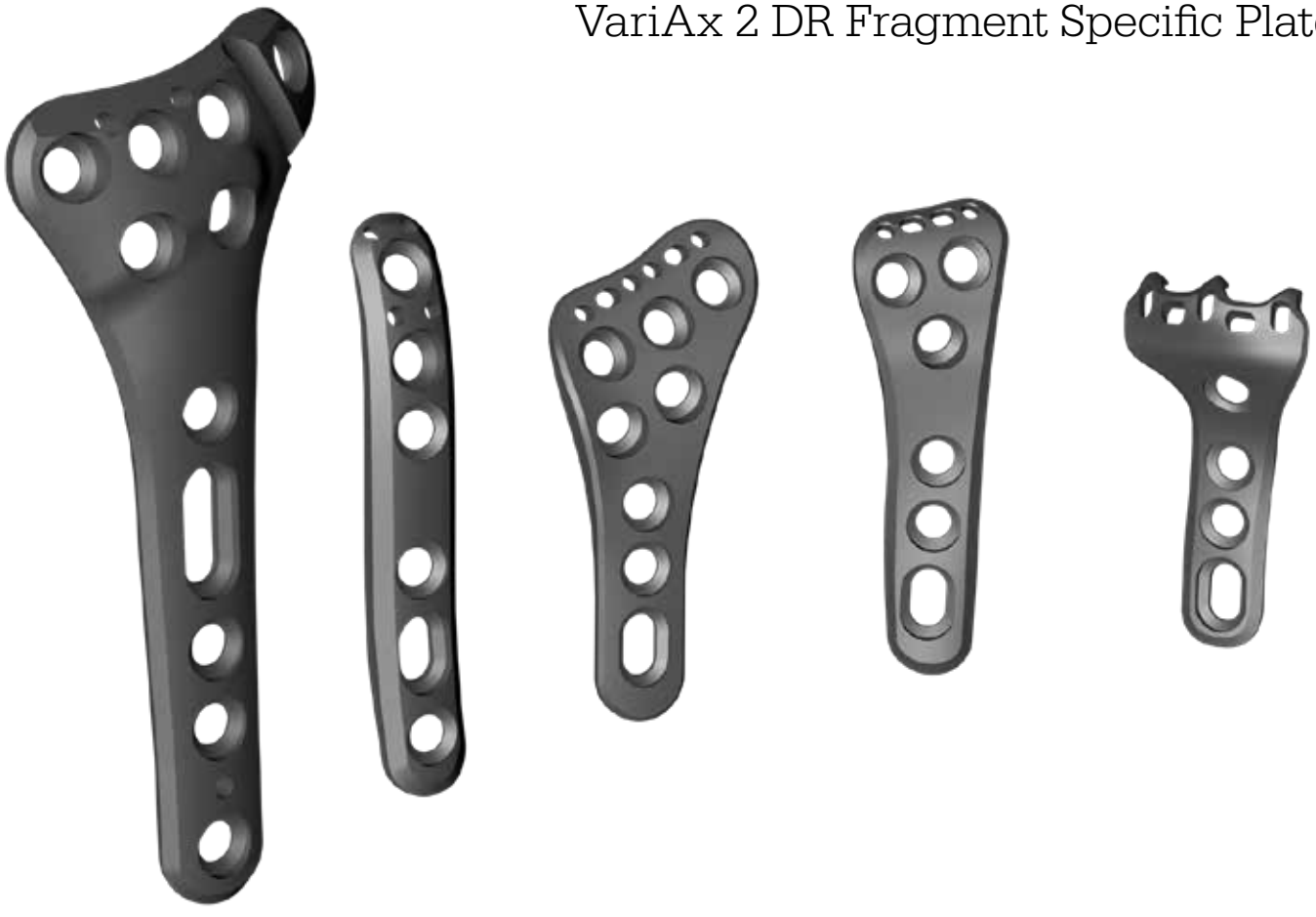
stryker

VariAx® 2
Distal Radius Locking Plate System

Operative technique

VariAx 2 DR Dorsal Plates

VariAx 2 DR Fragment Specific Plates



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.

MRI Safety Information

MRI safety information A patient with Variax 2 Distal Radius Locking Plate System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.	
Device name	VariAx 2 Distal Radius Locking Plate System
Static magnetic field strength (T)	1.5 T and 3.0 T
Maximum spatial field gradient	30 T/m (3000 gauss/cm)
RF excitation	Circularly Polarized (CP)
RF transmit coil type	Integrated Whole Body Transmit Coil
Operating mode	Normal Operating Mode
Maximum whole-body SAR (W/kg)	2 W/kg (Normal Operating Mode)
Scan duration	2 W/kg whole-body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks) followed by a wait time of 15 minutes if this limit is reached, for the total scanning session duration of up to 1 hour (or 60 minutes).
MR image artifact	The presence of this implant produced an image artifact of approximately 32 mm from the VariAx 2 Distal Radius Locking Plate System when imaged with a gradient echo pulse sequence and a 3.0 T MRI system.
Additional instructions	**CAUTION** The MRI safety information provided is based on testing which did not include supplementary devices. If there are supplementary devices (i.e. plates, screws, wires, etc.) present in proximity to the VariAx 2 Distal Radius Locking Plate System, this could result in additional MRI effects and the information provided above may not apply.

VariAx 2

Distal Radius Locking Plate System

Contents

Indications, Precautions and Contraindications

VariAx 2 Distal Radius Plating System

The devices are non-active implants intended to provide temporary stabilization for bones or bone fragments.

Indications for use

The VariAx 2 Distal Radius System is indicated for the treatment of fractures, non-unions, malunions and deformities of the distal radius.

The Stryker VariAx 2 Distal Radius Plating System is only to be implanted by a physician with special skill in e.g. traumatology in a sterile operating room environment in hospitals or specially equipped offices. No specific, additional training is needed for using the VariAx 2 Distal Radius Plating System. Stryker medical devices must be used sterile. All Stryker implants are single use only and must not be re-used under any circumstances.

Contraindications

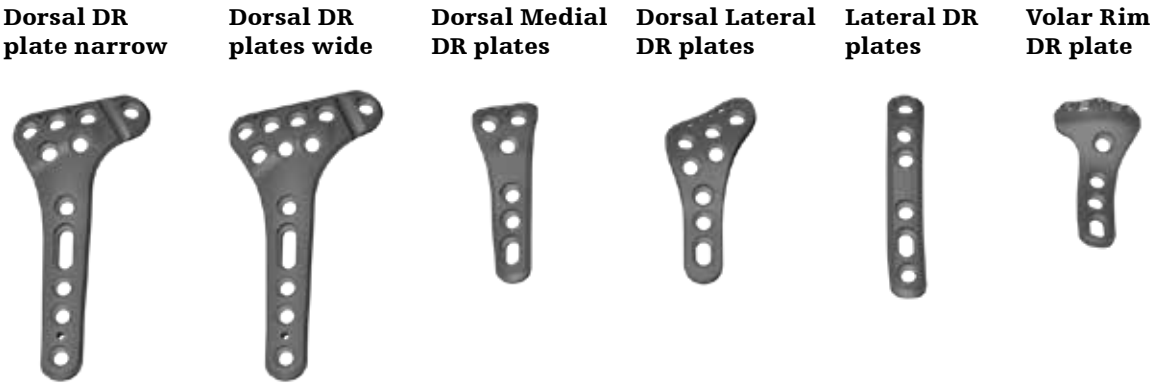
The physician's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment. The following contraindications may be of a relative or absolute nature, and must be taken into account by the attending surgeon:

- 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.
- 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.

System overview

Implants: plate and screw platform

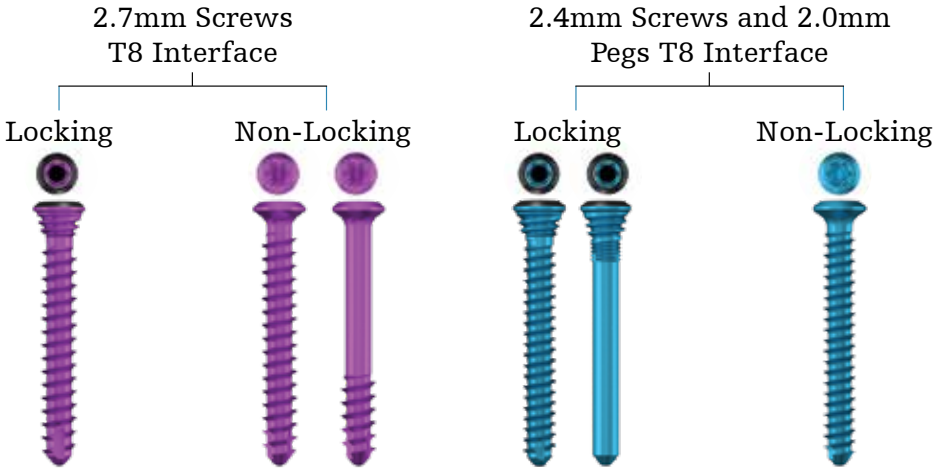
VariAx 2 DR Dorsal and DR Frag Specific Plates



Color Coding and Screw/Peg Options

⚠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.



Locking and Non-Locking screws can be used in any round hole.

Locking screws are laser marked with a 'dot' and 'ring' marking on the screw head to differentiate them from non-locking screws.

Pre-Angled Distal Screw Holes

The distal screw holes are angled to give a predetermined screw pattern in the distal bone block. When drilling at a 0 degree angle relative to the plate hole, the screw trajectories relative to the plate surface will be achieved.

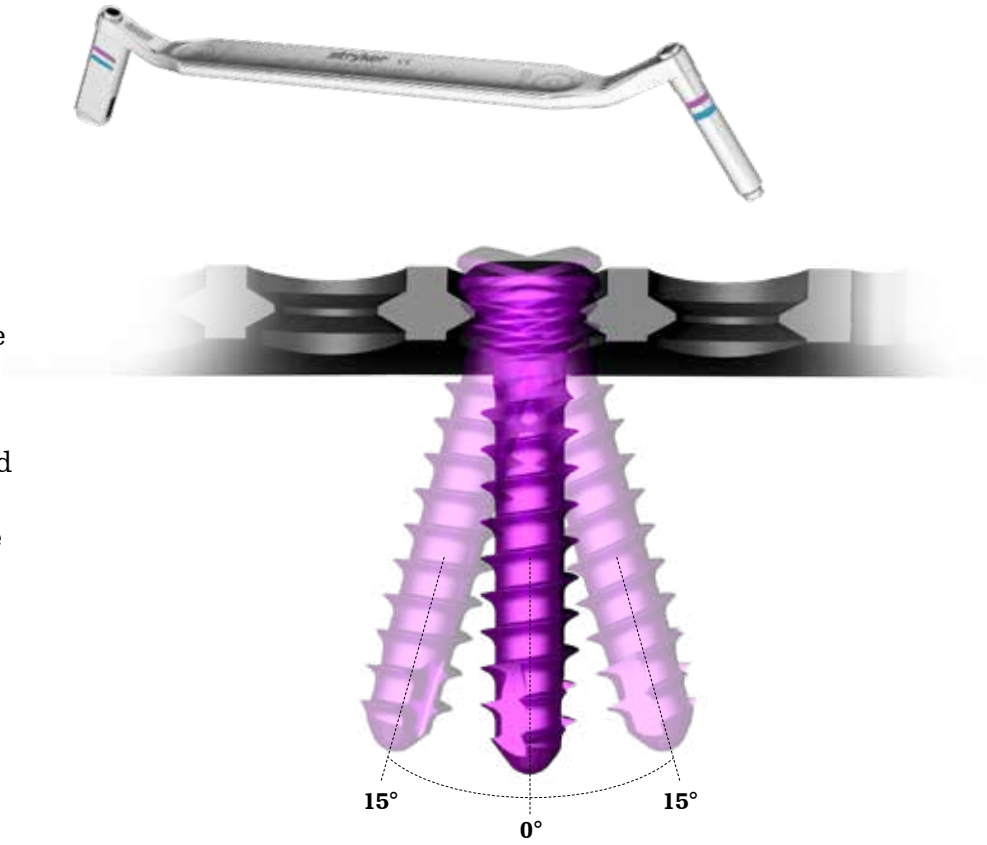
System overview
Instrumentation

SmartLock 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.



⚠CAUTION

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.

⚠CAUTION

- First fully engage the drill guide in the hole and then aim the drill in the desired direction.
- Make sure to drill perpendicular to oblong holes.
- Only use non-locking bone screws in oblong holes.

System overview
Instrumentation

Drills & Drill Guides for Lagging

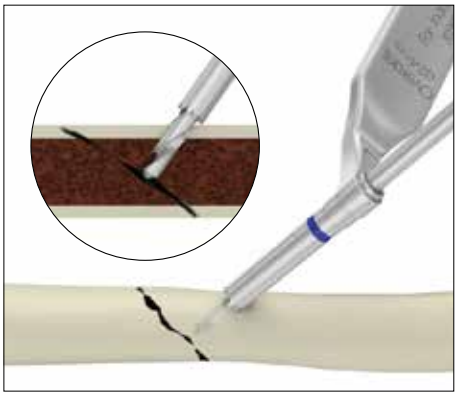
In addition to the standard Drills and Drill guides, a number of solutions are also available to perform a lag screw technique independently.

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.

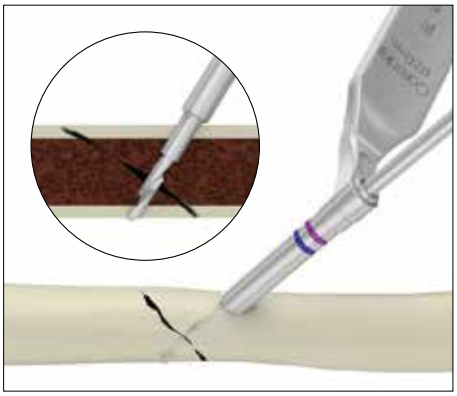
⚠CAUTION

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.

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).



Step 1



Step 2

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 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.

System overview
Instrumentation

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.

Large Handle (703920)

Ratcheting Insert (703922)

Medium Handle (703921)

AO Coupling Insert (703923)

CAUTION

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.

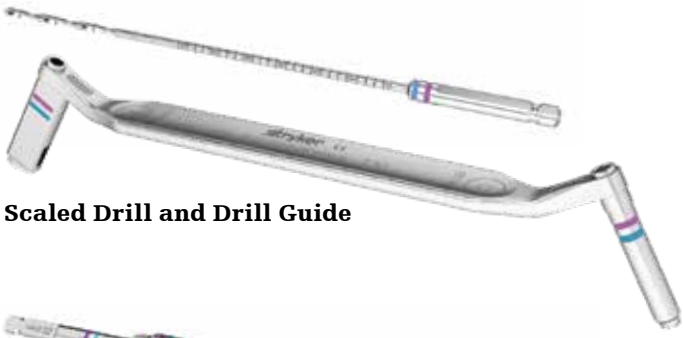
NOTICE

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

System overview
Instrumentation

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 and 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) may be used either independently or through a plate hole.



Scaled Drill and Drill Guide

SpeedGuide

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.

Taps

⚠CAUTION

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.

Joystick for plate positioning and temporary fixation

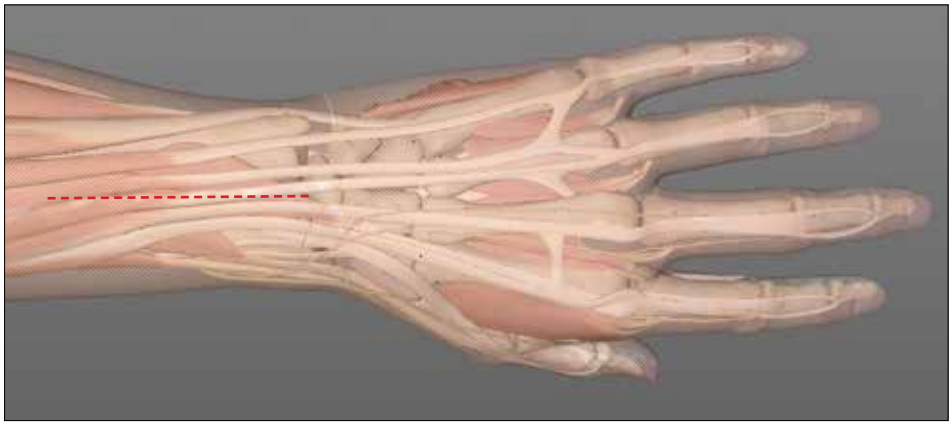
The joystick for T8 holes can be used in any VariAx circular hole to aid in plate positioning. Additionally, they can also be used to temporarily fix the plate to the bone by inserting a K-wire with a diameter up to 1.6mm through a joystick that is already engaged in the plate hole.

After inserting the joystick tip in the circular hole, turn the knob on the upper part of the joystick clockwise to fix it in the hole. To remove the joystick, simply remove any K-wire and turn the knob counter-clockwise to disengage the tip from the hole.

Operative technique

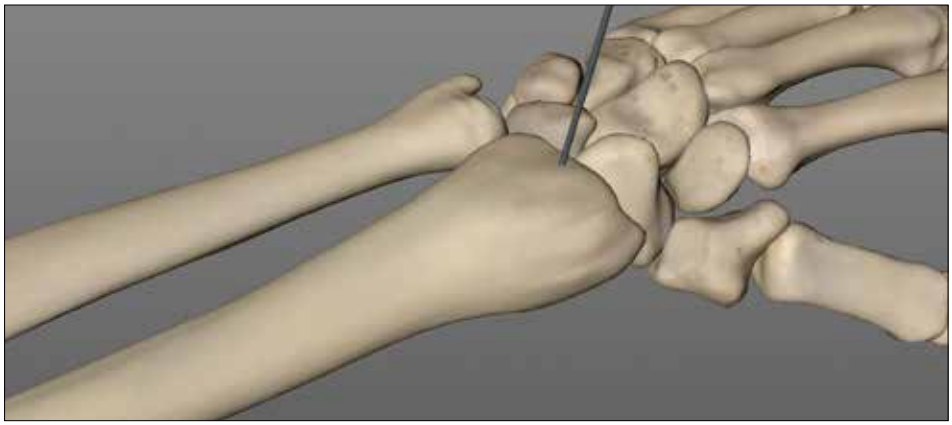
DR Dorsal Plates

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



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

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.



The fracture is reduced. The use of an external traction device and/or K-wire for temporary fixation may be helpful.

If necessary, adapt the plate for correct anatomical position. Removal of Lister's Tubercle might be necessary.

NOTICE

The distal lateral aspect of the plate can be bent along the groove with bending pliers to better match patient anatomy.

⚠ WARNING

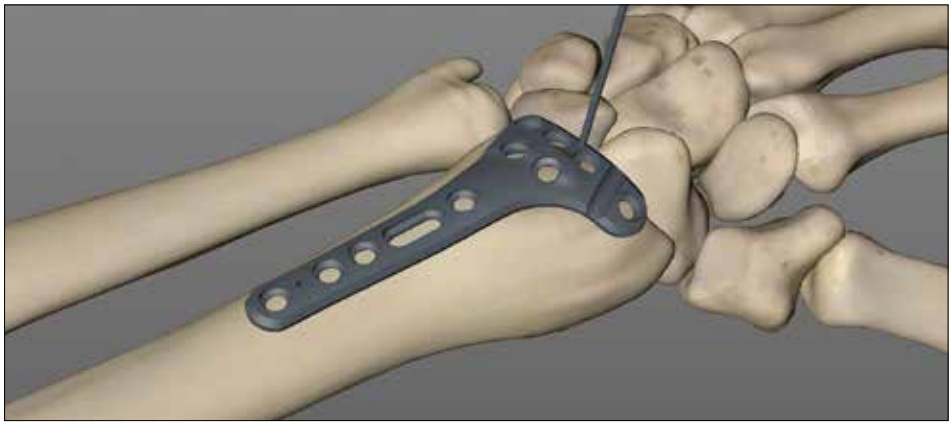
- The plate bending pliers are designed to be used only in circular holes.
- Always attach the bending pliers to two adjacent holes to prevent deformation of the screw holes.
- Do not re-bend plates.

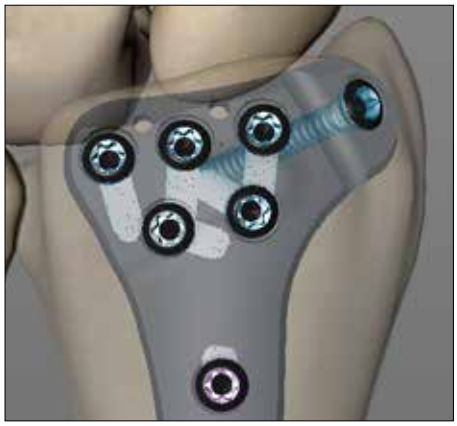
Operative technique

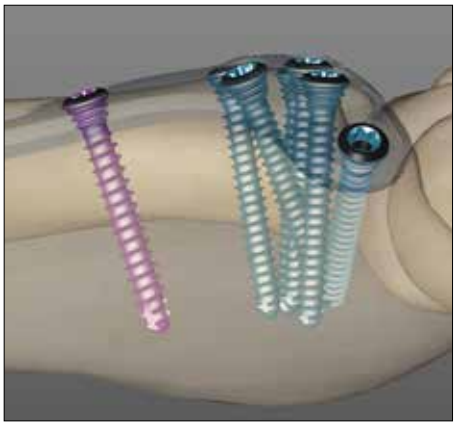
DR Dorsal Plates

The plate should be placed slightly proximal the distal edge of the distal radius to avoid inserting screws/pegs into the joint.

The fixed angled screw trajectory provides support to the subchondral surface for a more stable construct. The distal portion of the plate is partially thickened for better screw head protection when screws are angled within the 15 degree variable angle arc.

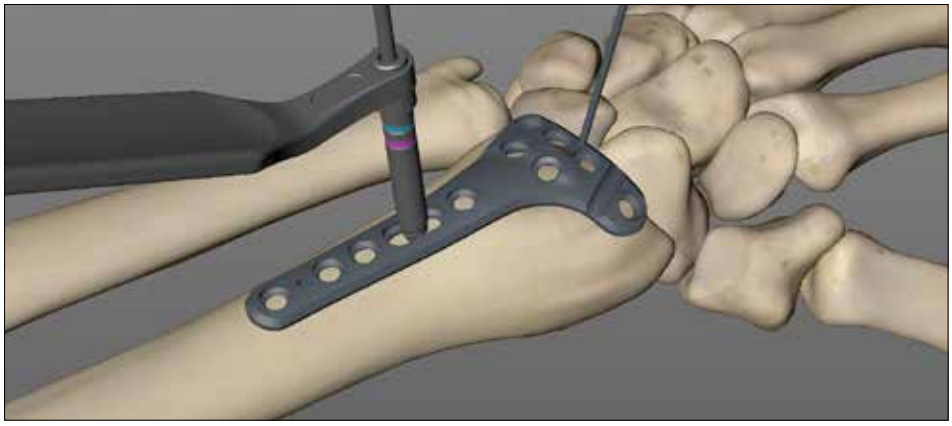






The first pilot hole should be drilled in the oblong gliding hole.

If required, compression of the fracture site may be achieved by pulling the plate proximally with an eccentrically placed screw in the oblong hole.



Operative technique

DR Dorsal Plates

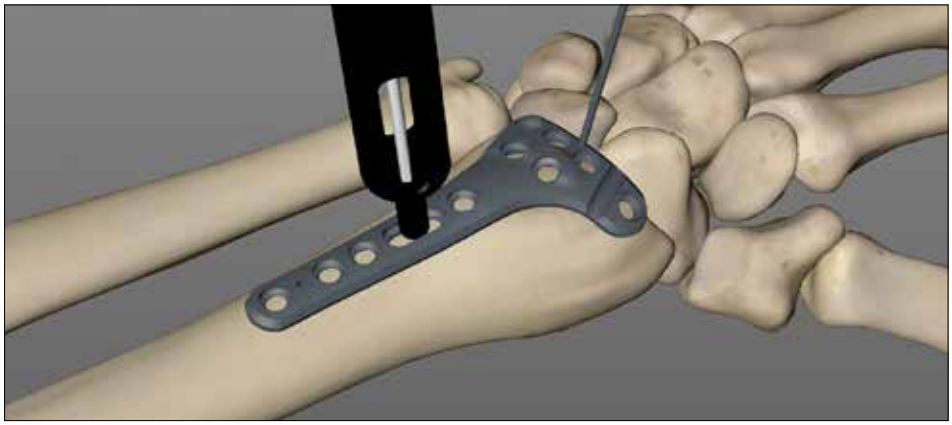
Measure the depth of the hole to determine screw length.

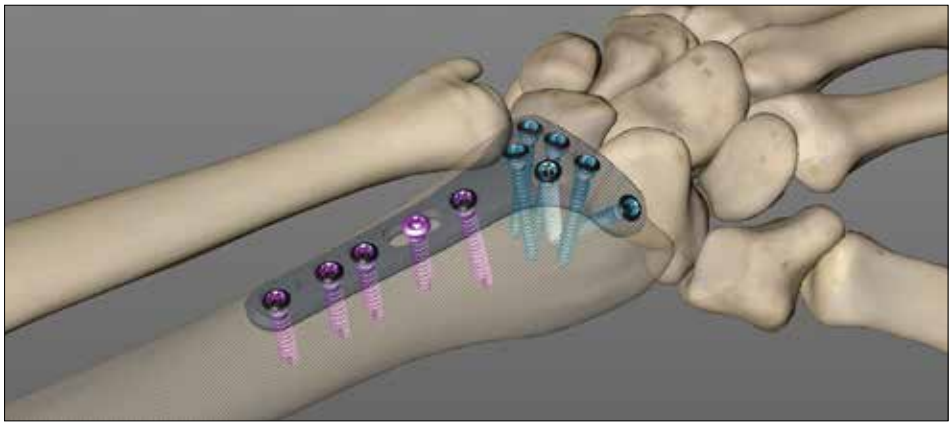
The screw is placed in the oblong gliding hole but not completely tightened to allow adjustment of the plate in a distal or proximal direction.

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

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

Place locking or non-locking screws in the proximal end of the plate.





⚠CAUTION

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

Close the incision.

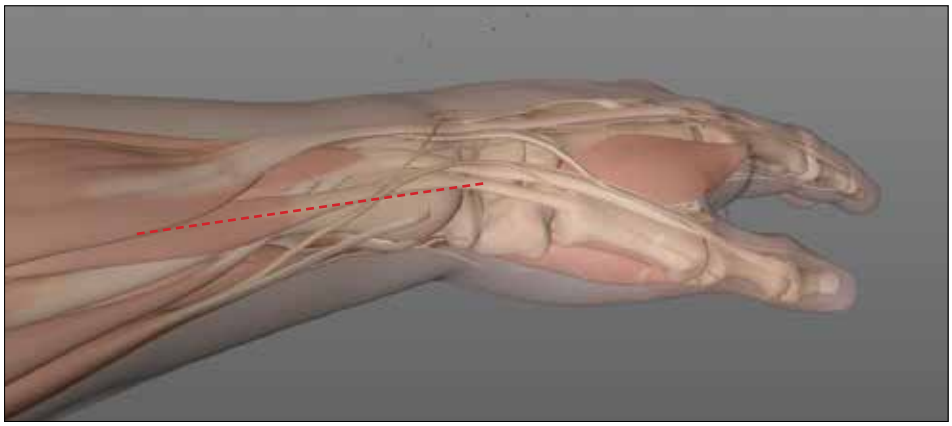
⚠CAUTION

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

Operative technique

Lateral DR Plates

An incision is made along the radial column.



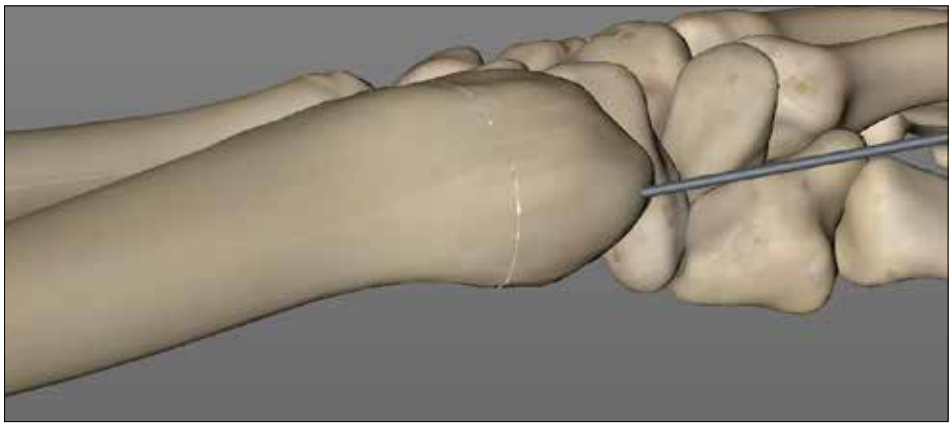
WARNING

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

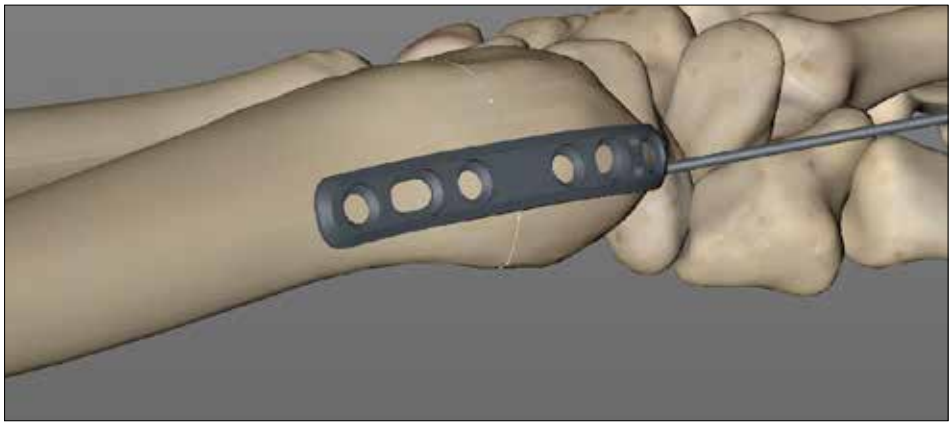
The first dorsal compartment is released. The tendons are retracted volarly.

The brachioradialis can be elevated or the the plate can be placed directly on the brachiaradialis insertion.

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



The plate may be slipped over the K-wire (07-40281) and placed along the radial column.



NOTICE

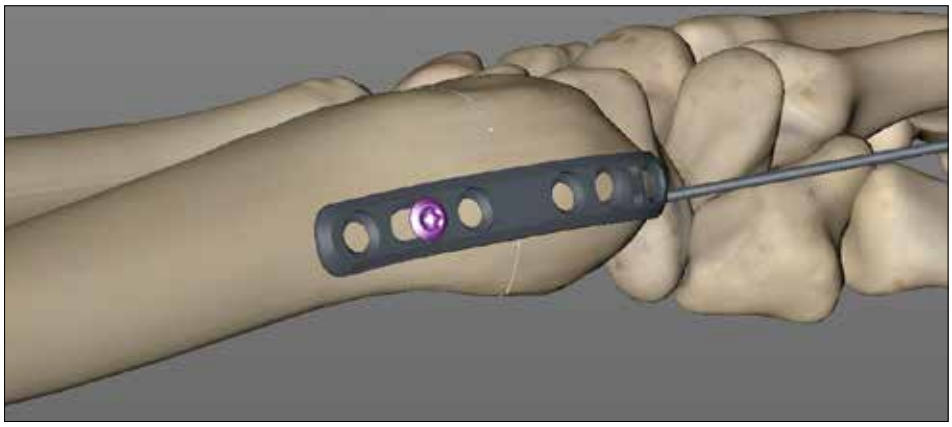
The plate should sit along the radial edge of the radius.

Confirm correct plate placement by use of fluoroscopy.

Operative technique

Lateral DR Plates

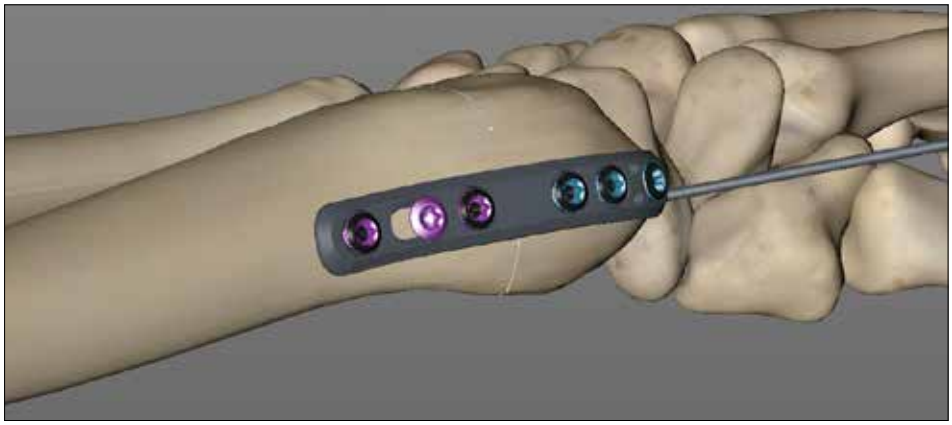
A non-locking screw placed in the oblong hole will compress the plate to the bone. If required, compression of the fracture site may be achieved by pulling the plate proximally with an eccentrically placed screw in the oblong hole.



A non-locking screw may also be placed in the oblong shaft-hole, instead of using the K-wire, for preliminary fixation of the shaft portion of plate.

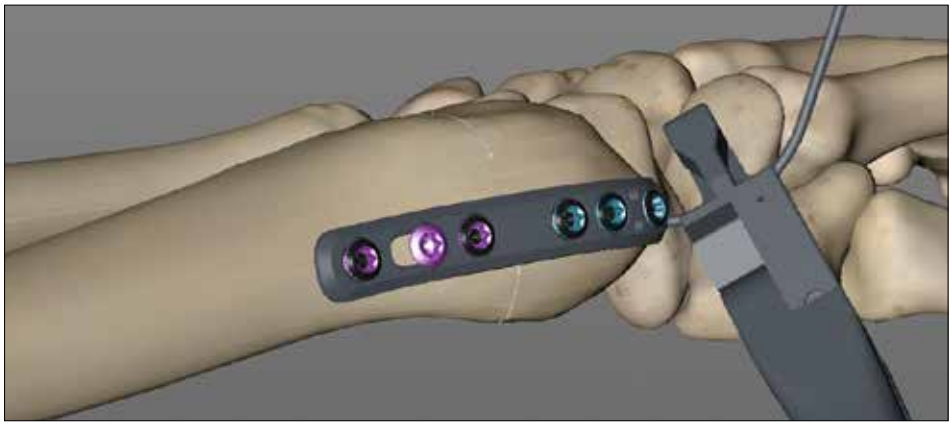
Fill the remaining screw holes with either locking or non-locking screws, as necessary.

K-wires may also be used in conjunction with the distal screws.



The 3 in 1 K-wire bender/cutter/inserter is used to bend K-wires distally.

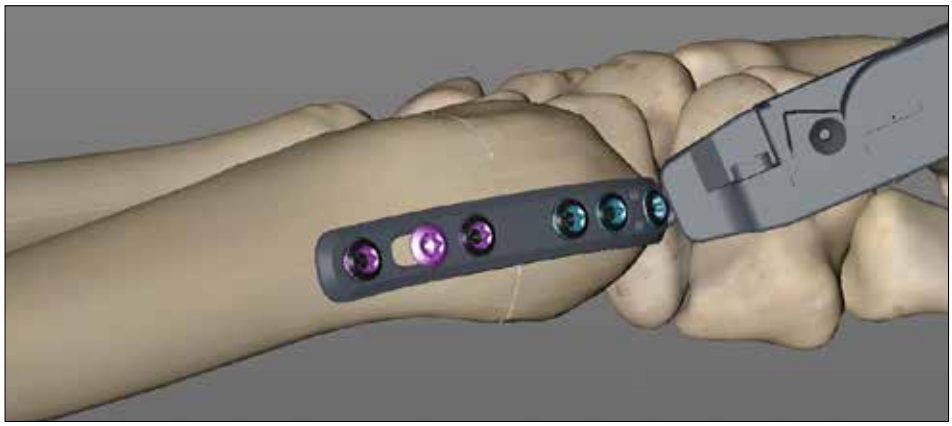
It is recommended only one K-wire be placed distally at a time in order to make proper use of the K-wire Bending Pliers (64-20118).



Operative technique

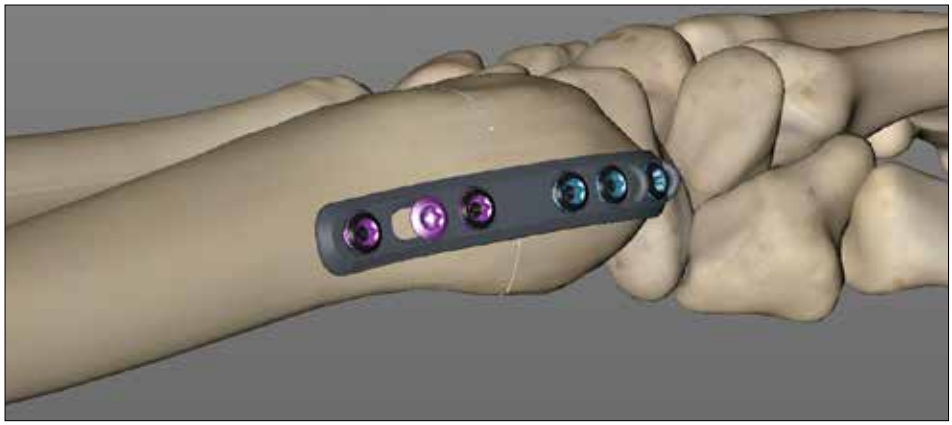
Lateral DR Plates

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



Ensure the non-locking screw in the oblong shaft hole is fully tightened.

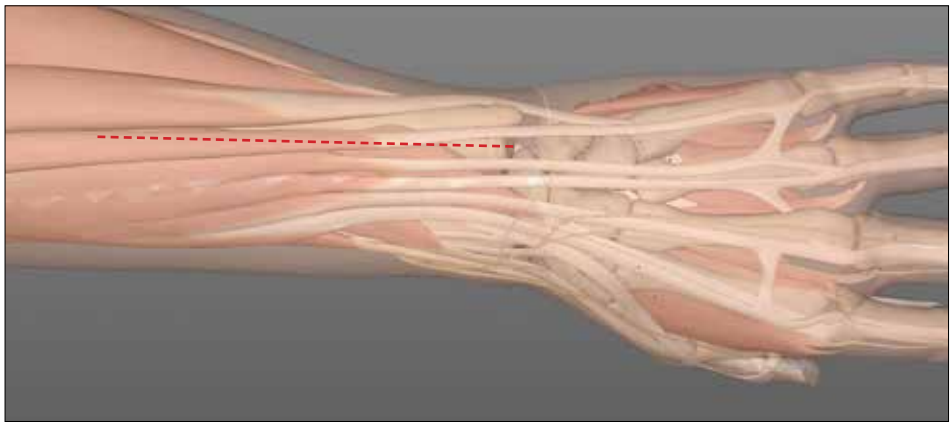
The incision is closed.



Operative technique

Dorsal Medial DR Plates

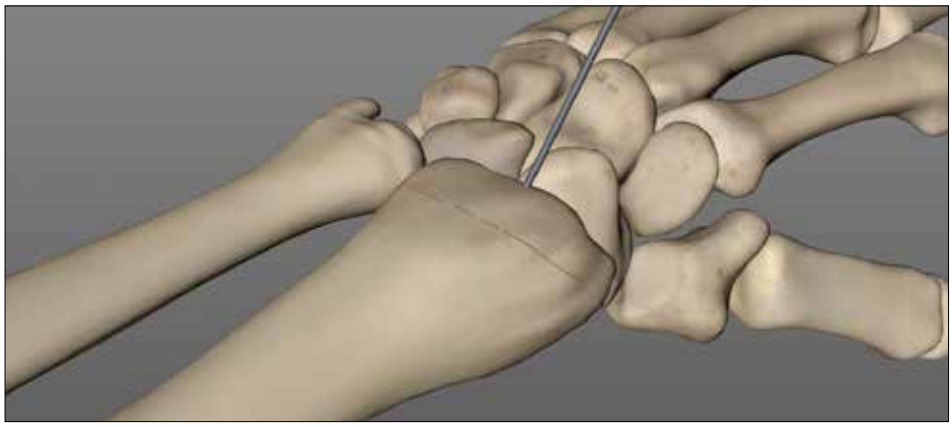
When plate is being used in conjunction with the lateral plate, incision is made between the 4th and 5th extensor compartments.



⚠ WARNING

Care is taken to protect the superficial radial and dorsal ulnar nerve branches.

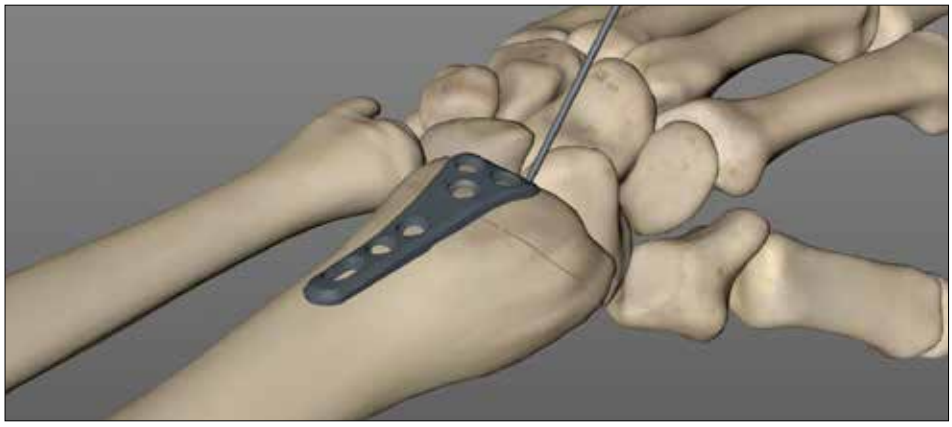
Incise the extensor retinaculum between the 4th and 5th compartments and sub periosteally expose the dorsal ulnar portion of the radius.



The fracture should be reduced and stabilized with traction and palmar flexion of the wrist or direct pressure. Ensure dorsal and ulnar fragments are reduced with K-wire if necessary. The K-wire may be placed through the ulnar corner fragment.

The plate is slipped over the K-wire (07-40281) and placed along the dorsal ulnar corner.

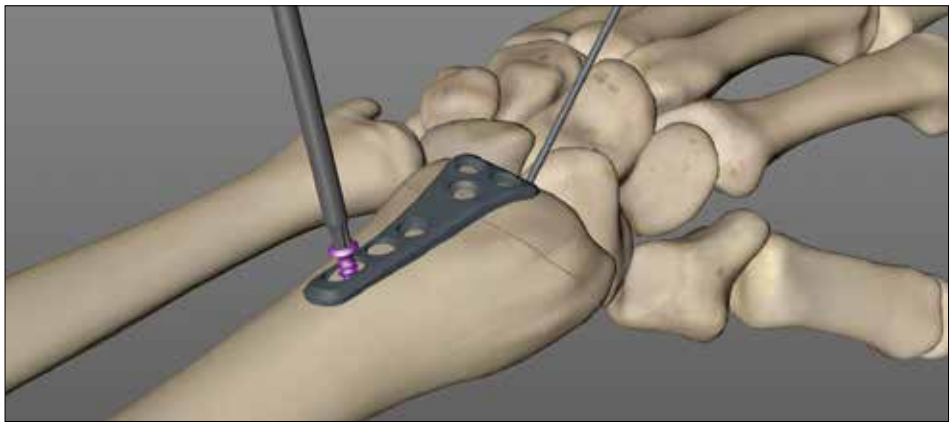
Confirm correct plate placement by use of fluoroscopy.



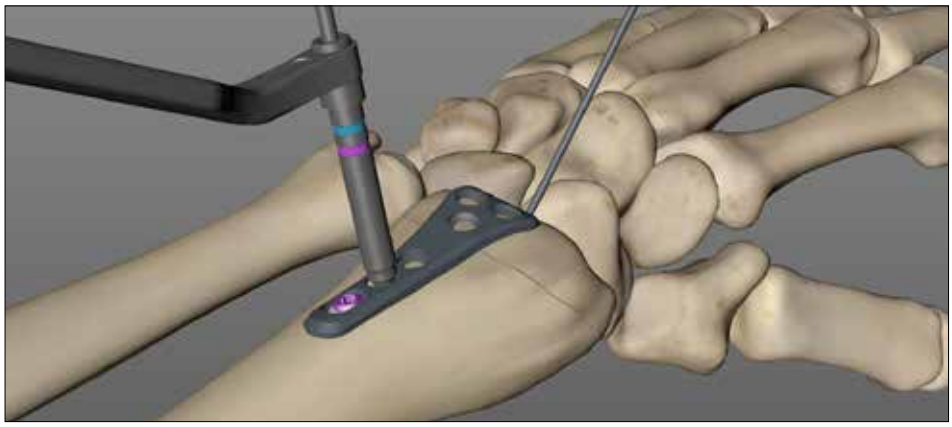
Operative technique

Dorsal Medial DR Plates

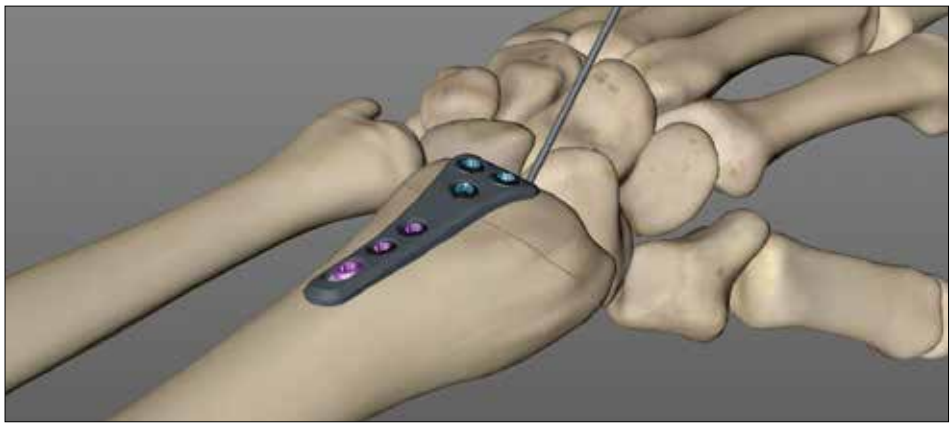
A non-locking screw placed in the proximal oblong hole will compress the plate to the bone. If required, compression of the fracture site may be achieved by pulling the plate proximally with an eccentrically placed screw in the oblong hole.



Fill the remaining screw holes, distally to proximally, with either locking or non-locking screws, as necessary.



K-wires may also be used in conjunction with the distal screws.

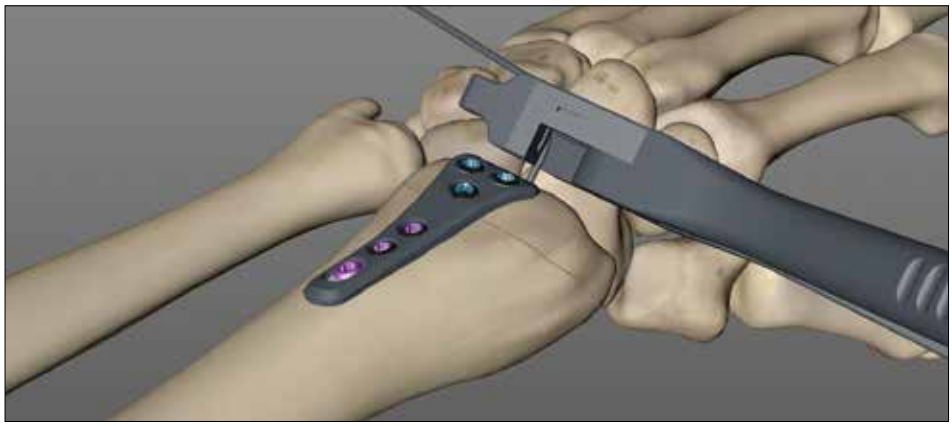


Operative technique

Dorsal Medial DR Plates

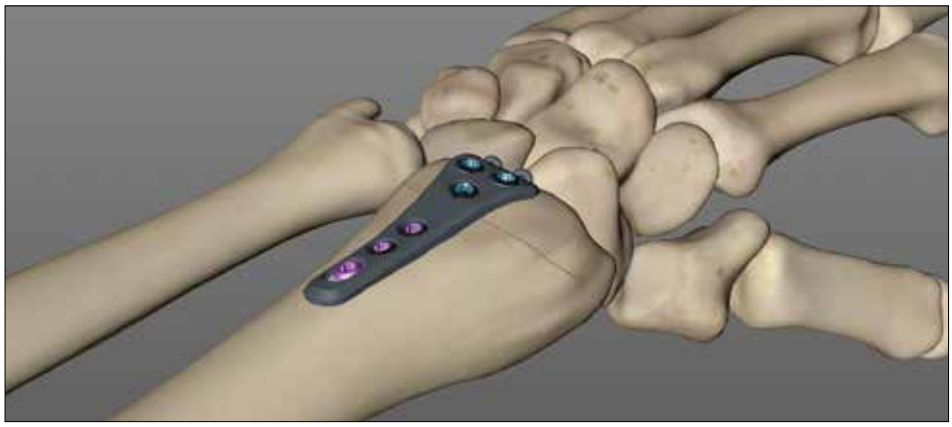
The 3-in-1 K-wire bender/cutter/inserter is used to bend K-wires distally.

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).



Ensure the non-locking screw in the oblong shaft hole is fully tightened.

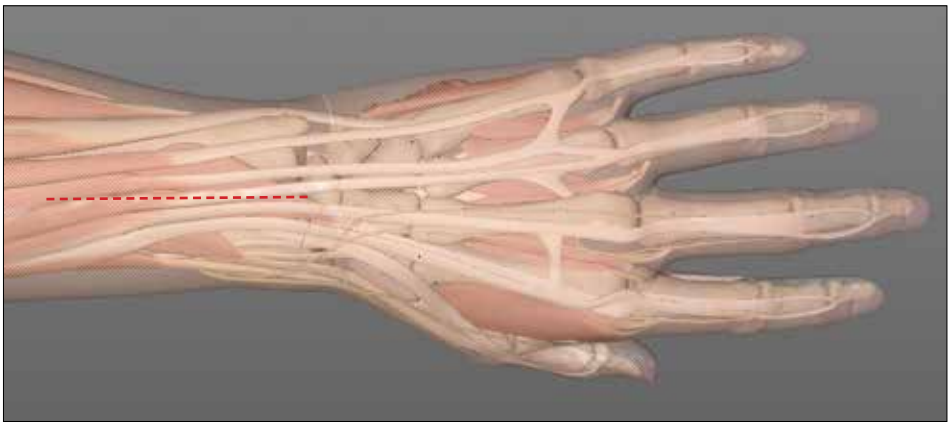
The incision is closed.



Operative technique

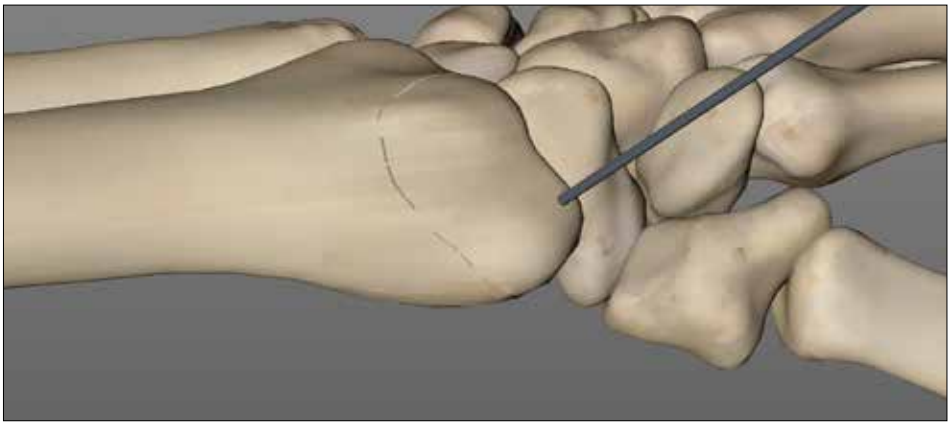
Dorsal Lateral DR Plates

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



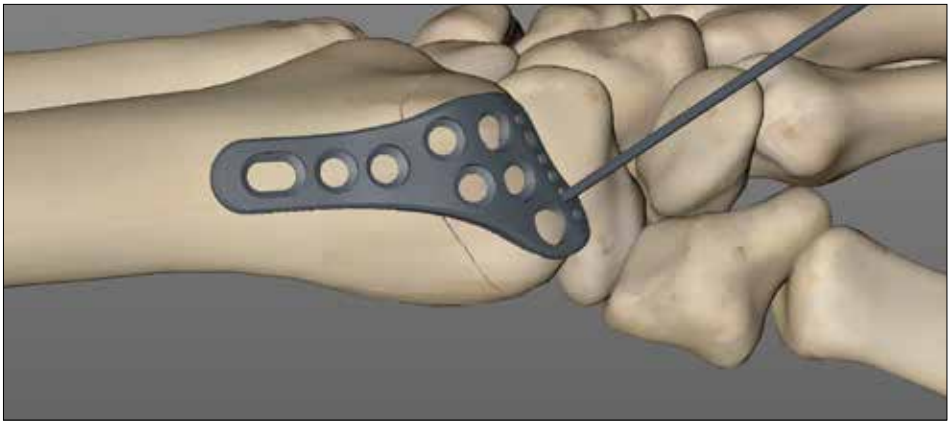
Dissection is performed down to the extensor retinaculum. The third compartment is opened and the extensor pollicis longus is displaced radially.

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.



The fracture should be reduced and stabilized with traction and palmar flexion of the wrist. Ensure dorsal and radial fragments are reduced with K-wire if necessary. The K-wire may be placed through the radial corner fragment.

The plate is slipped over the K-wire (07-40281) and placed along the dorsal radial corner.

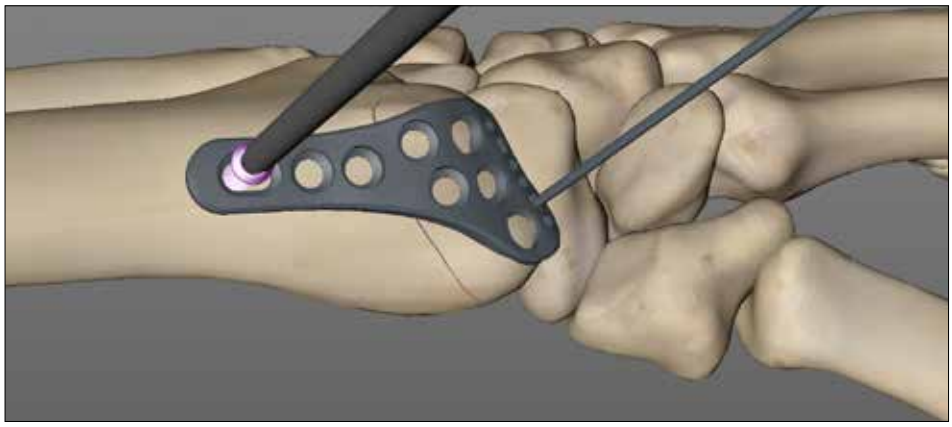


Operative technique

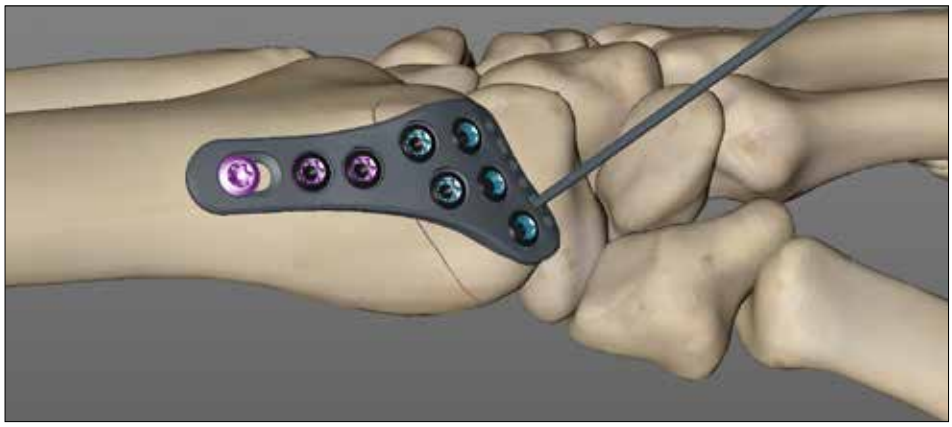
Dorsal Lateral DR Plates

A non-locking screw placed in the proximal oblong hole will compress the plate to the bone. If required, compression of the fracture site may be achieved by pulling the plate proximally with an eccentrically placed screw in the oblong hole.

Fill the remaining screw holes, distally to proximally, with either locking or non-locking screws.

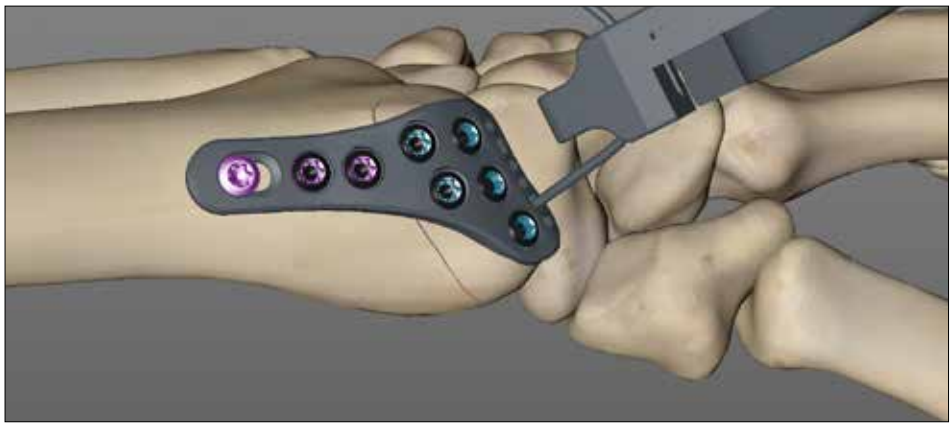


K-wires may also be used in conjunction with the distal screws.



The 3-in-1 K-wire bender/cutter/inserter 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).



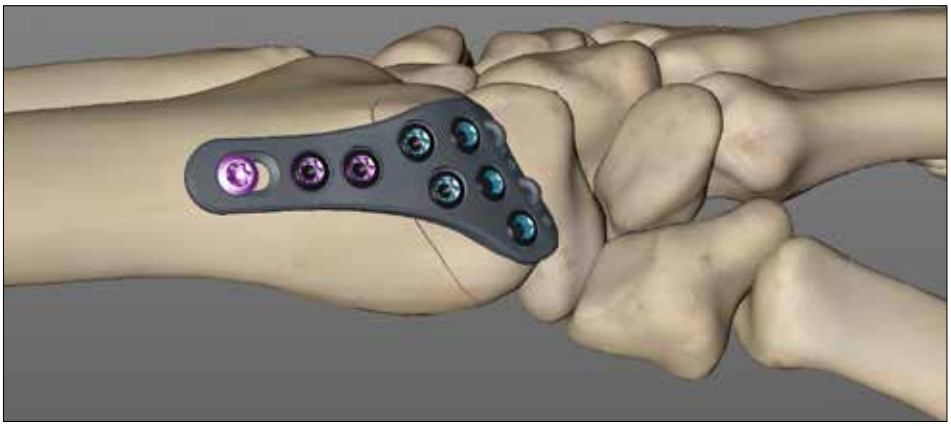
Operative technique

Dorsal Lateral DR Plates

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

Ensure the non-locking screw in the oblong shaft hole is fully tightened.

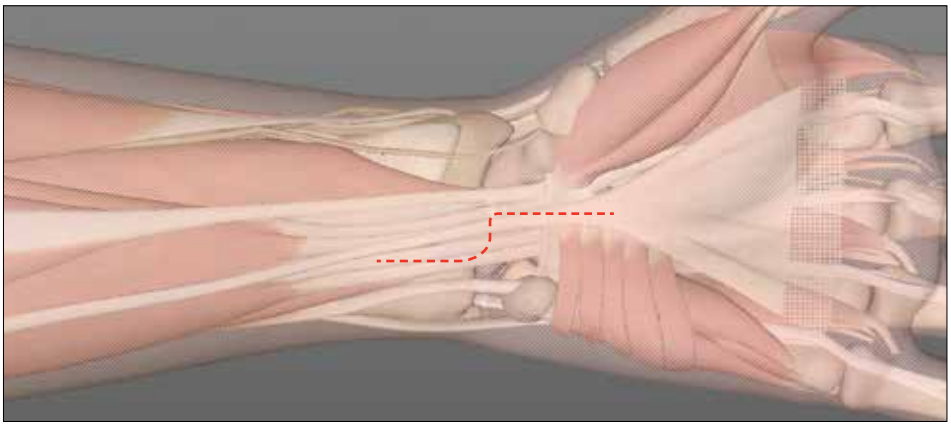
The incision is closed.



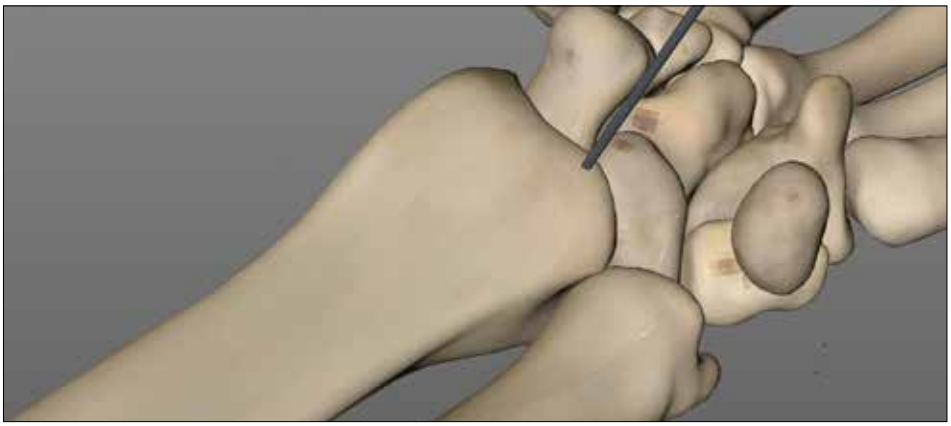
Operative technique

Volar Rim DR Plates

Incision is made through a standard volar Henry approach. Alternatively, a direct medial approach may provide superior exposure. For the direct medial approach, an extended carpal tunnel approach can be used distally and incorporated proximally to form an interval between the flexor tendons and the ulnar neurovascular bundle.



The fracture should be reduced and stabilized. The volar capsule should remain in place. Ensure the volar fragments are reduced and stabilized with a K-wire if necessary. The K-wire should be placed at the distal volar rim of the lunate facet.

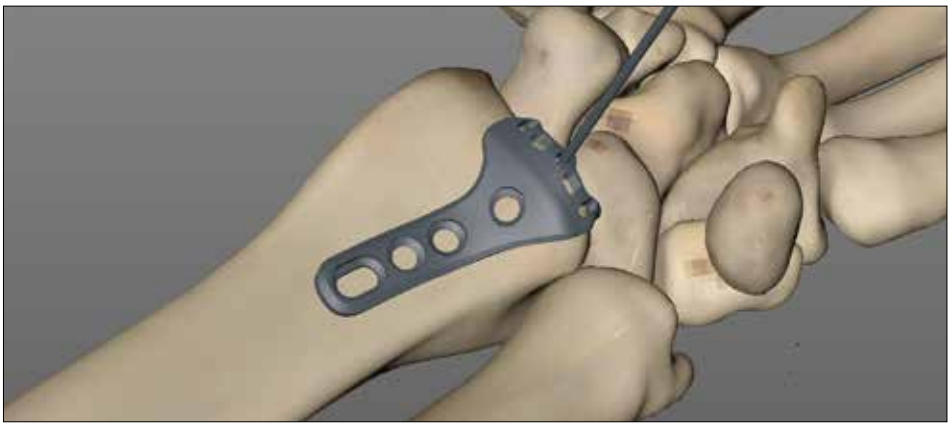


NOTICE

For the Volar Rim DR Plate the K-wires are used for temporary fixation.

The plate is slipped over the K-wire (07-40281) and placed above volar capsule on the volar ulnar corner.

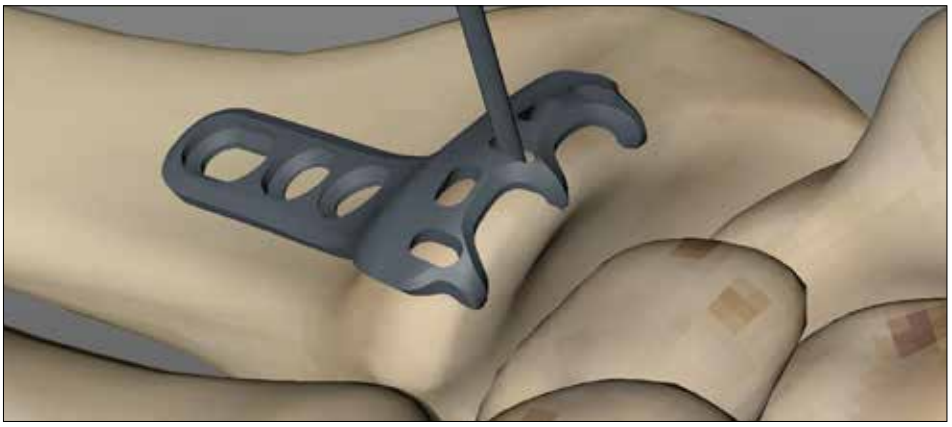
The vertical K-wire slots allow for distal or proximal adjustment and the horizontal K-wire slots allow for lateral or medial adjustment of the plate.



Operative technique

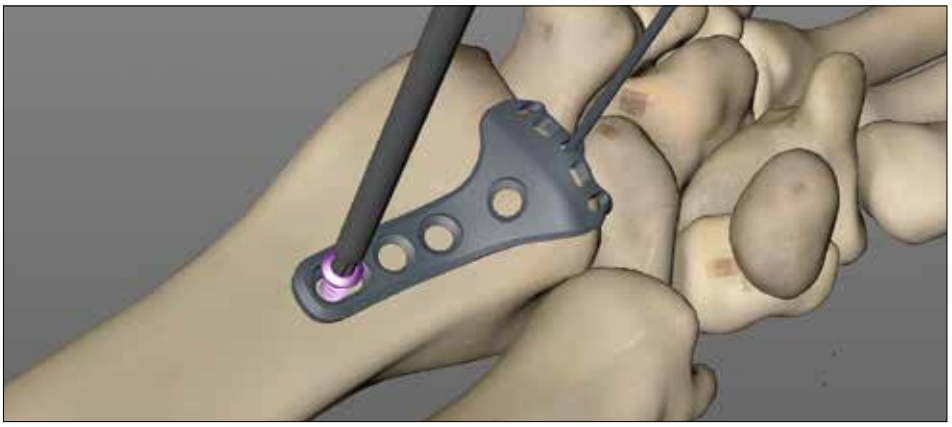
Volar Rim DR Plates

Ensure distal hooks penetrate the volar capsule and stabilize volar rim fragments.



With the plate in proper position, a non-locking screw is placed in the proximal oblong hole, compressing the plate to the bone.

If required, compression of the fracture site may be achieved by pulling the plate proximally with an eccentrically placed screw in the oblong hole.



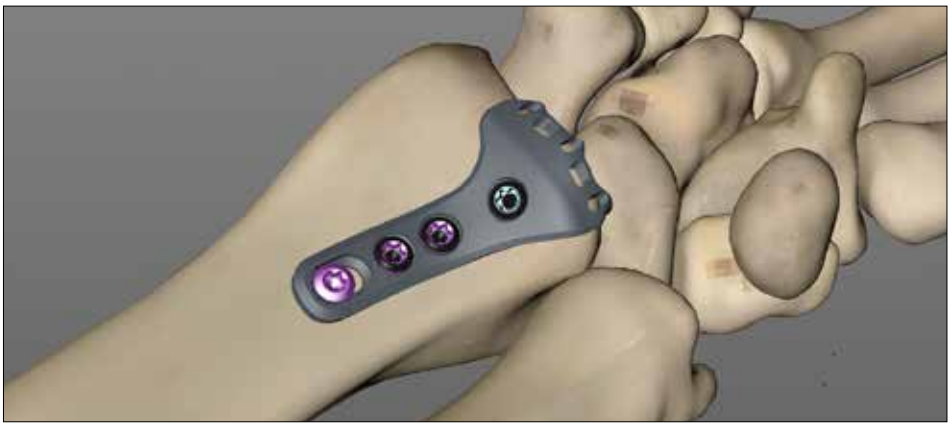
⚠CAUTION

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

After stabilizing the distal fragments, fill the remaining screw holes with either locking or non-locking screws, as necessary.

The distal K-wire holes can be used for placing sutures in the volar capsule. #2-0, #3-0 XBraid S Sutures are suitable for use in the Volar Rim plate.

Temporary K-wires can now be removed.



Operative technique

Volar Rim DR Plates

Ensure the non-locking screw in the oblong shaft hole is fully tightened.

The incision is closed.

Notes

Notes

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Content ID: VAX-ST-72, 07-2021

CE 0123

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