ANTHEM®

Distal Radius Fracture System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

ANTHEM®

Distal Radius Fracture System

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The ANTHEM® Distal Radius Fracture System is a comprehensive fixation system designed to treat a wide variety of wrist fractures with anatomically contoured plates for intraoperative versatility. Market-leading polyaxial locking technology allows for ±20° of angulation (40° cone) in polyaxial volar, fragment specific, and diaphyseal metaphyseal plates. MonoAx® locking technology enables a thin volar plate design to facilitate distal plate placement in the treatment of complex, intra-articular fractures. Innovative instruments allow for secure retraction and streamlined plate positioning, drilling, and screw insertion.

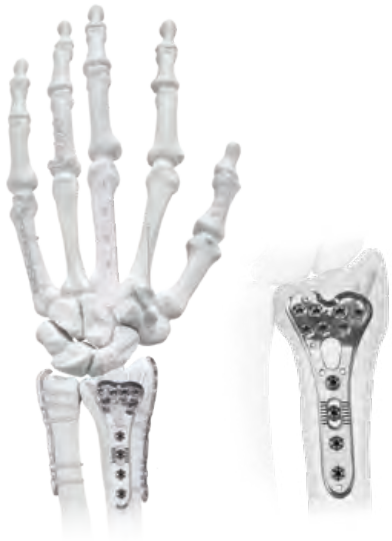
ANTHEM® II Double Row Volar Plate

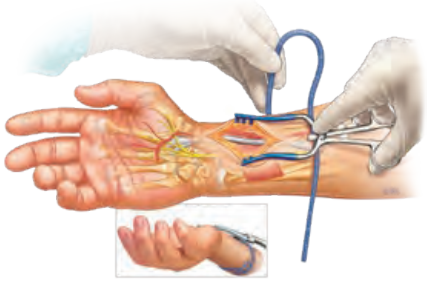
ANTHEM® II 7 Volar Plate

ANTHEM® II MonoAx® Volar Plate

Comprehensive Plate Offering

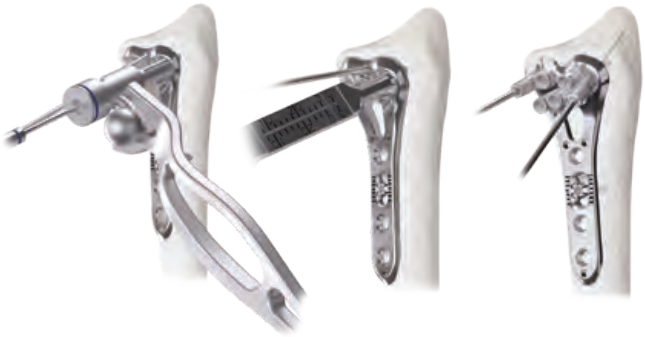
- A comprehensive system with implants to address a wide variety of wrist fractures
  - ANTHEM® Double Row Volar Plate
  - ANTHEM® 7 Volar Plate
  - ANTHEM® II Double Row Volar Plate
  - ANTHEM® II 7 Volar Plate
  - ANTHEM® II MonoAx® Plate
  - ANTHEM® II Diaphyseal Meataphyseal Volar Plate
  - Bridge Plate
  - Dorsal Plates (Acute, Oblique)
  - Lateral Plate (Radial Styloid)
  - Lunate Facet Hook
  - Scalloped Plate
  - Ulna Plate
- Offered in stainless steel or titanium alloy





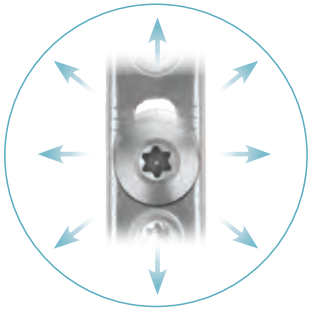
Unique Instruments

- One drill and driver to streamline procedure
- Stabilizing Radiolucent Weitlaner designed for secure retraction during the procedure
- Speed Lock Drill Guide quickly and rigidly attaches to polyaxial plates without threading
- Calibrated drill bits allow for streamlined procedural flow
- MonoAx® Threaded Drill Guides and K-Wire Sleeves to help confirm screw trajectories prior to insertion in MonoAx® plates



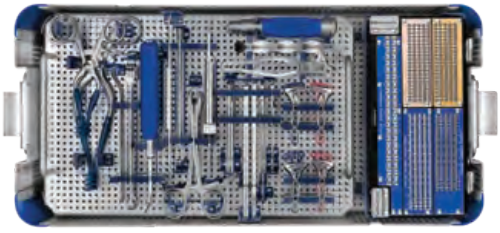
Positioning Slot and Screw

- Allows multidirectional fine-tuning of plate position
- Accepts 2.5mm Positioning Screw and 2.5mm Non-Locking Screw



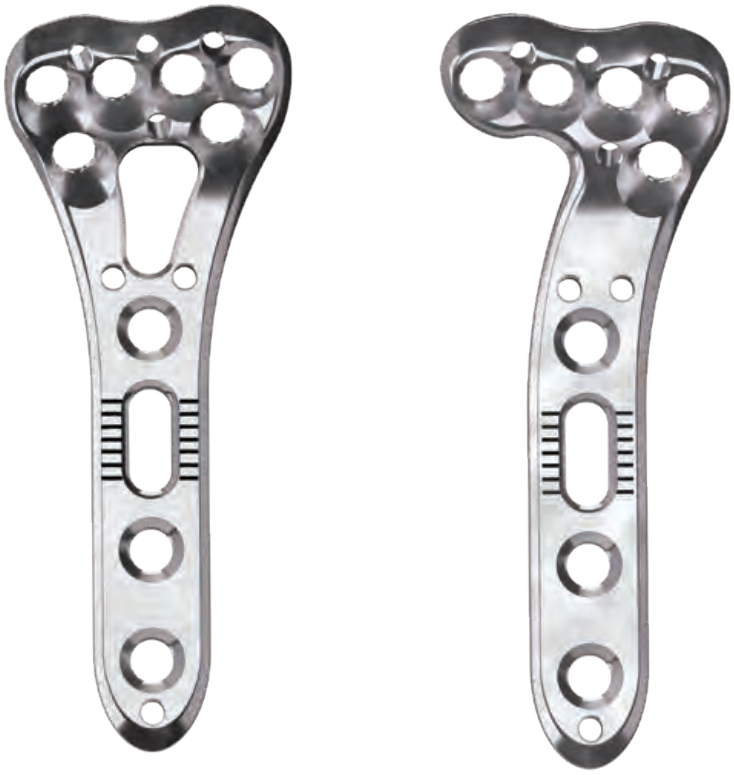
Ideal Case Flow

- Graphic case trays are designed for an ideal procedural flow
- Modular graphic case design allows for customization based on surgeon preference and fracture pattern



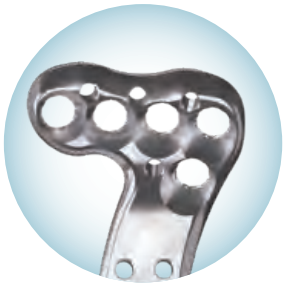
ANTHEM® II Polyaxial Volar Plates

Anatomic polyaxial plates feature ±20° of angulation (40° cone). Double row plates feature an additional screw hole to maximize buttressing, compared to the ANTHEM® 7 Volar plate that allows for fracture site visibility.



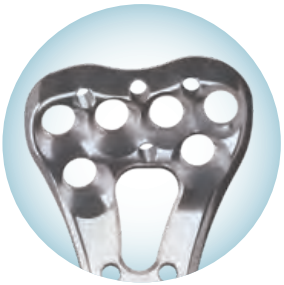
Polyaxial Locking

Locking screws allow for ±20° of angulation (40° cone)



Innovative Design

7 Volar Plate allows clear view of fracture line



Maximized Buttressing

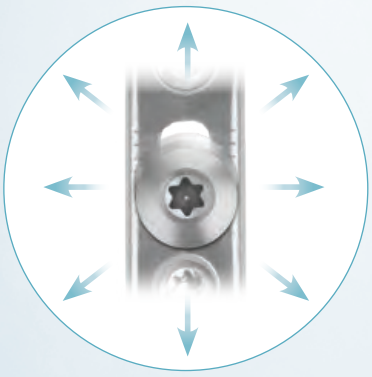
Double Row Plate has additional screw hole and graft hole

K-Wire Hole Trajectories

K-wire holes are parallel to distal screw trajectories

Positioning Slot and Screw

Allows multidirectional fine-tuning of plate position

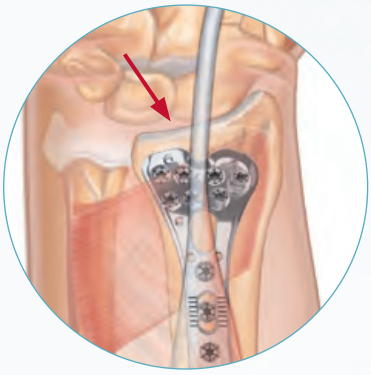


ANTHEM® II MonoAx® Volar Plate

Anatomic monoaxial plate is designed for distal placement to buttress intra-articular fracture fragments

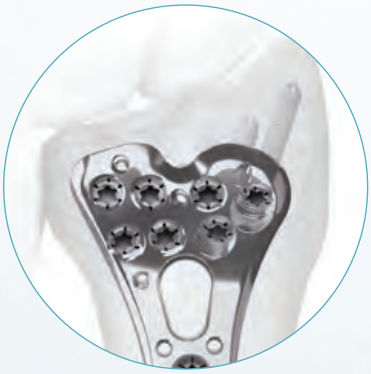
FPL Groove

Designed to help minimize flexor tendon irritation



Radial Styloid

Screw trajectory designed for maximized purchase



MonoAx® Locking

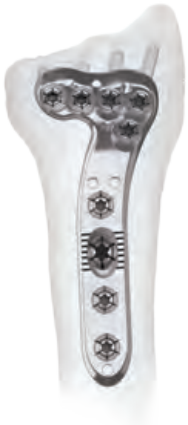
Monoaxial locking technology allows for precise targeting of fragments

Distal Plate Placement

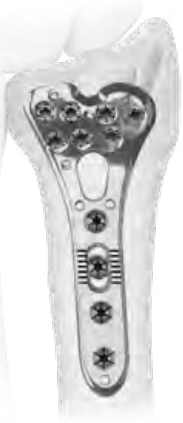
Thin design facilitates distal placement to buttress intra-articular fragments

Comprehensive Plate Portfolio

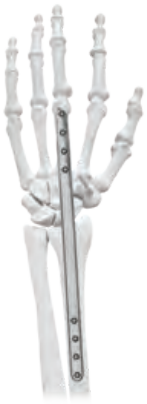
ANTHEM® II Double Row Volar Plate



ANTHEM® II 7 Volar Plate



ANTHEM® II MonoAx® Volar Plate



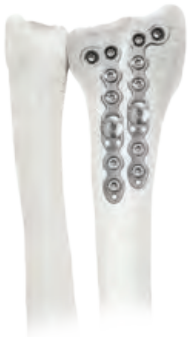
Bridge Plate

Lateral Plate

Ulna Plate

ANTHEM® II Diaphyseal Metaphyseal Volar Plate

Lunate Facet Hook Plate



Dorsal Plates

Scalloped Plate

IMPLANT OVERVIEW

ANTHEM® Double Row Volar Plates

- Polyaxial holes allow for ±20° angulation (40° cone)
- Double Row Volar Plate aids in buttressing
- Plate contour accommodates anatomies with a significant volar tilt

ANTHEM® II Polyaxial Volar Plates

- Polyaxial holes allow for ±20° angulation (40° cone)
- FPL groove in the head of the plate designed to help minimize flexor tendon irritation
- 7 Plate designed for visibility of the intermediate column
- Double Row Volar Plate features an additional screw hole compared to the ANTHEM® II 7 Plate for maximized buttressing
- Reduced volar tilt compared to ANTHEM® volar plates to accommodate a wide range of patient anatomies

MonoAx® Volar Plates

- Thin MonoAx® plate design facilitates distal placement to buttress intra-articular fragments
- FPL groove in the head of the plate designed to help minimize flexor tendon irritation

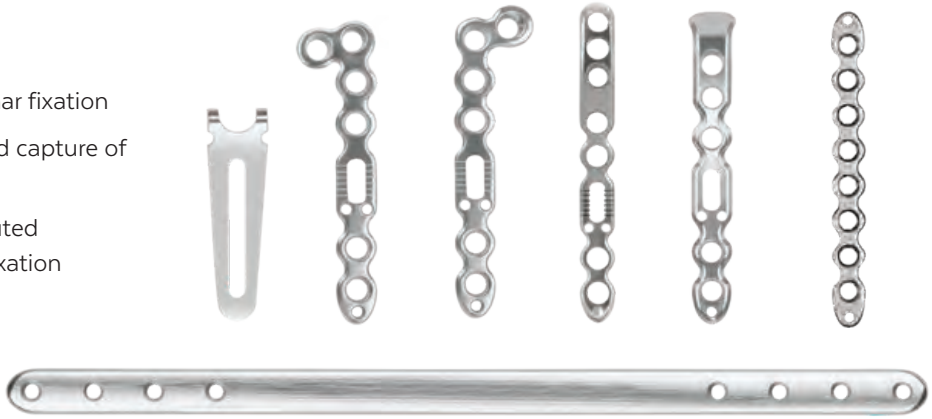
IMPLANT OVERVIEW

ANTHEM® II Diaphyseal Metaphyseal Volar Plates

- Long plates to aid in treatment of fractures of the distal radius that extend into the radial shaft
- Polyaxial holes allow for ±20° angulation (40° cone)
- FPL groove in the head of the plate designed to help minimize flexor tendon irritation
- Side cuts in the shaft allow for plate bending
- Anatomic bow and twist to accommodate radial shaft anatomy
- Unique limited contact underside to help support healing of periosteum
- Plate head accepts 2.5mm screws and plate shaft accepts 3.5mm screws

Fragment Specific Plates

- Included in set for radial, dorsal, and ulnar fixation
- Lunate facet hooks to aid in support and capture of lunate facet fragments
- Bridge plates are designed for comminuted fractures, as an alternative to external fixation



Screws

- 1.8mm Locking Peg
- 2.0mm Locking Screw
- 2.5mm Locking Screw
- 2.5mm Non-Locking Screw
- 2.5mm Positioning Screw

Locking Peg | Locking Screws | Non-Locking Screw | Positioning Screw

SCREW COMPATIBILITY

If screw/plate locking is desired in a Polyaxial Locking Hole, only use locking screws. MonoAx® Locking Screws may not be used in a Polyaxial Locking Hole.

2.5mm Polyaxial Locking Holes	
1.8mm Locking Peg	
2.0mm Locking Screw	
2.5mm Locking Screw	
2.5mm Non-Locking Screw	

2.5mm MonoAx® Locking Holes	
1.8mm Locking Peg	
2.0mm Locking Screw	
2.5mm Locking Screw	
2.5mm Non-Locking Screw	

2.5mm Positioning Hole	
2.5mm Non-Locking Screw	
2.5mm Positioning Screw	

2.5mm Slot	
2.5mm Locking Screw	
2.5mm Non-Locking Screw	

3.5mm Polyaxial Locking Holes	
3.5mm Locking Screw	
3.5mm Non-Locking Screw	

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

● 2.5mm Polyaxial Locking Holes ● 2.5mm MonoAx® Locking Holes ● 2.5mm Positioning Holes
● 2.5mm Slot ● 3.5mm Polyaxial Locking Holes ● 3.5mm Non-Locking Slots

SCREW INSERTION WITH 1.2Nm TORQUE-LIMITER

The 1.2Nm Torque-Limiting Device or 1.2Nm Torque-Limiting Handle may be used to insert locking screws under power or in dense bone to help ensure proper tightening torque is not exceeded. Attach the T8 Driver to the 1.2Nm Torque-Limiter. If inserting under power, use the Torque-Limiting Device to insert the locking screw until the maximum torque has been reached and an audible click is heard. Perform final tightening manually with the Torque-Limiting Handle and T8 Driver.

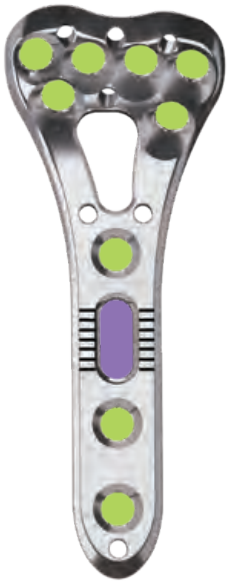
SCREW COMPATIBILITY

ANTHEM® II 7 Polyaxial Volar Plate

ANTHEM® II MonoAx® Volar Plate

ANTHEM® Double Row Polyaxial Volar Plate

ANTHEM® II Double Row Polyaxial Volar Plate



● 2.5mm Polyaxial Locking Holes ● 2.5mm MonoAx® Locking Holes ● 2.5mm Positioning Holes
● 2.5mm Slot ● 3.5mm Polyaxial Locking Holes ● 3.5mm Non-Locking Slots

SCREW COMPATIBILITY

If screw/plate locking is desired in a Polyaxial Locking Hole, only use locking screws. MonoAx® Locking Screws may not be used in a Polyaxial Locking Hole.

ANTHEM® II Diaphyseal Metaphyseal Volar Plate

● 2.5mm Polyaxial Locking Holes ● 2.5mm MonoAx® Locking Holes ● 2.5mm Positioning Holes
● 2.5mm Slot ● 3.5mm Polyaxial Locking Holes ● 3.5mm Non-Locking Slots

SCREW COMPATIBILITY

If screw/plate locking is desired in a Polyaxial Locking Hole, only use locking screws. MonoAx® Locking Screws may not be used in a Polyaxial Locking Hole.

Lateral Plate

Dorsal Plates

Ulna Plate

Lunate Facet Hook Plate

● 2.5mm Polyaxial Locking Holes ● 2.5mm MonoAx® Locking Holes ● 2.5mm Positioning Holes
● 2.5mm Slot ● 3.5mm Polyaxial Locking Holes ● 3.5mm Non-Locking Slots

SCREW COMPATIBILITY

If screw/plate locking is desired in a Polyaxial Locking Hole, only use locking screws. MonoAx® Locking Screws may not be used in a Polyaxial Locking Hole.

Bridge Plates

Scalloped Plates

● 2.5mm Polyaxial Locking Holes ● 2.5mm MonoAx® Locking Holes ● 2.5mm Positioning Holes
● 2.5mm Slot ● 3.5mm Polyaxial Locking Holes ● 3.5mm Non-Locking Slots

SURGICAL TECHNIQUE

ANTHEM®

Volar Plating

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

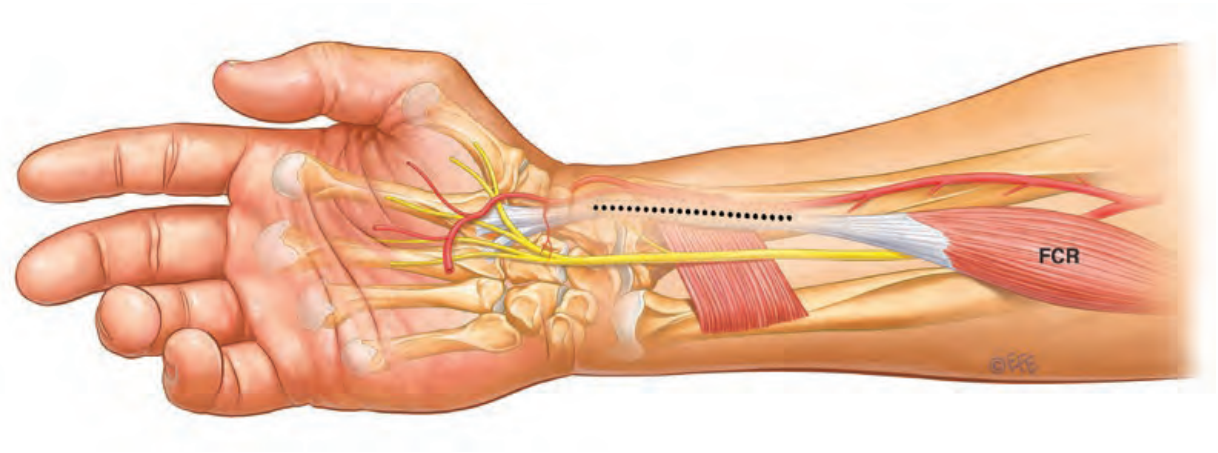
STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs. Estimate the appropriate length and location of screws to ensure proper selection of plate type, plate position, and screw placement.

STEP 2 APPROACH

The patient's arm is placed in the supine position.

Create an incision over the flexor carpi radialis (FCR) tendon using the FCR approach.



If necessary to cross the wrist, the incision should cross obliquely.

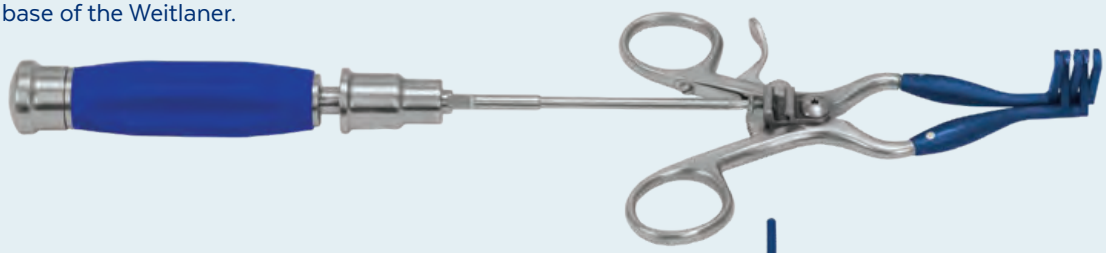
ASSEMBLY OF THE STABILIZING RADIOLUCENT WEITLANER

The Malleable Band provides intraoperative stability to the Weitlaner. Radiolucent arms eliminate the need for removal during fluoroscopy.

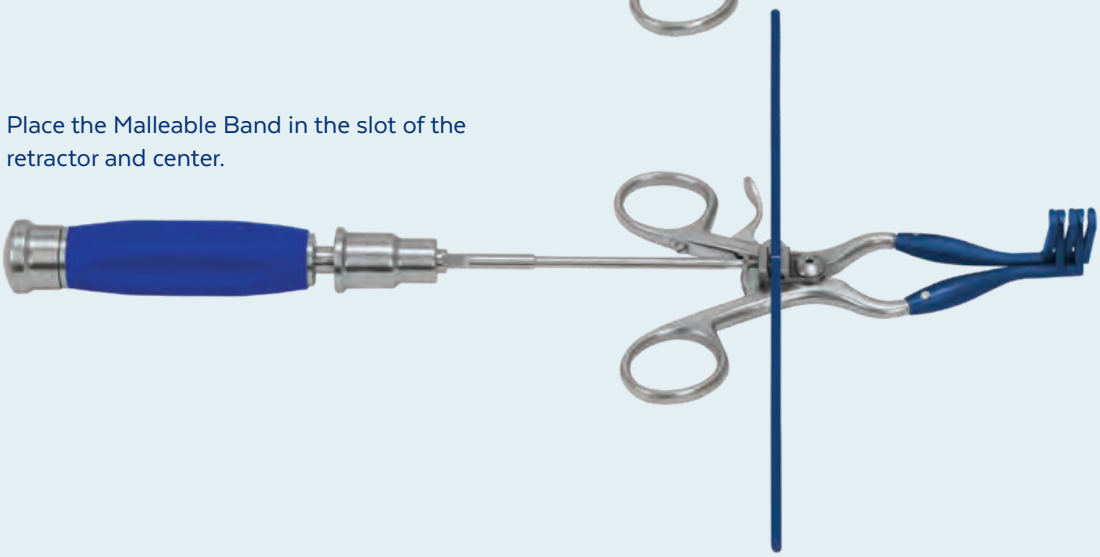
Instruments: T8 Driver, Malleable Band, Stabilizing Weitlaner, and Quick-Connect Handle

To attach the T8 Driver to the Quick-Connect Handle, pull the base of the handle towards the silicone end and insert the quick-connection end of the T8 Driver into the handle. Release the base of the handle and listen for an audible click when properly locked into place.

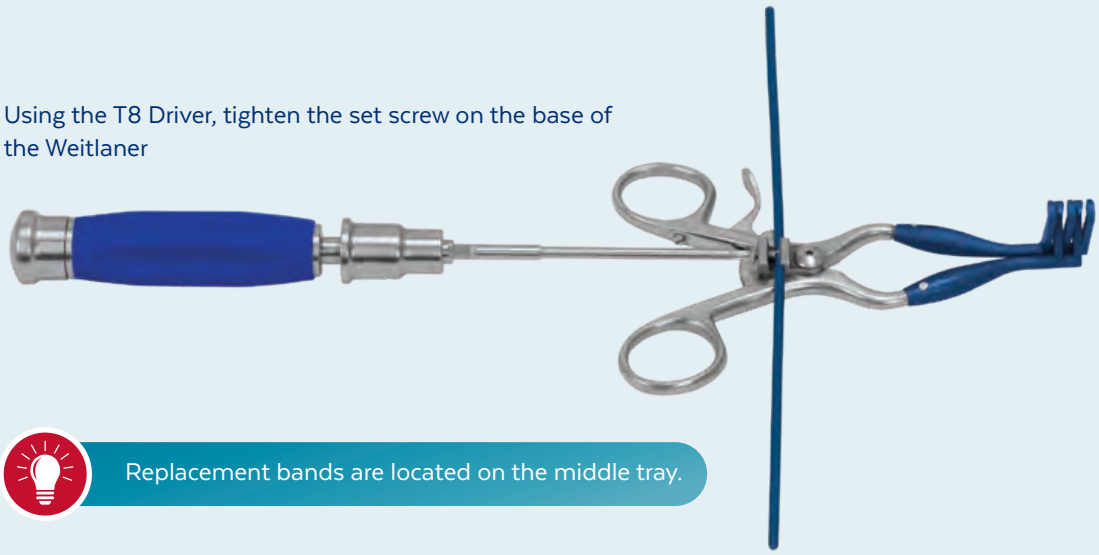
Using the T8 Driver, loosen the set screw on the base of the Weitlaner.



Place the Malleable Band in the slot of the retractor and center.



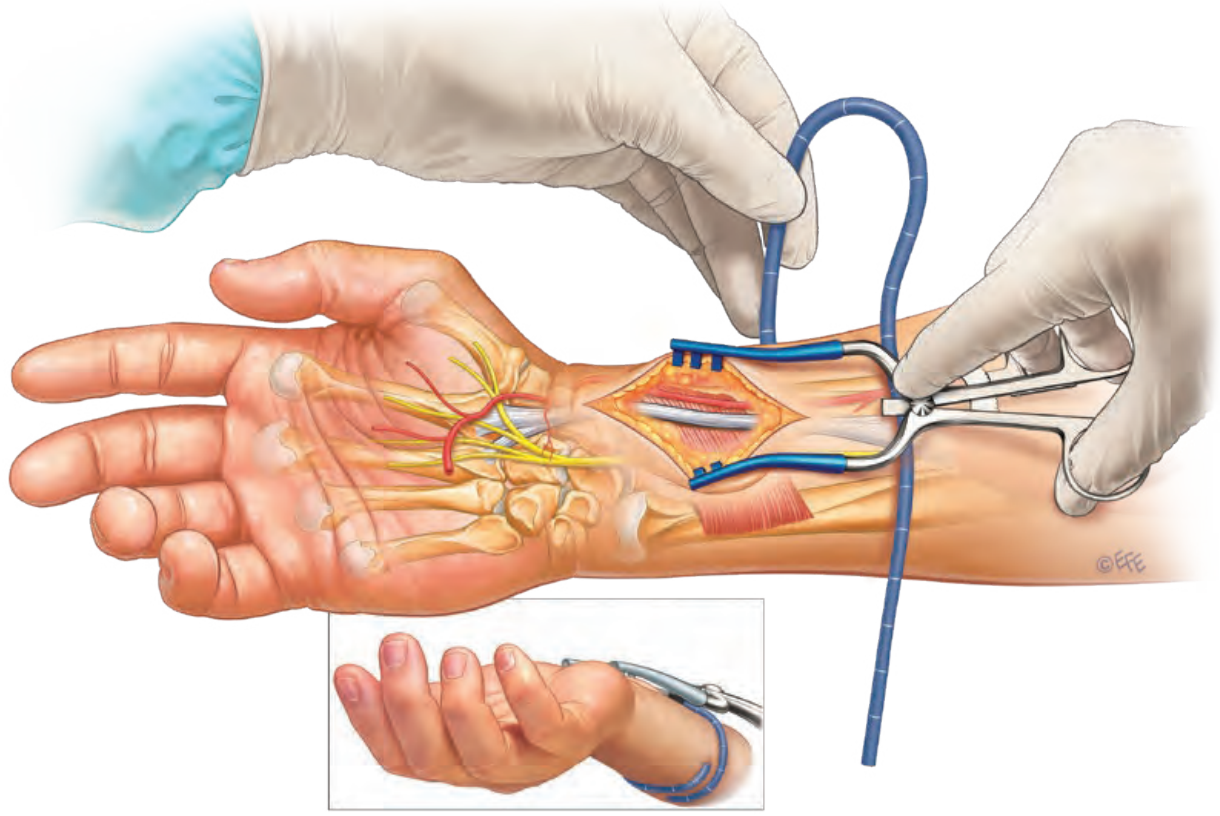
Using the T8 Driver, tighten the set screw on the base of the Weitlaner

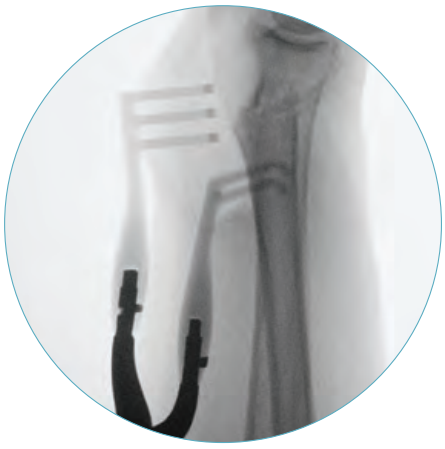


Replacement bands are located on the middle tray.

STEP 3 RETRACTION

Position the Stabilizing Radiolucent Weitlaner and retract. Wrap the Malleable Band around the patient's arm to secure the Weitlaner.



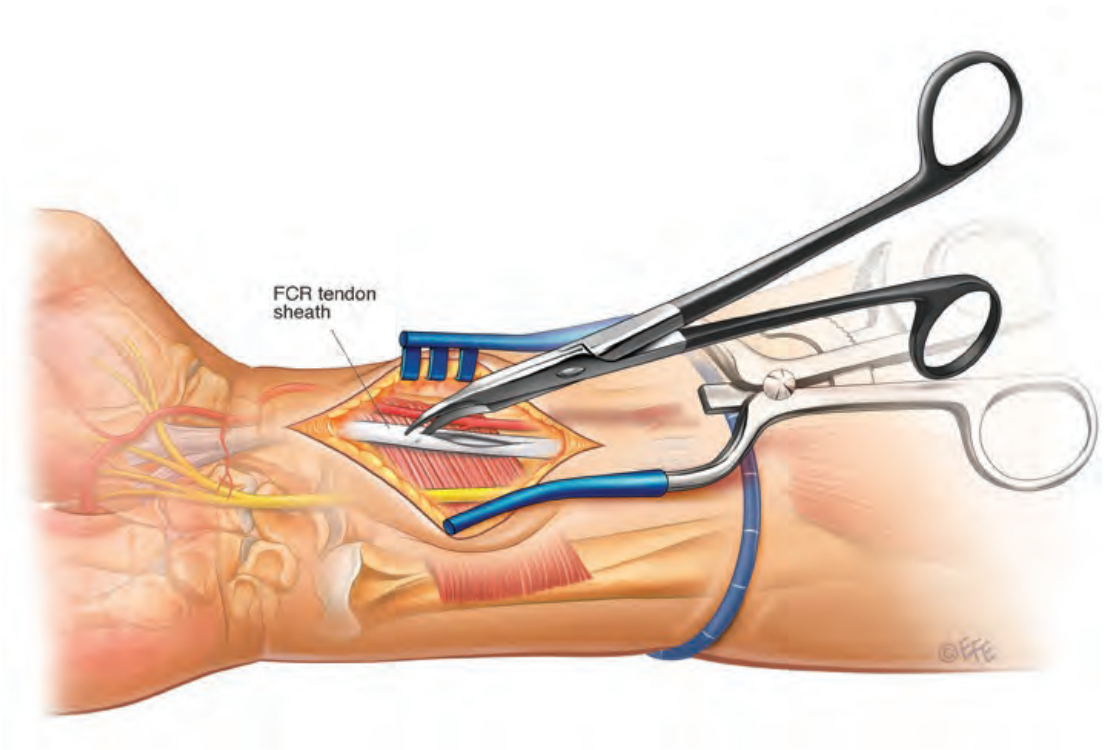


STEP 4 DISSECTION

Three levels of dissection are used to access the radius: superficial, mid-level, and deep.

Superficial Dissection

Blunt dissection is used to access the FCR tendon. The FCR sheath is opened sharply.

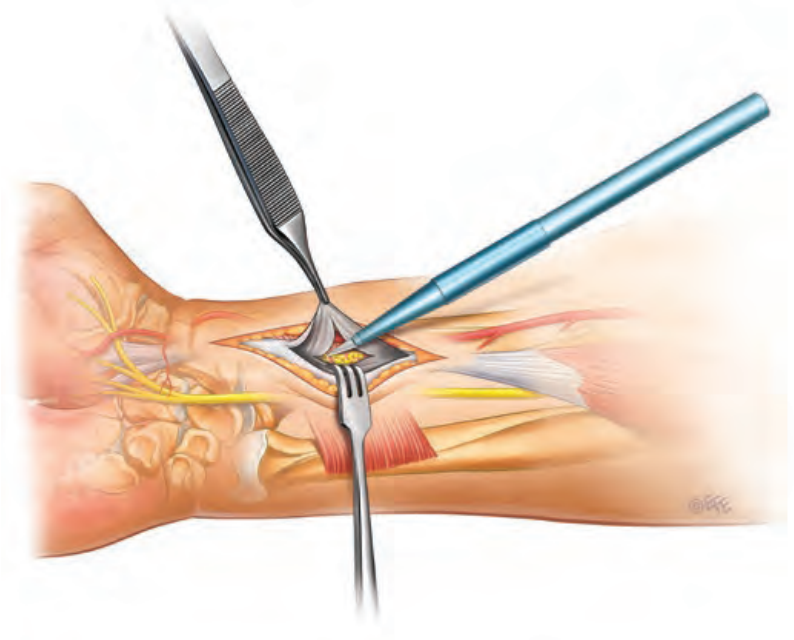


Carefully avoid any aberrant branches of the palmar cutaneous branch of the median nerve crossing the FCR tendon sheath.

DISSECTION (CONT'D)

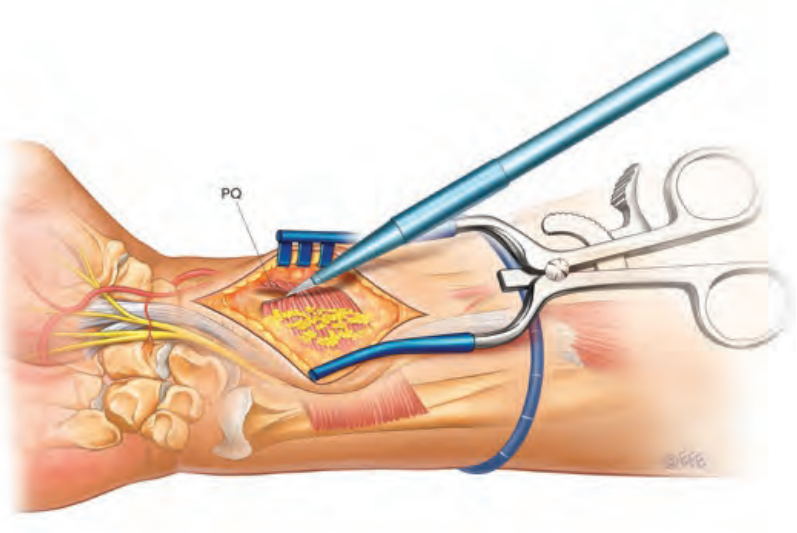
Mid-Level Dissection

With the FCR tendon retracted, the floor of the tendon sheath is exposed and released sharply to reveal the deep volar compartment.



Deep Dissection

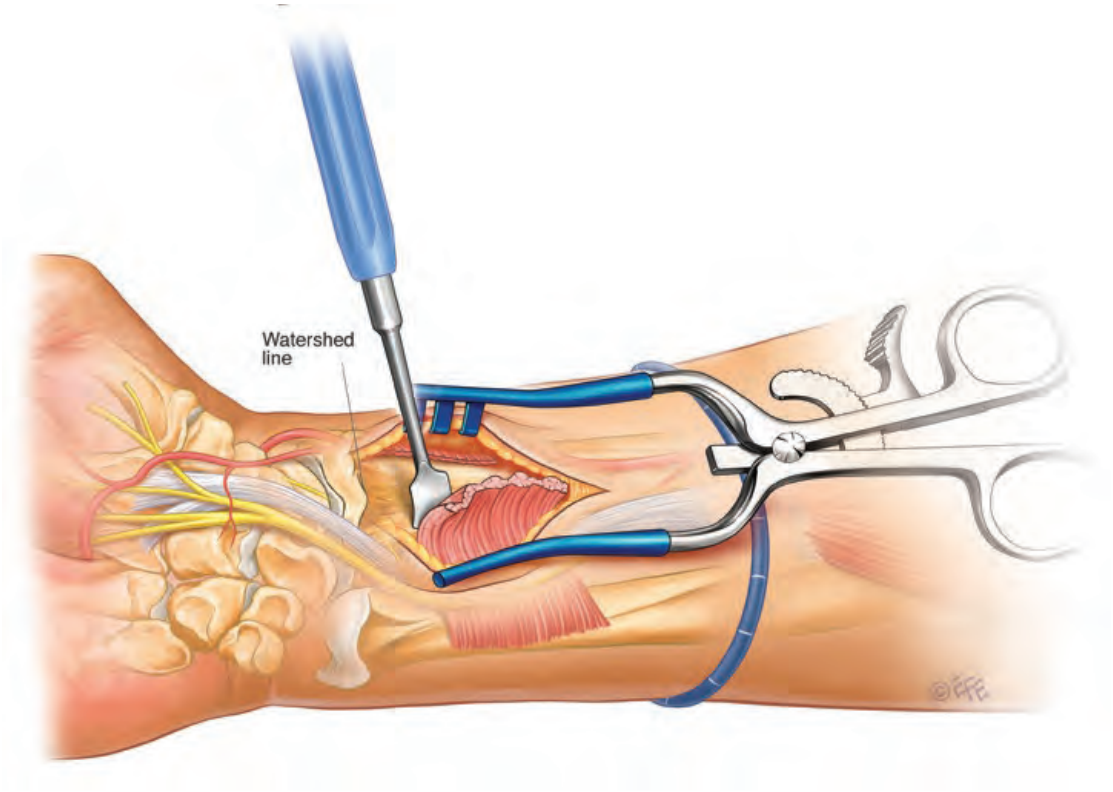
The plane between the flexor tendons and the pronator quadratus (PQ) muscle is bluntly developed. A loose fat pad may be encountered and excised. All flexor tendons, including the FCR tendon, should be retracted ulnarly and the radial artery retracted radially.



Exposure may be increased by releasing the FCR tendon sheath floor distally.

Exposing the Fracture

The PQ muscle is released sharply across the radial border of the distal radius. Using the **Distal Radius Periosteal Elevator**, move the PQ muscle transversely, proximal to the watershed line.



Any remaining PQ muscle distal to the fracture line may be debrided away to improve visibility of the fracture line.

STEP 5 FRACTURE REDUCTION

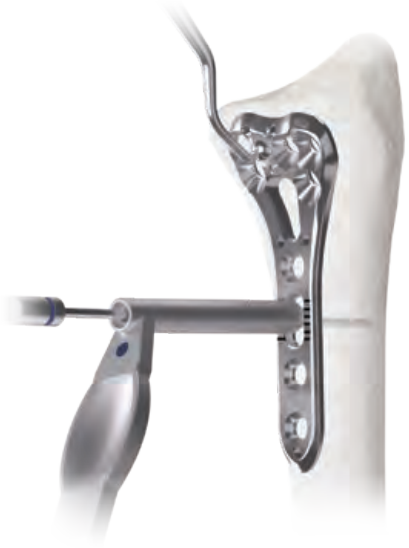
Using fluoroscopy, reduce the fracture using the appropriate method for the fracture type. Ensure the radial length, alignment, and rotation are properly restored. Confirm reduction using fluoroscopy. K-wires may be used for temporary fixation.

STEP 6 PLATE APPLICATION

Select the plate that best accommodates the fracture pattern and patient anatomy. Using the **Plate Positioning Tool**, position the plate 2mm proximal to the watershed line on the radius.

Plate positon relative to watershed line

Using the **1.8mm Drill Bit** and selected **1.8mm Polyaxial Soft Tissue Protector**, drill a hole through the center of the positioning slot.



Drilling through fixed angle end of 1.8mm Polyaxial Soft Tissue Protector into positioning slot

Measure hole depth using the calibrations on the drill bit or remove the drill guide and insert the **Depth Gauge** into the hole to determine the screw length

Depth Gauge

Use the T8 Driver to select the desired 2.5mm Positioning Screw or 2.5mm Non-Locking Screw. Use the Measuring Gauge in the screw caddy to verify length.

Insert the screw into the drilled hole using the T8 Driver. Verify plate placement using fluoroscopy. If using a 2.5mm Positioning Screw, adjust the plate proximal-distal or medial-lateral to the desired position. If using a 2.5mm Non-Locking Screw, adjust the plate proximal-distal to the desired position. Tighten the screw using the T8 Driver and Quick-Connect Handle. Once the plate is in an acceptable position, the plate may be fixed definitively using additional shaft screws or provisionally held with K-wires through K-wire holes in the plate.

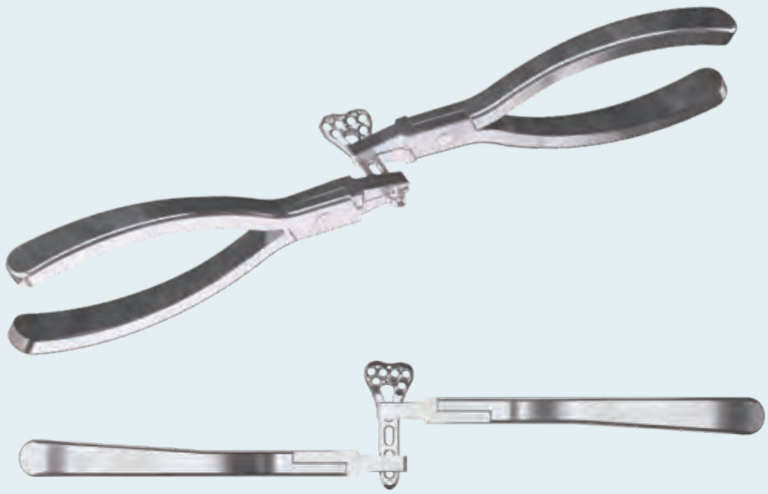
Avoid over-penetration of drills and screws during screw insertion.

BENDING AND CUTTING INSTRUMENTS

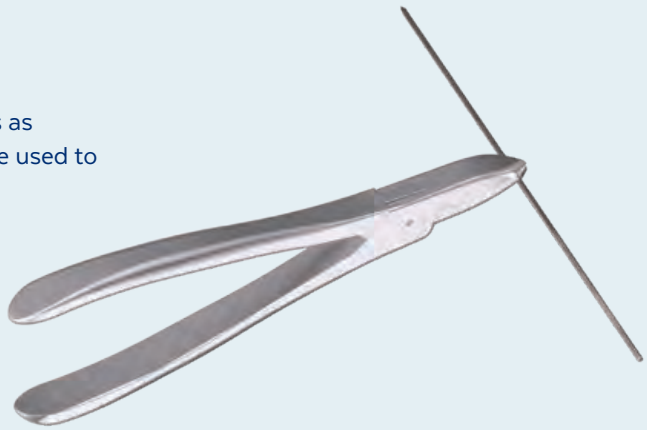
Plate bending may be necessary based on patient anatomy. Using **Plate Bending Pliers**, contour the plate as needed.

Note: Avoid excessive bending, over-contouring, bending and unbending, reverse bending, and bending directly over screw holes, which may compromise plate strength or screw locking, resulting in construct failure.

Plate Bending Pliers assist in out-of-plane and rotational bending.



Wire Bending Pliers may be used to bend K-wires as needed. The side cut in the jaw of the pliers can be used to cut K-wires.

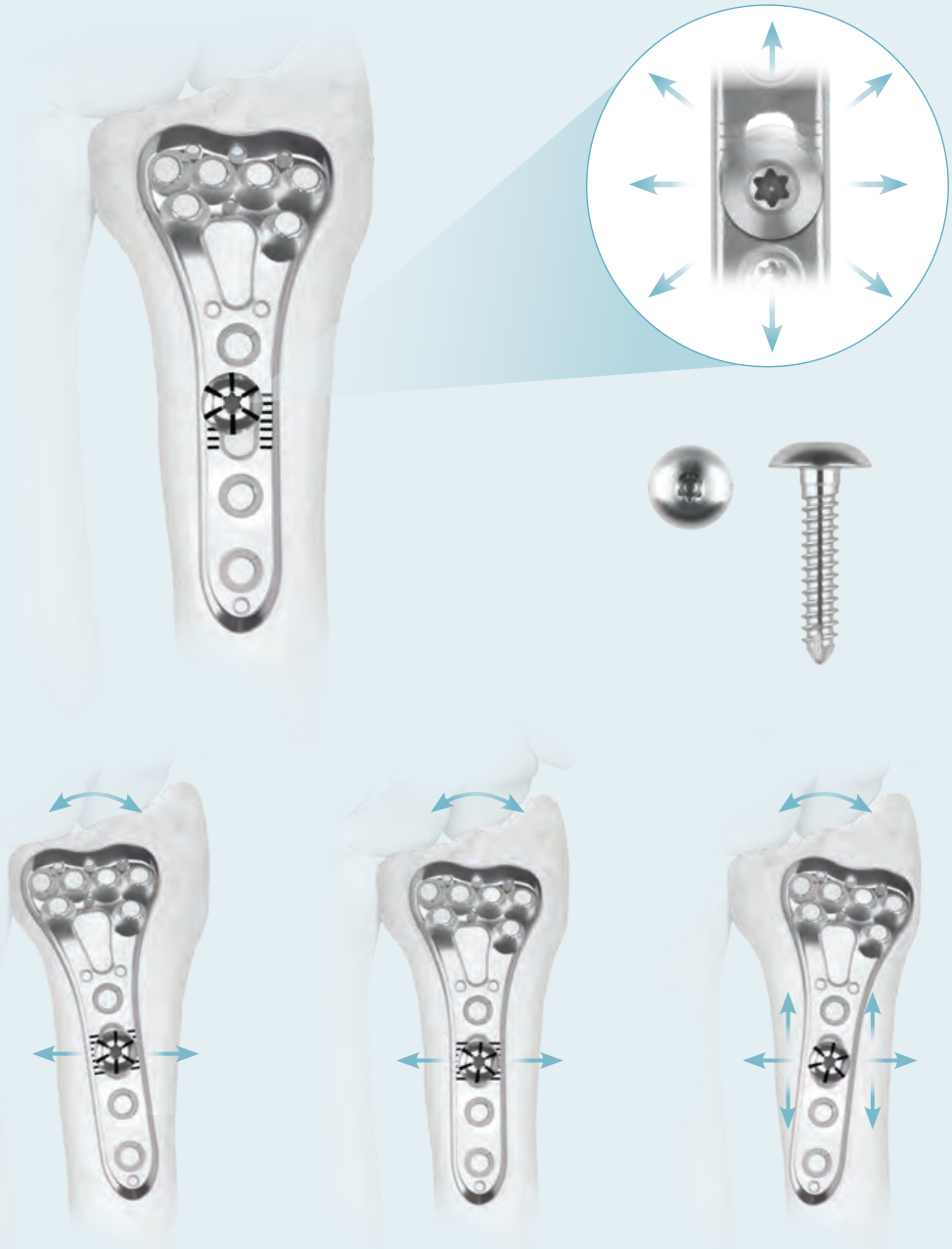


POSITIONING SLOT AND SCREW

The positioning screw allows for intraoperative, multidirectional fine-tuning of the plate position. The Positioning Slot accepts a 2.5mm Positioning Screw or a 2.5mm Non-Locking Screw.

The positioning hole and positioning screw allows for approximately 1mm of medial-lateral translation and 5mm of proximal-distal translation to optimize plate position.

The 2.5mm Non-Locking Screw allows proximal-distal adjustment of plate position.



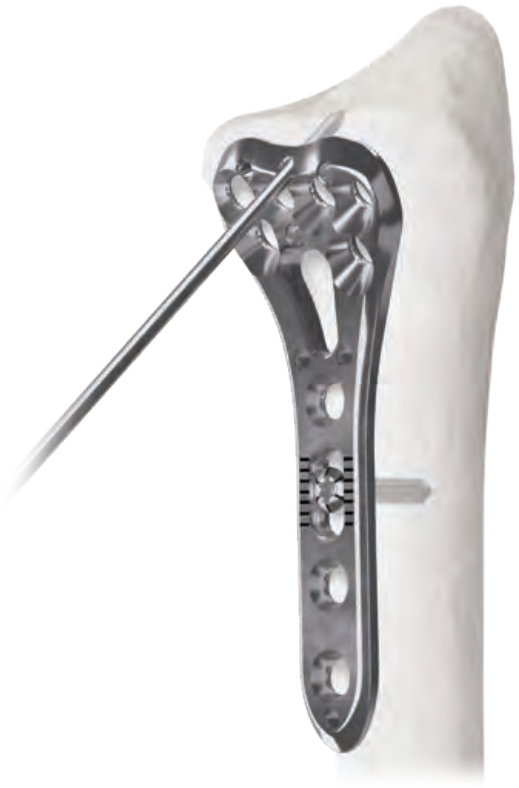
Medial-lateral translation

STEP 7 DISTAL PROVISIONAL FIXATION

As an alternative to shaft-first fixation, the plate may be first applied to the distal fragment and then reduced to the radial shaft.

With the fracture reduced, the distal fragment is provisionally held with K-wires.

Using the K-wire attachment for the drill, insert the **1.6mm K-Wire**. If desired, insert additional K-wires.



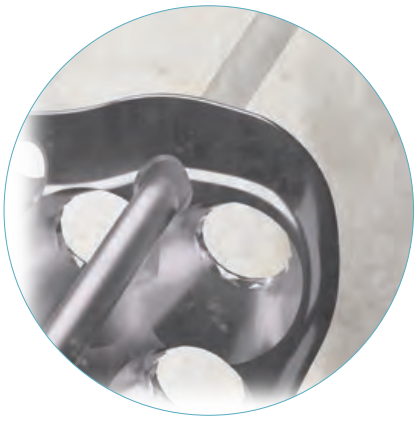
K-wire insertion

DISTAL PROVISIONAL FIXATION (CONT'D)

Confirm the trajectories of the K-wires using fluoroscopy.

The K-wire holes are designed to parallel the nominal angle of subchondral screws. K-wires allow for preliminary fixation of the distal fragment and extrapolation of distal subchondral screw position.

K-wire trajectories



K-wire hole

If the fracture is fully mobilized prior to shaft plate application, the distal fragment may be reduced to the plate and provisionally fixed with K-wires before distal subchondral screw placement.

STEP 8 DISTAL FIXATION

Once the fracture is reduced, use the 1.8mm Drill Bit and selected Drill Guide; drill the desired screw hole to the appropriate depth.

Measure screw length using the calibrations on the drill bit or remove the drill guide and insert the Depth Gauge.

Use the T8 Driver to select the desired 1.8mm Peg, 2.0mm Locking Screw, 2.5mm Locking Screw, or 2.5mm Non-Locking Screw. Verify screw length using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole. Verify screw and/or peg placement using fluoroscopy.

Screws may be inserted manually or under power. For manual insertion, use a Quick-Connect Handle and 1.2Nm Torque-Limiting Attachment or 1.2Nm Torque-Limiting Handle. If locking screws are inserted under power, use the 1.2Nm Torque-Limiting Attachment to ensure proper tightening torque and to prevent screw stripping or screwdriver damage.

If using a 2.0mm Locking Screw, use the **1.5mm Drill Bit** to pre-drill.

Depth Gauge

1.8mm Calibrated Polyaxial Soft Tissue Protector

Prior to placement of additional subchondral locking screws, consider placing a non-locking screw and using as a reduction screw to help reduce the distal fragment and lag to the plate. This reduction screw may be exchanged for a locking screw. All subchondral locking screws are designed to be placed 2mm short of the dorsal surface of the distal radius to avoid tendon injury.

DRILL GUIDE OPTIONS - POLYAXIAL SCREW HOLES

1.8mm Speed Lock Drill Guide

This drill guide may be used to drill nominal trajectories. The thumb lock quickly locks the drill guide to the plate at the nominal trajectory.

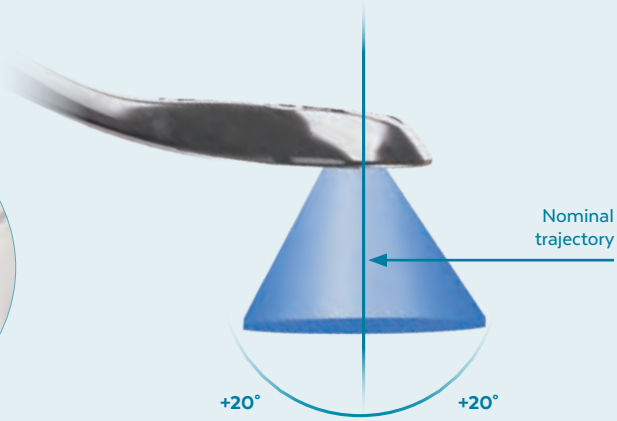
Speed Lock Drill Guide locked in place

1.8mm Polyaxial Soft Tissue Protector

This instrument allows for a 40˚cone of angulation (±20˚) on the polyaxial side and nominal trajectory on the nominal side.

Fixed angle end

Polyaxial end



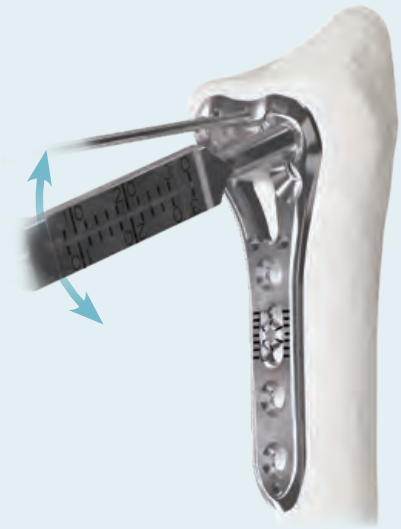
For proper locking, use the polyaxial drill guide for screw insertion within the ±20˚ cone. When using freehand insertion, screw angulation should not exceed this cone, as improper screw locking may result.

Nominal trajectory is the central axis of the range of polyaxial angulations.

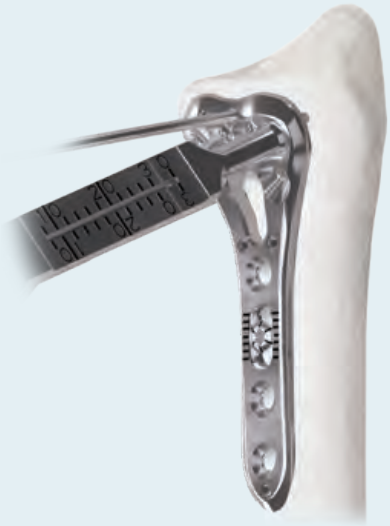
DRILL GUIDE OPTIONS - POLYAXIAL SCREW HOLES (CONT'D)

1.8mm Calibrated Polyaxial Soft Tissue Protector

The **1.8mm Calibrated Polyaxial Soft Tissue Protector** has a dedicated side to drill nominally or with a 40˚cone of angulation (±20˚). Use the 1.8mm Calibrated Drill Bit to drill through the desired end of the drill guide. Measure hole depth using the calibration on the drill bit.



Polyaxial end



Nominal end

Targeting Guide

Attach the corresponding **Targeting Guide** to the distal head of the plate. Lock into place by using a T8 Driver and Quick-Connect Handle to turn the screw towards the locked marking on the targeting guide (clockwise for left, counterclockwise for right). Insert the **Targeting Guide Drill Sleeve** or nominal side of the **1.8mm Calibrated Polyaxial Soft Tissue Protector** into the desired hole of the Targeting Guide. Insert the 1.8mm Drill Bit into the drill guide and drill the desired screw hole to the appropriate depth. Measure hole depth using the calibration on the drill bit or remove the Targeting Guide Drill Sleeve and insert the Depth Gauge with **Depth Gauge Cap**. The screw may be inserted through the Targeting Guide.

Targeting Guide

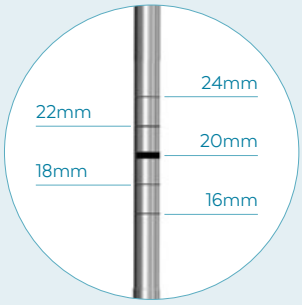
Targeting Guide and Calibrated Drill Guide

DRILL GUIDE OPTIONS - MonoAx® SCREW HOLES

2.5mm MonoAx® Locking Drill Guide

Secure the **2.5mm MonoAx® Locking Drill Guide** to the plate by threading it into the desired locking hole with the T8 Driver and Quick-Connect Handle. If desired, thread the **1.6mm K-Wire Sleeve** into the 2.5mm MonoAx® Locking Drill Guide.

The distal laser marks indicate readings from 16-24mm in 2mm increments, with the central bold laser mark indicating 20mm.



1.8mm Calibrated Drill Bit

2.5mm MonoAx® Locking Drill Guides and 1.6mm K-Wire Sleeves

1.8mm Threaded Drill Guide

Secure the **1.8mm Threaded Drill Guide** to the plate by threading it into the desired MonoAx® locking screw hole. The T8 Driver also fits on the end of the drill guide.

Note: When using this drill guide, the calibrations on the ANTHEM® II 1.8mm Calibrated Drill Guide will not apply. Remove Drill Guide and use a Depth Gauge to measure screw length.

1.8mm Threaded Drill Guide

MonoAx® Targeting Guide

Attach the corresponding **MonoAx® Targeting Guide** to the head of the plate. Lock into place by using a T8 Driver and Quick-Connect Handle to turn the screw clockwise. Insert the **MonoAx® Targeting Guide Drill Sleeve** into the desired hole of the MonoAx® Targeting Guide. Insert the 1.8mm Drill Bit into the MonoAx® Targeting Guide Drill Sleeve and drill the desired screw hole to the appropriate depth. Measure hole depth using the calibration on the drill bit or remove the MonoAx® Targeting Guide Drill Sleeve and insert the Depth Gauge with Depth Gauge Cap to determine the screw length. The screw may be inserted through the MonoAx® Targeting Guide.

MonoAx® Targeting Guide

Locking and unlocking MonoAx® Targeting Guide

MonoAx® Targeting Guide Drill Sleeve

STEP 9 PROXIMAL FIXATION

Shaft screw insertion varies depending on the reduction technique and fracture pattern. Using the 1.8mm Drill Bit and selected Drill Guide, drill the desired screw hole to the appropriate depth.

Measure screw length using the calibrations on the drill bit or remove the drill guide and insert the Depth Gauge.

Use the T8 Driver to select the desired 1.8mm Peg, 2.0mm Locking Screw, 2.5mm Locking Screw, or 2.5mm Non-Locking Screw. Verify screw length using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole.

Screws may be inserted manually or under power. For manual insertion, use a Quick-Connect Handle and 1.2Nm Torque-Limiting Attachment or 1.2Nm Torque-Limiting Handle. If locking screws are inserted under power, use the 1.2Nm Torque-Limiting Attachment to ensure proper tightening torque and to prevent screw stripping or screwdriver damage.

Verify placement using fluoroscopy.

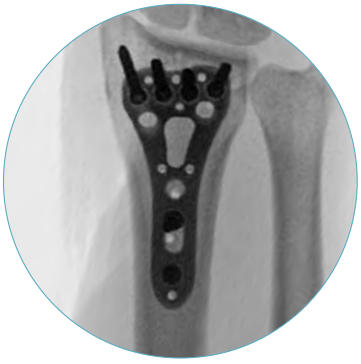
1.8mm Drill Bit and Speed Lock Drill Guide

Screw inserted with T8 Driver

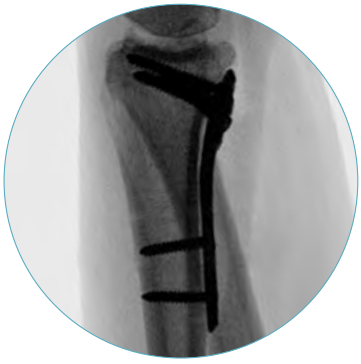
The 1.8mm Drill Bit may be used in the proximal shaft holes and the distal subchondral holes. With the exception of the positioning slot, all screw holes accept locking screws.

STEP 10 CONFIRM RECONSTRUCTION

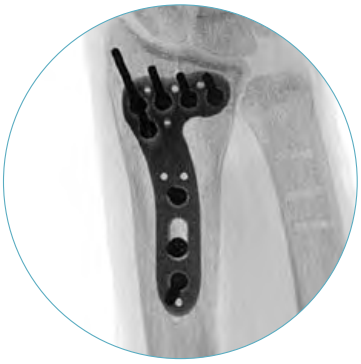
Confirm reduction, joint reconstruction, screw placement, and trajectories using fluoroscopy. Use multiple views to verify proper reconstruction and confirm the distal screws have not penetrated the articular surface.



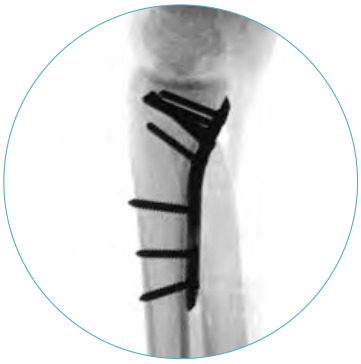
AP X-Ray
ANTHEM® II Double Row



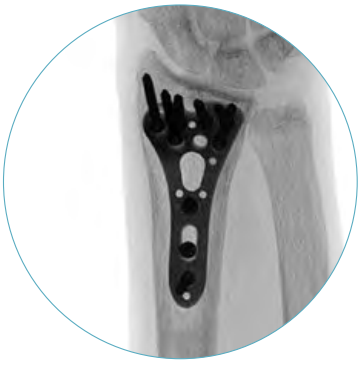
Lateral X-Ray
ANTHEM® II Double Row



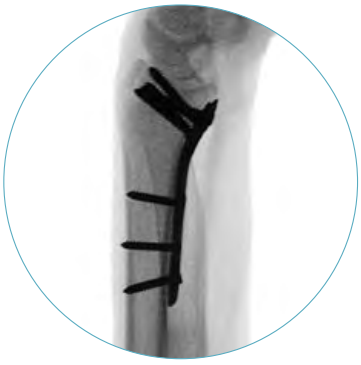
AP X-Ray
ANTHEM® II 7



Lateral X-Ray
ANTHEM® II 7



AP X-Ray
ANTHEM® II MonoAx®



Lateral X-Ray
ANTHEM® II MonoAx®

FINAL CONSTRUCT

ANTHEM® II Double Row Volar Plate

ANTHEM® II 7 Volar Plate

FINAL CONSTRUCT

ANTHEM® II MonoAx® Volar Plate

OPTIONAL: REMOVAL

If removal is required, use the T8 Driver to unlock the locking screws from the plate, but do not remove the screws from the plate. This prevents simultaneous rotation of the plate. Use the T8 Driver to remove all non-locking and locking screws from the plate. Once all screws are removed, the plate can be removed.

Non-self-retaining drivers are recommended for removal.

SURGICAL TECHNIQUE

ANTHEM®

Diaphyseal Metaphyseal Volar Plates

STEP 1 APPROACH

The approach, retraction, and dissection described on pages 16-21 may be extended proximally depending on the fracture pattern and length of plate used.

STEP 2 FRACTURE REDUCTION

Use the techniques described on page 21 for fracture reduction.

STEP 3 PLATE APPLICATION

Select the plate that best accommodates the fracture pattern and patient anatomy.

OPTIONAL: PLATE BENDING

Plate bending may be necessary based on patient anatomy. Using **Bending Irons** or the **Universal Bending Clamp** from the **ANTHEM® Small Fragment Set**, contour the plate as needed.

Note: Avoid excessive bending, over-contouring, bending and unbending, reverse bending, and bending directly over screw holes, which may compromise plate strength or screw locking, resulting in construct failure.

Bending Irons

Bending Irons feature multiple slots for out-of-plane and rotational bending.

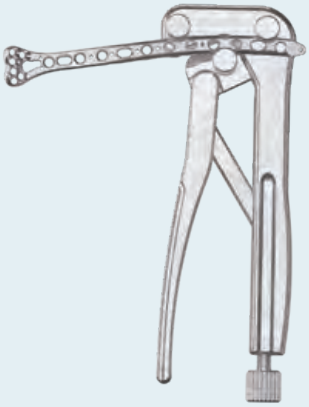
In-Plane Contour

Out-of-Plane Contour

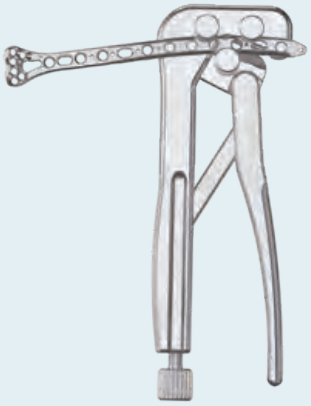
Twist Contour

Universal Bending Clamp

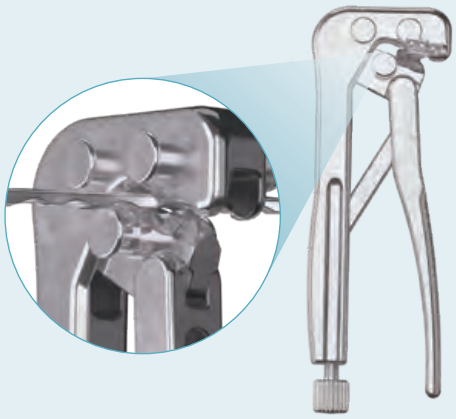
The Universal Bending Clamp may be used for plate contouring. Out-of-plane bending is achieved using the distal jaw of the clamp. Acute and broad in-plane bending is achieved through bending posts on either side of the clamp.



Broad In-Plane Bending



Acute In-Plane Bending



Out-of-Plane Bending

STEP 4 DISTAL PROVISIONAL FIXATION

Use technique described on page 25 for distal provisional fixation.

STEP 5 DISTAL FIXATION

Use technique described on page 27 for distal fixation.

STEP 6 PROXIMAL FIXATION

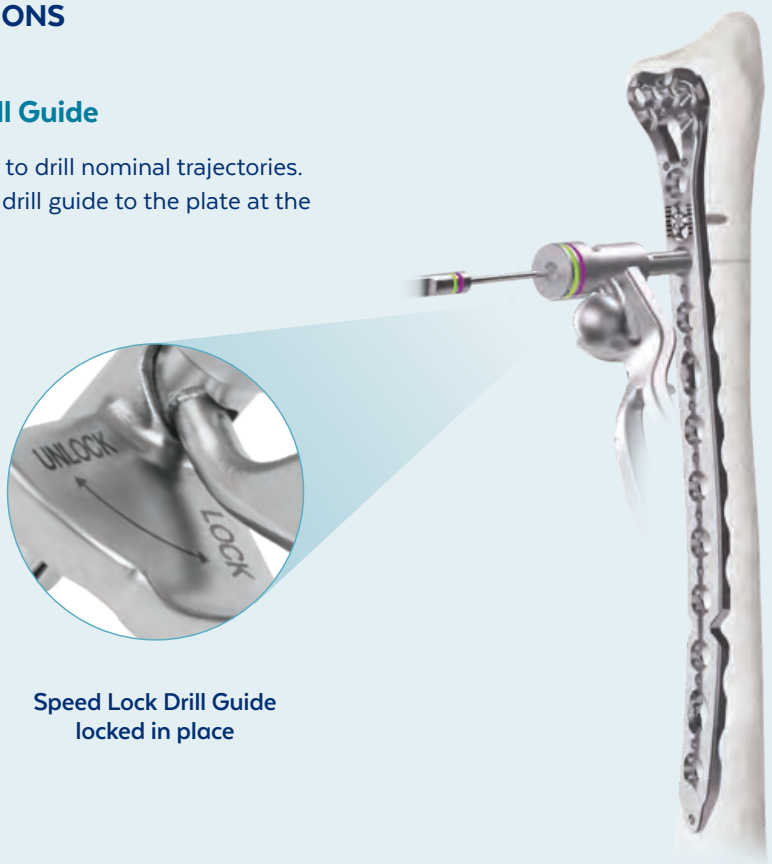
Use the **2.7mm Drill Bit** and selected Drill Guide to drill the desired screw hole to the appropriate depth.

Note: Instruments and screws for proximal fixation with 3.5mm screws are not included in the ANTHEM® Distal Radius Sets, and need to be brought into the OR separately.

DRILL GUIDE OPTIONS

2.7mm Speed Lock Drill Guide

This drill guide may be used to drill nominal trajectories. The thumb lock secures the drill guide to the plate at the nominal trajectory.

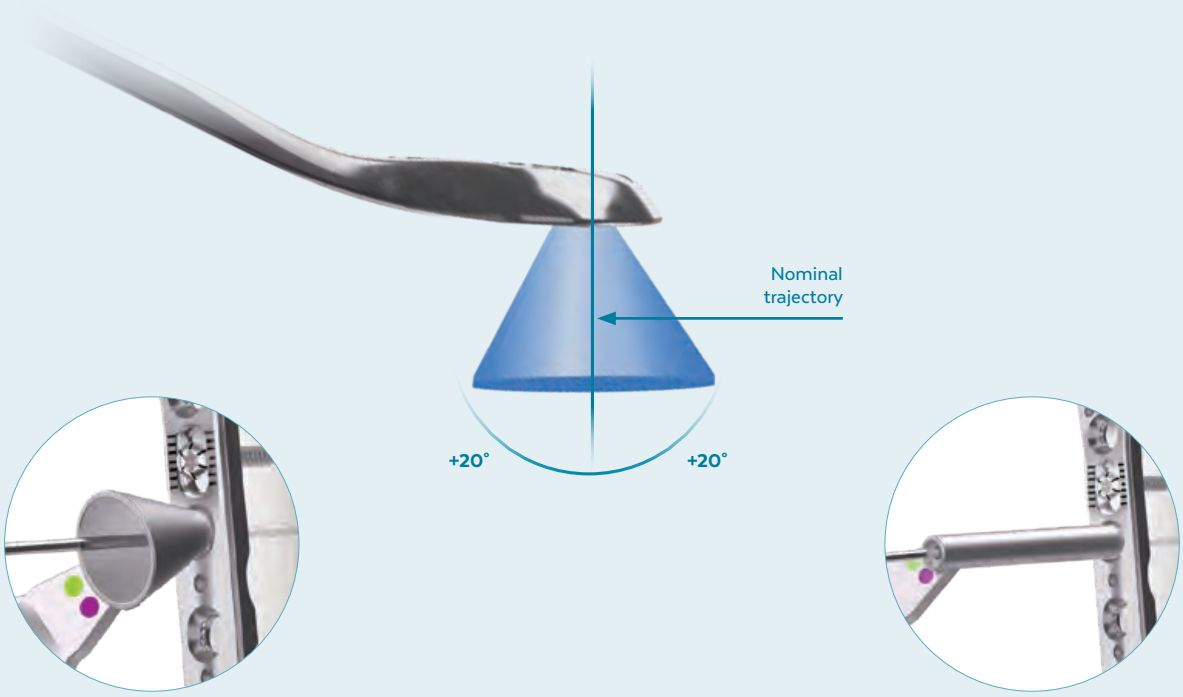


Speed Lock Drill Guide locked in place

DRILL GUIDE OPTIONS - POLYAXIAL SCREW HOLES

2.7mm Polyaxial Soft Tissue Protector

This instrument allows for a 40° cone of angulation (±20°) on the polyaxial side and nominal trajectory on the nominal side.



Polyaxial trajectory

Nominal trajectory

For proper locking, use the polyaxial drill guide for screw insertion within the ±20° cone. When using freehand insertion, screw angulation should not exceed this cone, as improper screw locking may result.

Nominal trajectory is the central axis of the range of polyaxial angulations.

PROXIMAL FIXATION (CONT'D)

Measure screw hole depth using the calibrations on the drill bit or remove the drill guide and insert the Depth Gauge.

Use the **T15 Driver** to select the desired 3.5mm Locking or 3.5mm Non-Locking Screw. Use the Measuring Gauge in the screw caddy to verify length.

Screws may be inserted manually or under power. For manual insertion, use a **2.5Nm Torque-Limiting Handle**. If locking screws are inserted under power, final tightening should be performed manually with the 2.5Nm Torque-Limiting Handle to prevent screw stripping or screwdriver damage.

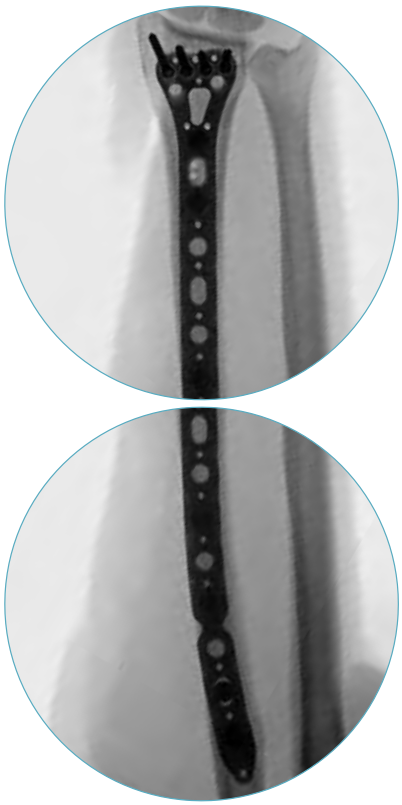
Verify placement using fluoroscopy.

Depth Gauge measurement

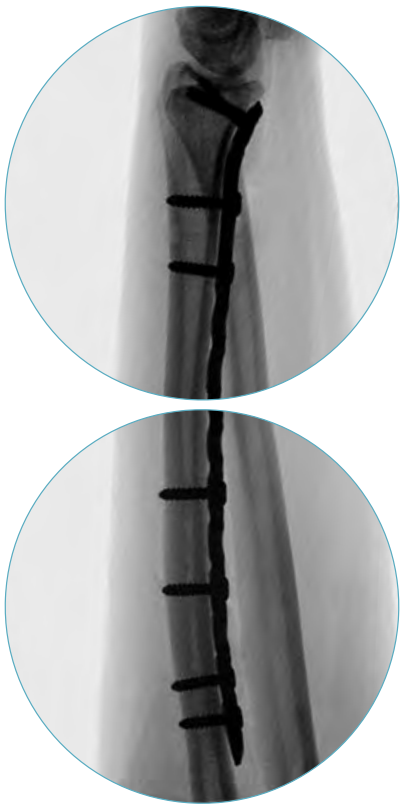
Proximal screw insertion

STEP 7 CONFIRM REDUCTION

Confirm reduction, screw placement, and trajectories using fluoroscopy. Use multiple views to verify proper reconstruction and confirm the distal screws have not penetrated the articular surface.



AP X-Ray
ANTHEM® II Diaphyseal Metaphyseal Volar Plate



Lateral X-Ray
ANTHEM® II Diaphyseal Metaphyseal Volar Plate

FINAL CONSTRUCTS

ANTHEM® II Diaphyseal Metaphyseal Volar Plate

OPTIONAL: REMOVAL

If removal is required, use the T8 Driver for 2.5mm screws and the T15 Driver for 3.5mm screws. Unlock the locking screws from the plate, but do not remove the screws. This prevents simultaneous rotation of the plate during removal. Once all locking screws are unlocked, remove all remaining screws from the plate using the T8 or T15 Driver. Once all screws are removed, the plate may be removed.

Non-self-retaining drivers are recommended for removal.

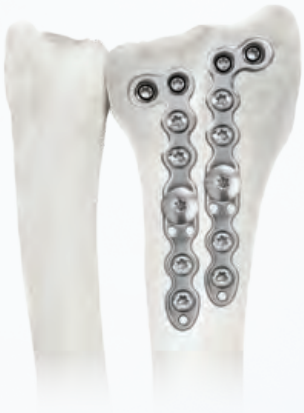
SURGICAL TECHNIQUES

ANTHEM®

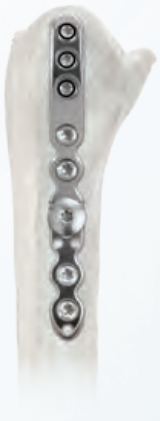
Fragment Specific Plating

The ANTHEM® Distal Radius Fracture System is a comprehensive system that includes fragment specific plates. These plates include the Lunate Facet Hook, Dorsal Acute and Dorsal Oblique, Lateral, Bridge, Ulna, and Scalloped plates. The surgical technique for each plate is provided in this section. Refer to the Volar plating technique for details on drill guides and removal instructions.

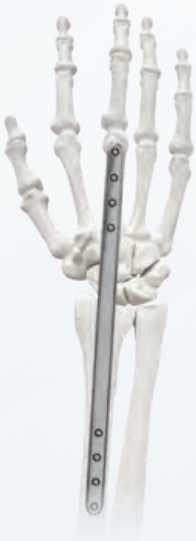
Lunate Facet Hook Plate



Dorsal Plates



Lateral Plate



Bridge Plate

Ulna Plate

Scalloped Plate

SURGICAL TECHNIQUE

ANTHEM®

Lunate Facet Hook Plating

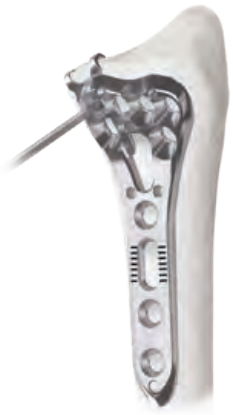
LUNATE FACET REPAIR

The Lunate Facet Hook Plate is designed for fracture patterns that involve the volar ulnar corner of the distal radius.

The plate internally fixes and/or buttresses the lunate facet with tines that hook over the rim of the facet.

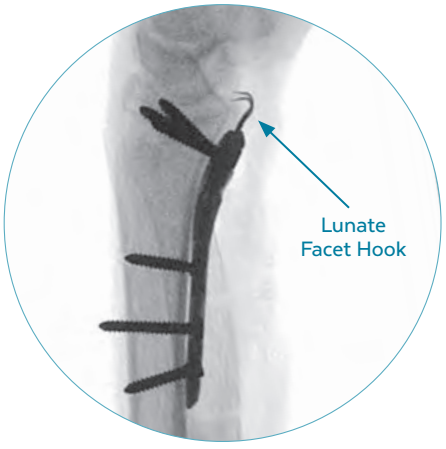
Lunate Facet Hook Plate Application Methods:

Option A
Independent Facet Hook



Option B
Prior to Volar Plate insertion

Option C
Following Volar Plate insertion



Option A: Independent Facet Hook

This fragment specific technique is used for isolated fractures of the lunate facet and may be used independently to capture the facet.

STEP 1 PLATE APPLICATION

With the fracture reduced, apply the plate using the **Lunate Facet Inserter**. Using the **Tamp** and **Mallet**, tamp the tines in or over the facet.

STEP 2 PROXIMAL FIXATION

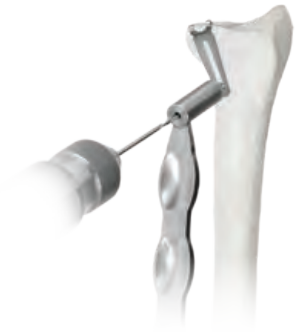
Drill a hole in the most proximal end of the slot in the plate using the Polyaxial Soft Tissue Protector and the 1.8mm Drill Bit. Measure the desired screw length with the Depth Gauge and insert a 2.5mm Non-Locking Screw using the T8 Driver. Confirm screw placement using fluoroscopy.

For final tightening, the 1.2Nm Torque-Limiting Handle is required.

Non-locking screws lag the plate to the bone and help to maintain fracture compression, avoiding late translation of the hook plate distally.

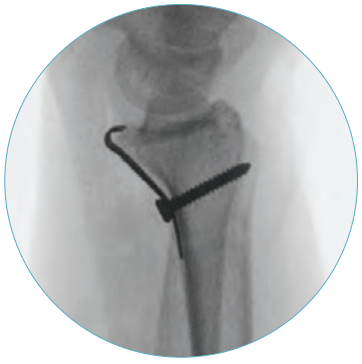
Lunate Facet Hook Plate applied to lunate facet

Tines placed using Tamp and Mallet



Proximal fixation using the 1.8mm Drill Bit and fixed angle end of the 1.8mm Polyaxial Soft Tissue Protector

Screw placement



Final fluoroscopic image

Final construct

Option B: Prior to Volar Plate Insertion

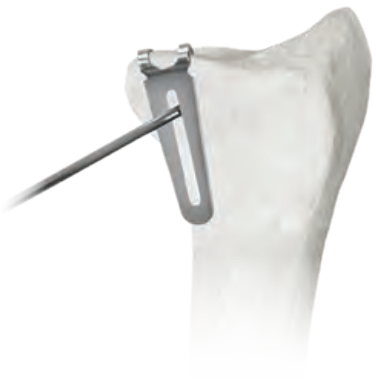
This method is used when lunate facet fixation is necessary prior to Volar Plate application.

STEP 1 PLATE APPLICATION

Apply the plate using the Lunate Facet Inserter. Using the Tamp and Mallet, tamp the tines in or over the facet.

STEP 2 PROXIMAL AND PRELIMINARY FIXATION

Insert the 1.6mm K-Wire. Using the K-wire for provisional fixation, place the Volar Plate over the K-wire onto the Lunate Facet Hook Plate.

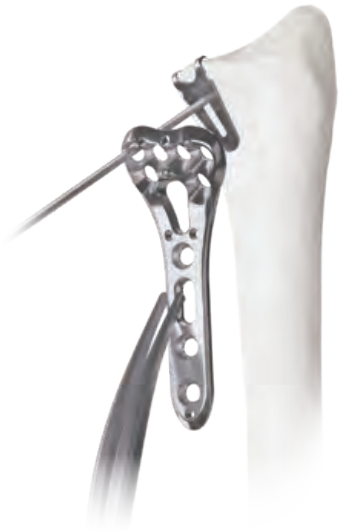


Lunate Facet Hook Plate positioned over K-wire

STEP 3 VOLAR PLATE APPLICATION

Follow the Plate Application steps beginning on page 22.

When positioned correctly, the ulnar-most subchondral locking screw aligns with the oblong hole of the Lunate Facet Hook Plate.



Volar Plate positioned over Lunate Facet Hook Plate

Option C: Following Volar Plate Insertion

When an unstable lunate facet fracture is identified following volar plate fixation, the Lunate Facet Hook Plate may be applied under the Volar Plate.

STEP 1 PLATE APPLICATION

Apply the Lunate Facet Hook Plate under the Volar Plate, lining up the Lunate Facet Hook Plate with the ulnar-most subchondral screw hole.

Remove the ulnar-most subchondral Volar Plate locking screw using the T8 Driver.

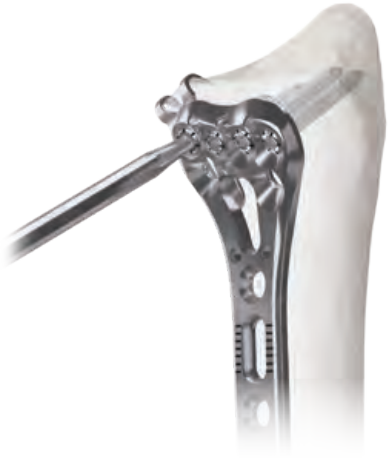
Use the **Freer Elevator** to raise the distal end of the plate. Tamp the Lunate Facet Hook Plate under the Volar Plate using the Lunate Facet Inserter to direct the hook plate into position. Center the slot with the hole in the Volar Plate.

Ensure the Tamp does not contact the Volar Plate during impaction.

Tamping Lunate Facet Hook Plate

STEP 2 SCREW INSERTION

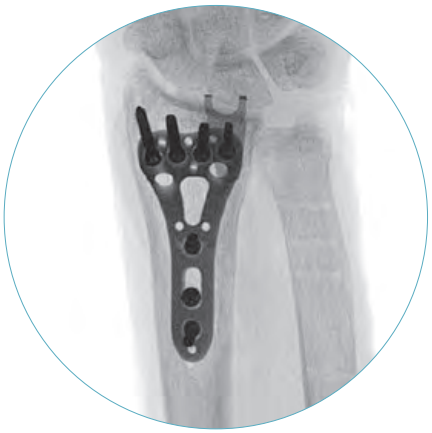
Use the T8 Driver to reinsert the ulnar-most subchondral 2.5mm Locking Screw into the Volar Plate.



Screw insertion

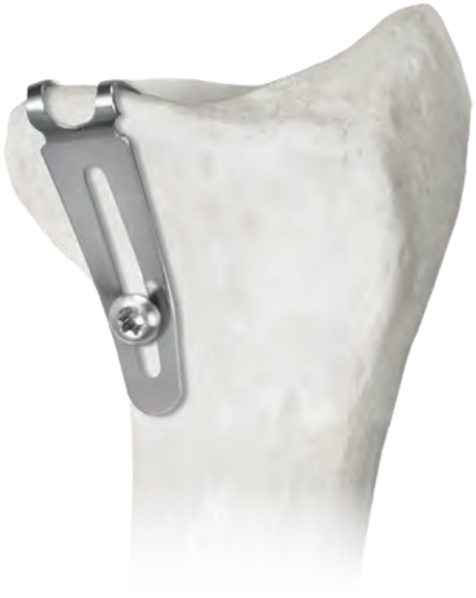
STEP 3 CONFIRM PLACEMENT

Confirm placement of the Lunate Facet Hook Plate using fluoroscopy.

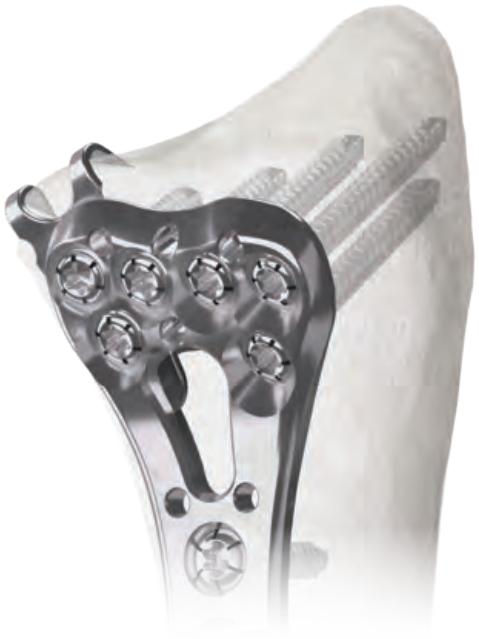


Final placement

FINAL CONSTRUCTS



Independent Lunate Facet Hook Plate



Volar Plate and Lunate Facet Hook Plate

Optional: Removal

Refer to optional removal instructions on page 34.

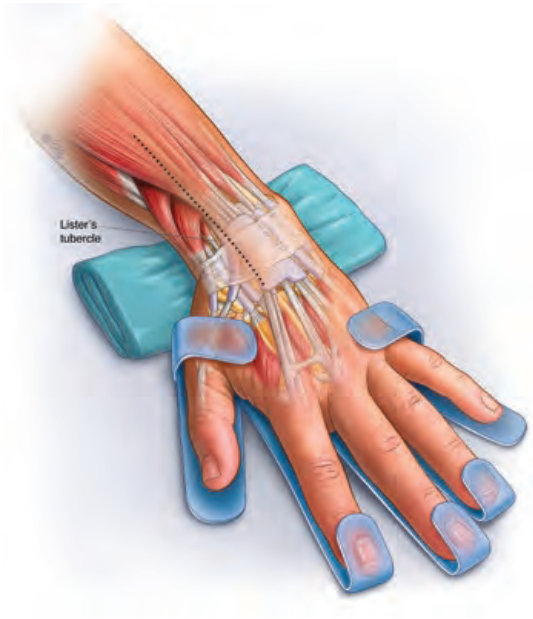
SURGICAL TECHNIQUE

ANTHEM®

Dorsal Plating

STEP 1 APPROACH

The patient's hand is positioned prone and secured with a lead hand or similar positioning device to maintain stability and orientation in the anterior-posterior (AP) plane.

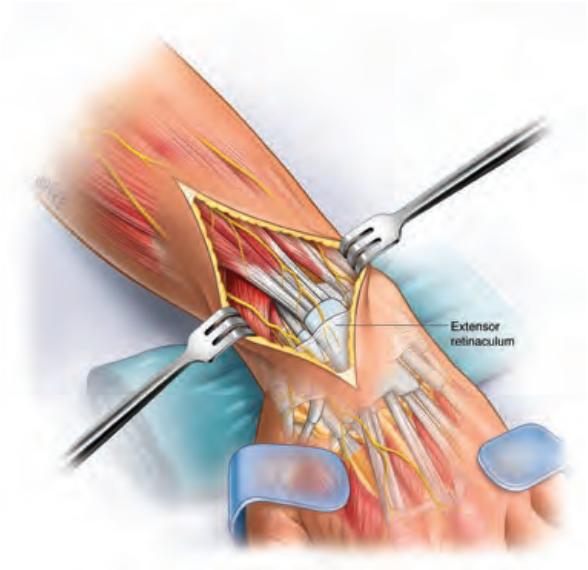


Hand position

STEP 2 EXPOSURE

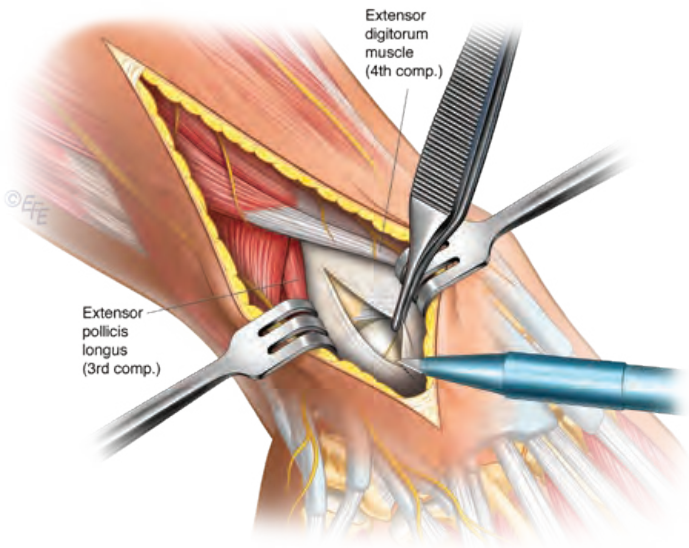
Create a longitudinal incision approximately 8-10cm overlying Lister's tubercle.

Elevate full thickness skin flaps by carefully raising the soft tissue directly above the extensor retinaculum to preserve the dorsal radial and ulnar sensory nerves.



Retracting skin flaps to expose retinaculum

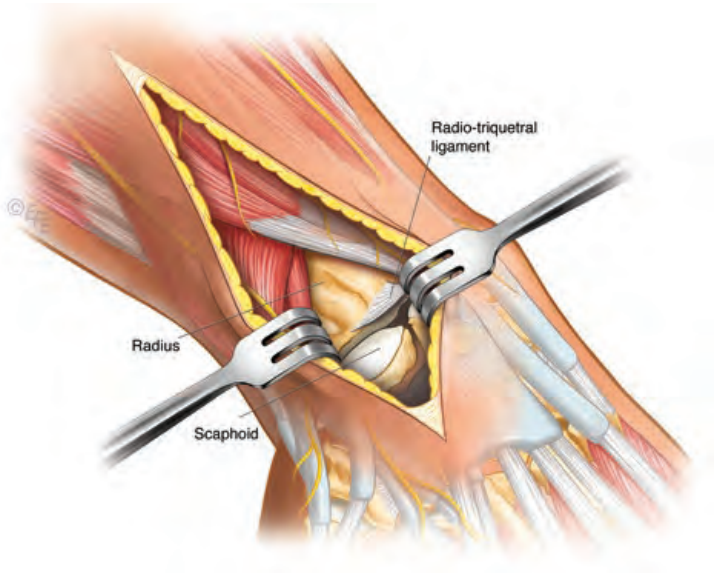
Create a longitudinal incision between the third and fourth dorsal compartment or through the fourth compartment.



Longitudinal incision

A double rectangular step cut allows for re-approximation of the retinaculum without transposition of the extensor pollicis longus (EPL) and allows tendon coverage.

To view the articular surface, a dorsal capsulotomy may be performed.



Wrist capsule

Carefully preserve the dorsal radioulnar ligaments.

STEP 3 REDUCTION

Using the **Dental Pick** or the Freer Elevator, elevate the articular fragments with allograft bone chips or suitable bone graft supplements.

Reduce the fragments under fluoroscopy using **Point-to-Point** or **Lobster Claw Reduction Forceps**. If preliminary fixation is required, use 1.6mm K-wires.

Traction on the wrist allows for direct visualization of the joint surface of the distal radius.

While reducing fragments under radiographic imaging, consider radial length (ulnar variance), articular reduction, palmar tilt, and radial inclination (height).

STEP 4 PLATE SELECTION

Select an acute or oblique Dorsal Plate that best fits the patient's anatomy and fracture pattern.

STEP 5 PLATE APPLICATION

Using the plate holding instrument, apply the plate to the midline of the dorsal and radial columns to buttress the fracture and maintain and restore volar and dorsal tilt.

If necessary, fix provisionally with K-wires and use fluoroscopy to determine correct placement.

Fix the plate through the positioning slot. Drill a hole in the center of the positioning slot using the 1.8mm Drill Bit and the 1.8mm Polyaxial Soft Tissue Protector. Using the Depth Gauge, measure hole depth. Insert the selected 2.5mm Positioning Screw with the T8 Driver. Adjust the plate proximal-distal or medial-lateral for optimal position. Tighten the positioning screw using the T8 Driver and the 1.2Nm Torque-Limiting Handle.

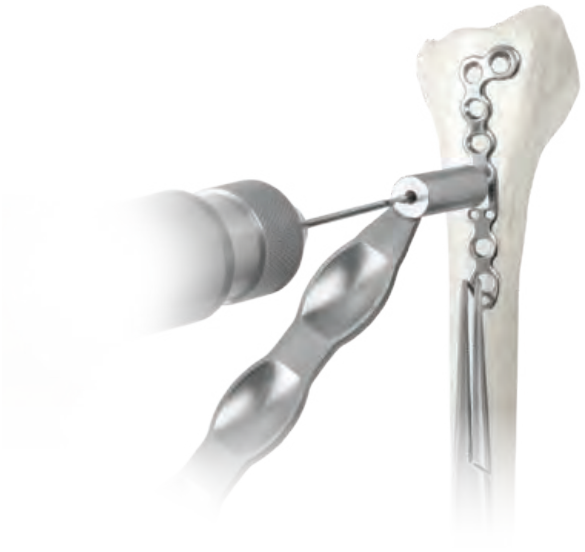
Application of oblique Dorsal Plate

STEP 6 PLATE FIXATION

Proximal Fixation

Insert proximal screws by pre-drilling a hole using the 1.8mm Drill Bit and selected drill guide. Use the Depth Gauge to measure the desired screw length.

Insert a 2.5mm Cortical Non-Locking Screw or a 2.5mm Locking Screw using the T8 Driver.



Pre-drilling of positioning slot using Soft Tissue Protector

Depth Gauge measurement

Distal Fixation

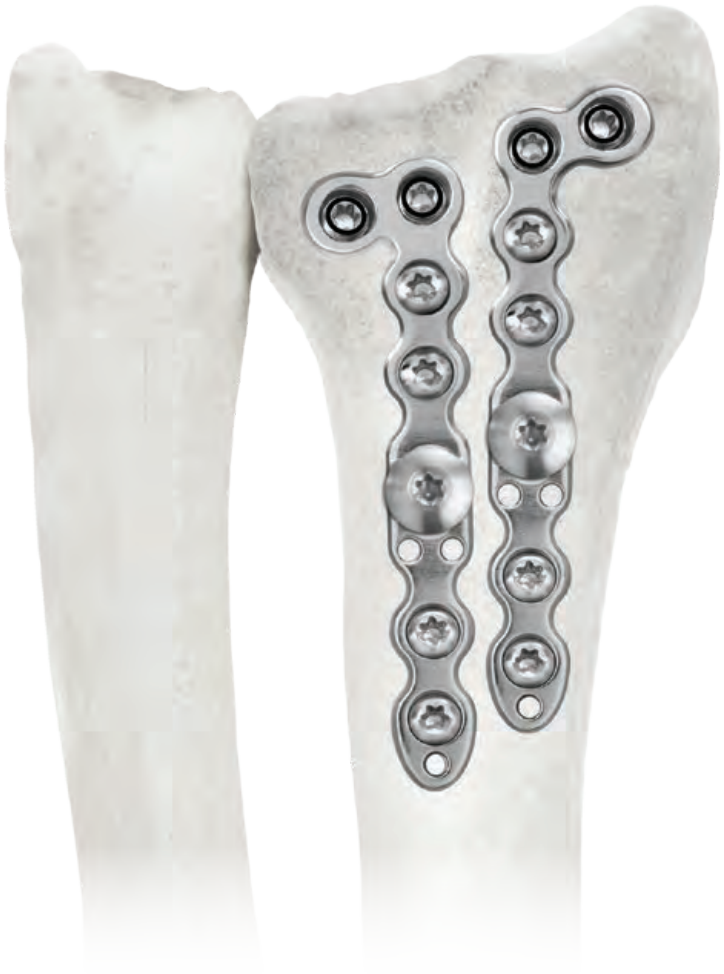
Insert distal subchondral screws by pre-drilling a hole using the 1.8mm Drill Bit and selected drill guide. Use the Depth Gauge to measure the desired screw length.

Insert 2.5mm Cortical Locking Screws, 2.0mm Locking Screws, or 1.8mm Smooth Locking Pegs using the T8 Driver. If using a 2.0mm Locking Screw for anything other than buttressing, the 1.5mm Drill Bit must be used.

Confirm placement using fluoroscopy and tighten all proximal and distal screws using the 1.2Nm Torque-Limiting Handle.

2.0mm Locking Screws may be used to capture smaller fragments distally.

FINAL CONSTRUCT



Dorsal Plates

Optional: Removal

Refer to optional removal instructions on page 34.

SURGICAL TECHNIQUE

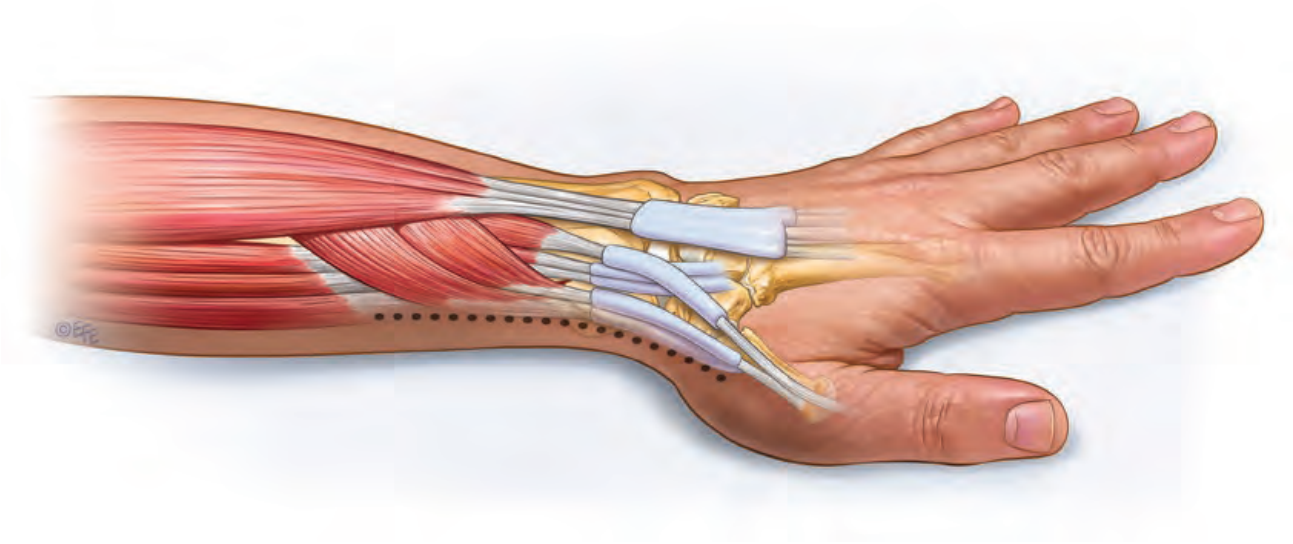
ANTHEM®

Lateral Plating

The Lateral Plate is designed for direct buttressing of distal radius fragments.

STEP 1 APPROACH

Create a lateral incision directly along the radial border of the wrist.

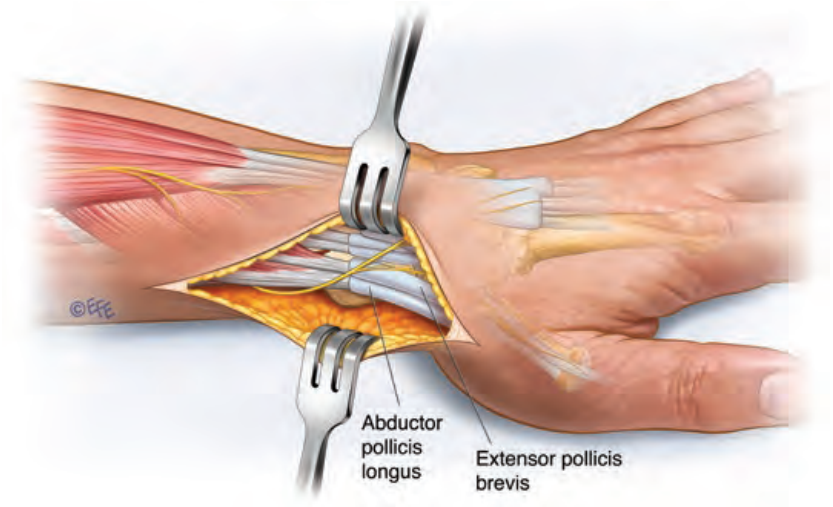


If the Lateral Plate is applied with the Volar Plate, the Lateral Plate may be placed through the same volar incision.

STEP 2 DISSECTION

Superficial Dissection

Blunt dissection is performed down to the first dorsal compartment of the wrist that contains the abductor pollicis longis (APL) and extensor pollicis brevis (EPB) tendons.

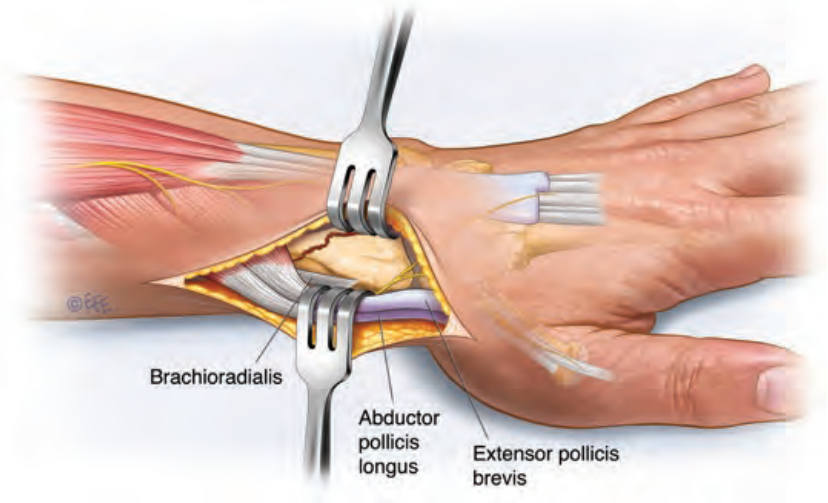


Branches of the radial sensory nerve are present in the surgical field and must be carefully dissected and protected.

Deep Dissection

Release the first dorsal compartment and retract the APL and EPB tendons to expose the brachioradialis tendon.

The brachioradialis tendon may be released for fracture exposure, reduction, and plate placement.

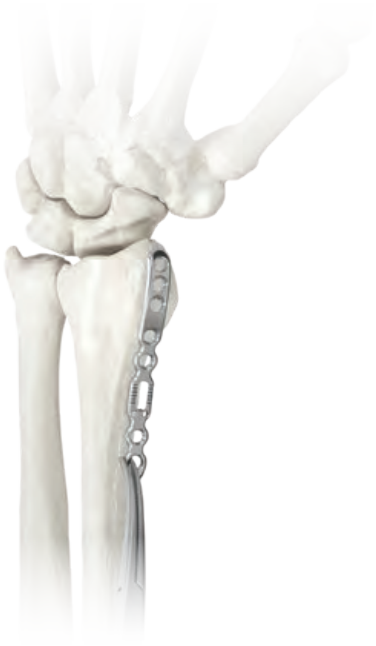


STEP 3 PLATE APPLICATION

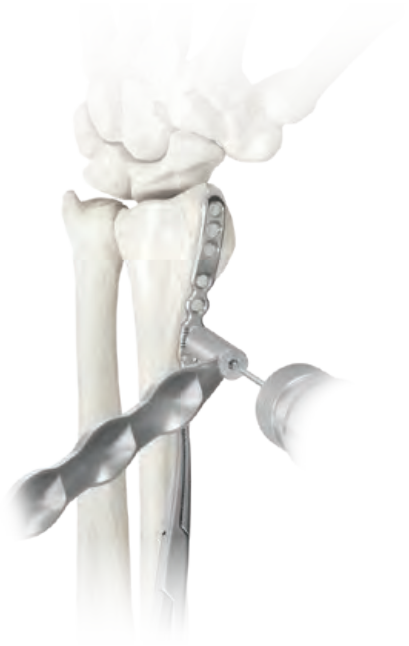
Reduce the fracture. Apply the plate to the lateral border of the radial shaft.

Using the 1.8mm Drill and selected drill guide, drill a hole through the positioning slot. Use the Depth Gauge to measure depth and select the desired 2.5mm Positioning Screw.

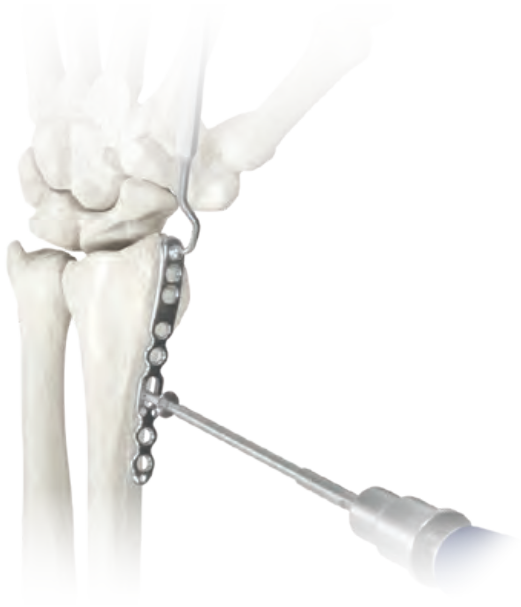
Insert the positioning screw using the T8 Driver. Adjust the plate proximal-distal or medial-lateral for optimal position. The **Plate Positioning Tool** may be used to stabilize the plate during screw insertion. Confirm plate placement using fluoroscopy.



Application of Lateral Plate



Pre-drilling of positioning slot



Positioning screw insertion

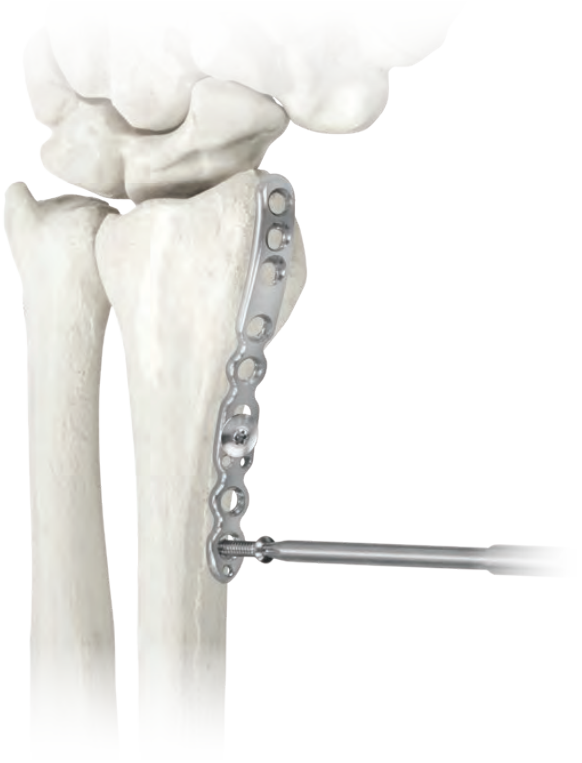
STEP 4 PLATE FIXATION

Proximal Fixation

Insert proximal screws by pre-drilling a hole using the 1.8mm Drill Bit and selected drill guide. Use the Depth Gauge to measure the desired screw length.

Insert 2.5mm Cortical Non-Locking Screws or 2.5mm Locking Screws using the T8 Driver.

Optimal plate position is achieved when the distal end of the plate meets the distal end of the radial styloid.



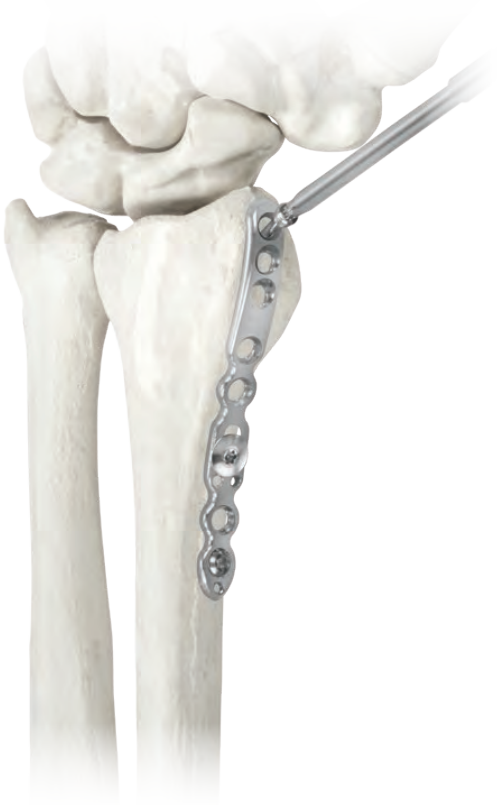
Distal Fixation

Insert distal subchondral screws by pre-drilling a hole using the 1.8mm Drill Bit and selected drill guide. Use the Depth Gauge to measure the desired screw length.

Insert 2.5mm Cortical Locking Screws, 2.0mm Locking Screws, or 1.8mm Smooth Locking Pegs using the T8 Driver. If using a 2.0mm Locking Screw for anything other than buttressing, the 1.5mm Drill Bit must be used.

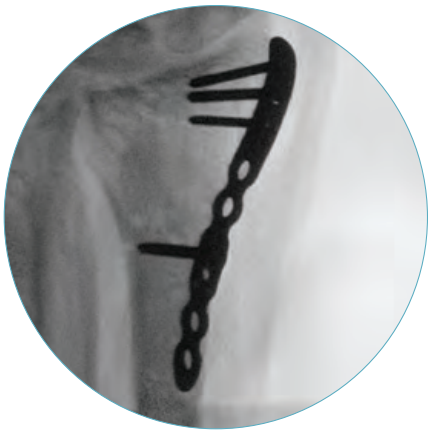
Confirm placement using fluoroscopy and tighten all proximal and distal screws.

The nominal angle for the distal subchondral screws is retrograde below the articular surface of the radiocarpal joint. For greater than nominal screw angulation, avoid inadvertent injury to the articular surface.

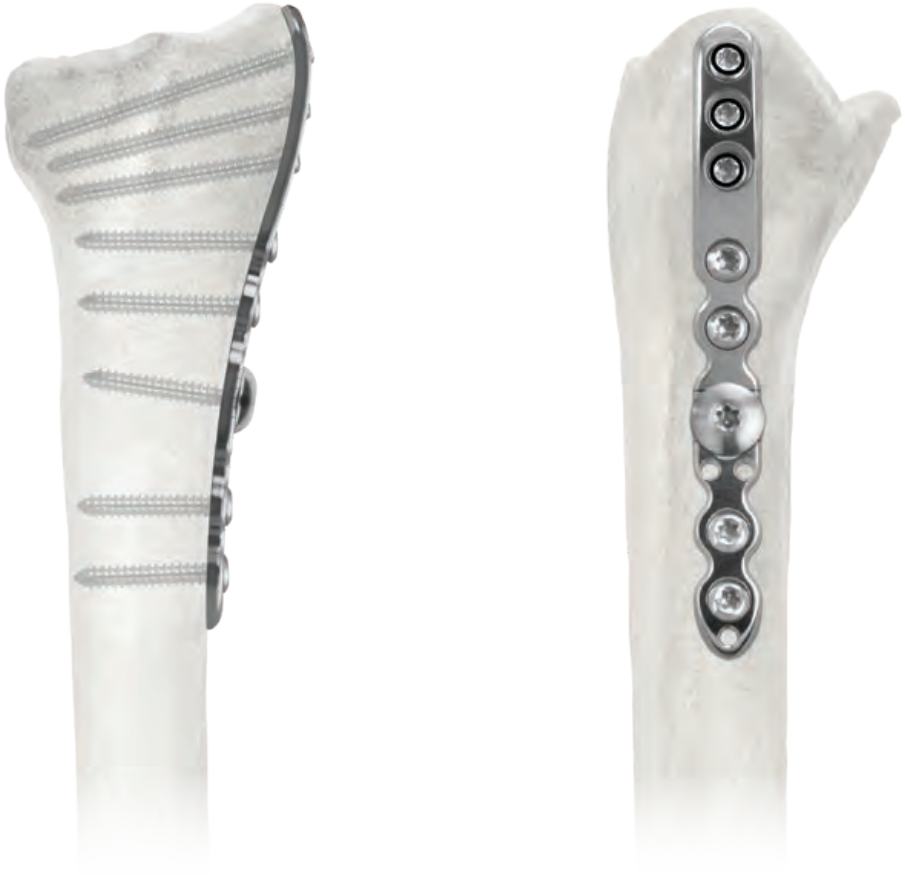


STEP 5 CONFIRM REDUCTION

Using fluoroscopy, verify screw trajectories and confirm plate placement.



FINAL CONSTRUCT



Lateral Plate

Optional: Removal

Refer to optional removal instructions on page 34.

SURGICAL TECHNIQUE

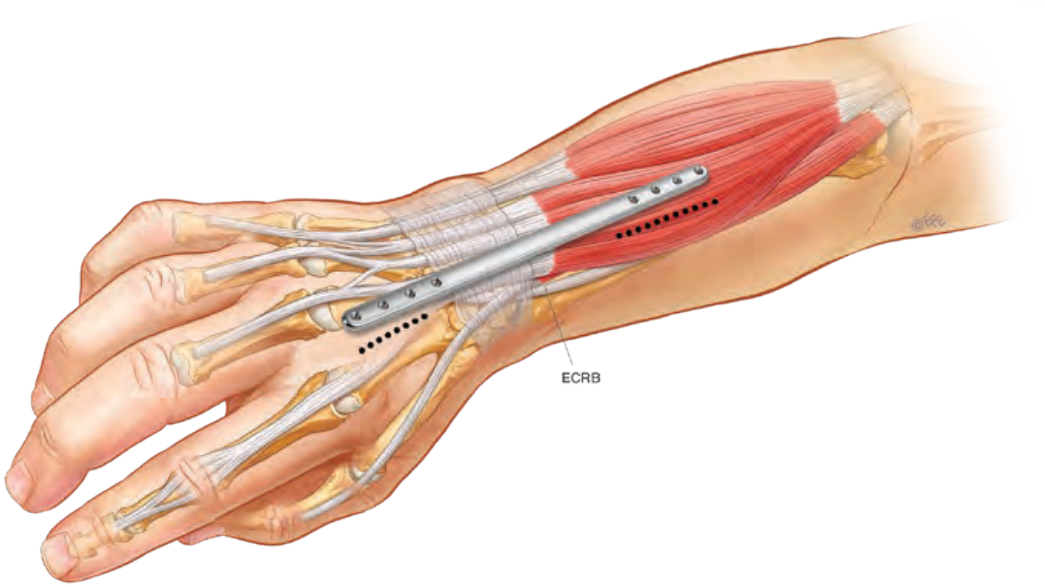
ANTHEM®

Bridge Plating

The Bridge Plate is designed for highly comminuted intra-articular fractures of the distal radius.

STEP 1 APPROACH

Place the plate on the dorsal surface of the hand and forearm as a guide to placement. Mark the incision line using a surgical marker.



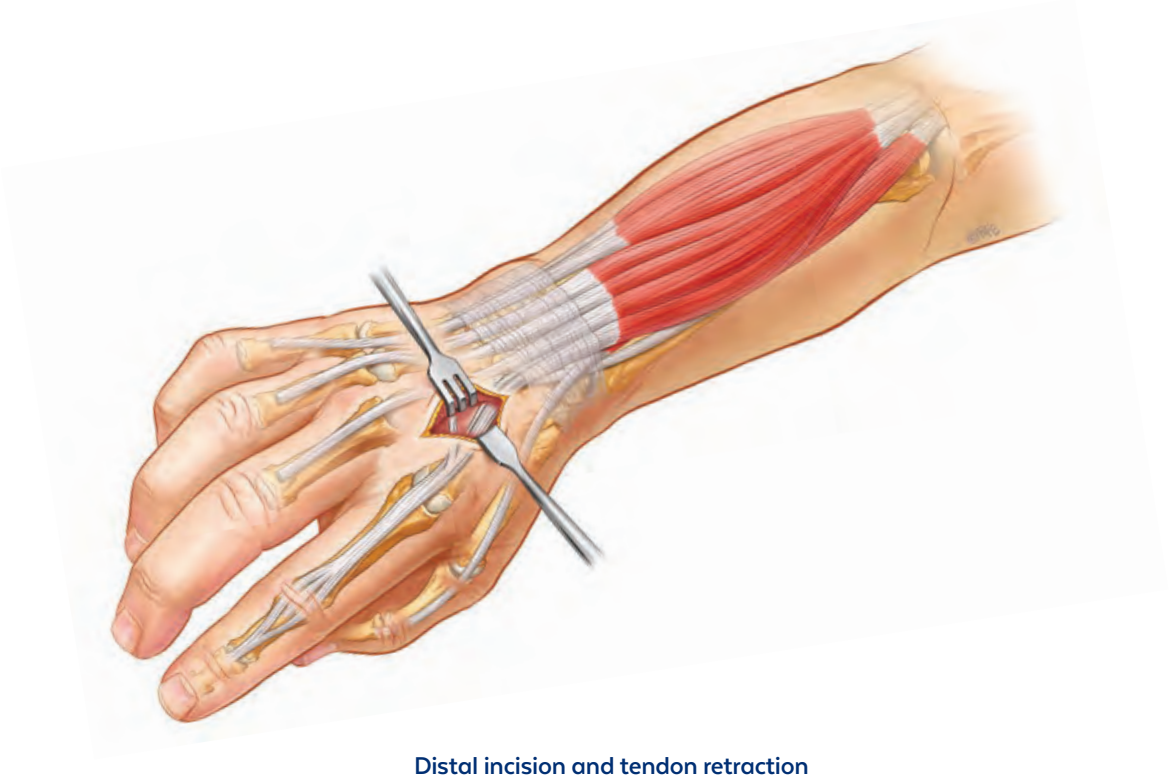
Distal incision with Bridge Plate

Use the index or middle metacarpal as a landmark. The incision should be made distally between the index and middle metacarpals to allow for access and placement.

STEP 2 DISTAL EXPOSURE

Create a distal incision.

Retract the tendons to perform blunt dissection to the extensor tendons.



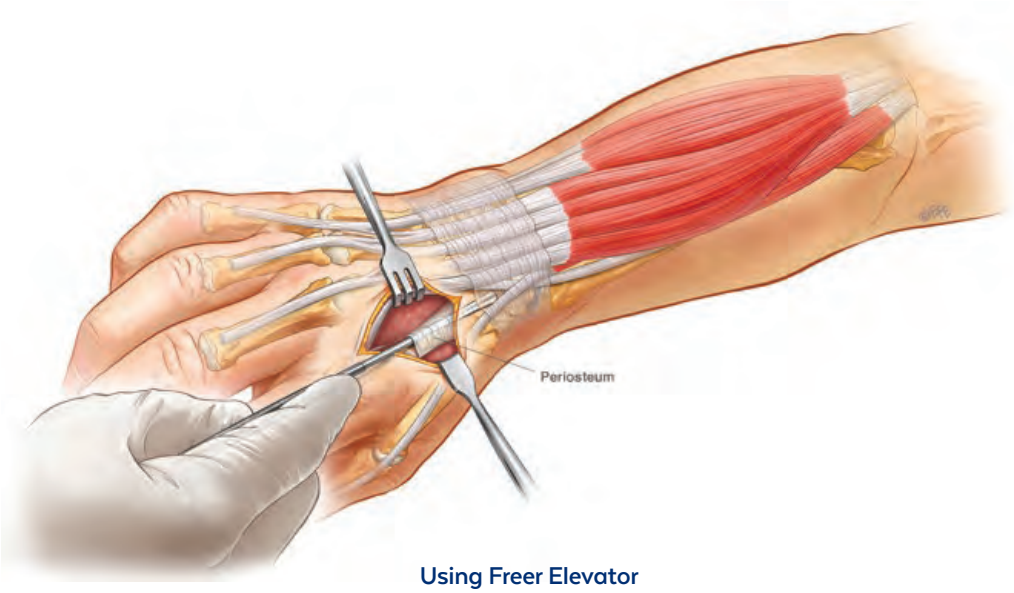
Distal incision and tendon retraction

If the index metacarpal is selected for plate fixation, all extensor tendons may be retracted ulnarly.

If the middle metacarpal is selected, the extensor tendons to the index and middle fingers may require separation by dividing the juncturae tendinum. If released, the tendinum should be repaired upon closure to help avoid an extensor lag.

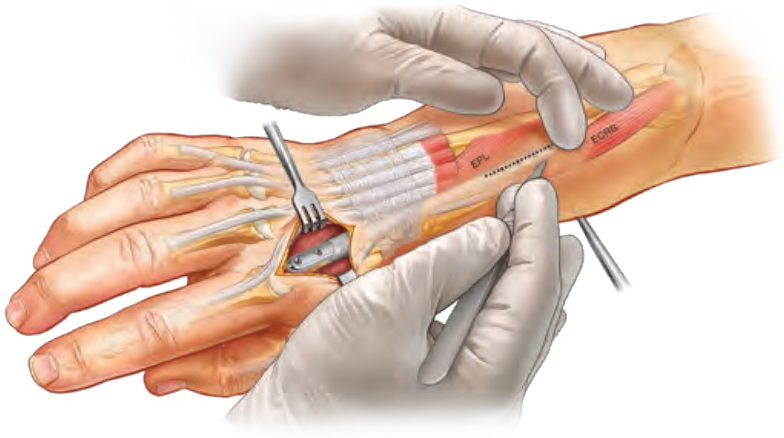
STEP 3 PLATE APPLICATION

With the extensor tendons retracted, the metacarpal is exposed subperiosteally. Position the **Distal Radius Freer Elevator** retrograde under the extensor retinaculum to create a path for plate placement.

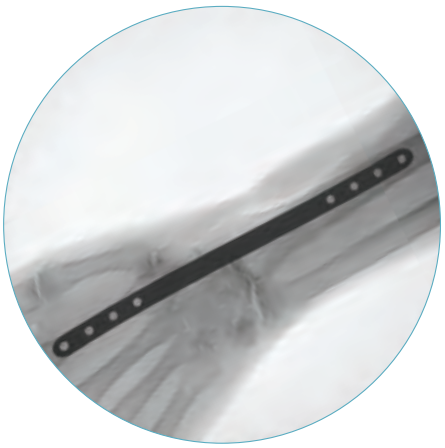


Using Freer Elevator

Insert the Bridge Plate through the incision and align with the radius. Palpate the Bridge Plate on the radius for proximal placement. Confirm placement using fluoroscopy.



Bridge Plate placement

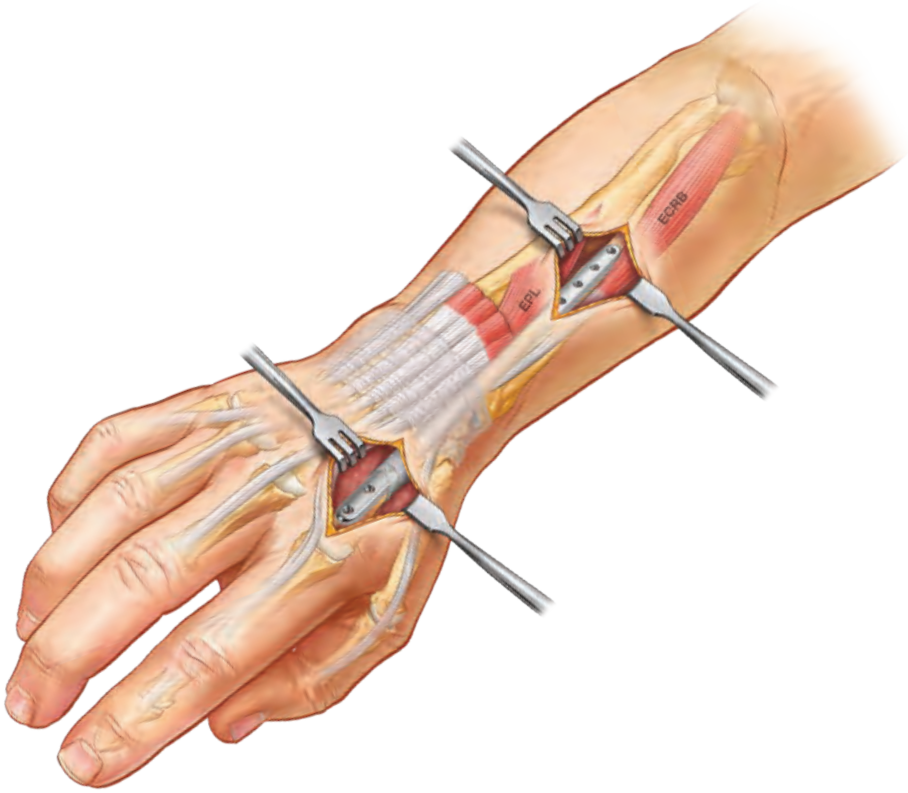


Placement confirmation

The Bridge Plate may be fixed to the index or middle metacarpal. Fixation to the index metacarpal allows for ease of exposure, tendon retraction, and access to the radial shaft through the second dorsal compartment. Wrist fixation in slight ulnar deviation may help to strengthen the power grip.

STEP 4 PROXIMAL EXPOSURE

With retrograde placement satisfied, create a proximal incision between the extensor carpi radialis brevis (ECRB) and EPL tendons.



Bridge Plate centered on radius

Place the Hohmann or Senn Retractor on either side of the radius to help center the plate.

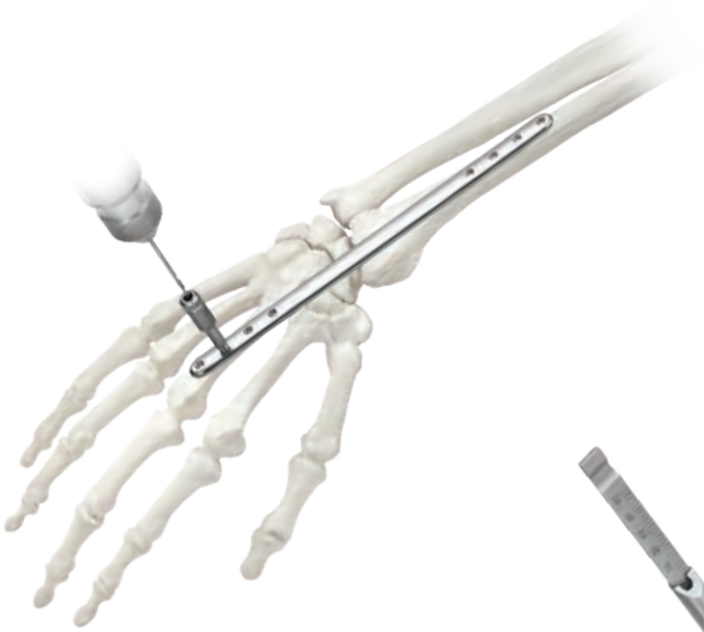
STEP 5 PLATE FIXATION

Distal Fixation

Thread the 1.8mm Threaded Drill Guide into the second most distal monoaxial hole of the plate. Using the 1.8mm Drill Bit, drill through the second most distal hole of the plate. Measure hole depth using the Depth Gauge.

Using the T8 Driver, insert a 2.5mm Cortical Non-Locking Screw.

Confirm screw placement using fluoroscopy.



Distal hole fixation

Using Depth Gauge

Prior to plate fixation, confirm satisfactory closed reduction of the fracture. If necessary, percutaneous or limited open reduction with K-wires or the Freer may be performed.

The holes in the Bridge Plate are monoaxial and require the 1.8mm Threaded Drill Guide.

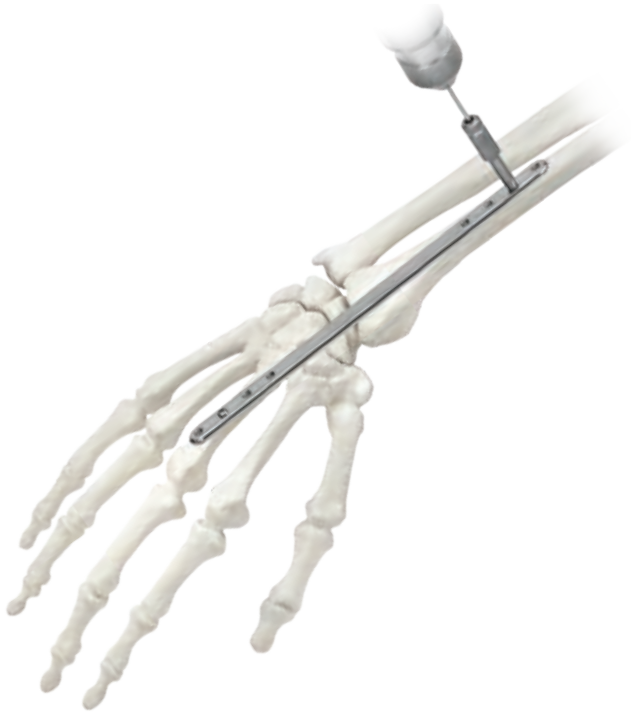
Proximal Fixation

Thread the 1.8mm Threaded Drill Guide into the second most proximal monoaxial hole. Using the 1.8mm Drill Bit, drill through the second most proximal hole. Measure the desired screw length using the Depth Gauge.

Using the T8 Driver, insert a 2.5mm Cortical Non-Locking Screw.

Confirm screw placement using fluoroscopy.

Gentle traction and/or a reduction maneuver may be performed prior to proximal fixation.

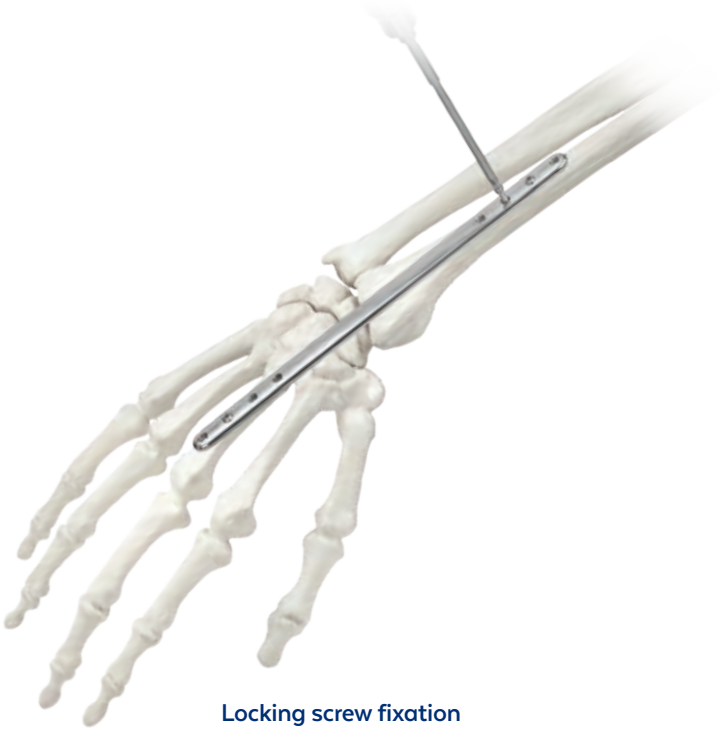


Drilling second most proximal hole

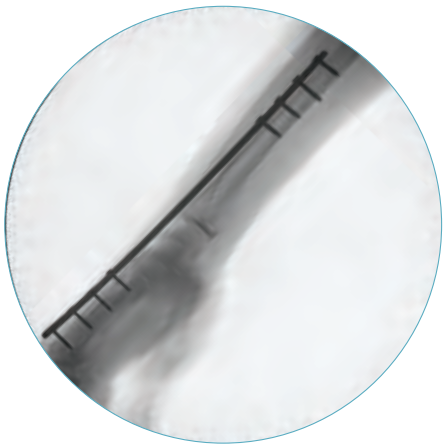
STEP 6 SCREW INSERTION

Once fracture reduction and plate placement are achieved, fill additional screw holes proximally and distally with 2.5mm Locking Screws using the 1.8mm Drill Bit and the selected drill guide. Confirm screw placement using fluoroscopy.

For final tightening, the 1.2Nm Torque-Limiting Handle is required.



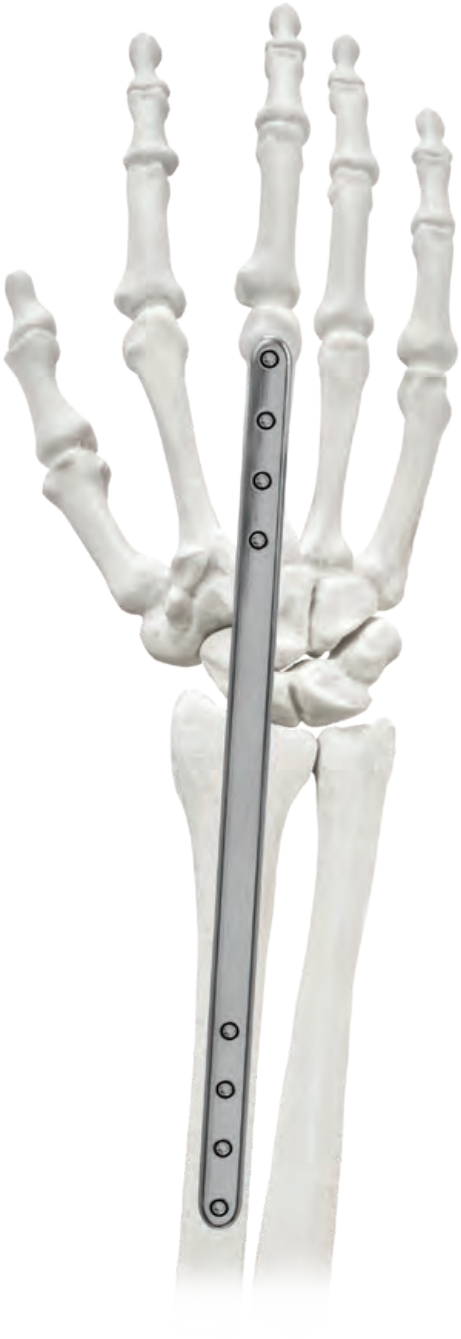
Locking screw fixation



Final placement

Following initial cortical screw fixation proximally and distally, fill the remaining holes with locking screws for stability.

FINAL CONSTRUCT



Bridge Plate

Optional: Removal

Refer to optional removal instructions on page 34.

SURGICAL TECHNIQUE

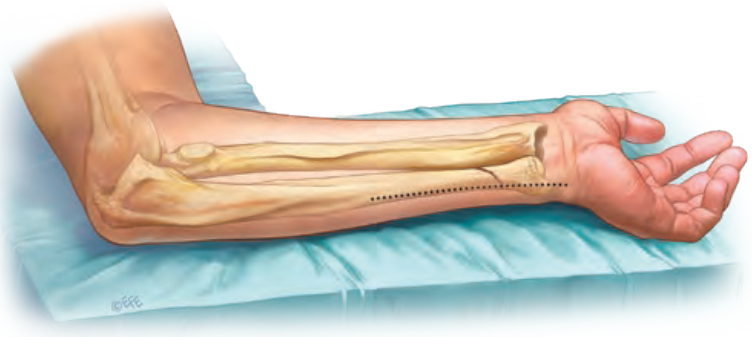
ANTHEM®

Ulnar Plating

Ulna Plates are used for fixation of an unstable ulna following distal radius repair.

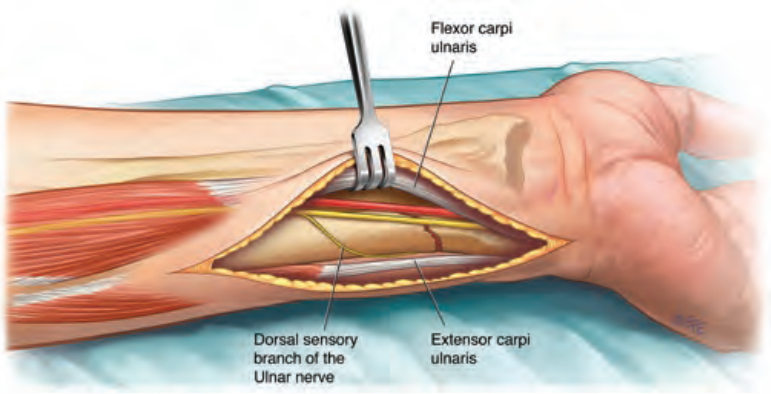
STEP 1 APPROACH

Using the subcutaneous ulnar approach, position the arm on a hand table and flex the elbow. Supinate the forearm to expose the subcutaneous border of the ulna.



STEP 2 EXPOSURE

Create a longitudinal incision approximately 1cm longer than the plate, distally and proximally. Split the interval between the extensor carpi ulnaris (ECU) and the flexor carpi ulnaris (FCU) to expose the ulnar shaft. The plate may be applied more dorsally, if desired.



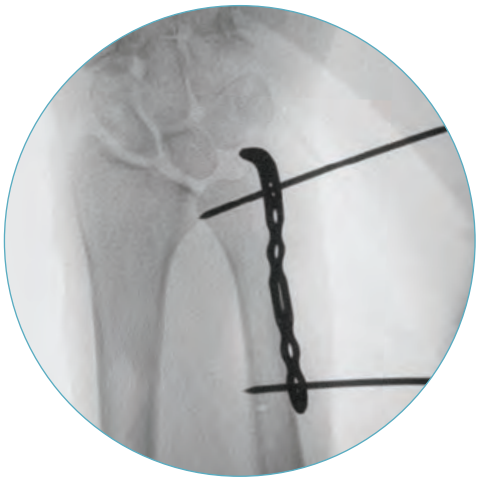
Carefully avoid the dorsal sensory branch of the ulnar nerve.

STEP 3 FRACTURE REDUCTION

Reduce the fracture and confirm reduction using fluoroscopy.

STEP 4 PROVISIONAL PLATE FIXATION

Using the Speed Lock Drill Guide, place 1.6mm K-wires in the most distal and proximal screw holes to provisionally hold the plate in position. Confirm K-wire placement using fluoroscopy.



K-wire placement

Using the most distal hole, a K-wire may be used for preliminary fixation.

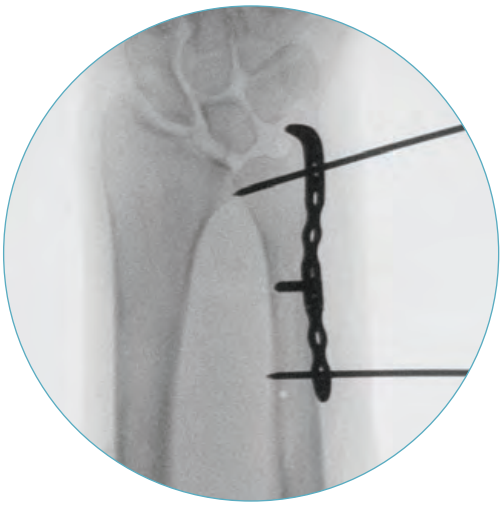
STEP 5 PLATE APPLICATION

Using the 1.8mm Drill Bit and Soft Tissue Protector, drill a hole through the center of the positioning slot.

Using the Depth Gauge, measure the desired hole depth.

Insert the positioning screw using the T8 Driver. Adjust the plate proximal-distal or medial-lateral for optimal placement.

Confirm placement using fluoroscopy.



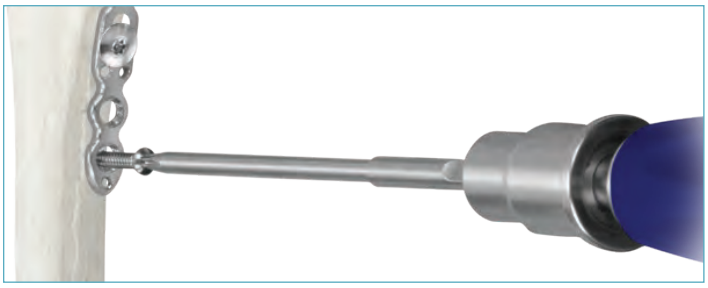
Positioning screw placement

STEP 6 SCREW INSERTION

Pre-drill for the remaining screws using the 1.8mm Drill Bit. Insert 2.0mm or 2.5mm Locking Screws. If using a 2.0mm Locking Screw for anything other than buttressing, the 1.5mm Drill Bit must be used.

For final tightening, the 1.2Nm Torque-Limiting Handle is required.

Confirm screw length and placement using fluoroscopy. Replace K-wires with locking screws.



STEP 7 CONFIRM REDUCTION

Using fluoroscopy, verify screw trajectories and confirm plate placement.

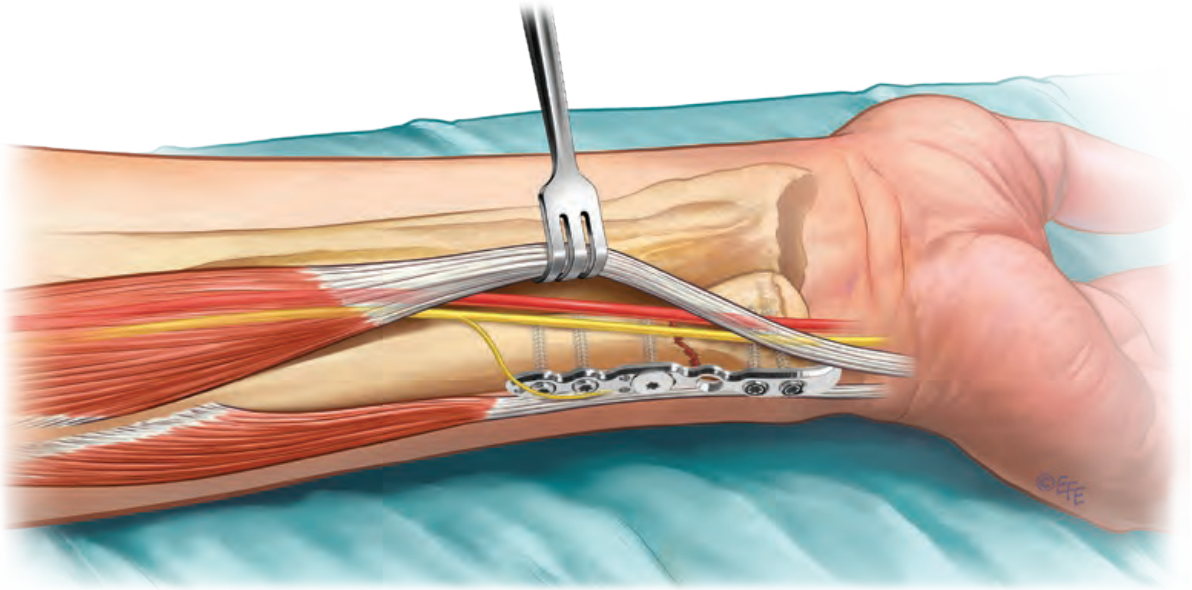
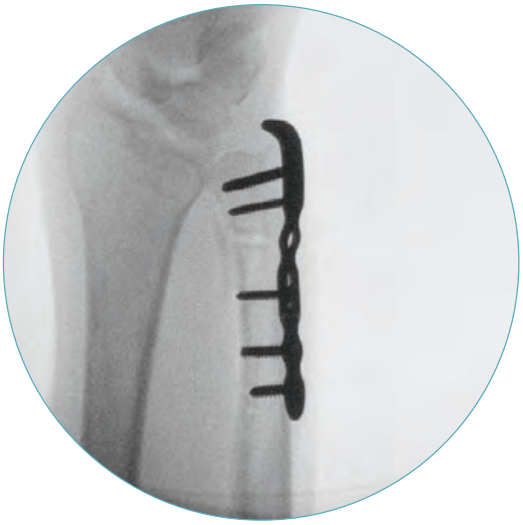


Plate placement



Final placement confirmed

FINAL CONSTRUCT

Ulna Plates

Optional: Removal

Refer to optional removal instructions on page 34.

SURGICAL TECHNIQUE

ANTHEM®

Scalloped Plating

STEP 1 PATIENT POSITIONING AND APPROACH

Place the patient in the desired operative position. Create an incision to access the fracture site.

STEP 2 FRACTURE REDUCTION

Reduce the fracture and confirm reduction using fluoroscopy.

STEP 3 PLATE SELECTION

Plate shape can be modified to accommodate specific anatomy and fracture patterns using plate bending instruments.

OPTIONAL: PLATE BENDING

Plate bending may be necessary based on patient anatomy. Using Plate Bending Pliers or **Mini Fragment Universal Bender**, contour the plate as needed.

Note: Avoid excessive bending, over-contouring, bending and unbending, reverse bending, and bending directly over screw holes, which may compromise plate strength or screw locking, resulting in construct failure.

Plate Bending Pliers facilitate in-plane, out-of-plane, and rotational bending.

OPTIONAL: PLATE BENDING

Mini Fragment Universal Blender

The Mini Fragment Universal Bender provides additional options for plate contouring. In-plane and out-of-plane bending is achieved using posts on the front of the clamp. The center post must be rotated to the 2.5mm plate size.

In-plane bending

Out-of-plane bending

STEP 4 SCREW INSERTION

Using the 1.8mm Drill Bit and selected Drill Guide, drill the desired screw hole to the appropriate depth.

Measure screw length using the calibrations on the drill bit or remove the drill guide and insert the Depth Gauge to measure screw length.

Use the T8 Driver to select the desired 1.8mm Peg, 2.0mm Locking Screw, 2.5mm Locking Screw, or 2.5mm Non-Locking Screw. Verify screw length using the gauges within the screw module. Using the driver, insert the appropriate length screw through the screw hole.

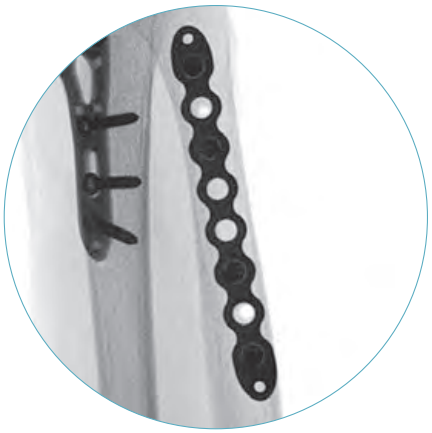
Screws may be inserted manually or under power. For manual insertion, use a Quick-Connect Handle and 1.2Nm Torque-Limiting Attachment or 1.2Nm Torque-Limiting Handle. If locking screws are inserted under power, use the 1.2Nm Torque-Limiting Attachment to ensure proper tightening torque and to prevent screw stripping or screwdriver damage.

Drilling with 1.8mm Calibrated Polyaxial Drill Guide

Screw insertion

STEP 5 CONFIRM REDUCTION

Using fluoroscopy, verify screw trajectories and confirm plate placement.



FINAL CONSTRUCT

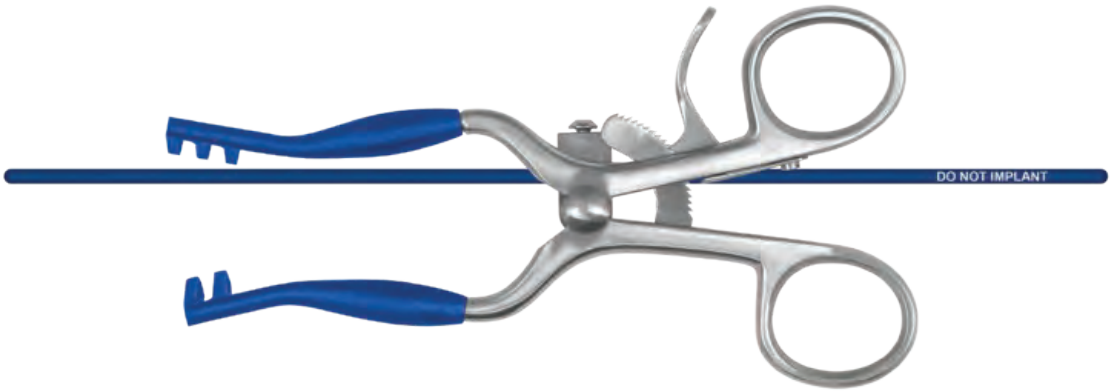
Scalloped Plate

Optional: Removal

Refer to optional removal instructions on page 34.

INSTRUMENT OVERVIEW

RETRACTORS



Stabilizing Radiolucent Weitlaner 2x3, 5", Blunt Tip 6171.0004

Stabilizing Radiolucent Weitlaner 3x4, 8", Blunt Tip 6171.0005

Malleable Wire Replacement 6171.7008

Distal Radius Hohmann Retractor, 15mm 6171.7017

Senn Retractor 6171.7006

REDUCTION INSTRUMENTS

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

1.6mm K-Wire, Threaded Trocar Tip, 150mm 6171.1316

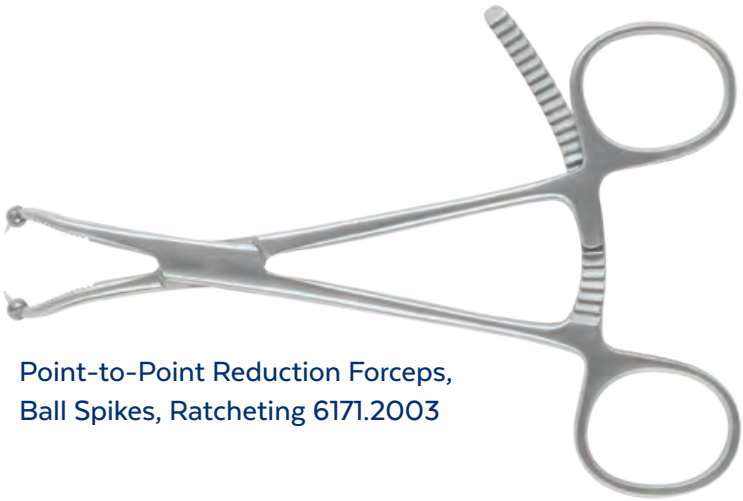
Dental Pick, Curved Tip, Short Handle 6179.7012

Plate Positioning Tool 6171.7007

Periosteal Elevator, Angled, Round Tip, 13mm 6171.7002

Distal Radius Freer Elevator 6171.7005

Lobster Claw Reduction Forceps, Ratcheting 6179.2001



Point-to-Point Reduction Forceps, Ball Spikes, Ratcheting 6171.2003

SCREW PREPARATION INSTRUMENTS

1.8mm Drill Bit, 100mm, AO Quick-Connect 6171.5018

1.8mm Drill Bit, 130mm, AO Quick-Connect 6171.5019

1.5mm Drill Bit, 100mm, AO Quick-Connect 6171.5020

ANTHEM® II 1.8mm Calibrated Drill Bit, 130mm, AO Quick-Connect 6171.5618

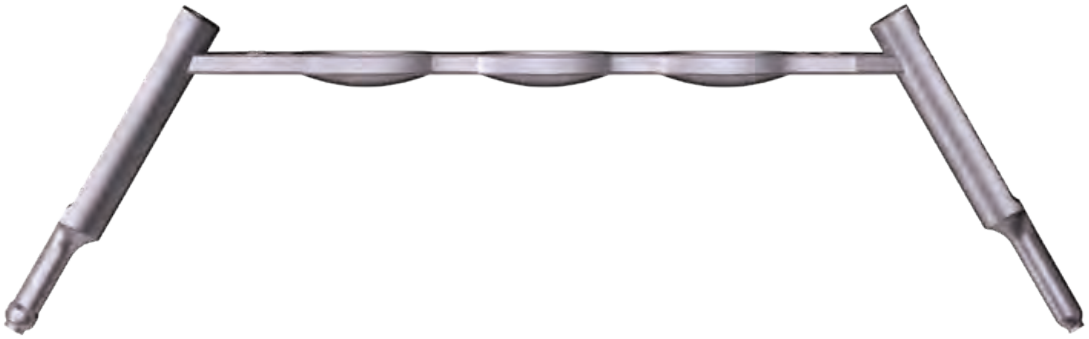
1.8mm Speed Lock Drill Guide 6171.3218

Targeting Guide Drill Sleeve 6171.3512

1.8mm Polyaxial Soft Tissue Protector 6171.3118

1.8mm Threaded Drill Guide 6185.3218

SCREW PREPARATION INSTRUMENTS (CONT'D)



ANTHEM® II 1.8mm Calibrated Polyaxial Drill Guide 6171.3718

Depth Gauge, 60mm 6179.7020

ANTHEM® VOLAR PLATE TARGETING GUIDES

Volar Plate Targeting Guide, Narrow, Left 6171.3506
Volar Plate Targeting Guide, Standard, Left 6171.3507
Volar Plate Targeting Guide, Wide, Left 6171.3508

Volar Plate Targeting Guide, Narrow, Right 6171.3509
Volar Plate Targeting Guide, Standard, Right 6171.3510
Volar Plate Targeting Guide, Wide, Right 6171.3511

Items in gray are additionally available.

ANTHEM® II POLYAXIAL VOLAR PLATE TARGETING GUIDES

Narrow, Left 6171.3514
Standard, Left 6171.3515
Wide, Left 6171.3516

Narrow, Right 6171.3517
Standard, Right 6171.3518
Wide, Right 6171.3519

ANTHEM® II MONOAX® VOLAR PLATE TARGETING GUIDES

Narrow, Left 6171.3520
Standard, Left 6171.3521
Wide, Left 6171.3522

Narrow, Right 6171.3523
Standard, Right 6171.3525
Wide, Right 6171.3526

Items in gray are additionally available.

TARGETING INSTRUMENTS

ANTHEM® II MonoAx® Targeting Guide Measuring Device 6171.3527

ANTHEM® II MonoAx® 1.6mm K-Wire Sleeve
6171.3318

ANTHEM® II MonoAx® 2.5mm Locking Drill Guide
6171.3119

SCREW INSERTION INSTRUMENTS

T8 Driver, SR, 100mm, AO Quick-Connect 6179.6008

Small Handle, AO Quick-Connect 6171.7000

Items in gray are additionally available.

SCREW INSERTION INSTRUMENTS

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

Small Torque-Limiting Handle, 1.2Nm, AO Quick-Connect 6171.7009

PLATE MODIFICATION INSTRUMENTS

Wire Bending Pliers 6179.2007

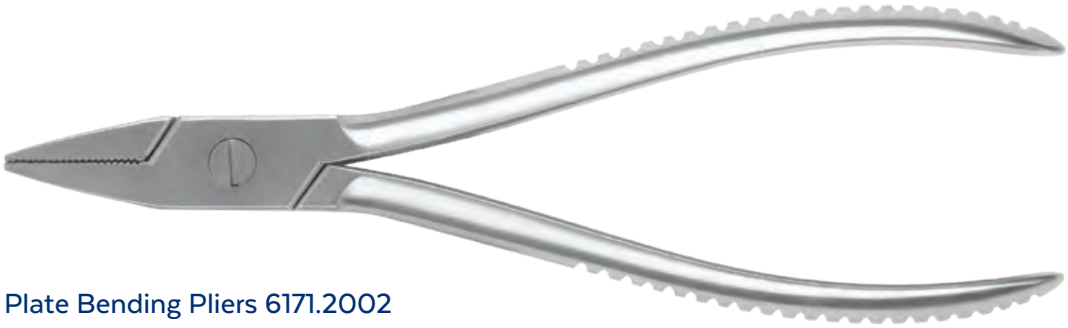


Plate Bending Pliers 6171.2002

LUNATE FACET HOOK INSTRUMENTS

Lunate Facet Inserter 6171.0003

Tamp 6171.7003

Mallet 603.977

AVAILABLE SETS

Refer to the ANTHEM® Distal Radius Set List Supplement (GMTGD290) for a complete description of each implant and instrument set.

ANTHEM® Distal Radius Fracture System Titanium Sets	
Set No.	**Description**
9171.9401	ANTHEM® II Ti Double Row Polyaxial Volar Plate Module
9171.9101	ANTHEM® II Ti 7 Volar Polyaxial Plate Module
9171.9501	ANTHEM® II Ti Diaphyseal Metaphyseal Volar Plate Module
9171.9201	ANTHEM® II Ti MonoAx® Volar Plate Module
9171.9301	ANTHEM® Ti Double Row Volar Plate Module
9171.9601	ANTHEM® Ti Distal Radius Fragment Specific Module
9171.9003	ANTHEM® Distal Radius Screw Module
9171.9002	ANTHEM® Ti Distal Radius Instrument Set

ANTHEM® Distal Radius Fracture System Stainless Steel Sets	
Set No.	**Description**
9171.9402	ANTHEM® II SS Double Row Polyaxial Volar Plate Module
9171.9102	ANTHEM® II SS 7 Volar Polyaxial Plate Module
9171.9502	ANTHEM® II SS Diaphyseal Metaphyseal Volar Plate Module
9171.9202	ANTHEM® II SS MonoAx® Volar Plate Module
9171.9302	ANTHEM® SS Double Row Volar Plate Module
9171.9602	ANTHEM® SS Distal Radius Fragment Specific Module
9171.9003	ANTHEM® Distal Radius Screw Module
9171.9001	ANTHEM® SS Distal Radius Instrument Set

IMPORTANT INFORMATION ON ANTHEM® FRACTURE SYSTEM

DESCRIPTION

TThe 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.
- 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.

IMPORTANT INFORMATION ON ANTHEM® FRACTURE SYSTEM

- 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 (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

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

DI201A Rev G

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Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
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GMTGD187
2.24 Rev E