, Trocar Tip	5
6206.1525	K-Wire, 2.5x200mm, Drill Tip	5
6206.2707	T-Handle, AO Quick-Connect, Limiting 7Nm	1
6206.3001	4.5/3.4mm Drill Guide	1
6206.3002	5.5/3.4mm Drill Guide	1
6206.3005	3.4mm Polyaxial Drill Guide	1
6206.3007	3.4mm Speed Lock Drill Guide	1
6206.4001	Large Hohmann Retractor, Standard	2
6206.4003	Large Hohmann Retractor, Narrow	2
6206.5034	Drill, 3.4x245mm, 150mm Calibration, AO Quick-Connect	2
6206.5234	Drill, 3.4x185mm, 90mm Calibration, AO Quick-Connect	2
6206.5445	Drill, 4.5x195mm, AO Quick-Connect	2
6206.5455	Drill, 5.5x195mm, AO Quick-Connect	2
6206.6125	T25 Driver, SR, 150mm, AO Quick-Connect	2
6206.6225	T25 Driver, NSR, 150mm, AO Quick-Connect	1
6206.7045	Tap, 4.5x195mm, AO Quick-Connect	1
6206.7055	Tap, 5.5x195mm, AO Quick-Connect	1
9206.0005	Large Fragment Instrument Graphic Case	

ANTHEM® Large Fragment
Titanium Cannulated Cancellous Screw Module 9206.9006

Part No.	Description	Qty
1206.6040	Cannulated Cancellous Screw, 5.5x40mm, Fully Threaded, Ti	2
1206.6045	Cannulated Cancellous Screw, 5.5x45mm, Fully Threaded, Ti	2
1206.6050	Cannulated Cancellous Screw, 5.5x50mm, Fully Threaded, Ti	2
1206.6055	Cannulated Cancellous Screw, 5.5x55mm, Fully Threaded, Ti	2
1206.6060	Cannulated Cancellous Screw, 5.5x60mm, Fully Threaded, Ti	2
1206.6065	Cannulated Cancellous Screw, 5.5x65mm, Fully Threaded, Ti	2
1206.6070	Cannulated Cancellous Screw, 5.5x70mm, Fully Threaded, Ti	2
1206.6075	Cannulated Cancellous Screw, 5.5x75mm, Fully Threaded, Ti	2
1206.6080	Cannulated Cancellous Screw, 5.5x80mm, Fully Threaded, Ti	2
1206.6085	Cannulated Cancellous Screw, 5.5x85mm, Fully Threaded, Ti	2
1206.6090	Cannulated Cancellous Screw, 5.5x90mm, Fully Threaded, Ti	2
1206.6095	Cannulated Cancellous Screw, 5.5x95mm, Fully Threaded, Ti	2

9206.0006	ANTHEM® Large Fragment Cannulated Ti Screw Module

ANTHEM® Large Fragment
Stainless Steel Cannulated Cancellous Screw Module 9206.9007

Part No.	Description	Qty
2206.6040	Cannulated Cancellous Screw, 5.5x40mm, Fully Threaded, SS	2
2206.6045	Cannulated Cancellous Screw, 5.5x45mm, Fully Threaded, SS	2
2206.6050	Cannulated Cancellous Screw, 5.5x50mm, Fully Threaded, SS	2
2206.6055	Cannulated Cancellous Screw, 5.5x55mm, Fully Threaded, SS	2
2206.6060	Cannulated Cancellous Screw, 5.5x60mm, Fully Threaded, SS	2
2206.6065	Cannulated Cancellous Screw, 5.5x65mm, Fully Threaded, SS	2
2206.6070	Cannulated Cancellous Screw, 5.5x70mm, Fully Threaded, SS	2
2206.6075	Cannulated Cancellous Screw, 5.5x75mm, Fully Threaded, SS	2
2206.6080	Cannulated Cancellous Screw, 5.5x80mm, Fully Threaded, SS	2
2206.6085	Cannulated Cancellous Screw, 5.5x85mm, Fully Threaded, SS	2
2206.6090	Cannulated Cancellous Screw, 5.5x90mm, Fully Threaded, SS	2
2206.6095	Cannulated Cancellous Screw, 5.5x95mm, Fully Threaded, SS	2

9206.0007	ANTHEM® Large Fragment Cannulated SS Screw Module

ANTHEM® Large Fragment
Cannulated Locking Screw Module 9206.9008

Part No.	Description	Qty
7206.5035	Cannulated Locking Screw, 4.5x35mm, CoCr	2
7206.5040	Cannulated Locking Screw, 4.5x40mm, CoCr	2
7206.5045	Cannulated Locking Screw, 4.5x45mm, CoCr	2
7206.5050	Cannulated Locking Screw, 4.5x50mm, CoCr	2
7206.5055	Cannulated Locking Screw, 4.5x55mm, CoCr	4
7206.5060	Cannulated Locking Screw, 4.5x60mm, CoCr	4
7206.5065	Cannulated Locking Screw, 4.5x65mm, CoCr	4
7206.5070	Cannulated Locking Screw, 4.5x70mm, CoCr	4
7206.5075	Cannulated Locking Screw, 4.5x75mm, CoCr	4
7206.5080	Cannulated Locking Screw, 4.5x80mm, CoCr	4
7206.5085	Cannulated Locking Screw, 4.5x85mm, CoCr	4
7206.5090	Cannulated Locking Screw, 4.5x90mm, CoCr	4
7206.5095	Cannulated Locking Screw, 4.5x95mm, CoCr	4
7206.5100	Cannulated Locking Screw, 4.5x100mm, CoCr	2
7206.5105	Cannulated Locking Screw, 4.5x105mm, CoCr	2
7206.5110	Cannulated Locking Screw, 4.5x110mm, CoCr	2

9206.0008	ANTHEM® Large Fragment Cannulated Locking Screw Module

ANTHEM® Large Fragment
Cannulated Instrument Set 9206.9009

Part No.	Description	Qty
6206.0020	Torque-Limiting Attachment, 3.5Nm, Hall Quick-Connect, Cannulated	1
6206.0035	Guide Wire Direct Measuring Device	1
6206.1118	Guide Wire, 1.8x200mm, Trocar Tip	10
6206.1618	Guide Wire, 1.8x200mm, Drill Tip	10
6206.2300	Inline Handle, Hall Quick-Connect, Fixed	1
6206.3008	1.8mm Polyaxial Wire Guide	1
6206.5536	Drill, 3.6x245mm, Cannulated, Quick-Connect	2
6206.5555	Drill, 5.5x195mm, Cannulated, Quick-Connect	2
6206.6425	T25 Driver, NSR, 150mm, Cannulated, Hall Quick-Connect	2
9206.0009	ANTHEM® Large Fragment Cannulated Screw Instrument Graphic Case	

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. Distal femur plates are indicated for diaphyseal, metaphyseal, epiphyseal, supracondylar, intra-articular, extra-articular, condylar, periprosthetic, and comminuted fractures, and for non-unions and malunions. 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 to adult patients, 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 femur plates are indicated for use in the diaphyseal and metaphyseal areas of long bones in adolescent pediatric patients. 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.

IMPORTANT INFORMATION ON THE ANTHEM® FRACTURE SYSTEM

- 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.
- 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		

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NOTES

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