



stryker

Trauma & Extremities

VariAx[®] 2

Distal Radius Locking 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 System

Disclaimer

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.

WARNING

- Follow the instructions provided in our cleaning and sterilization guide (OT-RG-1).
- All non-sterile devices must be cleaned and sterilized before use.

WARNING

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 has not been tested unless specified otherwise in the product labeling.

Consult Instructions for Use (www.ifu.stryker.com) for a complete list of potential adverse effects and adverse events, contraindications, warnings and precautions.

The surgeon must advise patients of surgical risks, and make them aware of adverse effects and alternative treatments.

WARNING

- The patient should be advised that the device cannot and does not replicate a normal healthy bone, that the device can break or become damaged as a result of strenuous activity or trauma and that the device has a finite expected service life.
- Removal or revision of the device may be required sometime in the future due to medical reasons.

WARNING

In the event of contamination, or expiration of shelf life or in the case of products supplied non-sterile, the product must be subjected to an appropriate cleaning process and sterilized by means of a validated sterilization procedure before use, unless specified otherwise in the product labeling or respective product technical guides.

WARNING

The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

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Indications and Contraindications

Indications

The VariAx 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 include:

- Compression fractures
- Intra-articular and extra-articular fractures
- Displaced fractures

Following additional indications apply only for the XXL Volar Distal Radius Plates:

Osteotomies, non-unions and malunions.

CAUTION

The Stryker VariAx Distal Radius Locking System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of VariAx Distal Radius Locking System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

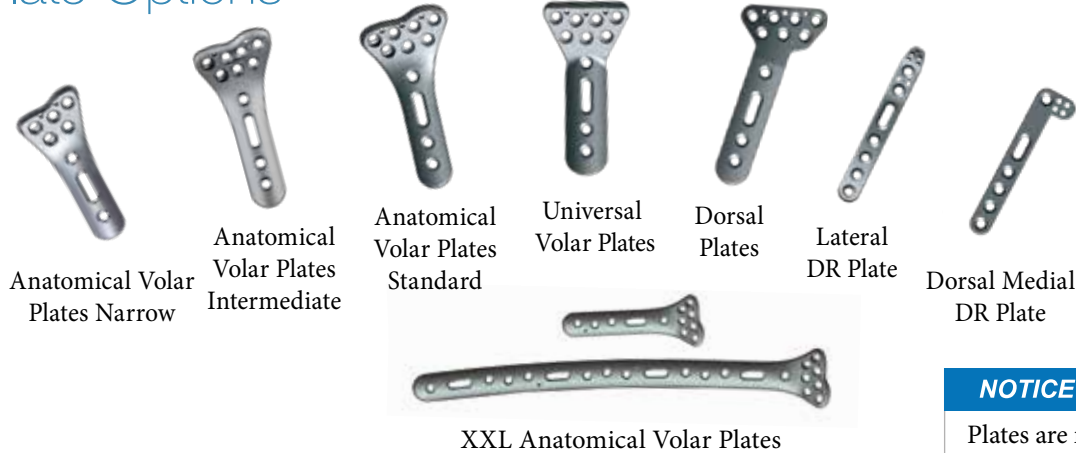
Contraindications

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 cannot 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



NOTICE

Plates are not scaled to size.

Color Coding and Screw/Peg Options



NOTICE

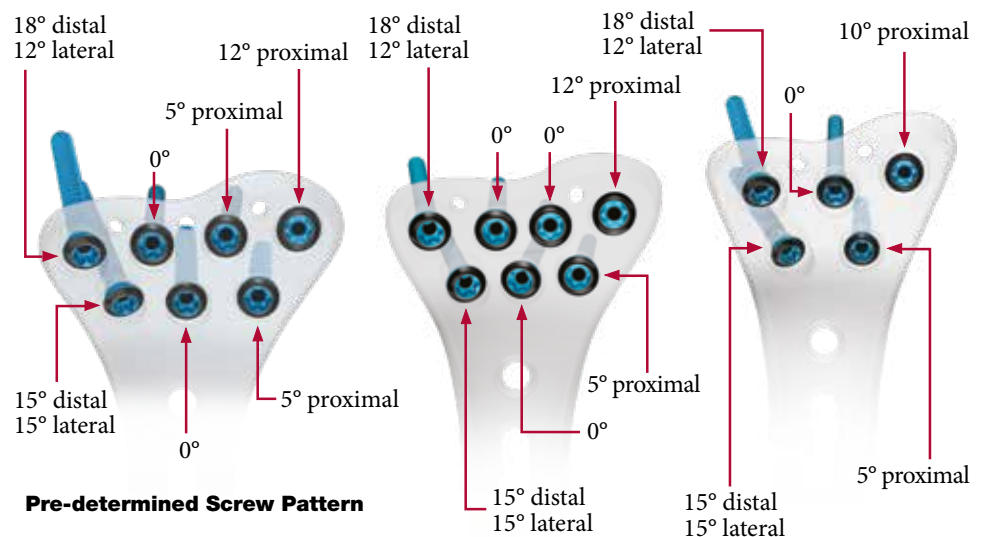
- Locking and Non-Locking screws can be used in any round hole.
- To avoid disengagement of the screwdriver blade from the screw during insertion, axial pressure is recommended.

CAUTION

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.



Overview

SmartLock¹ Polyaxial / Compression Drill Guide

⚠ WARNING

The SmartLock polyaxial drill guide allows for ± 15 degrees of custom angulation and may be used for more complex fractures. 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 centrally 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.

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.

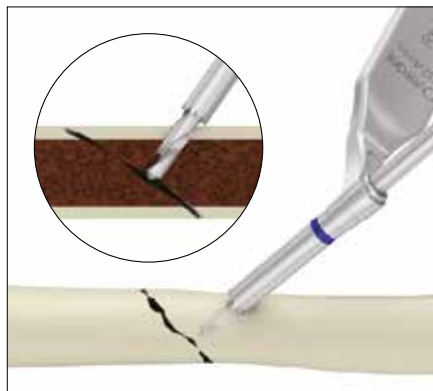
⚠ CAUTION

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.



⚠ CAUTION

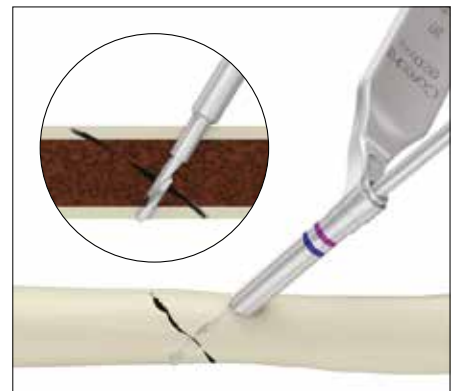
- When drilling eccentrically, the arrow marked on the compression side of the drill guide should be pointing towards the fracture line.
- Using one of the provided drill guides for screw hole preparation is mandatory. Not using a drill guide may lead to drilling out of specific locking range and compromise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



Step 1.

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



Step 2.

the standard drill bit through it to drill through the second cortex (Step #2). This standard drill is scaled in 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.

⚠ CAUTION

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.

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.

NOTICE

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.

Depth Measurement Options

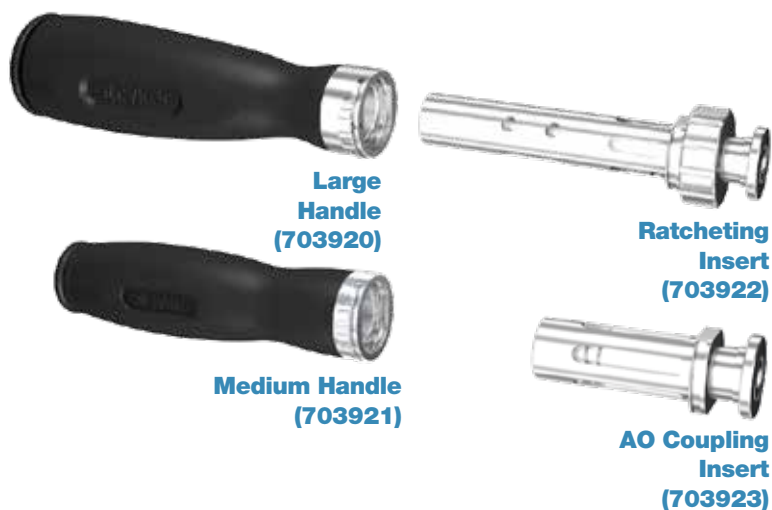
VariAx 2 offers various options to evaluate the screw length. All drills are scaled so that the surgeon may evaluate the screw length when using the drill through the dedicated drill guides.

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.

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.



NOTICE

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



Operative Technique

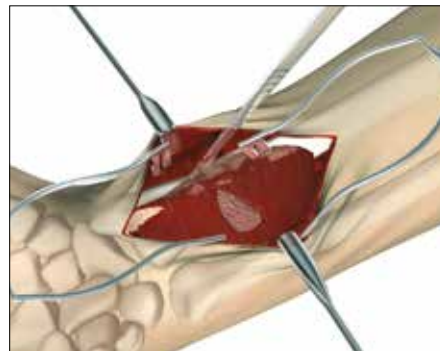
Anatomical Volar Plate



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.

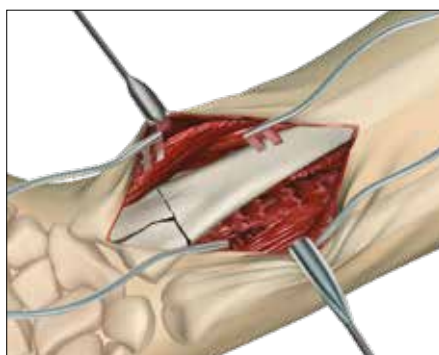


2. The FCR tendon is retracted ulnarly and dissection is carried down through the floor of the FCR sheath.



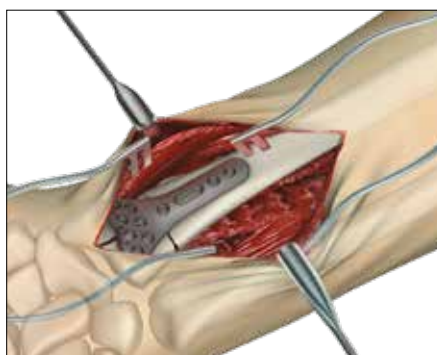
3. The Pronator Quadratus muscle is identified and dissected in its entirety off of the volar surface of the radius as an ulnarly based flap.

4. The insertion of the Brachioradialis may be released.



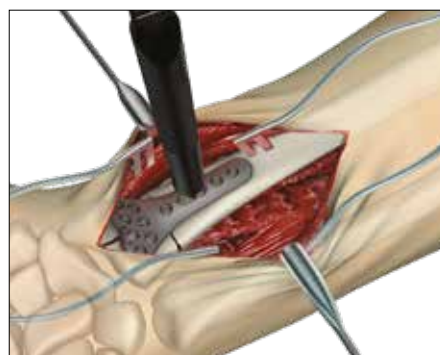
5. The fracture is visualized and reduced.

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.

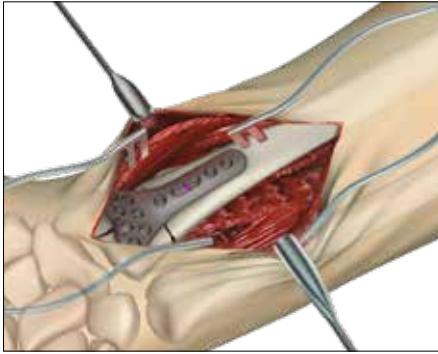
10. The first pilot hole should be drilled in the oblong gliding hole using the appropriate drill guide.

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

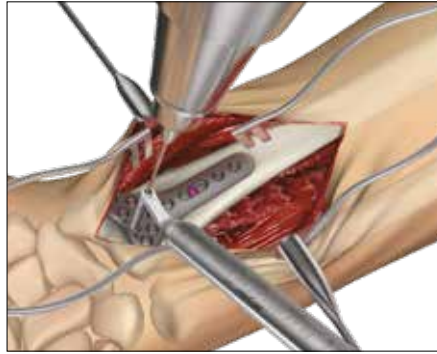
Operative Technique



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.

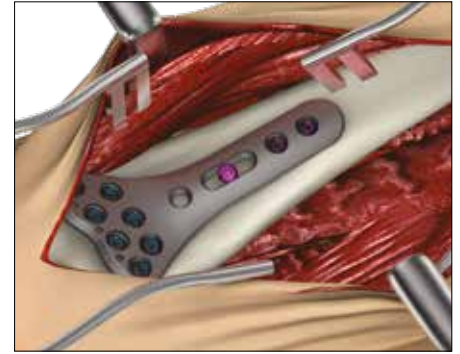


15. Using the desired drill guide, repeat drilling, measuring and placement of screws/pegs in the distal holes.
16. Place locking or non-locking screws in the proximal end of the plate.



CAUTION

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



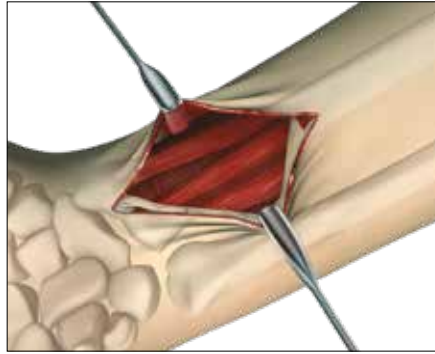
17. Verify proper placement of screws/pegs by use of fluoroscopy to ensure that neither penetrate the joint.
18. Close the incision.

Operative Technique

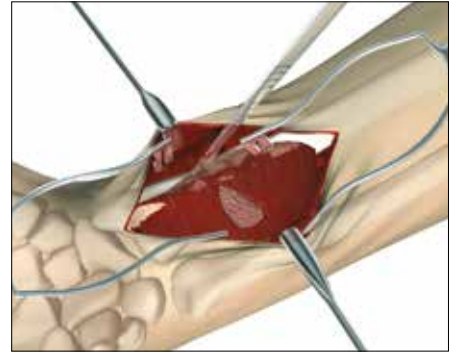
Universal Volar Plate



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.

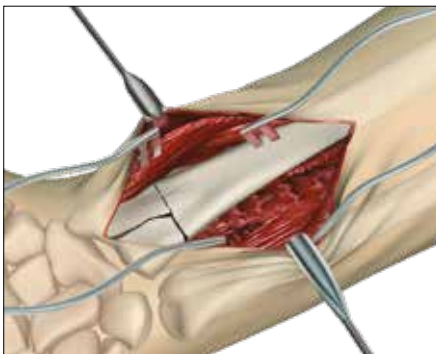


2. The FCR tendon is retracted ulnarily and dissection is carried down through the floor of the FCR sheath.



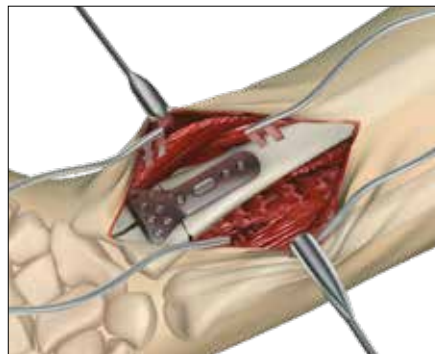
3. The Pronator Quadratus muscle is identified and dissected in its entirety off of the volar surface of the radius as an ulnarly based flap.

4. The insertion of the Brachioradialis may be released.



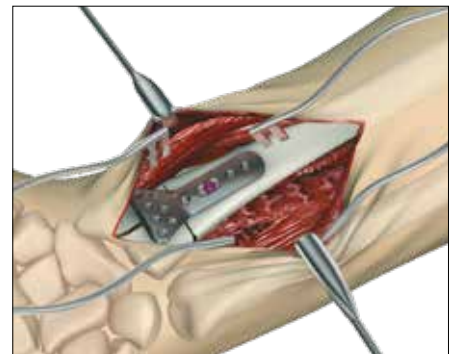
5. The fracture is visualized.

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.



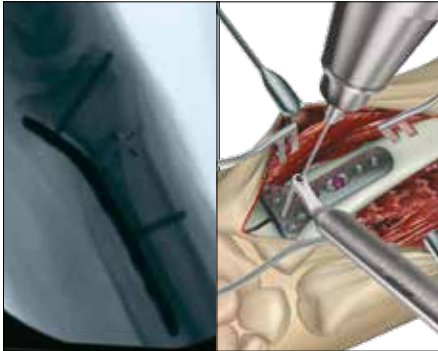
9. The first pilot hole should be drilled in the oblong gliding hole using the appropriate drill guide.

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.



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.

CAUTION

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

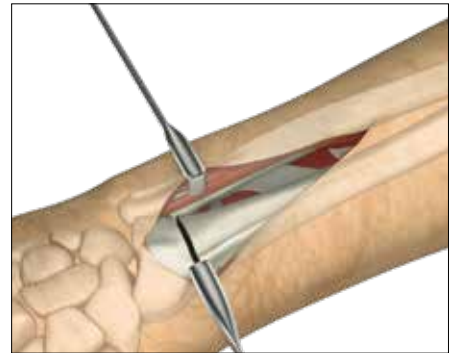
Dorsal Plate



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.



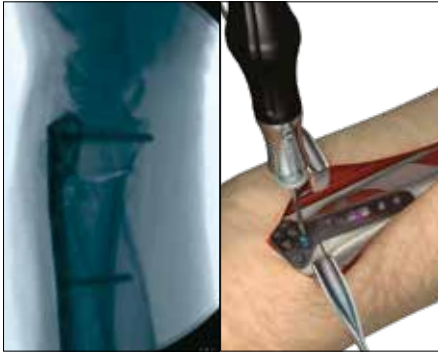
7. Measure the depth of the hole to determine screw length.

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.

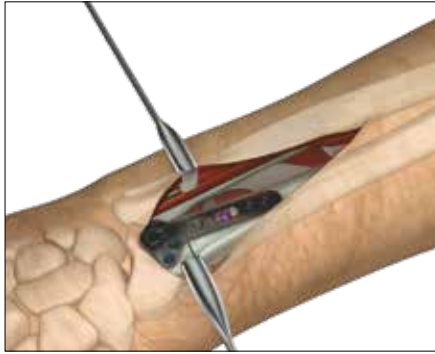
Operative Technique



Dorsal Plate



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



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.



CAUTION

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.

Operative Technique

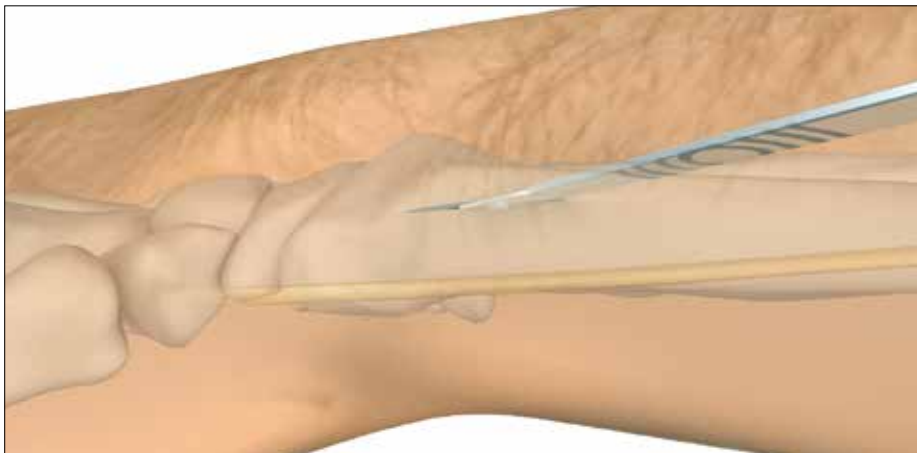


Lateral Distal Radius Plate

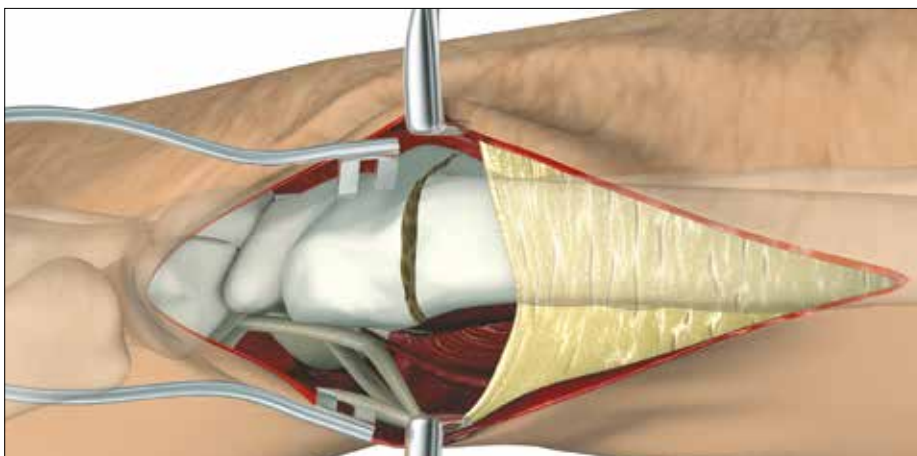
An incision is made along the radial column.

⚠ CAUTION

Care must be taken to avoid injury to the superficial branch of the radial nerve.



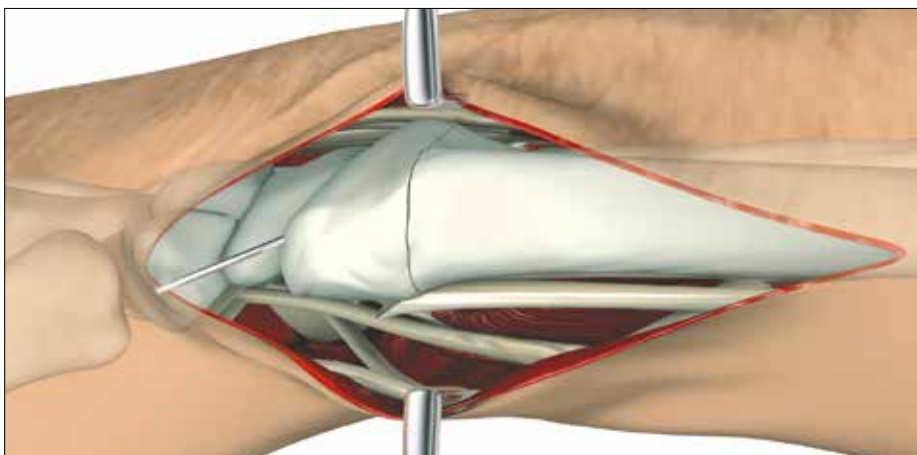
The first dorsal compartment is released. The tendons are retracted volarly.



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

NOTICE

Fragment specific plates should not be used in isolation.

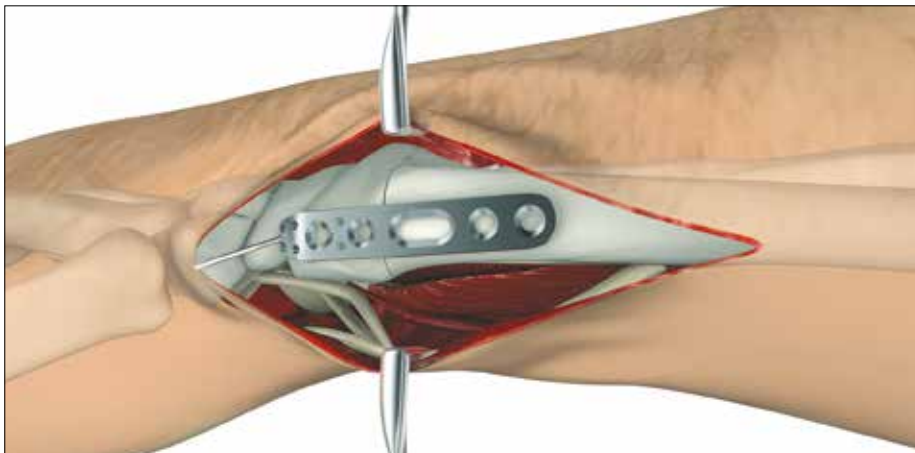


Operative Technique

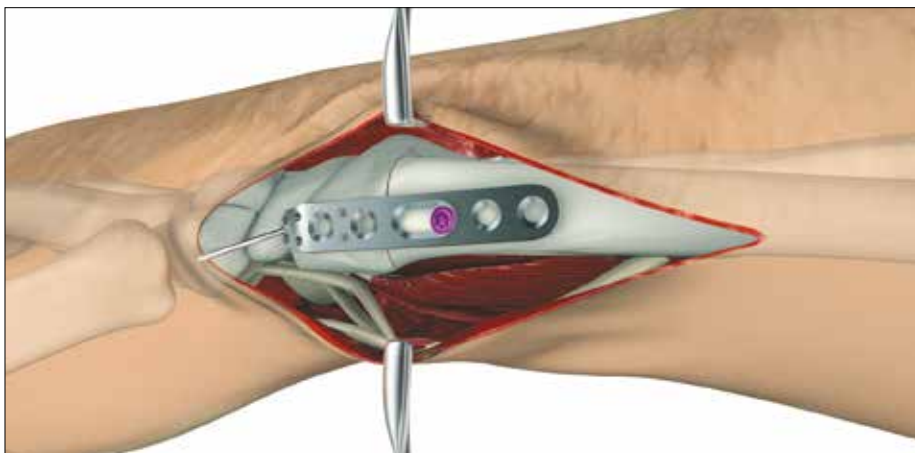


Lateral Distal Radius Plate

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



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

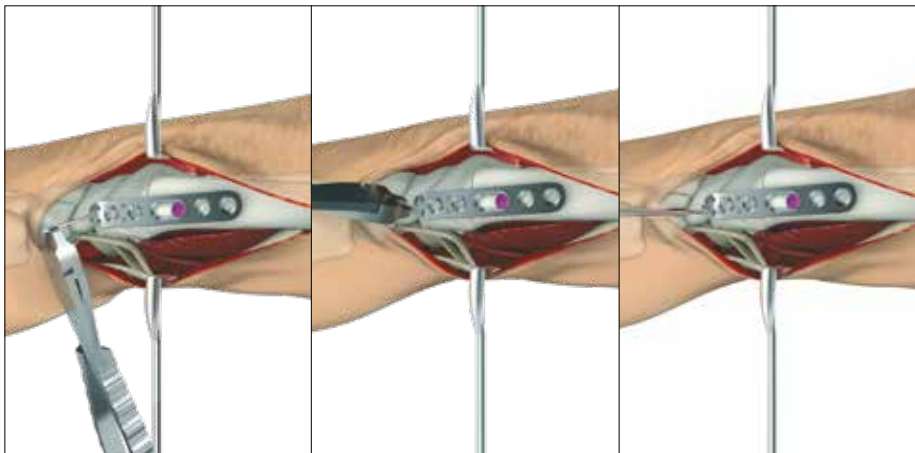


Lateral Distal Radius Plate

The 3 in 1 K-Wire bender/cutter/insertor is used to bend K-Wires distally.

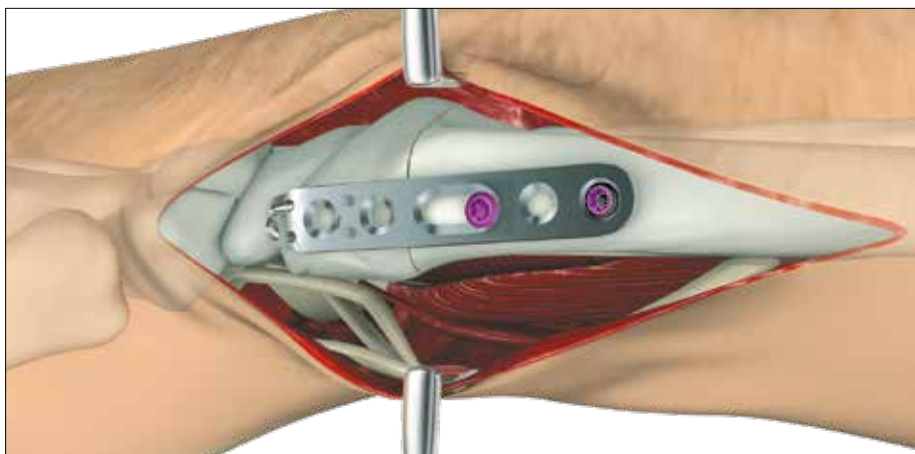
It is recommended only one K-Wire be placed distally at a time in order to make proper use of the K-wire Bending Pliers (64-20118).

After insertion, the tamp (64-00011) and mallet (43-09830) can be used to further insert the K-Wires.



K-Wires and screws can be placed in conjunction for more rigid fixation.

The incision is closed.

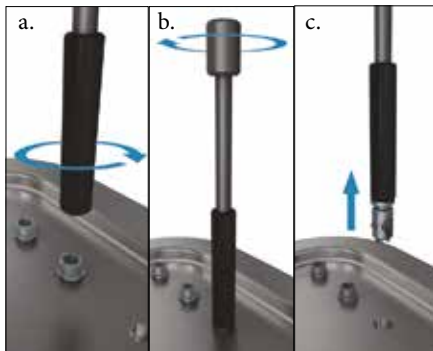


Operative Technique

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).

NOTICE

- 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.

CAUTION

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.

NOTICE

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.

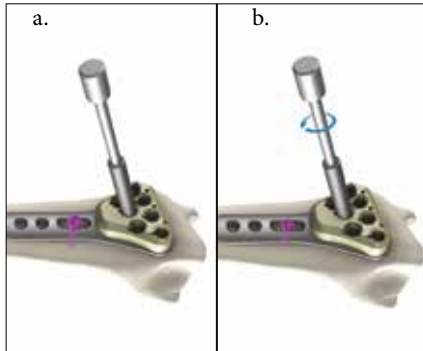


Intermediate Aiming Blocks and Plate

Operative Technique



Aiming Block



14. Removal of Aiming Block.

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



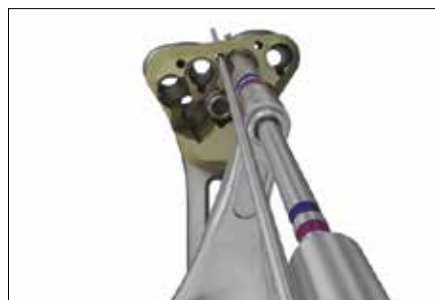
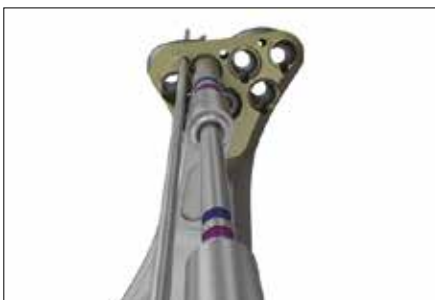
16. Remove Aiming Block from the plate. If necessary a screw can be placed in hole used for fixation of the Aiming Block. Ensure that all screw heads are fully seated onto the plate and fully tightened.

Optional Steps:

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

NOTICE

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



NOTICE

Left block is shown.

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

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The Instructions for Use, Operative Techniques, Cleaning instructions, patient information leaflets and other associated labeling may be requested online at www.ifu.stryker.com or www.stryker.com.

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