stryker®

Trauma & Extremities

VariAx® 2
Distal Radius Locking Plate System

Operative Technique

- Anatomical & Universal Volar Plates
- Dorsal Plates
- Fragment Specific Plates
- XXL Anatomical Volar Plates
- VariAx 2 Color Coded Screws and Instruments

Wrist

VariAx 2 Distal Radius Locking Plate System

This publication sets forth detailed recommended procedures for using Stryker devices and instruments.

It offers guidance that you should heed, but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required.

A workshop training is recommended prior to first surgery.

All non-sterile devices must be cleaned and sterilized before use. Follow the instructions provided in our reprocessing guide (L24002000). Multi-component instruments must be disassembled for cleaning. Please refer to the corresponding assembly/disassembly instructions.

Please remember that the compatibility of different product systems have not been tested unless specified otherwise in the product labeling.

See Instructions for Use (90-03200,90-01953, V15011 and V15013) for a complete list of potential adverse effects, contraindications, warnings and precautions. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

Contents

Indications, Precautions & Contraindications

Intended Use

The VariAx 2 Distal Radius Locking System including the XXL Volar Distal Radius Plates is intended for internal fixation of small bone fractures, primarily including distal radius fractures.

Indications

Compression, intra-articular and extra-articular fractures, and displaced fractures. Following additional indications apply only for the XXL Volar Distal Radius Plates: Osteotomies, non-unions, and malunions.

Precautions

Stryker systems have not been evaluated for safety and compatibility in MR environment and have not been tested for heating or migration in the MR environment, unless specified otherwise in the product labeling.

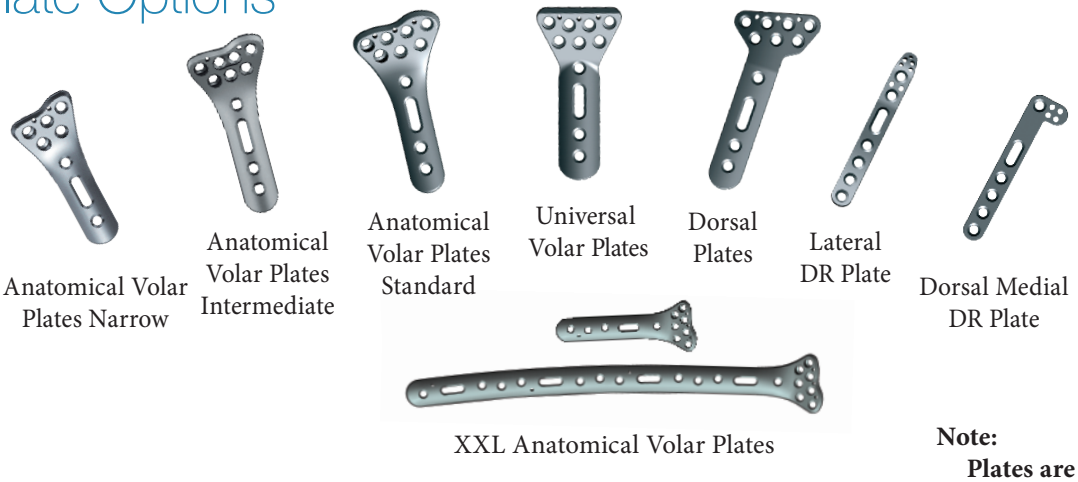
Contraindications

The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- Any active or suspected 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 can not provide adequate support and/or fixation of the devices
- Material sensitivity, documented or suspected
- Obesity. An overweight or obese patient can produce loads on the implant that can lead to failure of the fixation of the device or 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

Overview

Plate Options



Anatomical Volar Plates Narrow

Anatomical Volar Plates Intermediate

Anatomical Volar Plates Standard

Universal Volar Plates

Dorsal Plates

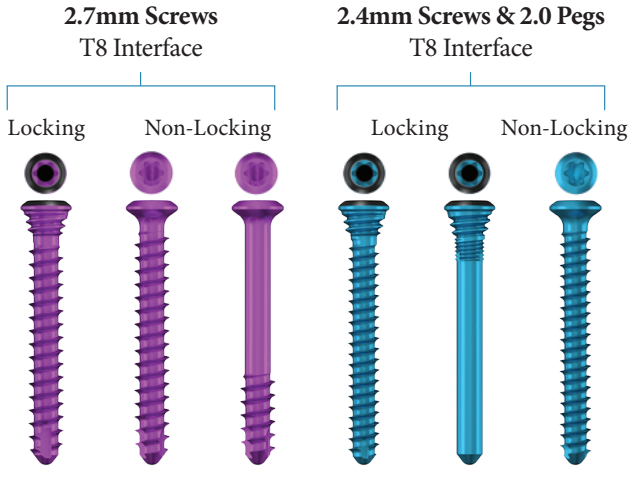
Lateral DR Plate

Dorsal Medial DR Plate

XXL Anatomical Volar Plates

Note:
Plates are not scaled to size.

Color Coding and Screw/Peg Options

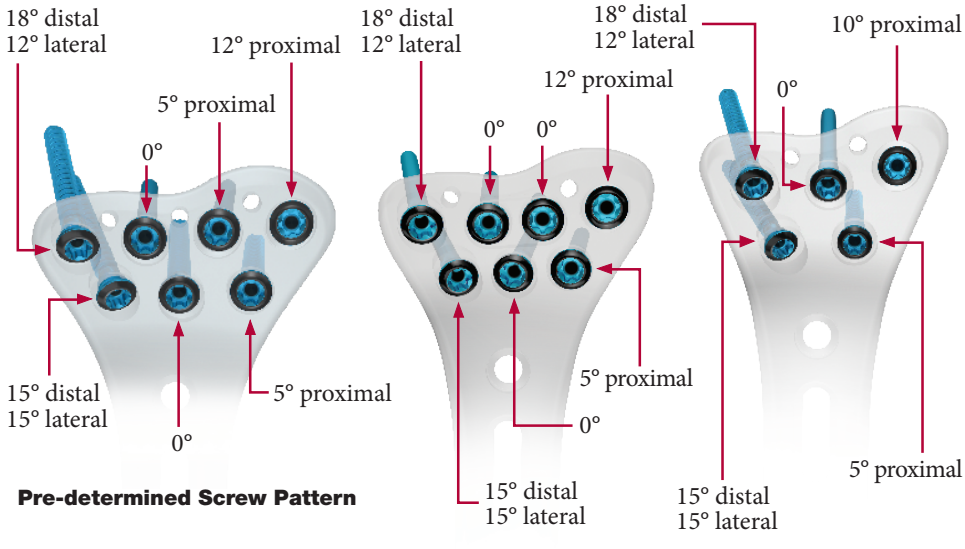


Note:

- **Locking and Non-Locking screws can be used in any round hole.**
- **To avoid disengagement of the screwdriver blade from the screw during insertion, axial pressure is recommended.**
- **When final tightening of the locking screw occurs, take care not to over-torque the screw. Excessive torque may damage the locking mechanism, the screw and/or the screwdriver blade.**

Pre-Angled Distal Screw Holes

The distal screw holes in the anatomic plates are angled to give a pre-determined screw pattern in the distal bone block. The image here shows the various trajectories. When drilling at a 0° angle relative to the plate hole, the screw trajectories shown here relative to the plate surface will be achieved. This is also the screw pattern achieved when using an aiming block.



Pre-determined Screw Pattern

Overview

SmartLock[1] Polyaxial / Compression Drill Guide

Allows for ±15 degrees of angulation. A lip on the drill sleeve will engage and allow toggling in the hole. The range in which the drill guide toggles will create a 30-degree cone and every angle in this range will be a locking position. This may allow the surgeon to aim where the screw/peg should be placed. Also, depending on the placement of the plate, there may be a need to angle a screw/peg out of the fracture line.

The 2.0mm drill guide for T8 Screws (703684) facilitates drilling a 2.0mm pilot hole for a 2.4 or 2.7mm T8 screw or a 2.0mm peg centrically for locking or non-locking screws. Additionally, the opposite side of the guide facilitates eccentric drilling for use in a compression hole when compression is desired.

Note:

- **When drilling eccentrically, the arrow marked on the compression side of the drill guide should be pointing towards the fracture line**
- **Using one of the provided drill guides for screw hole preparation is mandatory. Not using a drill guide may lead to drilling out of specified locking range and compromise the locking capabilities.**
- **First fully engage the drill guide in the hole and then aim the drill in the desired direction.**

Drills & Drill Guides for Lagging

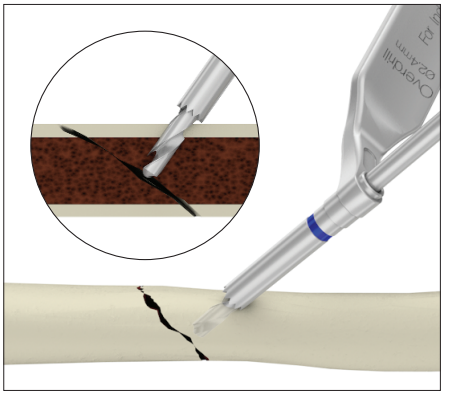
In addition to the standard Drills & Drill guides, a number of solutions are also available to perform a lag screw technique independently.

Dedicated overdrills for each screw size are available for overdrilling the near cortex when placing a lag screw independently. In addition to being marked with the actual drill diameter on the AO Coupling, these overdrills are also marked with a single color ring corresponding to the desired screw diameter. This marking matches the marking on the correct side of the lagging drill guide.

Note:

Always match the color ring marking on the drill bit with the color marking on the drill guide. Additionally, always match the screw anodization color with at least one of the color ring markings.

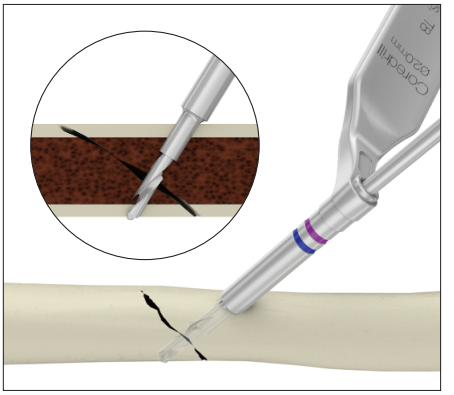
In order to insert a lag screw independently of a plate, the Independent Lag Screw Drill Guides (703688 for



Step 1.

2.4mm screws and 703884 for 2.7mm screws) should be used. First, the near cortex should be overdrilled using the side of the drill guide marked with a single color ring to create a gliding hole (Step #1)

The other side of the drill guide can then be used (marked with two color rings) by inserting the 'top-hat' end in the already drilled gliding hole and using the standard drill bit through it to drill through the second cortex (Step #2). This standard drill is scaled in



Step 2.

order to evaluate the appropriate screw length. Upon screw insertion,

this technique will serve to lag the far cortex towards the near cortex, hence applying compression.

Note:

Take care when using the Independent Lag Screw Drill Guide for overdrilling through a plate hole as the drill guide's tip could damage the plate hole.

1. The SmartLock Technology is patented by Professor Dietmar Wolter, Hamburg Germany

Overview

Modular Handle

VariAx 2 offers a modular handle system. This is composed of two handle grip sizes (medium and large) that can be interchanged with either a bi-directional ratcheting AO-Coupling insert or a standard AO-Coupling insert.
Both handle sizes are equipped with a spin-cap to allow insertion using a two-finger technique. In order to disengage the insert from the handle, push down on the button on the distal part of the handle and pull the insert away from the handle.

Note:

The inserts must be removed from the handles before cleaning.

The ratcheting insert can work in three modes: clockwise ratcheting, counterclockwise ratcheting or neutral. To switch between the different modes, simply twist the distal part of the insert to the desired driving direction.

Large Handle (703920)

Medium Handle (703921)

Ratcheting Insert (703922)

AO Coupling Insert (703923)

Note:

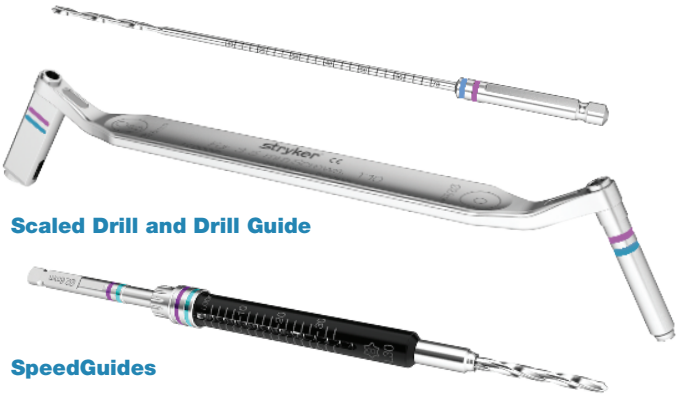
To ensure appropriate ratcheting function, perform appropriate maintenance on the insert by applying medical-grade lubricant oil through the marked cut-outs.

Depth Measurement Options

VariAx 2 offers various options to evaluate the screw length. All drills are scaled so that the surgeon may evaluate the screw length when using the drill through the dedicated drill guides.

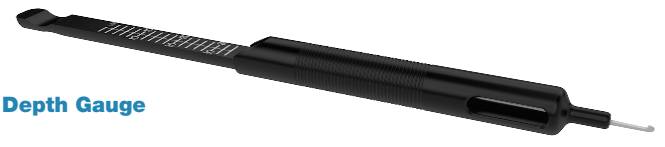
A SpeedGuide (703891 for 2.0 Drill Bit and 703888 for the Speed Guide Sleeve) is also offered that allows the surgeon to drill & measure the hole depth in one step with a single instrument. For further information on the SpeedGuide, please refer to the SpeedGuide Operative Technique.

Lastly, a standard Depth Gauge (705170 or 703885 for use with the aiming blocks) may be used either independently or through a plate hole.



Scaled Drill and Drill Guide

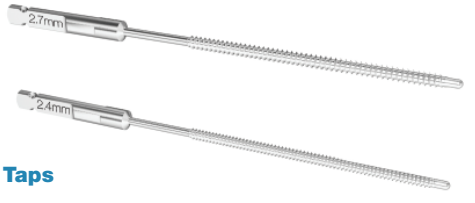
SpeedGuides



Depth Gauge

Taps

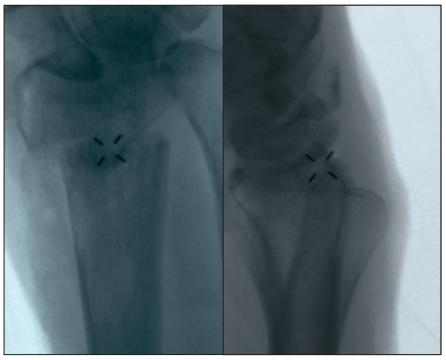
2.4mm and 2.7mm taps (703900 for 2.4mm screws and 703889 for 2.7mm screws) are available in the system. Although all screws are self-tapping, it is recommended to use a tap if excessive resistance is felt during insertion or if the bone is dense.



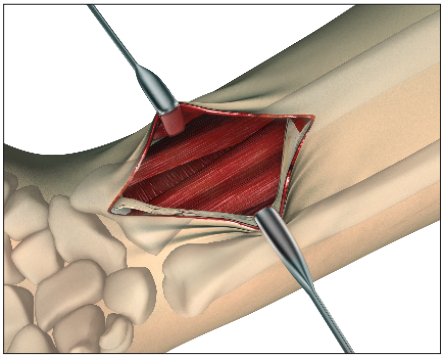
Taps

Operative Technique

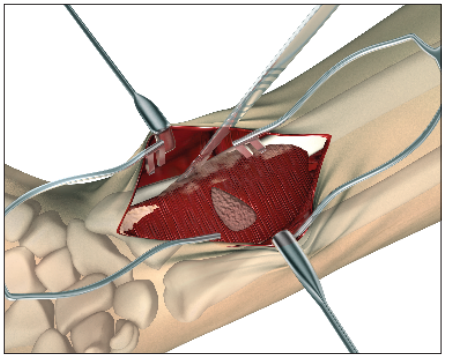
Anatomical Volar Plate



1. An incision is made approximately 5-8cm long just radial to the FCR tendon. If more exposure is necessary, the incision can be extended radially at 45 degrees along the wrist flexion creases.

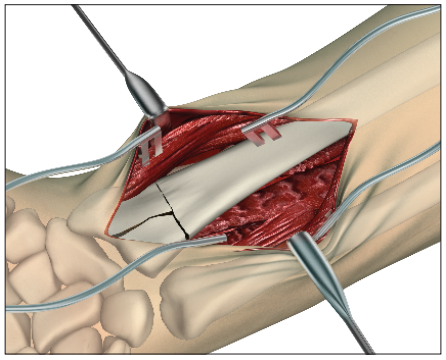


2. The FCR tendon is retracted ulnarly and dissection is carried down through the floor of the FCR sheath.



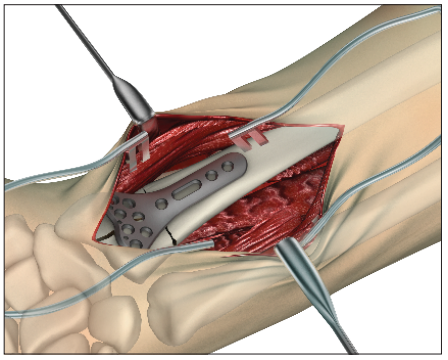
3. The Pronator Quadratus muscle is identified and dissected in its entirety off of the volar surface of the radius as an ulnarly based flap.

4. The insertion of the Brachioradialis may be released.



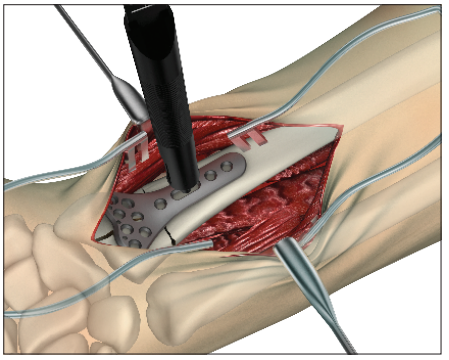
5. The fracture is visualized and reduced.

6. The use of external traction, and/or the use of K-Wires for temporary fixation may be helpful. The use of AP/Lateral fluoroscopy is helpful to determine correct fracture reduction and plate position.



7. Choose the appropriate implant according to patient anatomy and fracture pattern.

8. The plate should be placed slightly below the distal edge of the radius to support the volar articular fracture fragments and also to avoid inserting screws or pegs into the joint.



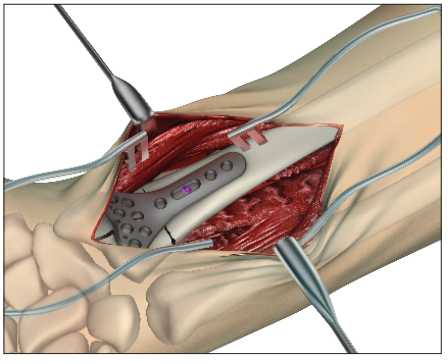
9. Zebra striped K-Wires (07-40281) and/or Olive K-Wires (56-40281) can be used for temporary fixation while evaluating the placement of the plate.

10. The first pilot hole should be drilled in the oblong gliding hole using the appropriate drill guide.

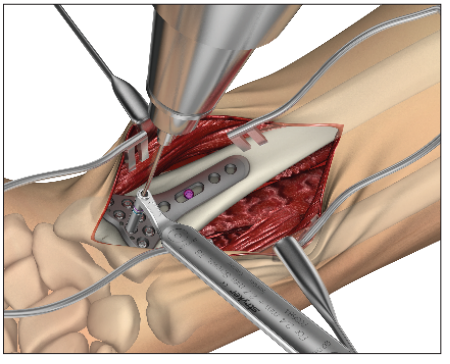
11. Use the depth gauge (705170 or 703885 for use with the aiming blocks) to determine screw length.

Operative Technique

Anatomical Volar Plate



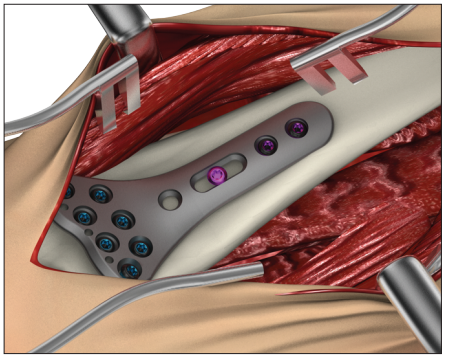
12. A non-locking screw is placed in the oblong gliding hole but not completely tightened to allow adjustment of the plate in distal or proximal directions.
13. After confirmation of the correct positioning of the anatomic volar plate by use of fluoroscopy, tighten the first screw.
14. Once the position of the plate has been determined, it is time to decide which drill guide to use based upon preference and/or fracture pattern.



15. Using the desired drill guide, repeat drilling, measuring and placement of screws/pegs in the distal holes.
16. Place locking or non-locking screws in the proximal end of the plate.

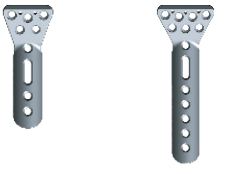
Note:

The tips of the screws in the distal holes should not stick out at the far cortex to avoid damage of the extensor tendons.

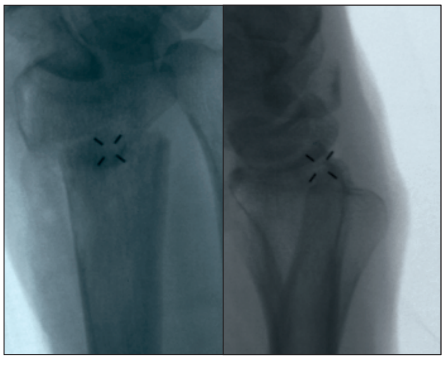


17. Verify proper placement of screws/pegs by use of fluoroscopy to ensure that neither penetrate the joint.
18. Close the incision.

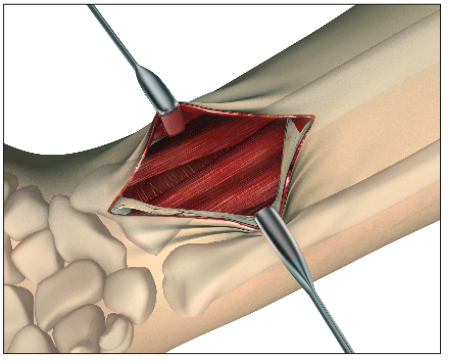
Operative Technique



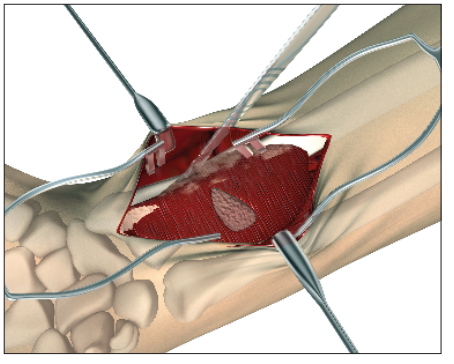
Universal Volar Plate



1. An incision is made approximately 5-8cm long directly over the FCR tendon. If more exposure is necessary, the incision can be extended radially at 45 degrees along the wrist flexion creases.

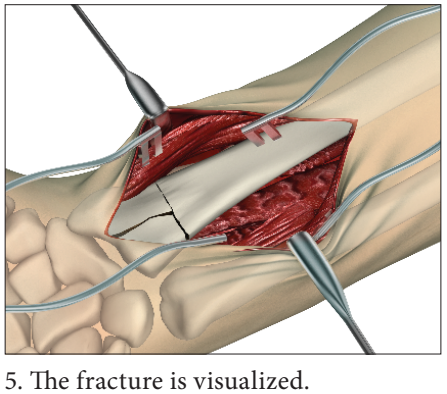


2. The FCR tendon is retracted ulnarly and dissection is carried down through the floor of the FCR sheath.



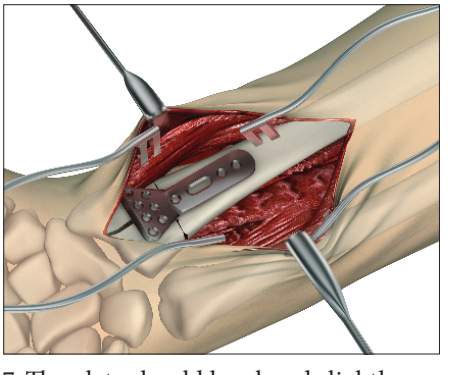
3. The Pronator Quadratus muscle is identified and dissected in its entirety off of the volar surface of the radius as an ulnarly based flap.

4. The insertion of the Brachioradialis may be released.



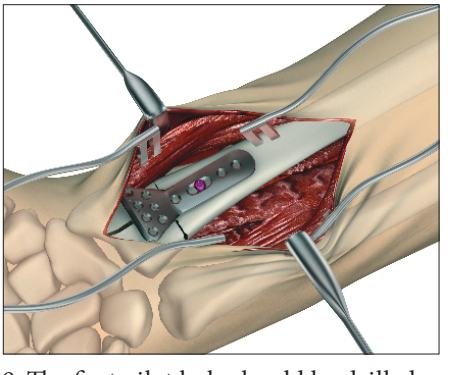
5. The fracture is visualized.

6. The fracture is reduced. The use of external traction, and/or the use of K-Wires for temporary fixation could be helpful.



7. The plate should be placed slightly below the distal edge of the distal radius to avoid inserting screws or pegs into the joint. The use of AP/Lat fluoroscopy is helpful to determine correct fracture reduction and plate position.

8. K-Wires can be used for temporary fixation.

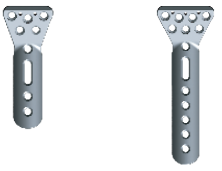


9. The first pilot hole should be drilled in the oblong gliding hole using the appropriate drill guide.

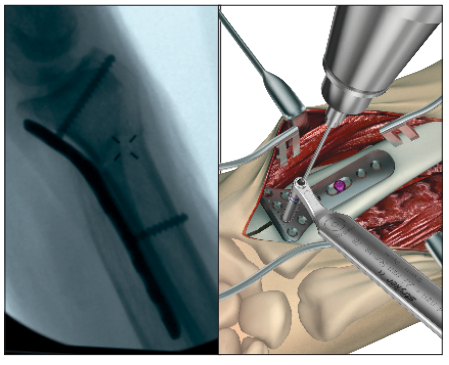
10. Measure the depth of the hole to determine screw length.

11. The screw is placed in the oblong gliding hole but not completely tightened to allow adjustment of the plate in distal or proximal directions.

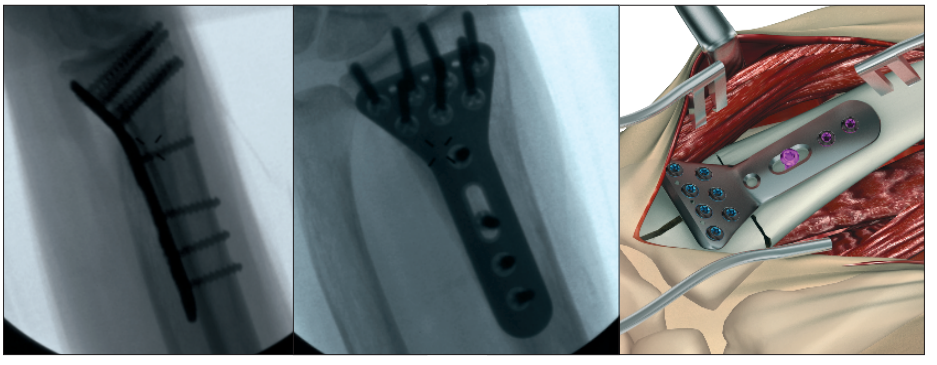
Operative Technique



Universal Volar Plate



12. After confirmation of the correct positioning of the volar plate by use of fluoroscopy, tighten the first screw.
13. Repeat drilling, measuring and placing of screws/pegs in the distal holes of the plate. The position and number of screws applied depends on the type of fracture.



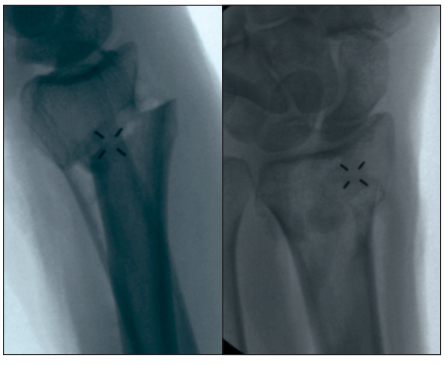
14. Place Non-Locking or Locking screws in the proximal end of the plate.
15. Verify proper placement of screws and pegs by use of fluoroscopy to ensure that neither penetrates the joint.
16. Close the incision.

Note:

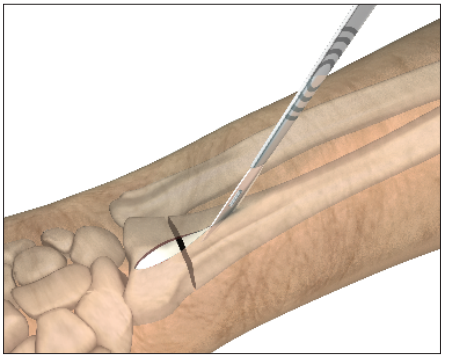
The tips of the screws in the distal holes should not stick out at the far cortex to avoid damage of the extensor tendons.

Operative Technique

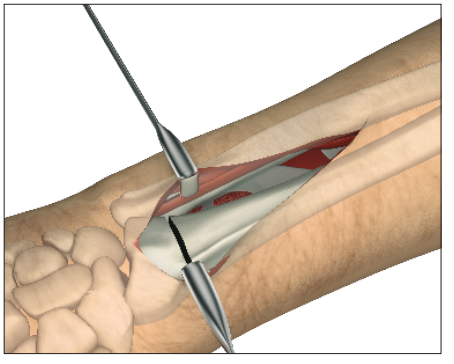
Dorsal Plate



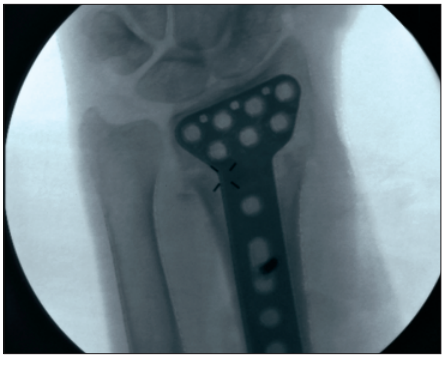
1. Longitudinal incision is made just ulnar to Lister's tubercle at the distal radius region.



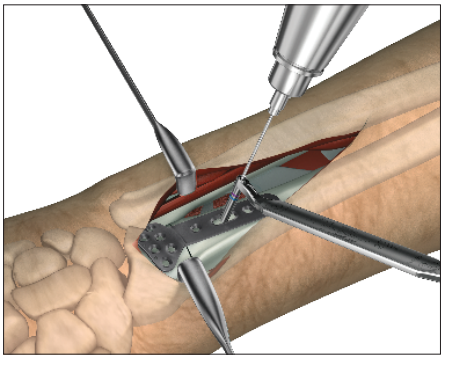
2. Dissection is performed down to the extensor retinaculum. The third compartment is opened and the extensor pollicis longus is displaced radially.



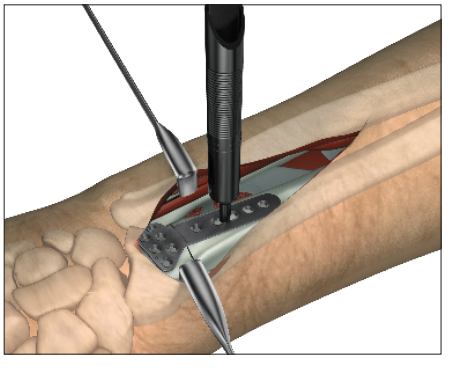
3. The second compartment wrist extensors are subperiosteally elevated radially and the fourth compartment is subperiosteally elevated ulnarly. The terminal branches of the posterior interosseous nerve may be excised for pain reduction.



4. The fracture is reduced. The use of an external traction device and/or K-Wires for temporary fixation may be helpful.
5. If necessary, adapt the plate for correct anatomical position. Removal of Lister's Tubercle might be necessary.



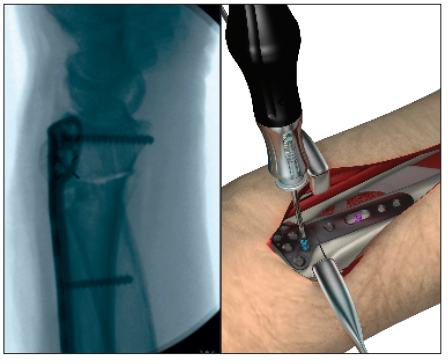
6. The plate should be placed slightly proximal the distal edge of the distal radius to avoid inserting screws/pegs into the joint. Correct positioning of the plate should be confirmed by use of fluoroscopy. The first pilot hole should be drilled in the oblong gliding hole.



7. Measure the depth of the hole to determine screw length.
8. The screw is placed in the oblong gliding hole but not completely tightened to allow adjustment of the plate in a distal or proximal direction.

Operative Technique

Dorsal Plate



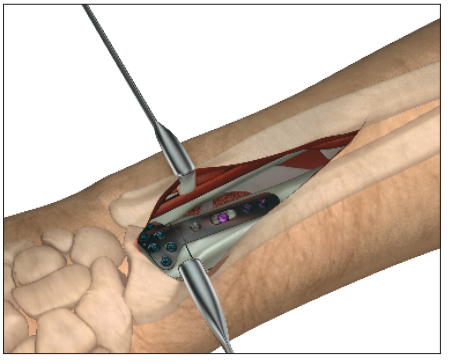
9. Confirm proper plate positioning by use of fluoroscopy and then tighten the first screw.

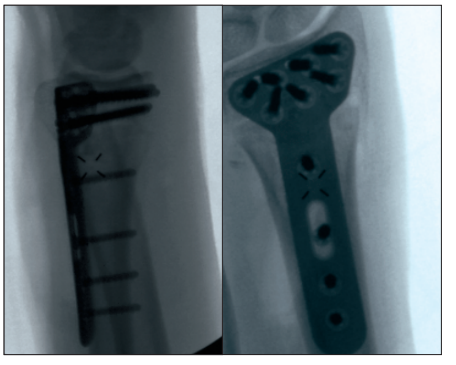
Note:

Screw length may need to be changed after plate is fully seated on bone.

10. Repeat drilling, measuring, and placing of screws/pegs into the distal holes of the plate. The position and number of screws applied depends on the type of fracture.

11. Place Non-Locking or Locking screws in the proximal end of the plate.





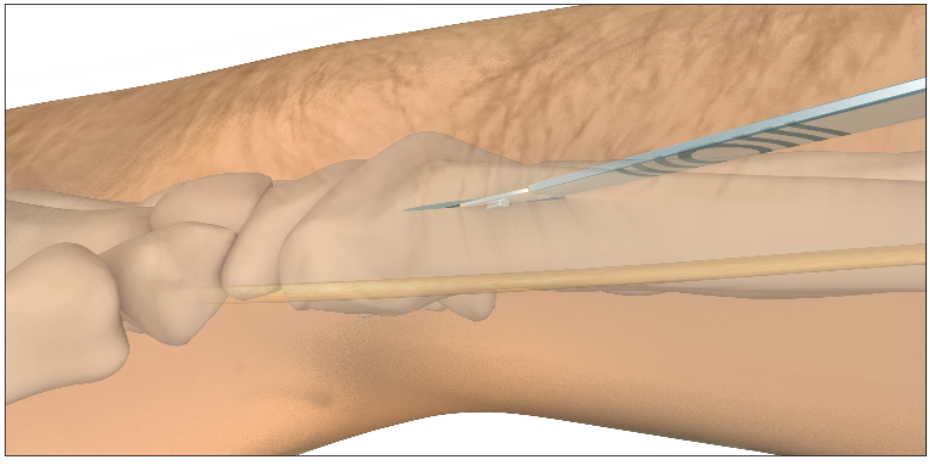
12. Verify proper placement of screws and pegs by use of fluoroscopy to ensure that they do not penetrate the joint.

13. Close the incision.

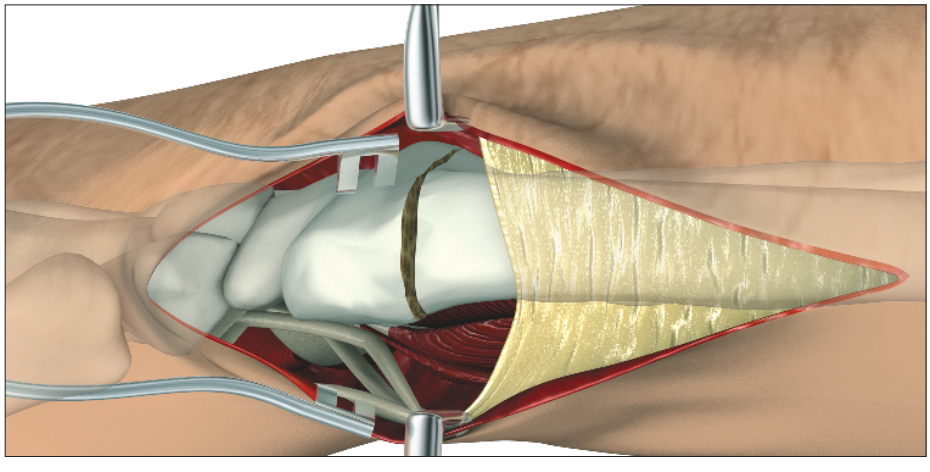
Operative Technique

Lateral Distal Radius Plate

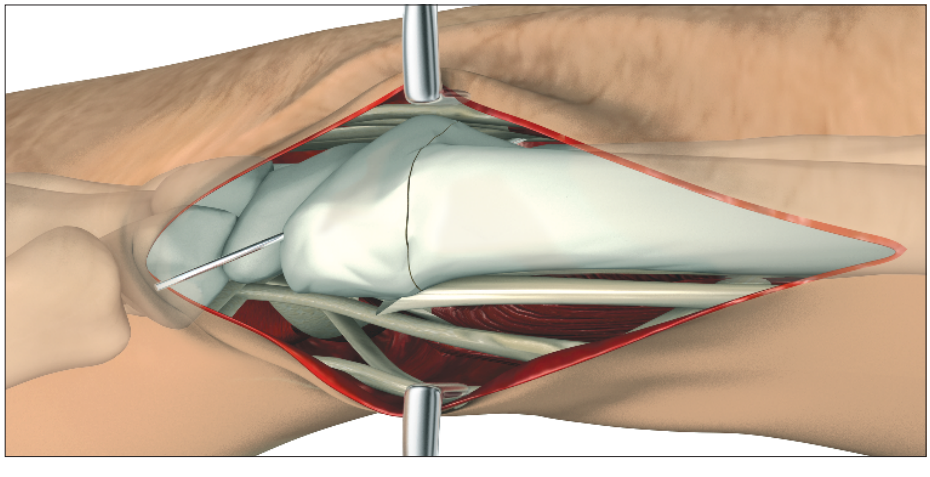
1. An incision is made along the radial column.
2. Care must be taken to avoid injury to the superficial branch of the radial nerve.



3. The first dorsal compartment is released. The tendons are retracted volarly.



4. The fracture should be reduced and stabilized with a K-Wire placed from the distal radial styloid and aimed dorsal and proximal.

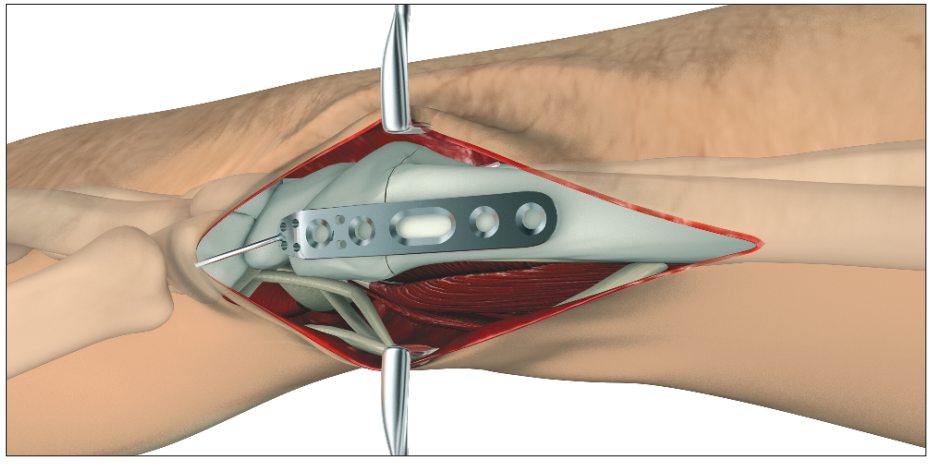


Note:
Fragment specific plates should not be used in isolation.

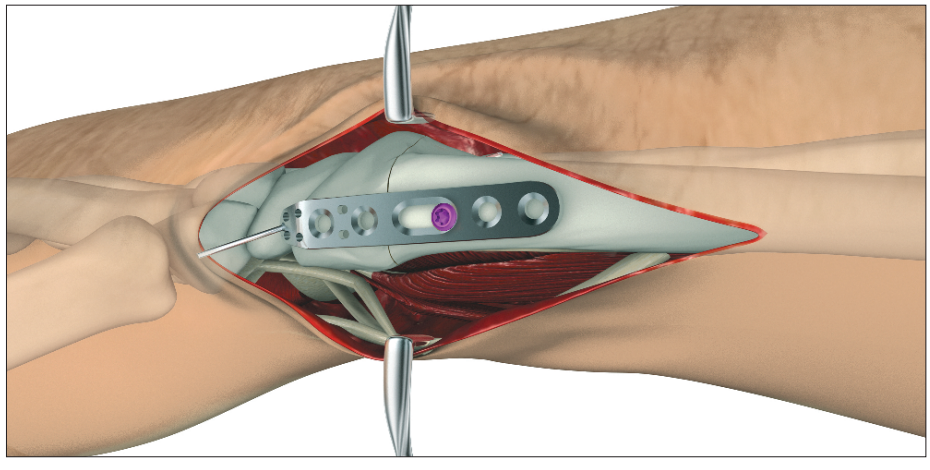
Operative Technique

Lateral Distal Radius Plate

5. The plate is slipped over the K-Wire (07-40281) and placed along the radial column.



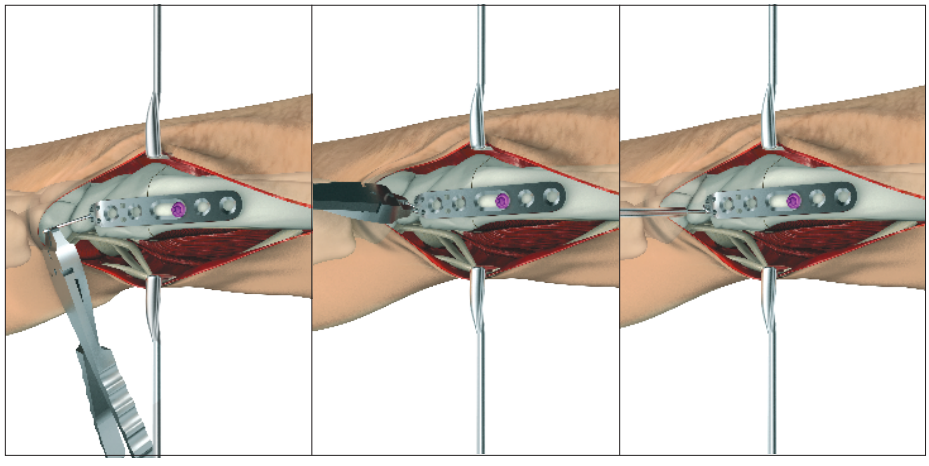
6. A Non-Locking screw placed in the oblong hole will compress the plate to the shaft, and by pulling the plate proximally will compress the fracture site.



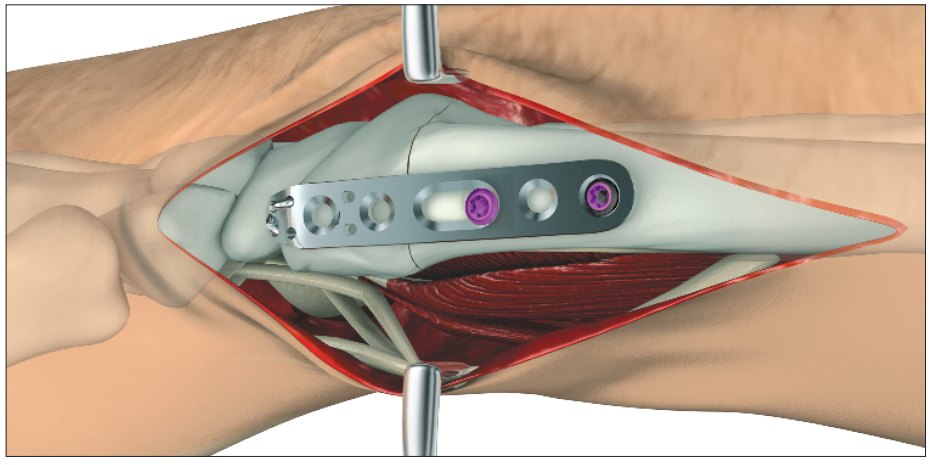
Operative Technique

Lateral Distal Radius Plate

7. The 3 in 1 K-Wire bender/cutter/ inserter is used to bend K-Wires distally.
8. It is recommended only one K-Wire be placed distally at a time in order to make proper use of the K-wire Bending Pliers (64-20118).
9. After insertion, the tamp (64-00011) and mallet (43-09830) can be used to further insert the K-Wires.

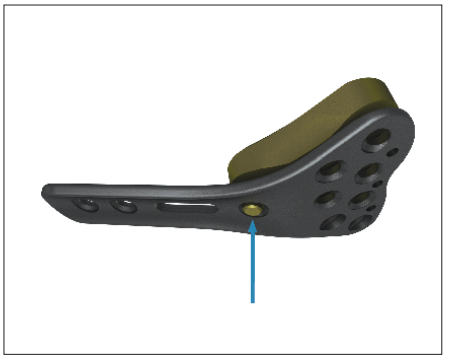


10. K-Wires and screws can be placed in conjunction for more rigid fixation.
11. The incision is closed.

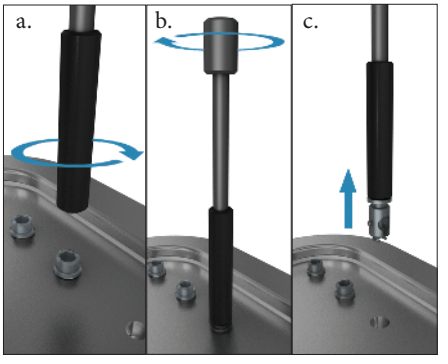


Operative Technique

Aiming Block



1. Choose the Aiming Block that corresponds to the plate that will be used (left/right, narrow/intermediate/standard). Place the peg on the underside of block into the shaft hole of the plate.



2. Remove the aiming block joystick (56-01310) from the tray.

a. Insert the joystick into the fixation pin (56-01210) and tighten the black grasping sleeve onto the fixation pin (Turn Clockwise).

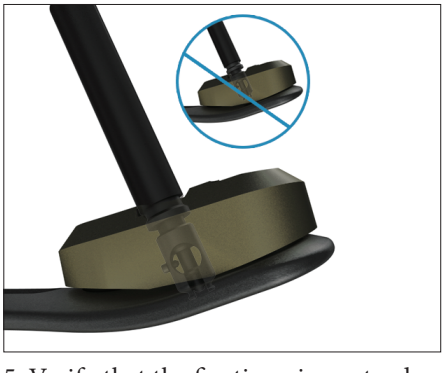
b. Turn the silver knob on the joystick counter-clockwise to open the fixation pin (approximately 2 turns).

c. Pull the joystick upward to remove the pin assembly from tray.

3. The surgeon should choose which hole to place the pin in the block to mount the Aiming Block to the plate. Any hole may be used, **except the most distal radial styloid hole because that hole has no slot to accommodate the tab on the pin.** Then align the tab on the fixation pin with the slot on the Aiming Block as shown in the highlighted area.

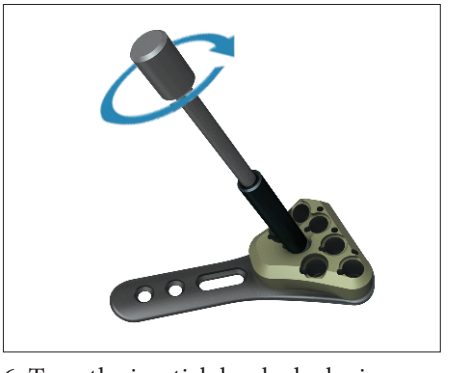
4. Place the joystick / fixation pin assembly through the Aiming Block and into the plate.

* The wings on the underside of the pin must be closed in order for the pin to fit through the hole in the plate.



5. Verify that the fixation pin protrudes from the bottom of the plate.

* If the pin does not fully protrude through the plate, slowly turn the joystick counterclockwise to close the pin. As the wings on the pin close, you will hear a click to verify the pin is fully through the plate.



6. Turn the joystick knob clockwise to spread the wings on the pin and tighten the Aiming Block to the plate (approximately 2 turns).

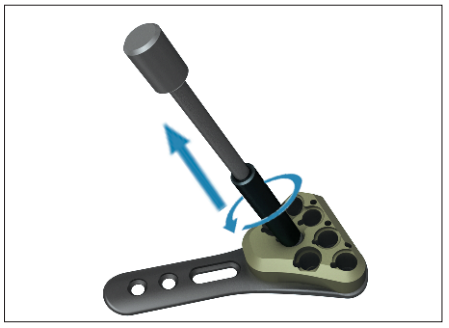
Attention:

Fixation pin should not be overly tightened as this may damage the threads on the pin. Only moderate effort is needed. (Finger tighten only).

Once the block is mounted to the plate, verify the alignment by passing a K-Wire through the K-Wire holes. This should be done prior to mounting the plate to the bone.

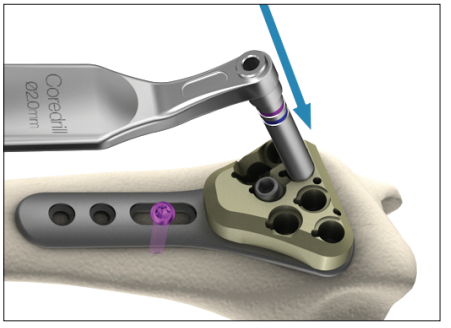
Operative Technique

Aiming Block



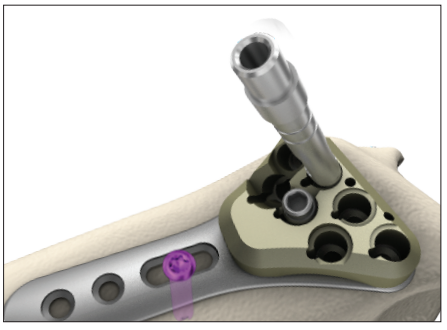
7. The joystick may be used to help position the plate on the bone. After plate is positioned, remove the joystick by loosening the black grasping sleeve from the fixation pin (counter clockwise).

8. K-Wires may be used through the plate / block assembly for temporary fixation.



9. The variable angle drill guide (703684) can be used in any hole to drill for the pre-determined trajectory.

Caution:
Aiming Block cannot be used with plates that have been intra-operatively contoured or bent.



10. Alternative to the use of the drill guide, an Aiming Block Drill Sleeve (56-02020) can be used to drill the pilot hole. Simply push the drill sleeve through an aiming block hole until fully seated. It is possible to insert two drill sleeves concurrently in the distal row of the aiming block to facilitate the drilling process.

11. Drill through the drill guide or drill sleeve. The scale on the drill bit can be used to determine the appropriate screw length.

Attention:
To prevent damage to the Aiming Block and/or plate, the variable angle drill guide must be used.

12. Measure depth with the depth gauge (703885) and choose the appropriate screw. Ensure that the tip of the measuring gauge is fully seated onto the plate.

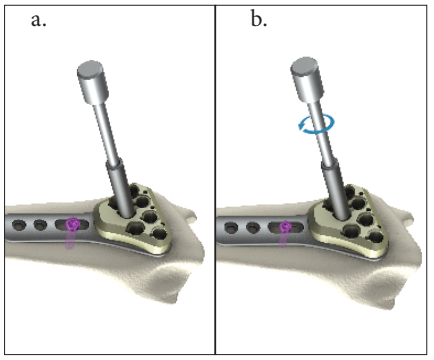
13. Screw can be inserted through the Aiming Block. Confirm screw placement under fluoroscopy.

Note:
If the intermediate plate aiming block (56-01810 for Right/56-01910 for Left) is used, the recommended position of the joystick/fixation pin is the most proximal medial hole of the aiming block. This ensures that all open holes can be accessed with the drill sleeve. If the joystick is placed in the proximal lateral or middle hole then the adjacent hole as shown here will not be accessible with the drill sleeve.

Intermediate Aiming Blocks and Plate

Operative Technique

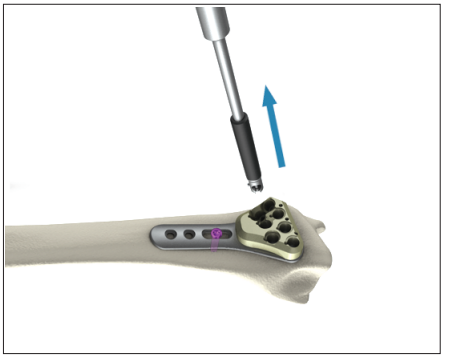
Aiming Block



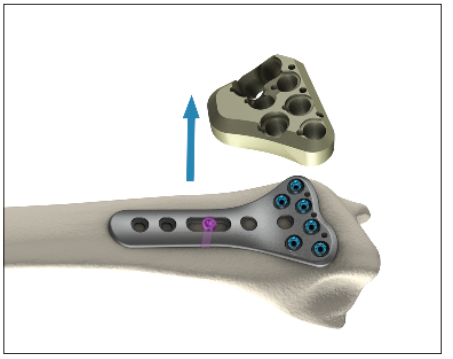
14. Removal of Aiming Block.

a. Attach the joystick to the fixation pin by tightening the black grasping sleeve. (clockwise).

b. Turn the joystick knob counter-clockwise to open fixation the pin. (approximately 2 turns).



15. Remove the joystick/fixation pin assembly from the Aiming Block.



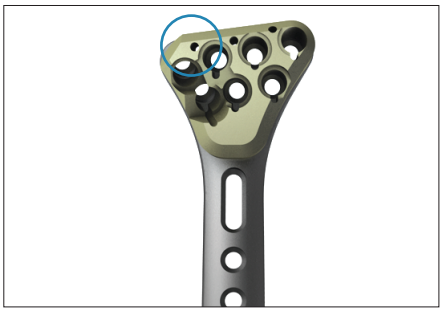
16. Remove Aiming Block from the plate. If necessary a screw can be placed in hole used for fixation of the Aiming Block. Ensure that all screw heads are fully seated onto the plate and fully tightened.

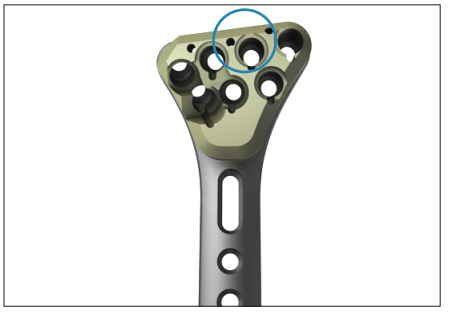
Optional Steps:

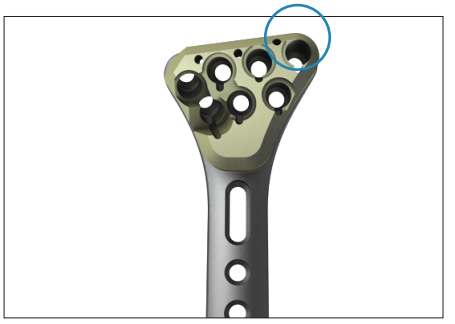
Under fluoroscopy, the K-Wire will approximate the trajectory of the adjacent screw on the ulnar side.

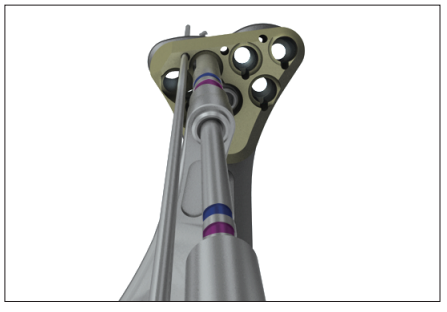
Note:

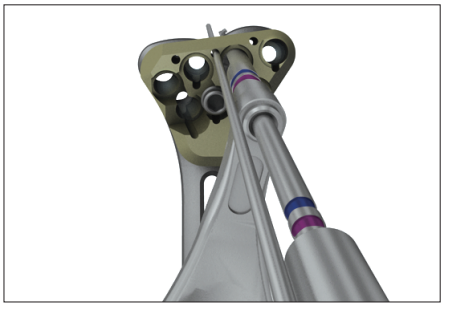
There is no K-Wire hole to approximate the distal most radial styloid screw.

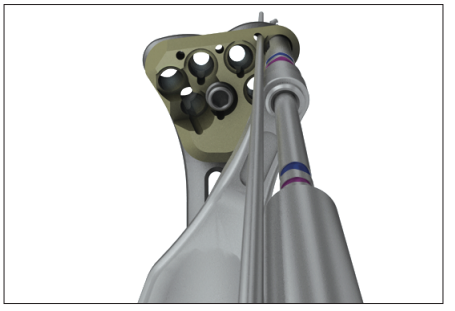












Note:

Left block is shown.

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