ANTHEM™

Distal Radius Fracture System

SURGICAL TECHNIQUE GUIDE

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SURGICAL TECHNIQUE GUIDE

ANTHEM™

Distal Radius Fracture System

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Distal Radius Fracture System

The ANTHEM™ Distal Radius Fracture System is a comprehensive fixation system designed to treat a variety of wrist fractures with anatomically contoured plates for intraoperative versatility.

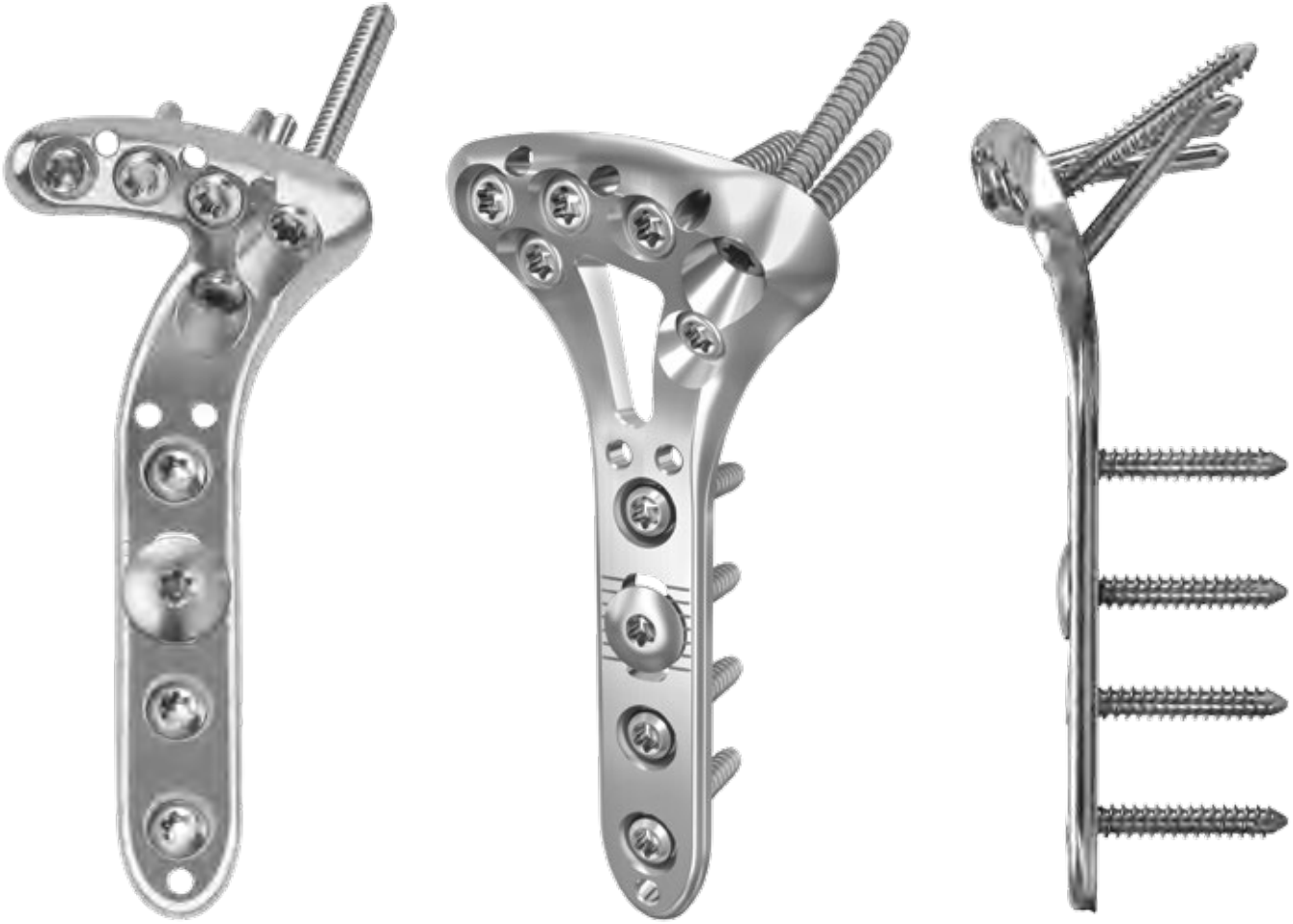
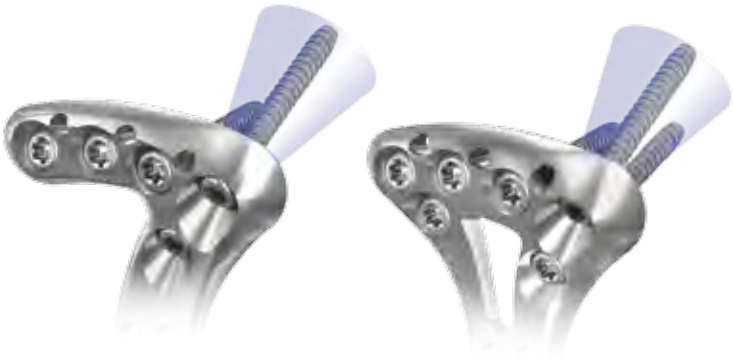


Plate Design

- Polyaxial holes offer ±20° cone of angulation
- ANTHEM™ 7 Volar Plate designed for visibility of the intermediate column exposure
- ANTHEM™ Double Row Volar Plate features an additional screw hole for maximum buttressing

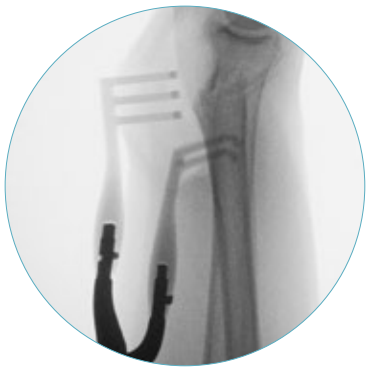


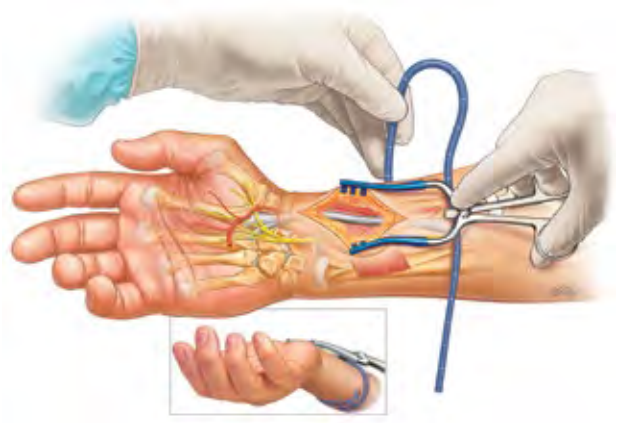
Unique Instruments

- One drill and one driver to streamline procedure
- Stabilizing Radiolucent Weitlaner designed for secure retraction during the procedure

T8 Self-Retaining Driver and 1.8mm Drill Bit

Speed Lock Drill Guide





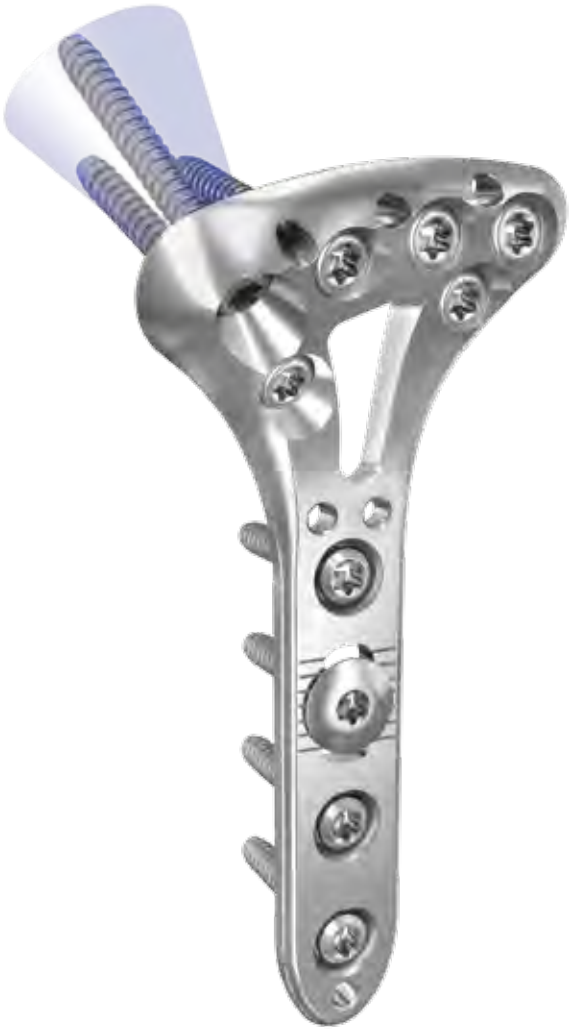
Stabilizing Radiolucent Weitlaner

Optimal Case Flow

- Graphic case trays are organized to optimize procedure flow
- Features all-in-one implant and instrument tray

Double Row Volar Plate

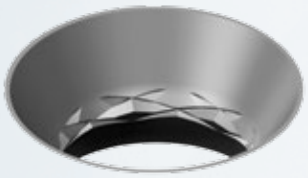
Anatomic plate featuring an additional screw hole to maximize buttressing.



Maximum Buttressing

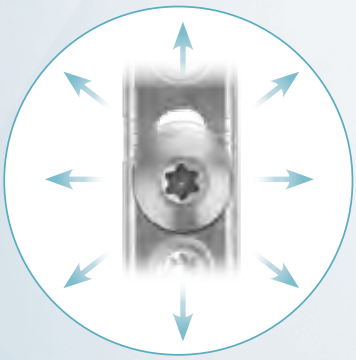
Polyaxial Design

- ±20° cone of angulation
- Allows for screw removal up to four times



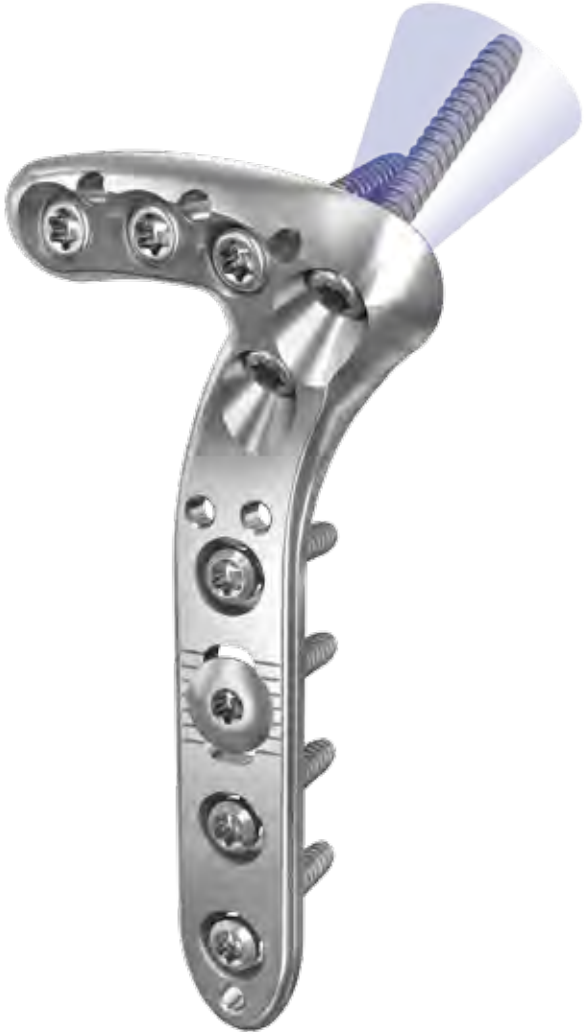
Positioning Slot and Screw

Allows multidirectional fine tuning of plate position



7 Volar Plate

Anatomic single row volar plate designed to increase intermediate column exposure of the distal radius, allowing for a clear view of the fracture line.



K-Wire Hole Trajectories

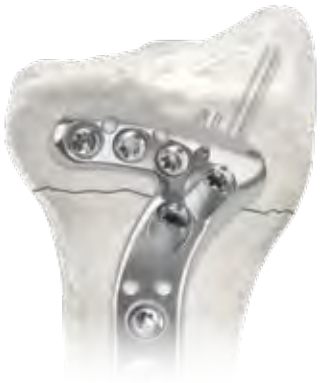
K-wire holes match screw trajectories

Radial Styloid

Screw trajectory optimized for maximum purchase

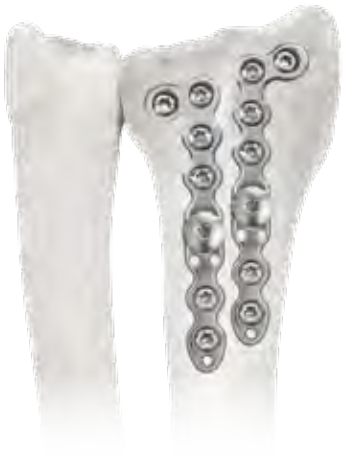
Innovative Plate Design

Allows clear view of fracture line



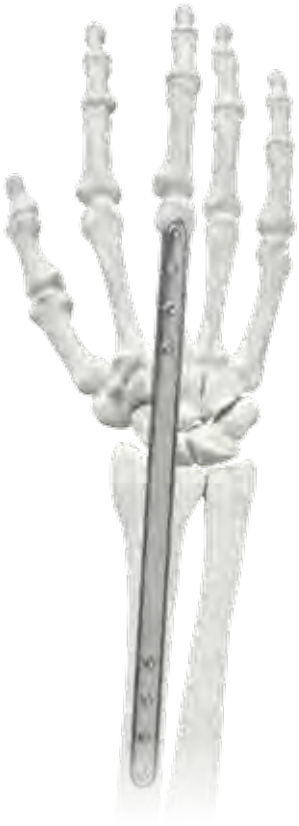
Comprehensive Plate Portfolio

Lunate Facet Hook Plate



Dorsal Plates

Lateral Plate



Bridge Plate

Ulna Plate

IMPLANT OVERVIEW

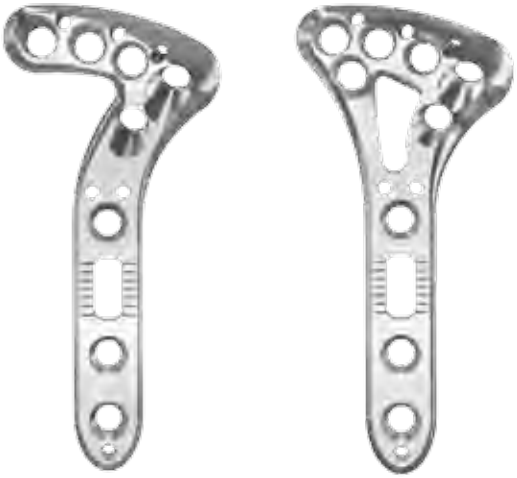
Volar Plates

ANTHEM™ 7 Volar Plate

- Designed to help increase intermediate column exposure of the distal radius, allowing for a clear view of the fracture line.

ANTHEM™ Double Row Volar Plate

- Designed for maximized buttressing and includes a graft hole.



Fragment Specific Plates

- Lunate Facet Hook Plate
- Dorsal (oblique and acute)
- Lateral
- Bridge
- Ulna

Screws

- 1.8mm Locking Pegs
- 2.0mm and 2.5mm Locking Screws
- 2.5mm Non-Locking Screws
- 2.5mm Positioning Screws

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

SURGICAL TECHNIQUE

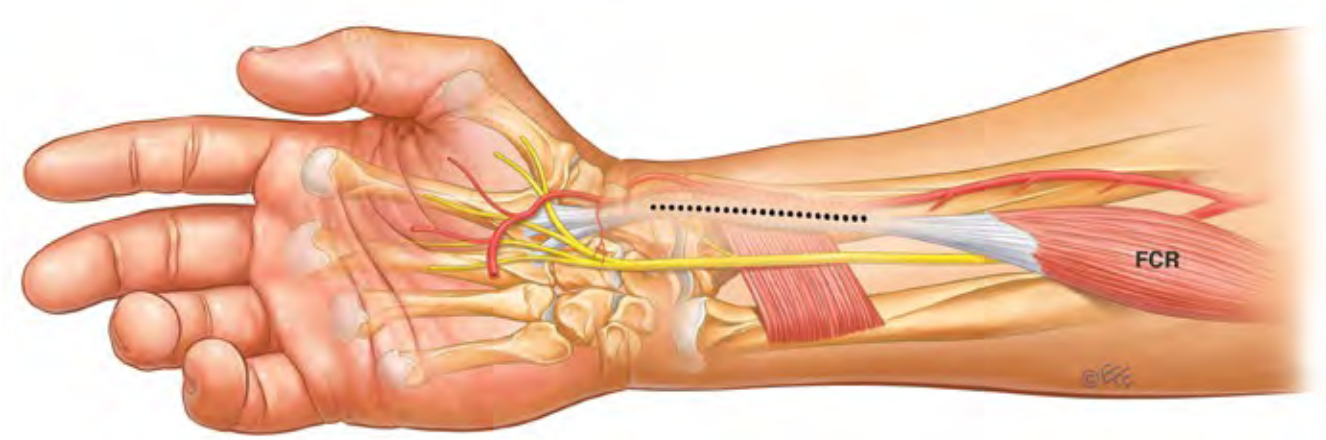
ANTHEM™
Volar Plating

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 APPROACH

The patient's arm is placed in supine position.

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



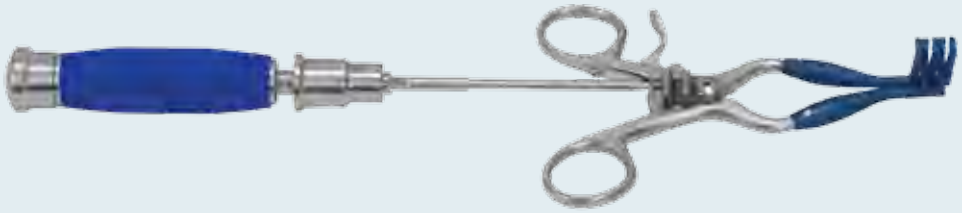
If necessary to cross the wrist, the incision should cross obliquely.

ASSEMBLY OF THE STABILIZING RADIOLUCENT WEITLANER

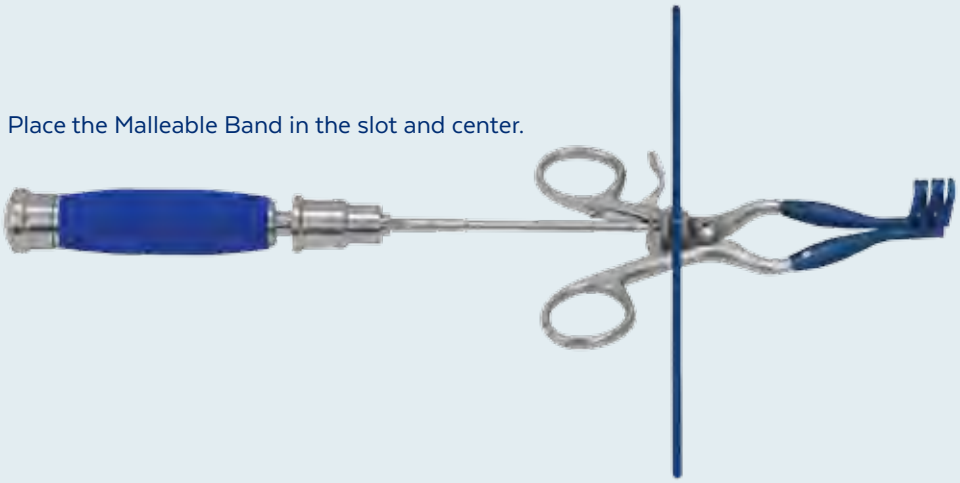
The malleable band provides intraoperative stability to the Weitlaner. Radiolucent arms eliminate the need for removal during fluoroscopy.

Instruments: T8 Driver and **Malleable Band**

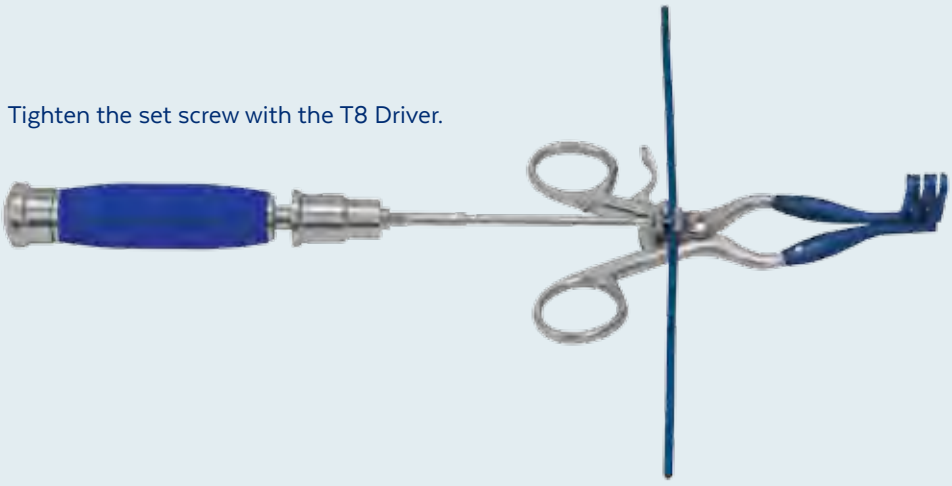
Using a T8 Driver, loosen the set screw.



Place the Malleable Band in the slot and center.



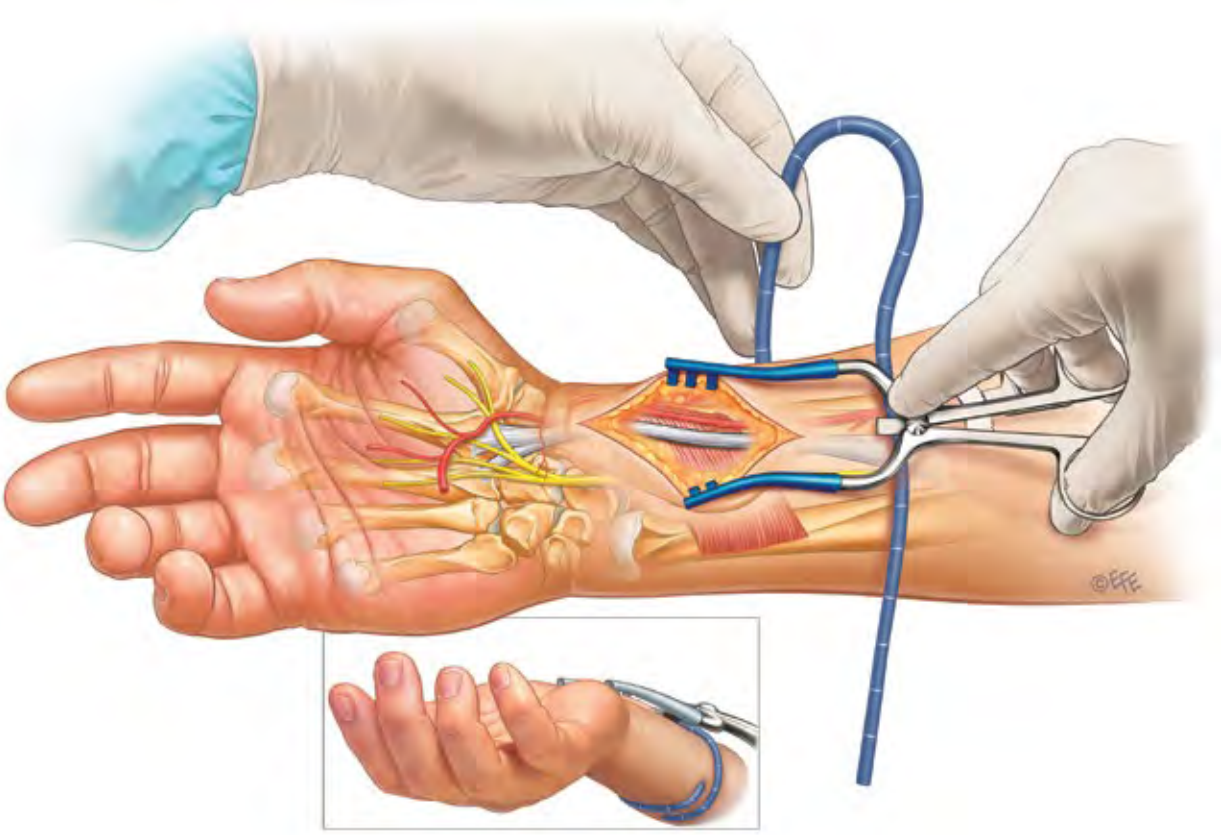
Tighten the set screw with the T8 Driver.

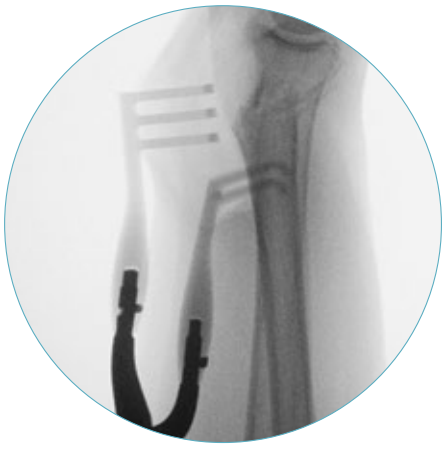


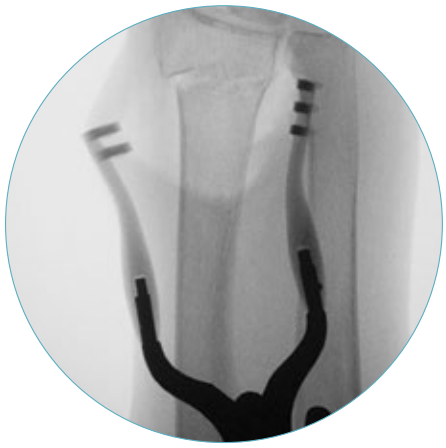
Replacement bands are located on the middle tray.

STEP 2 RETRACTION

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





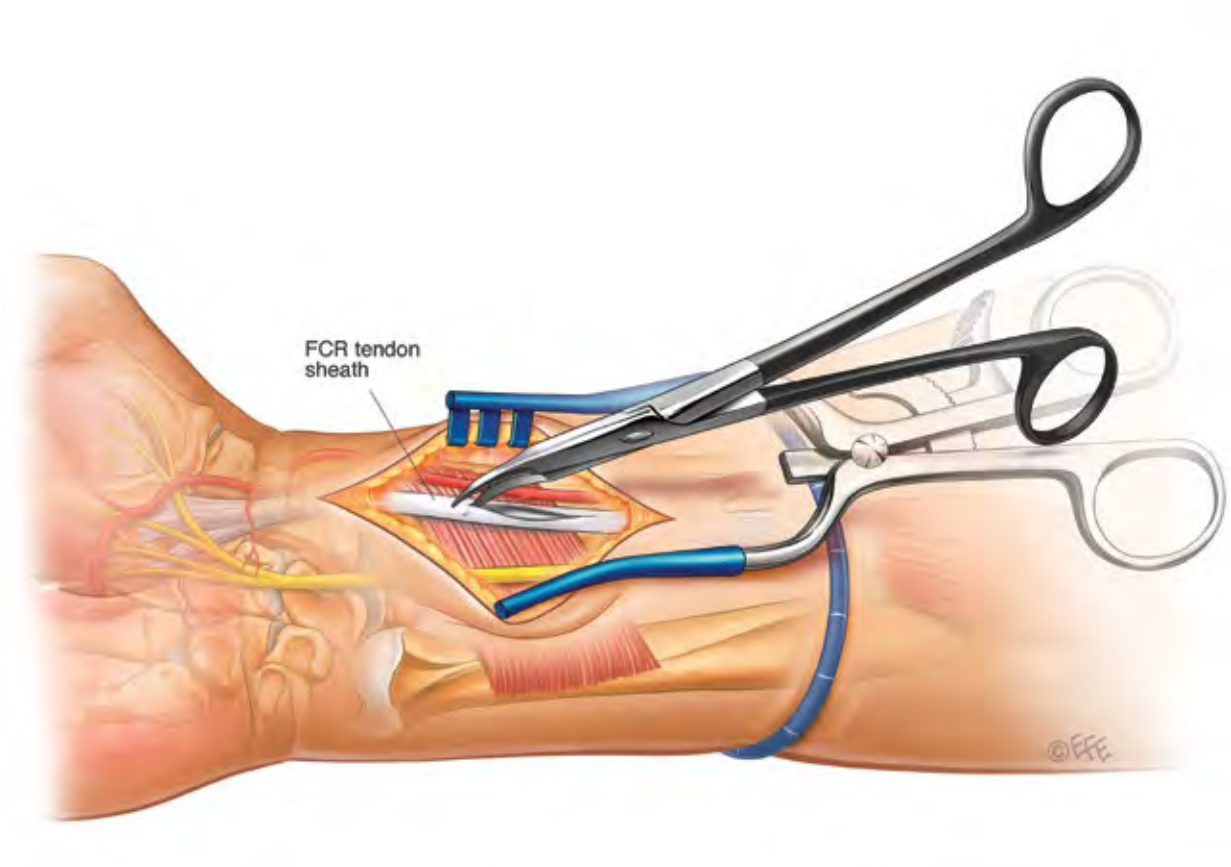


STEP 3 DISSECTION

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.

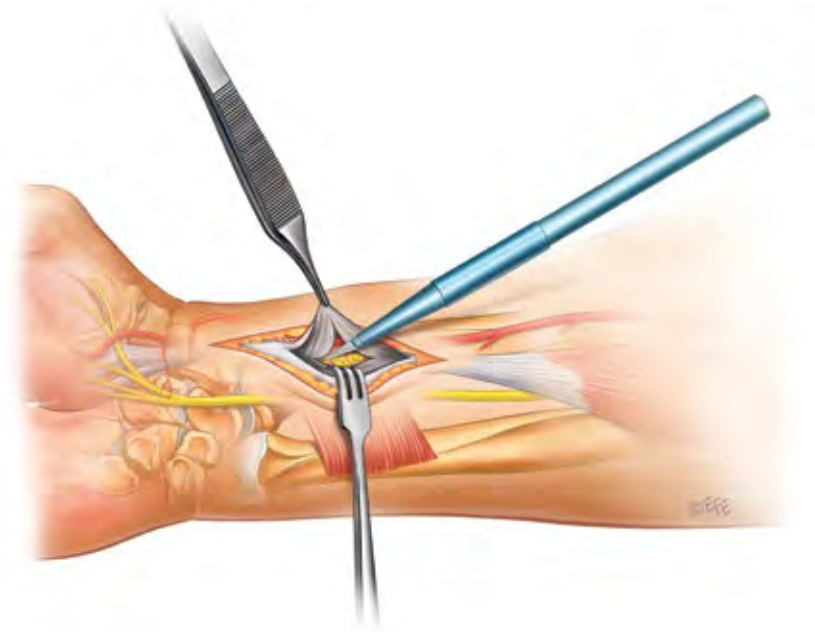


Carefully avoid any aberrant branches of the palmar cutaneous branch of the median nerve crossing the FCR tendon sheath.

DISSECTION (CONT'D)

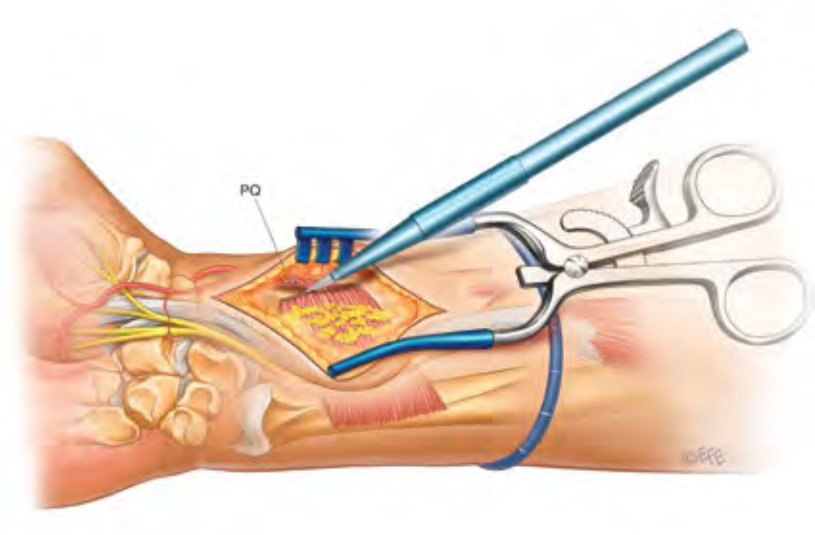
Mid-Level Dissection

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



Deep Dissection

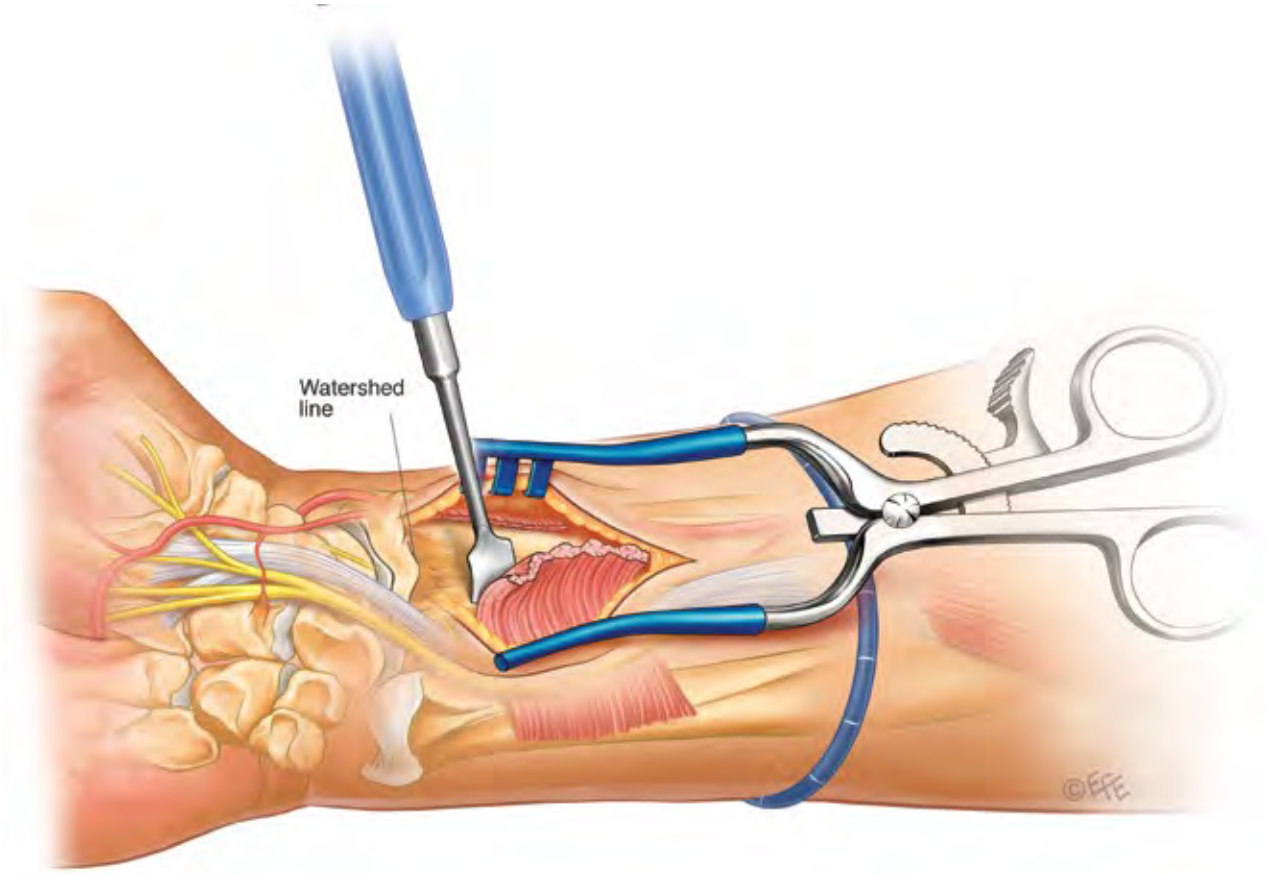
The plane between the flexor tendons and the pronator quadratus (PQ) muscle is bluntly developed. A loose fat pad may be encountered and excised. All flexor tendons, including the FCR tendon, should be retracted ulnarly and the radial artery retracted radially.



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**, the PQ muscle is moved 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 4 FRACTURE REDUCTION

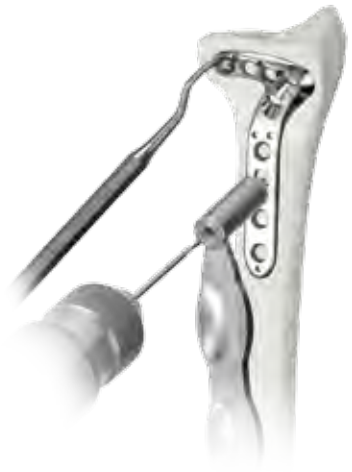
Using fluoroscopy, reduce the fracture using the appropriate method for the fracture type. Ensure that the radial length, alignment, and rotation are properly restored. Reduction should be confirmed using fluoroscopy. K-wires may be used for temporary fixation.

STEP 5 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 a **1.8mm Drill Bit** and **1.8mm Soft Tissue Protector**, drill a hole through the center of the positioning slot.



Drill through Soft Tissue Protector into positioning slot

Use the **Depth Gauge** to determine the screw length.

Depth Gauge

Use a T8 Driver to select the desired 2.5mm Positioning Screw.

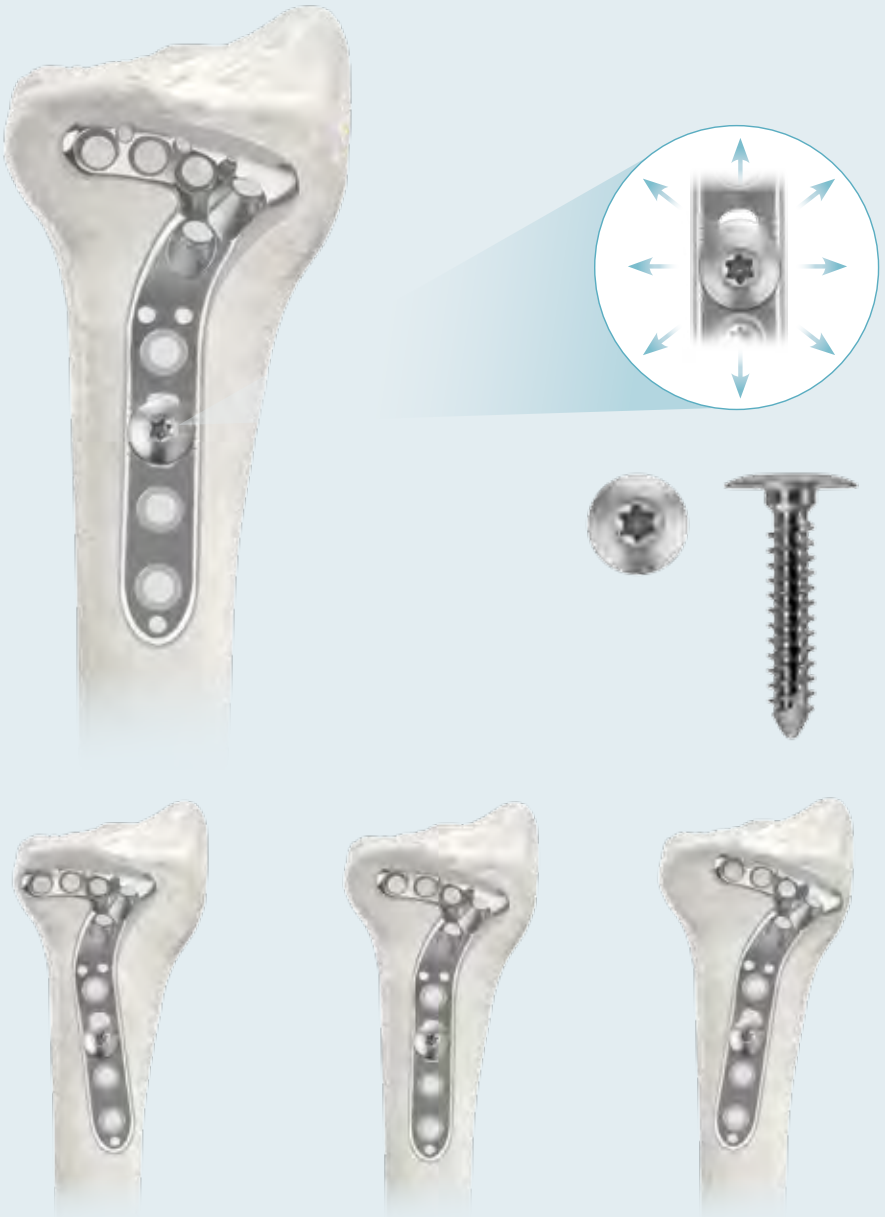
Use the **Measuring Gauge** to verify length.

Insert the positioning screw into the drilled hole using the T8 Driver and verify plate placement using fluoroscopy. Adjust the plate proximal-distal or medial-lateral to the desired position. Tighten the positioning screw using the T8 Driver. Once the plate is in an acceptable position with the positioning screw, the plate may be fixed definitively using additional shaft screws or provisionally held with K-wires through the plate shaft.

POSITIONING SLOT AND SCREW

The positioning screw allows for intraoperative, multidirectional fine tuning of plate position.

The positioning hole and positioning screw allows for 1.3mm of medial-lateral translation and 5mm of proximal-distal translation to optimize plate position.



Medial-lateral translation

STEP 6 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.

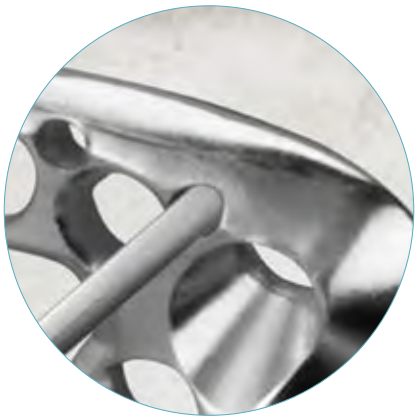
Using the k-wire attachment for the drill, insert a **1.6mm K-Wire**. Insert the k-wire closest to the radial styloid. If desired, insert additional k-wires.

K-wire insertion

Confirm the trajectories of the k-wires using fluoroscopy.

The k-wire holes are fitted to match 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.

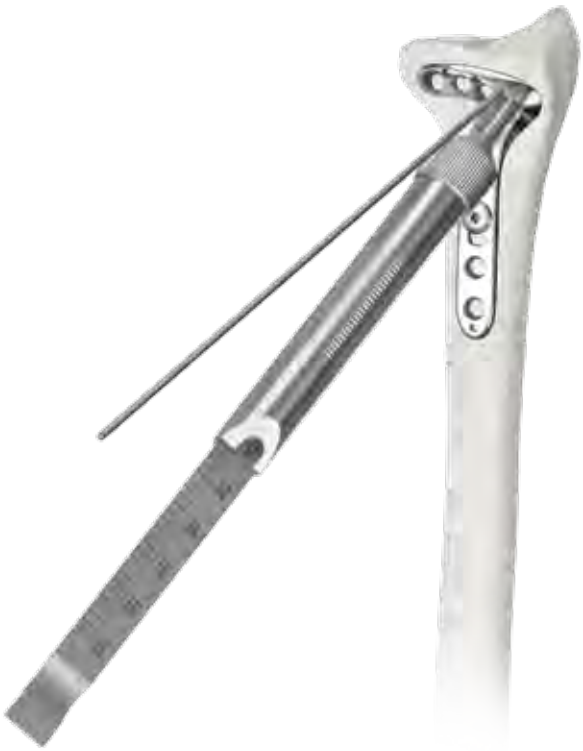
STEP 7 DISTAL FIXATION

Once the fracture is reduced, insert the 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. Verify screw and/or peg placement using fluoroscopy.

If using a 2.0mm locking screw for anything other than buttressing, a 1.5mm drill must be used.

Speed Lock Drill Guide



Depth Gauge

Prior to placement of additional subchondral locking screws, consider placing a non-locking cortical subchondral screw 2mm longer than measured 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

1.8mm Speed Lock Drill Guide

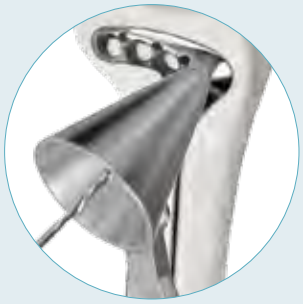
The Speed Lock Drill Guide may be used to drill nominal trajectories. The thumb lock quickly locks the drill guide to the plate at the nominal screw trajectory.

Speed Lock Drill Guide

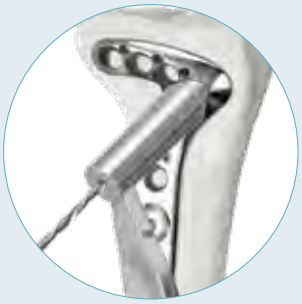
Speed Lock Drill Guide locked in place

1.8mm Soft Tissue Protector

The Soft Tissue Protector allows for a 40° cone of angulation on the polyaxial end and nominal trajectory on the nominal end.



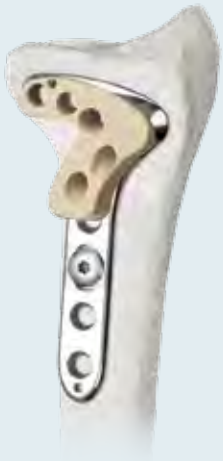
Polyaxial end



Nominal end

Targeting Drill Guide

The Targeting Guide may be used as a fixed angle drill and screw guide. Attach the corresponding Targeting Guide to the distal head and use the Targeting Sleeve Guide to drill each hole and insert screws through the Targeting Guide.



Targeting Drill Guide

Targeting Guide Drill Sleeve

STEP 8 PROXIMAL FIXATION

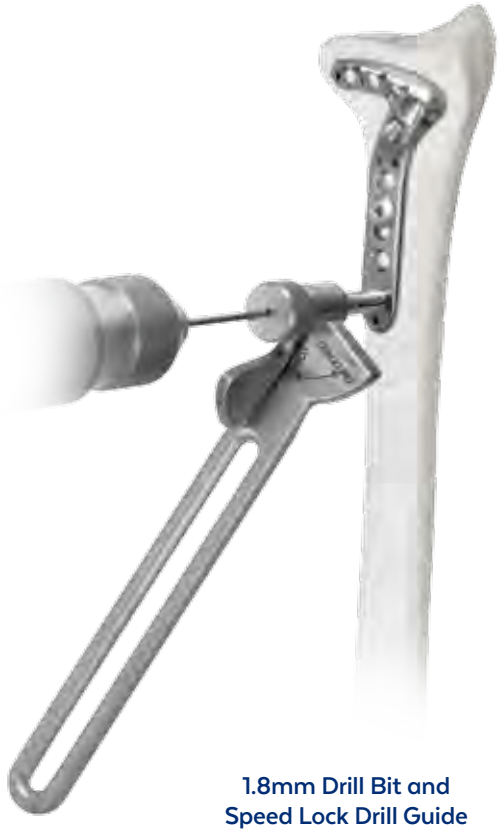
Shaft screw insertion varies depending on the reduction technique and fracture pattern.

Pre-drill a hole using the 1.8mm Drill Bit and selected Drill Guide into the shaft holes.

Measure hole depth using the Depth Gauge.

Insert the corresponding 2.0mm or 2.5mm cortical locking screw or 2.5mm non-locking screw using the T8 Driver.

Verify placement using fluoroscopy.



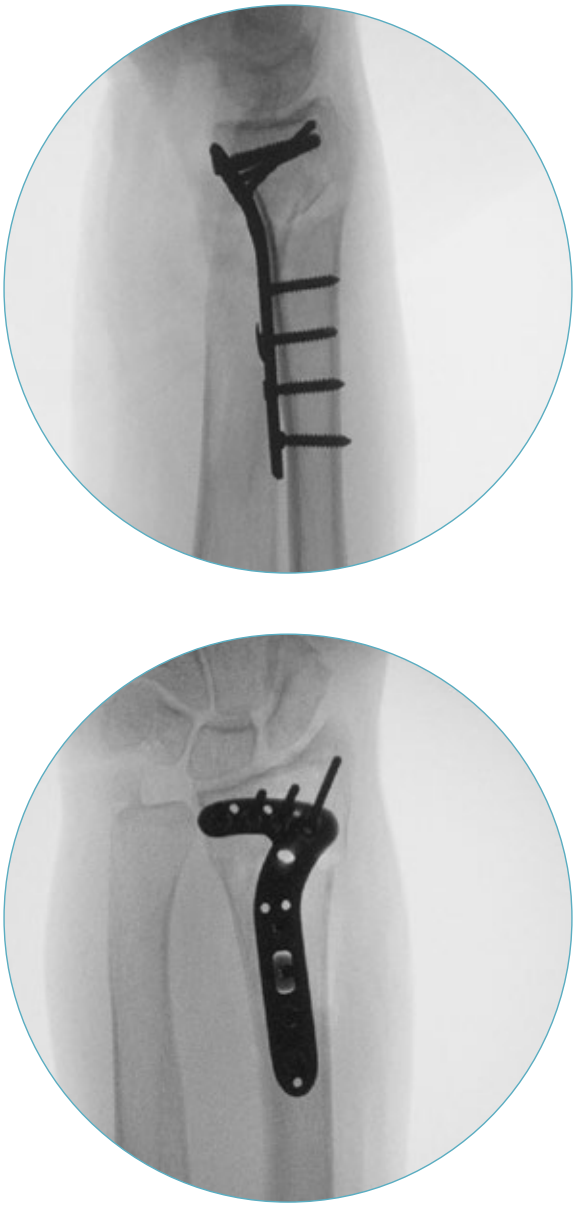
1.8mm Drill Bit and Speed Lock Drill Guide

Screw inserted with the T8 Driver

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

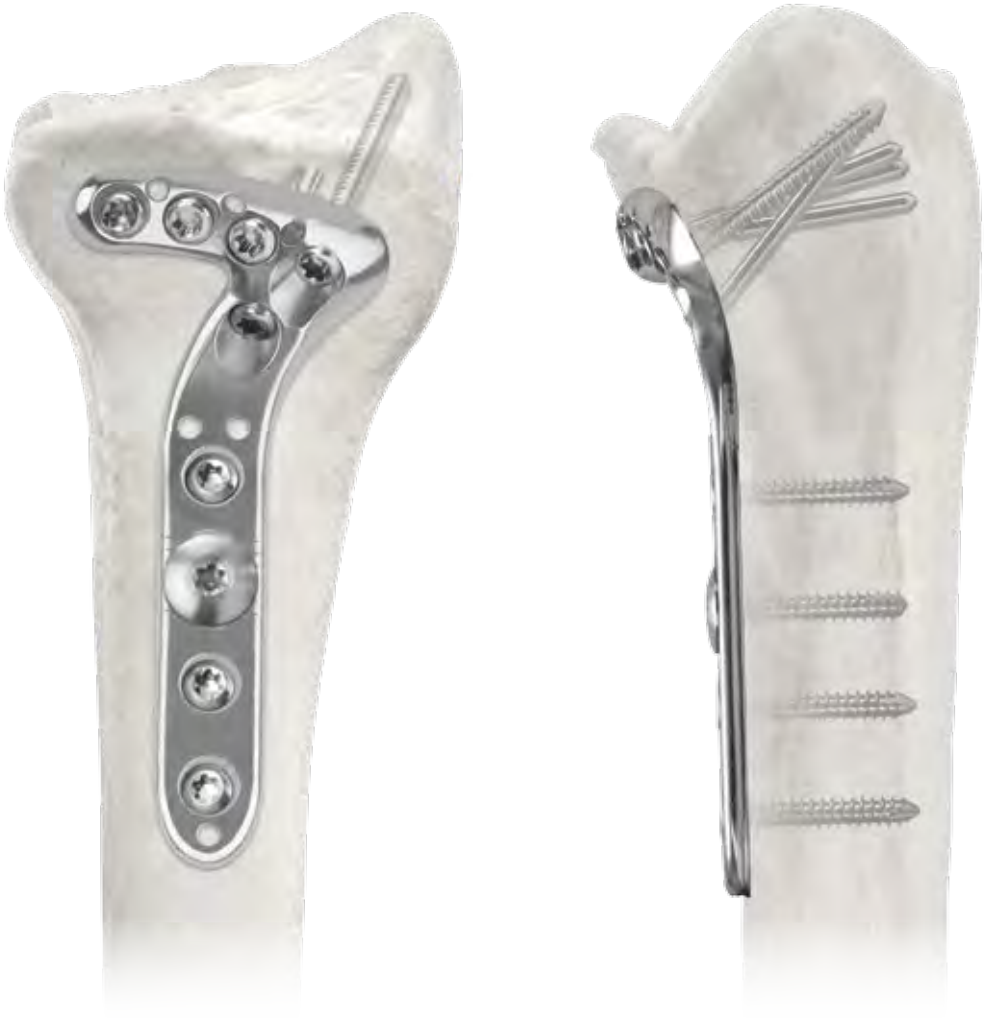
STEP 9 CONFIRM RECONSTRUCTION

Confirm 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.



Multiple views to confirm reconstruction

FINAL CONSTRUCT



OPTIONAL: REMOVAL

If removal is required, use a 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 a T8 Driver to remove all non-locking and locking screws from the plate. Once all screws are removed, the plate can be removed.

Straight drivers are recommended for removal.

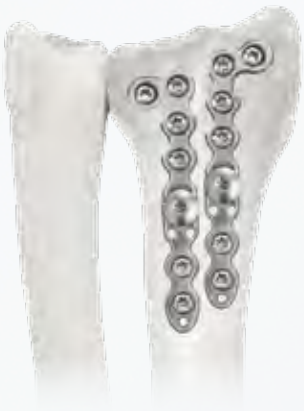
SURGICAL TECHNIQUES

ANTHEM™

Fragment Specific Plating

The ANTHEM™ Distal Radius Fracture System is a comprehensive system that includes fragment specific plates. These plates include Lunate Facet Hook, Dorsal Acute and Dorsal Oblique, Lateral, Bridge, and Ulna 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

SURGICAL TECHNIQUE

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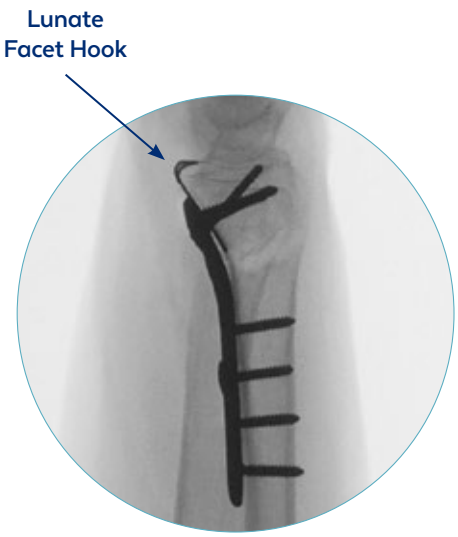
Lunate Facet Hook Plating

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.

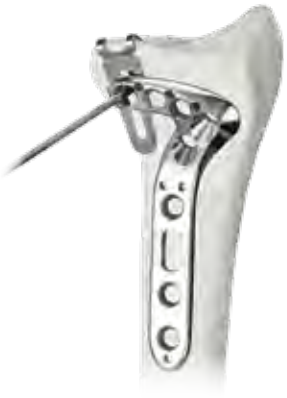
Lunate Facet Hook Plate Application Methods:

A) Independent Facet Hook

B) Prior to Volar Plate Insertion

C) Following Volar Plate Insertion

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.

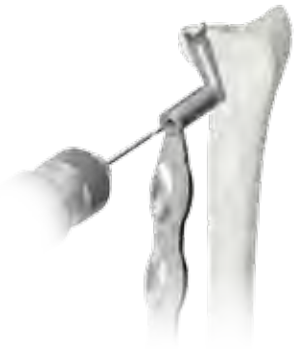
STEP 2 PROXIMAL FIXATION

Drill a hole in the most proximal end of the slot in the plate using a Soft Tissue Protector and a 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.

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

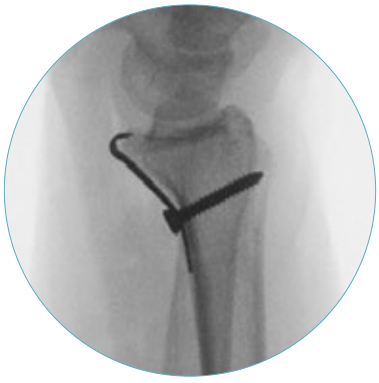
Lunate Facet Hook Plate applied to lunate facet

Plate tines placed using the tamp and mallet



Proximal fixation using 1.8mm Drill Bit and Soft Tissue Protector

Screw placement



Final fluoroscopic image

Final construct

Option B: Prior to Volar Plate Insertion

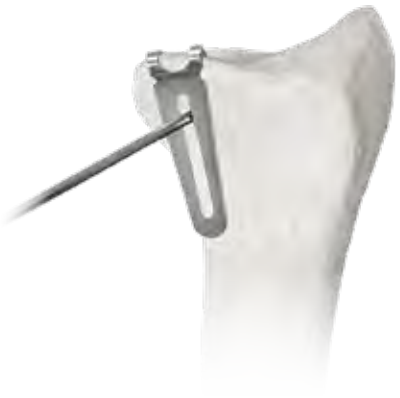
This method is used when lunate facet fixation is necessary prior to volar plate application.

STEP 1 PLATE APPLICATION

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

STEP 2 PROXIMAL AND PRELIMINARY FIXATION

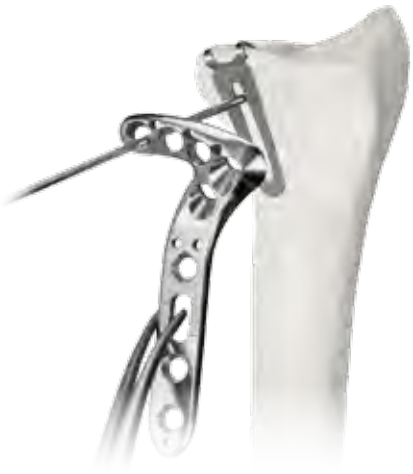
Insert a 1.6mm k-wire. Using the k-wire for provisional fixation, place the volar plate over the k-wire onto the Lunate Facet Hook Plate.



Volar Plate positioned over the k-wire

STEP 3 VOLAR PLATE APPLICATION

Follow the Volar Plate Application steps beginning on page 16.



Volar Plate positioned over Lunate Facet Hook Plate

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

Tamp Lunate Facet Hook Plate

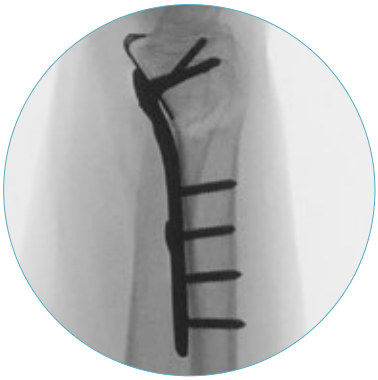
STEP 2 SCREW INSERTION

Use the T8 Driver to reinsert the ulnar-most subchondral volar 2.5mm locking screw into the Volar Plate.

Screw Insertion

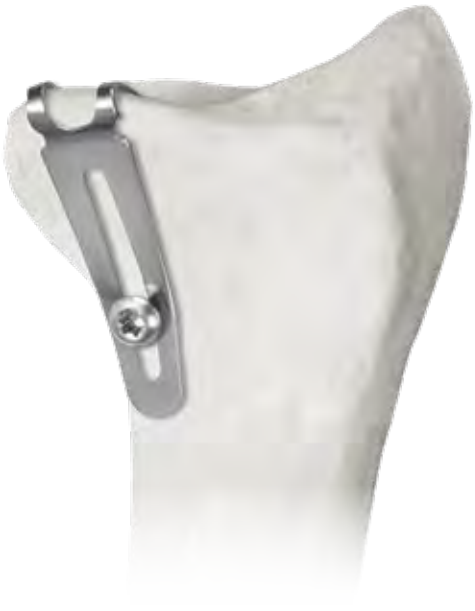
STEP 3 CONFIRM PLACEMENT

Confirm placement of the Lunate Facet Hook using fluoroscopy.

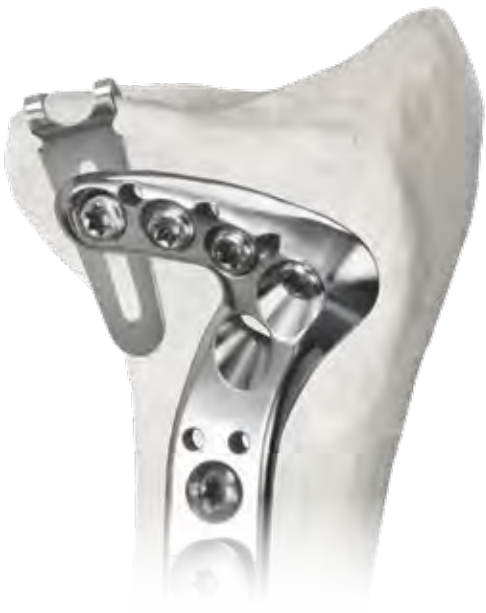


Correct placement of Lunate Facet Hook Plate

FINAL CONSTRUCTS



Independent Lunate Facet Hook Plate



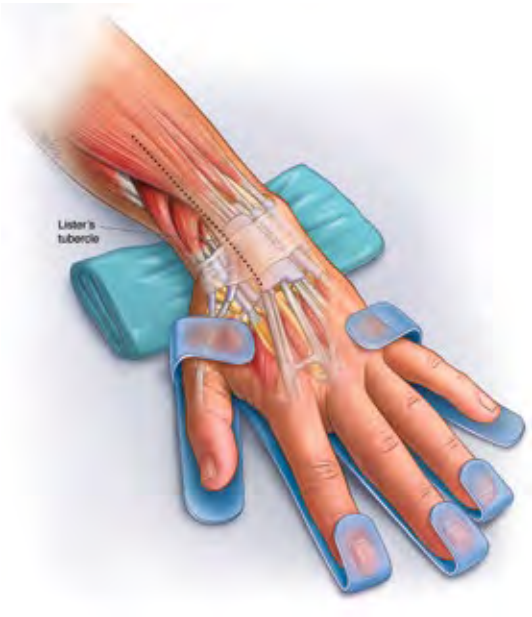
Volar Plate and Lunate Facet Hook Plate

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.

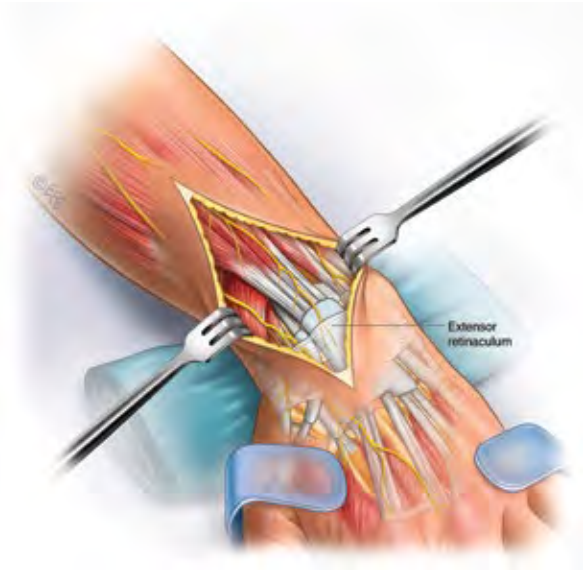


Hand position

STEP 2 EXPOSURE

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

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

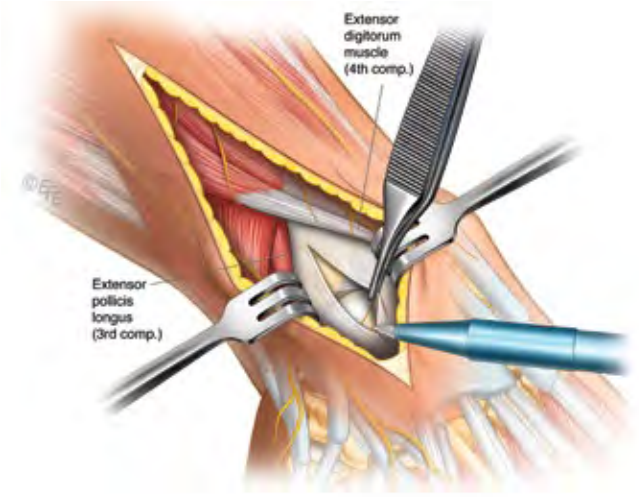


Retracting skin flaps to expose retinaculum

EXPOSURE (CONT'D)

Create a longitudinal incision between the third and fourth dorsal compartment or through a double rectangular step cut.

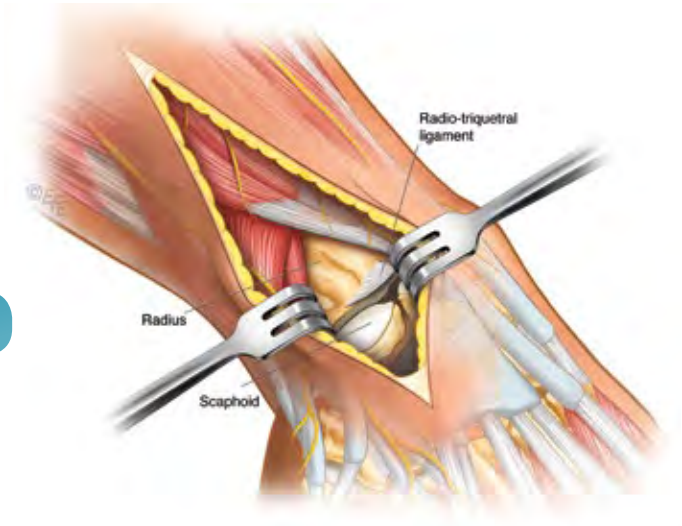
The double rectangular step cut allows for re-approximation of the retinaculum without transposition of the extensor pollicis longus (EPL) and allows tendon coverage.



Longitudinal incision

Enter the wrist capsule through a ligamentous sparing capsulotomy, preserving the radio-triquetral and dorsal intercarpal ligaments.

Carefully preserve the dorsal radioulnar ligaments.



Wrist capsule

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 radiographic imaging 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.

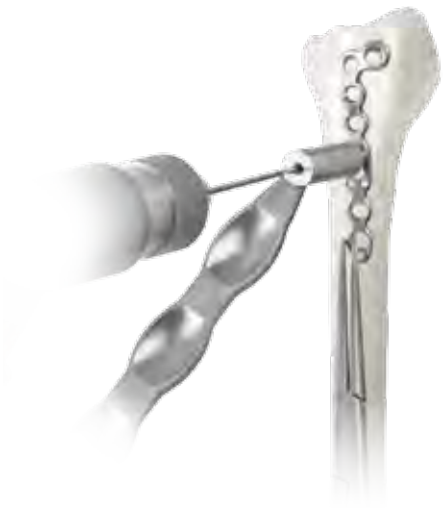
Application of Oblique Dorsal Plate

STEP 5 PLATE APPLICATION

Using a 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 a 1.8mm Drill Bit and the Soft Tissue Protector Guide. 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.



Pre-drilling of positioning slot using universal Drill Guide

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 2.5mm cortical non-locking screw or a 2.5mm locking screw using the T8 Driver.

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.

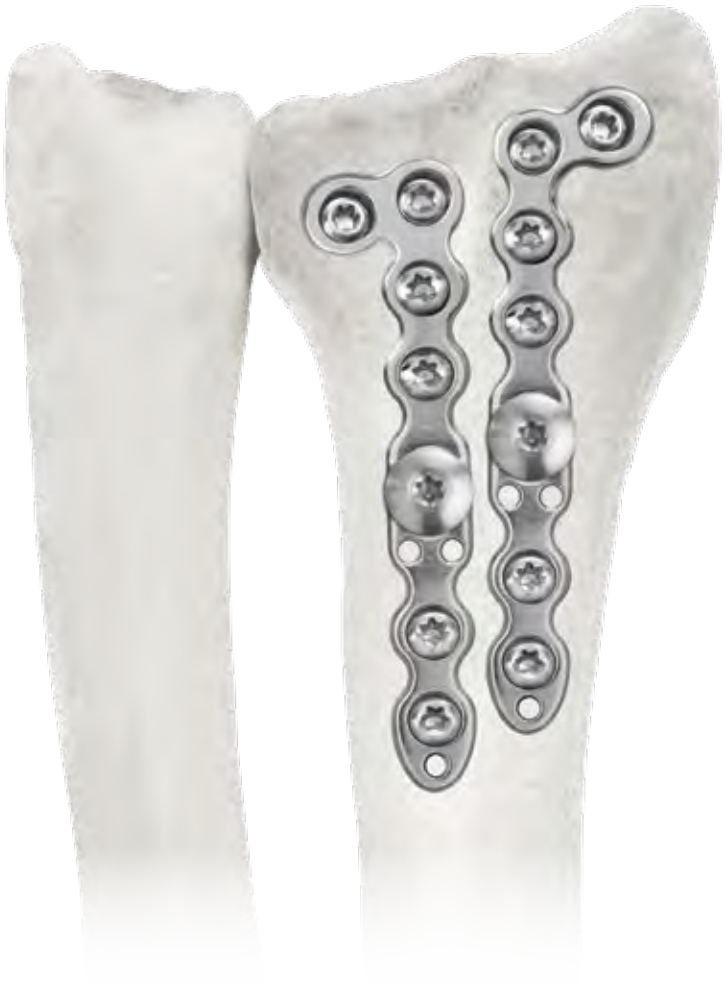
Insert either 2.5mm cortical locking screws, 2.0mm locking screws, or 1.8mm smooth locking pegs using the T8 Driver. If using a 2.0mm locking screw for anything other than buttressing, a 1.5mm drill must be used.

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

Depth Gauge measurement

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

FINAL CONSTRUCT



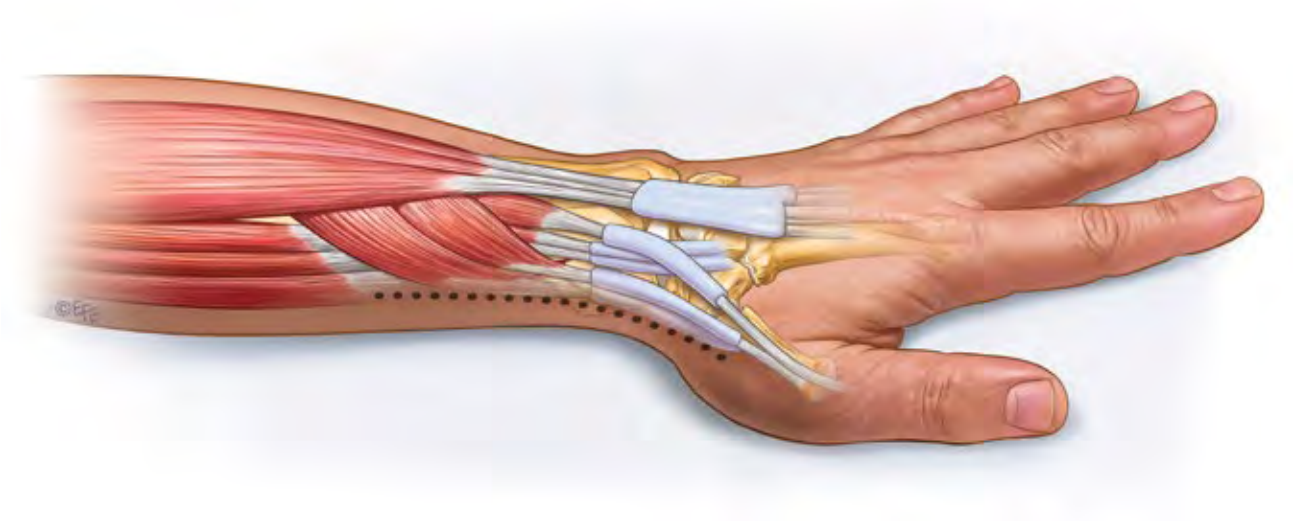
SURGICAL TECHNIQUE

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.



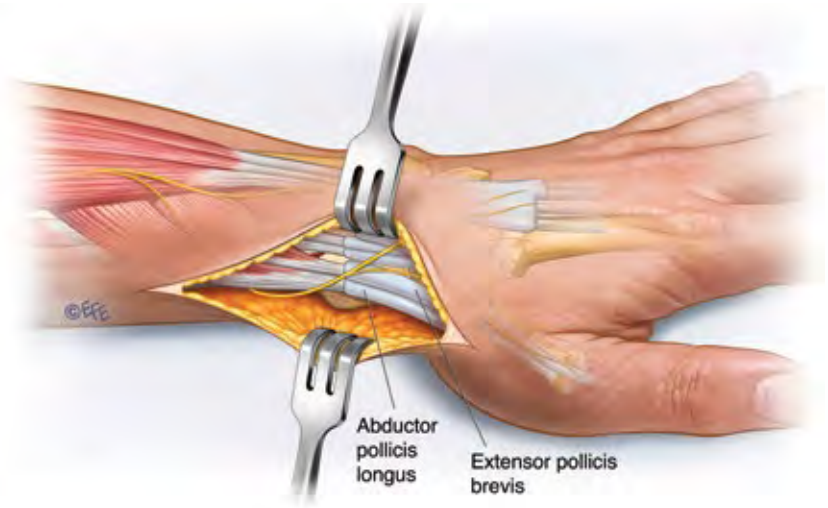
If the lateral plate is applied with a volar plate, the radial plate may be placed through the same volar incision.

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.

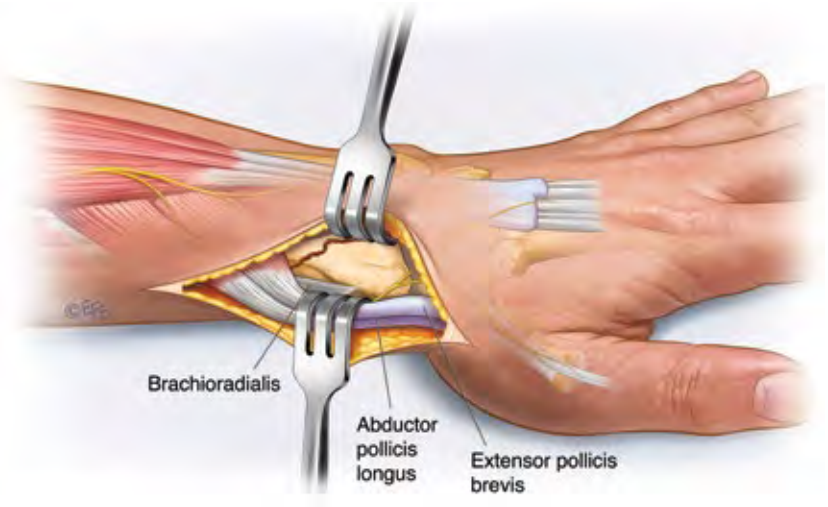
Branches of the radial sensory nerve may be present in the surgical field and must be carefully dissected and protected.



Deep Dissection

Release the first dorsal compartment and retract the APL and EPB tendons. The brachioradialis tendon is now exposed.

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

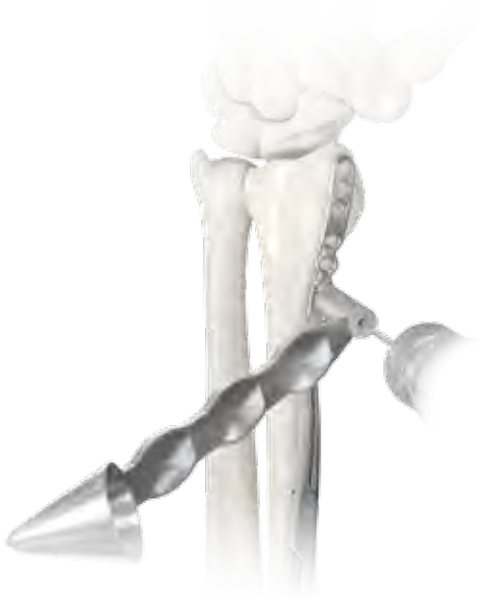


STEP 3 PLATE APPLICATION

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

Application of Lateral Plate

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



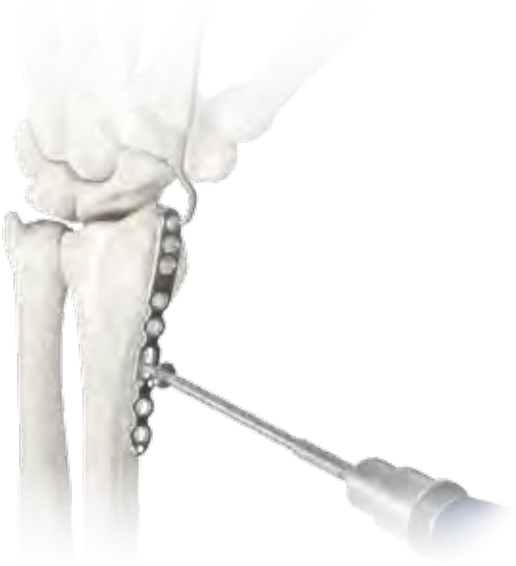
Pre-drilling of positioning slot

Insert the positioning screw using the T8 Driver.

Adjust the plate proximal-distal or medial-lateral for optimal position.

The Plate Positioner may be used to stabilize the plate during screw insertion.

Confirm plate placement using fluoroscopy.



Positioning screw insertion

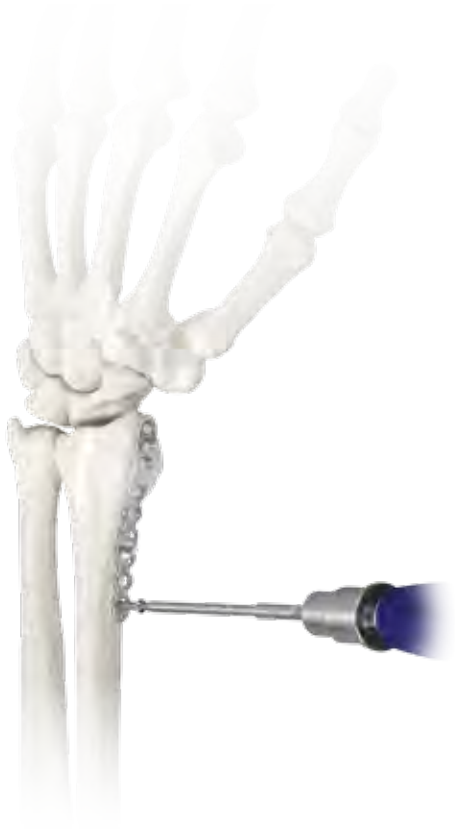
STEP 4 PLATE FIXATION

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.



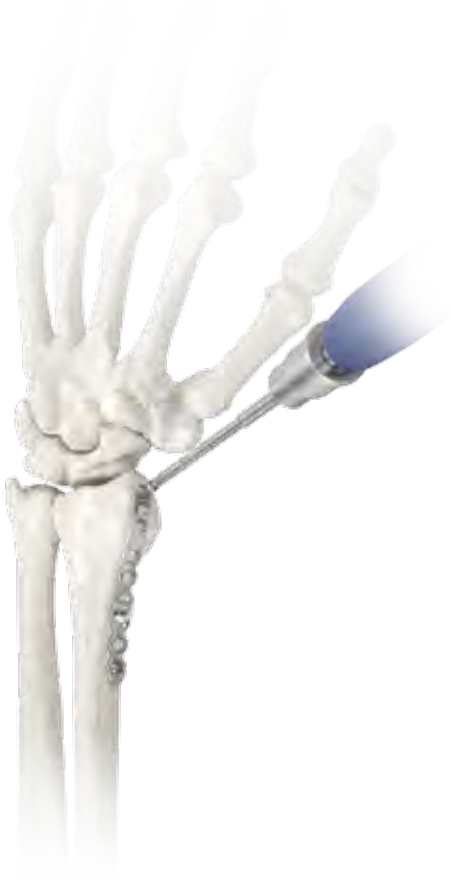
Distal Fixation

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, a 1.5mm drill must be used.

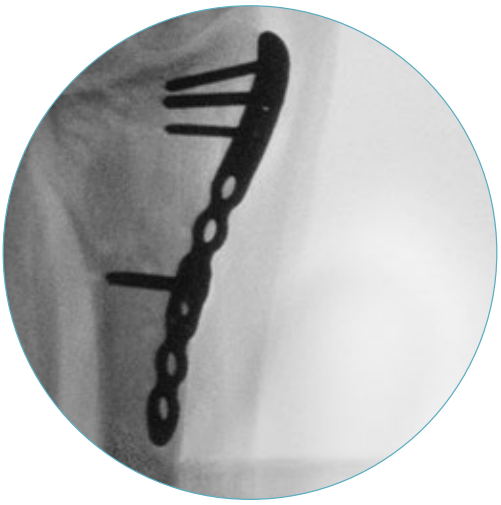
Confirm placement using fluoroscopy and tighten all proximal and distal screws.

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.

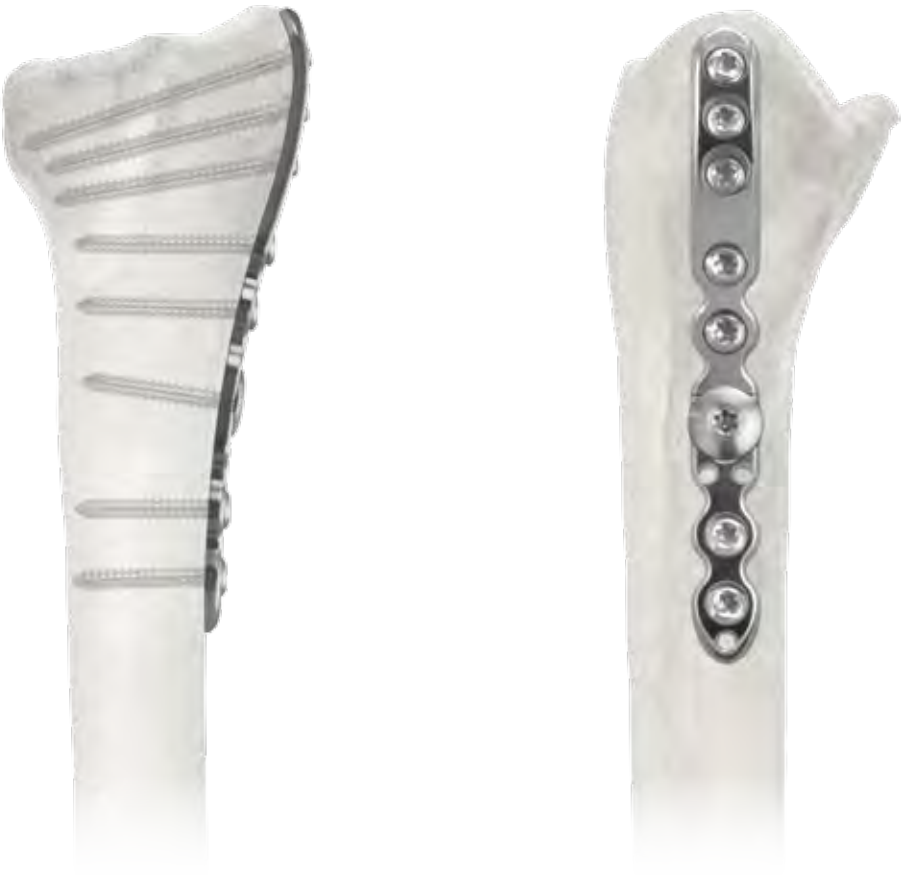


STEP 5 CONFIRM REDUCTION

Using fluoroscopy, verify screw trajectories and confirm plate placement.



FINAL CONSTRUCT



SURGICAL TECHNIQUE

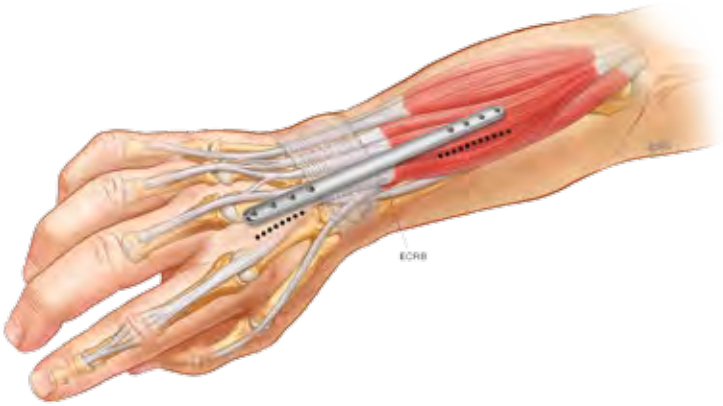
ANTHEM™
Bridge Plating

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.

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



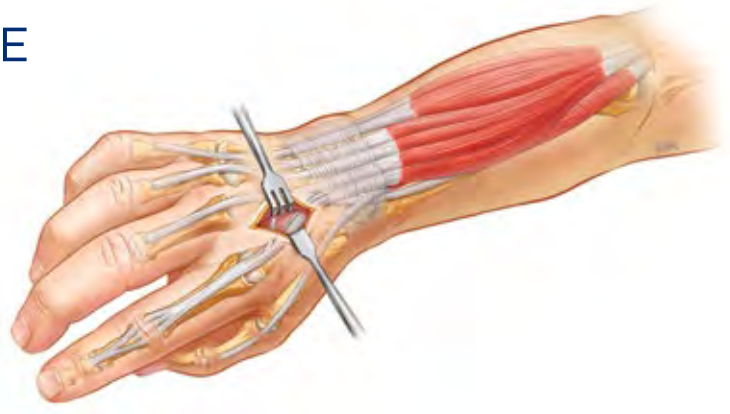
Distal incision with plate

STEP 2 DISTAL EXPOSURE

Create a distal incision.

Retraction of the tendons is needed as blunt dissection is performed to the extensor tendons.

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

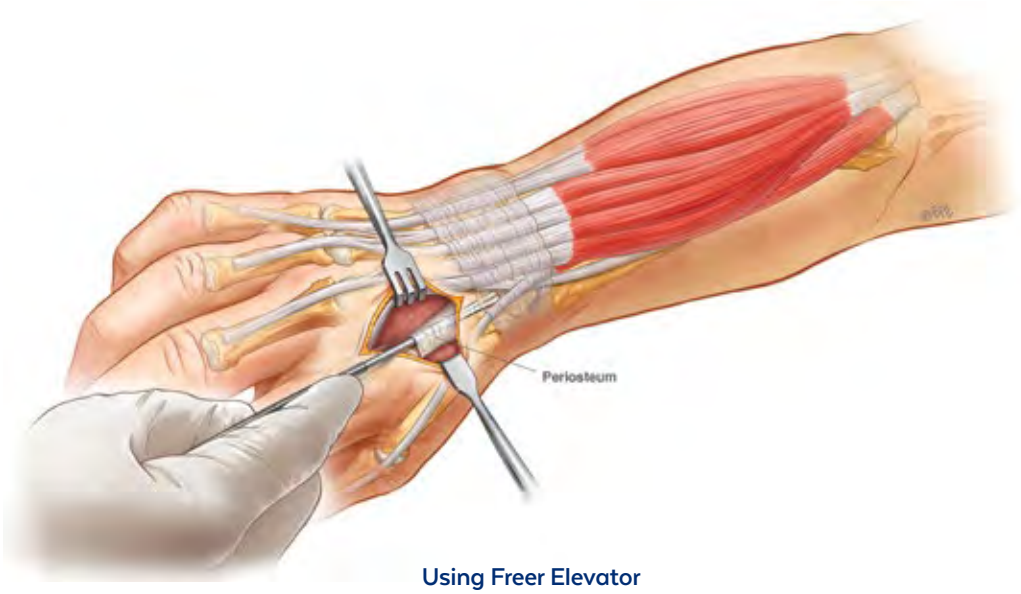


Distal incision and tendon retraction

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.

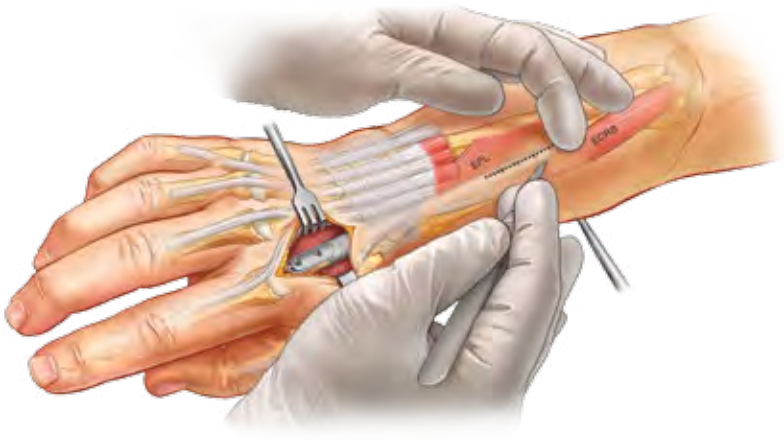
STEP 3 PLATE APPLICATION

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.

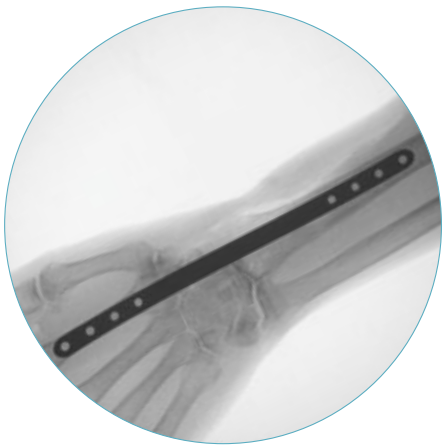


Using Freer Elevator

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



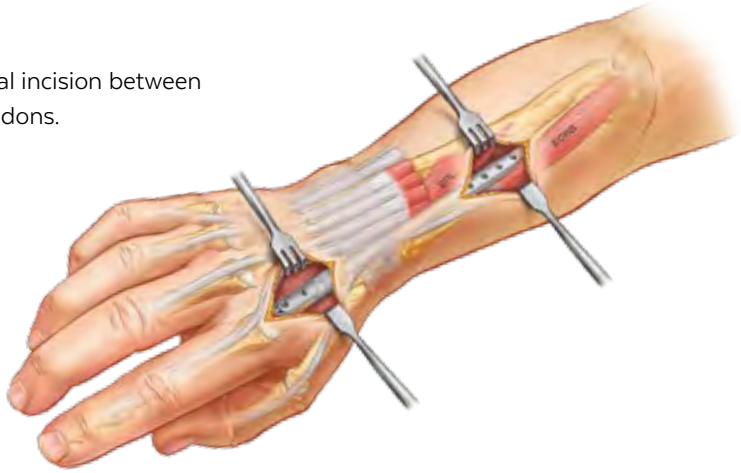
Placement confirmation

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.

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



Bridge Plate centered on radius

STEP 5 PLATE FIXATION

Distal Fixation

Using a 1.8mm Drill Bit, drill through the second most distal hole of the plate. Measure hole depth using the Depth Gauge.

Using a T8 Driver, insert the selected non-locking 2.5mm cortical screw.

Confirm screw placement using fluoroscopy.

Distal hole fixation

Using the Depth Gauge

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

Proximal Fixation

Using a 1.8mm Drill Bit, drill through the second most proximal hole. Measure the desired screw length using the Depth Gauge.

Using a T8 Driver, insert a non-locking 2.5mm cortical screw.

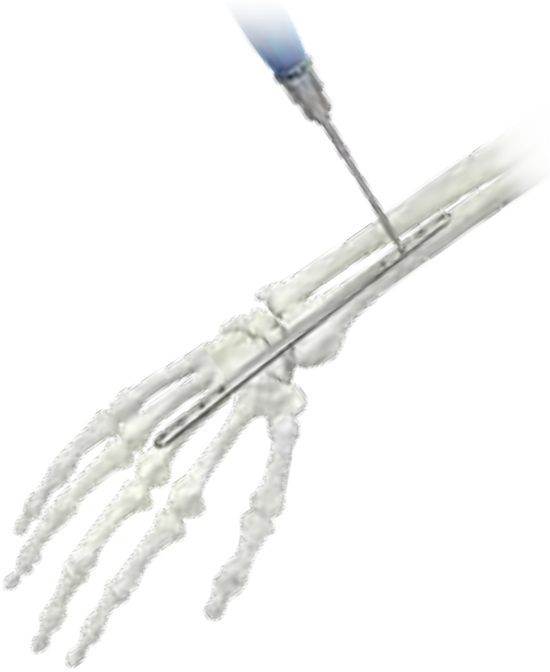
Confirm screw placement using fluoroscopy.

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

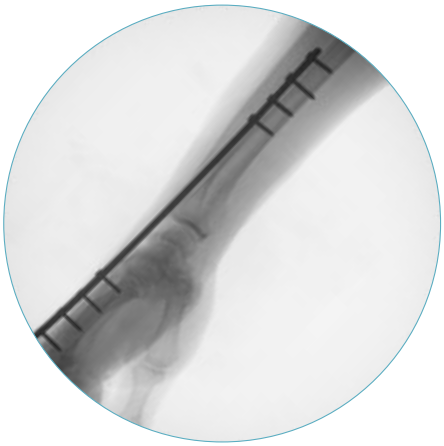
Drilling second most proximal hole

STEP 6 SCREW INSERTION

Once fracture reduction and plate placement are achieved, fill additional screw holes proximally and distally with locking 2.5mm locking screws using a 1.8mm Drill Bit and Drill Guide. Confirm screw placement using fluoroscopy.



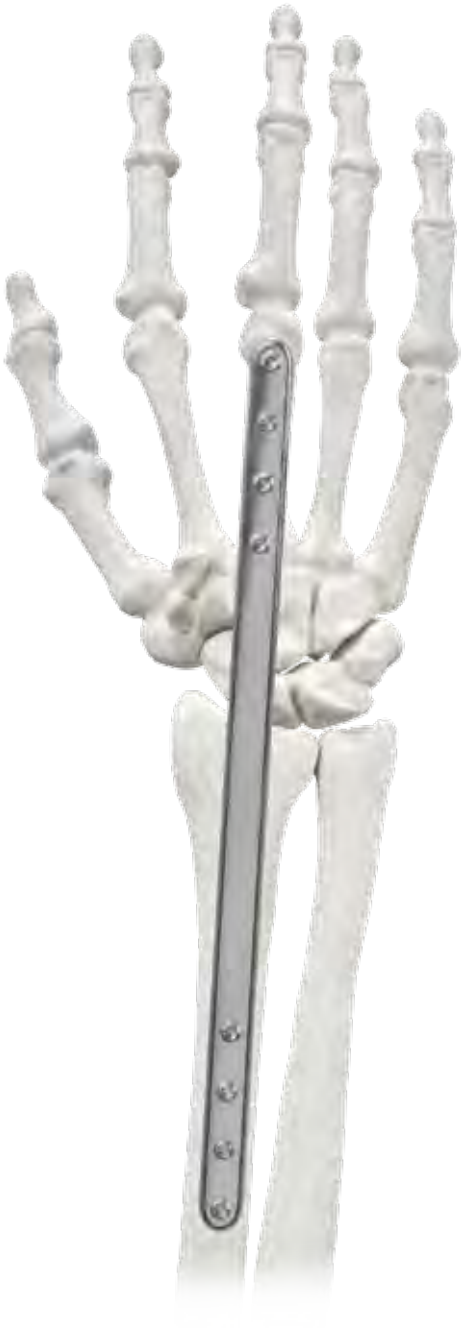
Locking screw fixation



Final placement

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

FINAL CONSTRUCT



SURGICAL TECHNIQUE

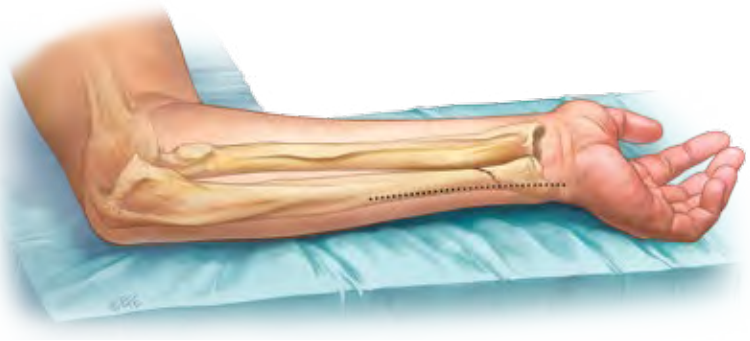
ANTHEM™

Ulnar Plating

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

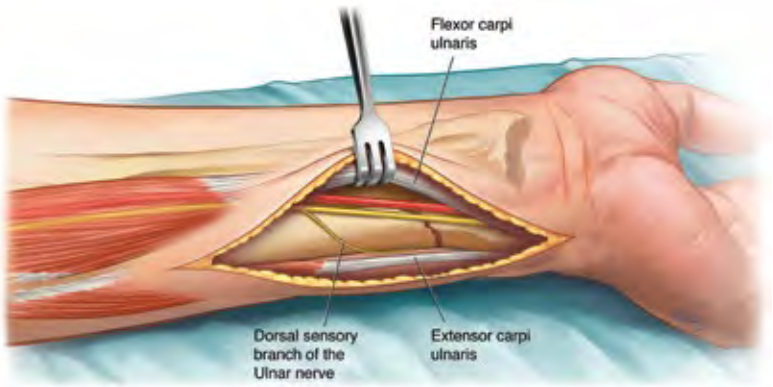
STEP 1 APPROACH

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.



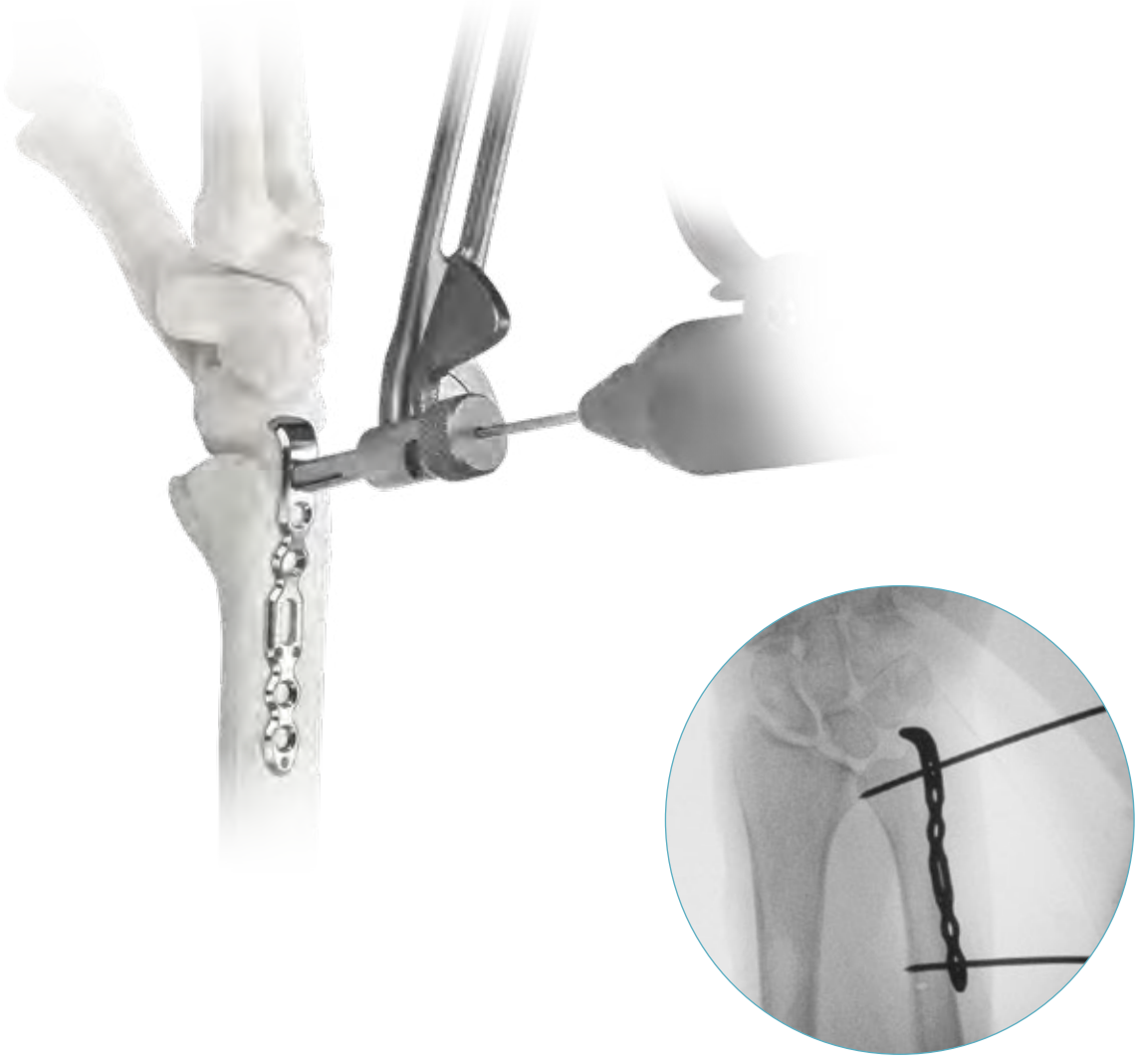
Carefully avoid the dorsal sensory branch of the ulnar nerve.

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.

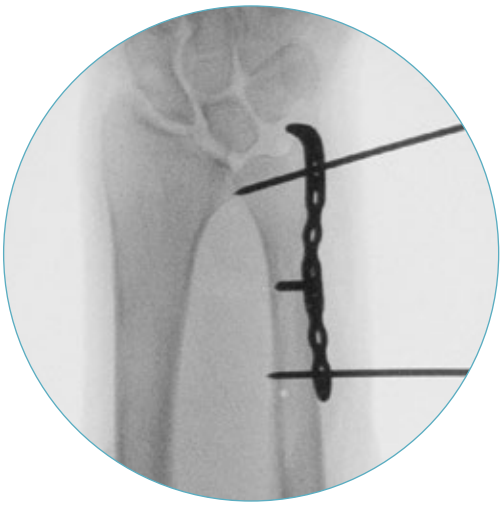
STEP 5 PLATE APPLICATION

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

Using the Depth Gauge, measure the desired hole depth.

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

Confirm placement using fluoroscopy.

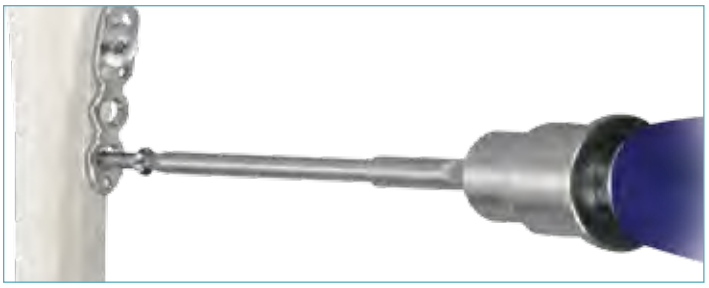


Positioning screw placement

STEP 6 SCREW INSERTION

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

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.

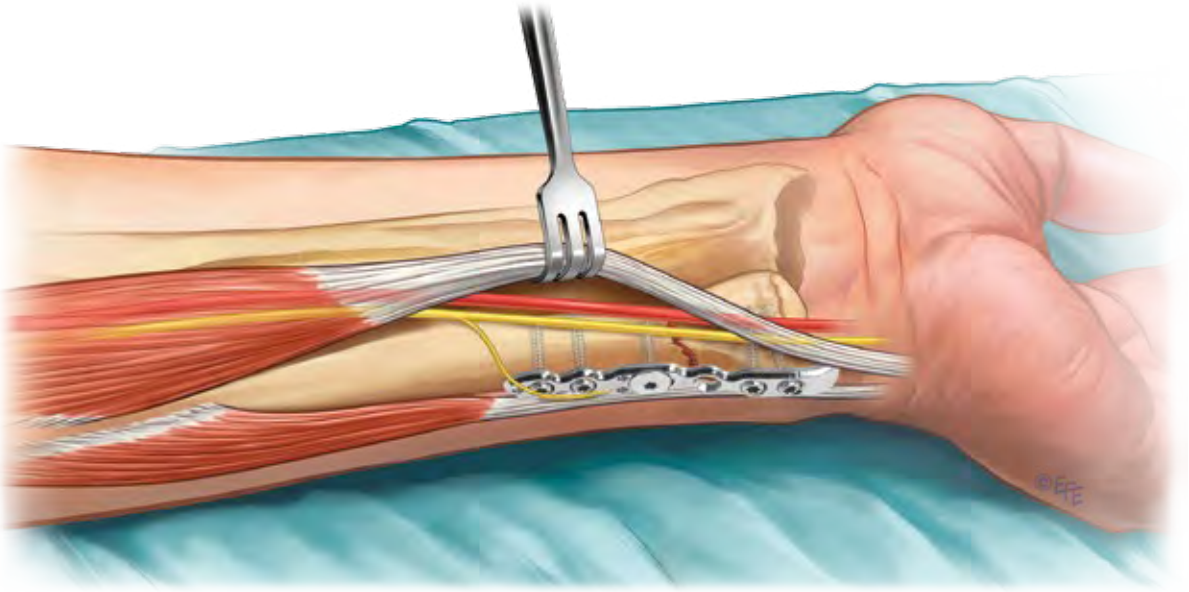
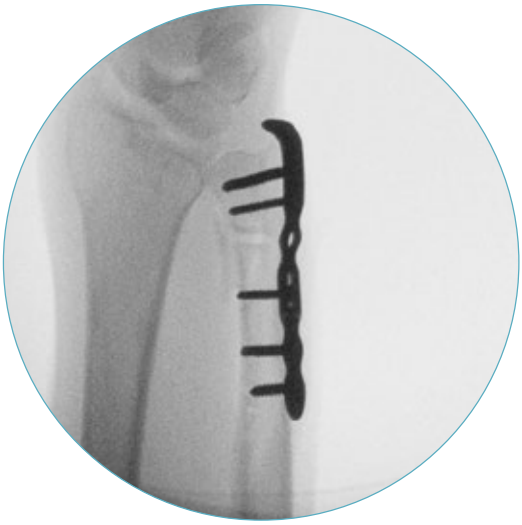


Plate placement



Confirming position

FINAL CONSTRUCT

ANTHEM™ SS Distal Radius
IMPLANTS 9171.9001

PART NO.	DESCRIPTION	QTY
2171.1324	ANTHEM™ Volar Plate, Double Row, Wide, Left, 4 Hole, SS	1
2171.1313	ANTHEM™ Volar Plate, Double Row, Standard, Left, 3 Hole, SS	1
2171.1314	ANTHEM™ Volar Plate, Double Row, Standard, Left, 4 Hole, SS	3
2171.1315	ANTHEM™ Volar Plate, Double Row, Standard, Left, 5 Hole, SS	1
2171.1303	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 3 Hole, SS	1
2171.1304	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 4 Hole, SS	1
2171.1305	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 5 Hole, SS	1
2171.1024	ANTHEM™ 7 Plate, Wide, Left, 4 Hole, SS	1
2171.1013	ANTHEM™ 7 Plate, Standard, Left, 3 Hole, SS	1
2171.1014	ANTHEM™ 7 Plate, Standard, Left, 4 Hole, SS	3
2171.1015	ANTHEM™ 7 Plate, Standard, Left, 5 Hole, SS	1
2171.1003	ANTHEM™ 7 Plate, Narrow, Left, 3 Hole, SS	1
2171.1004	ANTHEM™ 7 Plate, Narrow, Left, 4 Hole, SS	1
2171.1005	ANTHEM™ 7 Plate, Narrow, Left, 5 Hole, SS	1
2171.2303	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 3 Hole, SS	1
2171.2304	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 4 Hole, SS	1
2171.2305	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 5 Hole, SS	1
2171.2313	ANTHEM™ Volar Plate, Double Row, Standard, Right, 3 Hole, SS	1
2171.2314	ANTHEM™ Volar Plate, Double Row, Standard, Right, 4 Hole, SS	3
2171.2315	ANTHEM™ Volar Plate, Double Row, Standard, Right, 5 Hole, SS	1
2171.2324	ANTHEM™ Volar Plate, Double Row, Wide, Right, 4 Hole, SS	1
2171.2003	ANTHEM™ 7 Plate, Narrow, Right, 3 Hole, SS	1
2171.2004	ANTHEM™ 7 Plate, Narrow, Right, 4 Hole, SS	1
2171.2005	ANTHEM™ 7 Plate, Narrow, Right, 5 Hole, SS	1
2171.2013	ANTHEM™ 7 Plate, Standard, Right, 3 Hole, SS	1
2171.2014	ANTHEM™ 7 Plate, Standard, Right, 4 Hole, SS	3
2171.2015	ANTHEM™ 7 Plate, Standard, Right, 5 Hole, SS	1
2171.2024	ANTHEM™ 7 Plate, Wide, Right, 4 Hole, SS	1
9171.0001	ANTHEM™ SS Distal Radius System Graphic Case	

ANTHEM™ SS Distal Radius
IMPLANTS 9171.9001 (cont'd)

PART NO.	DESCRIPTION	QTY
2171.0777	ANTHEM™ Bridge Plate, SS	1
2171.1100	ANTHEM™ Scalloped Plate, SS	1
2171.0999	ANTHEM™ Lateral Plate, SS	1
2171.0555	ANTHEM™ Ulna Plate, SS	1
2171.2155	ANTHEM™ Dorsal Plate, Right, Acute, SS	1
2171.2188	ANTHEM™ Dorsal Plate, Right, Oblique, SS	1
2171.1155	ANTHEM™ Dorsal Plate, Left, Acute, SS	1
2171.1188	ANTHEM™ Dorsal Plate, Left, Oblique, SS	1
2171.0444	ANTHEM™ Lunate Facet Hook, 19mm, SS	1
9171.1001	ANTHEM™ SS Distal Radius System Fragment Specific Module	

ANTHEM™ Ti Distal Radius
IMPLANTS 9171.9002

PART NO.	DESCRIPTION	QTY
1171.1324	ANTHEM™ Volar Plate, Double Row, Wide, Left, 4 Hole, Ti	1
1171.1313	ANTHEM™ Volar Plate, Double Row, Standard, Left, 3 Hole, Ti	1
1171.1314	ANTHEM™ Volar Plate, Double Row, Standard, Left, 4 Hole, Ti	3
1171.1315	ANTHEM™ Volar Plate, Double Row, Standard, Left, 5 Hole, Ti	1
1171.1303	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 3 Hole, Ti	1
1171.1304	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 4 Hole, Ti	1
1171.1305	ANTHEM™ Volar Plate, Double Row, Narrow, Left, 5 Hole, Ti	1
1171.1024	ANTHEM™ 7 Plate, Wide, Left, 4 Hole, Ti	1
1171.1013	ANTHEM™ 7 Plate, Standard, Left, 3 Hole, Ti	1
1171.1014	ANTHEM™ 7 Plate, Standard, Left, 4 Hole, Ti	3
1171.1015	ANTHEM™ 7 Plate, Standard, Left, 5 Hole, Ti	1
1171.1003	ANTHEM™ 7 Plate, Narrow, Left, 3 Hole, Ti	1
1171.1004	ANTHEM™ 7 Plate, Narrow, Left, 4 Hole, Ti	1
1171.1005	ANTHEM™ 7 Plate, Narrow, Left, 5 Hole, Ti	1
1171.2303	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 3 Hole, Ti	1
1171.2304	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 4 Hole, Ti	1
1171.2305	ANTHEM™ Volar Plate, Double Row, Narrow, Right, 5 Hole, Ti	1
1171.2313	ANTHEM™ Volar Plate, Double Row, Standard, Right, 3 Hole, Ti	1
1171.2314	ANTHEM™ Volar Plate, Double Row, Standard, Right, 4 Hole, Ti	3
1171.2315	ANTHEM™ Volar Plate, Double Row, Standard, Right, 5 Hole, Ti	1
1171.2324	ANTHEM™ Volar Plate, Double Row, Wide, Right, 4 Hole, Ti	1
1171.2003	ANTHEM™ 7 Plate, Narrow, Right, 3 Hole, Ti	1
1171.2004	ANTHEM™ 7 Plate, Narrow, Right, 4 Hole, Ti	1
1171.2005	ANTHEM™ 7 Plate, Narrow, Left, 5 Hole, Ti	1
1171.2013	ANTHEM™ 7 Plate, Standard, Right, 3 Hole, Ti	1
1171.2014	ANTHEM™ 7 Plate, Standard, Right, 4 Hole, Ti	3
1171.2015	ANTHEM™ 7 Plate, Standard, Right, 5 Hole, Ti	1
1171.2024	ANTHEM™ 7 Plate, Wide, Right, 4 Hole, Ti	1
9171.0002	ANTHEM™ Ti Distal Radius System Graphic Case	

ANTHEM™ Ti Distal Radius
IMPLANTS 9171.9002 (cont'd)

PART NO.	DESCRIPTION	QTY
1171.0777	ANTHEM™ Bridge Plate, Ti	1
1171.1100	ANTHEM™ Scalloped Plate, Ti	1
1171.0999	ANTHEM™ Lateral Plate, Ti	1
1171.0555	ANTHEM™ Ulna Plate, Ti	1
1171.2155	ANTHEM™ Dorsal Plate, Right, Acute, Ti	1
1171.2188	ANTHEM™ Dorsal Plate, Right, Oblique, Ti	1
1171.1155	ANTHEM™ Dorsal Plate, Left, Acute, Ti	1
1171.1188	ANTHEM™ Dorsal Plate, Left, Oblique, Ti	1
1171.0444	ANTHEM™ Lunate Facet Hook, 19mm, Ti	1
9171.1002	ANTHEM™ Ti Distal Radius System Fragment Specific Module	

ANTHEM™ Distal Radius
IMPLANTS 9171.9003

1.8mm LOCKING PEGS

PART NO.	DIAMETER/LENGTH	QTY
7171.4810	1.8x10mm, CoCr	2
7171.4812	1.8x12mm, CoCr	2
7171.4814	1.8x14mm, CoCr	2
7171.4816	1.8x16mm, CoCr	2
7171.4817	1.8x17mm, CoCr	2
7171.4818	1.8x18mm, CoCr	8
7171.4819	1.8x19mm, CoCr	8
7171.4820	1.8x20mm, CoCr	8
7171.4821	1.8x21mm, CoCr	8
7171.4822	1.8x22mm, CoCr	8
7171.4823	1.8x23mm, CoCr	8
7171.4824	1.8x24mm, CoCr	4
7171.4826	1.8x26mm, CoCr	4
7171.4828	1.8x28mm, CoCr	4
7171.4830	1.8x30mm, CoCr	2

2.0mm LOCKING SCREWS

PART NO.	DIAMETER/LENGTH	QTY
7171.5010	2.0x10mm, CoCr	2
7171.5012	2.0x12mm, CoCr	2
7171.5014	2.0x14mm, CoCr	2
7171.5016	2.0x16mm, CoCr	2
7171.5017	2.0x17mm, CoCr	2
7171.5018	2.0x18mm, CoCr	8
7171.5019	2.0x19mm, CoCr	8
7171.5020	2.0x20mm, CoCr	8
7171.5021	2.0x21mm, CoCr	8
7171.5022	2.0x22mm, CoCr	8
7171.5023	2.0x23mm, CoCr	8
7171.5024	2.0x24mm, CoCr	4
7171.5026	2.0x26mm, CoCr	4
7171.5028	2.0x28mm, CoCr	4
7171.5030	2.0x30mm, CoCr	2

ANTHEM™ Distal Radius
IMPLANTS 9171.9003

2.5mm LOCKING SCREWS

PART NO.	DIAMETER/LENGTH	QTY
7171.5510	2.5x10mm, CoCr	2
7171.5512	2.5x12mm, CoCr	2
7171.5514	2.5x14mm, CoCr	2
7171.5516	2.5x16mm, CoCr	2
7171.5517	2.5x17mm, CoCr	2
7171.5518	2.5x18mm, CoCr	8
7171.5519	2.5x19mm, CoCr	8
7171.5520	2.5x20mm, CoCr	8
7171.5521	2.5x21mm, CoCr	8
7171.5522	2.5x22mm, CoCr	8
7171.5523	2.5x23mm, CoCr	8
7171.5524	2.5x24mm, CoCr	4
7171.5526	2.5x26mm, CoCr	4
7171.5528	2.5x28mm, CoCr	4
7171.5530	2.5x30mm, CoCr	2

2.5mm NON-LOCKING SCREWS

PART NO.	DIAMETER/LENGTH	QTY
7171.6510	2.5x10mm, CoCr	2
7171.6512	2.5x12mm, CoCr	10
7171.6514	2.5x14mm, CoCr	10
7171.6516	2.5x16mm, CoCr	10
7171.6517	2.5x17mm, CoCr	10
7171.6518	2.5x18mm, CoCr	10
7171.6519	2.5x19mm, CoCr	10
7171.6520	2.5x20mm, CoCr	10
7171.6521	2.5x21mm, CoCr	10
7171.6522	2.5x22mm, CoCr	10
7171.6523	2.5x23mm, CoCr	10
7171.6524	2.5x24mm, CoCr	10
7171.6526	2.5x26mm, CoCr	2
7171.6528	2.5x28mm, CoCr	2
7171.6530	2.5x30mm, CoCr	2

ANTHEM™ Distal Radius
IMPLANTS 9171.9003 (cont'd)

2.5mm POSITIONING SCREWS

PART NO.	DIAMETER/LENGTH	QTY
7171.7510	2.5x10mm, CoCr	4
7171.7511	2.5x11mm, CoCr	4
7171.7512	2.5x12mm, CoCr	4
7171.7513	2.5x13mm, CoCr	4
7171.7514	2.5x14mm, CoCr	4
7171.7515	2.5x15mm, CoCr	4
7171.7516	2.5x16mm, CoCr	4
7171.7517	2.5x17mm, CoCr	4
7171.7518	2.5x18mm, CoCr	4
7171.7519	2.5x19mm, CoCr	4
7171.7520	2.5x20mm, CoCr	4
9171.9003	ANTHEM™ Distal Radius Screw Module	

ANTHEM™ Distal Radius Fracture System
INSTRUMENTS 9171.9001 AND 9171.9002

PART NO.	DESCRIPTION	QTY
6171.0004	Stabilizing Radiolucent Weitlaner 2x3 5", Blunt Tip	1
6171.0005	Stabilizing Radiolucent Weitlaner 3x4 8", Blunt Tip	1
6171.7017	Distal Radius Hohmann Retractor, 15mm	2
6171.7006	Senn Retractor	2
6171.7002	Periosteal Elevator, Angled, Round Tip, 13mm	1
6171.7005	Distal Radius Freer Elevator	1
6179.7012	Dental Pick, Curved Tip, Short Handle	1
6171.7007	Plate Positioning Tool	1
6179.2001	Lobster Claw Reduction Forceps, Ratcheting	2
6171.2003	Point-to-Point Reduction Forceps, Ball Spikes, Ratcheting	2
6179.7020	Depth Gauge, 60mm	1
6171.3218	1.8mm Speed Lock, Drill Guide	1
6171.3118	1.8mm Soft Tissue Protector	1
6171.7000	Small Handle, AO Quick Connect	2
6179.6008	T8 Driver, SR, 60mm, AO Quick Connect	5
6179.1116	1.6mm K-wire, Trocar Tip, 150mm	10
6171.1316	1.6mm K-wire, Threaded Trocar Tip, 150mm	5
6171.5018	1.8mm Drill Bit, 100mm, AO Quick Connect	5
6171.5019	1.8mm Drill Bit, 130mm, AO Quick Connect	5
6171.3512	Targeting Drill Guide	1
6185.3218	1.8mm Threaded Drill Guide	1

ANTHEM™ Distal Radius Fracture System
INSTRUMENTS 9171.9001 AND 9171.9002 (cont'd)

PART NO.	DESCRIPTION	QTY
6179.2007	Wire Bending Pliars	1
6171.2002	Plate Bending Pliars	2
6171.0003	Lunate Facet Inserter	1
6171.7003	Tamp	1
603.977	Mallet	1
6171.7008	Malleable Wire Replacement	5
6171.3511	Targeting Guide Drill Guide Sleeve	1
6171.5020	1.5mm Drill Bit, 100mm, AO Quick Connect	2
6171.5012	Torque Limiting Attachment, 1.2Nm, AO Quick Connect	1
6171.3500	Targeting Guide, Narrow, Left, PEEK	1
6171.3501	Targeting Guide, Standard, Left, PEEK	1
6171.3502	Targeting Guide, Wide, Left, PEEK	1
6171.3503	Targeting Guide, Narrow, Right, PEEK	1
6171.3504	Targeting Guide, Standard, Right, PEEK	1
6171.3505	Targeting Guide, Wide, Right, PEEK	1
6171.3506	Targeting Guide, Double Row, Narrow, Left, PEEK	1
6171.3507	Targeting Guide, Double Row, Standard, Left, PEEK	1
6171.3508	Targeting Guide, Double Row, Wide, Left, PEEK	1
6171.3509	Targeting Guide, Double Row, Narrow, Right, PEEK	1
6171.3510	Targeting Guide, Double Row, Standard, Right, PEEK	1
6171.3511	Targeting Guide, Double Row, Wide, Right, PEEK	1

IMPORTANT INFORMATION ON ANTHEM™ FRACTURE SYSTEM

DESCRIPTION

The ANTHEM™ Fracture System is a family of plates and screws designed to be used for internal bone fixation. The implants are available in various sizes and shapes to accommodate patient anatomy, and may be contoured or straight, with locking and non-locking screws. ANTHEM™ implants are manufactured from titanium alloy, cobalt chromium molybdenum alloy, or stainless steel. 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. Small fragment and distal fibula plates may be used in all pediatric subgroups (except neonates) and small stature adults. Distal radius plates may be used in adolescents (12-21 years of age).

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.

PRECAUTION

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

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

MR SAFETY INFORMATION

The ANTHEM™ Fracture implants have not been evaluated for safety and compatibility in the MR environment. They have 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.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients in the following cases:

- 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.

CAUTIONS

Pre-operative

- These implants are 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 malunion 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 accidentally contaminated.

CLEANING

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

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

The following cleaning methods should be observed when cleaning instruments 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. 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 following ANSI/AAMI/ISO 17665-1:2006 Guidelines for Steam Sterility Validation to assure a Sterility Assurance Level (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) 7.5 in 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 Law (USA) 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		

DI201 REV A

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Customer Service:
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CE 0297

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10.17 Rev B